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Market insights: Asia-Pacific and Japan

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

**ASEAN**
- Malaysia
- Indonesia
- Vietnam
- Thailand
- Singapore
- Australia
- China
- India
- Japan
- South Korea

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### Key highlights

- **India and China have introduced initiatives to strengthen domestic manufacturing.** The Indian government has prioritized a “Make in India” campaign aimed at building drugs and medical devices. In China, biopharma and advanced medical devices have been positioned as the priority sectors under the government’s Made in China 2025 plan. Meanwhile, 12 countries, including Japan, Malaysia, Singapore and Vietnam, have signed the Trans-Pacific Partnership. This pact will help improve the export potential of these countries by reducing import barriers.

- **The government continues to promote local innovation, primarily through increased funding support.** For example, the Australian government has recently announced plans to invest US$1.84 million in a biomedical research fund to help commercialize breakthrough discoveries. Japan has also undertaken several measures to boost innovative research. This includes a premium for innovative drugs and setting up funding agencies that promote R&D in pharmaceuticals and medical devices.

- **Curbing health care expenditures, in particular drug prices, is another pivotal area for many nations in the Asia-Pacific region.** Both China and India have revisited their pricing policies to impose stricter controls. Japan, meanwhile, has been the most aggressive in its reforms, announcing its decision to impose direct price controls on “high-selling” drugs. At the same time, the country has set ambitious targets for increasing generic drug utilization.

### ASEAN

**Malaysia: Focus on increasing the export capabilities of the industry**

The signing of the Trans-Pacific Partnership (TPP) has put Malaysia in the spotlight. Recall that the legislation gives innovators companies an additional period of data exclusivity for patented products when there are regulatory delays. This statute has angered patient advocates in Malaysia who believe the law will delay access to affordable generics. The government, meanwhile, argues it can use compulsory licensing to make sure patients have access to needed medicines.

Since it reduces trade barriers, the TPP should benefit exporters of both drugs and medical devices. In particular, the pact will encourage the local production of medical devices, especially higher-value technologies. Malaysia, striving to become the regional export hub for medtech, has recently approved 11 medical technology projects with an investment of more than US$120 million.2

Like South Korea, Malaysia also wants to become a leader in the halal drug manufacturing. As of August 2015, the country had nearly 110 halal-certified pharmaceutical manufacturers.1 However, lack of formal guidelines is acting as an impediment for the players operating in this field.6

Important recent regulatory shifts include new medtech guidelines related to mandatory incident reporting, device labeling and harmonization with foreign regulatory assessments. In addition, the ministry of health is studying the efficacy of the world’s first licensed vaccine for dengue, Sanofi’s Dengvaxia.5, 6

**Indonesia: Coping with the increased demand through domestic manufacturing**

Indonesia’s universal health care plan has sparked demand for pharmaceuticals and medical devices. However, the shortage of locally manufactured drugs, along with rising import costs, hampers the progress of this plan. Consequently, the government is planning to introduce economic stimulus packages to strengthen domestic production, especially of raw materials. In addition, the government is contemplating relaxing foreign ownership laws. Meanwhile, domestic companies in Indonesia continue to boost their manufacturing capacity to keep pace with the increasing demand.

Building a sustainable health system has become a priority as the country implements its universal health care programs. To rein in escalating costs, the government has proposed a co-payment initiative that will allow the private insurers to supplement the universal health care policy.8

The Indonesian government intends to participate in the TPP.10 As in Malaysia, Indonesia’s pro-TPP stance has resulted in protests about possible delayed access to generics. On the innovation front, Indonesia is making progress in stem-cell research. Its Stem Cell and Cancer Institute will initiate preclinical trials for allogeneic stem cells (cells that come from another person) for treatment of osteoarthritis sometime later in 2016.11
Vietnam: Emphasis on immunization amid increasing quality concerns
Vietnam has stepped up its efforts to strengthen its extended program on immunization, which expands pediatric coverage and enhances quality of inoculations.12 This is expected to offer greater opportunities to both foreign and domestic manufacturers with high-quality vaccines.

On the regulatory front, the ministry of health has launched an online drug registration service to ease administrative procedures, while tightening drug quality standards.13, 14 In addition, the government is developing a draft decree to more strictly manage medical devices.15

Thailand: Moving toward direct price controls and tackling the growing protests on TPP
The country is attempting to fix nonuniform pharmaceutical pricing in public and private hospitals.16 One solution for this includes the government’s proposal to include drug pricing within the approval framework for patented drugs, introduced as part of Thailand’s drugs bill. This will require innovator companies to submit their pricing structures as part of the registration process. In another move, Thailand’s Internal Trade Department, Public Health Ministry and the Food and Drug Administration (FDA) have mandated the display of drug prices on the packaging to stop private hospitals from overcharging patients. These moves are being strongly opposed by various parties, including political outfits, private hospitals and multinational pharma companies. These bodies argue that the different cost structures of private and public hospitals justify the differential pricing and that bureaucracy may increase if pricing details are included in the approval process.17

