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To EY clients and friends:

Welcome to the fourth edition of our EY Life Sciences Report for Asia, providing coverage for the key markets in Asia-Pacific, Japan and India.

During the last few months, we’ve seen many significant tax legislative developments and emerging tax trends likely to impact most, if not all, companies in the sector. In this edition, our Tax updates: significant developments section focuses on Australia, China, South Korea, Singapore and Japan, with select highlights, including:

- **Australia** – important insights from the Australian Taxation Office (ATO) Pharma Cluster, a newly established project team tasked with analyzing risk areas for companies operating within the life sciences sector and key insights, including the ATO perspective on transfer pricing methodology, local value drivers, limited risk characterizations, operating profit and APAs.

- **South Korea** – increased levels of tax audit activity and the potential for a more contentious tax controversy environment; special tax audits for pharmaceutical companies relating to “promotional” expenses; and a 2017 tax reform proposal that includes a corporate tax rate increase and a limiting of tax preference items such as R&D credits, utilization of loss carryovers and interest expense deductions.

- **Singapore** – liberalization of the tax deduction regime for payments made under cost-sharing agreements (CSAs) to ease compliance burden and enhance taxpayer benefit (e.g., a 100% deduction and elimination of requirements to provide a detailed breakdown of underlying expenditures) and introduction of a base erosion and profit shifting (BEPS)-compliant IP Development Incentive (IDI) for purposes of encouraging R&D and incentivizing IP income.

We are also excited to include two featured articles, each written specifically for this publication.

The first article, “Impact of BEPS final reports on the life sciences sector – Asian focus,” explores the specific BEPS actions that may have a disproportionate impact on life sciences companies. In particular, Actions 8-10 and Actions 5 and 13. The former are related to transfer pricing, specifically the entitlement of intangibles-related returns. The latter concern transparency, documentation and reporting. In this article, we discuss the latest developments related to these actions in the Asia-Pacific territories and their impact on the industry.

The second article, “Under the microscope: a focus on tax corporate governance in Australia,” explores the concept of “justified trust,” the ATO’s latest initiative to restore public confidence. The justified trust initiative stems from the question: has the ATO fulfilled its public duty? Theoretically, justified trust is achieved where the ATO has collected sufficient objective evidence that would lead a reasonable person to conclude that a particular taxpayer has paid the right amount of tax. In many regards, the ATO’s approach to achieving justified trust in a taxpayer is informed by the strength of the taxpayer’s tax corporate governance (TCG). As such, in connection with achieving justified trust, taxpayers will need to demonstrate that they have a robust and operationally effective TCG framework.

In addition to our featured articles, our Market insights section highlights numerous sector trends and provides brief yet informative updates on various regulatory and legislative developments for several key markets in Asia. Our Mergers and acquisitions and Financing and IPOs sections provide helpful summaries of recent global and local trends via charts and short captions, with an increased focus on Asian markets.

We hope you enjoy this issue. You’ll find this report – and much more – at our digital home Vital Signs, and you can engage with us via Twitter (@EY_LifeSciences) or email.

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In this edition, we highlight key sector, regulatory and legislative trends for the following markets:

- ASEAN
  - Indonesia
  - Malaysia
  - Philippines
  - Vietnam
- Australia
- China (mainland)
- India
- Japan
- South Korea
Key highlights

- The developed markets of Australia and Japan are experimenting with health care models to drive improved patient health outcomes and reduce their health care cost burden. Australia has adopted a community pharmacy model to offer disease management services, such as home services by pharmacists and dose administration for patients. Japan is moving toward a value-based health care model that involves value-based pricing of medicines based on robust cost-effectiveness studies.

- Other Asian countries are pursuing traditional means of price controls and enhanced transparency. For instance, India is replacing its existing pricing policy and is also looking at amending its Drugs and Cosmetics Act to mandate the prescription of generic drugs. Likewise, Vietnam is attempting to monitor and control pharmaceutical bidding in their local market. It is also replacing specialty medicines with bioequivalents. Malaysia announced new solutions for curting drug prices, mandating that pharmaceutical companies register drug prices with the country’s Ministry of Health.

- Enhancing access to new quality drug therapies continues to be a top priority for emerging markets in the region. Countries such as the Philippines and China are attempting to smooth the way for foreign companies’ operations in their domestic market. China is working on its foreign drug approval process system to build an environment that is attractive to global multinationals. The new approval reform will enable multinational corporations (MNCs) to gain faster market access to China.

- Many markets across Asia are rolling out regulatory changes to address unmet medical needs by streamlining the market access process for drugs and medical devices. For example, Australia’s Therapeutic Goods Administration (TGA) has announced several changes to the existing regulatory regime, including acceptance of priority review notifications, revision of the orphan drug program and allowance of the marketing of medical devices approved by comparable overseas regulators. Similarly, China and Japan have allowed conditional approvals for medicines and medical devices approved abroad.

- With the increasing penetration of technology in the sector, major Asian markets are leveraging novel technologies and platforms across the pharma value chain. For example, the Japanese Government is attempting to popularize cancer genomic medicine and increase the application of artificial intelligence and genetic analysis in clinical settings. Concurrently, China is adopting blockchain technology to improve operational efficiencies within its pharma supply chain.

\*China\* refers to mainland China in this publication.

ASEAN

Indonesia: encouraging localization to minimize import dependencies

By 2025, the Indonesian Ministry of Health (MoH) plans to significantly reduce its reliance on imported raw materials through increased domestic manufacturing and sourcing. In this regard, the Indonesian authorities are undertaking new investments, mainly in the field of R&D, to find substitutes for imported drug materials and to improve the quality of manufactured products. Along with pharmaceuticals, medical devices will be covered under a separate regulation, promoting independent production of raw materials, medicines and medical equipment. These efforts are expected to provide a remedy for drugmakers struggling with high costs of raw materials and currency fluctuations.

Malaysia: proposing regulations to boost market attractiveness

The Malaysian Government has released a new set of guidelines for the registration of medical devices. As a result of these new requirements, companies will need to report the level of serious threat posed to public health within 48 hours from discovery. In addition, Malaysian regulators have released clarifications on the process of registering drug and medical device combination products. Going forward, the procedure for obtaining approval will depend on a product’s primary mode of action by which the claimed effect or purpose of the product is achieved. Furthermore, any unregistered combination products must be registered by 1 July 2018.

In addition, the Government has proposed several solutions for controlling drug prices and increasing transparency. For instance, a plan announced in June will obligate all pharmaceutical companies to register drug prices with the Ministry of Health (MoH). The MoH will then calculate a recommended retail price for each medicine, which will be displayed on the packaging. In addition, the Government will continue its efforts to establish pharmaceutical price control mechanisms to enable greater access to affordable medicines.
Philippines: seeking new opportunities from cross-border collaborations and impending medical marijuana legalization

The Philippines is working with multiple bilateral partners to explore trade and investment opportunities across different industries, including life sciences. One such crucial partner for two-way investments is India. The partnership offers opportunities for Filipino firms to set up factories in India and also enables the establishment of a pharmaceutical manufacturing hub, to be called “Pharmazone,” in the Philippines. This cooperation is likely to help Filipino companies expand their regional presence. It could also give the people of the Philippines easier access to affordable and quality medicines. Another cooperation opportunity comes from the Russian Government, which has offered to provide affordable medicines, other pharmaceutical products and health care solutions to the country as part of this bilateral deal. This treaty was a by-product of multiple business-to-business (B2B) projects across various industries (worth US$875 million) and was signed by Filipino and Russian companies in May.

Simultaneously, there is a new bill awaiting approval in the Philippines Senate to legalize medicinal marijuana and other similar drugs with medicinal value if they are properly prescribed. Legalizing cannabis in the country will benefit thousands of patients suffering from serious and debilitating diseases. The final bill will need the endorsement of President Rodrigo Duterte, who appears to be in favor of medical marijuana.

Vietnam: improving mechanisms for a better regulated sector with added engagement of the private sector

The Vietnamese Government is actively working on guidelines for regulating the life sciences sector. The long-awaited Pharmaceutical Law, along with Decree No. 54, went into effect on 1 July 2017. The decree establishes a legal framework for foreign invested enterprises (FIEs) to import drugs and drug ingredients in the near future and to help Vietnam fulfill its World Trade Organization (WTO) commitments. This guidance will allow MNCs to sell imported products to wholesalers registered with the Ministry of Health (MoH). The MoH will publish the list of registered wholesalers and their partner FIEs on its website to increase transparency into the distribution system. Another regulation implemented this year requires registration of all medical devices imported into Vietnam for marketing authorization (MA) licenses. This move will streamline the registration of imported medical devices and bring them on par with domestic products. Previously, most foreign medical devices required import licenses, while domestic products had to be registered for MA.

Blossoming in recent years, the pharmaceutical industry is still plagued with inadequate measures to control drug pricing for both specialty medicines and other types of pharmaceutical products. In this regard, the Government plans to closely control pharmaceutical bidding in the local market through creation of a national pharmaceutical trading center. It will also seek measures to replace specialty medicines with bioequivalents. Moreover, private investors are tapping into the growth potential of the domestic health care sector. One example is a collaboration agreement among private companies, the MoH and the Vietnam National Cancer Hospital for developing radiation oncology centers in Vietnam. Another global player has recently conducted a five-day biomedical engineering (BME) training course for engineers from southern Vietnamese hospitals to improve their capabilities. The growing interest of the private sector is a step forward in Vietnam’s pursuit to improve its access to health care.
Australia

Expediting access to new drugs and devices with regulatory reforms and a better reimbursement regime

As discussed in our previous edition, Australia is continuing its efforts to boost innovation by injecting investments into the sector. **To increase market access to new drugs**, the Government is undertaking several measures that are expected to make the regulatory environment more conducive to the requirements of industry players. Australia’s Therapeutic Goods Administration (TGA) has begun to accept priority review notifications, accelerating medicine approval from about eight months to five months. This process is similar to that followed by the US Food and Drug Administration (USFDA) for medicines with large unmet needs in the domestic market. Additionally, the TGA is revising its orphan drug program to align it with global practices, making certain indications now eligible to be classified as rare diseases.11

For the medical devices segment, the Government has laid out an ambitious regulatory and R&D plan to incentivize the sector and expedite innovations. As part of this effort, the TGA is considering allowing the marketing of medical devices approved by comparable overseas regulators or regulators participating in the International Medical Device Regulators Forum (IMDRF). This will advance the registration process by eliminating duplicate application evaluations.12 The TGA is also developing regulations for medical device software (including mobile medical apps) in sync with USFDA and IMDRF guidelines.13

Besides these market access initiatives, as part of a nationwide program called National Research Infrastructure Roadmap, the country will build a high-performance computing facility to model and simulate new medical technologies for next-generation medical devices.14 However, all the efforts may not reap sufficient benefits, as government inefficiency and “red tape” may result in Australia losing business to countries with more agile systems.15

Concurrently, the Australian Government is undertaking action to **improve patients’ access to medicines and disease management services**. Some of the critical initiatives in this space include:

- Recent price cuts on more than 1,100 medicines are expected to generate cumulative savings worth US$449.6 million (AUD$590 million)16 over a period of four years for patients and taxpayers.
- Inclusion of new drugs (such as AbbVie’s Humira, MSD’s Zolniza, Roche’s Esbriet) on Pharmaceutical Benefit Scheme (PBS) list, worth US$108 million (AUD$142 million), will be effective July 1, 2017.17
- Community Pharmacy program will expand to increase patient access to medication management services.
- The Federal Government is paying US$452.6 millionb (AUD$600 million) for the pharmacy program, which includes services such as Home Medicines Review (review of patient’s medication at home by pharmacist), and Dose Administration Aids (packaged medicines according to patient’s dosage requirement).c

These initiatives are intended to enhance the efficiency of the Australian health care system by generating cost savings and improving patient health outcomes.

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* Converted using average spot rate for March 2017, i.e., AUD$1 equals US$0.76213, accessed on 20 July 2017.
* Converted using average spot rate for June 2017, i.e., AUD$1 equals US$0.75427, accessed on 20 July 2017.
China

Working toward an MNC-friendly environment, improved drug quality and streamlined pharma supply chain

China’s tough regulatory environment, including a rigorous drug approval system, slow processes and an unfavorable IP environment, are posing challenges to the growth of pharmaceutical MNCs in the country. The China Food and Drug Administration (CFDA) has introduced reforms that have the potential to eliminate hurdles slowing foreign drug approvals and thereby provide a thrust to the sector by enabling faster market access to foreign players.\(^{19}\) As a key initiative under these reforms, foreign drug manufacturers will be able to seek drug approvals on the basis of international trials, avoiding the requirement of China-based trials. This move looks promising for biopharma innovation and may prompt MNCs to consider China much earlier in their global development plans.\(^ {20}\) Further, the country has recently published an updated National Reimbursement Drug List that includes various MNC blockbuster drugs (such as GlaxoSmithKline’s Viread and AstraZeneca’s Iressa), making them available to a wider market.\(^ {21}\)

Additionally, in line with the European Medicine Agency’s conditional marketing authorization and the USFDA’s breakthrough therapy program, China has modified its orphan drug review process to offer conditional approvals for medicines that are approved abroad for rare diseases without requiring local trials. Besides, the CFDA is also looking to grant conditional approval to medicines that can cater to large unmet medical needs.\(^ {22}\)

Despite these potentially significant reforms, many MNCs remain cautiously optimistic. There are still several unanswered questions about how these access-related reforms will be implemented in practice. In addition, MNCs expect that they will continue to be adversely affected by pricing pressure and tendering processes designed to lower the cost of health care and promote domestic players.

