Contents

2 Market insights

10 Tax updates: significant developments

22 Featured articles
   22 Reinventing pharma sales and marketing through digital in India
   26 Intelligent automation – will IA provide relief to a sickly pharmaceutical industry?
   30 Megatrends in ASEAN markets have health care industry charting new waters

36 Mergers and acquisitions (M&A)

40 Financing and IPOs

44 Appendix
   44 EY thought leadership
   46 Contacts
To our clients and friends:
Welcome to the fifth edition of our EY Life Sciences Report for Asia, providing coverage for the key markets in Asia-Pacific, Japan and India.

One of the primary themes for this edition of the report is innovation and technology. As an industry, we’re witnessing an unparalleled period of innovative and technological advancement, which is disrupting existing business models and forcing companies to quickly adapt. Our Market insights section discusses the impact of such advancements on Asian markets, including:

► How developed markets are increasing industry regulations to stay ahead of innovative technologies in the field of medical devices – Australia, for example, is incorporating regulatory changes to improve market access to personalized and 3D printed medical devices
► How industry investment in R&D and manufacturing is, and will continue, driving innovation across Asia as such markets focus on developing world-class R&D capabilities
► How artificial intelligence (AI) is being adopted to streamline drug discovery and improve process efficiency as an example of industry players striking the balance between availability of innovative therapies and cost-savings to make the health care system more efficient and affordable
► How countries are investing to become industry specialists; for example, South Korea’s focus on establishing itself as a biotech hub by investing in novel technologies, such as gene editing

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

► The first article, “Reinventing pharma sales and marketing through digital in India,” explores six commercial trends that will shape the future of pharmaceutical sales and marketing in India, and how integrated commercial models will be the new normal.
► The pharmaceutical industry has been facing immense pressure to bring down costs yet increase innovation to find the next blockbuster drug. The second article, “Intelligent automation – will IA provide relief to a sickly pharmaceutical industry?” examines how intelligent automation (IA) can create greater efficiency, improve user experience, and increase insight into the commercial value chain.
► “Megatrends in Asian markets have health care industry charting new waters,” the third article, explores how health care reforms in Asian markets are reshaping the pharma landscape, bringing both challenges and opportunities for multinational companies in the region.

In addition to our featured articles, our Tax developments section provides brief yet informative updates on various tax and legislative developments for the 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.

Rick Fonte
EY Asia-Pacific Life Sciences
Tax Leader

Patrick Floc’hel
EY Japan Life Sciences
Global Leadership Team

Sriram Shrinivasan
EY Global Life Sciences Emerging Markets Leader and EY Global Generic Pharmaceutical Leader
In this edition, we highlight key sector, regulatory and legislative trends for the following markets:

- ASEAN
  - Indonesia
  - Philippines
  - Thailand
  - Singapore
- Australia
- China (mainland)
- India
- Japan
- South Korea
- Taiwan
Key highlights

The developed markets of Australia and South Korea are increasing industry regulations to stay ahead of innovative technologies in the field of medical devices, while other Asian markets are focusing on the basics. Australia is incorporating required regulatory changes to improve market access to personalized and 3D printed medical devices. South Korea is making strides toward adopting a value-based evaluation system for medical devices that involves fast-track approval of next-gen medical devices along with fetching them higher reimbursement rates. On the other hand, India and Taiwan are still in the process of building a basic regulatory framework for medical devices. India is inching closer to finalizing its Medical Devices Rules, and Taiwan, too, has initiated a separate bill for medical device regulation.

Industry investment in R&D and manufacturing will drive innovation across Asia as Asian markets continue their endeavor to emerge as an R&D powerhouse. Many markets across the region are pushing for greater investment to foster innovation in the sector. In Australia, the Government is planning to invest US$26.6 million to develop new medical solutions and improve health outcomes. Japan has set aside a budget to stimulate efficient and low-cost drug discovery. South Korea is relentlessly focusing on establishing itself as a biotech hub, with a growing focus on novel technologies such as gene editing. In addition, South Korea is adopting artificial intelligence (AI) to streamline drug discovery and improve process efficiency. At the same time, several of the Asian countries are continuing efforts to bolster local manufacturing capabilities to give a boost to their economies. The Indian Government has introduced several measures to reduce its import dependence for both generics and medical devices. Singapore’s Government has invested S$2.4 billion to improve its indigenous production capabilities. And China is developing its biomedical infrastructure.

Asian markets continued to roll out measures for price controls and to increase patient access to affordable health care, as addressing unmet medical needs remains a priority in the region. Japan is continuing to revamp its existing pricing regime and push for generics penetration. Concurrently, Australia is enhancing its price control mechanisms to derive cost savings, while India and the Philippines are also regulating the pricing environment to give more people access to medications. Additionally, India has announced a social health care program as part of its Union Budget FY19.

ASEAN

Indonesia: industry staring at mandatory halal certification

Indonesia’s pharmaceutical market has emerged as one of the most attractive destinations for multinational investors in the ASEAN region, because it is supported by growing urbanization and implementation of a universal health coverage scheme. In addition, the Government’s efforts toward trimming down the number of sectors included in the country’s Negative Investment List, which lays down foreign ownership restrictions in certain areas, bodes well from MNCs perspective. However, the attractiveness of the market is tempered by the Halal Product Assurance Law, which, by 2019, will apply to all medicines, chemicals and biological products. Pharmaceutical companies will be required to comply with all halal standards, especially those that pertain to ingredients or medicines imported into Indonesia. This will present a challenge to multinational drugmakers with portfolios that do not include halal products and that, as a result, may see their products taken off the Indonesian market. Furthermore, obtaining halal certification could be a cumbersome process, requiring adjustments spanning across the entire supply chain. However, at the same time, the mandate will provide new business opportunities to suppliers that cater to halal pharmaceutical ingredients.

Philippines: continuing efforts to expand access to affordable health care

The health care market is garnering significant attention from the Philippines Government as it has proposed to increase funding in the sector by 12.4% in FY18. In particular, the Government is exploring mechanisms to control drug prices and increase availability of low-cost generic medicines. Recently, the Philippines’ House Committee on Trade and Industry approved a bill to expedite the establishment of a Drug Price Regulatory Board with the objective of reducing costs and increasing patient access to overpriced medicines. In addition, as part of the Philippines Medicines Policy (2017-2022), the Government has announced its aim to strengthen the generic drug industry through the establishment of pharmaceutical economic zones, as well as to facilitate the import of raw materials for the manufacture of low-value drugs.
Thailand: strengthening Intellectual Property Rights (IPR) regime

Thailand is attempting to better its regulatory environment with a focus on improving intellectual property protection. The Government’s efforts in this space were recognized with removal of Thailand from the US Priority Watch List of intellectual property violators in December 2017. To further strengthen its endeavor, the Government is extending support to the medical sector to increase R&D activity through creation of an Intellectual Property Innovation-Driven Entrepreneurship Center (IP-IDE). This center aims to encourage Thai medical device firms to innovate and serve both the domestic and foreign markets.

Simultaneously, under the new “Thailand 4.0” growth model, the Government envisions transforming the country from its current reliance on heavy industries to producing its own knowledge and know-how, with special emphasis on biotechnology and medical devices. Moreover, because of the growing global demand for medical devices, the Ministry of Commerce plans to increase the nation’s shipments of medical equipment exports by 20%-25% per year.

Singapore: developing indigenous pharma manufacturing

As part of its 5-year Research, Innovation and Enterprise 2020 plan, the Singapore Government has committed to invest nearly US$2.4 billion (SGD$3.2 billion) to advance manufacturing and engineering in the pharmaceutical market. Additionally, the Agency for Science, Technology and Research (A*Star), the National University of Singapore (NUS) and key in-bound big pharma players, such as GSK, Pfizer and MSD, have signed a memorandum of understanding (MoU) to launch a manufacturing initiative called the Pharma Innovation Program Singapore (PIPS). The initiative would combine Singapore’s public sector research capabilities with the domain expertise of the pharma companies to ensure that Singapore’s pharma manufacturing sector remains competitive. The PIPS scheme involves developing continuous manufacturing to improve active pharmaceutical ingredients and exploring biocatalysis technologies to make high-value complex chemicals more sustainably.

---

a Converted at an average spot rate for September 2017; i.e., SGD$1 equals US$0.74, accessed on 28 February 2018
Australia

Accelerating access to innovative yet affordable treatments

Australia is focused on striking the right balance between ensuring availability of innovative therapies and the need to derive cost-savings to make the health care system more efficient. In line with this objective, the Australian Lower House passed an amended Pharmaceutical Benefits Scheme (PBS) in February 2018 with expectations of delivering savings worth US$1.3 billion (AUD$1.8 billion) over the 5-year term of the agreement. As part of this bill, the Government has announced the following price changes of drugs on F1 formulary:

- Extension of 5% reduction for single-brand drugs by two years, until April 2020
- Introduction of two anniversary price cuts – 10% reduction after being listed for 10 years on PBS, followed by an additional 5% reduction after 15 years
- Catch-up reduction for drugs completing 10 years or 15 years on PBS as of June 2018; subsequently being liable for annual reductions on 01 April every year
- Increase in price cut on listing of first additional new brand of a medicine

In addition to the cost savings, this bill will enable the Government to enlist all the new innovative medicines on PBS, thereby increasing the access to breakthrough medicines. Furthermore, the Government is planning to invest US$26.6 million (AUD$35 million) in R&D efforts to develop new medical solutions and improve health outcomes. To further boost the innovation, productivity and competitiveness of Australia’s medical technology and pharmaceutical sector, the Government is injecting another US$5.6 million (AUD$7.4 million) toward 20 industry-led projects. Oncology, in particular, has caught the fancy of the federal bodies. Some of the key measures undertaken by the Government in this therapy area include:

- Launch of a national cancer program to eliminate cancer among children by identifying and recommending new treatment options
- Funding of over US$31.2 million (AUD$40 million) for world-leading medical research projects to improve the lives of cancer patients, including in areas such as melanoma research
- Investment of a total of US$6.5 million (AUD$8.6 million) to support cancer research through Cancer Australia, combined with US$1.6 million (AUD$2.1 million) coming from its funding partners, who include Cure Cancer Australia, the National Breast Cancer Foundation and Cancer Council NSW
- Subsidy of US$349.6 million (AUD$460 million) through the PBS to increase the access to cancer medicines—expected to exponentially reduce the prices of leukemia and lymphoma drugs

Concurrently, the Therapeutics Goods Administration (TGA) continues to prioritize reformation of medical devices, an area highlighted in our previous edition. The TGA recently announced new guidelines for priority review of medical devices that are expected to significantly improve the time to market. Additionally, the TGA is looking at possible regulatory changes related to personalized and 3D printed medical devices, as their usage is becoming more popular due to the advantages of improved quality. Through these efforts, the regulatory authority is seeking to close the regulatory loopholes, to mitigate the risks to patients and to meet requirements for health care providers and manufacturers.

---

\( ^a \) Converted at an average spot rate for October 2017; i.e., AUD$1 equals US$0.78, accessed on 27 February 2018

\( ^b \) Converted at an average spot rate for February 2018; i.e., AUD$1 equals US$0.76, accessed on 27 February 2018

\( ^c \) Converted at an average spot rate for November 2017; i.e., AUD$1 equals US$0.76, accessed on 27 February 2018

\( ^d \) Converted at an average spot rate for November 2017; i.e., AUD$1 equals US$0.76, accessed on 27 February 2018
China

Aiming to create an innovation-fostering regulatory environment while addressing the shortage of essential drugs

As mainland China’s pharmaceutical market continues to be plagued by a tough pricing regime and drug counterfeiting, the Government is committed to improving the sector’s attractiveness around the world. Ongoing regulatory changes aim to catalyze the pace of pharmaceutical development in the world’s second-largest pharmaceutical market.19 In a recent move, the CFDA (China Food and Drug Administration) adopted guidelines from the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use to further its goal of reforming the review and approval system.20

Simultaneously, the CFDA is looking into several reforms to promote restructuring and drug innovation by improving the data protection policy for clinical trial data and revising patent regulations. China is also revamping its drug regulatory system to facilitate the introduction of new treatments that are increasingly in demand due to China’s aging population and the rising incidence of chronic disease. This move is likely to create a growth opportunity for MNCs and leading local innovative drugmakers, and is expected to close the innovation gap with developed international markets.

Positive moves on the regulatory side are also reflected in the blooming biotechnology industry in China. As one of the most dynamic and impactful industries, biotech has become China’s major sector of strategic importance. Its relevance has been outlined in the recent 13th Five-Year Plan, which projects China’s biotechnology sector will account for over 4% of the country’s gross domestic product by 2020. Further, the plan envisions creating up to 20 life science parks for biomedicine with an output surpassing US$1.5 billion\(^h\) (CNY10 billion).21

To guard against fake prescription medicines and the circulation of counterfeit drugs, the CFDA has released a draft forbidding the online sale of prescription drugs. The draft lists fines between US$750 (CNY5,000) and US$3,000 (CNY20,000) for online platforms used for any such sale. Additionally, it imposes stringent scrutiny of nonprescription drugs sold online.22

Despite ongoing efforts to reform its health care sector and drug approval process, China has recently experienced a shortage of essential drugs. As a solution, the CFDA and several other Government agencies have initiated consultations with pharmaceutical manufacturers to address the undersupply of 27 medicines on a national shortage list. Additionally Chinese authorities plan to expand an online monitoring network that would communicate early-warning signals for shortages. Although most of the listed medicines are typically low-priced and low-margined, China’s recurring drug shortages present opportunities for international drugmakers. Some of the MNCs have already implemented local partnerships with Chinese associations to promote the development of urgently needed drugs.23

\(^{h}\) Converted at an average spot rate for October 2017; i.e., CNY1 equals US$0.15, accessed as on 05 March 2018
India

Striving to increase access to affordable treatments and to bolster its medical devices sector

India, the third-largest pharmaceutical market in Asia, is increasingly gaining the much-needed Government focus on expanding affordable health care. The biggest step in this direction came in the form of an announcement of the world’s largest National Health Protection Scheme as part of the Union Budget FY19 (announced in February 2018). For this, the Government has set aside an investment worth US$307.6 million (INR20 billion) to provide coverage of up to US$7,690 (INR0.5 million) per year to 500 million people belonging to financially vulnerable households for the treatment of serious ailments.24 Further, to enhance price control mechanisms in the country, the governing bodies have introduced several measures that are expected to impact both pharma as well as the medical devices sector:

- In October 2017, the Drug Price Control Order proposed an amendment to bring nonscheduled drugs under its ambit and modify the method of price setting of such drugs.
- In an amendment to the Drugs and Cosmetics Act, the Central Drugs Standard Control Organization proposed mandating disclosure of the maximum retail price as well as ex-factory price on medicines by biopharma companies. The proposal also deliberated on the labeling of the landed price on imported drugs.25
- After exercising price control on coronary stents, the National Pharmaceutical Pricing Authority has extended price capping to knee implants, slashing the prices by 69%, thereby expecting to yield savings of US$240 million (INR15 billion) per year.26

These changes are creating apprehensions among the industry players. In response to the recent price cuts and fearing the inclusion of more medical devices under price control, medical device companies have pre-emptively proposed voluntary price cuts in trade margins on medical devices.27

In parallel, the Government remains committed to establishing India as a global manufacturing hub for medical devices with this sector expected to increase significantly, reaching US$14 billion by 2022.28 The Government has already laid the foundation for such growth, with the Ministry of Health and Family Welfare moving closer to finalizing the Medical Device Regulation Bill that entails comprehensive regulation of these products.29 To spearhead indigenous development of medical devices, the Association of Indian Medical Device Industry, in association with the Government, has launched India’s first medical technology institute, the Kalam Institute of Health Technology, in Andhra Pradesh. The institute seeks to identify the gaps in the field and to streamline Government spending to foster innovation in the medical devices sector.30

Additionally, to encourage foreign investment in medical devices, the Indian Government has broadened the scope of medical devices to include a wide range of items, including software tools, instruments, apparatus, appliances, implants and material used alone or in combination.31 As the nation already allows 100% foreign direct investment via automatic route, this move is expected to fuel local manufacturing of medical devices, thereby helping to reduce the country’s over-reliance on imports (currently, India imports 70%-90% of its medical devices).

