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To our clients and friends:

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

First, we are very pleased to share that Sriram Shrinivasan has recently joined EY in the role of Global Emerging Markets Leader – Life Sciences and as EY Global Generic Pharmaceutical Leader. Sriram is based in Mumbai, India, where he will also serve as a partner in the EY India member firm’s Advisory practice, focusing on performance improvement. Sriram has kindly agreed to join us as executive co-sponsor for this report, and we look forward to his invaluable insights.

Second, we would like to extend our thanks and appreciation. In our first report, we acknowledged that the new normal in Asia is rapid change and that staying abreast of sector developments has been an ongoing challenge for many clients. We indicated that we understood the need for frequent in-depth analysis presented in an easy-to-digest format, and that with this report, we were endeavoring to do just that. In the several months following publication of our first report, we have received a tremendous amount of positive feedback, as well as invaluable comments and suggestions on how to further refine the report format and content. Again, thank you. Your comments are critical as we continue to refine this report to improve its overall value to our readers.

In this issue, we are excited to include three featured articles, all written specifically for this publication.

The first article, authored by Sriram Shrinivasan, explores the ongoing shift in Asia from “branded originals” to “unbranded generics” and considers the strategies and capabilities pharmaceutical companies will need to develop to be successful in this future state environment.

The second article, authored by Suresh Nair, Indirect Tax Partner from Ernst & Young LLP in India, discusses India’s anticipated Goods and Services Tax (GST) and explores the potential impacts and considerations for pharmaceutical companies. As we have recently experienced in other markets, notably Malaysia and China, transitioning to a new indirect tax regime presents significant challenges, requiring adequate lead times and commitment of resources. We strongly encourage companies to begin assessing the potential impacts to their business and developing a transition plan.

The third article, authored by Abhay Bangi, Transaction Advisory Services Partner from Ernst & Young Solutions LLP in Singapore, explores how companies can achieve significant value and cost savings through the regional negotiation of distributor agreements.

In addition to our featured articles, our Market insights section highlights a number of sector trends and provides brief yet informative updates on various regulatory and legislative developments for a number of 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 Flochel
EY Global Pharmaceutical Sector Leader

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EY Global Life Sciences Emerging Markets Leader and EY Global Generic Pharmaceutical Leader
Market insights: Asia

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

- ASEAN
  - Indonesia
  - Malaysia
  - Singapore
  - Thailand
  - Vietnam

- Australia
- China
- India
- Japan
- South Korea
- Taiwan
ASEAN

Indonesia: Promoting localization through policy changes and increased investment

As discussed in the last edition of this newsletter, Indonesia is continuing its efforts to strengthen domestic production of raw materials for drugs and medical equipment. It has already increased the permissible ownership of foreign firms in API operations from 85% to 100%. It also launched bonded logistics centers (PLBs) wherein imported products can be stored for up to three years without imposition of import duties and import-related taxes. PLBs play a critical role in streamlining the supply of raw materials such as APIs, 90% of which are imported by local companies. In another move, the government rejected the use of the world’s first anti-dengue vaccine, developed by Sanofi, despite being one of the world’s largest disease-endemic nations. The government has clearly stated it is developing a domestic version of the vaccine with state-owned firm PT Bio Farma. The new vaccine is expected to be rolled out in 2019.

Additionally, by leveraging the government’s fiscal incentives such as tax allowances and tax holidays, Indonesia is attracting the interest of companies such as Kalbe Farma, Panasonic Healthcare, Pharmaniaga and others, which are pitching investments for increasing their production capacity and making the country an export hub in ASEAN.

Malaysia: Prioritizing the biotech and medical device sectors to propel the country’s economic growth

To carve Malaysia’s place as a life sciences leader in the ASEAN region, the government of the country has been revising its framework to promote the medical device space. The government recently marked the medical device industry as one of its key sectors for economic growth as per the latest Malaysia Plan for national development (2016-20). This announcement will boost the confidence of domestic companies such as ABio Orthopaedics, Straits Orthopaedics, Granulab, Vigilenz Medical Devices, Kossan Latex and Top Glove. It will also help strengthen the country’s competitiveness globally, building on its current leadership in the production and export of catheters and surgical/examination gloves. Close on the heels of this news, the country’s Medical Device Authority revised conformity declaration requirements for registration of medical devices. The amended regulations provide step-by-step guidance to firms applying for device registrations.

Malaysia is also witnessing advancement on its National Biotechnology Policy (NBP), introduced in 2005 to develop the sector as a major contributor to the economy (8%-10% of GDP in 2020). NBP has so far contributed approximately US$5.0 billion (MYR20 billion) to national GDP. The nation has completed the first two phases, Capacity Building (2005-10) and Science to Business (2011-15), and has now entered the final phase, aiming to make

Key highlights

- Building on their previous efforts, all Asian markets continued to roll out regulatory changes to promote localization. India revised its foreign direct investment (FDI) policy to move toward an automatic route to boost M&A and private equity deals in the pharma sector. Similarly, Indonesia increased the limit for foreign ownerships in active pharmaceutical ingredient (API) businesses. Australia and China are focusing on forming trade agreements to boost their export potential. And Thailand is working to provide tax incentives for 13-15 years to attract foreign investment of over US$2.8 billion (THB100 billion) in 10 years.

- Emerging markets such as Vietnam, China and India are working toward making health care accessible and affordable to the wider population by regulating drug prices. Vietnam is expanding to 563 the number of products that will be sold 5%-10% below market price. India’s price regulator issued notice to firms perceived to be overcharging and intends to reduce trade margins for wholesalers and retailers to a maximum of 35%. Likewise, China is attempting to lower the margins on pharmaceuticals through pilot purchase programs. Developed nations such as Australia and Japan, meanwhile, continue to try new ways to contain their health care costs.

- R&D is at the heart of the pharma industry. Therefore, clinical trials are becoming a key focus area for Australia and India, which are easing norms for conducting clinical trials. Australia announced investment of US$5.25 million (AUD7 million) to overcome red tape and facilitate clinical trials. India has exempted academic institutions from the mandatory government permission to conduct clinical trials. Meanwhile, Taiwan is focusing on developing its infrastructure base for conducting clinical research and development within its own territory.

- Open innovation is also being promoted in the region. Multiple Singapore-based entities are developing Asia’s first liver cancer or hepatocellular carcinoma registry. Similarly, in Japan, Takeda, Astellas and Daiichi Sankyo have partnered to build a biomarker database for use in drug discovery, clinical trials and clinical diagnostics.

- With technology becoming an integral part of the pharma sector, countries such as Singapore, India and Australia are adopting digital technologies to streamline processes. India launched an e-portal, SUGAM, aimed at facilitating online submissions and approvals for both pharmaceuticals and medical devices while also increasing transparency. Concurrently, Australia launched an online database to help companies meet minimum patient targets faster to kick-start trials.

- India, China and South Korea have led initiatives for building patient trust in health care providers and the industry by scrutinizing physician-pharma relationships. India banned gifts by pharma companies to physicians, while South Korea is launching a probe to curb anti-competitive practices by pharma companies.

China refers to the mainland China in this publication.
Malaysia a world-class bio-based hub by 2020. NBP will focus primarily on agriculture, health care and industrial biotechnology. Simultaneously, the country is witnessing an influx of foreign investment in manufacturing from companies such as Novartis, Bemis, Dr. Reddy’s, Scitech and others, which intend to leverage the country’s growth potential and geographical location to expand their presence in the region.

Singapore: Focusing on digitization and revision of the regulatory framework

Singapore continued to make progress in the digital health space. SingHealth, the country’s largest health care group, signed a Memorandum of Understanding with Medtronic for the creation of a Centre of Excellence to focus on developing innovative solutions (including technologically enabled devices) for the treatment of diabetes across Southeast Asia. Similarly, Philips established a new Asia-Pacific health center, including a “Continuous Monitoring Care Room” that enables providers to remotely supervise and monitor their patients.