**Bolstering quality and data integrity** is a major focus area for the industry. The CFDA has been under scrutiny because of allegations that 83% of its trial results were fabricated.\(^ {23}\) As a result, over the next five years, the CFDA is expected to shift toward day-to-day operational monitoring to ensure regulatory compliance. This involves yearly inspections of 300 to 400 pharmaceutical manufacturers along with 120 to 140 inspections for high-risk drugs. The reformed governance model also requires companies to re-conduct pharmacokinetic and bioequivalence studies for generics approved before 2010.\(^ {24}\)

Simultaneously, the nation is witnessing the adoption of innovative technologies to improve operational efficiencies in the supply chain. To streamline the sector’s distribution model, China’s National Health and Family Planning Commission introduced a “two invoice” system. The aim of the policy is to improve transparency and eliminate excessive profit margins associated with multi-tier distribution systems.\(^ {25}\) In addition, IBM, in partnership with Hejia (a Chinese supply chain management firm) has launched a blockchain technology application system called the Yijian, the first such tool in China. It is expected to help pharma retailers track drugs and increase transparency throughout the supply chain.\(^ {26}\)
India

Introducing reforms to propel growth of medical devices and revamping the pricing regime

In the Union Budget FY18 (announced February 2017), the Government primarily emphasized two key areas – growth of the medical devices sector and affordable drugs for the people. In medical devices, the focus is to attract investments and ensure access to low-cost products to reduce the country’s heavy reliance on imports (~75% of medical devices are imported). As part of its initiative, the Government:

- Released notification of a medical devices rule (to take effect January 2018), stating norms on licenses and standards for the manufacture and import of medical devices and the classification of devices, as well as post-approval controls and enforcement.
- Proposed a digital platform for convenient interaction between manufacturers and regulators under the Medical Devices rule.
- Added four more medical devices, including orthopedic implants, diagnostic equipment and catheters, to the National List of Essential Medicines – for example, the Government announced a 69% cap on knee implants.
- Initiated preparation of a database to monitor overpriced drug and medical devices.
- Inaugurated a Medical Devices Park in Telangana to support innovation, R&D and manufacturing of medical devices.

To improve patient access to medicines, the Government is following a two-pronged approach. As a first step, the Government intends to replace the existing National Pharmaceutical Pricing Policy (2012) to curtail medicine prices so that essential medicines and medical devices are affordable for the poor. Simultaneously, the Health Ministry is also considering amending the Drugs and Cosmetics Act to make prescription of generic drugs mandatory for doctors. This alteration is likely to spur the generics market in India to 90% (currently, ~80%) in the next three years. This step is also likely to help regulators break the strong link between pharmaceutical companies and doctors.

Besides the two key areas of focus in the recent budget, the nation continues to work toward positioning itself as a global biotechnology hub by 2020. As part of its national biopharma mission, the Department of Biotechnology, in collaboration with the World Bank, has launched a flagship program, “Innovate in India,” with an investment of US$250 million to encourage entrepreneurship and domestic production within the biopharma sector. In addition, the country appears to be making big strides in the development of indigenous vaccines. For example, an Indian firm recently showcased successful pre-clinical trials of the Zika vaccine and is now initiating phase I studies.

Despite all these initiatives, India continues to fall behind on its intellectual property regime (IPR) due to a weak IP framework, lengthy pre-grant proceedings and limited international IP agreements. This became more evident with the Global Intellectual Property Center (GIPC) Index ranking the nation at 42 among 45 participating countries. However, the incumbent Government remains committed to building an IPR-conducive environment by introducing a nationwide IPR policy. MNCs continue to remain wary of IPR in the country even though not a single compulsory license has been issued in 2015 and 2016. Instead, MNCs have started to offer voluntary licenses to Indian companies to navigate the challenges presented by the current patent protection regime.

The introduction of Goods and Services Tax (GST) reform in India is expected to bring significant changes for the Indian pharma industry. The reform is aimed at easing the taxation structure for the sector, encouraging manufacturers to provide affordable medicines to the consumers. However, it is being contemplated that 1Q17 will see muted growth in the sector. The slowdown will result principally from certain negative impacts, such as a 5% tax on some previously exempted life-saving drugs (for the treatment of HIV-AIDS, tuberculosis, malaria and diabetes). This is in addition to the categorization of formulations under a 12% tax bracket and APIs under an 18% tax bracket.
Market insights

Japan

Striving to strike a balance between innovation, access and cost curtailment

Driven primarily by a rapidly aging population, Japan is struggling with rising health care costs amid lackluster GDP growth. Japan’s Ministry of Health, Labor and Welfare (MHLW) continues its quest for cost containment strategies. As discussed in previous editions, increasing penetration of generics from 56% to more than 80% by September 2020 is one of the most important tools being adopted by the Government.46 Moving to a value-based health care model is another method to drive delivery of better care at lower costs and is gaining relevance as a central component of Japan’s vision for future health care. This new paradigm is associated with the underlying importance of cost effectiveness and value-based pricing of medicines. The plan, proposed in early July (to be introduced in April 2018), will set usage of standard processing time for the completion of cost-effectiveness assessments, which are leveraged for setting the prices of new drugs.47 Simultaneously, the country is attempting to create an environment for domestic innovation to thrive. MHLW is working on popularizing cancer genomic medicines in clinical settings. Under this national project, industry, the Government and academia will form a consortium to promote treatments and R&D, employing artificial intelligence and genetic analysis. This will help create a database of cancer genome information and clinical information, and will promote the development of drugs and other treatments.48 The MHLW and the industry have agreed to expand support for start-ups and plan to set up a council to promote them. The new office will advise companies on how to receive marketing authorization and include their product in the National Health Insurance (NHI) price list. The council will also share information on overseas pharmaceutical regulations to help the start-ups expand business abroad.49

In the field of Medical Devices, the MHLW is planning to launch conditional early approval for these products. The new system will enable health care stakeholders to obtain critical devices in a timely manner, helping companies and patients to avoid the long wait for approval commonly experienced in Japan. The initial plan is to cover medical devices that cater to serious diseases for which there is no effective treatment available. This move reflects the nation’s equal emphasis on the medical devices sector, as earlier this year a similar system was introduced for pharmaceuticals.50
South Korea

Continuing to channel investments into its biotech sector and increasing health care coverage rates

In the last edition, we discussed the South Korean Government’s enforcement of punitive measures against corrupt practices in the country. Recently, a major pharma company came under the scrutiny of the South Korean Ministry of Health and Welfare (MOHW), incurring a hefty penalty of US$48 million and suspension of all its products from state insurance reimbursement for allegedly bribing doctors. The case signals the MOHW’s strong commitment to the nation’s anti-graft laws.51

To attain its goal of becoming a major biotechnology hub by 2020, South Korea continues to inject investments into the biotech sector. The Government plans to invest US$274 million in 2017 to boost the sector’s strength in R&D and innovation.52

Further, South Korea is in the process of establishing a US$101.8 million (KRW113.5 billion) fund to support biotech start-ups and aid them in the development of new technology.53 Besides these initiatives, the country is also witnessing activities specific to drug R&D. Recently, the Korea Pharmaceutical and Bio-Pharma Manufacturers Association (KPBMA) announced the creation of an artificial intelligence-backed center for drug development. The new technology will eliminate inefficiencies from the initial phase of drug discovery and accelerate development of new therapies.54

Furthermore, the Korea Centers for Disease Control and Prevention announced the establishment of the country’s first biosafety level-4 (deadliest human viruses) lab for conducting research on high-risk diseases.55

Also, in an attempt to reduce the medical financial burden on South Korea’s nationals by 18%, the President recently announced a reform to increase the health insurance coverage rate to 70%. This new plan will cover several medical treatments, including dentures, dental implants, dementia treatment, MRIs and ultrasounds. The plan is expected to have a positive impact on related segments, such as medical equipment and biosimilars. The Government has said it will invest US$26.8 billion (KRW30.6 trillion) until 2022 to help achieve this objective.56
In this edition, we highlight significant tax developments and trends that are directly impacting or are likely to impact the sector in the following markets:

- China (mainland)
- Singapore
- South Korea
- Australia
- Japan
China

The business climate for the biopharma industry is changing rapidly with the introduction of BEPS and myriad enacted and proposed regulatory and R&D reforms. China recently simplified its clinical trial and accelerated drug-approval processes. These reforms enable MNCs to conduct China clinical trials simultaneously with overseas trials and use data from international clinical studies when seeking approval to import their products into China. The accelerated approval process enables MNCs to launch their products overseas simultaneously and in China. MNCs are cautiously optimistic toward the development, and we expect that the loosening of these regulatory rules could impact the design, implementation and monitoring of R&D processes in the biopharma industry, with implications throughout the value chain, including sales and marketing, data collection and analysis. In this issue, we explore the tax implications of these potential changes in a post-BEPS environment.

R&D functions

China is becoming an important R&D hub for biopharma, with numerous companies establishing regional and Chinese hubs in Shanghai. The R&D function is an important component of the value chain and, with more R&D hubs located in China, the Chinese tax authorities now have greater opportunity to evaluate whether profits from the value chain are fairly allocated among related parties in China and overseas. Pre-BEPS, the normal practice was for R&D hubs to retain a simple cost-plus markup for its functions, and all residual profits were repatriated to the intellectual property (IP) owner. Post-BEPS, there was a paradigm shift whereby more emphasis is now placed on economic substance. The typical arrangement is for the funding and R&D risk to shift contractually to the principal or IP owner. Such structures are sustainable only if the principal is supported with appropriate economic substance, such as R&D resources capable of managing the R&D process, and having the seniority and competency to make strategic decisions that will influence the risk outcome.

The Chinese tax authorities have recently visited several R&D centers to educate themselves as to the phases of the R&D process and the associated value drivers. As a result, we understand that the Shanghai State Tax Bureau is now looking into the appropriate remuneration associated with such functions. For a well-structured R&D process where most of the risk-taking functions and value are driven and managed outside of China, a cost-plus method is often acceptable. Occasionally, we have seen tax authorities raise the profit split method as a point for discussion and potential adjustment, albeit unsuccessfully.

However, as a result of the aforementioned reforms, allowing for an expedited clinical trial process and a reduction of the new drug launch timeline for the Chinese market, we expect to see the involvement of Chinese R&D resources earlier in the new drug development process. Performing clinical trials in China during earlier stages of the new drug development process will increase the R&D-related tax risks of the Chinese R&D organization. The complexity of the related work is expected to increase the demand for more experienced R&D resources and could potentially require an overall increase in R&D headcount. It is important to consider proactively how these potential changes should be reflected in a company’s existing transfer pricing policy. It should be noted that the Chinese tax authorities currently expect to see markups on R&D services that are higher than many of the peer authorities in the US and Europe. We expect that, in the future, as China R&D organizations increase their capabilities and headcount, and are perceived to play more important roles in the new drug development process, this will become an area to pay more attention to. As such, it is critical that companies regularly and strategically monitor and manage their Chinese transfer pricing policies and documentation relating to their Chinese R&D functions. Doing so will be especially important as Chinese R&D organizations evolve and mature, and as the Chinese tax authorities begin pursuing even higher returns for what they will consider services of increasing value and strategic importance.

Sales and marketing functions

As indicated above, MNCs are now able to launch new drugs simultaneously in China and overseas, with the local Chinese team often referring to global product launch guidelines and locally executing on the strategy. However, as result of a simultaneous product launch, the Chinese sales and marketing team could potentially participate earlier in, or have a greater level of participation in, the design of the overall product launch strategy. Such becomes quite likely as the collection of market and patient data from the Chinese market will become critical to a successful worldwide product launch.

Chinese tax authorities have historically placed significant emphasis on the sales and marketing functions in China. In addition to the development, enhancement, maintenance, promotion and exploitation (DEMPE) functions, the Chinese transfer pricing also requires full consideration of the promotion function when allocating profits to value-creating activities performed in China (i.e., DEMPE plus promotion, or DEMPEP).

This DEMPEP standard is already being utilized by the Chinese tax authorities to challenge the limited risk models many MNCs currently operate, or are attempting to operate, in China. By arguing, for example, that some form of valuable marketing intangible has been created in China under the “promotion” prong...
of the DEMPEP standard, the Chinese tax authorities will often attempt to pursue returns higher than what is usually expected from limited risk models. We expect that, as Chinese sales and marketing functions evolve and play a more significant role in global product launches, or are perceived as doing so by the tax authorities, the existing challenges around promotion-related returns will become even more exacerbated. As such, as with R&D functions, it is critical that companies regularly and strategically monitor and manage their Chinese transfer pricing policies and documentation relating to sales and marketing.

Transparency

There has been much discussion and concern over the transparency of information that comes with greater tax and transfer pricing disclosures. Tax disclosure risks will be heightened through more rigorous information collection and analysis by the Chinese tax authorities as a result of the 1,000 enterprise initiative and the newly launched Golden Tax System. For transfer pricing, 2017 will be the first year that local tax authorities will be collecting the local file and master file under BEPS Action 13. The local file and master file will include greater disclosure on the local and global value chain. Chinese tax authorities are expected to combine this additional information with the data they have already collected through the 1000 enterprise initiative, etc., to enhance their industry and digital/analytics audit capabilities. For companies operating in China, the consistency of information is key.

We recommend that every company ensure that their data is aligned along two fronts: i) alignment of value-creating functions and internal transfer pricing policies; and ii) alignment of transfer pricing and customs import pricing strategy and documentation.

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South Korea

Controversy trends

Overall tax audit environment

It is expected that the intensity of tax audits will continue to increase as the Government seeks to fund recently announced planned spending increases. It is also anticipated that taxpayers will encounter an increased challenge when appealing tax audit assessments, and in general should expect less-favorable outcomes compared with past results. As a result of this evolving audit landscape, and a five-year statute of limitations, taxpayers who have not been audited recently and/or are in an operating loss position should expect to be targeted. It is highly recommended that taxpayers proactively review their tax compliance, tax governance and tax audit documentation processes as part of an overall reassessment of their level of audit preparedness.