Similarly, the increasing demand for generics has resulted in growing dependence on China for active pharmaceutical ingredients (APIs) with India sourcing 66% of its APIs from China in FY17. In a bid to limit its import dependence on China for APIs, the Department of Pharmaceuticals, in collaboration with pharma players, has proposed to extend financial assistance to local drug makers. The initiative seeks to enable pharma companies to procure the latest technology, revamp old manufacturing facilities, refurbish plants and machinery and gain access to other infrastructure facilities, such as subsidized electricity to help companies produce APIs at internationally competitive prices.32

---

1 Converted at an average spot rate for February 2018; i.e., INR1 equals US$0.015, accessed as on 06 March 2018
2 Drugs that do not fall under the price control mechanism
3 Converted at an average spot rate for August 2017; i.e., INR1 equals US$0.016, accessed as on 06 March 2018
Japan

Revamping the drug pricing system while attempting to sustain a pro-innovation climate

The aging population of Japan continues to be a main struggle, thus straining Government budgets. As a result, Japan continues to introduce measures for cost curtailment. One such example is the Ministry of Health, Labor and Welfare’s (MHLW’s) target of achieving generic drug penetration of ≥80% by 2020. Building on this step, the MHLW plans to introduce a project in April 2018 to strengthen the use of generics in priority prefectures that are currently experiencing low uptake of these drugs. Further, in December 2017, Japan’s Central Social Insurance Medical Council (Chuikyo) adopted a new drug pricing policy, overhauling the pricing system for both established and new drugs through the following changes:

- Incrementally reduce off-patent drug prices. At a 10-year mark since the availability of generics and ≥80% substitution by generics, the price of off-patent drugs would be slashed to 2.5x that of generics and would gradually come to par with generics after 6 more years. However, if the generic substitution is below 80% after 10 years of availability, the originator drug price will fall to 1.5x that of generics over the next decade
- Cut the prices of innovative and expensive new drugs by narrowing the list of manufacturers and drugs falling under the ambit of innovation premiums
- Make annual, rather than biennial, revisions of drug fee schedules, effective FY2021

To address the increasing disconnect and industry objections, the Japanese Government has set aside a budget for an R&D environment that fosters efficient, low-cost drug discovery, with the goal of making Japan a major power in drug discovery. Toward that end, the Government has earmarked measures that include funding startups or projects that facilitate the use of artificial intelligence (AI) in drug development; reviving a research-based drug industry; and promoting drugs of Japanese origin in global markets.
South Korea

Cultivating a culture of innovation to create a place for itself on the global map

As discussed in last edition, South Korea continues on its journey to become a global biotech hub by expanding the country’s presence in the global biotech market from its current 1.7% to 5.0% by 2025 and by adding 120,000 new biotech jobs by 2025. To meet this ambitious target, the Government is expected to invest US$320 million (KRW349 billion) in biotech in 2018, a 10.5% increase over 2017. Of the total investment, approximately US$60 million (KRW59.4 billion) is targeted for pharmaceutical R&D, to back development of 100 novel drugs by 2026. Concurrently, the Government, along with industry players and foreign investors, seeks to create an R&D fund worth US$900 million (KRW1 trillion) to provide financial assistance to health care startups and to initiate a technology transfer covering the entire drug development process. Regulatory authorities are also aiming to simplify gene therapy and organ transplantation regulations to accelerate research and commercialization of various novel technologies, including CRISPR gene scissors. All these measures together are expected to boost domestic biopharma R&D, thus enabling the sector to emerge as a new growth engine for the nation.

In the field of medical devices, the South Korean Ministry of Food and Drug Safety (MFDS) is working toward drafting regulations to better govern new medical devices and technologies. Recently, Government authorities, including the Ministry of Health and Welfare (MHW) and the MFDS, and medical technology companies agreed to adopt a new value-based evaluation system for medical devices and related technologies. Under this program, the regulatory bodies plan to deploy “fast-track” approval procedures for next-generation medical devices and also to allow higher health insurance reimbursement rates for innovative medical devices, to reflect their value. South Korea has also become a member of the International Medical Device Regulatory Forum (IMDRF) to maintain medical device regulations in accordance with international standards. These steps are being touted to ensure the safe and quick launch of innovative medical devices in Korea and other global markets and to help South Korean companies gain first-entrant advantage. Additionally, in late 2017, the MFDS released a new draft of medical device safety regulations that updated adverse-event reporting guidelines. This revision to the safety regulations illustrates the country’s increased focus on enhancing the safety management of medical devices.

All the above highlighted measures have become necessary, with the nation witnessing an increased adoption of innovative technologies across the life sciences sector. The Korea Pharmaceutical and Bio-pharma Manufacturers Association (KPBMA) has launched a joint task force to purchase an AI platform to streamline the drug discovery process and improve its efficiency. As of now, 18 local drugmakers have collaborated on this innovation. Two more pharma companies are expected to be added to this R&D effort in future. Samsung Medical Center (SMC), in partnership with Microsoft Korea, is building an AI-based precision health care system to analyze medical data, optimize clinical decision-making and establish disease-specific prediction models. To further aid the integration of such disruptive technologies within the industry, the MFDS has established a formal approval criteria for the new generation of medical devices based on AI and big data to allow wider patient access to more accurate diagnostic and treatment options and also to enable companies to develop and commercialize their products in less time and at a lower cost.

Taiwan

Seeking regulatory harmonization to extend its regional attractiveness

Taiwan continues to improve the regulatory environment of its life sciences sector. Recently, the Taiwan Food and Drug Administration (TFDA) took a first step to separate the management of medical devices from the Pharmaceutical Affairs Act of 1993 by releasing draft regulations for medical devices. Additionally, the TFDA set up a joint program with Japan’s Ministry of Health, Labor and Welfare to accelerate the review of new drugs in Taiwan. Under the collaboration, Taiwan will leverage compiled reviews from Japan’s Pharmaceuticals and Medical Devices Agency at the time of drug approval process in Taiwan, with the applicant’s consent. This joint program is expected to facilitate simultaneous reviews/approvals and reduce time to market, thereby raising Taiwan’s profile as a destination for multinational pharmaceuticals.
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)
- South Korea
- Japan
- Singapore
- Australia
- India
China

Customs compliance – a challenge for cross-border supply chains

China's economic growth coupled with an aging population is driving demand in the pharmaceutical and medical devices industries. The potential of China's market is attracting an influx of new companies, alongside established multinational corporations (MNCs). All are trying to capture market share in the early stages of the growth curve.

The industry is also highly regulated, however. Strict controls over pricing and safety/quality standards have been imposed through measures such as registrations and licensing. The practices of relevant authorities are evolving to align with regulatory and market developments. Among various considerations, customs valuation (determination of the import price) and trade compliance issues represent a huge challenge.

Import pricing and adjustments

The issues surrounding import pricing and adjustments between related parties apply to all MNCs with local subsidiaries in China, but considerations unique to the industry place additional challenges on pharmaceutical and medical device companies with import operations:

- The Government used to restrict the profit margin earned by pharmaceutical distributors to a “reasonable” range. Although there have been changes to the previous restrictions in recent years, increased transparency requirements have placed additional pressures on MNCs to find the balance between their import price and corresponding domestic sales price. For example, given the requirement to disclose pricing at each step in the supply chain, distributors might be asked to further reduce bid price if it is considered unreasonably high compared with their import price.

- Pharmaceutical and medical device companies usually incur considerable marketing and advertising expenditure in order to generate local sales and grow market share in China. Such expenditures also increasingly attract close scrutiny from Customs, particularly concerning the nature and “appropriateness” of these costs when the importer tries to support their import price from the China side (e.g., through the subtractive/deductive valuation method, similar to transfer pricing’s resale minus approach).

- It is typical for distinct products to earn different profit margins; and pre- and post-market specialist/technical support services may also need to be factored into the product pricing (especially for medical devices/consumable products). However, the profit margin variance among different products/categories remains a challenge when having valuation discussions with Customs.

- We have seen some MNCs switch their import/distribution arrangements from third-party to related-party distributors (or vice versa) for commercial and compliance reasons – for example, to ensure that their distributor has a current Good Supply Practice license. Associated with the import/distribution model change, any increase or decrease to the import price means that Customs may impose an additional assessment if the importer cannot provide supportable justification for the import price adjustment.

Also, with greater localization, there is a trend for pharmaceutical companies to send products in bulk for production in China. If there is a significant reduction in the import price, this may be questioned by Customs because the reduction may not be fully supportable, especially when the production moved to China is limited to minor processing (e.g., repacking). Customs authorities are increasingly looking at the functions and risks of the Chinese subsidiaries from both a customs and transfer-pricing perspective. Where a change in business model takes place, e.g., on shoring of functions and risks, and documentation of the change is required for transfer pricing purposes, it is important to bear in mind that Customs will scrutinize the report to see if the price reductions are reasonable. There appears to be a need for greater alignment between customs and transfer pricing. There are many cases where the inconsistencies have triggered an immediate Customs audit.

- Many major pharmaceutical and medical device companies that have previously had valuation discussions with Customs are now required to provide officials with an annual update on their financial results and to keep them apprised of any changes to their import pricing arrangements. This increases the importers’ compliance burden and the risk of mismanaging the customs valuation appraisal (a sensitive topic in China) on an ongoing basis.

From the importers’ side, many companies review their financial results when closing the fiscal year, which may necessitate a year-end true-up or true-down of the past 12 months’ import transactions. In situations where a true-up is required, this will lead to an outstanding duty and/or import value-added tax (VAT) liability that must be settled with Customs.

Equally important, the importer will also have to obtain the import declaration documents corresponding to the true-up adjustment, in order to support the overseas payments. To date, Customs does not have an established mechanism to facilitate this year-end adjustment process, resulting in the potential for “trapped cash” in China, but we note that (on a trial basis) there have been discussions between Customs and importers to explore ways to set up a formal program to satisfy this need.

In addition to the above, China recently restructured its Customs clearance administration by creating Tariff Collection and Administration Centers to centralize the monitoring of import declarations nationwide. The centers segregate responsibilities...
based on tariff chapters in order to take an industry-focused approach. Consequently, this reform will continue to result in more inquiries being received by importers because this change allows Customs to assess the import data/information for pharmaceutical and medical device companies in different ports throughout China, thereby establishing industry benchmarks that will be applied nationwide.

On a positive note, Customs has implemented an Advance Ruling program that enables importers to apply for a formal ruling on customs valuation. Thus, successful applicants may gain more certainty about their import pricing arrangements, duty costs and customs compliance risks, given the abovementioned import pricing issues facing many MNCs. However, this initiative is too new to judge its effectiveness.

Clinical trials

Clinical trials complicate the customs valuation process and are unique to the pharmaceutical industry. Before any pharmaceutical product can be introduced into the Chinese market, it must undergo a clinical trial in China.

For the importation of clinical trial materials, many factors must be addressed to ensure smooth clearance through Customs. Considerations include licensing issues and customs valuation.

In the Customs valuation process, clinical trial materials are not yet commercialized (i.e., no sales price), so the transaction value method (the preferred, most commonly used customs valuation method) cannot be used. Therefore, both the importer and Customs must assess a reasonable customs value for clinical trial materials. This may be achieved by using one of the other customs valuation methods, but the actual application of an alternative method tends to be more complicated to implement in practice. Difficulties include the matter of how to determine a reasonable research and development cost for inclusion in the dutiable value; another question is whether it is appropriate to reference another country’s import price for assessment purposes.

This continues to create challenges for many pharmaceutical companies attempting to introduce new products into the Chinese market.

The two-invoice system

This is a hot topic for high-value medical devices/consumables companies. The Government has implemented the two-invoice system for the purposes of removing superfluous tiers of distributors from the supply chain, to reduce prices paid by consumers/patients.

For imported medical devices/consumables companies, the two-invoice requirement means there are only two transaction layers before the products are sold to hospitals and/or medical service providers: from the importer/national distributor to the regional distributor, and then to the hospital.

This is unlike traditional supply chain models, which generally involve multiple layers of distributors because of the high demand for pre/post market support (e.g., specialist/technical support services). This change requires MNCs to strategically revisit their current cross-border transaction arrangements and the associated import pricing structure. Once again any business model change should have the functional and risks profile changes reflected in the prices and margins of the respective related parties.

Conclusion

While the large and lucrative Chinese market presents abundant opportunities for MNCs, Customs presents numerous challenges for importers’ cross-border business operations.

Customs is focusing particular scrutiny on the importation of life science products. Companies must be proactive and diligent about evaluating and developing strategies for addressing risks related to both Customs valuation and trade compliance.

Bryan Tang, Partner, Indirect Tax, Ernst & Young (China) Advisory Limited  
bryan.tang@cn.ey.com

Joanne Su, Partner, Transfer Pricing, China Life Sciences Tax Co-Leader Ernst & Young (China) Advisory Limited  joanne.su@cn.ey.com

Titus von dem Bongart, Partner, Ernst & Young (China) Advisory Limited, EY Life Sciences Tax Co-Leader, China  titus.bongart@cn.ey.com

South Korea

Controversy trends

Overall tax audit environment

On 31 January 2018, the South Korean tax authority announced its tax administration policy for 2018. Major items include reduction of tax audits on small and medium-sized companies, and heightened scrutiny of large South Korean MNCs and their nonprofit-affiliated companies for tax evasion and illegal means of wealth transfer.

In addition, the tax authority announced that it will reduce the team of tax auditors who mainly perform special tax audits, which are similar to dawn raids. The auditors do not provide companies prior notice. They target companies suspected of engaging in tax avoidance/criminal transactions or with issues of significant concern or focus for the tax authority (e.g., management service fees, beneficial ownership, tax credit/exemption, guarantee fee for an intercompany loan, etc.). As such, the number of special tax audits is expected to gradually decrease.
As far as the pharmaceutical industry is concerned, the tax auditors continue to focus on pharmaceutical companies’ disbursements made for sales promotion activities and those for facilitation of relationships with doctors and pharmacists. It is often the case that pharmaceutical companies are assessed additional taxes and penalties in a tax audit for these types of disbursements and resort to filing a tax appeal with the Tax Tribunal and then to the court (if not successful at the Tax Tribunal level).

In particular, with the introduction of South Korea’s new health care reform (“K-Sunshine Act,”) local pharmaceutical companies would be required to keep records of all benefits (e.g., samples, research subsidies, food and beverages) provided to doctors, pharmacists and other health professionals. Due to the K-Sunshine Act taking effect on 1 January 2018, the tax authority will require detailed expense reports along with supporting documents in future tax audits. Please see “Sector impacts of the legislation change” for further details.

Tax appeals and litigation
As mentioned above, some pharmaceutical companies have filed tax appeals with the Tax Tribunal or the court. Such appeals are related to issues over the economic benefits provided to doctors and pharmacists, intercompany transactions, sales commissions paid to contract sales organizations (CSOs), etc.

Although the outcome of the majority of tax appeal cases is yet to be finalized, there was a Tax Tribunal case that ruled in favor of the taxpayer. The case concerned the deductibility of expenses related to local sales promotion activities. According to the decision issued by the Tax Tribunal, a pharmaceutical company’s disbursements related to meals and drinks served in a restaurant to a group of doctors and pharmacists may be viewed as a deductible expense if there is sufficient supporting evidence, such as documents. The tribunal said the evidence must substantiate that the seminars or sales promotion events were held to introduce new products or to explain usage of the drugs. In past tax audits, such disbursements were disallowed as a deduction and were re-classified as an entertainment expense, which is subject to a statutory deductibility limit. Given this, pharmaceutical companies should revisit the nature of their disbursements to identify those that may qualify as a deductible expense and prepare/maintain supporting documents.

Sector impacts of the legislative change
South Korea enacted the 2018 tax reform bill on 19 December 2017, (the 2018 Tax Reform) after it was passed by the National Assembly on 5 December 2017. The 2018 Tax Reform also includes provisions in line with the Organisation for Economic Co-operation and Development (OECD) Base Erosion and Profit Shifting (BEPS) Action 2 (to neutralize the effects of hybrid mismatch arrangements) and Action 4 (to limit base erosion involving interest deductions and other financial payments), among others. Unless otherwise specified, the 2018 Tax Reform will generally become effective from fiscal years beginning 1 January 2018. The Enforcement Decrees, which provide more specific guidance on the laws, were promulgated on 13 February 2018.

The 2018 Tax Reform aims to create jobs, redistribute wealth and expand the tax revenue base. Due to the 2018 Tax Reform, many taxpayers would be expected to pay more taxes as the overall tax cuts and deductions will decrease and the tax rates for both corporations and individuals will increase from 1 January 2018. Major tax law revisions include:

Effect for fiscal years that began on 1 January 2015, certain corporations were subject to the AET that expired as of 31 December 2017. Under the 2018 Tax Reform, certain corporations will be subject to a revised AET regime effective for fiscal years beginning on 1 January 2018 with a sunset clause due to expire 31 December 2020. Major changes in the revised AET over the previous provision include:

- The tax rate applied on accumulated earnings is increased from 11% to 22% (inclusive of local income tax).
- Dividends, unlike in the previous provision, would no longer be used to decrease accumulated earnings.