On the regulatory front, Singapore’s Changi Airport became the first airport in Asia to launch a community of cargo partners to strengthen its ability to handle pharmaceutical products.

Lastly, with favorable policies and increased demand for quality products, Singapore is attracting companies such as Catalent Pharma Solutions and Ferring Pharmaceuticals to set up a clinical supply facility and enable R&D of new medicines. Initiatives such as development of Asia’s first liver cancer or hepatocellular carcinoma registry will further strengthen the country’s R&D position globally.

Thailand: Seeking reforms to become a manufacturing hub for ASEAN

The Thai pharmaceutical industry is asking the government for additional investment incentives, such as extending current tax incentives from eight years to 13-15 years, to attract potential foreign investment of more than US$2.8 billion (THB100 billion) in 10 years. This would help increase annual pharma exports to an estimated US$2.1 billion (THB75 billion) by the next decade, versus 2015’s US$0.3 billion (THB10 billion). Apex Medical Corporation, a Taiwanese medical device manufacturer operating through a JV with Thai-based Samaphan International Co., is planning to establish Thailand as its hub for Cambodia, Laos, Myanmar, Vietnam and North Asia over the next three-five years. The country will serve as its regional headquarters for North Asia.

Vietnam: Driving growth through inclusiveness, localization and regulations

Vietnam is considering pharmaceuticals as a spearhead sector for its economic growth. As part of this effort, the government plans to prioritize the processing and production of pharmaceutical products and traditional medicines within Vietnam. It is also reaching out to international partners such as India to take part in the country’s Make in Vietnam initiative. Firms headquartered in Turkey, South Korea and New Zealand have also expressed interest in potential investment in the country.

Furthermore, the country is considering regulations to allow the sale of certain pharmaceuticals through supermarkets, alongside establishment of night services at pharmacies and drug stores. Concurrently, the government is taking many steps to make health care accessible and affordable to the masses. Under its price stabilization program, it expanded sale of 563 Vietnam-produced drugs till March 2017 at a price 5%-10% below the market price. It also continued its prior efforts to strengthen immunization of the population by adding vaccines for inactivated polio and rota under the National Expanded Program on Immunization.
Australia

Accelerating innovation and improving the nation’s competitiveness in clinical trials amid growing concern over rising health costs

Australia has a global reputation for good doctors and scientists but is still struggling to attract new large-scale national or interstate clinical trials. In an attempt to overcome the current problem of red tape that varies across states and territories, the government announced an investment of US$5.25 million (AUD7 million) to facilitate easier conduct of clinical trials. It also set up an online database creating clinical trial recruitment awareness among patients, especially for Phase III, as 50% of all trials fail to meet their patient targets.18

The government is not holding back in its effort to boost innovation, injecting fresh investment into life sciences. The new funds are aimed at advancing Australia’s place in the global life sciences industry. Initiatives in this direction include:

- The US$15 billion (AUD20 billion) Medical Research Future Fund to provide financial support for health and medical research and localize innovation
- The Medical Technologies and Pharmaceuticals Growth Centre to position the country as an Asia-Pacific hub for medical technology
- A US$19 million (AUD25.4 million) initiative to support tropical disease research19

With an increasing cost burden on the health care system, the country is trying to find the right balance between ensuring access to treatment and controlling costs. To this end, the regulator initiated price cuts of up to 60% on a large portion of common prescription medicines and patent-protected drugs under the Pharmaceutical Benefits Scheme (PBS). These reductions became effective along with the country’s annual price changes in April 2016.20 In addition, the government is planning to negotiate many more such measures under the PBS in the 2016-17 budget. Some of the potential outcomes include removal of over-the-counter (OTC) medicines such as paracetamol and aspirin from the PBS and introducing a 5% price cut for patented drugs after five years on the PBS.21

Lastly, Australia is working on various trade agreements. China has emerged as a viable partner for Australia, with the China-Australia Free Trade Agreement (ChAFTA) signed in December 2015. Under the agreement, up to 10% of current Chinese tariffs on Australian pharmaceuticals and health products (including the 4% tariff on hearing aids and implants) will be phased out.22 Australia is also negotiating a free trade agreement with India.23
China

Curbing fraudulent and insufficient practices via better control and monitoring

The China Food and Drug Administration (CFDA) launched follow-on initiatives to speed up drug approvals. The government body introduced the “Green pass process” to expedite foreign innovation fast-track approvals for drugs manufactured in China. In addition, the regulator agreed to prioritize approvals of new medicines with superior clinical value as well as drugs belonging to certain categories, including rare diseases, AIDS, viral hepatitis and malignant tumors.

However, while the government is enabling companies for faster market access, it also increased its monitoring for irregularities. China’s price regulator plans to bring foreign and domestic life sciences companies under the ambit of anti-trust investigations to check for potential violation of regulation for competition. To curtail pharmaceutical premium pricing, the government shouldered a pilot program to receive lower costs in exchange for volume buying and potential reimbursements. Consequently, it could enforce price cuts for three patented drugs out of five under the pilot. In addition, the country has doubled the number of hospitals in its pilot program aimed at eliminating the 15% drug price markups hospitals charge. All of these measures are in addition to the growing scrutiny of physician-industry relationships.

In line with the government’s 2020 goal of having China-made generic and biosimilar versions of more than 99% of branded drugs without patent protection, the government modified bioequivalence testing rules and set new deadlines for generic pharma companies to align the quality and efficacy of their drugs with brand-name drugs. This is a huge change from the previous norm, where new generics were primarily approved based on comparisons with already-existing generic drugs, leading to lower-quality products entering the market.

Apart from tighter checkpoints, China is also undertaking steps to boost domestic manufacturing and international trade opportunities. In the past, it undertook several trade agreements such as the one with Australia and ASEAN and is currently spearheading talks for implementation of a Regional Comprehensive Economic Partnership (RCEP) with India and other East and Southeast Asian nations. In addition to RCEP, it is negotiating trade pacts including bilateral agreements with Norway, Sri Lanka and Maldives, among others.

On the tax front, China replaced business tax with value-added tax (VAT) across all industries, including medical services, effective 1 May 2016, to align the country’s indirect tax policies with international practices. The reform will reduce the tax burden on industries, since business tax was levied on gross revenue of business while VAT is charged on the difference between a commodity’s price before taxes and its cost of production.
India

Increasing transparency and quality to boost India’s credibility in the global life sciences industry

India is striving to maintain itself as a preferred destination for clinical trials. In a first, the government has exempted academic institutions from the requirement of permission from the Drug Controller General of India (DCGI) for conducting clinical trials. Simultaneously, to improve the drug/device approval process, the Union health ministry modified some norms and policies. It expanded its expert panel for approval of new drugs, including biologicals. The new committee now has a broader representation from different therapy areas and product classes. Following the “Digital India” movement, India launched SUGAM, an online services portal for filing applications for import and registration of drugs, medical devices and diagnostics. The e-portal aims to bring all pharma-related submission (clinical trials, test licences, manufacturing, marketing, import-export of products, etc.) under its scope to facilitate transparency and eliminate corruption in the system.

Following the increasing scrutiny into pharma-physician relationships by its counterparts in other countries, the Indian government mandated an official code of marketing practices which includes a ban on gifts to doctors. This move will likely bring a shift in the commercial model of the pharma firms operating in India and also improve patients’ trust in pharma and physicians.

In an attempt to expand treatment access, the National Pharmaceutical Pricing Authority (NPPA) issued notice to 263 firms evidenced to be overcharging in 2015-16. It also plans to cap the trade margins at 35%, in contrast to margins exceeding 2,000% that are being charged by wholesalers and developers. This will result in a steep decline in drug prices. The industry is also looking to reach out to the wider population of medtech start-ups working toward cost-effective devices for people residing in rural areas.

The biotechnology sector also witnessed some activity. The government passed a bill to support establishment of a national-level biotech center in New Delhi, under the aegis of UNESCO, to promote research, expertise and technology transfers in South Asia. In addition, the Pharma Ministry issued new guidelines for biosimilars, allowing licensing of a reference biologic in a member country of the International Council for Harmonisation for products not marketed in India.