Notwithstanding the above, the Government recently announced the following as part of its 2017 tax reform proposal certain enhancements to taxpayers’ audit protection rights:

► Tax audit notice period extended from 10 to 15 days before commencement of a tax audit.
► Tax auditors may not request information that is not directly related to the tax audit – further guidance on “information directly related to tax audit” is expected.

Pharmaceutical industry

As discussed in the last edition, the tax authority has been performing special tax audits investigating the legitimacy of certain companies’ sales and marketing expenditures, in particular, sales rebates, purported to be incurred for stimulating local sales and facilitating relationships with doctors and hospitals. The tax authority has been successful in disallowing deductions claimed with respect to improper or illegal “sales rebates,” which is broadly defined to include many different types of payments (e.g., excessive speaker fees paid to doctors, financial assistance for doctors in relation to golf or other entertainment offered at seminars, and special cashback arrangements targeting certain customers). Recent special tax audits have focused on sales commissions paid to contract sales organizations (CSOs). The tax authority is concerned that companies are passing along illegal or improper sales rebates to their customers by embedding such payments into the sales commissions paid to the CSOs, which the CSOs then pass along.

In addition, other areas recently subject to increased audit scrutiny include:

► Transfer pricing, including companies with operating losses
► Deductibility of intercompany service fees, including management service fees
► Performance bonus/severance payments to executives/directors failing to comply with required shareholder approvals and related formalities

BEPS update

Master file and local file requirements

Korea’s Ministry of Strategy and Finance enacted transfer pricing documentation legislation on 7 February 2017 in line with BEPS Action 13, effective as of 1 January 2016, for submission of the master file (MF) and local file (LF) in Korea for entities with total revenue of more than KRW100 billion and total related party transactions of more than KRW50 billion.

If the thresholds are met, the Korean entity must file the MF and LF within 12 months from the fiscal year-end. Both must be Korean.
However, the MF can be submitted in English first with the Korean-translated version submitted within 30 days. The threshold for documenting transactions for the LF is KRW1 billion for tangible transactions and KRW200 million for non-tangible transactions. Transactions covered under an APA are exempt from the LF.

The template for the MF and LF has been enacted into regulation that provides detailed guidance on information to be included. The table of contents is similar to the OECD BEPS Action 13 recommendations, but the level of detail and type of information required is much more detailed.

**Country-by-country report and advance notification**

A country-by-country report (CbCR) must be submitted in Korea within 12 months from fiscal year-end if the consolidated revenue of the ultimate parent entity (UPE) exceeds KRW1 trillion for the previous fiscal year. Since the CbCR rules were enacted on 1 January 2016, the first filing threshold must be determined based on FY2015 consolidated revenue. The CbCR must be filed in both Korean and English.

South Korea’s Ministry of Strategy and Finance also requires an advance notification of the CbCR to be filed within six months from a South Korean entity’s fiscal year-end. This is a one-page form to be submitted either electronically or by hard copy to the district tax office. The form stipulates who will file the CbCR and where. If the UPE’s country is a signatory of the automatic exchange of the CbCR Multilateral Competent Authority Agreement (MCAA), and the advance notification is filed by the due date, the CbCR must be submitted in the UPE country and not in South Korea; otherwise, the South Korean entity must file the CbCR in South Korea, notwithstanding the automatic exchange of the CbCR. Surrogate filing of the CbCR is also allowed.

**Sector impacts of draft 2017 tax reform**

On 2 August 2017, Korea’s Ministry of Strategy and Finance announced the 2017 tax reform proposal (2017 Proposal) aiming to create jobs, redistribute wealth and expand the tax revenue base. Unless otherwise specified, the amendments put forth in the 2017 Proposal will generally become effective for fiscal years beginning on or after 1 January 2018:

- The top tax rate will be increased to 25%, with the addition of a fourth tier, for taxable income exceeding KRW200 billion. Currently, the Korean corporate income tax rate is a progressive three-tier rate structure, with a top rate of 22% for taxable income exceeding KRW20 billion.

- Currently, tax losses can be carried forward 10 years. Tax loss carry-forwards can be utilized by a domestic company in a particular year, limited to 80% of the company’s taxable income in that year. Please note that, for a small and medium-sized enterprise (SME), utilization is not limited to this threshold, and 100% of the taxable income can be utilized, thus not affected by this change.

- The 80% utilization threshold for companies other than SMEs will be gradually reduced to 60% for the fiscal year starting from 1 January 2018, and then 50% for the fiscal year starting from 1 January 2019.

- Currently, a basic tax credit ranging from 3% to 8% is permitted with respect to corporate investment to promote job creation. Under the 2017 Proposal, the tax credit for job creation will be permitted even if there is no corporate investment, subject to proposed limitations/caps. The proposed change will be temporarily available for two years (one year for large companies).

- Certain corporations will be subject to a revised accumulated earnings tax (AET) regime, with a sunset clause due to expire on 31 December 2020. Revisions to the AET include: (i) the tax rate applied on the AET is increased from 11% to 22% (inclusive of local income tax); and (ii) dividends would no longer be used to decrease accumulated earnings.

- Large companies currently claim a tax credit for qualifying R&D expenditures at a rate of 1% to 3% under the current expense method or at 30% of the incremental portion of the current-year R&D expenditures under the incremental expense method. The rate of 1% to 3% under the current-year expense method will be lowered to 0% to 2%, but there will be no change to the tax credit rate under the incremental expense method.

- The existing R&D tax credit rates for medium-scale companies and SMEs will remain the same (8% and 25% respectively for those under a current-year expense method or 40% and 50% respectively for those under an incremental expense method).

- Consistent with BEPS Action 4, the deductibility of interest payments made to foreign-related parties will be limited. The proposed rule will apply to a domestic corporation (including the branch of a foreign corporation), other than financial institutions and insurance agencies, with foreign related party transactions. A domestic corporation would be able to deduct net interest expense up to 30% of adjusted taxable income.

The domestic corporation must use the method that results in a larger disallowance of interest expense deduction computed either under the proposed interest expense limitation or the existing 2:1 debt-to-equity safe harbor rules. The proposed rule will be effective for fiscal years beginning on or after 1 January 2019.

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Japan

BEPS impact to inbound investment structures

Japan has implemented many of the Organisation for Economic Co-operation and Development’s (OECD’s) BEPS recommendations, including signing up for the Multilateral Instrument (MLI) in June, which will potentially modify 35 of Japan’s tax treaties. As a result, many multinational life sciences companies investing into Japan have been or are currently in the process of reviewing their structures to analyze whether they are compliant with the new international tax standards.

Companies operating in Japan through a commissionaire or “toiya” structure are assessing the future viability of such arrangements. Once the MLI takes effect and modifies Japan’s existing tax treaties, commissionaire structures are expected to create an agency permanent establishment (PE). Groups are looking to restructure their operations in Japan to reduce the risk of creating an agency PE; for example, by converting from a commissionaire arrangement to a more traditional buy-sell model, such as a limited risk distributor.

Another concern is that the MLI restricts the applicability of the “preparatory or auxiliary activity” exemptions, thus lowering the threshold for creating a PE. Companies that hold a stock of goods in a warehouse in Japan generally should not have a PE under the current rules. However, under the post-MLI application of the treaty, this arrangement could create a PE. Even if the goods are held in a third-party warehouse, if the taxpayer has regular, unrestricted access to the warehouse, there is concern that this may create a fixed place of business PE.

Holding company structures will also be impacted, and many companies are assessing whether they have sufficient substance and business purpose to qualify for treaty benefits, such as reduced rates of dividend withholding tax.

As companies assess the potential impacts of these changes, we expect that many will determine it necessary to restructure their operating/supply chain models and/or holding company and financing arrangements.

2017 Japan tax reform and CFC rules

In the last edition, we discussed several proposals included in the Japanese Government’s 2017 tax reform plan. As indicated, the proposal that has attracted the most attention was the reform of the Japanese controlled foreign corporation (CFC) rules, which would affect many Japanese-headquartered life sciences companies with overseas subsidiaries. The new rules cast a larger net and could result in a much larger number of Japanese foreign subsidiaries being classified as CFCs. The impact of being a CFC is that the foreign subsidiary’s taxable income is subject to Japanese corporate tax on a current-year basis — with a foreign tax credit available for foreign taxes paid by the CFC. The proposed changes to the Japan CFC rules have now been enacted and will come into force for accounting periods beginning on or after 1 April 2018.

Japanese-headquartered groups are actively reviewing their structures to analyze the potential impact. The stricter regime will affect certain holding, finance and IP licensing structures and introduces a much broader definition of passive income. Examples of structures that may be impacted include offshore holding companies in locations such as the Netherlands, the UK, Singapore and Hong Kong; cash and treasury management operations; and situations where intellectual property has been transferred or licensed offshore.

Additionally, whereas the current CFC rules apply where the effective rate of tax is less than 20%, the new rules would apply where the effective rate of tax is less than 30%. The new regime does, however, retain the “active business” exception, with some modifications. Currently, most jurisdictions have a headline corporate tax rate of less than 30%, and the majority of Asia-Pacific jurisdictions’ rates are much less than 30%. In addition, if US tax reform proceeds forward as currently anticipated, even the US corporate tax rate could drop to less than 30%. That means that many Japanese foreign subsidiaries, including US subsidiaries, could become CFCs with reportable income.

Controversy trends

In the area of tax audits, we are seeing an increased focus on cross-border transactions. The Japanese National Tax Agency (NTA) has been strengthening its relationships with other countries’ tax authorities; for example, through the exchange of information based on tax treaties. This is already having the result of the NTA requesting overseas tax authorities to provide information and answer questions with respect to the counterparty based in that overseas jurisdiction, particularly where the effective tax rate in that jurisdiction is low. Hong Kong is a recent example.

In response to this increased scrutiny, many taxpayers are seeking to gain certainty over the tax treatment of their cross-border transactions by seeking advance rulings. Japan has an extensive APA program, and many life sciences companies already have APAs in place. Companies with unilateral APAs are seeking to renew as a bilateral APA, which provides even greater certainty. The NTA is making efforts to expedite the APA process, and our recent experience is that, in some cases, a unilateral APA could be concluded within one year and a bilateral APA within two years.

Outside of transfer pricing, we are also seeing that companies are much more interested in approaching the NTA for an advance “informal ruling” on various tax positions. One example would be to seek guidance on whether an internal reorganization meets the requirements for tax-free treatment. The process for an informal ruling involves the taxpayer working with their advisor to prepare a memorandum describing the transaction and the anticipated tax

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treatment, which is then discussed at a meeting with the NTA. The NTA would then provide its verbal comments on the tax treatment during the meeting. Although such rulings are not written or binding, our experience is that they are generally respected during a future tax audit, provided that full disclosure of the facts was made at the time of the ruling and the facts have not subsequently changed.

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Singapore

Draft Income Tax (Amendment) Bill 2017

The draft Income Tax (Amendment) Bill 2017 was published for public consultation during the period 19 June 2017 to 10 July 2017. The legislation as currently drafted is not final and is subject to change pending feedback received by the Ministry of Finance (MoF). It is therefore imperative that businesses continue to monitor the development of this draft legislation. We highlight below two of the proposed changes likely to be of significant interest for life sciences companies operating in Singapore:

1. Liberalization of tax deduction for payments under cost sharing agreements (CSAs)

To ease compliance, it was proposed in the 2017 Singapore budget that businesses may opt to claim a tax deduction under section 14D of the Income Tax Act equal to 75% of the payments made under a CSA and incurred for qualifying R&D projects (a CSA is defined as any agreement or arrangement made by two or more persons to share the expenditure of R&D activities to be carried out under the agreement or arrangement). A detailed breakdown of the underlying expenditures covered by the CSA, with adjustments for disallowed expenditures, would no longer be needed. However, an R&D claim form, including a description of the R&D activities performed, would still be required under the proposed change.

As a result of post-budget feedback, the MoF has decided to liberalize the treatment of the CSA payments by allowing a 100% deduction of the payments. This proposed change has been incorporated into the draft Income Tax (Amendment) Bill 2017. However, this change will be applicable only from the year of assessment (YA) 2018 and thereafter. Accordingly, taxpayers will still have to contend with the deductibility requirements applicable under current law with respect to CSA payments made for the years prior to YA 2018.

We believe this will serve as a welcome relief for many life sciences companies, especially those that have previously encountered difficulties in obtaining the required level of detailed, line item support for the costs charged under a CSA from headquarters.

2. Adjustments arising from adoption of FRS 115 – Revenue from Contracts with Customers

FRS 115 - Revenue from Contracts with Customers applies to all contracts that a business entity has with customers, excluding certain exceptions. It is effective for annual periods beginning on or after 1 January 2018. However, earlier adoption is permitted.

As revenue recognition plays a fundamental part in the preparation of a business entity’s financial statements, which are then used for tax purposes, the adoption of FRS 115 has income tax implications for some taxpayers, at least in the transitional year. The Inland Revenue Authority of Singapore (IRAS) issued a public consultation paper on 12 October 2015 to provide guidance on its proposed positions on the income tax implications arising from the adoption of FRS 115.

The IRAS took the following proposed positions in its consultation paper:

- Accept the accounting revenue determined in accordance with FRS 115 as the revenue figure for tax purposes, except in certain situations
- Require tax adjustments for significant financing components recognized as interest income or expenses
- Treat the profit or loss arising from transitional adjustments as taxable income or a deductible loss in the year in which FRS 115 is first adopted, where the income is derived from a trade, business, profession or vocation.

The transitional tax adjustments arising from the adoption of FRS 115 have now been included in the draft Income Tax (Amendment) Bill 2017. The proposed legislation is consistent with positions proposed by the IRAS in its consultation paper in October 2015. Any transitional gain or loss will be taxed or allowed a deduction based on the tax rate(s) applicable to the taxpayer for the initial YA. A formula is required to be applied to the transitional gain or loss to determine the tax rates applicable, based on the total income, subject to different tax rates and income exempt from tax (if applicable) for the initial YA.