From an intellectual property aspect, Thailand’s signing of the TPP is worrying a large faction of the local industry and consumer groups. The clause of “data exclusivity” (DE) after patent protection is the biggest challenge that the local industry has cited. DE will allow the innovator companies to extend its exclusivity period and thus hamper the growth of local generics players and result in increased drug prices.18 It may also limit the country’s ability to issue compulsory licenses.19

In the biotech industry, the focus is on developing hubs in the country. Currently, a panel of members is creating a national strategy for biotech and to attract investments into the sector.20

Singapore: Providing funding support to nurture novel start-ups
Singapore is focused on bolstering its R&D expertise. One of the key areas here is indigenous drug development of novel biologics. Working with Duke University, Singapore’s Agency for Science, Technology and Research (A*STAR) has discovered its first clinical candidate, ETC-159, an anti-cancer agent.21 Singapore is also increasing funding for translational medicine: via the National Research Foundation of Singapore, the government has allocated US$13 billion over the next five years to advance academic research into the commercial setting.22 Most of the funds will go to collaborative laboratories that conduct research; funds will also be used to train scientists.23

Singapore has also made two major investments to spur growth of its domestic medtech industry.24 EDBI, the corporate investment arm of the Singapore Economic Development Board, has invested an undisclosed sum in Massachusetts-based life science tools company Rapid Micro Biosystems. In another initiative, the homegrown accelerator JFDI has partnered with Germany’s Medical Innovations Incubator to augment medical technology start-ups. Both of these initiatives are expected to result in technology transfer and job-creation opportunities in Singapore.25 Singapore is also investing in digital health opportunities. EDBI has joined forces with Philips to jointly invest in digital health companies that are working on population health management tools for the Asian market.26 Meanwhile, the pan-Asian insurance group AIA and Asian market.26 Meanwhile, the pan-Asian insurance group AIA and Japanese tech builder Konica Minolta have formed a new Singapore-based incubator for digital health companies.27

Market insights: Asia-Pacific and Japan

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Australia

Reforms to fuel industry growth and improve accessibility appear to be the government’s near-term agenda.

After several rounds of negotiations over 10 years, the Trans-Pacific Partnership (TPP) was finalized in October 2015. It establishes a preferential trade zone among 12 member countries: Australia, Brunei, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, the US and Vietnam.27 The trade pact is a victory for the Australian government as it restores the five-year patent protection term for biologics, with a provision for extending this period.28 At the same time, the deal paves the way for increasing exports. Note that changes in import tariffs used to protect the interests of the local companies might negatively impact the domestic industry.29

Australia is taking strides to improve its R&D environment. The nation has identified biotechnology as a potential future growth opportunity. The government has recently announced plans to invest US$184 million in a biomedical research fund to help commercialize breakthrough discoveries.30 The Biomedical Translation Fund is expected to become operational in 2016. Similarly, private investors have set up a Medical Research Commercialisation Fund worth US$139 million.31

To improve patient access to medicines, the Australian government has earmarked US$1 billion in subsidies for hepatitis C drugs such as Sovaldi (Gilead), Harvoni (Gilead), Daklinza (Bristol-Myers Squibb) and Ibavyr (Pendopharm).32 As a result of these subsidies, which are effective March 2016, treatment costs could fall to just AU$37.7 (vs. AU$100,000) for the members (patients) of the country’s Pharmaceutical Benefits Scheme (PBS).33 To create budget to cover the hepatitis C medicines, the federal government has removed 17 nonprescription drugs from the Pharmaceutical Benefits Scheme, a step that is forecasted to save roughly half a billion Australian dollars over the next five years.35

Medical marijuana is also emerging as a new opportunity for Australian life sciences companies. In October 2015, the federal government lifted its ban on growing cannabis for medical purposes and is currently amending its Narcotics Drugs Act.36 The government also plans to establish a body for regulating cultivation and importation of the drug.37 Victoria is set to become the first state to legalize marijuana cultivation, with other states also expected to follow this path.
China

The Chinese life sciences industry is in the middle of major health care reforms. Streamlining the regulatory environment, improving quality, curbing health care costs and boosting the domestic industry are the key drivers of these reforms.

The China Food and Drug Administration (CFDA) has instituted several initiatives designed to expedite the drug approval process. The integral aspects of the reforms include:

- Simplifying approval of clinical trials
- Allowing simultaneous country clinical studies by multinational corporations
- Expanding the fast-track approval to many new categories of drugs (e.g., pediatric/geriatric drugs, drugs treating China-prevalent diseases and internationally innovative drugs)

These efforts are designed to reduce the drug approval time frame from 6-8 years to 2-3 years. By 2016, the CFDA aims to eliminate the current backlog of 18,000 drug applications. At the local level, provincial governments are working to reduce the contribution of drug sales to hospitals’ revenue. As part of this initiative, they have already implemented a zero markup policy on drug sales for the hospitals in 100 major cities.41 These reforms separate drug prescription and dispensation while increasing medical service fees to compensate for lost drug sales.