Lastly, India continued with its two-pronged strategy of the “Make in India” program and discouraging API dependence on China. As part of this, the government amended the FDI policy in the pharma sector to reduce delay in M&A and private equity deals. Under the revised policy, the government increased FDI in automatic route from 49% to 74% in brownfield projects and allowed 100% automatic FDI in greenfield projects. In addition, the Department of Pharmaceuticals drafted a bulk drug policy while the government evaluated the financial viability of providing US$9 billion (INR600 billion) for establishing three new bulk drug manufacturing parks and three medical device parks. Further, the government withdrew exemption of 76 medicines from customs duties, thereby inflating costs of some imported drugs by approximately 35%, including key HIV drugs. Similarly, it has hiked the import duty on medical devices, a move that is witnessing serious criticism by the industry, which is demanding a rollback. The government is also strengthening alternative medicines, including Ayurveda and Yoga.
Japan

Generic growth, open innovation key themes even as long-term systemic pricing pressure looms

In the last edition, we discussed the pricing pressures faced by pharmaceutical companies in Japan. The good news is that there is some respite from price cuts as the government has deferred the scheduled price revision of April 2017. However, this relief might be only temporary. There are regular discussions in health ministry circles related to “out-of-cycle repricing” of drugs that are projected to rake in huge profits, especially those drugs that are likely to get indication expansions." The prime minister’s announcement of not increasing the consumption tax rate has made the industry all the more nervous, as they fear that the revenue shortfall for the government may be compensated by special price cuts. Further, the Central Social Insurance Medical Council (Chuikyo) has given a green light to begin the cost-effectiveness assessment pilot for seven drugs, including Sovaldi (sofosbuvir) and Opdivo (nivolumab). Based on the appraisal results, repricing could occur by April 2018.35

Even as the generics market is growing fast (12%-15% YOY revenue growth in FY15 for the leading companies), generics companies are struggling to maintain their profitability due to price cuts.36 To offset this, companies are trying to minimize their cost of operations. For example, Meiji Seika Pharma is planning to use low-cost locations such as India to manufacture Japan-bound drugs. It has recently invested US$28 million to set up Japan-bound tablet production lines capable of producing 3 billion tablets per year.37 To capitalize on the sharp growth, generics companies are rapidly increasing their sales forces in Japan. Towa Pharmaceutical, Sawai Pharmaceutical, Nichi-Iko Pharmaceutical and Meiji Seika Pharma have all announced aggressive plans to ramp up the number of medical representatives in the country.38

The OTC segment has seen some positive developments in Japan. To reduce its health care spending, the government has launched a new scheme to promote Rx-OTC switching. As part of this, the Ministry of Health, Labour, and Welfare will invite requests for these switches from various stakeholders, such as consumers, pharma companies and disease societies.39 In addition, the government has introduced the concept of family pharmacies and health care hub pharmacies to promote fewer visits to hospitals. These pharmacies will likely increase the sales of OTC products in Japan by increasing their availability.40

The concept of open innovation is catching on in Japan. Takeda, Astellas and Daiichi Sankyo recently announced a collaboration to build a biomarker database to be used in drug discovery, clinical trials and clinical diagnostics. The companies have agreed not to claim intellectual property over these findings and will make this research available for wider use.41 Otsuka’s subsidiary Taiho Pharmaceutical has invested in an open innovation fund, the Remiges BioPharma Fund. It has also set up Taiho Ventures with a corpus of US$50 million to invest in promising drug discovery start-ups.42
South Korea

Working toward an environment conducive to the growth of domestic companies

The South Korean Government is showing its intent to fix regulatory hurdles, an absolute necessity for promoting a culture of local innovation and R&D. The government has launched a new pilot program to unify the approval review processes for medical devices and health technology assessment (HTA) under a new process called “Integrated Service for Medical Device Approval and Health Technology Assessment.” This will allow companies to apply simultaneously for HTA and device approval, thereby saving the additional 9-12 months that was earlier required for HTA. The program will be fully rolled out after completion of the pilot in July 2016. In biopharmaceuticals, the government promised a shorter review process for treatments of rare and incurable diseases.

In addition, ongoing efforts of the government and industry are helping the local biopharma sector move up the value chain. This is evident from the fact that the industry regulator, the Ministry of Drug and Food Safety, granted marketing approval to five locally developed drugs in 2015, up from an average of one or two approvals in prior years. South Korea has also witnessed an increase in approvals for clinical trials for drugs developed by local companies: 64 first-stage clinical trials approved between January and April of 2016 versus 51 in the same period last year.

To enhance export opportunities, the country is working to establish cross-country platforms. The government has already signed an agreement with Mexico with the view of expediting entry of Korea-manufactured drugs in the Mexican market. It is also in talks with Saudi Arabia and the United Arab Emirates to gain entry for Korean-manufactured medical technology in the Middle East. Lastly, to keep in sync with the rise of industry scrutiny globally, South Korea initiated investigations into industry practices. The country is actively probing potentially anti-competitive practices of local as well as multinational pharmaceutical companies with respect to rebates to hospitals.

Taiwan

Strengthening infrastructure and streamlining regulations to boost industry growth

Taiwan is emerging as a leading destination for biopharmaceutical research and trials in the region as a result of several government initiatives toward the development of infrastructure. Some of the key efforts in this direction include:

- Subsidized formation of research centers in regional teaching hospitals
- Establishment of centers of excellence in clinical trials at leading institutions

International biotech firms such as Agilis Biotherapeutics, Lixte Biotechnology and Boehringer Ingelheim have already started leveraging Taiwan’s infrastructure to conduct clinical research and trials through collaborations with academic institutions, including the regional centers.

The recent policy revision by the mainland Chinese Food and Drug Administration, allowing the use of clinical data from four Taiwanese hospitals during drug application submissions, is a first step toward regional harmonization of clinical trials data guidelines. This will help lower drug development costs by reducing the need for overlapping trials for the companies undertaking clinical studies in Taiwan.

Furthermore, the market has introduced a fast track review process for drug approvals for multinationals to boost the market’s attractiveness. Under this new program, a sponsor will need to undergo only an administrative review by the Taiwanese Food and Drug Administration if its clinical trial protocol is already approved by any of the following 10 countries: US, UK, France, Japan, Switzerland, Canada, Australia, Belgium, Sweden or Germany. This eliminates the need for technical review and will speed drug approval.
**Featured article:** The rise of unbranded generics – what does the future hold for Asian markets?

By Sriram Shrinivasan, Global Emerging Markets Leader and Global Generic Pharmaceutical Leader, Ernst & Young LLP, India

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New Zealand and Australia currently insure close to 100% of their populations. Vietnam has also made great strides in covering more than half of its population, with plans to achieve 80% coverage by 2020. Other countries have recently rolled out ambitious plans to increase coverage; Indonesia, for instance, plans to insure 260 million people, nearly 100% of the population, by 2019.

As nations advance their universal coverage ambitions, the cost burden of health care will shift from patients (out-of-pocket expenditure) to payers (government-owned or private). With cost containment emerging as a key agenda item for governments and payers, Asian markets are likely to prioritize initiatives that shift drug use from branded to unbranded generics.

Emergence of multiple segments

In Asia, it will still be several years, if not decades, before market dominance shifts from branded generics to the more commoditized unbranded generics. During this period, we are likely to witness the emergence of three distinct segments (unbranded generics, branded generics and patented products). To be most successful, pharma companies operating in these markets must adopt *multi-channel, multi-segment approaches*. Historically, pharma companies in Asian markets have focused their attention largely on physicians as the main customers. In the future, they will require a new mind-set, advanced capabilities and tools to manage relationships and influence other stakeholders, including payers, governments, distributors and hospital purchasing organizations.