Life sciences companies – in particular, medical technology companies, which have long-term contracts with customers to supply equipment, consumables, and installation and training services – are likely to have transitional gains or losses. Often, life sciences companies are granted tax incentives for carrying out substantial activities in Singapore and have income subject to tax at the concessionary and normal tax rates. Such companies with transitional loss and significant exempt income in the initial YA, or companies previously under a tax incentive with transitional profit and subject to a normal rate in the initial YA, will likely be adversely impacted.
Intellectual property (IP) regime

As announced during the 2017 Singapore Budget, to encourage the use of IPs arising from R&D activities, IP income will be incentivized under a new base erosion and profit shifting (BEPS)-compliant IP regime named the IP Development Incentive (IDI). Accordingly, the scope of the two existing incentives, namely the Pioneer Certificate (PC) and the Development and Expansion Incentive (DEI), where these apply to activities other than production or manufacturing, will be amended to exclude IP income. However, existing incentive recipients will continue to have such income grandfathered and covered under their existing incentive awards until 30 June 2021.

The IDI is a discretionary incentive that would be administered by the Singapore Economic Development Board (EDB). The EDB has been engaging with businesses to understand the implementation considerations for companies carrying out different activities and operations. The introduction of the IDI, originally scheduled to take effect on 1 July 2017, will be delayed. The EDB will release further details by the end of 2017.

We expect further details to be released to include how the qualifying IP income is defined, the applicable concessionary tax rate, and how the regime may complement and interact with the existing incentives.

Life sciences companies that are enjoying tax incentives or negotiating new tax incentives would be potentially impacted by the introduction of the IDI and the changes to the PC and DEI (other than for production/manufacturing). The delayed implementation will provide more time for companies to review their business activities and plans, and better assess the potential tax impact.

Australia

Life sciences sector remains a focus area for the Australian Taxation Office (ATO)

EY recently met with the ATO Pharma Cluster, a newly established project team that has been tasked with analyzing risk areas characteristic of participants within the Life Sciences sector. The Pharma Cluster as defined by the ATO has responsibility for the broad life sciences sector, which includes companies involved in the development, manufacture and/or distribution of over-the-counter (OTC) products, patented drugs, generic drugs, medical devices, animal health and other associated products. The ATO Pharma Cluster shared a number of viewpoints derived from its ongoing consultation with sector participants, regulatory authorities and government bodies. We believe the views shared by the ATO Pharma Cluster are likely to have a material impact on taxpayers within the life sciences sector, particularly those that are engaged with the ATO in an ongoing review process or compliance assurance program.

During this meeting, the ATO Pharma Cluster shared their views regarding these matters:

- Sector features and ATO focus: the ATO recognizes that life sciences is a highly segmented and diversified sector and acknowledged that there is no “one size fits all” approach to addressing tax risks for all sector participants.
- ATO guidance: the ATO is expected to issue formal guidance on inbound supply chains. Although not sector-specific, the guidance will be relevant for life sciences taxpayers with turnover of AUD$50 million and AUD$250 million. Given the ATO’s recognition that there is no one-size-fits-all approach to the industry, there is currently no plan to issue formal guidance specific to the industry. This represents a change in position for the ATO.
- APAs: transparency is the key to the timely conclusion of APA negotiations. Taxpayers seeking the ATO’s assurance on their transfer pricing arrangements should be prepared to provide detailed information regarding the global value chain.
- Compliance activities: all major multinational corporations (MNCs) in the life sciences sector should expect to be subjected to a Streamlined Assurance Review (SAR) as part of the Top 1000 Tax Performance Program, even if already subject to a separate compliance program.

Sector features and ATO focus

The focus of the ATO Pharma Cluster has been on understanding the population of, and differences within and among, the subsegments of the life sciences sector (including OTC drugs, patented drugs, generic drugs, medical devices and animal health). To develop their understanding, the ATO Pharma Cluster has been in dialogue with various key industry participants and regulatory bodies, including, for example: life sciences sector participants; the Pharmaceutical Benefits Scheme (PBS) authorities; the Therapeutic Goods Administration (TGA); Medicines Australia; the Medical Technology Association of Australia (MTAA); and various government agencies, including regulators responsible for the standard of clinical trials in Australia.
The purpose behind the ATO’s consultation process is to understand the value contributed by Australian participants at a subsegment level. In particular, the ATO has highlighted transfer pricing to be the number one area of concern and noted that a primary objective was to understand how the value contributions of Australian participants should be reflected within MNC transfer pricing policies.

One highlighted area of focus has been the role and value of clinical trials in the context of the Australian market, particularly in relation to risk borne as the local trial sponsor, the attractiveness of Australia as a market for clinical trials and the value contributed by Australian clinical trials to MNC global operations.

**ATO guidance**

**Formal guidance**

The ATO previously indicated that industry-specific guidance would be published during the year. However, with the ATO now seeing for itself the highly segmented and diversified nature of the life sciences sector, they have come to the view that there is likely limited utility (if any) in adopting a one-size-fits-all approach (particularly as it relates to target margins or benchmarks for specific activities). As a result, the ATO communicated during the meeting that it is not currently their intention to provide industry-specific guidance in the near future.

The ATO will, however, be issuing formal guidance (likely in the form of a Practical Compliance Guideline) in relation to inbound supply chains for MNCs. This guidance will not be industry specific and will only apply to taxpayers with a turnover of $50 million to $250 million, which the ATO expects to include approximately 400 life sciences sector participants. The ATO Pharma Cluster may provide input into this guidance concerning the likely effect on life sciences industry participants.

In the absence of specific guidance, the ATO view is that the correct approach to determining arm’s length outcomes should be to examine the Australian contributions relative to offshore contributions in the context of the global value chain and relevant commercial and financial relations. This approach should include an economic analysis based on the OECD's five comparability factors.

Further, although the ATO was hesitant to provide specific guidance regarding acceptable levels of profitability for the life sciences industry generally, it did posit that returns attributable to Australian “box-movers” (i.e., low-function distributors/logistics services providers) of pharmaceutical goods would not be appropriate for life sciences industry participants more generally. The reasoning is that the ATO regards the Australian arms of pharmaceutical MNCs to have a higher level of functionality (including more advanced marketing and regulatory activities) compared with these entities.

**Informal guidance**

During the meeting, the ATO expressed its current perspectives with respect to transfer pricing comparability studies:

- The ATO stated that it does not have a preference regarding the most appropriate transfer pricing method to be applied in the industry, as this will be assessed based on what is most appropriate and reliable in the particular taxpayer’s circumstances. In the life sciences sector, the methods that have more commonly been considered by the ATO have been the comparable uncontrolled price (CUP), profit split, and transactional net margin method (TNMM). In particular, in any compliance product (including risk reviews, audits and APAs), the ATO will seek to obtain information regarding third-party arrangements at the global level (including in-licensing agreements) to assess whether any of these arrangements are suitable for use in applying the CUP method.

- Where the TNMM is ultimately selected as the most appropriate and reliable method, the ATO noted that it would first look to apply this method on an appropriately segmented basis. For example, where a business is composed of multiple business segments (e.g., patented drugs, generics and animal health), the ATO will expect separate consideration of the appropriate return for each business segment. This may extend to the preparation of different benchmarking analyses for each business segment or, at a minimum, consideration of whether a different point within the identified range is appropriate based on the characteristics of the different segments.

- In this regard, the ATO’s fact-gathering processes, including functional interviews, during compliance and assurance programs (such as client risk reviews or APA negotiations) are likely to be undertaken on a detailed and segmented basis.

- In terms of local comparable companies, the ATO did acknowledge that, within the life sciences industry, it is generally difficult to identify Australian comparable companies. Although there are certain instances where local comparable companies may be available (the ATO specifically mentioned the distribution of medical devices and OTC products), it was specifically recognized that there is a lack of third-party Australian comparables for the pharmaceutical subsegment.

- Where reliable local comparables cannot be identified, the ATO stated it is open to considering foreign comparables, provided that these have a functions, assets and risks profile similar to the Australian taxpayer, possibly in conjunction with (or as an alternative to) a “buildup” approach, which adds incremental profitability to a distribution (box-mover) return to obtain a range of returns more commensurate with the Australian taxpayer’s level of functionality. In general, at a minimum, this approach
involves adding an additional return associated with the local marketing and detailing function. EY has in general advocated the use of such an approach to our Life Sciences clients.

- Lastly, the ATO indicated that it generally does not accept that life sciences companies in Australia can be characterized as “limited risk.” This conclusion is based largely on the perceived value-added activities undertaken by industry participants and, in particular, the role of the Australian entity as a sponsor in relation to clinical trials activities. The ATO stated the view that they have not yet been satisfied that the risk associated with fulfilling this role can be passed to affiliates, particularly in the context of the BEPS transfer pricing framework (i.e., in a DEMPE context).

In light of the above, we recommend industry participants review their transfer pricing documentation to determine whether a limited risk characterization has been used and/or whether they act as a sponsor in relation to local clinical trials. We also recommend revisiting any benchmarking analyses that have been relied upon, to ensure these appropriately reflect and differentiate the appropriate return for each business segment.

**APAs**

The ATO confirmed that APAs continue to be a viable means for taxpayers to seek assurance on their transfer pricing arrangements. However, the ATO specifically noted that it is likely to view taxpayers unfavorably if the initial APA submission applies a single whole-of-business return across multiple discrete functions (e.g., manufacturing, distribution and clinical trials) or business segments (e.g., patented/unpatented medicines, medical devices, OTC products and animal health), or where the taxpayer is unwilling to provide a sufficient level of transparency on the global value chain during the APA discussions. The required level of transparency is likely to extend to information regarding the profitability and economic substance of key entities within the value chain, particularly IP owners/residual profit earners. The ATO also noted general concern regarding the uncertainty around the extent of information required throughout the APA process and committed to providing clarity on information requirements in the early stages of engagement where possible.

Having noted taxpayer concerns about the time frames and level of information required to be provided following acceptance into the APA program, the ATO cited a recent example whereby an APA was concluded in a relatively short period due to taxpayer cooperation and transparency. In this case, the APA was concluded within 18 months. The taxpayer was an Australian pharmaceuticals distributor of a variety of products (including patented medicines). Notwithstanding the different business segments and the comments regarding assessing separate returns to the various business segments, the APA was concluded using the TNMM to assess the whole-of-business distribution return for the Australian entity, evidencing ATO openness to adopting a whole-of-business approach where appropriate. However, this whole-of-entity approach was only deemed appropriate after considering the materiality of the various business segments and the appropriate returns to each segment. We further note that the agreed return is broadly consistent with distribution returns in the industry, based on our experience (after applying a buildup approach), albeit toward the higher end.

**Compliance activities**

The ATO has introduced the Streamlined Assurance Review (SAR) program for the Top 1000 taxpayers, which is a new taxpayer compliance program focusing on understanding the overall tax performance of the selected taxpayer, the nature of its major business activities, and its tax risk management and governance framework.

The ATO indicated that all major MNC taxpayers in the life sciences sector should expect to be subjected to a SAR as part of the Top 1000 Tax Performance Program. The ATO’s goal is to complete all 1,000 SARs within four years. However, at the time of our meeting, which was at the end of the program’s first year, the ATO had commenced fewer than 100 reviews and concluded none. The
form of ATO review sign-off was also a work in progress. Since our meeting, we have seen few draft SAR review reports. As might be expected, these are drafted in respect to key areas of tax risk potential next steps, and are only summary comments on tax risk management and tax governance.

The ATO also acknowledged that taxpayers subjected to client risk reviews (CRRs) may cover many of the material issues that are the focus of the SAR. The ATO noted that, although successful completion of a CRR would not prevent the same taxpayer from being selected for a SAR, the ATO would not automatically look to reopen issues covered by the CRR, which should simplify the SAR process.

Key messages

Based on our discussions with the ATO Pharma Cluster, we consider the following to be the key messages to life sciences sector participants:

- The ATO is open to taxpayers seeking certainty by concluding an APA.
- The ATO is currently considering whether entering an APA can also address the risk of diverted profits tax (DPT) applying to the relevant transactions. At this stage, the ATO is considering the option of including language in APA agreements that indicates that no tax benefit arises in relation to the transactions covered by the APA (which would clearly preclude the DPT from applying to these transactions).
- Functional interviews during compliance and assurance programs (such as CRRs or APA negotiations) are likely to be undertaken on a detailed and segmented basis. Further, a full review of taxpayers’ global value chain(s) will continue to be central to the ATO’s review and compliance activities, and a critical part of successful APA negotiations.
- Early engagement by taxpayers is encouraged. The ATO is looking to communicate information requirements upfront in any engagement with taxpayers (including APAs).
- Transfer pricing documentation or remuneration policies that rely upon a functional characterization of the Australian distribution entity as a limited risk entity or a box mover are unlikely to be accepted by the ATO.
- Although transfer pricing is the primary focus area for the ATO Pharma Cluster, the ATO is also considering broader tax aspects of the industry, including IP migration, thin capitalization and debt loading.

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All Base Erosion and Profit Shifting (BEPS) Actions have potential impact on companies in the life sciences sector. However, there are specific actions that may have a disproportionate impact on life sciences companies. In particular, these are Actions 8–10 and Actions 5 and 13. The former are related to transfer pricing, specifically the entitlement of intangibles-related returns. The latter concern transparency, documentation and reporting. Below, we discuss the latest developments related to these actions in the Asia-Pacific territories and their impact on the industry.