These reforms are designed to promote the domestic industry. The government is encouraging local innovation by launching a three-year pilot program, the Marketing Authorization Holder (MAH) system, across 10 provinces.44 Under MAH, all domestic R&D institutions and research personnel of Chinese nationality can also file drugs for approval. Apart from MAH, the government has deemed biopharmaceutical and medical device manufacturing as high priority products for its “Made in China 2025” initiative.45 To further boost the domestic industry, authorities are also offering incentives for hospitals to use domestically produced medical devices.46

Apart from these reforms, increasing health insurance coverage continues to be a priority in China. In August 2015, the country released guidelines on full implementation of critical illness insurance. Through its expansion, the government aims to improve affordability by reducing the out-of-pocket ratio from 34% in 2014 to less than 30% by the end of 2017.47

Pricing reforms are another priority in China as the government aims to reduce overall health care costs. Provincial tenders now occur annually, and the CFDA’s role is limited to monitoring—not setting—prices.41 These changes create an opportunity for pharma to interact directly with hospitals, empowering local health systems to negotiate pricing.42

Market insights: Asia-Pacific and Japan

Adapt or fail: changing models in global medtech

As published in MedTech Strategist, Parthenon-EY’s Dan Shoenholz and Keyuri Shah outline strategies medical device companies can use to succeed in a new health care landscape or risk being overcome by change.

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, cyberattacks and breaches of data systems are becoming an increasing challenge. Recent incidents involving the loss of protected health information and 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’s 8th annual Pulse of the Industry medical technology report, we review the noteworthy financial performance, deal-making and financing trends that surfaced in the last 12 months and discuss the future implications of these trends.

EY’s 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.

Market insights: Asia-Pacific and Japan
India

An increasing focus on “Make in India” and growth of online sales are shaping the dynamics of the industry.

With the Make in India campaign, the country aims to strengthen its domestic capabilities of manufacturing of active pharmaceutical ingredients (APIs) and medical devices. After convening a task force, “the Katoch Committee,” India created reforms aimed at promoting API manufacturing, simplifying foreign investment, awarding tax benefits and fostering industry-academia relationships.46

On the medtech front, the government is building its first dedicated industrial park in Andhra Pradesh. In a separate effort, the Department of Industrial Policy and Promotion and the Ministry of Commerce hope to raise at least US$50 billion in direct foreign investment for medical devices. To streamline device creation and approval, the government has also prioritized creating medtech-specific regulations.49

As India puts reforms in place to encourage manufacturing capabilities, it is also focused on enhancing the credibility of its exported products. For instance, it has created a trace-and-track system for exported drug formulations.52 All drugs manufactured by non-small-scale industry will need to adhere to this system by 1 April 2016. To strengthen quality control, India’s Central Drugs Standard Control Organization (CDSCO) plans to set up a Central Drug Testing Laboratory and build offices in all states to ensure proper implementation of regulations.53 CDSCO is also recruiting additional drug inspectors to perform quality checks. On the post-market front, the government is setting up new adverse drug reaction monitoring centers under the Pharmacovigilance Program of India (launched in early 2015).52

Improving affordability continues to be a key requirement in India. The country is extending the pricing controls used for pharmaceuticals to imported medical devices such as cardiac stents, pacemakers and implants.54 The central government also plans to expand the Jan Aushadhi program, which provides unbranded generic versions of 439 life-saving medicines and 250 medical devices at lower prices through Jan Aushadhi stores.55 It has also formed a public-private task force to ensure universal access to quality health care by 2030.55

On the biotech front, the government has released its National Biotechnology Development Strategy 2015–2020 to establish India as a world-class bio-manufacturing hub, and the CDSCO is revising its biosimilar guidelines.55, 56

As in other countries, systems to simplify the regulatory approval process are also underway. CDSCO has introduced an IT-enabled system to speed drug approval applications and improve clinical trial monitoring.57 The union health ministry has abolished conducting repeat preclinical or toxicity studies on animals if similar data from another country have been submitted.58

The rise of online medicine sales is yet another area garnering a lot of attention. While the government is developing guidelines to regulate this new segment, the industry associations (e.g., the All India Organization of Chemists and Druggists and the Indian Medical Association) are not happy with this growing trend. A formal regulatory framework that protects the rights of stakeholders and guides online pharmacy sales is urgently needed.
Japan
Proposed pricing controls for “high-selling” drugs haunt international drugmakers. Ambitious generic targets set by the government are stirring up the market.

To rein in health care spending, the Japanese government has undertaken several measures aimed at reducing drug prices. The most recent one is a controversial rule to reduce prices of “high-selling” drugs. As part of the rule, if a product’s annual sales are in the range of ¥100 billion–¥150 billion and its actual sales are at least 1.5 times projected sales, it will face a price cut of up to 25%. If the drug generates sales of over ¥150 billion and stands at 1.3 times its sales outlook, then it will face a price cut of 50%. Industry bodies have expressed strong opposition to this decision, terming it arbitrary, unreasonable and counter to the government’s agenda of promoting innovation. This rule will most certainly affect the current pricing strategy of many of the long-listed medicines, which have seen strong price spikes in Japan.61

At the same time, the government aims to increase the volume of generics prescribed from 54.7% of all medicines to 80% by 2020.61 Achieving this target will come at the expense of the long-listed (off-patent) branded drugs, which form a significant part of the business mix of several pharmaceutical companies in Japan. The pressure on the long-listed drugs will have several implications for Japanese pharma companies. Midsize and small companies with significant exposure to the Japanese market will obviously be more affected than the larger Japanese companies that have a better international mix.