Operating in a multi-segment, multi-stakeholder world

We highlight a few capabilities that pharma companies need to develop to succeed in the new environment:

- Using digital to help payers and government. Globally, payers and governments want to interact with pharma companies on a range of issues, not just the pricing of drugs. In one European
market, for instance, payers wanted more frequent and more transparent interactions on a range of issues, including treatment protocols, clinical guidelines, disease management and total cost of care analyses. Information on underserved markets and more efficient delivery of health care services are especially valued by payer stakeholders. Thus, as some of the Asian markets move into payer-managed environments, pharma companies could explore building digital tools (e.g., dashboards) to enable better collaboration and support for these organizations.

- **Partnering with generics companies, payers and distributors**
  - **Generics:** In the multi-segment environment, traditional pharma companies may find it impractical to build in-house capabilities catering to each segment. Instead of viewing generics products as competition, pharma companies could consider offering them as part of a therapeutic continuum. Doing so will likely require partnering. For instance, MNCs, which have a forte in branded originals, would likely need to partner with generics developers that are more adept at managing the supply chain if they want to be competitive in this high-volume, low-cost space. Takeda’s joint venture with Teva Pharmaceutical Co. Ltd. in Japan illustrates how companies can collaborate in a changing environment.
  - **Payers:** Innovative partnerships with payers will also be important. MNCs should explore working with payers to accelerate adoption of more sophisticated cost-containment measures (e.g., risk-sharing, value-based agreements) to improve access to products and improve health outcomes overall. Carefully defining the parameters for these novel contracts is critical to enabling the parties to trust each other.

- **Distributors:** In Asia, strong and efficient distribution channels that can deliver products to underserved and fragmented markets is a must. In such an environment, pharma companies may need to look at distribution partnerships and a channel strategy aligned with the market segments they seek to play in.

- **Offering services to differentiate branded products.** To differentiate branded drugs (both branded generics and originals) from generics and justify the price premiums, pharma companies will need to complement drugs with patient services that result in improved patient experience and outcomes. These services could include mobile applications, health camps, lifestyle interventions, customized packaging of products, health data tracking and personalized analytics. While many companies have already started their digital journeys, many still need a strong governance model to make sure all the digital initiatives of the company take into account the multi-channel and multi-segment world. This will avoid a costly rewrite of digital strategies in the future.

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The rise of unbranded generics represents both a threat and an opportunity for MNC pharma companies. The most successful players will identify strategies that allow them to rapidly iterate in today’s ever-changing marketplace. The good news is that knowledge gleaned from other markets can be deployed as companies develop Asia-specific strategies. This gives companies the power to be proactive, not reactive.
“GST will be the best example of co-operative federalism. Together we will take India to new heights of progress. ...We continue to work with all parties and states to introduce a system that benefits all Indians and promotes a vibrant and unified national market. ...This reform will promote ‘Make in India,’ help exports and thus boost employment while providing enhanced revenue.”
– Prime Minister of India, Mr. Narendra Modi, 3 August 2016

India’s proposed GST: ushering a new era of reform

GST is expected to transform the Indian economy in the medium to long term. The new GST framework would result in the development of a common Indian marketplace, reduce the cascading effect of multiple layers of taxes and increase revenue buoyancy for the Central Government (Government) and most of the state governments. By leveraging an advanced technology infrastructure and systems, the GST framework is expected to bring greater transparency and simplicity in tax administration and compliance. It is also anticipated that supply chain and other operational planning opportunities and efficiencies may be available, depending on a company’s facts. However, in the short term/transitional phase, all companies, including those in the pharmaceutical industry, are likely to face a number of challenges, some quite significant, including possibly negative financial impacts, the need to reassess existing supply chain structures, the need for reconfiguration of IT systems and more. It is therefore critical that companies become familiar with the proposed GST legislation, begin assessing the impacts that GST is likely to have on their business operations, and begin to develop/implement a plan to manage this mega-change by the expected implementation date.

Where it stands today

The Government has consistently expressed its strong commitment to implementing GST and has taken a number of significant steps in that direction.

In 2016, the Finance Ministry released the Model GST Law, which outlined the construct of the proposed legislation and provided further insights on the proposed GST mechanics. This was an important development on the path to implementation and provided much desired visibility into the intricacies of the proposed tax. In addition, in an effort to promote broad support for the proposal, the Government agreed to provide 100% compensation to states for any loss of revenue resulting from GST, for a period
of five years. The Government has also made significant progress toward establishing the IT infrastructure for the Goods and Services Tax Network (GSTN), a company responsible for developing the technology infrastructure required to support and enable the GST. The globally renowned IT firm Infosys was awarded the government contract for developing the IT infrastructure for GSTN and the work is currently in progress.

Under the Constitution of India, however, the power to levy indirect taxes is divided between the Central (federal) and state governments. In order to implement GST, the Constitution would need to grant authority to both Central and state governments to levy the tax on the same transaction. Although the GST Bill (conferring the above said powers) was cleared by the Lower House in May 2015, it has since been pending clearance from the Upper House since the current ruling party lacked adequate representation. Finally, after over a year of inactivity and political posturing, a number of critical milestones have been achieved within a very short time period, namely:

- The GST Bill was cleared in the Upper House of Parliament on 3 August 2016 with unanimous support from all members.
- On 1 September 2016 the GST was approved by 50% of the state assemblies in India; and
- On 8 September 2016 the President provided consent for enactment of the GST Bill, which concludes the process of amending the Constitution. The Bill has now been enacted and the Central and state governments now have the power to levy GST.

Current tax structure in India
Given below is a snapshot of major indirect tax levies.

<table>
<thead>
<tr>
<th>Tax Type</th>
<th>Levied On</th>
<th>Approximate Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Service tax</td>
<td>Provision of services</td>
<td>15%</td>
</tr>
<tr>
<td>Value Added Tax (VAT)</td>
<td>Sale of goods within the State</td>
<td>5%/12.5%/14.5%</td>
</tr>
<tr>
<td>Customs duty</td>
<td>Import of goods</td>
<td>29.44%</td>
</tr>
<tr>
<td>Central Sales Tax (CST)</td>
<td>Inter-state sale of goods</td>
<td>2%</td>
</tr>
<tr>
<td>Entry tax/octroi/local body tax</td>
<td>Entry of goods within State/local limits</td>
<td>Tax rate depends on the nature of goods</td>
</tr>
<tr>
<td>Excise duty</td>
<td>Manufacture of goods</td>
<td>12.50%</td>
</tr>
</tbody>
</table>

These are indeed key milestones for the GST journey in India and pave the way for the final step in the implementation process, which involves establishment of the GST Council within 60 days of the date of enactment. The GST Council shall have recommendatory powers with reference to deciding GST rates, thresholds, exemptions etc., and will be critical to shaping and establishing the final GST rules and requirements.

Currently, the official proposed date for implementation of GST is 1 April 2017.

Salient features of the Model GST Law

As illustrated in the chart below, the current indirect taxation regime and related compliance requirements and obligations in India are complicated and cumbersome. The rights to levy indirect taxes are spread among the Government (e.g., tax on manufacture and services), state governments (e.g., tax on sale and entry into notified areas) and municipal authorities (e.g., tax on entry into municipal limits).

Under the Model GST Law, GST has been defined as a tax on the supply of goods and services. Simply put, GST constitutes a supply-based levy, whereby the current triggering events for levy of tax, such as manufacture, sale, rendering/receiving of service, etc., would cease to exist.

It is proposed that **multiple indirect taxes** would be subsumed into a dual-structure GST levy, with two components of tax – Central GST (CGST) and State GST (SGST) – being applied to **every** supply
of goods and services within the same state (i.e., intra-state sales). Import and inter-state movement of goods and services would be subject to Integrated GST (IGST). See illustrative summary below.