As in the legacy AET regime, the revised AET would apply to large corporations whose equity capital exceeds KRW50 billion or corporations that are members of an enterprise group with restrictions on mutual investment. AET may be reduced by making qualified investments, payroll increases and disbursements encouraging the mutual growth of large corporations and small and mid-sized enterprises.

Expansion of qualified reasons for issuing revised import VAT invoices
Effective from 1 January 2018, qualified reasons that allow taxpayers to be issued revised import VAT invoices have been expanded. Before the revision of relevant tax law (i.e., Article 35 of the Value Added Tax Law (VATL)), the customs authority issued revised import VAT invoices in one of these instances:

- The taxpayer made amended filings on a voluntary basis (i.e., not as a result of additional assessment of customs duty).
- The taxpayer was assessed additional customs duty or made amended filings in anticipation of additional customs duty assessment, etc. (i.e., in a customs audit situation), provided that the reason for adjustment of customs duty base meets the conditions prescribed under the VATL. The qualified conditions under the VATL include by reason of simple mistake of the importer, or if the importer can substantiate that no fault lies with him.
Due to the revision of the VATL, minor negligence of the importer has been added as a qualified condition under which the customs authority may issue revised VAT invoices in a customs audit situation described above.

Implementation of the new K-Sunshine Act
The South Korean Government introduced the new health care legislation requiring local pharmaceutical and medical device companies to keep records of all benefits provided to health professionals such as doctors and pharmacists. Such benefits include, for example, samples, research subsidies, and food and beverages provided during detailing and sales promotion-related meetings. The new legislation is called the K-Sunshine Act because of its similarities to the Physician Payments Sunshine Act in the US. Its purpose is to bring transparency and stability to the market.

The K-Sunshine Act requires the companies to establish and maintain an expense reporting system to collect the relevant data. The companies should prepare an expense report and supporting documents within three months from the end of each fiscal year and should retain them for five years. If requested by the Ministry of Health and Welfare (MOHW), the companies should submit these items to the MOHW. The information could be used to investigate whether the relevant parties have been involved in an illegal kickback scheme. Failure to submit the expense report and supporting documents upon MOHW’s request will result in a fine of only KRW2 million (less than US$2,000). However, noncompliance would likely result in intensive scrutiny from the authorities and/or trigger other investigations.

In the short-term, the K-Sunshine Act may discourage sales and promotion activities in the industry by reducing the frequency of contact with doctors and pharmacists. Also, pharmaceutical and medical device companies would need to make investments to establish the expense reporting system and to prepare and maintain required documents. However, in the long-term, despite such concerns, some pharmaceutical companies are in favor of the K-Sunshine Act, saying it could help them monitor their expenses, detect any immoral business conduct, and protect them against false charges.

From a South Korean tax perspective, non-deductible sales and promotion expenses will decline if pharmaceutical and medical device companies move away from face-to-face marketing and promotion to focus on online sales and marketing.

Pharmaceutical and medical device companies should consider investing sufficient time and effort to set up an expense reporting system and to maintain supporting documents to be prepared in the event of a tax audit.

BEPS update

Automatic exchange of CbCR
South Korea is a signatory of the Multilateral Competent Authority Agreement (MCAA) on the exchange of country-by-country reports (CbCR). It has activated exchange relationships with 51 jurisdictions as of December 2017, according to the OECD. If an exchange relationship is not activated between South Korea and the tax jurisdiction of the ultimate parent entity, a CbCR notification form should be submitted. The form, stating the surrogate filing entity, should be submitted to the South Korean tax authority within 6 months from the South Korean entity’s fiscal year-end. If the CbCR notification form is not filed to the South Korean tax authority within the statutory due date, the CbCR form must be submitted to the South Korean tax authority within 12 months from the South Korean entity’s relevant fiscal year-end.

Filing of CbCR in South Korea
In November 2017, the South Korean tax authority issued a guideline indicating that the CbCR filing should be made via e-filing, through a portal called “AXIS.” The person responsible for uploading information in HomeTax (i.e., an electronic tax return filing portal) should go to the website and provide an email address. After 2-3 days, an email with an ID and password for logging on to the AXIS portal will be provided. An electronic certificate, or key, is also required to log on.

Exceptions apply to South Korean entities that ceased operations during 2017 and are subject to filing CbCR in South Korea by the end of 2018. These entities would be allowed to submit CbCR to the South Korean tax authority via email, given their special circumstance.

Key amendments to transfer pricing regulations
- Pursuant to the 2018 Tax Reform, the penalties imposed on taxpayers who fail to file master file/local file/CbCR or who file false information increased from KRW10 million per documentation to KRW30 million per documentation. This revised penalty regime will be applicable from 13 February 2018.
- A taxpayer who wishes to obtain an Advance Pricing Agreement (APA) on or after 1 January 2019 will be required to file the APA application by 31 December 2018.
Effective from fiscal years beginning on 1 January 2018, taxpayers who file local file within the statutory deadline (i.e., within 12 months from the fiscal year-end) will be granted a waiver of the underreporting penalty in those cases where transfer pricing income adjustment is made as a result of a tax audit. An underreporting penalty is generally computed as 10% of the underreported tax amount. Before the amendment, South Korean entities that prepared contemporaneous transfer pricing documentation and submitted it together with the annual corporate income tax return by the statutory filing due date (i.e., 3 months from fiscal year-end) were eligible for the waiver.

Jae Cheol Kim, South Korea Life Sciences Tax Leader
EY Han Young (South Korea) jae-cheol.kim@kr.ey.com

Japan

Japanese tax audit developments

We continue to see Japanese tax authorities increasing their level of scrutiny during tax audits. Areas of particular focus include transfer pricing (TP), donation income and expense challenges, Japan’s controlled foreign corporation (CFC) rules, and R&D tax credits.

Japanese companies continue to pursue overseas M&A opportunities. The target company often has different TP policies from the acquiring company, and it can take several years for the Japanese company to reconcile the TP policies of the target with that of its own. Where there are inconsistencies, we see the Japanese tax authorities challenging the taxpayers transfer pricing and making adjustments. As a result, more Japanese companies are applying for APAs, with an emphasis on bilateral APAs. Further, Japanese companies are increasing the size of their in-house tax departments in Japan, partly to deal with increased obligations resulting from Japan’s adoption of the BEPS TP documentation requirements of country by country reporting, master file and local file.

Under Japanese tax law, donation income and expenses may be recognized where a transaction takes place at a price that is not equal to the fair market value of the goods or services. A donation can take place between two third parties, even where there is no common ownership. A party that receives the economic benefit should recognize donation income, which is taxable. For example, donation income could be recognized by a Japanese company that purchases goods or services for less than fair market value. The party that provides an economic benefit would recognize a donation expense. The tax deductibility of a company’s total annual donation expenses is severely restricted. For example, where a Japanese company bears the promotional expenses of a global campaign for a product, Japanese tax authorities may challenge the deductibility of the expenses by arguing that the overseas subsidiaries should have borne some of the expenses. In an inbound context, year-end TP adjustments can be challenged as a nondeductible donation expense where there is inadequate documentation, including an agreement made in advance. We are seeing tax examiners challenging transactions with related parties using the donation income theory rather than TP. This can have adverse consequences, because a donation income adjustment is not eligible for a corresponding adjustment under a tax treaty, raising the potential for double taxation.

The Japanese CFC rules changed as of 1 April 2018 to include paper companies, cashbox companies and companies on a country “black list” potentially to be classified as CFCs if their effective tax rate for the year is under 30%. Under the previous regime, the effective tax rate test was under 20%. Although there is an exception for companies with an active business, the new regime will capture more subsidiaries. With the US cutting its federal corporate tax rate to 21%, it is possible that some US companies may be considered CFCs. As a consequence, Japanese companies are reviewing their global structures to identify CFC risk and, where possible, are restructuring. We expect tax audit activity in this area to increase in 2018 and 2019.

Japan offers generous R&D credits, which can substantially reduce a company’s effective tax rate. A company may claim an R&D credit for up to 20% (or higher in certain cases) of its Japanese corporate tax liability for the year. Japanese tax examiners continue to focus on the eligibility of qualifying expenditures for the R&D credit, including reviewing in detail personnel costs and depreciation of equipment. One of the conditions to qualify for the R&D credit is that the Japanese company must be the economic owner of the resulting IP. Hence, in an inbound setting, a Japanese company that performs contract R&D services for an overseas group company is not eligible for the R&D credit.

US tax reform and Brexit

US tax reform is generating keen interest from Japanese companies. Many Japanese life sciences companies have substantial operations in the US. The fundamental reform is causing Japanese companies to review the impact not just on tax liabilities but also on the supply chain. For instance, one area being considered is whether it may be beneficial to develop intellectual property (IP) in the US, or even to transfer certain IP from Japan to the US. This may be attractive in terms of the applicability of the new base erosion and anti-abuse tax (BEAT), as well as the foreign derived intangible income (FDII) provisions.
As the UK and EU continue to negotiate the terms of Brexit, it was announced that the European Medicines Agency (EMA) will move from London to Amsterdam by 30 March 2019. Japanese life sciences companies are evaluating the impact of this relocation, along with tax changes such as the lower corporate tax rates in the UK and some EU countries, as well as the stricter Japanese CFC rules mentioned above. Some companies may consider moving certain of their operations, such as regulatory affairs, from the UK to the Netherlands or other EU countries. However, this will depend on the terms of the final Brexit agreement, as the UK has indicated that it wishes to remain a part of EMA.

Jonathan Stuart-Smith, Partner, EY Japan Life Sciences Tax Co-Leader
Ernst & Young Tax Co. (Japan) jonathan.stuart-smith@jp.ey.com

Tatsuhide Kanenari, Partner, EY Japan Life Sciences Tax Co-Leader, Transfer Pricing, Ernst & Young Tax Co. (Japan) tatsuhide.kanenari@jp.ey.com

Singapore

Budget accounts for major changes

Singapore’s FY2018 budget (1 April 2018 to 31 March 2019) sets forth a strategic and integrated plan to position the nation for the future, which is expected to bring three major shifts in the coming decade:

1. A shift in global economic weight toward Asia
2. Emergence of new technologies
3. The aging population of Singapore

Health care was identified as a key area of expenditure growth. Singapore has more than doubled its health care spending from SGD$3.9 billion in 2011 to an estimated SGD$10.2 billion in 2018. In the coming decade, with an aging population and the attendant increase in chronic diseases, Singapore will need to build more hospitals, nursing homes and eldercare centers to meet the rising demand and must also invest in new medical technologies to improve quality of care. This will cause health care spending to increase from 2.2% of gross domestic product (GDP) to almost 3% of GDP over the next decade.

Life sciences companies will have tremendous opportunities to work together with the different stakeholders – payers, providers, technology innovators and others – to create scalable solutions for sustainable aging in the long run.

Efforts to foster innovation

- To support businesses in building their own innovations, the tax deduction for labor costs and consumables incurred on qualifying R&D projects performed in Singapore will be increased from 150% to 250%. This change will become effective from the year of assessment (YA) 2019 to YA 2025.
- To encourage businesses to register and protect their intellectual property (IP), the existing 100% tax deduction on qualifying IP registration costs, which is scheduled to expire after YA 2020, will be extended through YA 2025. Further, the tax deduction will be increased to 200% for the first SGD$100,000 of qualifying IP registration costs incurred for each year of assessment. This change will become effective from YA 2019 to YA 2025.
- To support businesses in buying and using new solutions, the existing 100% tax deduction for qualifying IP in-licensing costs will be increased to 200% for the first S$100,000 of qualifying IP in-licensing costs incurred for each YA. Qualifying IP in-licensing costs include payments made by a qualifying person to publicly funded research performers or other businesses. They exclude related party licensing payments, or payments for IP where any allowance was previously made to that person. This change will become effective from YA 2019 to YA 2025.

The above measures will be a welcome relief for life sciences companies that invest heavily in R&D. The proposed 250% R&D tax deduction does not impose a cap on qualifying expenditures. Therefore, life sciences companies incurring significant R&D expenditures on qualifying R&D projects performed in Singapore will be able to correspondingly enjoy greater benefits.

Proposed enhancements and adjustments

The Start-Up Tax Exemption (SUTE) scheme will be adjusted to provide for a 75% exemption on the first SGD$100,000 of normal chargeable income (NCI) and a 50% exemption on the next SGD$100,000 of NCI. All other conditions of the scheme remain unchanged. This change will take effect on or after YA 2020 for all qualifying companies.

The Partial Tax Exemption (PTE) scheme will be adjusted to provide for a 75% exemption on the first SGD$10,000 of NCI and 50% exemption on the next SGD$190,000 of NCI. All other conditions of PTE remain unchanged. This change will take effect on or after YA 2020 for all companies (except those that qualify for the SUTE scheme) and individuals.

- The existing 250% tax deduction for qualifying donations made between 1 January 2016 and 31 December 2018 will be extended for donations made on or before 31 December 2021.
A goods and services tax (GST) will be implemented on 1 January 2020 on imported services consumed in Singapore. Business-to-business imported services will be taxed via a reverse-charge mechanism. Only businesses that make exempt supplies or do not make any taxable supplies need to apply the reverse charge. The taxation of business-to-consumer imported services will take effect through an Overseas Vendor Registration (OVR) regime, which requires overseas suppliers and electronic marketplace operators that provide local consumers with significant supplies of digital services to register with the Inland Revenue Authority of Singapore for GST.

This is consistent with recommendations provided by the Organisation of Economic Co-operation and Development and aims to level the playing field for local suppliers.

To support the expected increase in health care, security and other social spending, the GST rate will be raised from 7% to 9% during 2021 and 2025. The exact timing will depend on the state of the economy, growth of the country’s expenditures, and how buoyant the existing taxes are.

Tan Ching Khee, Partner, Ernst & Young Solutions LLP, Singapore Life Sciences Tax Leader  ching-khee.tan@sg.ey.com

**Australia**

**Insights into the direction, tools and activities of the Australian Taxation Office (ATO)**

In the October 2017 *EY Life Sciences Report*, we commented that the life sciences sector continued to remain a focus area for the Australian Taxation Office (ATO), and we set out some of the views espoused by the ATO pharma cluster in a meeting with EY in late 2017. In this article, we have gazed into the crystal ball and provided further insights on: (i) where we believe the ATO is proceeding with the life sciences sector; (ii) our views on the ATO’s approach to the art of information-gathering and (iii) our views on the ATO’s increasing arsenal of tools at their disposal for dealing with taxpayers they deem difficult.

**Where is the ATO going with the life sciences sector?**

The ATO’s focus on the life sciences sector, in particular the pharmaceutical subsector, occurs through two parallel streams – the first stream involves a series of risk reviews and audits of high-profile companies, and the second involves reviews of companies by means of the Streamlined Tax Assurance Review (STAR) project on the “Top 1000” Australian companies if they have not been covered by a targeted review.

In some respects, there is not a huge difference in the workload that companies experience between these parallel streams (particularly at the risk review and STAR stage). Numerous pharmaceutical companies have been caught up in the first stream and are subject to various “products” from the ATO, including client risk reviews and audits. For taxpayers caught up in the second stream, there may be some reservations about how streamlined the STAR process really is – in some instances, it may appear to be as comprehensive as the other products but with a shorter time frame. Having said that, the STAR project is relatively embryonic – as the ATO begins to process more and more taxpayers through it, efficiencies may emerge.

A key feature of both these streams is the ATO’s focus on transfer pricing. One area of scrutiny relates to the value of the contributions made by local teams in Australia with regard to regulatory support (for getting products registered with the Therapeutic Goods Administration (TGA) and maintaining those registrations) and market access (for getting products funded by way of the Pharmaceutical Benefits Scheme (PBS). This is an interesting area as it is not uncommon for a multinational company to consider that the vast bulk of the content that goes into the relevant submissions is undertaken offshore. However, this sometimes appears to be at odds with the ATO’s view that the local employees may be providing significant value in preparing these submissions and in responding to queries from the TGA and Pharmaceutical Benefits Advisory Committee (PBAC).

In this regard, the ATO may consider that the work of the local Australian employees in effect produces an intangible asset that may be labeled a “marketing intangible” or a “regulatory intangible.” There are numerous conceptual difficulties with such an argument, because it gives rise to several questions. For example, does an asset (as defined using accounting standards) arise from the activities of the local Australian employees? If so, can it be recognized for accounting purposes? Is this really just part of the goodwill of the local Australian company rather than a separate identifiable asset? If it is an asset, can it be used to bolster the thin capitalization position of the local Australian company?