Replenishing the R&D pipelines will become a key priority to offset the losses from long-listed drugs. To bolster pipelines, M&A is expected to increase among domestic Japanese pharma. This scale will also be important, as companies face pressure to globalize to reduce their dependence on in-country drug sales. Increased generics utilization will also have ramifications for drug distributors, which anticipate increased inventory and transaction costs as a result of increases in both the number of suppliers and products carried. As Japanese distributors deal with this new dynamic, identifying new business models and maintaining profitability will be a priority.

Although the government is keeping a tight leash on drug prices, it is investing to improve the regulatory infrastructure. The Pharmaceuticals and Medical Devices Agency (PMDA) is building large databases to collect and analyze clinical data and real-world medical data, for development of more effective post-marketing safety measures. To meet these requirements, pharmaceutical companies will need to make some adjustments in their IT systems. For example, the drugmakers will need to submit clinical data required for marketing authorization in the Clinical Data Interchange Standards Consortium format. The PMDA is also looking to invest ¥1.32 million to recruit 13 new full-time PMDA employees to increase the agency’s regulatory and safety review capabilities.62

Bolstering innovation is also a key priority for the government. It has established the Agency for Medical Research and Development (AMED), a Japanese version of the US’s National Institutes of Health and the UK’s National Institute for Health Research.62 The new agency will support and fund new product development in both the pharma and medical devices sectors. The AMED will receive budgetary funding of ¥126.5 billion in FY16 (up 1.3% from ¥124.8 billion in FY15).63 The Ministry of Health, Labor and Welfare has launched a forum in the form of a private panel for the health minister to promote health care start-ups in the country. The government has also decided to continue with the innovation premium for innovative drugs that satisfy certain conditions.

Top Asia-Pacific and Japan IPOs, 2015

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<tr>
<th>Company</th>
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While the IPO window in the US and Europe showed signs of closing in 2015, it was thrown wide open in Asia-Pacific. Fifty-four Asia-Pacific-headquartered companies raised US$4.4 billion in 2014, 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$1.75 billion) and medical technology (US$915 million).

Chinese life sciences companies dominated the Asia-Pacific IPO market with 25 public offerings for more than US$3.1 billion, or roughly 70% of all capital raised in the region. Of the 17 companies that raised more than US$100 million, 11 are based in mainland China. South Korea finished a distant second with 12 IPOs for US$567 million, while Australia and Japan each had six IPOs.

South Korea

Building biosimilars and R&D capabilities are the key short-term growth drivers of the industry.

South Korea is racing to become the biosimilars capital of the world and aims to have 22% of global biosimilar market share by 2020. In particular, two companies — Celltrion and Samsung Bioepis — are changing the face of the global biosimilars market. Indeed, Samsung Bioepis recently won EU approval for the first Enbrel biosimilar, Benepali. It also has biosimilar versions of Remicade, Herceptin, Lantus and Humira in late stages of development. Depending on the strength of the equity markets, Samsung Bioepis plans to raise up to US$1 billion via a listing on the US exchanges in 2016. Celltrion also won a nod from European regulators for Remsima, a Remicade biosimilar being reviewed by the U.S. Food and Drug Administration. Like other countries in the region, innovation/R&D is a top priority for South Korea. The Ministry of Science, ICT and Future Planning has announced its plans to invest US$68.5 million in the biotech sector over the next three years. This includes providing financial, marketing and business development support to 10 home-grown biotech and medical device companies. To develop R&D expertise, domestic biosimilars have pledged to raise their R&D expenditure by 10%-20% in 2016. Many companies hope to follow the example set by Hanmi Pharmaceuticals, which in 2015 signed six licensing deals and collaborative projects, including a US$4.2 billion diabetes deal with Sanofi.

Outside of biosimilars, Korean pharmas continue to look for growth opportunities in new arenas. One area generating much focus is halal-certified drug manufacturing. Halal-designated products are made using ingredients and manufacturing processes that adhere to Islamic dietary law. Ildong Pharmaceutical is one of the leading players in this new field, becoming the first Korean company to obtain halal certification from the Korea Muslim Federation.
The debate about drug pricing has reached a fever pitch. As populations age and the incidence of chronic disease continues to rise, governments, private payers, health systems and patients around the globe are searching for solutions to make health care spending sustainable.

The economic drivers that guide the pricing of telecommunications, mobile phones or clothing don’t apply to the pricing of drugs. There are multiple reasons for this, including market exclusivities and a disconnect between the economic buyer (the payer) and the end user (the patient). But the primary reason for high drug prices is the structure of the current system, which relies on unit-based pricing, a methodology that is too one-dimensional for the current needs of the marketplace. This structure has resulted in incentives that encourage biopharma companies to make pricing decisions that are driven by what is possible rather than what is rational.

As a result, biopharma companies have taken the following approach when charging for their drugs: establish a public, unit-based list price for the product and then negotiate, on a market-by-market basis, specific, undisclosed discounts or rebates based on in-country regulations and health technology assessment (HTA) criteria. This approach has had two benefits: 1) it is simple to implement; 2) it preserves pricing flexibility, especially in markets that use reference pricing.