<table>
<thead>
<tr>
<th>Transaction</th>
<th>CGST</th>
<th>SGST</th>
<th>IGST</th>
<th>Basic Customs Duty (“BCD”)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sale goods within State A (i.e., intra-state sale)</td>
<td>✓</td>
<td>✓</td>
<td>✗</td>
<td>✗</td>
</tr>
<tr>
<td>Sale of goods from State A to State B (i.e., inter-state sale)</td>
<td>✗</td>
<td>✗</td>
<td>✓</td>
<td>✗</td>
</tr>
<tr>
<td>Import of goods in India from outside India</td>
<td>✗</td>
<td>✗</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Stock transfer of goods from a warehouse in State A to another warehouse in State B (i.e., stock transfer)</td>
<td>✗</td>
<td>✗</td>
<td>✓</td>
<td>✗</td>
</tr>
<tr>
<td>Exempted goods and services and transactions below prescribed threshold</td>
<td>✗</td>
<td>✗</td>
<td>✗</td>
<td>✗</td>
</tr>
</tbody>
</table>

While certain items, such as alcohol for human consumption, have been exempted from GST, other items, such as petroleum and petroleum products, have been deferred, subject to a separate future notification as would be decided by the GST council.

As indicated previously, the Government has established a company, GSTN, dedicated solely to providing IT infrastructure and services to the Central and state governments, taxpayers and other stakeholders in connection with the implementation and administration of GST.

GSTN would provide a common portal for obtaining tax registrations, making GST payments, filing GST returns, claiming refunds, etc. The contract for developing the requisite IT infrastructure has been awarded to Infosys, with the first phase of the project having already been completed.

Under the proposed GST regime, input tax credit can be availed only if the vendor uploads invoice details into the GSTN and the buyer confirms the auto populated purchase register generated by the GSTN. This represents a major paradigm shift in the way the tax credit is currently availed, which is reliant on the hard copy purchase invoices and offline reconciliation. Upon implementation, the entire GST process would be electronically managed, and it is expected that corresponding compliance requirements would increase. For instance, in the event there is any invoice that is not reflected in the purchase generated by the GSTN as part of the invoice uploaded by any given vendor, the buyer would need to inform the supplier to upload the corresponding invoice details into the system, else credit would not be eligible to the buyer. In addition, the Model GST Law mandates that unless the seller actually pays the corresponding GST, the buyer would not be allowed to avail the said credit of GST, even though the amount of GST due on the sale is properly reflected in the sale register and aligns with the corresponding purchase register.

**Considerations for the pharmaceutical industry**

**Opportunities to create supply chain efficiencies**

It is not uncommon for midsize to large companies to operate 20-25 warehousing locations in India; one of the key reasons for this arrangement is the current indirect tax regime.

Under the current regime, interstate sale of goods (i.e., sale of goods from state A to state B) attracts tax (Central Sales Tax) which is not creditable to the buyer, whereas interstate movement of goods across warehouses of the same company is not subject to tax. Hence, pharmaceutical companies have adopted a decentralized supply chain model whereby multiple warehouses located in different states in India have been operated to avoid tax leakage from the direct interstate sale of goods.

Since GST on interstate sale of goods would be creditable under the Model GST Law, there exists an opportunity for companies to revisit current supply chain structures, the number of warehouses being operated, etc. Similarly, there may exist opportunities to optimize sourcing strategies to achieve significant supply chain cost savings. For example, companies have historically designed their sourcing strategies with the primary goal of minimizing indirect taxes incurred under the current regime (i.e., whether to procure from within the state or from outside the state). Post-implementation, these tax limitations/restrictions would cease to exist, thereby affording more flexibility and enabling companies to shift their focus to non-tax sourcing considerations, including purchase price, logistics cost, etc. As a result, through proactive planning, the transition to GST could provide pharmaceutical companies with a competitive advantage in terms of pricing of the goods and margins.

**Inverted duty structure**

Currently, Central excise duty (tax on manufacture) is levied at 12.5% for API, whereas the formulations manufactured therefrom are subject to Central excise duty at 6% on the Maximum Retail Price (MRP) of said goods minus a special abatement. This results
India’s looming Goods and Services Tax (GST) – considerations for the pharmaceutical industry

in substantial accumulation of input tax credit for the manufacturer with no legal provision to obtain a refund of this credit pool. The Model GST law provides for refund of credits accumulated under the current indirect tax regime resulting from the higher tax rate on inputs vis-à-vis the lower tax rate on outputs. The transitional provision provides for transfer of such accumulated credits into the proposed GST regime. This obviously represents a welcome proposal and potentially significant benefit for the pharmaceutical industry, which so far has been unable to monetize the amounts of blocked credits.

Job work model
Companies in the pharmaceutical industry in India often rely upon third-party entities to manufacture finished formulations for and on their behalf. This arrangement is commonly referred to as a “job work” model or “loan licensee” model. Under the current regime, tax obligations of parties under a job work model are relatively clear and simple, namely:

- The principal supplies input material to the job worker’s premises with no tax implication and limited documentation.
- The job worker makes the payment of excise duty on the manufactured formulations based on the MRP of said goods as declared by the principal.

Similar special provisions for GST free movement of input goods/material for job work have been provided in the Model GST law. However, the process that companies will need to follow to allow for such free movement of input goods/material could become
relatively cumbersome under the GST regime. It is proposed that the job work process require approval of the Jurisdictional Commissioner by way of special order. In cases in which the permission is not granted or delayed, supply of input materials for job work would attract GST. This requirement of obtaining permission could be time consuming, especially during the transition phase, and may create operational and financial challenges for companies.

The pharmaceutical industry would greatly benefit to the extent the Government were to convert the proposed job-work-related approvals requirement to a self-declaration model. This would result in greater efficiency and allow companies to avoid the possibility of a GST outlay (i.e., negative cash outflow). For this reason, industry should actively engage with and lobby the Government to incorporate this change.

Tax-free zones
Many companies engaged in the manufacture of pharmaceutical products have set up their plants in locations where the Government has offered indirect tax exemptions/ incentive schemes (such as Baddi and the state of Jammu and Kashmir, among others). These schemes provide for either upfront exemption or refund of indirect taxes paid.

Continuity of these location-based indirect tax benefits under the GST regime is critical, as companies have made significant capital investments in such areas due in part to the availability of these tax incentives. If the incentives are discontinued prematurely, such companies are likely to face financial challenges. This may also indirectly impact the cost of medicines and the ultimate price to be paid by the patients. The GST Council to be formed by the Government will be tasked with determining the fate of such exemptions under the GST regime.

The pharmaceutical industry has represented to the Government that current benefits should be grandfathered under the GST regime. One of the models the Government could consider if amenable to grandfathering such benefits is to require companies to pay GST on their finished goods (to achieve continuity of levy of GST at every stage of the supply chain), then allow them to claim refund of benefits otherwise available in the applicable regime. Again, as such incentives have represented a significant benefit for the industry in India, it is important that developments in this area be closely monitored and considered in terms of the potential financial impact, and that the industry continue to actively engage with and lobby the governments from which they are currently receiving such incentives.

Free supplies
Pharmaceutical companies routinely supply medicines free of charge as samples for physicians and as supplies to the World Health Organization and Government as part of health awareness programs, patient assistance programs, etc. Currently, while free supplies are subject to Central excise levy (tax on manufacturing), they are typically not subject to state VAT/CST. In addition, there are often cases where stock is transferred for destruction purposes or transferred for relabelling to meet regulatory requirements, and these transfers are also not subject to state VAT/CST.

Under the proposed GST regime, supplies made free of charge and other intra-company movements, as illustrated above, would be subject to tax. This represents a major change and could potentially have significant negative impacts on companies’ budgets, levels of available spending in connection with such programs and the overall cost of supporting patient assist programs.

In addition, it appears valuation of free supplies/transfers for levy of GST (since there would be no invoice value) could be based on GST Valuation Rules, which rely on concepts of comparable sales price, cost plus method, etc. Such practice could be operationally cumbersome and may be prone to litigation.

Therefore it is again important that the pharmaceutical industry actively engage with and lobby the Central and state governments in support of exempting these types of transactions from GST (i.e., zero value transactions) and not requiring any reversal of input tax credits.