The BEPS reports indicate that, like the rest of the world, the Asia-Pacific markets are at various stages. We have generally classified them, for purposes of this article and based on their movement to date, as follows:

- Fast movers, which this article will focus on: Australia, China, India and Japan
- Slower-moving markets: Hong Kong,* Malaysia, Indonesia, Singapore,* South Korea and Taiwan
- Quietly watching: ASEAN – Thailand, Philippines and Vietnam

* Hong Kong and Singapore are associate markets of the Organisation for Economic Co-operation and Development (OECD).

**Actions 8-10**
Aligning transfer pricing outcomes with value creation

Life sciences companies’ supply chains are quite complex, with intellectual property (IP) typically licensed or cost shared as necessary to support global operations. In the sector, the fruits of R&D are generally subject to patent. The industry is extremely research intensive. R&D expenditures as a percentage of revenue are typically in the 18% to 20% range for large pharma and biotech companies, with some as high as 30% to 40%. The valuations and revenues of life sciences companies are dependent on the success or failure of their patented IP. Once a company is successful, the management and protection of its IP is of great importance. Through intercompany licensing or cost sharing, the licensee or cost-sharing participant becomes the beneficial owner of the IP and funds future development (in whole or part) pursuant to a given arrangement, and is entitled to a return on this investment through exploitation of the IP. As beneficial owner, the licensee/cost-sharing participant will also be responsible for product liability and commercial risk. The responsibilities for protection and defense of the IP often stay with the licensor or are shared between the licensor and the participating party.
licensee and licensor. In the typical life sciences supply chain structure, IP owners are compensated as entrepreneurs earning residual returns. Other functions (distribution, logistics, etc.) are typically compensated on the basis of earning target profit returns; for example, through a cost-plus service fee or by providing an agreed net operating margin to other companies in the supply chain.

Actions 8-10 may disrupt the status quo by rejecting the compensation of IP based solely on IP funding and management. Instead, there could be an increased focus on people functions related to the actual development of the IP. In particular, Action 8-10 recommendations focus more on a broader array of functions related to IP (i.e., development, enhancement, management, protection and exploitation (DEMPE)), the allocation of risk-related return based on the location of the people who manage and control these risks, and the capacity to bear such risks financially.

In the Asia-Pacific region, China is a fast mover with respect to considering DEMPE and intangibles. The State Administration of Taxation (SAT) issued a consultation draft of the new transfer pricing rule in September 2015 to reflect the guidance in BEPS Actions 8-10. The SAT adopted basic principles similar to those of the OECD, whose view is that intangible-related returns should be allocated to the parties that perform important DEMPE functions. At the same time, the SAT added “promotion” activities to other DEMPE activities (i.e., DEMPEP) and emphasized frontline functions such as performance of R&D, collection of marketing information and the management of customer relationships. The DEMPEP principles have been finalized and incorporated in Bulletin 6, which took effect on 1 May 2017.

As indicated in the consultation draft, intangibles include patents, non-patented know-how, trade secrets, trademarks, brands, customer lists, sales channels, franchises, government licenses and copyrights. The specific enumeration of customer lists and sales channels reflects China’s view of the importance of its markets and local marketing activities.

Based on recent experiences in transfer pricing audit cases, the SAT is enforcing this view by often asserting that local manufacturers/distributors of multinational pharmaceutical companies should earn super profits through the creation of certain marketing intangibles. These marketing intangibles are created through their large sales forces benefiting from significant market demand, good infrastructure and other Chinese market-specific factors. In addition, the SAT may view the product permits/government licenses in the Chinese life sciences industry as valuable intangibles owned by a local subsidiary. Therefore, the SAT would expect a double-digit operating margin for a multinational pharmaceutical manufacturer with marketing and distribution functions (expect a higher margin above the median/industry average for global top 10 pharmaceuticals) during a transfer pricing investigation.

Clinical trial and contract R&D activities have also been focus areas of the SAT during a transfer pricing audit. Chinese tax authorities usually scrutinize the substance of the overseas principals and actual R&D activities/contribution of local entities to assess the appropriateness of a cost-plus method, cost base or markup rate method. They could view contract R&D and the collection of information in clinical trials as important functions in the value creation of intangible property and expect a higher return (or markup) for such services.

The SAT has increased its scrutiny on outbound intercompany service payments since mid-2014. In March 2015, the SAT issued Announcement 16 to standardize and strengthen the position of the SAT on service charges and royalty charges to overseas related parties. For service fee charges, the service recipients must receive direct or indirect economic benefits from the services. The announcement stipulates six types of service charges that will be considered as non-arm’s length charges and therefore nondeductible. In principle, the SAT adheres to the internationally accepted and OECD-sanctioned “benefit test.” However, it takes a strict view on what activities meet the benefit test. For example, the SAT takes a broader view than the OECD on what activities constitute “shareholder activities” that cannot be charged out, thus imposing a strong presumption that management, control and oversight activities fall within this category.

Life sciences is an industry of focus for Chinese tax authorities when selecting the transfer pricing audit targets. Various tax authorities are assisting the SAT in risk assessment for this industry. Multinational pharmaceutical companies in China are under the spotlight and, now that the SAT is armed with the BEPS

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[i] The services must have no relation with the risks assumed by the enterprise; (ii) the services such as the control, administration and supervision on the enterprises carried out by the related parties for the protection of the investment interests of the enterprises’ direct or indirect investors; (iii) the services that are rendered by the related parties and have been paid for by the enterprises to the third parties or have been conducted by the enterprises themselves; (iv) the concrete services that are conducted for the enterprises by the related parties within the groups and are not accepted by the enterprises, even though the enterprises obtain extra benefits because they are affiliated to these groups; (v) the services whose costs have been disbursed in other related transactions; and (vi) other services that cannot, directly or indirectly, bring economic benefits to the enterprises.
recommendations under Actions 8-10 and the published Circular 42, companies can expect that trend to continue. China has mutual agreement procedure (MAP) and APA regulations to support the avoidance of double taxation, and the SAT is willing to enter discussions with competent authorities on a MAP case. However, MAP/APA is more often considered a strategic approach to mitigate double taxation. If considering an APA, companies should also consider the related transparency aspects under Action 5, as discussed below.

India, as a member of the G-20, has participated in the BEPS project and is a party to the consensus. India has endorsed the final report of the BEPS project on Actions 8-10. India’s tax administration’s position is that guidance in the final reports on Actions 8-10 is in keeping with its long-standing views. This position was recently stated in a revised version of the United Nations’ transfer pricing manual. These issues include:

- Aligning transfer pricing outcomes with value creation
- Giving importance to the DEMPE functions with respect to intangibles for remunerating the group entities of multinational enterprises (MNEs)
- Testing contractual allocation or contractual assumption of risk on the parameters of exercising control over risk (and/or the financial capacity to bear the risk), and the disregarding of such contractual allocation or assumption of risk
- Harmonizing contracts with the conduct of parties
- Identifying and accurately delineating the transaction by analyzing the economically relevant characteristics
- Preventing the capital-rich but low-functioning entities (the “cash box” entities) from contributing to BEPS
- Not recognizing commercially irrational transactions that are between independent parties and cannot be seen

The Indian tax administration holds the view that the guidance flowing from Actions 8-10 should be utilized by both the transfer pricing authorities and the taxpayers in situations of ambiguity in interpretation of the Indian tax law. However, India has not endorsed the guidance in the BEPS report pertaining to low value-adding intra-group services (LVAIGS) under Action 10 and has not opted for the simplified approach.

Transfer pricing aspects of marketing intangibles have been a focus area for the Indian tax administration. The Indian tax authorities are of the view that the functions carried out by Indian subsidiaries of an MNE group relating to marketing, market research, and market development and expenditures incurred on such activity promote/ add value to brands/trademarks that are legally owned by foreign parent associated entities (AEs). Based on this premise, Indian tax authorities have held that the functions deserve compensation.
In effect, they use the “bright line test” to determine insignificant advertising, marketing and promotion (AMP) expenditures incurred by the Indian entities and thereby carry out an adjustment for the nonroutine expenditure incurred, to be recovered on a cost-plus markup basis. A case on this issue is pending a verdict from the Supreme Court of India. In view of BEPS Action 8-10 papers, the Indian tax authorities are carrying out thorough functional analyses to determine whether the distributor should be compensated for enhancing the value of trademarks and other marketing intangibles. The Indian tax administration has expressed a view that compensation, if required to be paid, need not always be a separate and independent payment; it can be part of the price of another transaction. Depending on the individual case, the profit split method may be considered to eventually better reflect value contribution rather than a net profit-based analysis such as the transactional net margin method.

Regarding recent transfer pricing audits of certain contract R&D centers, according to the Indian tax administration, facts have emerged that the funds for R&D activities are provided by the AE that bears the financial risk of the R&D activities, but the strategic decisions pertaining to the day-to-day activities and allocation of budgets to different streams of R&D activities are made by the Indian subsidiary. The Indian tax administration is also of the view that the other important aspects of R&D activities, such as technically skilled manpower and know-how for R&D activities, are developed and owned by the Indian subsidiaries. Accordingly, control over risks of R&D activities rests both with the AE and the Indian company, but the Indian company controls more risks. Therefore, the Indian tax authorities hold that a routine cost-plus return may not be appropriate in such cases. The Indian subsidiaries, they say, should be entitled to a suitable return for their functions (including strategic decision-making and monitoring of R&D activities), the use of their tangible and intangible assets, and the exercise of control over the risks.

The Indian tax administration is also of the view that, in addition to the cost advantages, India provides location-specific advantages (LSAs) to MNEs. Examples of these advantages are: highly specialized skilled manpower and knowledge, access and proximity to growing local/regional markets, a large customer base with increased spending capacity, a superior information network, a superior distribution network, incentives and market premium. Further, where local comparables are not available or the foreign AE has been adopted as the “tested party,” the quantification and allocation of LSAs has been identified as an issue by the Indian tax administration.

On intra-group services, Indian tax authorities continue to focus on areas such as a need test, actual receipt test, benefit test, quantification – whether shareholder or duplicative services or incidental benefits – and pass-through cost.

**Australia** is also expanding its transfer pricing rules in line with the October 2015 OECD transfer pricing guidelines, effective since 1 July 2016.

From that point onward, new OECD Transfer Pricing Guidelines for Multinational Enterprises and Tax Administrations serve as guidance for the application of Australian transfer pricing legislation and effectively incorporate BEPS Actions 8-10 in the Australian transfer pricing landscape.

The Australian Tax Office (ATO) has been using the principles underlying the changes in the OECD guidelines for several years, further proving their transfer pricing expansion efforts. In recent risk reviews, audits and APAs, the ATO has taken a much more focused approach in questioning whether the IP owner and/or funding entity should be entitled to the full intangibles-related returns or whether part of those returns should accrue to the Australian taxpayer. This focus has increased over the last few years and is now the common approach that is enforced by the Pharma Cluster within the ATO. The Pharma Cluster centralizes the ATO’s knowledge base and key thinking for the life sciences sector and is required to review and sign off on any life sciences cases. It also coordinates with and gathers information from other government agencies in relation to processes and the involvement of the local taxpayer’s personnel. In essence, the approach of the Pharmaceutical Cluster is to assume that the Australian entity contributes to the intangibles and thus should be rewarded accordingly, unless the taxpayer can prove this is not the case.

To prepare for this approach, taxpayers should ask themselves several questions, including: what are the components of the value chain and what are the key value drivers/competitive advantages, the position of the Australian entity in the value chain and, in relation to these value drivers, what are the nonroutine activities and DEMPE functions performed by Australian personnel (if any) and what support is provided from overseas in relation to these activities? This should be done on a sufficiently granular level, e.g., per drug or family of drugs, as recent experience shows that the ATO is no longer satisfied with an overall assessment of activities. The analysis should cover all aspects of the value chain, from local clinical trials to the level of detailing performed.

This approach is also relevant in APA negotiations.

In addition to the new OECD guidance, companies must consider other transparency initiatives (such as the voluntary tax transparency code encouraged for adoption from FY2016); anti-avoidance rules (such as the Multinational Anti-Avoidance Law from 1 January 2016, as well as the diverted profits tax, for income tax years beginning on or after 1 July 2017); and increased penalties and expanded documentation requirements (such as country-by-country (CbC) reporting, including master and local file requirements). Furthermore, the ATO received new funding in the federal budget with a new Tax Avoidance Taskforce, to raise AUD$3.7 billion over four years.
While there is no particular change in the legislation following the introduction of BEPS with regard to intangibles ownership, before the introduction of BEPS, Japan had a long-held view that functional contribution is of critical importance in determining the value attributed to intellectual property.

The definition of intangibles is broad. It includes industrial processes such as innovation to improve operations. Furthermore, even before the introduction of BEPS, Japan’s broad definition of intangibles included human resource elements such as network and organization, further emphasizing people activities and functions. The following was already included in the Commissioner’s Directive on the Operation of Transfer Pricing in Japan:

“When examining licensing transactions of intangible properties, it shall be noted that not only the legal ownership of the intangible properties but also the degree of contribution of a corporation or a foreign-related person to the activities for the formation, maintenance or development of the intangible property ... need to be taken into account.”

The Japanese tax authorities clarified that, when considering the degree to which intangible property contributes to the income of a corporation or a foreign related party, the following should be taken into account:

- Patents and trade secrets derived from technical innovation
- Know-how derived from the experience of employees and other human resources through business activities such as management, front-office operations, production, R&D and sales promotion
- Production processes, negotiation procedures and development, distribution and financing networks

As such, the OECD is catching up with Japan’s long-held view that people functions are of critical importance in determining the value attributed to intellectual property.

Jurisdictions in the Asia-Pacific region that are reserved on other parts of the BEPS reports are starting to take action with respect to Actions 8-10, such as Singapore, which is an OECD associate market. In a recent announcement on 12 January 2017, Singapore
released revised transfer pricing guidelines stating its commitment to the arm’s length standard and clarifying that profits should be taxed where the real economic activities generating the profits are performed and where value is created, in accordance with BEPS Actions 8-10. Likewise, Taiwan and Hong Kong (another OECD associate market) have also been making strides toward implementing Actions 8-10, with Taiwan enacting transfer pricing changes early in 2015 and Hong Kong publishing a consultation paper that proposes the introduction of transfer pricing rules in Hong Kong.