None of these questions are easy to answer, and it is not sufficient to consider just the first level of impact (i.e., the creation of an asset) without thinking through all of the consequential issues to follow.

The above debate also applies to areas outside any potential “marketing intangible” or “regulatory intangible.” Examples include clinical trials where the local Australian company may help to conduct or oversee clinical trials undertaken in Australia that have been devised offshore.
So, the obvious question is what happens if the ATO arguments are correct and there is some sort of “additional” local asset as discussed above? If such arguments are true, it may mean that the characterization of the local Australian company should be modified to include the provision of such services. That would likely lead to the conclusion that the local Australian company should be rewarded appropriately for such services. As such, this may mean that the returns that Australian companies in the life sciences sector previously derived may need to be increased.

It will be interesting to see whether the parallel review activity by the ATO will culminate in this outcome and whether this will become a broader industry trend. If so, this will have knock-on consequences, especially where the local company has an international related-party transaction with a company resident of a country that has concluded a double tax treaty in Australia – in these circumstances, the mutual agreement procedure (MAP) provisions of the relevant treaty may need to be invoked to ensure that double taxation does not arise.

Information-gathering by the ATO

As noted above, the ATO is conducting a significant amount of review activity on Australian taxpayers in the life sciences sector. In this regard, it might appear that the ATO has forgotten all that it has learned about the life sciences sector and, in particular, the pharmaceutical industry, through reviews, consultative projects and cluster activities over the last 20 years.

Historically, the ATO approach was to ask written questions and for companies to provide written responses, which were generally accepted. Such responses were only assertions without specific supporting evidence. This does not suggest that such assertions were incorrect, as companies generally understood their obligation to respond truthfully.

However, the ATO’s adoption of an “assurance model” based on the concept of “justified trust” (as discussed in the October 2017 report) has flipped this notion on its head. ATO auditors are now required to have assured themselves that the evidence supports the positions adopted. This is a significant shift on the “Knowledge Scale” as depicted herein.

In order to move along the scale, we have seen the ATO use their information-gathering powers much more extensively. This includes the use of interviews (both accountable informal interviews and those carried out under formal powers – known as “section 353-10 interviews”). We have also seen a significant increase in the use of discovery powers – formal notices that require production of information or evidence with sanctions for noncompliance.

The discovery processes often require the location and filtering of significant amounts of electronic data. Our experience is that these processes are time-consuming and expensive for clients because of the breadth of questions the ATO is asking. The ATO is also seeking to shorten the time it takes to complete these projects, perhaps not fully appreciating the time, cost and resources that compliance requires.

In addition to these domestic powers, we are seeing activity that is designed to access information located overseas. This is through requests for information from foreign revenue authorities and the use of evidence bar notices (referred to as “section 264A notices”) on domestic companies. The latter works to require third parties (including related entities) offshore to produce documents. If the documents are not produced in the timeframe allowed, they cannot be used in court to support the taxpayer’s challenge to any assessments.

Companies must understand that the ATO now has extremely broad access powers, which they are increasingly using as standard tools rather than as a last resort.

Hybrid mismatch rules

Following the tightening of the General Anti-Avoidance Regime (referred to as Part IVA), introduction of the Multinational Anti-Avoidance Law (MAAL) and the diverted profits tax (DPT), the latest tool in the ATO toolkit is the hybrid mismatch rules, which were released in exposure draft form on 7 March 2018.

The hybrid mismatch rules will prevent entities that are liable for income tax in Australia from being able to avoid income taxation, or to obtain a double non-taxation benefit, by exploiting differences among the tax treatment of entities and instruments across different countries. The hybrid mismatch rules are subject to further consultation, and the date of commencement is “the first 1 January, 1 April, 1 July or 1 October to occur after the day this Act receives the Royal Assent.” The likely start date is 1 October 2018.

These rules are based on the Organisation for Economic Co-operation and Development (OECD) base erosion and profit shifting (BEPS) action item No. 2, “Neutralising the Effects of Hybrid Mismatch Arrangements.” They are modified for the Australian tax landscape.
Here are a few observations about these complex new rules:

- It is clear that the Government expects that affected taxpayers will restructure out of hybrid arrangements into arrangements that do not attract the operation of the hybrid mismatch rules. However, this raises the question as to whether Part IVA could apply to the restructuring. Presumably, the answer is no, based on CPH Property Pty Ltd v. Federal Commissioner of Taxation (1988) 88 FCR 21. However, it is not clear whether the ATO would agree with this conclusion. The ATO expressed a different view in the context of the MAAL provisions at the time they were introduced.

- Australian subsidiaries will find it difficult to comply with the “imported hybrid mismatch” rules. Broadly stated, these rules are intended to prevent Australian taxpayers from entering into arrangements that shift the effect of an offshore hybrid mismatch into Australia through the use of a non-hybrid instrument such as an ordinary loan. The difficulty is that from an Australian subsidiary’s perspective, it may be impossible to tell what happens in the global group after the payment is made in Australia. The need to trace a payment made by an Australian subsidiary through a global group, to ensure that the receipt of the payment is not subject to any potential hybrid treatment, may be virtually impossible to undertake without significant cooperation from the offshore parent company, ultimate parent company and any intermediaries.

- A new “integrity” rule concerns intra-group financing arrangements within multinational groups. The rule will apply where the routing of funds through foreign interposed entities results in an Australian income tax deduction (e.g., interest on a loan) and there is imposition of foreign income tax on the payment at a rate of less than 10%. While it is not entirely clear, it is likely that the 10% foreign income tax is an “effective tax” rate rather than a headline rate. If that is correct, it may prove difficult to navigate.

In many respects, the hybrid mismatch rules are significantly more stringent than the DPT and MAAL because they are so far-reaching and difficult to comply with.

India

Union Budget 2018

On 1 February 2018, the Indian Finance Minister presented the Union Budget, which was the last full budget of the current Government under the leadership of the Prime Minister. The most significant announcement from the perspective of the life sciences and health sectors relates to the national health coverage scheme. Described by some as the world’s largest such plan, it would cover roughly 100 million poor and underprivileged families – approximately 500 million people.

In terms of tax reform proposals, the budget has eliminated the existing 3% education cess (i.e., additional levy over tax amount) and introduced a comprehensive 4% health and education cess to partially fund the spend. It has also provided a 25% tax rate (vs. current rate of 30%), excluding surcharge and cess, on companies registered in India with a total turnover not exceeding INR2.5 billion (approximately USD$38.5 million) in FY 2016-17. As the Indian life sciences sector is highly fragmented with numerous small- and medium-size players, the rate reduction should benefit many companies.

On the international tax front, India has been a supporter of the Organisation for Economic Co-operation and Development (OECD) base erosion and profit shifting (BEPS) action plans and has been proactive in implementing the measures. India has adopted the modified PE rule (as per BEPS Action 7) while signing the multilateral instrument (MLI), which would result in automatic alteration of certain bilateral tax treaties widening the PE definition. However, the definition of “business connection” under Indian domestic tax law (which is a test of tax residency) was limited in scope and covered only persons who had the authority to conclude contracts, thereby nullifying the effect of the expanded definition in the tax treaties. Hence, in India’s budget, it has been proposed to align this definition in the domestic law with BEPS Action 7 to include persons who habitually play a principal role leading to the conclusion of contracts.

Life sciences companies having agency arrangements, marketing support agreements and any indirect sales and marketing footprint through, say, an affiliate in India should examine the feasibility and risks of such models going forward.

In the last budget, the Indian Government had introduced master file and country-by-country reporting (CbCR) compliances in India. Moving a step ahead, India has mandated electronic filing of master file (along with CbCR) with a view to automate first-level risk analysis.
Transfer pricing and dispute resolution

The Government is continuing its efforts to foster a non-adversarial tax regime and to curb transfer pricing disputes, building off of the incredible success of the advance pricing agreements (APA) regime. Since the regime was introduced in 2013, India has signed 203 APAs (185 unilateral and 18 bilateral). This includes several APAs signed by pharma companies for transactions such as R&D services, royalties and intragroup services.

India will now support bilateral dispute resolution through acceptance of bilateral APA and mutual agreement procedure applications, even in the absence of Article 9(2) in tax treaties (i.e., provision for corresponding adjustment to avoid economic double taxation). Consequently, a window of bilateral dispute resolution opportunities has opened with important trading partners, such as France, Germany and Italy.

The Indian Government has also recently rationalized the safe harbor margins for various transactions (originally introduced in 2013), which had not resulted in the anticipated level of success expected from taxpayers. Among other things, the safe harbor margins prescribed for specified contract R&D services have been now reduced from 29% to 24% on operating costs. Safe harbor rules (SHR) have also been expanded to include the receipt of low-value-adding services with markup not exceeding 5%, thereby reducing the burden of documentation and the anticipated level of controversy for taxpayers who are comfortable with the revised margins in the SHR.

Tax treatment of expenses relating to health care professionals (HCPs)

There is an ongoing tax controversy trend relating to pharmaceutical and medical devices companies around the tax deduction of expenses relating to HCPs, grants, sponsorships, gifts, samples, etc. Tax authorities have sought to disallow these expenses. Efforts have included treating them as noncompliant with guidelines issued under the Indian Medical Council Act, 1956 (legislation concerning the professional conduct of HCPs). Some taxpayers (e.g., pharmaceutical companies) have argued that the council’s regulations govern medical practitioners and do not apply to them. In a set of recent judicial precedent(s), a tax tribunal ruled that Medical Council regulations cannot be a measure by which to decide allowance of a tax deduction when they don’t intrinsically apply to a pharmaceutical company.

However, it is anticipated that tax authorities will appeal these rulings. Hence, this is expected to be a continued issue in the short term.

Goods and services tax (GST)

The introduction of a Goods and Services Tax (GST) from 1 July 2017 was a significant step forward in reforming India’s indirect tax structure. The challenges of aligning the interests of the federal and state governments, addressing concerns of taxpayers, and taking key corrective decisions has been adeptly handled through the GST Council, an independent body with representation by relevant stakeholders.
From a GST implementation standpoint, the life sciences sector has, by and large, navigated this phase without significant issue or business disruption. Given that the GST has also done away with regressive trade barriers, such as check post at entry points for goods into states or local municipal areas in the erstwhile indirect tax regime, this has contributed to ease in doing business and a pan India single market.

The generic GST rate for pharma formulations continues to be at 12%, which is higher than in the earlier regime. As a rule of thumb, exemption to goods under GST is limited. However, many in the industry anticipate a GST rate of 5%, as it would benefit patients and encourage health care initiatives. This is an area to watch.

For the first time in India, the entire indirect tax compliance framework is electronic via a new IT infrastructure (Goods and Services Tax Network (GSTN)) developed specifically for this purpose. One of the key challenges for taxpayers over the last 6 months has been addressing this compliance requirement under GST through the GSTN IT platform. Due to the size and scale of GST compliance requirements and taxpayer base, GSTN is taking time to stabilize. Given the unprecedented scale of this exercise, the Government has proactively sought to address these concerns by giving relief to taxpayers by extending the due date for returns, waiving off late fees in case of delay in filing, etc.

While ease of doing business is key to the Government’s initiatives, a study has revealed that there still exists the possibility of tax evasion in the GST regime, as there is no effective tracking of the movement of taxable goods. To address this concern, a process for tracking the movement of goods has been proposed. It is referred to as the “E Way Bill.” In essence, every movement of goods (with certain exceptions) would require a supporting document (E Way Bill) generated from an electronic portal that would be common for all industries. This requirement would require companies to invest in and leverage technology solutions to mitigate against supply chain disruptions.

One could say that while the GST regime continues to improve, there are areas that require progress at a practical level. In the coming months, it is expected that the GST Council will further relax some of the cumbersome legal provisions to benefit taxpayers. There is also a move to simplify compliance. The Government is cognizant of the challenges faced by the industry and is closely working with industry bodies to support business and ensure that there are no revenue leakages.

As evident from above, India’s tax laws and administration are going through a continuous reform under Prime Minister Modi’s Government. Several grass-roots level and structural measures are being taken to reduce administrative bureaucracy and increase transparency. These include e-audits and the use of advanced technology to increase tax collection. These are steps in the right direction. However, given the legacy and size of the tax administration, it is unlikely that implementation and results will come swiftly.

Rahul Patni, Tax and Regulatory Services, Ernst & Young LLP (India) rahul.patni@in.ey.com
Himanshu Tanna, Director, International Tax Services, Ernst & Young LLP (India) himanshu.tanna@in.ey.com
The pace of transformation has increased, competition has intensified and business models have been profoundly disrupted. This shift is happening at breakneck speed across industries, and pharma is no exception.

Customers have rapidly embraced technology and expect a standard of service that is higher than ever before. With the consumer firmly in the driver’s seat, traditional pharma players must look toward digital to reimagine the customer experience.

To better understand the state of the market in India and the vision for digitization in the industry, we have engaged leaders from major pharma companies and hospital chains across India. The EY Digital Maturity Index (EYDI), an online digital readiness-assessment tool, helped us to gauge the current state of the pharma companies.

This article is based on EY India’s recently launched thought leadership report titled Reinventing pharma sales and marketing through digital in India. It provides insights into the digital readiness of Indian pharma companies, barriers to embracing digital, and future digital trends that are expected to reshape the Indian pharma industry.

Indian pharma’s journey to the digital world has just begun

On our five-step digital maturity journey, Indian pharma companies are significantly behind their global counterparts. EYDI results demonstrate that most Indian companies are still at the “beginners” and “conservatives” stages. This is lagging behind the global trend, which is for more digital practitioners. Of the Indian companies that were surveyed, only 7% have moved toward the “explorers” stage.

The EY Digital Maturity Index (EYDI), a five-step digital maturity framework, found that India’s pharma companies are largely just beginning their digital journey.

93% Of the companies in India are still focusing on disparate strategies

53% Beginners

40% Conservatives

7% Practitioners

40% Explorers

7% Disrupters

Globally, most pharma players are explorers, with companies now cautiously making a move toward being digital practitioners.

Source: Reinventing pharma sales and marketing through digital in India, EY report.
Digital intent is strong. Execution is not.

86% of the senior pharma leaders have a strong positive inclination toward digital as a strategic rather than a tactical approach. However, lack of clear digital strategy/value proposition and change management are perceived as the barriers to embracing digital.

We found that Indian pharma companies tend to get caught up in technology hype and rollout initiatives without a clear understanding of stakeholders’ needs and market dynamics. Gaps in technology, lack of an integrated approach — resulting in multiple agendas that create silos, and cultural resistance have been identified as some of the major barriers to embracing digital. Resistance to invest in digital often comes from leaders, who are either skeptical of the ROI or believe that they can grow without digitization.

Summarizing his thoughts on the matter, a senior Indian digital leader in the pharma industry said “Whatever was being done manually earlier is now being done digitally. But we are not adding additional value.”

What’s holding Indian pharma back (according to pharma leaders)?

<table>
<thead>
<tr>
<th>Digital intent is strong ...</th>
<th>... but execution is not</th>
</tr>
</thead>
<tbody>
<tr>
<td>86%</td>
<td>87% See lack of value proposition in digital solutions for physicians</td>
</tr>
<tr>
<td>Consider digital a core strategic enabler</td>
<td>Consider digital not central to business strategy</td>
</tr>
<tr>
<td>80% See lack of sufficient and authentic data as key barrier</td>
<td></td>
</tr>
</tbody>
</table>

Data will become the new currency of digital marketing, and analytics will be the key enabler

Companies are gradually realizing that there is a great amount of untapped data that can be accessed only by digital means. With renewed interest among Indian pharma companies in gaining dynamic customer insights and personalizing customer experience, data will form the backbone of sustained and effective digital marketing. Robust and meaningful analytics will hold the potential power to unlock new sources of value and differentiate it from competitors.

Sales force excellence has now become a key digital priority. Indian pharma companies have embarked on the journey to sales force automation. However, only few Indian pharma companies are spearheading the game with advanced analytics and closed-loop customer relationship management (CRM) systems. Despite differing levels of maturity, most of the Indian pharma companies are driving initiatives to maximize sales force efficiency, as well as some form of call reporting solution (web or mobile).
4Ps to be the success factor for digital innovations

Our overall analysis indicates that any successful digital solution will have these four elements:

- **Painless**: Offer a hassle-free experience and minimize invasive “push” sales tactics
- **Prompt**: Provide more real-time, dynamic content with two-way communication
- **Personal**: Understand the customer journey and co-create with them
- **Purposeful**: Make sure every interaction is impactful, and deliver a consistent message across channels

Digital will play an ever-increasing role in this era of profound transformations, characterized by increasingly informed patients/physicians, a new range of customers and new, disruptive entrants. To stay relevant, pharma companies need to adopt a more nimble approach and make data the currency of marketing.