GST is expected to have a far-reaching impact on companies’ business operations. Pricing of products and services, supply chain and procurement, IT systems, accounting, tax compliance and other

**GST – readiness beyond tax function**

- **Timely manage risks and opportunities**
  - Start early: 12-15 months for readiness and implementation

- **Significant impact on policies, procedures and controls and supply chain planning**

- **IT implementation takes time and requires testing**

- **Governance**
  - GST Steering Committee, PMO and Change management are critical

- **Comprehensiveness**
  - Mapping of all possible scenarios for flow of goods and services

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areas will be affected. Employees will also need retraining.

With respect to accounting, the chart of accounts and standard operating procedures will need updating and working capital requirements, cash flow and tax cost planning will likely need to be reassessed. With respect to IT systems, enterprise resource planning systems will likely need to be reconfigured – including creating new tax masters, which can be quite time consuming and expensive. Creating awareness and educating key internal and external stakeholders, including suppliers and distributors, will need to represent a key component of every company’s GST change management process and implementation plan.

The next couple of months will be critical in determining whether GST will be implemented in April 2017 or, instead, some later date. It is currently very unclear whether the Government will be ready by April 2017 with the necessary administrative construct and support. It is also uncertain whether the GSTN, which is vital to implementation, will be completely functional by then.

Nonetheless, we expect GST to be implemented in the near future, and pharmaceutical companies need to prepare. Any delay in a company’s ability to implement and comply with the new GST requirements could result in reputational, business continuity and compliance risks.

We recommend that pharmaceutical companies begin now the process of assessing the potential impacts to their business and developing a transition plan to achieve four key objectives by 1 April 2017: a) engage the Government on issues and requirements that are important to the business in an effort to influence the GST rule-making process; b) avoid any business disruption on the cut-over date; c) achieve 100% compliance with all legal and procedural requirements under the GST; d) identify and implement any available tax and business/operational planning or cost management opportunities, recognizing that implementation of such opportunities may require long lead times.
“As distributors become more sophisticated and pharmaceutical distribution networks get even more complex, regional negotiation of distribution contracts can result in significant economic benefits and improved service levels for pharmaceutical companies.”

– Abhay Bangi

### The evolving pharmaceutical business in Asia-Pacific

Until recently, optimizing cost base and working capital was a relatively low priority for big pharmaceutical companies. In the last few years, however, we have witnessed a fundamental change in mindset. Many companies are focusing on optimizing the overall operating model within Asia-Pacific, with the objective of reducing overall “cost to serve” and improving the working capital position through a regional focus. Some of the key driving factors behind this shift have been the ongoing macroeconomic headwinds in many emerging markets, currency volatility, growing competition from local players and biotech companies, and product portfolios being increasingly skewed toward off-patent drugs.

For a number of pharmaceutical companies operating in Asia-Pacific, a “quick win” in cost reduction has come from renegotiating distributor contracts at a regional level, rather than on a country-by-country basis.

Significant economic benefits and improved service levels are achievable from this exercise – typically a reduction in distribution (excluding demand generation) and logistics fees by 5%-10% (Exhibit 1) and cash release of about 2% of revenue through improvement of receivable terms, based on EY experience.

### Why regional negotiation of distributor agreements can drive significant economic benefits

1. **Stronger negotiating power by leveraging scale and stimulating competition**

Negotiating at the regional level allows pharmaceutical companies to gain a negotiating advantage and increased bargaining power – leveraging their scale to commit higher volumes to distributors. By consolidating demand, it forces distributors to provide better quotes either through lowering of distribution margins or reduced payment terms.
1. Standardized contract terms

Through a master service agreement, general contract terms can be standardized across all markets, providing for greater control and consistency. This helps to govern the relationship between the pharmaceutical company and distributor on an equal footing across markets and command consistent service levels across the region.

Contracts that are locally negotiated are overtly influenced by local dynamics and relationships that exist in each country. This can lead to varying levels of service, impacting business performance.

2. Transparency

Negotiating at the regional level also means that a formal RFP process is required to be conducted across the region for all markets. As bids come in across the region, pharmaceutical companies can compare bid quotes on a like-for-like basis, making comparison easy. In contrast, if bidding is local, it will be harder to compare across markets since the basis for quotes may differ (cost plus vs. margin vs. activity-based costing), as well as the level of granularity (e.g., by activities or channels).

3. Key steps in negotiating a regional distributor agreement in Asia-Pacific

Reassess existing operating model by country. The pharmaceutical business in Asia-Pacific is quickly evolving, impacted by numerous regional and country-specific factors, including adoption of universal health care in many markets, increased competition from local competitors and biotech companies, consolidation of government purchasing programs, and the growth of pharmacy and regional hospital chains. As a result, an operating model that was optimal for a specific market just last year may no longer represent the best choice, either currently or in the short-term future.

Ideally, pharmaceutical companies would reassess and adjust as needed their choice of operating model within each market on a regular basis to maintain alignment with rapidly changing market conditions and the company's strategic direction. Unfortunately, however, typical agreements with third-party distributors/logistics service providers (LSPs) involve 3+1 year contracts, thus committing pharmaceutical companies to a chosen operating model for at least three years. This results in significant restrictions on a company's ability to be flexible and adaptive to market conditions, but also increases the importance of reassessing and selecting optimal country-specific operating models at the time of contract renewal or renegotiation.

Consequently, the critical first step in negotiating a regional distributor agreement is for the principal (i.e., pharmaceutical company) to take advantage of this opportunity to reassess existing operating models to validate that either such models should remain, or that a change(s) is warranted. Such decision will significantly impact the expected growth rate of the business, cost structure and profitability levels in each market over the life of the new contract.

Based on recent client experiences, we are seeing that as a result of performing this analysis, many companies are determining that a change in operating model is appropriate in one or more markets. Recent examples include:

- Moving from a distributor to an agent model in Thailand due to a decline in business and margins
- Moving from a distributor to an LSP model in a number of countries, including the Philippines, where the company's business is highly concentrated with a few key accounts, thereby providing an opportunity to drive improved margins
- Moving from an agent to a distributor model across all of Asia-Pacific to accelerate growth of the business

Exhibit 2 provides a good illustration of the agent, distributor and LSP models.

4. Flexibility

The presence of a regional team leading the negotiation can aid in breaking deadlocks in local negotiations by elevating the conversation to focus on overall benefits at a portfolio level across all markets. Based on EY experience, distributors are often more willing to be flexible and negotiate when provided with options on a portfolio basis (both countries and services).
As markets increase in attractiveness (i.e., measured by size of the pharmaceutical market, therapeutic area fit and growth rate) and maturity (i.e., measured by various maturity factors, including pharmaceutical regulations, ease of doing business, value-based outcome, collection risk in the country, macro stability and predictability), principals can evolve their operating models from agent to distributor to LSP (Exhibit 3). Or, as we have recently seen with several clients, they can choose to move from a distributor to an agent model in the face of declining business and margins.