The reports on Actions 8-10 are receiving a lot of consideration from the Asia-Pacific jurisdictions, particularly in the life sciences community because of the significance that intangible properties play in the industry. It is important to review the current supply chain to understand which member(s) of the group exercise control over risk and which member has the financial capacity to assume those risks and to control the performance of outsourced DEMPE functions. Due to the difference in each jurisdiction’s view on DEMPE, such as China and Australia with their extra focus on promotion and local market access, it is essential that companies undertake a DEMPE analysis whereby they review substance and critically significant people functions for IP owners when assessing the potential future audit risk to the company.

**Action 5**
Countering harmful tax practices more effectively, taking into account transparency and substance

The final report on Action 5 covers two main areas: (i) harmful tax practices; and (ii) transparency. Of these two areas, the focus in the Asia-Pacific markets has been on transparency. Action 5 of the final BEPS reports recommends disclosure of summaries of specific rulings with affected tax authorities, in the absence of an existing compulsory spontaneous exchange agreement among the jurisdictions. The disclosure recommendation under Action 5 will also have great impact on life sciences multinationals. Rulings regarding transfer pricing arrangements among members of the supply chain (i.e., manufacturers, principals and limited-risk distributors), as well as rulings regarding the existence or nonexistence of permanent establishments, are prevalent in the sector. Summaries of such rulings may be subject to disclosure under Action 5.

**China (mainland)** is one of the Asia-Pacific jurisdictions at the forefront in establishing guidelines around transparency recommendations in Action 5. Effective from 1 December 2016, there is a new Bulletin 64 on the administration of APAs in mainland China. The bulletin puts taxpayers on notice that their unilateral APAs signed after 1 April 2016 will be exchanged as agreed under the Action 5 final report.

Similarly, another fast-moving jurisdiction in the region to watch with respect to Action 5 is India. The Competent Authority of India has decided that all future unilateral APAs will contain a provision allowing the exchange of the high-level details of all concluded unilateral APAs with the competent authorities of all such countries where the Indian applicant’s related parties are located, including immediate, intermediate and ultimate parent companies.

Furthermore, Japan proactively shares unilateral APAs entered into from 2010 (and still effective post-1 Jan 2014) with counterparty countries based on Action 5.

In the same announcement discussed above released 12 January 2017, Singapore also enacted an automatic exchange of unilateral APA information by the Inland Revenue Authority of Singapore (IRAS) in accordance with Action 5. The automatic exchange is subject to meeting certain conditions, such as having tax treaties in place or an exchange of information instrument. The exchange will take place by December 2017 for unilateral APAs that were issued on or after 1 January 2012 and were still in effect on 1 January 2016, or on or after 1 January 2015 but before 1 April 2017. For those unilateral APAs issued after 1 April 2017, the exchange will take place within three months after the agreement date.

**Hong Kong** has stated its commitment to implementing the BEPS minimum standards, including Action 5, in a recently released consultation paper; we expect rules to be finalized this year. The rest of the other Asia-Pacific jurisdictions have been silent regarding Action 5 and appear more focused on the transparency recommendations, such as implementing the CbC reporting under Action 13. It is expected that they will continue watching those at the forefront of implementing the recommendations under Action 5, such as mainland China and India, and could implement similar guidelines if they feel they aren’t receiving enough transparency from the Action 13 recommendations.

Life sciences companies operating in the region with existing rulings in these jurisdictions, or contemplating entering into new rulings or agreements, should monitor the latest Action 5 developments and be aware if the current or new agreement would be subject to spontaneous exchange with other tax authorities. Companies are especially focused on rulings/agreements related to transfer pricing specific to their operations in a territory, and how consistent that agreement is across the other jurisdictions in which they operate.

**Action 13**
Guidance on transfer pricing documentation and CbC reporting

Like the Action 5 report, Action 13 calls for more transparency. One of the requirements is that summaries of certain rulings and APAs may need to be disclosed in either or both of the master file
and local file. The master file requires the listing and summaries of rulings that relate to the “allocation of income among countries.” In addition to considering the application to those rulings relevant to the life sciences industry, such as unilateral APAs, permanent establishment or principal rulings, consider how broad the definition of “allocation of income” could be construed to apply to other rulings involving investment into certain activities or regions as a way to shift income from other jurisdictions.

The disclosure of rulings’ summaries in the local file are required when the rulings relate to a material controlled transaction in a jurisdiction that is not party to the ruling and the other jurisdiction has introduced transfer pricing documentation that requires the filing of an OECD-type local file. In addition to the summary of the rulings in these files, it may be possible that the full ruling itself could be requested by certain jurisdictions that are subject to exchange of information under certain treaties.

As it relates to CbC, companies have raised concerns about how the information regarding their complex supply chains will be viewed by the various jurisdictions and potentially used for transfer pricing comparison among countries with similar activities. Life sciences companies are especially concerned with the potential impact on their reputation and a heightened risk of tax controversy that these new recommended disclosures may bring, particularly around the summaries of APAs and rulings.

At this point, most jurisdictions in the Asia-Pacific region have drafted or implemented a requirement for CbC reports. However, not all have commented on the master/local files. As expected, the fast movers in the region have commented on all three prongs for Action 13.

On 27 June 2016, the Australia Tax Office issued the final version of the high-level design of the local file as part of transfer pricing documentation under BEPS Action 13. The local file requirements apply for income years starting on or after 1 January 2016 and will require a more granular disclosure of the nature of certain transactions, such as intangible property. For each of these, a copy of the relevant agreement will need to be provided to the ATO with the local file. Unlike other jurisdictions, where the local file is a transfer pricing documentation report, the Australian local file (ALF) requires the disclosure of source data and documents, including legal agreements, through an electronic form. In other words, globally prepared local files may not satisfy all of the requirements for Australia transfer pricing documentation and the ALF.

In Circular 42 published in June 2016, the Chinese SAT issued the new transfer pricing documentation to implement the three-tiered documentation structure proposed in BEPS Action 13. Information disclosure on supply chain, group intangible arrangements and group financing arrangements are required in the master file consistent with OECD requirements. Similarly, a value chain analysis is requested in the local file to provide more transparency of multinational corporations’ business and tax arrangements. Circular 42 applies for FY2016 and onward.

China’s new transfer pricing documentation and disclosure requirements are more comprehensive, detailed and thorough than those required under the previous transfer pricing regulations, in both breadth and depth. These changes will have a wide-ranging impact on taxpayers with respect to information collection, financial data conversion, group transfer pricing policy-making and global supply chain analysis.

Once again a fast mover in the region, China has one of the earliest deadlines for submission of the CbC reports (the deadline is 31 May annually). China-based multinationals whose global consolidated revenue exceeds the threshold of CNY5.5 billion should prepare and submit the CbC report and the detailed requirements for disclosure, and ensure they are consistent with the OECD’s CbC recommendations. For multinationals that must prepare the CbC report according to relevant provisions of other countries, the SAT can ask for the CbC report from the Chinese subsidiaries when undertaking a transfer pricing audit in case the SAT fails to obtain the report from the CbC Multilateral Competent Authority Agreement (MCAA) Information Exchange Mechanism.

A master file for China is required for compliance purposes if taxpayers’ annual global related party transactions exceed CNY1 billion or if there are any cross-border related party transactions and the entity’s ultimate parent has already prepared a master file. The master file should be completed within 12 months of the fiscal year end of the group’s ultimate parent company. The detailed requirements of the master file are generally consistent with OECD’s recommendations in Action 13, including the disclosures on intangible arrangements, patent lists and group financing arrangements. In addition, Circular 42 requests: more detailed descriptions of functions/activities of a group’s R&D facilities; descriptions of functions, risks/assets transferred within the group due to business restructuring (if any); and bilateral APAs and other tax rulings relating to the allocation of income among countries.

With respect to the local file, Chinese taxpayers who exceed the threshold will prepare the local file and should complete it by 30 June. The detailed requirements of the local file go beyond the OECD’s local file requirements by including quantitative value chain analysis, an analysis of LSAs, etc. The local file also requires disclosure of the latest financial statement of each supply chain

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b (1) Amount of transfer of tangible asset ownership (in the case of toll manufacturing, value should be based on annual import and export prices for customs purposes) exceeds CNY200 million; (2) amount of transfer of financial assets exceeds CNY100 million; (3) amount of transfer of intangible asset ownership exceeds CNY1100 million; (4) aggregate amount of other related party transactions exceeds CNY40 million.
participant. Hence, life sciences companies will have to assess the practicality and other implications of providing sensitive information relating to the rest of their multinational group.

In addition to the CbC report-related provisions already implemented in Indian tax law, India has proposed that the transfer pricing documentation rules be amended to prescribe the information and documents as recommended for the master file under Action 13 applicable for tax year 2016-17. Indian tax law also contains penalty provisions in case of any noncompliance, unless the taxpayer can demonstrate “reasonable cause” for noncompliance.

Likewise, Japan has also implemented the master file and local file in addition to requiring CbC reporting. The CbC report and master file will be required if global sales for fiscal years commencing from fiscal year end 1 April 2016 are greater than JPY100 billion. For the local file, Japan has introduced a contemporaneous requirement. Companies that have transactions with a single overseas related party exceeding JPY5 billion in the preceding fiscal year or intangible transactions exceeding JPY300 million (also applied per foreign entity) must prepare and save the local file by the time of the tax return. This is seen as a significant change, and the tax authorities have allowed an additional year for companies to prepare, meaning that contemporaneous local file requirements apply to fiscal years commencing from 1 April 2017.

The local file will be requested in a tax audit, with the deadline set by the auditor up to a maximum of 45 days. In practice, the examiner may give a much shorter deadline, as the expectation is that the local file will be ready to submit because it has been
prepared contemporaneously. If the information is not provided, the examiner will have the right to employ presumptive taxation or secret comparables. For companies that do not meet the thresholds, the existing local documentation rules still apply. For these companies, the examiner can set a deadline of up to a maximum of 60 days for the taxpayer to submit the local file documentation.

Of the slower-moving markets, South Korea is the next one applying the three-tier approach. Korean tax law already has transfer pricing rules setting out the master file and local file documentation requirements effective for fiscal years starting on or after 1 January 2016. The 2016 tax reform proposal includes draft CbC requirements as well.

Those countries defined as “slower-moving” or “quietly watching,” such as Malaysia, Singapore and Vietnam, have actually been taking action with respect to Action 13. They have issued similar guidelines concerning CbC reporting on revenue thresholds, alternative filing and notification requirements, and penalties. In Singapore, on 6 January 2015, the IRAS released revised transfer pricing guidelines that are broadly in line with the 2010 OECD Transfer Pricing Guidelines for Multinational Enterprises and Tax Administrations, as well as the recent BEPS discussion drafts on transfer pricing. Notably, the new guidelines include a requirement to have contemporaneous transfer pricing documentation maintained and submitted within 30 days upon the IRAS’s request. The new guidelines also provide the Singapore dollar value thresholds that trigger the requirement to prepare transfer pricing documentation and a two-tiered approach toward the documentation content (i.e., group-level documentation and entity-level documentation). If taxpayers do not have transfer pricing documentation in place, the IRAS might not be as supportive concerning the transfer pricing positions or might not allow certain transfer pricing year-end adjustments. The new guidelines will have an immediate effect. This was further supported by the most recent transfer pricing guidelines, released on 12 January 2017, which were aligned with master file and local file requirements under Action 13. However, gaps still remain between Singapore and OECD approaches.

Lastly, on 24 February 2017, the Vietnamese Ministry of Finance adopted a decree that espouses the three-tiered approach to transfer pricing documentation developed as part of Action 13 (CbC reporting, master file and local file). The decree applies to fiscal years starting on or after 1 January 2017.

The value chain of life sciences companies is quite complex. With disclosure of IP structure and financials of overseas related parties both in the master file and local file, life sciences companies need to think about how to manage the risks and ensure the consistency and clarity in information disclosures. The local tax authorities are not familiar with the industry issues and challenges, and therefore robust documentation to explain the key industry issues (e.g., a marketing and distribution model, a large sales force and product permits) is important to help tax authorities understand the industry features and relevant transfer pricing issues.

A chart summarizing the status, timing and requirements of the CbC, master file and local file for each of the jurisdictions in the Asia-Pacific region as of 20 July 2017 is included. Countries are still implementing legislation and releasing additional guidance on the operation of the rules; for updated information, please visit www.ey.com.
CbC reporting
Implementation overview

<table>
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<th>Status</th>
<th>For fiscal years commencing from</th>
<th>Voluntary filing</th>
<th>MCAA signatory</th>
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**CbC reporting**

+1 = delay in commencement of secondary filing by one year

crossmark represents this delay

✓ = Yes

✗ = No

? = Not clear

**Notification**

UPE: if the UPE is a tax resident in [country], it shall notify the competent tax authority about being the UPE.

SPE: if the SPE is a tax resident in [country], it shall notify the competent tax authority about being the SPE.

CE: if there are CE tax residents in [country], they shall notify the competent tax authority about the reporting entity (i.e., the entity that is required to file a CbC report).

RFY: this generally means an annual accounting period with respect to which the UPE of the multinational enterprise group prepares its financial statements.

**Disclaimer**

This material has been prepared for general information and discussion purposes only and is not intended, and should not be relied upon, as accounting, tax or other professional advice. The information contained hereafter is based on tax legislation, its rules and regulations and thus it may be modified or changed at any time by a country’s administrative, judicial or legislative authorities, which may have a significant effect on the conclusions contained hereunder. Please refer to a country advisor for specific advice.