A model under threat
In the past, this lack of pricing transparency worked to manufacturers’ advantage. However, in today’s environment, where the list prices of drugs are high and publicly available, the public doesn’t discriminate between the perceived cost of a medicine and the amount actually spent. Moreover, the heterogeneity of drug costs globally — for instance, certain cancer drugs can cost half as much in Europe as in the US — reinforces perceptions that pricing practices are “unfair,” fueling the industry’s negative reputation.

Biopharma’s historical pricing model is now under threat. One reason: the temporal misalignment between when drug costs occur and when their benefits are realized complicates drug pricing decisions. With very few exceptions, the benefits associated with a therapy won’t be measurable until many years in the future. However, companies must still be rewarded for the difficult and risky work of innovation, requiring high up-front price tags for many specialty products. Resource-constrained payers, meanwhile, need drug utilization policies that are consistent with tight annual budget cycles.

Hit hard by their own budget constraints, payers are therefore adopting new restrictions that limit the use of newly launched products. As multiple drugs with similar indications and clinical impact compete for share in therapeutic battlefields such as oncology or diabetes, it can be difficult to differentiate newer entrants from existing players. A flood of biosimilars creates additional downward price pressure in categories that have historically enjoyed pricing flexibility.

In this environment, steep discounts and aggressive rebating strategies to establish market access have become the norm in competitive markets. The more comparable the drugs – or the greater the number of competitors in a particular market – the greater the likelihood payers will act aggressively to rein in drug costs.

We’ve seen it already, especially in the Asia-Pacific region, where curbing health care expenditures is a priority for many nations. Both China and India have revisited their drug pricing policies to impose stricter controls. Japan, meanwhile, has been the most aggressive in its reforms, announcing it will impose direct price controls on “high-selling” drugs and change incentives to bolster generic use. Industry groups have already expressed strong opposition to the direct price controls, calling them “arbitrary” and in conflict with the Japanese government’s agenda to promote innovation. One class of drugs most likely to be affected by the policy shift: the next-generation hepatitis C medicines, which have had strong launches in Japan.

A drop-off in IPOs in the final quarter of 2015 may signal the beginning of the end for this latest bull run. Regardless of how the IPO market fares in the coming months, it is worth remembering that 78 biotechs went public in 2015, compared with 95 (the all-time record) in 2014. Biotechs raised US$5.2 billion in those 2015 debut offerings, the industry’s third-highest IPO total ever. The average IPO deal value was comparable to 2014’s (US$67 million vs. US$71 million). Top IPO earners were NantKwest in the US (US$238 million) and Adaptimmune in Europe (US$191 million). Most of the IPO activity occurred in the US: 34 biotechs raised at least US$50 million and 13 raised at least US$100 million.

To access more in-depth insights and data from the financing article in Beyond borders 2016, please visit Vital Signs - EY’s perspectives on life sciences, at ey.com/vitalsigns.
The number of early stage venture rounds reached a new high-water mark in 2015, at 235. These seed and Series A financings raised a combined US$3.5 billion, also a new record. Boston Pharmaceuticals, which raised the largest-ever biotech seed investment when it pulled in US$560 million in November 2015, won the honors for the largest venture round of the year. Net prices of the Gilead products dropped as the biotech sought deals that would keep the products on payers’ formularies.

Value is in the eye of the beholder

Gone are the days when the primary buyer of a drug was the individual physician. In the current cost-constrained environment, payers, whether government or private, have much more influence, prioritizing budgetary certainty and the development of evidence-based protocols that enable the delivery of the highest value of care to the greatest number of people. Although patients and caregivers continue to place a high priority on advancements that improve quality of life, the current environment means such innovations may result in nice-to-have, not need-to-have products, depending on how much they cost.

It's still true that stakeholders value product efficacy and safety. But as with improvements in quality of life, these attributes are now necessary but not sufficient. Thus, drivers of value long embraced by European health systems have emerged as drivers of acceptability around the globe:

- Significant differentiation compared to the standard of care
- The ability to identify subsegments of the population most likely to benefit
- Real-world outcomes
- Up-front affordability of the medicine
- Total cost to the health care system
- The time required to achieve cost savings

One of the critical challenges in developing balanced pricing strategies stems directly from the fact that there is no single definition of product value. Even in Europe, where HTA bodies evaluate clinical and cost-effectiveness evidence, there is no standard definition of health care value. Not only do the value formulas vary from country to country, but how those formulas are implemented within a given health care system varies. As a result of the financing, Immunocore was valued at US$1 billion.

New pricing models needed

Intuitively, biopharma companies realize that their pricing strategies must take into account how other health care stakeholders define product value. Executives also understand that the current status quo can't continue forever. Yet, too often, companies still assemble pricing plans that rely on outdated methodologies and fail to account for the downstream consequences the decision may have on the deployment of care.

What is needed is a more systematic approach that optimizes pricing flexibility across the different markets where the product will be sold. To work, this approach must be grounded in an honest assessment of how other stakeholders, including the payers, value the medicine’s different features. Moreover, companies must acknowledge that because of cost constraints, infinite resources to support access to innovation no longer exist. Thus, biopharmaceutical companies will be able to design smarter commercial strategies that lead to greater value creation only if they integrate their customers’ value drivers into their pricing decisions at the outset.