**Establish distributor assessment criteria for RFP:** Having established the optimal choice of operating model in the market, or reassessed the operating model alternatives in each market, principals need to establish a robust set of selection criteria by which to assess distributors on a holistic and uniform basis during the RFP process. Based on industry leading practices and EY experience, we have identified eight key selection criteria on which distributors should be evaluated:

**Exhibit 2**
Principals can choose from three different operating models

<table>
<thead>
<tr>
<th>Activities:</th>
<th>Logistics services</th>
<th>Distribution services</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agent</td>
<td>Delivery to distributor/LSP</td>
<td>Goods receipt</td>
</tr>
<tr>
<td></td>
<td>Main DC storage</td>
<td>Redressing</td>
</tr>
<tr>
<td></td>
<td>Regional DC storage</td>
<td>Pick pack and dispatch</td>
</tr>
<tr>
<td></td>
<td>Delivery to customs</td>
<td>Sales and marketing</td>
</tr>
<tr>
<td></td>
<td>Order taking and processing</td>
<td>Invoicing</td>
</tr>
<tr>
<td>LSP</td>
<td>Can be done by pharma or distributor</td>
<td></td>
</tr>
</tbody>
</table>

**Fee Model**
- Activity based
- Percentage of revenue

Typically done by pharma company
- Typically done by distributor/LSP/agent
- Can be done by pharma or distributor

Source: EY experience

**Exhibit 3**
Operating model choice is based on maturity and attractiveness of the market

**Key maturity factors**
- Pharma regulations
- Ease of doing business
- Value-based outcome
- Collection risk in the country
- Macro stability and predictability

**Key attractiveness factors**
- Size and pharma market/relevant therapeutic areas
- Growth rates

Source: EY analysis
Driving value and cost savings through regional negotiation of distributor agreements in Asia-Pacific

1. **Company**
   - The distributor’s credentials and track record, both in working with other principals and their general reputation in the region or local market
   - Current financial position of the distributor and ability to fund current operations and subsequent growth

2. **Coverage**
   - Product and channels: the extent of coverage across all distribution channels, including having an array of complementary products to appropriate trade sectors in the territory (including government, retail and community pharmacies, general physicians)
   - Customer base: ability to demonstrate a wide coverage of customer base and broad distribution footprint

3. **Capabilities**
   - Account management: organization and account management structure dedicated to pharmaceutical companies; local account manager allocation
   - Effective service levels (accessibility, responsiveness, commitment to service excellence)
   - Experience and deep knowledge in the pharmaceutical business
   - Ability to meet defined metrics and report monthly
   - Accurate and timely financial reporting capable of respecting principal’s accounting calendar

4. **Capacity**
   - Breadth of services: sales, customer service, order processing, inventory management, warehousing, logistics and distribution, receivables collection

5. **Costs and contract**
   - Distribution margin charged and other costs to serve (on an activity basis) for both logistics and distribution activities
   - Working capital (payment) terms

6. **Compliance**
   - Local regulatory approval know-how
   - Quality standards and control systems

7. **Continuity Risk**
   - Readiness: infrastructure and systems to transition customers in and out of the agreement
   - Robustness of transition plan to avoid loss of sales

8. **Commercial Alignment**
   - Ability to grow the business in conjunction with the principal
   - Resource allocation to scale for principals
   - Dedicated resources and plans for transition plan

*Effective management of regional RFP process:* To achieve the desired outcome, the RFP process needs to be managed effectively and efficiently. In our experience, there are three key elements to this. First, the RFP package needs to be structured to allow for consistent quotes across activities and markets.

Second, distribution spend analytics is essential to analyze historical spend by distributor and by markets. Such analytics help to pinpoint outlier markets for further analysis and understanding of market nuances to assist in the negotiation process.

Finally, bids need to be assessed through a free cash flow analysis (which incorporates impact to both P&L and balance sheet) to determine the most optimal bids. This process provides valuable insights and provides inputs for the creation of a robust negotiation strategy by market with clear targets for lower fees/terms and improved service levels.

*Establish robust distributor management framework:* A robust distributor management framework should be created with careful consideration across four parameters: process, organization, KPIs and governance. Doing so outlines the relationship structure and considerations across markets for principal and distributor, and facilitates ease of benchmarking. Adequate baselining of current practices is required to identify what works and what does not within and across markets. The baselines eventually serve as inputs to the regional contract and facilitate effective management of distributors for the benefit of the principal.

**Conclusion**

 Whether pharmaceutical companies are renewing their contracts with distributors or negotiating new ones, they should set clear goals in terms of economic benefits that can be realized and then commit to making the investments required to achieve such benefits. In our experience, companies that (i) follow the above illustrated steps, (ii) establish a steering committee of cross-functional leaders for timely decision-making and (iii) establish a dedicated project team that invests on the front end to create a robust analytical framework typically improve their negotiating positions and results.
The Pfizer-Allergan deal, potentially the largest-ever life sciences deal, was cancelled due to changes in regulations by the U.S. Treasury Department. The new regulations also effectively diminish the prospect of any future tax-inversion deals.

Total deal value in life sciences was US$88 billion in 2Q2016, up nearly 75% year-over-year (YOY). However, deal volume dipped from 2Q2015, a quarter that comprised a higher number of small-value transactions. In total value across different sectors, life sciences was third following technology, and consumer products and retail.

The 2016 life sciences M&A value is set to exceed that of 2015 as the deal value in 1H2016 has already surpassed that witnessed in 1H2015.
Abbott's big-ticket acquisition of St. Jude Medical made the medical devices subsector the largest contributor to overall industry M&A in terms of value in 2Q2016. The subsector accounted for 46% of total deal value in the quarter and reflected a whopping increase of 394% from 2Q2015. Deal value in the health research and testing segment witnessed an increase of 28% from 2Q2015. Deal amount in the other two subsectors of pharmaceuticals and biotech was up by 17% and 4%, respectively, in comparison to 2Q2015.

The medical devices subsector appears to be going through another phase of consolidation, following the high level of M&A activity witnessed in 2014. The segment posted healthy revenue growth in 2015, and this could be a key driver for the renewed M&A activity. The yet-to-close acquisition of St. Jude Medical by Abbott Laboratories for US$31 billion validates this trend.

In pharmaceuticals, the quarter witnessed a second massive asset swap after GlaxoSmithKline’s US$20 billion swap with Novartis in March 2015. In 2Q2016, Sanofi announced it would trade its ill-fitting animal health business, Merial, for Boehringer Ingelheim’s consumer brands. With this swap, Boehringer Ingelheim is expected to become the second largest animal health company globally, while Sanofi will achieve a simplified corporate structure and also bolster its consumer health business in the wake of major patent expiries of Lantus. Asset swaps create a win-win situation for both the entities and hence big pharma appears to be embracing this new M&A model.
In contrast with the global picture, Asia deal value slumped in 2Q2016, declining 71% YOY to US$7.7 billion. The number of deals came down to 172 from 201 in 2Q2015. Asia accounted for more than a third of the global deal-making by count. In terms of value, however, the region’s contribution to global industry M&A stood at only 6%, thus implying that the region is largely driven by small-value transactions.

The subsector deal-making in Asia also saw a downward trend, except in health research and testing. Transaction value in this subsector jumped by 42% YOY in 2Q2016, primarily driven by majority acquisition of China-based DHY & Co by Ningbo Free Trade Zone Yifan Medical Investment Co Ltd. Meanwhile, all the remaining three subsectors witnessed a sharp decline in terms of deal value. In fact, pharmaceuticals recorded its lowest deal value over the last eight quarters, marking a sharp drop of 70% YOY. Biotech and medical devices also posted steep YOY declines of 93% and 53%, respectively.
Mainland China accounted for as much as 75% of the total deal value in 2Q2016. This was driven by nine deals worth over US$100 million each. South Korea was a distant second, contributing only 10% of the transaction value in the quarter. By count, Mainland China alone accounted for 51% of Asian transactions in the quarter. South Korea and Japan made up 35% of Asian deal volume.

As seen in 2015, China M&A deals in 2Q2016 were largely domestic consolidation and included many sub-billion-dollar deals. On the whole, the majority of the deals were within the region and interestingly, there were no major deals involving an acquirer based outside of Asia in the current quarter. Continuing consolidation signals the maturation of domestic players; competition for assets will only increase, limiting the M&A window for multinationals.

In 2Q2016, there was only one multibillion-dollar deal, in which China-based Zhuhai Winbase agreed to acquire the entire share capital of Toshiba Medical Systems Corp from its existing joint venture partners.

In the previous quarter, China-based biopharmaceutical company Sinovac Biotech was targeted by two separate investor groups – one led by the company CEO and current investor group, the other an outside consortium led by funds such as Peking University V-Ming (Shanghai) Investment and Heng Feng Investments (International). Similar private investments were also made in 2Q2016 in China.