Some jurisdictions that have not implemented the OECD’s recommendations for master file and local file may have reporting obligations that gather similar information. For example, the US has not implemented the OECD’s recommendations for master file and local file but, for a foreign ultimate parent with a constituent entity in the US, the US has several reporting obligations that gather similar information (e.g., reporting obligations under section 6038A (form 5472) of the Internal Revenue Code and transfer pricing documentation under section 6662 (e)/(h) of the Internal Revenue Code).

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**CbC reporting**

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In recent years, the tax affairs of multinational enterprises (MNEs) have come to the forefront of public scrutiny – in this context, the life sciences sector is squarely in focus.

Much of the public scrutiny is attributable to the work by the Organisation for Economic Co-operation and Development (OECD) regarding base erosion and profit shifting (BEPS), which has served to increase global awareness of tax strategies of MNEs. In addition, instances of whistle-blower activity such as the widely publicized Luxembourg Leaks and Panama Papers, and Australia’s ongoing Senate inquiry into corporate tax avoidance have dissipated public confidence that MNEs are paying their fair share of tax.

Consequently, tax administrators globally are under pressure to restore public confidence in their tax systems. The latest initiative by the Australian Taxation Office (ATO) to restore public confidence focuses on the concept of “justified trust.” The ATO’s justified trust initiative stems from the question: has the ATO fulfilled its public duty? In the words of ATO Deputy Commissioner Jeremy Hirschhorn: “If we were to tell a citizen jury what we had done to assure the tax paid by an individual company, would they be satisfied that we had done enough to make sure that the tax they have paid is correct?”

Advanced by the OECD in 2013, the concept of justified trust not only guides the activities of the ATO but informs the ATO’s philosophy on how it interacts with the tax-paying community. The ATO’s justified trust initiative is not industry specific, meaning that taxpayers in every sector of the life sciences industry, including pharmaceutical and medical devices, are likely to be impacted.

Justified trust
Theoretically, justified trust is achieved where the ATO has collected sufficient objective evidence that would lead a reasonable person to conclude that a particular taxpayer has paid the right amount of tax.

As part of this process, the ATO evaluates taxpayers using the following criteria:

- Tax governance framework – the ATO needs to confirm the existence, application and testing of a tax risk management and governance framework.
- Identification of tax risks – the ATO reviews risks or concerns previously communicated to the market through, for example, taxpayer alerts, Practical Compliance Guidelines or public rulings.
- Understanding significant and new transactions – the ATO seeks to understand current business activities, particularly significant or new transactions, and the tax outcomes.
- Understanding why the accounting and tax results vary – the ATO analyzes the various streams of economic activity and how they are treated for taxation and excise purposes.

Much of the above criteria would be familiar to taxpayers, with the second, third and fourth criteria forming the basis of the ATO’s traditional approach to reviews and audits. Applying the justified trust framework to the life sciences sector, the following themes emerge:

- Transfer pricing – the ATO is concerned that several MNEs in the industry may be incorrectly classifying their Australian operations as limited risk distributors (LRDs) and therefore adopting inappropriate comparables for benchmarking purposes. The ATO considers that “value-adds,” such as regulatory approval skills and the Australian direct distribution system, mean that Australian operations are more significant than otherwise portrayed. The ATO is seeking to challenge taxpayers’ LRD classifications on the basis that these operations are more appropriately classified as full risk distributors and are therefore entitled to greater returns.
The board is appropriately informed about tax matters and is actively involved in overseeing the TCG framework.

4. Periodic internal control testing for TCG is undertaken.

In particular, the ATO expects the board to oversee the implementation and continued operation of an effective TCG framework (including internal controls) that identifies, escalates and manages tax risk. It is the board that must ultimately be satisfied that tax risk is appropriately dealt with within the organization. This expectation applies to boards of Australian-headquartered businesses and the Australian boards (or the Australian equivalent) of Australian subsidiaries of multinational groups for both public and private companies.

The guide also sets out guidelines to help taxpayers test and assess the operational effectiveness of their TCG framework. These self-assessment procedures should be used as a tool for assuring the board (and management, more generally) as to the operational effectiveness of the organization’s TCG framework. The self-assessment procedures will also be used by ATO officers to test taxpayers’ TCG frameworks as part of compliance activity. To the extent that a taxpayer’s framework does not fully meet all elements of the self-assessment procedures, taxpayers are encouraged to record why their framework does not exactly align with ATO “better practice” and how the deviation is justified. The ATO refers to this as the “if not, why not?” approach, and has indicated it will take these explanations into account when assessing TCG in reviews and audits.

ATO activity on justified trust
To give effect to the justified trust initiative, the ATO has commenced Streamlined Assurance Reviews of the top 1,000 Australian taxpayers to assess the extent to which the top 1,000 MNEs and public companies are paying the right amount of tax. Streamlined Assurance Reviews operate in much the same way as traditional risk reviews but are more targeted and expand the line of questioning to incorporate TCG frameworks. In relation to the TCG framework, the ATO will be assessing the level of controls and the extent (and appropriateness) of gaps against suggested better practices in the guide. The outcome of these reviews is a letter highlighting what the ATO perceives to be specific tax risks and
associated ratings of those risks. The letter also sets out risk ratings on the taxpayer’s tax risk management and governance framework, with a conclusion as to whether the ATO is assured that the right amount of tax has been paid. A further audit may be commenced depending on the outcome of this review.

Acknowledging that there has been a significant degree of review and audit activity in the life sciences sector over recent years, the impact of this project is to widen the net in terms of the taxpayers being selected for review. This will particularly be the case for those taxpayers not already undergoing an ATO review or audit, or those who have undergone one recently. Unfortunately, it is not the case that, if a company has already recently been through or is currently undergoing an audit or comprehensive risk review, it won’t also or subsequently be selected for a Streamlined Assurance Review, as an audit or other review often won’t touch on the tax governance framework of a taxpayer. This is notwithstanding the potential for overlap.

The Streamlined Assurance Review project is expected to take three to four years, and taxpayers have begun to receive requests for information. The requests are specifically aimed at addressing the four criteria for establishing justified trust.

Reportable tax position schedule

In addition, the ATO has expanded the scope of information to be disclosed in the reportable tax position (RTP) schedule and has commenced expanding the number of taxpayers required to lodge the RTP schedule to include those with an annual turnover in excess of AUD$250 million. Broadly, the three categories of disclosure are:

- **Category A**: a position about as likely or less likely to be correct than incorrect
- **Category B**: a position in respect of which uncertainty about taxes payable or recoverable is reflected in financial statements
- **Category C**: a reportable arrangement

The ATO has made substantial changes to RTP category C for the 2017 income year. RTP category C now covers several specific issues that are of concern to the ATO, with reference to recent ATO published guidance on what it perceives to be significant tax risk areas.

**Considerations for the life sciences sector**

The centralization of intellectual property (such as patents, licenses and trademarks) and functions (such as procurement, marketing, manufacturing and distribution) into regional or global hubs, while being one of the main drivers of efficiency and risk management for life sciences MNEs, is also the reason why the ATO has focused so heavily on the life sciences sector in recent years and will continue to do so. This was highlighted in Australia’s Senate inquiry into corporate tax avoidance in 2015.

Given the size and global structure of life sciences MNEs, it is expected that many of those that have Australian operations will be subject to the ATO’s Streamlined Assurance Reviews and will need to lodge RTP schedules, if they are not doing so already. Accordingly, life sciences MNEs must be able to evidence clearly the principles of TCG referred to above. Organizations should take the opportunity to apply the self-assessment procedures in an effort to provide the board and management with the requisite assurance that the organization’s TCG framework is operationally effective.

Of particular relevance to life sciences MNEs, governance policies and frameworks are typically set by the global head company and apply broadly at the global level. The question then for those MNEs with operations in Australia is whether those global governance policies are sufficient to fall within the “better practices” as set out in the guide. Accordingly, directors and officers of both global head companies and Australian companies may wish to consider whether the following are adequately addressed in the global governance frameworks:

- Has the organization implemented a documented and board-approved framework for identifying and managing tax risk in Australia?
- Are you familiar with the board-level policies governing the Australian company’s TCG framework, and are you aware of the underlying management-level policies and procedures (including responsibilities)?
- Are you satisfied with the regularity, content and presentation of reporting of Australian tax matters at board meetings?
- Are you comfortable that the thresholds and timing for escalation of Australian tax risks to the board are set at an appropriate level?
Do the frequency, detail and content of Australian tax risk reporting to the board enable you to form a well-considered view of tax risk within the Australian company?

Do you understand the Australian company’s tax profile, including its effective tax rate and the basis for any significant deviation from the standard corporate tax rate?

Can the board assure itself as to the operational effectiveness of the TCG framework? (This may include obtaining assurances from management that tax risks are being managed appropriately.)

Directors in Australian companies and global head companies alike should take appropriate steps to address the ATO risks, to not only build confidence for the ATO but to build stakeholder confidence that the Australian company is complying with its Australian tax obligations. And while Australian subsidiaries of foreign MNCs will commonly look to whether they are in line with the expectations of their global parent and may be tempted to defer decision-making on governance to the head office, it is important that the Australian board and management be involved in the decision-making and management of tax risk. From the ATO’s perspective, it is not sufficient that the Australian tax or finance team refer tax decision-making to HQ, thereby circumventing the Australian board and management. In this regard, the global governance framework of a MNC may need to be adapted.

In addition, taxpayers should consider their processes in making disclosures in the RTP schedule. Specifically, if taxpayers are confident that disclosures do not need to be made under categories A and C, they will need to understand and document the basis for forming that opinion.
Mergers and acquisitions (M&A)

Life sciences M&A activity in 2016, the lowest by value since 2014, was plagued by geopolitical issues such as Brexit and the US presidential elections. However, 1H17 saw an uptick in M&A activity, both in value and volume (compared with 1H16), potentially suggesting a reversal of the declining M&A trend. In addition, potential US tax reforms pertaining to corporate taxation and repatriation of foreign funds are expected to create a conducive dealmaking environment, enabling companies to deploy the freed cash in M&A deals. In addition to M&A deals within the US, these reforms are likely to impact cross-border dealmaking with either of the target or acquirer nation from the US.

The number of deals in 1H17 surged to 1,188, an increase of 6% from 1,123 deals in 1H16. This was largely due to a high proportion of small-value transactions (nearly 39% of the total deals value less than US$50m in 1H17 vs. 35% in 1H16). Also, total deal value in 1H17 increased to ~US$146.6b, up nearly 2.4% from US$143.1b in 1H16. There were 23 deals valued at more than US$1b in 1H17 vs. 21 deals valued at more than US$1b in 1H16. M&A deals in 1H17 were driven by two mega-ticket acquisitions. The first such deal involved the acquisition of Switzerland-based Actelion Pharmaceuticals Ltd by the US-based Johnson & Johnson. The deal was valued at US$29b and has by far been the largest deal of 2017. This was closely followed by the acquisition of CR Bard by its compatriot medical devices supplier Becton Dickinson for US$24.2b. Cumulatively, these deals represent nearly 36% of total deal value in 1H17.

Similar to 2016, life sciences consolidated its position at fifth (last 12 months ending June 2017) on the basis of total deal value, following oil and gas, technology, consumer products and retail, and diversified industrial products.
Life sciences M&A value share by subsector

The pharmaceuticals subsector led the deal value at ~US$66.3b (417 deals) in 1H17, contributing 45% to total M&A activity in the first half of 2017. Health research and testing witnessed a staggering growth of ~3x to reach US$11.4b in 1H17 (vs. US$3.2b in 1H16). This increase was stimulated by two deals (each worth more than US$1b) cumulatively accounting for 54% of the total deal value of the health research and testing subsector.

M&A in medical devices remains active, with an increase of 3% year-over-year in deal volume to a total of 317 deals in 1H17. However, consolidation in prior years has resulted in fewer high-value deals and reduced total deal value. Medical devices’ M&A deal value in 1H17 suffered a 6% year-over-year decline to US$5.2b in 1H17, leading to a contribution of 36% to the total deal value (vs. 39% in 1H16). These deals showcase companies’ attempts at expanding their brand portfolio with a major focus on innovation and certain therapeutic areas. The acquisition of CR Bard by Becton Dickinson for US$24.2b validates the trend.

By contribution to the overall industry M&A by value in 1H17, the subsectors biotechnology and health research and testing accounted for 11% (down from 23% in 1H16) and 7% (up from 2% in 1H16) respectively.

Top 10 global life sciences M&A, 1H17

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<tr>
<th>Target company</th>
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<th>Country</th>
<th>Acquiring company</th>
<th>Country</th>
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<td>Actelion Pharmaceuticals</td>
<td>Big Pharma</td>
<td>Switzerland</td>
<td>Johnson and Johnson</td>
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<td>CR Bard</td>
<td>Medical Devices</td>
<td>US</td>
<td>Becton Dickinson</td>
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<td>Patheon NV</td>
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<td>VWR Corp</td>
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<td>Generics</td>
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<td>Nidda Healthcare</td>
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<td>Takeda</td>
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<td>PAREXEL International</td>
<td>Life sciences tools</td>
<td>US</td>
<td>Pamplona Capital Management</td>
<td>UK</td>
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<td>Generics</td>
<td>US</td>
<td>Fresenius Kabi</td>
<td>Germany</td>
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<td>Specialty Pharma</td>
<td>US</td>
<td>Allergan</td>
<td>US</td>
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<td>Completed</td>
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The Johnson & Johnson (J&J)-Actelion deal was completed on 16 June 2017 after the launch of a cash tender offer on 25 January 2017. As part of this acquisition, Actelion and J&J created a new company, Idorsia Ltd., for drug discovery operations and early stage clinical development assets. Actelion’s innovative products for pulmonary arterial hypertension (PAH) are expected to complement the existing Janssen product portfolio and its intent to grow in attractive therapeutic areas. The acquisition of CR Bard by Becton Dickinson for US$24.2b validates the trend.