- A mobile app for Indian hepatologists, for instance, provides them with clinical calculators to understand the patients’ general condition, liver disease severity and renal function. The app further empowers physicians with therapy options based on the genotype and liver status, real-time guidance on drug interactions and interactive product monographs.
- A leading pharma company has targeted physicians’ need for peer guidance by developing a mobile app that helps them get real-time guidance from fellow doctors. The company has also gone a step further in engaging with doctors practicing in specialty therapy areas by helping them increase their digital footprint.

The untapped potential of patient-centricity in a digital world

Only a third of the pharma leaders recognize the need to become patient-centric, and of those, only a few have earnestly started working in this direction. Indian pharma companies have begun to capitalize on the rise of health apps to engage more with patients, but such apps remain largely underleveraged, with an abysmal number of downloads, due to non-dynamic content. Real-time disease monitoring and intervention are not yet a reality. The industry’s mindset, regulations and a lack of widespread user adeptness with smartphones limit pharma marketing practices.

**Building and sustaining patient-centric models will require pharma companies to redesign their digital agenda and operating models.** Indian pharma companies have acknowledged this and are beginning to utilize advances in digital technology to engage more with customers in a way that is targeted, personal, timely and purposeful.

**Few players have ventured into clinical decision support and peer guidance.** Most of the pharma companies are looking into unexplored areas such as remote monitoring solutions, augmented reality, etc., to forge a patient-centric approach. For example, a leading pharma company has launched a flash glucose monitoring system that enables real-time sharing of data on blood glucose levels with doctors for accurate and intensive monitoring. Also, a mobile app for vertigo patients acts as an interactive personal trainer by using augmented reality to guide patients through vestibular rehabilitation.

**Key success factors**

Success of these initiatives remains limited because of lack of awareness among patients. Therefore, it is important to create a holistic and seamless experience for patients by reaching them through multiple channels.

- One such successful initiative aims to combine digital and direct marketing platforms. The program has a dedicated YouTube channel with videos on nutrition, lifestyle advice and patient stories. There is a Facebook page as well, education and awareness interactive kiosks at doctors clinics, and WhatsApp-based patient and caregiver compliance and counseling services.
- A campaign for migraine patients utilizes digital and social media, as well as offline support from the field force, to create awareness. Within 9 months of its initiation, the campaign achieved a reach of over 47 million with print PR, nearly 200,000 website visitors and over 14 million through social media.
Reinventing pharma sales and marketing through digital in India

The future of the industry
Integrated commercial models will be the new normal

Six commercial trends that will shape the future of pharmaceutical sales and marketing in India digitalized

Find out more

This article is based on EY India’s recently launched thought leadership report titled “Reinventing pharma sales and marketing through digital in India.” This report provides detailed insights on digital readiness of Indian pharma companies, barriers to embracing digital, and future digital trends that are expected to reshape the Indian pharma industry.

**EY Digital maturity Index (EYDI)** is an online digital readiness assessment tool developed with a five-step framework to gauge the digital maturity level of the pharma companies across 15 parameters spanning two key dimensions: organizational readiness (strategy and culture, governance and capability) and stakeholder engagement (sales reps, physicians and patients).
Featured article

Intelligent automation – will IA provide relief to a sickly pharmaceutical industry?

By

Sabine Dettwiler
Executive Director, Zurich Life Sciences
Ernst & Young (Switzerland)
Email: sabine.dettwiler@ch.ey.com

Hugo Walkinshaw
Asia-Pacific Life Sciences Advisory Leader
Ernst & Young (Singapore)
Email: hugo.walkinshaw@sg.ey.com

Ker-Shuen Too
Digital Operations APAC Advisory Centre,
Senior Manager
Ernst & Young (Singapore)
Email: ker-shuen.too@sg.ey.com

Kellie Pearson
APAC Advisory Centre, Manager
Ernst & Young (Singapore)
Email: kellie.pearson@sg.ey.com

Tanushree Jain
Knowledge Life Sciences Analyst
Ernst & Young (India)
Email: tanushree.jain@in.ey.com

Kanika Goel
Knowledge Life Sciences Analyst
Ernst & Young (India)
Email: kanika.goel@in.ey.com

Executive summary

The pharmaceutical industry has been facing immense pressure to bring down costs yet increase innovation to find the next blockbuster drug. This article examines how intelligent automation (IA) supports those efforts by creating greater efficiency and improving the experience of patients and health care professionals. Additionally, IA has increased analysis and insights, specifically within the commercial value chain.

Introduction

Ever since the blockbuster model has been on the decline, pharmaceutical companies have been operating in an environment of constant pressure to cut costs yet innovate at the same time. As patents from these blockbuster drugs come to an end and cheaper generic alternatives enter the market, pharmaceutical companies are increasingly looking for cost effective measures. Intelligent automation (IA) will be a step toward easing some of that pressure, as digital labor takes over some of the repetitive, deterministic, high-volume tasks. This frees up resources for higher-value activities.

While robotic process automation is primarily being deployed to control costs, increase productivity and raise process quality, more intelligent solutions are entering the market. These solutions have the ability to mimic an aspect of human intelligence – they can learn and make certain cognitive decisions. And so, while “robots” have been on the rise in back-office functions, new and more sophisticated solutions will increasingly support innovation across the entire pharma value chain, resulting in better organizational performance as well as enhanced customer satisfaction.

In this article, we will hypothesize ways in which pharmaceutical companies could turn to intelligent automation for support in commercial functions and how complementary technology may further spur innovation with regard to the customer. Patients, health care professionals and other stakeholders have come to expect more in the delivery of health care outcomes. It is no longer enough for pharmaceutical companies to “provide a pill.” They must deliver health care outcomes that are effective and cost-efficient, and that align with governments’ agenda to make health care services accessible to all. And the direction toward “beyond the pill” involves “intelligent” solutions to enable the full potential of such services.

As with any new technology, there will be challenges to overcome. We will highlight those that are associated with implementing intelligent automation. Despite the challenges, IA will have a huge impact on the business model of pharmaceutical companies and could transform the entire industry toward better outcomes for patients around the world.
What is IA?

IA is the application of a software that mimics human action and connects multiple fragmented systems through automation without changing the current enterprise IT landscape. IA solutions range from rule-based robots who perform tasks as they have been configured to do, to cognitive robots who are capable of continuously learning and can make certain decisions. All IA solutions are intended to improve the way humans work and to enable us to use our time more efficiently.

Intelligent Automation is a broad term to cover four distinct automation solutions; (1) robotic process automation (RPA), (2) cognitive RPA, (3) intelligent chatbots and (4) artificial intelligence. These solutions are system software that automates what humans do. The extent of automation depends on the solutions deployed:

- **Robotic process automation**: Used where processes are highly rule-based and standardized, and for which there are significant transaction volumes
- **Cognitive RPA**: Used where processes have variations and the automation solution is required to “learn” new tasks
- **Intelligent chatbots**: Used to respond to conversational speech and chats with humans, for example, providing information to queries
- **Artificial intelligence**: Used in non-routine cognitive work, involves interactions with humans and complex, ambiguous reference materials. Ingests information in a similar manner to non-specialist humans, e.g., reads and writes documents to form insights and analysis

IA is an integral part of the workforce of the future. By taking up the mundane, repetitive tasks, IA frees up humans to focus on:

- Strategy and decision-making
- Insights and subjective assessments
- Advanced analysis and interpretation
- Management and optimization

Illustration of the “golden journey” of intelligent automation

- **Robotic process automation** (RPA)
  Example: Automation Anywhere, Blue Prism, UiPath

- **Cognitive RPA** (including machine learning, natural language processing)
  Example: Arago, WorkFusion

- **Intelligent chatbots**
  Example: Kore.ai, Conversable

- **Artificial intelligence (AI)**
  Example: Watson, Holmes

Chatbots and artificial intelligence to utilize the outputs produced by robotic process automation
How can IA address challenges faced by a pharmaceutical company’s commercial value chain?

Access to drugs
Consumers have come to expect and demand immediate access to products and services in other industries, and it is no different for the pharmaceutical industry. Currently, when an illness surfaces, patients see their doctors, are prescribed the appropriate medication and expect to promptly receive their medication in order to commence treatment. To meet this demand, pharmaceutical companies have teams and functions in place to plan appropriately and ensure that they have supplies available in the right place at the right time in order to meet demand. New technologies within intelligent automation are supporting the customer-centric experience by harnessing the large amounts of data available (e.g., patient consumption data, wearables, pharmacy dispensing systems), which can support demand forecasting and trigger the process to fulfill demand and enable the expectations of the patient to have access to medicines anytime, anywhere.

Boston Scientific, a leading medical device company has already introduced an Automation Anywhere Bot to help their customer services team streamline four processes that were either manual or impossible to do. The pilot trial was successful, and the company has now extended their use of the bots to include over 50 processes, which has resulted in cost savings and error-free transaction processing.

Enhance interactions with key opinion leaders (KOLs)
An integral part of a sales representative’s job is the need to frequently meet with physicians and KOLs to engage in discussions about therapies and provide information on available products. Without coordination of these meetings, their frequency and the amount of information provided can overwhelm health care providers. Worse, they may be presented with different, conflicting information or the exasperation of having to repeat themselves.

A single database that compiles all of a company’s interactions with health care providers, including the topics of discussion, will enable a coordinated and seamless engagement approach. Sales, medical and market access representatives may be documenting the outcomes of their physicians’ visits in different databases, files and folders. RPA can be leveraged to access these different sources of information and to compile data, enabling a single view of engagement with any physician across the entire organization (e.g., functions, therapeutic areas and regions). RPA can comb the internet to identify the latest relevant news, based on key words. Going one step further, predictive analytics can anticipate topics that a KOL may be interested in. This makes for meaningful, relevant discussions between the physician and any company stakeholder.

Provision of consistent information
Access to the wealth of medical information on the internet has empowered patients with greater control over their health. At the same time, this channel has left patients exposed to misleading or fraudulent information and an inaccurate self-diagnosis. Given that pharmaceutical companies cannot control this channel of information, the question becomes, “What can pharmaceutical companies do to improve the quality of medical information on the internet?”

Pharmaceutical companies have long deployed human resources to answer queries via the phone or a chatting tool. Recently, the trend has been to leverage chatbots to interact with physicians online and suggest courses of action based on the queries and input provided. By identifying key words and phrases, the chatbot can find the relevant information in an information database. The physician will have the ability to rate the chatbot’s responses, refining the chatbot’s accuracy. Deploying chatbots is a cost-effective effective way of providing accurate answers to frequently asked questions for physicians 24 hours a day, 7 days a week. Where a more complex response is required, physicians have the option of reaching out to company representatives with their queries.

Benefits of intelligent automation

<table>
<thead>
<tr>
<th>Low risk</th>
<th>Accuracy</th>
<th>Consistency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non invasive technology</td>
<td>The right result, decision or calculation the first time</td>
<td>Identical processes and tasks, eliminating output variations</td>
</tr>
<tr>
<td>RPA can be overlaid on existing systems, allowing creation of a platform compatible with ongoing developments in sophisticated algorithms and machine learning tools</td>
<td>Intelligent</td>
<td>Productivity</td>
</tr>
<tr>
<td>Geographical independence without business case impact</td>
<td>Capable of continuous learning and decision-making</td>
<td>Capable of continuous learning and decision-making</td>
</tr>
<tr>
<td>Reliability</td>
<td>Retention</td>
<td>Scalability</td>
</tr>
<tr>
<td>No sick days, services are provided 24/7/365</td>
<td>Shifts toward more stimulating tasks</td>
<td>Instant ramp up/down to match demand peaks and troughs</td>
</tr>
</tbody>
</table>
Merck (MSD) in Italy launched its first chatbot for physicians in 2016. The chatbot can tailor content based on the physician’s specialization and can answer complex questions by accessing data available in MSD Health. This solution is currently being piloted for registered physicians. Following from the success achieved, MSD intends to integrate the chatbot with Apple’s Siri and other voice-recognition systems so that physicians can verbally ask the chatbot a question instead of typing it out, saving time and increasing efficiency.

It is not hard to imagine the same solution being expanded to serve a broader range of health care professionals and possibly patients.

**Data and analytics**
Pharmaceutical organizations are increasingly turning to technology to help make sense of the plethora of medical data, or big data, available to improve patient safety. One such example is Celgene’s collaboration with IBM Watson Health to create an outcome- and evidence-based drug safety support system aimed at improving patient outcomes. This highly automated solution is designed to enable the rapid collection, collation and analysis of safety data from various sources, including anonymized electronic medical records and medical claims databases. This approach will help stakeholders to better interpret side effects associated with products, enabling better-informed decisions and improving patient safety.

Going one step further, pharmaceutical companies are exploring the possibility of leveraging data to predict and possibly mitigate a patient’s next medical incident. Teva Pharmaceutical Industries, in partnership with IBM Watson Health, will combine cloud-connecting drug delivery and app technology to provide actionable insights, such as instructing the patient to collect their medicines, take their medicines or visit their general practitioner (GP). Using IBM Watson Health’s cognitive processing capabilities and algorithms, data will be used to calculate the prospective risk of a health event, such as an asthma attack. Teva will deliver that information directly to patients and caregivers via a smart device application. Medtronic is using the same predictive technology to warn diabetes patients of abnormally low blood sugar up to three hours in advance in order to prevent a hospital or GP visit, allowing diabetic patients to better self-manage their condition.

**Conclusion**
The pharmaceutical industry continues to face the dilemma: does it focus on providing affordable drugs, or does it continue to invest in R&D and innovation despite the cost implications? Our point of view is that this is not necessarily an either-or question but one of how things can be done better, leveraging IA and digital solutions to become more efficient while reducing labor costs. However, IA goes beyond just providing cost solutions and relieving humans of repetitive, manual tasks. IA drives value by creating a better customer experience, increasing the accuracy and relevance of the information provided. And it frees up resources to focus on two ever-crucial activities: R&D and innovation, which will ultimately lead to more affordable medicine and more robust health care systems.

At EY, our Intelligent Automation Center of Excellence has the capabilities to support pharmaceutical companies through their digital transformation. We take a business-led, IT-supported approach that focuses on providing business value, expediting speed to services and increasing business agility.
Featured article
Megatrends in ASEAN markets have health care industry charting new waters

(ASEAN includes the following countries Myanmar, Vietnam, Laos, Thailand, Cambodia, Philippines, Malaysia, Singapore, Indonesia, Brunei Darussalam)

By Ishita Dhamani
EY ASEAN Life Science Leader, Advisory
Ernst & Young (Singapore)
ishita.dhamani@sg.ey.com

By Igor Diaz Gondra
Senior Associate Life Sciences, Advisory
Ernst & Young (Singapore)
igor.diaz.gondra@sg.ey.com

Health care reforms in ASEAN markets are reshaping the pharma landscape, bringing challenges for multinational companies doing business in the region. Nonetheless, great opportunities exist.

The health care sector in ASEAN markets is expected to grow at a 9.2% compound annual growth rate (CAGR) between 2016 and 2021, experiencing one of the highest growths worldwide (Berger, 2017). However, a differentiation between mature and emerging markets within Asia is required, because pharmaceutical strategies have to fit a country’s individual needs and develop further, go-to-market models will gradually mirror those currently employed in mature markets to include local R&D and manufacturing capabilities.

Zooming in on the ASEAN market, we can observe three megatrends that are shaping the future of the health care industry. First, the adoption of universal health care systems, where governments are heavily investing in infrastructure, R&D and drug manufacturing. Second, the rise of a class, with increasing disposable income. And third, the aging populations.

However, ASEAN’s health care access is seen as a highly significant challenge. A lack of reimbursement and public funding are considered key challenges, followed by the absence of health care infrastructure and affordability (PwC, n.d.). Other barriers in the region include increasing health care costs and the high dependence on out-of-pocket expenses. These challenges have prompted governments to take action.