In this context, the definition of the payer will also shift. Going forward, the payer may be a traditional insurer – either the government or a private organization. But it could also be a physician group that is at risk financially for its prescribing decisions or even an individual patient. Indeed, in an era when the industry has moved to tailoring medicines to individuals’ needs based on specific genetic or environmental information, these new pricing approaches, if applied smartly, will allow companies to design pricing arrangements that are tailored to the individual needs of the payer in question.
Effective trade policies and capabilities are critical for enabling companies to access markets quickly, effectively and cost efficiently while at the same time maintaining compliance with a myriad of regulatory, customs and indirect tax requirements. Those companies with best-in-class trade capabilities often enjoy a significant competitive advantage compared to their peers. Historically, however, many companies operating in Asia have struggled to achieve desired levels of trade effectiveness and performance or, at the very least, have been unable to identify and capitalize on available opportunities to significantly reduce cost and mitigate risk in their supply chains. This inability to identify and capitalize on such opportunities is often present even at companies with highly effective trade capabilities. That’s because the limitations are often attributable to factors outside the control and visibility of the company’s internal trade and finance functions. For many companies operating in Asia, such limitations have related principally to regional complexity and supply chain visibility.

The high degree of operating complexity encountered throughout Asia is one reason it’s more difficult to achieve desired levels of trade effectiveness in this region. Unlike in Western markets, there isn’t the same degree of harmonization for regulatory processes, customs procedures and indirect tax requirements. These different requirements, coupled with often restrictive trade barriers, increase the complexity and risk of doing business in Asia. That complexity and risk is also heightened by a lack of standardization in accepted local business practices and ways of working. In such an environment, it is easier to misstep, elevating the level of business risk. In addition, it is often more difficult to identify and quantify areas of the potentially significant opportunity.

Supply chain visibility – or lack thereof – is another reason why achieving trade effectiveness in Asia is so challenging. Lack of access to accurate and comprehensive trade data prevents many companies from being able to accurately define, visualize and analyze their import and export transactions. As a result, many companies have to make decisions based on what they believe is happening rather than what is actually happening. Unfortunately, there can be significant gaps between these two states. Historically, such gaps have resulted principally in lost opportunity. In today’s highly fluid and evolving regulatory and tax environment, however, such gaps are becoming more likely to result in costly business risks. Such risks include potential underpayment of customs duties and indirect taxes, exposure to underpayment penalties, financial statement errors and reputational risk.

The good news is that processes and tools are now available to help companies overcome these historical challenges. Within the last six to eight months, significant innovation has been made in approaches for obtaining accurate and comprehensive trade data. This access to data, combined with advancements in trade analytics tools and methodologies (i.e., “trade analytics”), is enabling companies to quickly achieve significant improvements in their trade effectiveness. Such improvements have resulted in substantial prospective and retrospective cost savings, trade flow efficiencies, and opportunities to proactively identify and mitigate areas of potential controversy and exposure.

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Bars to trade effectiveness

One of the most significant barriers that companies encounter when attempting to drive trade effectiveness is poor supply chain visibility (i.e., an inability to accurately define, visualize and analyze their import and export transactions). This inability results in large part from a lack of access to accurate and comprehensive trade data. Without access to this data, companies are much less likely to be in a position to identify and capitalize on available opportunities to reduce
For the second year in a row, the biotechnology sector’s financing total reached unprecedented heights. In total, biotech companies raised nearly US$71 billion in 2015, easily surpassing the record-setting US$56 billion amassed the year prior. Fueling this best-ever financial picture were record capital raises in three categories: follow-on public financing rounds (US$21.8 billion), debt (US$32.1 billion) and venture capital (US$11.8 billion). It was also another stellar year for initial public offerings, with more than US$5.2 billion raised in IPOs, the third-highest total over the past two years. During this period, biotechs have filled their coffers with cash to drive future research and development focusing capital costs, mitigate risk and/or enhance trade flow efficiency. This lack of data access and its implications are often not well understood by key stakeholders within a number of organizations. Yet understanding the origins of the problem and the limitations it creates is critical to fully appreciating why internal trade functions are currently so constrained, and why accessing and analyzing this data can unlock substantial benefits.

Each time goods cross a border, companies must file a customs entry, usually electronically. The data on the customs entry is legally required to be presented at an invoice line item level and can be in excess of 100 fields per import/export line. To complete the entry, the company’s customs broker must combine several sources of data, including Importer/Exporter Enterprise Resource Planning (ERP), transactional data received from the company, customers’ broker determinations (e.g., harmonized-system classification determinations, customs valuation adjustments), shipping data and source/destination data. In the process, the customs broker creates a new and unique data set that now resides outside of the company’s ERP systems. It is this unique data that is submitted electronically to the customs authority, but not to the company. Unfortunately, no other single source of data provides the information needed to derive meaningful insights and achieve true trade effectiveness. ERP data is insufficiently detailed, and the data attributes that are available are not in a single location; thus, substantial effort is required to collate information that is not fit for purpose. Meanwhile, other data sources, including data from shipping or logistics systems, are too narrowly focused.