By contribution to the overall industry M&A by value in 1H17, the subsectors biotechnology and health research and testing accounted for 11% (down from 23% in 1H16) and 7% (up from 2% in 1H16) respectively.
Mergers and acquisitions – Asia

Asia M&A activity in life sciences

In contrast to global M&A activity, Asian M&A deal value in 1H17 slowed down to US$12.5b, a decline of 33.8% from US$18.9b in 1H16. The size of deals in 1H17 was significantly lower than what was recorded in 1H16, which saw two deals that were each worth more than US$1b. Not a single deal crossed the US$1b mark in 1H17. Thus, the region’s contribution to global M&A stood at only 8%, hinting toward a significant difference in average deal size between Asia and global M&A.

However, Asia accounted for ~33% of the global dealmaking by volume, with the number of deals in 1H17 increasing to 389 from 379 in 1H16.

Asia life sciences M&A value by subsector (US$b)

As opposed to the total M&A activity (by value) in Asia, regional subsector dealmaking witnessed a trend similar to that seen in global M&A. The pharmaceutical subsector recorded the highest contribution, 62%, to the transaction amount in 1H17, primarily triggered by acquisition of iNova Pharmaceutical (Australia) by investment firms Pacific Equity Partners and the Carlyle Group in Australia. Overall, subsectors, including pharma, medical devices, and health research and testing, reported a downward trend in terms of deal value. In contrast, biotechnology M&A value experienced a steep climb over 1H16 levels, rising 202% to US$2.4b in 1H17. This sharp increase is attributable to seven deals worth more than US$100m in 1H17 (vs. no deal $100m in 1H16).

By compound annual growth rate since 1H14, subsector dealmaking values witnessed a significant uptick across all but one subsector. The pharmaceutical subsector observed a decline of 3% during this period.
China (including Hong Kong) alone accounted for as much as 67% of total deal value in 1H17. This was driven by two deals worth more than US$500m each out of the total of three such deals recorded in Asia in 1H17. However, in absolute terms, China’s contribution to Asian M&A activity has dropped to US$8.4b in 1H17, a decline of 16% from US$10b in 1H16. This points toward the country’s significance in the overall regional M&A landscape. South Korea was a distant second, accounting for 16% of the total deal value in Asia. The country’s contribution increased from US$1.2b in 1H16 to US$1.9b in 1H17, registering an increase of 60% in total deal value. Following suit was Australia, with an 11% contribution to the region’s deal value. All the remaining regions combined represented only 6% of total Asian M&A deal value.

By count, China again accounted for more than 50% of total Asian transactions in 1H17. China M&A deals in early 2017 largely included domestic consolidation and sub-billion-dollar deals. South Korea and Australia together represented 20% of Asia’s deal volume.

In 1H17, there were 29 M&A deals worth more than US$100m each (vs. 36 deals in 1H16). Of these 29 deals, 19 target companies were domiciled in China. As a result, China was responsible for 7 of the 10 largest deals in 1H17. Most of these top 10 deals involved private investors as their acquirers.

In the largest deal of the year, investors Pacific Equity partners and the Carlyle Group acquired iNova Pharmaceuticals from Canada-based Valeant Pharmaceuticals in a leveraged buyout transaction. Since 2016, Valeant had been looking for an acquirer for iNova to reduce its debt and simplify the company’s operating model. Post-acquisition, the two acquirer firms plan to use their combined knowledge to boost the growth of iNova in offshore markets.

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**Asia life sciences M&A by target country, 1H17**

<table>
<thead>
<tr>
<th>Country</th>
<th>Target</th>
<th>Acquirer</th>
<th>Value (US$m)</th>
<th>Deal description/rationale</th>
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<tbody>
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<td>China</td>
<td>iNova Pharmaceuticals</td>
<td>Pacific Equity Partners and the Carlyle Group</td>
<td>930.0</td>
<td>iNova Pharmaceuticals (Australia) Pty SPV agreed to acquire iNova (Australia) from Valeant Pharmaceuticals International Inc. in a leveraged buyout.</td>
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<td>China</td>
<td>Yunnan Baiyao Holding</td>
<td>Jiangsu Yuyue Tech</td>
<td>829.7</td>
<td>Jiangsu Yuyue Technology Development acquired a 10% stake in Yunnan Baiyao Holding.</td>
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<td>Zhuhai Weixing Industrial</td>
<td>Zhuhai Hengqin Weichuang</td>
<td>661.8</td>
<td>Zhuhai Hengqin Weichuang acquired a 100% share of the target from Livzon Pharmaceutical Group.</td>
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<td>China</td>
<td>Jeil Pharm-Pharm Mfr Bus Shareholders</td>
<td>Grand Full Development</td>
<td>444.7</td>
<td>Grand Full Development agreed to acquire a 50.7% interest in China-based Bloomage BioTechnology.</td>
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<tr>
<td>China</td>
<td>Guizhou Xingbang Pharm</td>
<td>Harbin Yuheng Group Co. Ltd.</td>
<td>437.9</td>
<td>Harbin Yuheng Group’s investment arm Xizang Yuxi Venture Capital Investment Co acquired a 21% stake in Guizhou Xingbang Pharm Co Ltd.</td>
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<tr>
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<td>Dongyang HC</td>
<td>Leguh Issuer Designated</td>
<td>416.5</td>
<td>US-based Leguh Issuer Designated Activity agreed to acquire the whole of Dongyang HC Co Ltd.</td>
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<td>Shanghai ChemPartner</td>
<td>Quantum Hi-Tech (China) Bio</td>
<td>397.5</td>
<td>Quantum Hi-Tech (China) Biological Co acquired the entire share capital of Shanghai ChemPartner in a stock swap transaction.</td>
</tr>
<tr>
<td>China</td>
<td>Zhenxing Biopharm &amp; Chem</td>
<td>Hangzhou Zhemintou Tianhong</td>
<td>396.1</td>
<td>Hangzhou Zhemintou Tianhong Investment Partnership intends to launch a tender offer for a 27.5% stake.</td>
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<tr>
<td>China</td>
<td>Wuhan Zhongyuan Ruike</td>
<td>CSL Behring Asia Pacific</td>
<td>351.8</td>
<td>CSL Behring Asia Pacific of Hong Kong acquired 80% interest in Wuhan Zhongyuan Ruike Biological Products Ltd.</td>
</tr>
</tbody>
</table>

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Source: Thomson ONE; Capital IQ.
After a record-setting 2015, the biopharmaceutical industry saw a drop in overall financing in 2016 – its first since 2012 – as investors reacted to industry-specific challenges such as the sustainability of drug pricing, as well as broader macroeconomic and political risks. Total investment in 2016 fell 27% to US$51.9b, down from 2015’s historic high watermark of US$71.1b.

However, in 1Q17, biotech venture and follow-on financings are outpacing 2016’s numbers, even as IPO proceeds continue to dwindle. These metrics imply that, at least for now, the 2016 downturn is unlikely to resemble the beginning of the financing drought that lingered following the 2008 global financial crisis.

The commercial leaders (defined as companies with more than US$500m in revenue during 2016) raised US$25.7b in 2016, down 14% from 2015’s debt-driven all-time high of US$29.8b. The cash raised by commercial leaders in 2016 was almost entirely composed of debt financings by industry bellwethers Shire, Amgen and Gilead Sciences. The industry’s noncommercial leaders raised US$26.3b in innovation capital in 2016 – down from US$41.4b in 2015 but still higher than the prior 15-year average of US$18.8b.

Innovation capital is the amount of capital raised by companies with revenues of less than US$500m.

Source: EY; Capital IQ; and VentureSource.
Early stage venture capital financing for biotech companies remains plentiful and the single biggest cause for optimism in a down year for overall biotech financing. Seed and Series A financing rounds represented 36% of the total US$10b in US and European biotech venture funding for the year, building on last year’s record of 34%. In 2016, investors poured US$3.6b into 291 seed and Series A biotech venture rounds in the US and Europe. This figure surpasses the previous 15-year averages (US$1.3b and 163 financings). The year’s largest early stage financings were raised by biotech companies exploring new approaches to detecting and treating cancer.

In 2016, 47 US and European biotechs went public, 41% fewer than in 2015 but still the fourth-highest tally since 2000. Those 47 companies raised US$2.1b in their IPOs, in line with the previous 15-year-average haul. During the first quarter of 2017, at least five biotechs squeezed onto the public markets in the US and Europe. The immuno-oncology-focused Jounce Therapeutics, which grossed more than US$117m in its January 2017 IPO, managed to price its shares at US$16 each, above its predicted US$13b to $15b range.

Asian IPOs

Asian IPO activity in life sciences

IPO activity in Asia surged to US$2.2b in 1H17 from US$0.5b in 1H16, a significant rise of ~3.5x in terms of capital raised. Compared with 16 Asia-headquartered companies in 1H16, a total of 33 Asia-based companies raised capital in 1H17, registering a 106% increase in the number of IPOs closed. However, compared with 2H16, 1H17 saw a drop in IPO activity, a decline of 61% in capital raised. This was mainly due to two big IPO deals worth ~US$2b each in 2H16 while there was not even a single deal worth more than US$1b in 1H17. However, the number of IPOs closed in 1H17 – 33 – was the highest since 1H14.

IPO activity (both in terms of capital raised and deals closed) in Asia in 1H17 was in line with IPO activity in the US and Europe. In Asia, all the subsectors, excluding life sciences tools and services, registered an increase in the number of IPOs closed in 1H17. The activity in life sciences tools and services remained stagnant, with only two companies offering their IPOs. Despite of this dormant growth in IPO volume in life sciences tools and services, the total capital raised witnessed a steep climb of 316% in 1H16. This was a result of an IPO closing at more than US$0.5b, the biggest IPO in Asia in 1H17.

In addition, the pharmaceuticals subsector observed the highest growth, with total IPOs valued at US$1.0b in 1H17, a ~5x rise from US$0.2b in 1H16. This significant rise is attributable to six IPOs worth more than US$50m each (including three IPOs worth more than US$100m) compared with two closings worth more than US$50m each in 1H16. As a result, this subsector accounted for nearly half (47%) of the total new capital raised in 1H17. Life sciences tools and services companies raised 24% of the capital in the same period, while the remaining two subsectors, biotechnology and medical devices, contributed to 16% and 13% respectively.

Asian life sciences IPOs by subsector (US$b)

Source: Capital IQ.
Of the total 33 IPOs in 1H17, ~61% were from companies based in China. Of those 20 IPOs, three generated more than US$100m each, including one IPO that closed above US$500m. Five South Korean companies and three companies each in India and Australia also completed public offerings during this period. The remaining two IPOs were from companies in Taiwan and Japan.

During 1H17, the average capital raised per IPO was highest for companies headquartered in India (due to comparatively fewer IPOs closed), followed by China.

Thirteen IPOs in 1H17 raised more than US$50m each. Of these, only four could raise more than US$100m. Of the top 10 IPOs, 8 companies were based out of China, and the other 2 were from India and South Korea.

China-based life sciences tools and services firm WuXi Biologics’ listing on the Hong Kong Stock Exchange was the largest Asian IPO during 1H17. The company garnered total capital of ~US$509.7m. This was followed by India-based pharmaceutical company Eris Lifesciences Limited, which raised US$269.8m.
EY thought leadership

EY perspective on life sciences
The following is a sample of recent life sciences-related thought leadership produced by EY. Please visit ey.com/vitalsigns for the full EY library of industry insights and reports.

Progressions BioPharma 4.0: platform models to capture value
A fundamental reimagining of health care is underway. Technology, demographics and economics are shifting power away from drug developers and placing it in the hands of consumers (patients), payers and emerging digital entrants. These stakeholders are more informed, more connected and more demanding. They require better outcomes, better returns and better experiences. In this changing health care climate, biopharma will continue to lose power – unless it too changes.

Beyond borders: biotechnology report 2017 - staying the course
It was supposed to be a bad year for biotech. For this sector, the simplest of truisms has always held: what goes up must eventually come down. Markets peaked in 2015 and declined in 2016; payer pressure and US election year rhetoric weighed on the sector; drug approvals fell sharply; and biotech companies faced a dwindling supply of public market capital to fund R&D in key US and European markets.
Building an engaging aging strategy

In this article, the first in a series exploring the upsides of aging, EY outlines the potential opportunities that could arise if there is engagement on the aging topic. In 2017, it is still possible to change the conversation and seize the upside of the disruption that will be caused by the massive demographic shift currently underway.

Value-based health care and value labs

US payers continue to struggle to manage medical product costs on two fronts: first, high-volume, high-cost chronic diseases; and second, high-cost specialty products. Although stakeholders are interested in value-based models that link a drug’s performance to emerging evidence of improved patient outcomes, such agreements are difficult to implement and too limited in scope to drive a shift to value-based reimbursement.

Capital Confidence Barometer - Life Sciences | 15th edition

In the EY 15th Capital Confidence Barometer survey of life sciences executives, we found that M&A expectations, although not quite back to the penultimate high of October 2015, have continued at near-record levels. In fact, despite the economic and political uncertainties at the time of this survey, 54% of life sciences executives expect to pursue deals in the next 12 months, up from 45% six months ago.

Building creative partnerships for lifelong wellness

As individuals, each one of us is on an aging journey. But our journey is not one that we travel alone. Our success at making a shift to lifelong wellness depends on traditional and nontraditional partners working together toward a common goal: to live long and live well with joy, dignity and connection. This installment from the EY Engaged Aging series explores these ideas more fully and asks: “What new partnerships will seize the upside of aging?”
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### ASEAN

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<th>City</th>
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</tr>
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### India

#### India

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<th>Phone</th>
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EYG no. 05785-174Gb
1708-2395995

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