Spending on ASEAN health care in US$b in 2016 vs. 2021

<table>
<thead>
<tr>
<th>Country</th>
<th>2016</th>
<th>2021</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indonesia</td>
<td>27.3</td>
<td>43.3</td>
</tr>
<tr>
<td>Singapore</td>
<td>17.0</td>
<td>28.8</td>
</tr>
<tr>
<td>Thailand</td>
<td>16.4</td>
<td>22.9</td>
</tr>
<tr>
<td>Philippines</td>
<td>15.6</td>
<td>22.9</td>
</tr>
<tr>
<td>Vietnam</td>
<td>15.0</td>
<td>22.7</td>
</tr>
<tr>
<td>Malaysia</td>
<td>13.2</td>
<td>22.4</td>
</tr>
<tr>
<td>Myanmar</td>
<td>1.4</td>
<td>2.3</td>
</tr>
<tr>
<td>Cambodia</td>
<td>1.0</td>
<td>1.4</td>
</tr>
<tr>
<td>Laos</td>
<td>0.2</td>
<td>0.3</td>
</tr>
</tbody>
</table>

f = BMI forecast.
Source: BMI Research
Health care expenditure compound annual growth rate (CAGR) vs. GDP CAGR (2018f–2021f)

<table>
<thead>
<tr>
<th>Country</th>
<th>Health care expenditure USD CARG 2018–2021</th>
<th>Health care expenditure GDP CARG 2018–2021</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indonesia</td>
<td>9.6%</td>
<td>8.4%</td>
</tr>
<tr>
<td>Singapore</td>
<td>11.1%</td>
<td>5.7%</td>
</tr>
<tr>
<td>Thailand</td>
<td>10.1%</td>
<td>6.2%</td>
</tr>
<tr>
<td>Philippines</td>
<td>11.0%</td>
<td>9.2%</td>
</tr>
<tr>
<td>Vietnam</td>
<td>10.3%</td>
<td>9.3%</td>
</tr>
<tr>
<td>Malaysia</td>
<td>12.0%</td>
<td>9.6%</td>
</tr>
<tr>
<td>Myanmar</td>
<td>12.1%</td>
<td>5.7%</td>
</tr>
<tr>
<td>Cambodia</td>
<td>9.7%</td>
<td>6.8%</td>
</tr>
<tr>
<td>Laos</td>
<td>8.5%</td>
<td></td>
</tr>
</tbody>
</table>

f = BMI forecast. Source: BMI Research

Health care spending – Public vs. Private

<table>
<thead>
<tr>
<th>Country</th>
<th>Total health spend (government vs. private health spend) USD$b</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indonesia</td>
<td>32,858</td>
</tr>
<tr>
<td>Singapore</td>
<td>3,624</td>
</tr>
<tr>
<td>Thailand</td>
<td>2,814</td>
</tr>
<tr>
<td>Philippines</td>
<td>1,611</td>
</tr>
<tr>
<td>Vietnam</td>
<td>1,811</td>
</tr>
<tr>
<td>Malaysia</td>
<td>4,973</td>
</tr>
<tr>
<td>Myanmar</td>
<td>32</td>
</tr>
<tr>
<td>Cambodia</td>
<td>71</td>
</tr>
<tr>
<td>Laos</td>
<td>39</td>
</tr>
</tbody>
</table>

f = BMI forecast. Source: BMI Research

Total health spend (government vs. private health spend) USD\$b

Govt. health spend, USD\$b
Private health spend, USD\$b
Health spending per capita, USD
Examples include Indonesia's initiative to encourage private investment in the health care space, with ventures such as private hospital groups. On the other hand, Vietnam is experiencing a demand for private health care due to the Government's tax incentives for foreign investors (Vietnam, n.d.). Both countries have consolidated their national drug procurement systems as well as established a universal health care system that aims to offer free care to the entire population in the coming years. Thailand, on the contrary, already has a well-established health care system, where private investment is experiencing rapid growth as demand for quality services increases. However, public health care leaves the local population without the same level of quality while medical tourism is gaining momentum (Deloitte, n.d.). The Philippines is attracting more investment for hospital infrastructure plans through public-private partnerships (PPPs) while the Government has proposed a program to enhance health facilities prioritizing those located in or near poor provinces (Deloitte, n.d.). Myanmar is having difficulty producing enough drugs to supply its domestic market, and the Government continues to work toward ensuring all citizens access to basic health care services (Deloitte, n.d.).

We have selected Indonesia and Vietnam as key examples of the direction in which other ASEAN developing countries’ health care systems are heading in the coming years.

Indonesia's economic packages encourage foreign investment

Indonesia is currently the largest ASEAN market in terms of health care expenditure. Major changes are reshaping the health care system, both public and private – and, therefore, the pharmaceutical industry (research, n.d.). As of August 2017, the Indonesian Government introduced 16 economic packages to reduce bureaucracy, improve competitiveness and boost economic activity (research, n.d.). Relaxed enforcement of the foreign direct investment law has encouraged foreign investments such as new factories, which will reduce the reliance on imports and mitigate exposure to currency exchange fluctuations.

Indonesia's health care changes began in 2007, when the Indonesian Government founded the National Procurement agency (LKPP) to supply drugs to public health centers. To reduce pharmaceutical and medical spending, the Government developed various policies that created a centralized public procurement system (bpjs-kesehatan.go.id, n.d.). In 2012, the Ministry of Health implemented a centralized e-procurement system, e-tendering and e-catalog to improve effectiveness, transparency and accountability in the tendering process (team, n.d.). Two years later, Indonesia launched its universal health coverage (UHC), aiming to cover all the population by 2019. As of September 2017, 70% of Indonesians were covered under UHC, while the remaining 30% were paying out-of-pocket or relying on other types of insurance (bpjs-kesehatan.go.id, n.d.). In 2014, the Public Health Insurance Implementing Body (BPJS) was established
to assure the quality and sustainability of the country’s UHC program, known locally as Jaminan Kesehatan Nasional (JKN). The BPJS is also responsible for providing capitation and reimbursement for health care facilities and is expected to play a key role in the future of the JKN (bpjs-kesehatan.go.id, n.d.).

The pharmaceutical industry in Indonesia is undergoing major changes with the implementation of the JKN scheme and the increasing purchasing power of Indonesians. The universal health care system will dramatically increase the demand and consumption of drugs, especially generics. The demand for private health care is also expected to increase as a result of the rising upper-middle class, who are seeking more personalized care. However, challenges persist, including malpractice and corruption. A lack of protocols and standards might hold back foreign investment and slow down the manufacturing sector.

Total health care expenditure in Indonesia

Expenditure US$b

<table>
<thead>
<tr>
<th>Year</th>
<th>2013</th>
<th>2017</th>
<th>2021</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>21</td>
<td>27</td>
<td>38</td>
</tr>
</tbody>
</table>

Compound annual growth rate (CAGR)

<table>
<thead>
<tr>
<th>Year</th>
<th>2010</th>
<th>2015</th>
<th>2020f</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2.7%</td>
<td>3.0%</td>
<td>3.2%</td>
</tr>
</tbody>
</table>

Source: BMI, EY Analysis
Centralized drug procurement fortifies Vietnam’s bargaining power

There is greater foreign investment in the local pharma sector, which is set to boost the growth in pharma and support modernizing of Vietnam’s health care system (research, n.d.). Vietnam has become a prime investment hub for MNCs as it has all the necessary structural elements. In its favor are a large, young and cheap labor force, a desirable location with easy access to the sea, and a stable political environment. MNCs relocating from China due to lower production costs is a likely scenario that will benefit the manufacturing sector (research, n.d.).

Vietnam took a major leap forward in 2009 when it decided to develop a national health insurance program. The program is expected to cover 70% of the total population by 2018 and 80% by 2020. To accomplish universal health coverage (UHC), the Ministry of Health (MOH) and Vietnam Social Security (VSS) have been actively addressing several issues, such as stable and sustainable funds, reduced out-of-pocket payments and extending government subsidies to the poor. To achieve these goals, the Government is planning to implement a basic health services package (BHSP) in order to control health care costs, ensure service quality and respond to health policy priorities (research, n.d.). From 2014 to 2016, the MOH issued two key circulars to regulate the pharmaceutical industry in the procurement process space. Circular 9 (Vietnam, n.d.), provides a list of drugs for procurement through a bidding process and Circular 11 addresses the bidding process to supply drugs to public health facilities (11/2016/TT-BYT, 63/2014/ND-CP, & 09/2016/TT-BYT, n.d.). In 2017, the procurement system was centralized at a national level under four different schemes, depending on the drug lists and other decentralized procurement systems for health care facilities (Thao, n.d.). This centralization will allow the Government to maximize its bargaining power by leveraging economies of scale with contractors and promote a more transparent system.

Despite the low per capita spending on medicines and the climate of cost containment of medicines covered by the public health care system, Vietnam’s overall pharmaceutical market will continue to offer longer-term benefits for pharmaceutical companies, especially for local manufacturers (Vietnam, n.d.). However, the Vietnamese health care system is facing challenges. One of the main challenges is the poor regulatory standards in health care. It is an area in which the pharmaceutical industry has traditionally been unclear and has often implemented on a case-by-case basis, sometimes representing a market-entry barrier to foreign companies (research, n.d.). Other key challenges for Vietnam’s health care sector are patients’ self-medication habits and a preference for national-level hospitals, which grow increasingly overcrowded, rather than local district or provincial hospitals. In addition, because Vietnam imports raw materials to manufacture drugs, mostly from China and India, it must contend with the effects that currency exchange fluctuations have on its overall health care budget (research, n.d.).

Total health care expenditure in Vietnam

**Expenditure US$bn**

*Compound annual growth rate (CAGR)*

![Expenditure US$bn chart](chart)

**Expenditure as a % of GDP**

<table>
<thead>
<tr>
<th>Year</th>
<th>2013</th>
<th>2015</th>
<th>2020f</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.17%</td>
<td>7.24%</td>
<td>7.08%</td>
<td></td>
</tr>
</tbody>
</table>

Source: BMI, EY Analysis

---

Megatrends in Asian markets have health care industry charting new waters
What lies ahead for health care in ASEAN developing markets?
The outlook for the pharmaceutical industry in ASEAN is promising. Countries’ adoption of universal health coverage (UHC) programs will increase expenditures on drugs, particularly generics. Private investors and public-private partnerships will play a key role in providing health care infrastructure and premium services. Governments are focusing their efforts on expanding health care coverage in rural areas and addressing the most urgent needs. And the rising incidence of non-communicable diseases among the middle class continues to increase health care spending. Finally, the implementation of electronic systems will simplify health care delivery, save costs, and offer more transparent and efficient service (analysis, n.d.).

Implications for multinational pharmaceutical companies
Cost-containment measures from health care payers will bring challenges to multinational pharmaceutical companies attributed to aging population and growing prevalence of chronic diseases. Governments in the region are focusing on cost-efficiency measures through pricing pressures on pharmaceutical companies, generic substitution policies and rational prescribing initiatives. However, significant commercial opportunities for multinational pharmaceutical companies over the long-term are expected. In ASEAN, pharmaceutical sales are expected to generate USD 40 billion by 2020 (BCG, 2016).

The next five years’ key growth drivers include governments’ commitment to health care, improvement of medical services provision and enhancement of the operational environment together with robust macroeconomic fundamentals, economic policies reforms and the trade integration (Association of Southeast Asian Nations) which aims to promote free movement of goods, services and skilled labor (research, n.d.).

ASEAN diverse market characteristics lays out challenges for multinational pharmaceutical companies. Nonetheless, great opportunities are yet to be explored. For example, branded generics can be an access point, and although they carry higher price tags than unbranded generics, many consumers are willing to pay a premium for drugs sold by well-known brands. This short-medium term strategy can be leveraged to build long-term growth in the region by establishing R&D facilities specific to the region’s needs, framing public-private partnerships, creating strong local distribution networks or establishing joint ventures. MNCs must concentrate their efforts to tailor specific action plans for each of the markets to benefit from these opportunities.
Megatrends in Asian markets have health care industry charting new waters
Mergers and acquisitions (M&A)

In 2017, the life sciences M&A value continued to witness a slowdown for the third consecutive year. The M&A deal value fell, primarily owing to policy delays, including corporate tax reforms and policy guidelines on repatriation of cash held overseas by US companies. In addition, continued pricing pressure and market access challenges impacted the contribution of the US in overall M&A deal value, with US deals representing 54% of the 2017 M&A value compared with 65% in 2016.

Overall, the total global life sciences M&A deal value in 2017 contracted to ~US$228.6 billion, down nearly 14% over US$265.4 billion in 2016. There were 9 deals valued at ≥US$5 billion each in 2017, compared with 10 deals valued at ≥US$5 billion in 2016. The total M&A amount in 2017 was driven by two mega ticket acquisitions. The first and the largest deal of the year involved the acquisition of Switzerland-based Actelion Pharmaceuticals Ltd. by the US-based Johnson & Johnson for US$29.0 billion. This was closely followed by the acquisition of CR Bard by its compatriot medical devices supplier, Becton Dickinson for US$24.2 billion. Together these deals represented nearly 23% of total deal value in 2017.

On the other hand, 2017 saw a year-over-year uptick of 11% in global life sciences M&A activity in terms of volume, with the number of deals in 2017 surging to 2,578. This increase was witnessed across all subsectors and was largely due to a high proportion of small-value transactions – nearly 42% of the total deals valued at less than US$50 million in 2017 vs. 40% of such deals in 2016.

Compared with its fifth position in 2016, life sciences was in fourth position as of 01 January 2018 on the basis of total deal value, following the technology, consumer products and retail, and oil and gas sectors.
Life sciences M&A value share by subsector

The pharmaceuticals subsector led the deal value at ~US$100.4 billion (912 deals) in 2017, contributing 44% to the total M&A activity in 2017. Despite having maximum contribution to total M&A deal value in 2017, the subsector witnessed a year-over-year decline of 18%. The decline was mainly due to a drop in the number of mega ticket acquisitions: 3 transactions worth ≥US$5 billion in 2017 vs. 5 similar deals in 2016. Similarly, the biotech M&A deal value, contributing 18% to total sector deal amount, saw a steep year-over-year decline of 32% in 2017, primarily due to fewer high-value deals; there were two deals worth ≥US$5 billion vs. 3 deals worth ≥US$5 billion the previous year. The deals in 2017 showcase companies’ attempts at gaining advantage in leading technologies such as CAR-T, CRISPR (clustered regularly interspersed short palindromic repeats) and gene therapy, Gilead Science’s US$11.1 billion acquisition of chimerical antigen receptor T-cell (CAR-T) therapy specialist Kite Pharma validates this trend.

In contrast, health research and testing witnessed a staggering growth of ~4x year-over-year to reach US$19.1 billion in 2017. This increase was catapulted by one deal worth ≥US$5 billion, accounting for 26% of the total deal value of this subsector in 2017 vs. the absence of any such deal in 2016.

In terms of contribution to the overall industry M&A by value in 2017, the medical devices subsector accounted for 30% (up from 29% in 2016) and, health research and testing subsector accounted for 8% (up from 2% in 2016).

Nine of the top 10 deals of 2017 were closed during the first half of the year. The weak latter half was primarily due to uncertainty around tax reforms.

The top M&A deals in 2017 were largely spurred by pursuit for economies of scale in light of increasing consolidated customers and access to complementary product lines or new market geography. The combination of Johnson & Johnson (J&J)-Actelion, completed on 16 June 2017, adds the latter’s on-market and pulmonary arterial hypertension (PAH) specialty portfolio to the acquirer’s current product offerings. As part of this acquisition, Actelion and J&J separated Actelion’s R&D segment into a new biotech company, Idorsia Ltd., which is responsible for drug discovery operations and early-stage clinical development assets.

In another such deal, involving Becton Dickinson and CR Bard, Becton Dickinson was able to achieve scale in the hospital supply market while adding Bard’s surgery devices to its portfolio. It also helped the acquirer expand its offerings beyond diabetes to other areas, including oncology, peripheral vascular disease, urology, hernia and cancer.

Further, 2017 saw an increase in private investors’ participation in M&A activity. Three out of the top 10 deals in 2017 involved acquisition of life sciences companies by venture capitalists.