In addition to creating a significant barrier to achieving trade effectiveness, companies’ lack of ready access to this data puts them at greater risk during audit, as they are less able to proactively defend their positions. Keep in mind, a third-party broker submits data to the appropriate government agency on behalf of the company. That scenario results in data asymmetry: the government has full access to the data, but the company, which is legally responsible for the information, does not. This situation increases the company’s risk as the government agencies auditing the company’s customs, indirect taxes and direct taxes are increasingly more likely to have better information and knowledge about the company’s transactions than the company does.

The evolution of trade analytics capabilities

Significant advancements have recently been made in trade analytics capabilities, and the traditional barriers to achieving trade effectiveness no longer exist. First, data access is no longer an issue. Electronic customs declarations are now required in virtually every country, and it is now possible to access this unique data set. During the last 12 months, well-defined processes for requesting, and successfully obtaining, such data directly from customs authorities or customers’ brokers’ entry systems have been established for virtually every country in Asia. Such data can now be directly and quickly obtained with virtually no involvement from company personnel. By directly accessing this data from external sources, not only can companies now access the complete set of trade data they need to perform meaningful analyses (i.e., the company’s importer/exporter ERP transactional data combined with the customs broker’s data) but they can also avoid the complexities and frustrations of internal ERP data extraction, inaccuracy and data cleansing.

Second, significant advancements in data analytics mean that highly intuitive and robust analytical tools are now available. As previously noted, the data on the customs entry is legally required to be presented at an invoice line item level; thus, even one year of trade data represents an unmanageable volume of data. Given the amount of data to be analyzed, advanced analytics are required to convert such information into actionable insights.

Finally, every company’s supply chains, trade flows and products are very different, as are their business and trade priorities, objectives, challenges and opportunities. Data access and analytics tools capable of processing and analyzing trade data are of minimal value unless combined with processes and customized tests designed to identify actionable insights and opportunities specific to each company. Just as every available analytical test may not be relevant for every company, nor will every available test necessarily be sufficient. Consequently, a static analytical tool or engine that simply produces predetermined test results without taking into consideration each company’s unique needs will more often than not fail to identify the insights of greatest potential benefit. Only by combining the right data, technology and process can a company truly optimize its trade effectiveness. Proven processes, including a rapidly expanding inventory of customized analytics tests developed specifically for trade, are now available.

Financing: Excerpts from Beyond Borders 2016, EY’s global biotechnology report

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The power of trade analytics

Trade analytics can inform and support companies on a wide range of supply chain, customs and tax decisions and opportunities in Asia, ranging from macro-strategic to micro-operational. One of the key benefits of an effective trade analytics offering is that it requires no effort for companies to obtain the transactional-level trade data they need to accurately define and visualize their import and export transactions, both physical and financial, and for both current and prior periods. Most companies have never had this level of visibility or insight — they have instead relied on what they believe is happening. Trade analytics offers utilize advanced data analytics and processes to analyze and model this unique data set, enabling them to identify potentially substantial prospective and retrospective cost savings, trade flow efficiencies and opportunities for risk mitigation. Based on recent developments in trade analytics processes, data can now be obtained and analyses performed for any country in the world. The results are delivered in easy-to-read dashboards that clearly present and summarize the company’s current state profile, gaps and business opportunities. This makes it easy for companies to identify and prioritize potential investment areas and next steps (see exhibits 1 and 2 on the following page for two sample screenshots of analyses performed for customs duty).
Mainland China dominated M&A in 2015. Chinese-based life sciences companies accounted for 81%, or US$42.9 billion, of all Asia-Pacific M&A value. Japan and South Korea were tied for a distant second with 5% of M&A value, followed by Australia with 3%. All other Asia-Pacific countries accounted for less than 1.5% of the industry’s M&A total.

Of the 532 M&A deals that had announced terms, more than 60% were of companies domiciled in China, and an astonishing 96% of those deals transpired between Chinese buyers and sellers. In fact, only 12% of all Asia-Pacific M&A deals involved companies in different countries. Despite the tremendous growth prospects within Asia-Pacific, US companies spent less than US$230 million in total to acquire 10 companies in the region. None of them were based in China.

In 2015, there were 11 M&A deals worth more than US$1 billion, and 27 worth more than US$500 million. Of those 27 deals, 22 targeted Chinese companies. In fact, China was responsible for 9 of the 10 largest deals in 2015, including the top two, which involved investor groups taking public companies private.

In the case of WuXi PharmaTech, a buyout group consisting of its management team acquired the company at an 11% premium and stopped its trading on the New York Stock Exchange. Another NYSE-listed company, Mindray Medical, is currently being targeted by investors aiming to take the imaging and diagnostic company private.
The total value of Asia-Pacific and Japan M&A reached US$53.2 billion in 2015, a jump of 83% from the previous year and a whopping 380% increase since 2011. With the total value of global life sciences M&A reaching US$504 billion in 2015, Asia-Pacific and Japan M&A growth rates have actually tripled the global growth rates since 2011. Roughly one-third of all life sciences M&A occurs within Asia-Pacific; however, average deal sizes (US$100 million) are still only one-fifth of the size of global deals.