### Top 10 Asia life sciences M&As, 2016

<table>
<thead>
<tr>
<th>Country</th>
<th>Year</th>
<th>Target</th>
<th>Acquirer</th>
<th>Value (US$m)</th>
<th>Deal description/rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mainland China</td>
<td>1Q</td>
<td>Toshiba Medical Systems Corp</td>
<td>Canon Inc</td>
<td>5,900</td>
<td>Canon agreed to acquire the entire share capital of Toshiba Medical Systems Corp</td>
</tr>
<tr>
<td>South Korea</td>
<td>2Q</td>
<td>Shandong Weigao Orthopaedic</td>
<td>Zhuhai Winbase Intl Chem Tank</td>
<td>1,109</td>
<td>Pending</td>
</tr>
<tr>
<td>Japan</td>
<td>3Q</td>
<td>Guangxi Wuzhou Zhongheng</td>
<td>Guangxi Investment Group</td>
<td>590</td>
<td>Guangxi Investment acquired a minority stake of 20.52% in Guangxi Wuzhou</td>
</tr>
<tr>
<td>Japan</td>
<td>1Q</td>
<td>Sinopharm Weiqida Pharm</td>
<td>Shanghai Shyndec Pharm</td>
<td>504</td>
<td>Shanghai Shyndec Pharm has signed an agreement to acquire Sinopharm Weiqida Pharm from China National Pharmaceutical Industry Corp and Han Yanlin</td>
</tr>
<tr>
<td>Mainland China</td>
<td>1Q</td>
<td>China Natl Accord-Assets</td>
<td>Shanghai Shyndec Pharm</td>
<td>493</td>
<td>An equity-based transaction for acquiring the assets of China National Accord Medicines Corporation</td>
</tr>
<tr>
<td>Mainland China</td>
<td>2Q</td>
<td>Shanxi Powerdone</td>
<td>Shanxi CY Pharm</td>
<td>470</td>
<td>Shanxi CY has signed an agreement to acquire Shanxi Powerdone from Harbin Gloria Pharmaceuticals</td>
</tr>
<tr>
<td>Mainland China</td>
<td>1Q</td>
<td>Sinovac Biotech</td>
<td>Investor Group</td>
<td>421</td>
<td>Offer to acquire the remaining stake by a management-led investor group</td>
</tr>
<tr>
<td>Mainland China</td>
<td>1Q</td>
<td>Sinovac Biotech</td>
<td>Consortium of Investors</td>
<td>362</td>
<td>Consortium made a proposal to acquire Sinovac in February 2016</td>
</tr>
<tr>
<td>Mainland China</td>
<td>2Q</td>
<td>LF Distribution</td>
<td>Neosota</td>
<td>350</td>
<td>Pending</td>
</tr>
<tr>
<td>Mainland China</td>
<td>2Q</td>
<td>Nanjing Pharmaceutical</td>
<td>Investor Group</td>
<td>308</td>
<td>Consortium of investors agreed to raise their stake to 34.29% from 8.96%</td>
</tr>
</tbody>
</table>

Source: Thomson ONE, Capital IQ
IPO activity was comparatively muted in 2Q2016. Eight Asia-headquartered companies raised a total of US$355 million in IPOs in the quarter, an 88% YOY decline. Similarly, the number of IPOs dropped from 22 in 2Q2015 to 8 in 2Q2016. 2Q2015 was among the most active quarters over the last two years.

Source: Capital IQ
Of the total eight IPOs, three were raised by South Korean companies. One company each based in Bangladesh, China, Vietnam, Malaysia and India closed an IPO during the quarter. The South Korean companies accounted for 67% of the total capital raised in the quarter.

While the IPO window in the US and Europe showed signs of closing in 2015, it was thrown wide open in Asia. Fifty-five Asia headquartered companies raised US$4.4 billion in 2015, an increase of 74% over the previous year, and just shy of the US$5.2 billion raised in the US and Europe. Spurred by the largest IPO globally in 2015 – China’s 3SBio – biotech companies garnered the most amount of capital (US$1.78 billion), directly followed by pharmaceuticals (US$1.66 billion) and medical technology (US$915 million).

In 2Q2016, medical device companies accounted for nearly 59% of the total capital raised. Pharmaceutical companies raised 32% of the capital in the quarter while there was only one IPO in the biotech subsector.

Of the total eight IPOs, three were raised by South Korean companies. One company each based in Bangladesh, China, Vietnam, Malaysia and India closed an IPO during the quarter. The South Korean companies accounted for 67% of the total capital raised in the quarter.

Three IPOs in 2Q2016 raised over US$50 million each. The two largest were both by South Korean medical device companies, ST Pharm and Rayence. The third-largest was by Bangladeshi firm Acme Laboratories, highlighting the growing importance of that country in the Asian pharmaceuticals market.
Appendix

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 EY’s full library of industry insights and reports.

Beyond borders 2016 global biotechnology report
The US and European global biotechnology clusters set new records in key financial barometers such as revenue, net income, financing and dealmaking. However, growth slowed in many of these indicators, followed by a swift erosion of public investor interest. Despite their impressive performance in 2015, commercial-stage biotechs face numerous challenges, particularly as pricing pressures rise due to payers’ increasingly aggressive cost-containment efforts. To restore investor confidence and set the stage for future growth, biotechs must demonstrate the value of their products to payers, physicians, patients and the public.

How the new EU Medical Device Regulation will disrupt and transform the industry
Sweeping reform of the rules that govern the medical device industry in Europe represent one of the most disruptive changes to affect the global medical technology sector in recent times. When the European Medical Device Regulation (EU MDR) replaces the current set of directives, companies will have three years to comply with a broad swathe of new rules for almost every kind of product in the medical device spectrum. The aftermath of the shake-up will be a stronger, more accountable medtech industry which may look substantially different to today’s.
**Life Sciences Global Corporate Divestment Study**

EY’s Global Corporate Divestment Study (GDS), focuses on the lessons corporates can learn from private equity firms — from improving portfolio reviews to divestment execution. The study is based on interviews with 900 global C-suite executives and 100 PE executives, plus external market data.

**Firepower index and growth gap report 2016**

Deal tectonics: at the fault line of growth goals and competitive pressures, mergers and acquisitions (M&A) in the biopharmaceutical industry skyrocketed in 2015, with the value of 2015 announced deals totaling more than US$300 billion, a new record for the industry. As the specialty pharmaceutical sector sees its ability to pursue large acquisitions evaporate, long-promised organic growth from big pharma new drug launches has finally arrived. But a renewed focus on value-based pricing, staunch competition across key therapeutic battlefields and consolidating payer clout may weaken the industry’s ability to reach revenue targets for both new and legacy therapeutics.

**Protecting information at life sciences companies**

How to safeguard the assets that matter most: as the life sciences sector continues to become more data-driven, cyberthreats and breaches of data systems are becoming an increasing challenge. Recent incidents involving the loss of protected health information and sensitive information at pharmacies, health systems, providers and payers have shown that attacks continue to become more sophisticated. These attacks also significantly impact an organization’s bottom line, brand and reputation.

**Pulse of the Industry medical technology report 2015**

In EY 8th annual Pulse of the Industry medical technology report reviews the noteworthy financial performance, deal-making and financing trends that surfaced in the last 12 months and discusses the future implications of these trends.

**EY Life Sciences Tax capabilities: Asia-Pacific and Japan**

EY is continuing to make significant investments in the life sciences sector in Asia-Pacific and Japan. Within Tax, such investments have included the further development of an extensive life sciences tax infrastructure and tax leadership team comprised of designated tax sector leaders and specialty practice resources at the Area, Region and member firm levels. These resources serve as the backbone of EY’s broader Asia-Pacific and Japan Life Sciences tax network, as well as designated single points of contact and coordination for EY account teams and client personnel.
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Title and contact information for various life sciences leaders from different regions, including Greater China, ASEAN, South Korea, India, and Japan, with their respective roles, locations, email addresses, and phone numbers.
# EY Life Sciences service line leaders

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### India

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