<table>
<thead>
<tr>
<th>Target company</th>
<th>Subsector</th>
<th>Country</th>
<th>Acquiring company</th>
<th>Country</th>
<th>Deal value (US$b)</th>
<th>Deal status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Actelion Pharmaceuticals</td>
<td>Big Pharma</td>
<td>Switzerland</td>
<td>Johnson and Johnson</td>
<td>US</td>
<td>29.0</td>
<td>Completed</td>
</tr>
<tr>
<td>CR Bard</td>
<td>Medical Devices</td>
<td>US</td>
<td>Becton Johnson</td>
<td>US</td>
<td>24.2</td>
<td>Completed</td>
</tr>
<tr>
<td>Kite Pharma</td>
<td>Biotechnology</td>
<td>US</td>
<td>Gilead Dickinson</td>
<td>US</td>
<td>11.1</td>
<td>Completed</td>
</tr>
<tr>
<td>Patheon NV</td>
<td>Medical Devices</td>
<td>Netherlands</td>
<td>Thermo Fisher</td>
<td>US</td>
<td>7.1</td>
<td>Completed</td>
</tr>
<tr>
<td>STADA Arzneimittel</td>
<td>Generics</td>
<td>Germany</td>
<td>Nidda Healthcare</td>
<td>Germany</td>
<td>6.8</td>
<td>Pending</td>
</tr>
<tr>
<td>VWR Corp</td>
<td>Medical Devices</td>
<td>US</td>
<td>Avantor Performance Materials</td>
<td>US</td>
<td>6.6</td>
<td>Completed</td>
</tr>
<tr>
<td>Medtronic PLC-Patient Care</td>
<td>Medical Devices</td>
<td>US</td>
<td>Cardinal Health</td>
<td>US</td>
<td>6.1</td>
<td>Completed</td>
</tr>
<tr>
<td>ARIAD Pharmaceuticals</td>
<td>Big Pharma</td>
<td>US</td>
<td>Takeda</td>
<td>US</td>
<td>5.3</td>
<td>Completed</td>
</tr>
<tr>
<td>PAREXEL International</td>
<td>LS tools</td>
<td>US</td>
<td>Pamplona Capital Management</td>
<td>UK</td>
<td>5.0</td>
<td>Completed</td>
</tr>
<tr>
<td>Akorn Inc.</td>
<td>Generics</td>
<td>US</td>
<td>Fresenius Kabi</td>
<td>Germany</td>
<td>4.8</td>
<td>Pending</td>
</tr>
</tbody>
</table>

Source: Thomson ONE; Capital IQ.
In line with the global trend, Asia life sciences M&A deal value in 2017 slowed down to US$30.4 billion, a decline of 25% from US$40.5 billion in 2016. The size of deals in 2017 was significantly lower than what was recorded in 2016, with two deals each worth ≥US$1 billion in 2017 compared with six such transactions in 2016. Thus, the region’s contribution to global M&A stood at 13%, 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 2017 continuing to increase since 2013. The region witnessed 851 M&A deals in 2017 vs. 794 in 2016.

Within Asia, the biotech subsector recorded the highest year-over-year growth in deal value – 42% – largely due to Nanjing Xinjiekou Department Store’s acquisition of Shiding Shengwu Biotechnology in China. This triggered the subsector to record the second-highest contribution to the transaction amount, 26%, in 2017 vs. 14% in 2016, the third-largest. By contrast, the other two sectors, pharma and medical devices, reported significant declines of 34% and 45%, respectively, in deal value.

On the basis of compound annual growth rate (CAGR) since 2013, subsector dealmaking values witnessed a significant uptick in biotech with 70% CAGR during 2013-2017. On the other hand, the pharmaceutical subsector observed weak growth (i.e., a 2% CAGR) during this period. The pharma subsector’s contribution to the total region M&A continued to dip and now stands at ~50% in 2017 (vs. 73% in 2013).
Asia life sciences M&A by target country/region, 2017

Source: Thomson ONE ("China includes Hong Kong SAR and Macau; "others" includes target companies based out of Taiwan, Vietnam, Malaysia, Singapore, New Zealand, Bangladesh, Philippines, Cambodia and Thailand).

Top 10 Asia life sciences M&A, 2017

<table>
<thead>
<tr>
<th>Country</th>
<th>Target</th>
<th>Acquirer</th>
<th>Value (US$m)</th>
<th>Deal description/rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>China</td>
<td>Harbin Pharm Group</td>
<td>Citic Capital Equity Invest</td>
<td>1,179.5</td>
<td>CITIC Capital Equity Investment is to launch a tender offer for a 51.7% share in Harbin Pharmaceutical, a pharmaceutical manufacturer, for CNY5.86 (US$0.99) in cash per share.</td>
</tr>
<tr>
<td>Shiding Shengwu Biotech Hong Kong</td>
<td>Nanjing Xinjiekou Dept Store</td>
<td>Nanjing Xinjiekou Department Store Co Ltd agreed to acquire 100% share of Shiding Shengwu Biotechnology from Sanpower Group in a stock swap transaction.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nova Pharmaceuticals</td>
<td>Pacific Equity Partners and the Carlyle Group</td>
<td>930.0</td>
<td>Nova Pharmaceuticals (Australia) Pty SPV agreed to acquire iNova (Australia) from Valeant Pharmaceuticals International Inc. in a leveraged buyout.</td>
<td></td>
</tr>
<tr>
<td>Yunnan Baiyao Holding</td>
<td>Jiangsu Yuyue Tech</td>
<td>829.7</td>
<td>Jiangsu Yuyue Technology Development acquired 10% stake in Yunnan Baiyao Holding.</td>
<td></td>
</tr>
<tr>
<td>Zhuhai Weixing Industrial</td>
<td>Zhuhai Hengxin Weichuang</td>
<td>661.8</td>
<td>Zhuhai Hengxin Weichuang acquired 100% share of the target from Livzon Pharmaceutical Group.</td>
<td></td>
</tr>
<tr>
<td>Jeil Pharmaceutical Co</td>
<td>Shareholders</td>
<td>617.9</td>
<td>Jeil Pharmaceutical Co spun off its entire pharmaceutical business to its shareholders.</td>
<td></td>
</tr>
<tr>
<td>CB Cardio Holdings</td>
<td>Blue Sail Med Co Ltd</td>
<td>617.0</td>
<td>Blue Sail Medical Co Ltd, a China-based medical device company, agreed to acquire a 62.61% stake in a Singapore-based manufacturer of irradiation apparatuses, CB Cardio Holdings.</td>
<td></td>
</tr>
<tr>
<td>Cardinal Health</td>
<td>Shanghai Pharma Century</td>
<td>576.0</td>
<td>Shanghai Pharma Century Global Ltd (based in Hong Kong) engaged in complete acquisition of Labuan-based Cardinal Health, a medical equipment and supplies merchant wholesaler, from Cardinal Health Cayman Islands Ltd.</td>
<td></td>
</tr>
<tr>
<td>Torrent Pharma Ltd</td>
<td>Torrent Pharma Ltd</td>
<td>557.5</td>
<td>Torrent Pharmaceuticals Ltd acquired branded formulation portfolio of Unichem Laboratories Ltd in a cash transaction.</td>
<td></td>
</tr>
<tr>
<td>Health Forward Holdings Ltd</td>
<td>China Biologic Products</td>
<td>536.4</td>
<td>China Biologic Products Holdings acquired 100% shares of a biologic manufacturer, Health Forward Holdings Ltd in a stock swap transaction.</td>
<td></td>
</tr>
</tbody>
</table>

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.

There were 11 M&A deals worth >US$500 million each in 2017 (vs. 12 deals in 2016). Of those 11 deals, six involved both target and acquirer domiciled in China. Also, China was responsible for 5 of the 10 largest deals in 2017. The top 10 deals showcased active involvement of private investors as the acquirers.

In the largest deal of the year, the investment arm of CITIC Capital Holdings Ltd acquired ~52% stake in China’s second-largest pharmaceutical manufacturing company, Harbin Pharm Group. Through the cash transaction, CITIC Capital intends to increase its holding in the pharma company while assuming the position of controlling shareholder of the business in which it has previously been an investor since 2005.
Asian IPOs

IPO activity in Asia continued to gain momentum (by volume), with 2017 witnessing the highest number of IPOs closed since 2013; 2017 alone accounted for 31% of the total number of IPOs raised since 2013. A total of 71 Asia-based companies raised capital through IPOs in 2017 vs. 46 of such IPO closings in 2016, highlighting a 54% increase in the number of IPOs closed during the year. However compared with 2016, 2017 saw a drop in IPO activity, with total capital raised during the year falling to US$4.2 billion, a significant decline of 30% in terms of capital raised. This was primarily due to two big IPOs worth ~US$2 billion each in 2016 while there was a single IPO that raised capital worth more than US$0.5 billion in 2017.

Source: Capital IQ.
While the IPO activity in the US and Europe continued to surge, the IPO activity (by value) in Asia in 2017 was stalled due to uncertainty around China’s National People’s Congress and changes in listing rules of the Hong Kong Stock Exchange. In addition, a shift in trend toward smaller deals has also impacted the total capital raised during the year.

In Asia, all the subsectors registered strong double-digit year-over-year growth in the number of IPOs closed in 2017. Despite a 75% growth in the number of IPOs closed in pharma in 2017 and continuing to remain as the largest contributor to IPO funding, the subsector witnessed a 34% year-over-year decline in the amount of capital raised. This was a direct result of the absence of even a single big IPO that resulted in capital of more than US$500 million, while in 2016 there was an IPO worth approximately US$2 billion.

On the other hand, the biotech subsector witnessed the highest growth in terms of capital raised, with total IPOs valued at US$0.9 billion in 2017, a ~3x rise from US$0.3 billion in 2016. This significant increase is attributable to three IPOs worth more than US$100 million each in 2017, compared with the closing of only one IPO worth more than US$100 million in 2016. This subsector accounted for the second-highest contribution, 21%, to the total new capital raised in 2017. The remaining two subsectors – life sciences tools and services, and medical devices – contributed 15% and 14%, respectively. The largest IPO of 2017 was raised by a life sciences tools and services company.
Of the total 71 IPOs raised in 2017, 46 belonged to companies based in China, with 11 generating more than US$100 million each, including one IPO that closed above US$500 million. In addition, eight companies in India, seven companies in Australia and six companies in South Korea also completed public offerings during this period. The remaining four IPOs were from companies in Japan, Singapore and Taiwan. Average capital raised per IPO was highest among companies headquartered in China, distantly followed by India.

Source: Capital IQ (includes mainland China, Hong Kong SAR and Macau).

Twelve IPOs in 2017 raised more than US$100 million each. Of these, only one resulted in capital exceeding US$500 million. Among the top 10 IPOs in Asia in 2017, nine companies were based out of China and one was from India.
Twelve IPOs in 2017 raised more than US$100 million each. Of these, only one resulted in capital exceeding US$500 million. Among the top 10 IPOs in Asia in 2017, nine companies were based out of China and one was from India.

China-based life sciences tools and services firm WuXi Biologics’ listing on the Hong Kong Stock Exchange was the largest Asian IPO during 2017. The company garnered total capital of ~US$509.7 million. This was followed by an India-based pharmaceutical company, Eris Lifesciences Limited, which raised US$269.8 million. One interesting IPO activity observed during the year involved the NASDAQ listing of China-based Zai Lab Limited boosting the company’s reputation and giving it an advantage in M&A activity.

### Top 10 Asian life sciences IPOs, 2017

<table>
<thead>
<tr>
<th>Issue company</th>
<th>Headquarter country</th>
<th>Subsector</th>
<th>Amount raised (US$m)</th>
<th>Exchange</th>
</tr>
</thead>
<tbody>
<tr>
<td>WuXi Biologics (Cayman)</td>
<td>China*</td>
<td>Life sciences tools and services</td>
<td>509.7</td>
<td>Hong Kong Stock Exchange</td>
</tr>
<tr>
<td>Eris Lifesciences Limited</td>
<td>India</td>
<td>Pharmaceutical</td>
<td>269.8</td>
<td>Mumbai Stock Exchange</td>
</tr>
<tr>
<td>Cisen Pharmaceutical Co. Limited</td>
<td>China</td>
<td>Pharmaceutical</td>
<td>176.9</td>
<td>Shanghai Stock Exchange</td>
</tr>
<tr>
<td>Tiansheng Pharmaceutical Group</td>
<td>China</td>
<td>Pharmaceutical</td>
<td>172.1</td>
<td>Shenzhen Stock Exchange</td>
</tr>
<tr>
<td>Shandong Sito Biotechnology</td>
<td>China</td>
<td>Pharmaceutical</td>
<td>156.0</td>
<td>Shenzhen Stock Exchange</td>
</tr>
<tr>
<td>Zai Lab Limited</td>
<td>China</td>
<td>Biotechnology</td>
<td>150.0</td>
<td>NASDAQ</td>
</tr>
<tr>
<td>DaShenLin Pharmaceutical Group Limited</td>
<td>China</td>
<td>Pharmaceutical</td>
<td>146.3</td>
<td>Shanghai Stock Exchange</td>
</tr>
<tr>
<td>Harbin Medisan Pharmaceutical Company Limited</td>
<td>China</td>
<td>Pharmaceutical</td>
<td>144.7</td>
<td>Shenzhen Stock Exchange</td>
</tr>
<tr>
<td>Wuhan Hiteck Biological Pharma Company Limited</td>
<td>China</td>
<td>Biotechnology</td>
<td>126.6</td>
<td>Shenzhen Stock Exchange</td>
</tr>
<tr>
<td>Getein Biotech Inc.</td>
<td>China</td>
<td>Biotechnology</td>
<td>107.9</td>
<td>Shanghai Stock Exchange</td>
</tr>
</tbody>
</table>

Source: Capital IQ. (*includes mainland China, Hong Kong SAR and Macau)
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.

---

**Life Sciences 4.0: Securing value through data-driven platforms**
In EY’s latest edition of our Progressions series, we explore how health is being reimagined as a result of scientific and technological change and rising customer expectations. We also examine the ramifications for life sciences companies’ market offerings, business models and the new capabilities needed as the disciplines of health care and technology merge to become “health technology.”

---

**Pulse of the industry: Medical technology report 2017**
As the pace of change accelerates, how can medtechs move ahead and stay there? Answering this question is a strategic imperative for medical technology companies no matter their size. In 2017, the velocity and scope of technological innovation are blurring the lines between medicine and technology, redefining traditional medtech and fundamentally altering business models.

---

**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.

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?”

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.

2018 M&A Firepower Report: Life Sciences Deals and Data

What lessons does 2017 provide for setting your company’s transaction strategy in 2018? In the wake of year-end US tax legislation, conditions are ripe for a surge in life sciences M&A as business leaders weigh strategic priorities for capital allocation decisions to generate inorganic growth. Despite relatively high target valuations, M&A remains essential for growth, especially as technology’s health care convergence threatens traditional business models.

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.
Contacts

EY Life Sciences sector leaders

Pamela Spence
Global Life Sciences Industry Leader
London
pspence2@uk.ey.com
+44 207 951 3523

Patrick Flochel
EY Japan Life Sciences Global Leadership Team
Tokyo
patrick.flochel@jp.ey.com
+81 3 3503 1542

Rick Fonte
Asia-Pacific Life Sciences Tax Leader
Singapore
richard.fonte@sg.ey.com
+65 6309 8105

Sriram Shrinivasan
Global Emerging Markets Leader and Global Generic Pharmaceutical Leader
Mumbai
siram.shrinivasan@in.ey.com
+91 22 6192 0380

Andrew Chen
Asia-Pacific Life Sciences Transactions Co-Leader
Shanghai
andrew.chen@parthenon.ey.com
+86 21 2228 3939

Abhay Bangi
Asia-Pacific Life Sciences Transactions Co-Leader
Singapore
abhay.bangi@sg.ey.com
+65 6309 6151

Hugo Walkinshaw
Asia-Pacific Life Sciences Advisory Leader
Singapore
hugo.walkinshaw@sg.ey.com
+65 6309 8098
Sung Yeon Cho
South Korea Life Sciences Leader
Seoul
sung-yeon.cho@kr.ey.com
+82 2 3787 6844

Hitesh Sharma
India Life Sciences Leader & Tax Partner, Ernst & Young LLP
Mumbai
hitesh.sharma@in.ey.com
+91 22 6192 0620

Felix Fei
Greater China Life Sciences Co-Leader
Shanghai
felix.fe@cn.ey.com
+86 21 2228 2586

EY Oceania
Gamini Martinus
Oceania Life Sciences Leader
Sydney
gamini.martinus@au.ey.com
+61 2 9248 4702

EY Japan
Hironao Yazaki
Japan Life Sciences Leader
Tokyo
yazaki-hrn@shinnihon.or.jp
+81 3 3503 1566
## EY Life Sciences service line leaders