The Asia-Pacific region has witnessed a significant uptick in M&A in three life sciences subsectors: biotechnology, medical technology and pharmaceuticals. Most of the focus is on buying pharmaceutical companies; 61% of 2015’s regional deal total (US$32.4 billion) was attributed to pharma M&A. Meanwhile, values for biotech deals have increased the most (up 540%) since 2011, followed by medtech M&A (up 356%).

Cost savings and improvements to supply chain operations resulting from correcting compliance and operational errors and inefficiencies, including:

- Identification of Incoterm noncompliance and double-payment of shipping costs to both supplier and shipper.
- Identification of use of incorrect invoice currency and/or use of multiple currencies by a single supplier, resulting in violations of company policy, taxes by customs brokers to declare the correct currency, and possibly over- or underpayments of customs duties.
- Customs broker rationalization allowing companies to decrease the number of parties declaring information to various governments on their behalf and, thus, reduce the risk of unidentified reporting errors and noncompliance.
- Assessment of customs broker performance, ranging from clearance times to error rates, to identify areas for operational improvement and cost savings, including decreasing the time required for goods to clear customs, thus reducing demurrage and storage fees.
- Assessment of business decisions regarding shipping methods utilized (e.g., sea vs. air) and whether such decisions are most cost efficient.
- Preparatory work and process improvement to increase likelihood of success in seeking Authorized Economic Operator status.

**Mergers and acquisitions (M&A) – Asia-Pacific and Japan**

**Scalable process, actionable insights and benefits**

The trade analytics process is highly scalable, allowing companies significant latitude to define their priorities and areas of focus. Companies have the flexibility to take a very broad approach and, thus, assess the results from all available analytical tests. They can also be more targeted, choosing to focus on specific tests targeting areas they believe are critical for their businesses and/or collaborating on the development of new analytical tests. Companies also have the flexibility of starting small and piloting the process on a limited number of select countries, or analyzing data for an entire region or regions. In our experience, based on results from more than 100 recent engagements and the outputs of more than 80 customized analytical tests, some of the more commonly identified insights and benefits that can be achieved through trade analytics include:

**Cost savings and improvements to supply chain efficiency resulting from supplier rationalization and consolidation, including:**

- Identification of regions or countries where supplier clusters are present and thus there is an opportunity to source goods purchased from both low-cost and high-cost countries.
- Identification of instances where significant volumes of the same goods are being imported from suppliers in multiple countries, allowing companies to negotiate more competitive pricing and consolidate suppliers.
- Identification of instances where goods are being sourced from an unusually high number of suppliers, and thus, alternate sourcing strategies may be beneficial.

**Proactive development and implementation of controversy management and risk mitigation strategies and overall improvements to internal controls upon identification of various reporting and/or operational inconsistencies or errors, including:**

- Identification of HS coding inconsistency resulting in the nonpayment or underpayment of customs duties.
- Visualizing both financial and physical trade flows to identify instances where the company’s actual transactions are inconsistent with the company’s tax operating models and transfer pricing strategies.
- Utilization of multiple and inconsistent Incoterms. In general, as well as with respect to the same supplier, resulting from weaknesses in internal controls, internal and external compliance issues, and failures by customs brokers to declare the correct Incoterms.

**Scenario modeling to understand the financial impact and scope of considerations for strategic supply chain decisions, including the evaluation of bonded facility implementation, distribution center location analysis, and government trade programs such as inward and outward processing regimes.**

The appropriate/reasonable way to develop a true appreciation for the advantages trade analytics can provide an organization is to see a demonstration of EY’s Global Trade Analytics offering. For more information, or to arrange for a demonstration, please contact Marc Bunch, Global Leader, EY Trade Analytics, at marc.bunch@hk.ey.com.
Mergers and acquisitions (M&A) — global


Total deal value in life sciences reached US$470 billion in 2015, a 22% increase over the prior year and a new record. In addition to nearly 2,000 total announced deals, life sciences was third in overall industry deal value in 2015, trailing only technology and consumer products and retail.

Driven in part by Pfizer’s massive acquisition of Allergan, M&A in the pharmaceutical sector drove most of 2015’s deal activity, accounting for nearly 83% of total deal value. There was also a surge in biotech M&A, with total deal value increasing 18% year-over-year. Medtech dealmaking slowed in 2015, dropping nearly 66% year-over-year in dollars committed. This drop was largely an artifact of 2014’s megadeal activity, which saw large medtech acquisitions such as Medtronic’s purchase of Covidien.

The yet-to-close Pfizer-Allergan deal, valued at more than US$190 billion, ranks as the largest-ever life sciences M&A deal. The all-stock merger will create a biopharma juggernaut and shifts Pfizer’s headquarters to the lower-tax jurisdiction of Ireland. Pfizer is no stranger to big M&A; in 1999, it acquired Warner-Lambert for US$90 billion, which until the Allergan transaction, held the top spot for the largest life sciences M&A deal. Prior to the Pfizer deal, Allergan was involved with the year’s largest divestiture as the company sold its generic division — the third-largest player — to Teva, the world’s largest generic drug company by sales. The US$40.5 billion acquisition catapulted Teva into the top ranks of all drugmakers and ended its long, tumultuous efforts to acquire fellow generic company Mylan.