### Greater China

<table>
<thead>
<tr>
<th>Region</th>
<th>Name</th>
<th>Function</th>
<th>City</th>
<th>Email</th>
<th>Phone</th>
</tr>
</thead>
<tbody>
<tr>
<td>China (Mainland)</td>
<td>Felix Fei</td>
<td>Assurance</td>
<td>Shanghai</td>
<td><a href="mailto:felix.fei@cn.ey.com">felix.fei@cn.ey.com</a></td>
<td>+86 21 2228 2586</td>
</tr>
<tr>
<td></td>
<td>Titus von dem Bongart</td>
<td>Tax Co-Leader</td>
<td>Shanghai</td>
<td><a href="mailto:titus.bongart@cn.ey.com">titus.bongart@cn.ey.com</a></td>
<td>+86 21 2228 2884</td>
</tr>
<tr>
<td></td>
<td>Joanne Su</td>
<td>Tax Co-Leader</td>
<td>Beijing</td>
<td><a href="mailto:joanne.su@cn.ey.com">joanne.su@cn.ey.com</a></td>
<td>+86 10 5815 3380</td>
</tr>
<tr>
<td></td>
<td>Steve Au Yeung</td>
<td>Advisory</td>
<td>Shanghai</td>
<td><a href="mailto:steve.auyeung@cn.ey.com">steve.auyeung@cn.ey.com</a></td>
<td>+86 21 2228 8888</td>
</tr>
<tr>
<td></td>
<td>Andrew Chen</td>
<td>Transactions</td>
<td>Shanghai</td>
<td><a href="mailto:andrew.chen@parthenon.ey.com">andrew.chen@parthenon.ey.com</a></td>
<td>+86 21 2228 3939</td>
</tr>
</tbody>
</table>

| Hong Kong/ Macau| Cary Wu            | Assurance                 | Hong Kong     | cary.wu@hk.ey.com         | +852 2849 9122 |
|                 | Karina Wong        | Tax                        | Hong Kong     | karina.wong@hk.ey.com     | +852 2849 9175 |
|                 | Edward Chang       | Advisory Co-Leader         | Shanghai      | edward.chang@cn.ey.com    | +86 10 5815 2321 |
|                 | Judy Tsang         | Transactions              | Hong Kong     | judy.tsang@hk.ey.com      | +852 2846 9016 |

| Taiwan          | Lin Tu             | Assurance Co-Leader        | Taipei        | lin.tu@tw.ey.com          | +886 2 2757 8888 ext. 88810 |
|                 | KyKy Lin           | Assurance Co-Leader        | Hsinchu       | kyky.lin@tw.ey.com        | +886 2 2757 8888 ext. 88856 |
|                 | Ann Shen           | Tax                        | Taipei        | ann.shen@tw.ey.com        | +886 2 2757 8888 ext. 88877 |
|                 | Jon Huang          | Advisory                  | Taipei        | jon.huang@tw.ey.com       | +886 2 2757 8888 ext. 88862 |
|                 | Audry Ho           | Transactions              | Taipei        | audry.ho@tw.ey.com        | +886 2 2757 8888 ext. 88898 |

### Oceania

| Australia       | Gamini Martinus    | Assurance                 | Sydney        | gamini.martinus@au.ey.com | +61 2 9248 4702 |
|                 | Leonid Shaflender  | Tax                       | Sydney        | leonid.shaflender@au.ey.com | +61 2 8295 6735 |
|                 | Denise Brotherton  | Tax                       | Melbourne     | denise.brotherton@au.ey.com | +61 3 9288 8758 |
|                 | Milan Milosevic    | Advisory                  | Sydney        | milan.milosevic@au.ey.com  | +61 2 9248 5028 |
|                 | Jason Wrigley      | Transactions              | Sydney        | jason.wrigley@au.ey.com    | +61 2 9248 5303 |

| New Zealand     | Jon Hooper         | Assurance                 | Auckland      | jon.hooper@nz.ey.com      | +64 9 300 8124 |
|                 | Aaron Quintal      | Tax                       | Auckland      | aaron.quintal@nz.ey.com   | +64 9 300 7059 |

### South Korea

| South Korea     | Sung Yeon Cho      | Assurance                 | Seoul         | sung-yeon.cho@kr.ey.com   | +82 2 3787 6844 |
|                 | Jae Cheol Kim      | Tax                       | Seoul         | jae-cheol.kim@kr.ey.com   | +82 2 3770 0961 |
|                 | Yong Sik Kim       | Advisory                  | Seoul         | yong-sik.kim@kr.ey.com    | +82 2 3787 6600 |
|                 | Hyo Suk Han        | Transactions              | Seoul         | hyo-suk.han@kr.ey.com     | +82 2 3770 0907 |

### ASEAN

| Singapore/ Brunei| Swee Ho Tan        | Assurance                 | Singapore     | swee.ho.tan@sg.ey.com    | +65 6309 8238 |
|                 | Ching Khee Tan     | Tax                       | Singapore     | ching-khee.tan@sg.ey.com | +65 6309 8358 |
|                 | Ishita Dhamani     | Advisory                  | Singapore     | ishita.dhamani@sg.ey.com | +65 9029 1483 |
|                 | Abhay Bangi        | Transactions              | Singapore     | abhay.bangi@sg.ey.com    | +65 6309 6151 |
## ASEAN (continued)

<table>
<thead>
<tr>
<th>Country</th>
<th>Name</th>
<th>Role</th>
<th>City</th>
<th>Email</th>
<th>Phone</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Indonesia</strong></td>
<td>Peter Surja</td>
<td>Assurance</td>
<td>Jakarta</td>
<td><a href="mailto:peter.surja@id.ey.com">peter.surja@id.ey.com</a></td>
<td>+62 21 5289 4012</td>
</tr>
<tr>
<td></td>
<td>Peter Ng</td>
<td>Tax</td>
<td>Jakarta</td>
<td><a href="mailto:peter.ng@id.ey.com">peter.ng@id.ey.com</a></td>
<td>+62 21 5289 5228</td>
</tr>
<tr>
<td></td>
<td>Ishita Dhamani</td>
<td>Advisory</td>
<td>Singapore</td>
<td><a href="mailto:ishita.dhamani@sg.ey.com">ishita.dhamani@sg.ey.com</a></td>
<td>+65 9029 1483</td>
</tr>
<tr>
<td></td>
<td>Bernard Ng</td>
<td>Transactions</td>
<td>Jakarta</td>
<td><a href="mailto:bernard.ng@id.ey.com">bernard.ng@id.ey.com</a></td>
<td>+86 21 2228 2005</td>
</tr>
<tr>
<td><strong>Thailand/Myanmar</strong></td>
<td>Saisan Inkaew</td>
<td>Assurance</td>
<td>Bangkok</td>
<td><a href="mailto:saisan.inkaew@th.ey.com">saisan.inkaew@th.ey.com</a></td>
<td>+66 2 264 9090</td>
</tr>
<tr>
<td></td>
<td>Su San Leong</td>
<td>Tax</td>
<td>Bangkok</td>
<td><a href="mailto:su-san.leong@th.ey.com">su-san.leong@th.ey.com</a></td>
<td>+66 2 264 9090</td>
</tr>
<tr>
<td></td>
<td>Ishita Dhamani</td>
<td>Advisory</td>
<td>Singapore</td>
<td><a href="mailto:ishita.dhamani@sg.ey.com">ishita.dhamani@sg.ey.com</a></td>
<td>+65 9029 1483</td>
</tr>
<tr>
<td></td>
<td>Abhay Bangi</td>
<td>Transactions</td>
<td>Singapore</td>
<td><a href="mailto:abhay.bangi@sg.ey.com">abhay.bangi@sg.ey.com</a></td>
<td>+65 6309 6151</td>
</tr>
<tr>
<td><strong>Philippines/Guam</strong></td>
<td>Ana Lea C Bergado</td>
<td>Assurance</td>
<td>Makati City</td>
<td><a href="mailto:ana.lea.c.bergado@ph.ey.com">ana.lea.c.bergado@ph.ey.com</a></td>
<td>+63 2 894 8354</td>
</tr>
<tr>
<td></td>
<td>Francis Ricamora</td>
<td>Tax</td>
<td>Makati City</td>
<td><a href="mailto:francis.j.ricamora@ph.ey.com">francis.j.ricamora@ph.ey.com</a></td>
<td>+63 2 891 0307</td>
</tr>
<tr>
<td></td>
<td>Joseph Ian Canlas</td>
<td>Advisory</td>
<td>Makati City</td>
<td><a href="mailto:joseph.ian.m.canlas@ph.ey.com">joseph.ian.m.canlas@ph.ey.com</a></td>
<td>+63 2 891 0307</td>
</tr>
<tr>
<td></td>
<td>Abhay Bangi</td>
<td>Transactions</td>
<td>Singapore</td>
<td><a href="mailto:abhay.bangi@sg.ey.com">abhay.bangi@sg.ey.com</a></td>
<td>+65 6309 6151</td>
</tr>
<tr>
<td><strong>Malaysia</strong></td>
<td>Yoon Hoong Hoh</td>
<td>Assurance</td>
<td>Kuala Lumpur</td>
<td><a href="mailto:yoon-hoong.hoh@my.ey.com">yoon-hoong.hoh@my.ey.com</a></td>
<td>+60 3 7495 8608</td>
</tr>
<tr>
<td></td>
<td>Janice Wong</td>
<td>Tax</td>
<td>Kuala Lumpur</td>
<td><a href="mailto:janice.wong@my.ey.com">janice.wong@my.ey.com</a></td>
<td>+60 3 7495 8223</td>
</tr>
<tr>
<td></td>
<td>Ishita Dhamani</td>
<td>Advisory</td>
<td>Singapore</td>
<td><a href="mailto:ishita.dhamani@sg.ey.com">ishita.dhamani@sg.ey.com</a></td>
<td>+65 9029 1483</td>
</tr>
<tr>
<td></td>
<td>Abhay Bangi</td>
<td>Transactions</td>
<td>Singapore</td>
<td><a href="mailto:abhay.bangi@sg.ey.com">abhay.bangi@sg.ey.com</a></td>
<td>+65 6309 6151</td>
</tr>
<tr>
<td><strong>Vietnam/Cambodia/Laos</strong></td>
<td>Ernest Yoong</td>
<td>Assurance</td>
<td>Ho Chi Minh City</td>
<td><a href="mailto:ernest.yoong@vn.ey.com">ernest.yoong@vn.ey.com</a></td>
<td>+84 8 3824 8210</td>
</tr>
<tr>
<td></td>
<td>Thinh X Than</td>
<td>Tax</td>
<td>Ho Chi Minh City</td>
<td><a href="mailto:thinh.xuan.than@vn.ey.com">thinh.xuan.than@vn.ey.com</a></td>
<td>+84 8 3824 8360</td>
</tr>
<tr>
<td></td>
<td>Ishita Dhamani</td>
<td>Advisory</td>
<td>Singapore</td>
<td><a href="mailto:ishita.dhamani@sg.ey.com">ishita.dhamani@sg.ey.com</a></td>
<td>+65 9029 1483</td>
</tr>
<tr>
<td></td>
<td>Abhay Bangi</td>
<td>Transactions</td>
<td>Singapore</td>
<td><a href="mailto:abhay.bangi@sg.ey.com">abhay.bangi@sg.ey.com</a></td>
<td>+65 6309 6151</td>
</tr>
</tbody>
</table>

## Japan

<table>
<thead>
<tr>
<th>Country</th>
<th>Name</th>
<th>Role</th>
<th>City</th>
<th>Email</th>
<th>Phone</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Japan</strong></td>
<td>Hironao Yazaki</td>
<td>Assurance</td>
<td>Tokyo</td>
<td><a href="mailto:yazaki-hrn@shinnihon.or.jp">yazaki-hrn@shinnihon.or.jp</a></td>
<td>+81 3 3503 1566</td>
</tr>
<tr>
<td></td>
<td>Jonathan Stuart-Smith</td>
<td>Tax Co-Leader</td>
<td>Tokyo</td>
<td><a href="mailto:jonathan.stuart-smith@jp.ey.com">jonathan.stuart-smith@jp.ey.com</a></td>
<td>+81 3 3506 2426</td>
</tr>
<tr>
<td></td>
<td>Tatsuhide Kanenari</td>
<td>Tax Co-Leader</td>
<td>Tokyo</td>
<td><a href="mailto:tatsuhide.kanenari@jp.ey.com">tatsuhide.kanenari@jp.ey.com</a></td>
<td>+81 3 3506 1364</td>
</tr>
<tr>
<td></td>
<td>Tetsuro Sano</td>
<td>Advisory</td>
<td>Tokyo</td>
<td><a href="mailto:tetsuro.sano@jp.ey.com">tetsuro.sano@jp.ey.com</a></td>
<td>+81 3 3503 1490</td>
</tr>
<tr>
<td></td>
<td>Takayuki Ooka</td>
<td>Transactions</td>
<td>Tokyo</td>
<td><a href="mailto:takayuki.ooka@jp.ey.com">takayuki.ooka@jp.ey.com</a></td>
<td>+81 3 4582 6422</td>
</tr>
</tbody>
</table>

## India

<table>
<thead>
<tr>
<th>Country</th>
<th>Name</th>
<th>Role</th>
<th>City</th>
<th>Email</th>
<th>Phone</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>India</strong></td>
<td>Ravi Bansal</td>
<td>Assurance</td>
<td>Mumbai</td>
<td><a href="mailto:ravi.bansal@in.ey.com">ravi.bansal@in.ey.com</a></td>
<td>+91 22 6192 0460</td>
</tr>
<tr>
<td></td>
<td>Rahul Patni</td>
<td>Tax</td>
<td>Mumbai</td>
<td><a href="mailto:rahul.patni@in.ey.com">rahul.patni@in.ey.com</a></td>
<td>+91 22 6192 1544</td>
</tr>
<tr>
<td></td>
<td>Murali Nair</td>
<td>Advisory</td>
<td>Mumbai</td>
<td><a href="mailto:murali.nair@in.ey.com">murali.nair@in.ey.com</a></td>
<td>+91 22 6192 0380</td>
</tr>
<tr>
<td></td>
<td>Krishnakumar V</td>
<td>Transactions</td>
<td>Mumbai</td>
<td><a href="mailto:krishnakumar.v@in.ey.com">krishnakumar.v@in.ey.com</a></td>
<td>+91 22 6192 0950</td>
</tr>
</tbody>
</table>
Further reading from EY Life Sciences

**Progressions 2018**

**Life Sciences 4.0: Securing value through data-driven platforms**

Increased customer expectations and rapid technological advances are disrupting the health care industry, causing power to shift across traditional stakeholder groups and creating opportunities for new entrants. As the data and algorithms that drive patient-centric health outcomes become the ultimate health care products, organizations that harness data-fueled insights will lead in this new industry paradigm.

Life Sciences 4.0 examines this power shift, creates a future vision for the health care industry and suggests how life sciences companies should respond.

To create value now and in the future, biopharmas and medtechs must adopt agile, data-centric business models presently only seen in other industries. That means life sciences companies must build – or participate in – interoperable information systems that deliver data-driven improvements to health outcomes. And they must form agile, often short-term, partnerships and collaborations.

As competition increases and capital becomes scarcer, we expect to see companies narrowing their focus from diversified business models.

---

**A new equation for delivering value**

Future value (FV) is driven by innovation (I) that focuses on outcomes with a high degree of personalization and is fueled by unlocking the power of data (D).

\[
FV = I^D
\]

**Future value** = \[ Innovation \]

Outcomes x Personalization

\[ Data \]

(Connect + Combine + Share)

For people
For physicians
For payers
For policymakers

Participatory
Precise
Predictive
Proactive

Data streams
Traditional and non-traditional partners
Platforms of care

---

“Embracing Life Sciences 4.0 is both a global urgent need and an opportunity. If companies leverage technology to create platform interfaces and combine their proprietary data with those from other health stakeholders, they can position themselves as powerful leaders and capture sustainable future value.”

— Pamela Spence, EY Global Life Sciences Industry Leader
About EY
EY is a global leader in assurance, tax, transaction and advisory services. The insights and quality services we deliver help build trust and confidence in the capital markets and in economies the world over. We develop outstanding leaders who team to deliver on our promises to all of our stakeholders. In so doing, we play a critical role in building a better working world for our people, for our clients and for our communities.

EY refers to the global organization, and may refer to one or more, of the member firms of Ernst & Young Global Limited, each of which is a separate legal entity. Ernst & Young Global Limited, a UK company limited by guarantee, does not provide services to clients. For more information about our organization, please visit ey.com.

How EY's Global Life Sciences Sector can help your business
As populations age and chronic diseases become commonplace, healthcare will take an ever larger share of GDP. Scientific progress, augmented intelligence and a more empowered patient are driving changes in the delivery of health care to a personalized experience that demands health outcomes as the core metric. This is causing a power shift among traditional stakeholder groups, with new entrants (often not driven by profit) disrupting incumbents. Innovation, productivity and access to patients remain the industry's biggest challenges. These trends challenge the capital strategy of every link in the life sciences value chain, from R&D and product supply to product launch and patient-centric operating models.

Our Global Life Sciences Sector brings together a worldwide network of nearly 17,000 sector-focused professionals to anticipate trends, identify their implications and help our clients create competitive advantage. We can help you navigate your way forward and achieve sustainable success in the new health-outcomes-driven ecosystem.