

# Asia on the move: Five current trends reigniting growth in the region's biopharmaceutical market

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## Introduction

Asia is well known for the dynamic nature of its markets and its rapid growth. At times, enthusiasm in Asia for the biopharmaceutical sector has been flat, due in part to China's market-access blockade, Japan's spending controls, and deceleration in India and Southeast Asia. Lately, though, events in key markets have been reigniting growth and interest in the region, bringing with them market changes that in many cases require companies to reassess their strategy and go-to-market model. In this paper we highlight recent changes in the region and share perspectives on their implications for pharmaceutical-company executives. Please note that a full description of the trends and events outlined is beyond the scope of this short paper and detailed deep dives are available upon request.

## Five things to know about Asia: Key trends shaping the market

### 1. CFDA reform in full stride in China; tsunami of new-product launches expected

Recent China Food and Drug Administration (CFDA) reforms provide the basis for more optimistic fundamentals to support industry growth through the encouragement of innovation. Over the past two to three years, the CFDA reforms have made significant progress in addressing critical gaps in the system: for example, the effort to clear the registration-application backlog has resulted in significant acceleration of the review timeline. In addition to efforts to clear the backlog, a series of reforms on drug-registration policy has been published. These are designed to further improve the registration process and to encourage pharmacos to bring innovation to China—for instance, by fast-tracking approval for therapies addressing severe or rare diseases, and through the acceptance of data from global trials for new drug applications (NDAs).

Thanks to these CFDA reforms, we observed a record number of approvals and new-product

launches in 2017: a total of 37 new products were launched in China versus a mere five or six each year over 2014–16. Additionally, by the end of 2017, some 180 candidates had been granted priority-review status, each of which will be gearing up for launch in the coming years. As an example of fast approval with priority-review status, AstraZeneca submitted its NDA for Tagrisso in early 2017, received approval in March 2017, and had the drug on the market by mid-April of the same year. Tagrisso was approved in China just 15 months after it received US approval—a record for recent years.

Against this optimistic backdrop of CFDA reform, development activity is accelerating in China, with a significant number of innovative compounds entering the pipeline. For the first nine months of 2017, approximately 110 new molecules (including biologics) were approved for clinical trial—almost triple the number of 2014. In total, some 770 compounds were in active development (including preclinical) in China, accounting for about 6 percent of global development activities.

Looking ahead, the CFDA is entering a new phase of reform to pave the way for further integration with global markets. Recent additions to the ongoing reform agenda include a scientific-review system that aims to shorten the clinical-trial application review to as little as 60 days, and implementing guidelines after joining the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use.

As a direct consequence of these reforms, we expect a significant number of new molecules to reach the market in the next few years, from both multinational corporations and local companies, creating a competitive environment for both development and commercialization.<sup>1</sup>

## 2. Price reform in Japan—affecting both on-patent and off-patent products

In December 2017, a proposal by the Japanese Ministry of Health, Labour and Welfare (MHLW) proposal to overhaul current drug-pricing regulations passed the Central Social Insurance Medical Council (Chuikyo), with the proposed changes due to take effect as of April 2018. This reform affects both new drug pricing and in-market price revisions, across all drug categories including patented prescription drugs, off-patent long-listed products (LLP), and generics (Gx).

The most notable changes are focused on in-market products:

- Moving from biennial price revisions to annual from 2021. The frequency of the National Health Insurance price revision will be changed from biennial to annual after 2021—“off-year revision”—for selected drugs (with high *yakkasa*<sup>2</sup>).
- Narrowing price-maintenance premium (PMP) criteria for patented products. PMP will be applicable only to selected drugs and full premium awarded only to a subset of companies. The scope of the premium will be limited to “truly innovative drugs” and the amount of premium matched to a company’s contribution to R&D.
- Accelerating price erosion for LLP and Gx. The originator price cut five years after loss of exclusivity (price cut of 1.5–2.0 percent) will be expanded to long-listed products where the generics’ share is less than 80 percent five years after their entry (from the current 70 percent). Also, additional price erosion ten years postexclusivity has been added to progressively reduce the price of LLPs to 1.0–1.5 times the Gx price, depending on Gx penetration.

- Including cost effectiveness in the price-revision process of selected products. Health-technology assessment price adjustment will largely be based on total treatment cost and benefit per patient, including public healthcare spending incorporating outpatient/inpatient cost, diagnostics cost, and so on. Lifetime cost will be considered in the case of chronic diseases. This may lead to revision of the price up or down with limits both ways. Incremental cost-effectiveness ratio will be based on cost per quality-adjusted life year.

## 3. Emerging funding pools in China and Southeast Asia

In China, the recent momentum on access reform has shown upward trends supporting expansion of reimbursement of innovative drugs. In February 2017, a National Reimbursement Drug List (NRDL) update added some 340 drugs, after an eight-year hiatus. On top of this NRDL update, national reimbursement negotiation was introduced as a new mechanism for innovative products to gain reimbursement status. In 2017, 36 products were listed in NRDL after successful negotiation, while eight products dropped out from the process. The NRDL negotiations came with significant price cuts (40–50 percent, on average, not taking into account patient-assistance programs). At the provincial level, the implementation of the new NRDL list (plus drugs entering NRDL via negotiation mechanism) is almost complete. Moving forward, more frequent NRDL updates are expected in the industry, as indicated by the Ministry of Human Resource and Social Security’s recently released draft document exploring dynamic updating of NRDL, instead of updates every few years.

At the same time, pharmaceutical companies in China have also started to experiment with new models to improve patients’ access to medicines. For example, Bristol-Myers Squibb has rolled out the first outcome-based insurance for hepatitis C therapy (Daklinza and

Sunvepra), while AstraZeneca has launched a pay-by-installment program for lung-cancer patients treated with Tagrisso.

With these positive trends and the improved outlook on access in China, especially for innovative products, China remains an important growth engine for many pharmaceutical companies.

The reimbursement environment in Southeast Asia is evolving, with universal coverage being introduced and further developed—although the emergence of the public funding pools has also been accompanied by pricing pressure and restrictions in an attempt by governments to maintain control of budgets.

Specialty products were previously driven by access to specific funding pools—for example, the Civil Servant Medical Benefit Scheme (CSMBS) in Thailand—as well as growth in the out-of-pocket markets. In recent years, however, new opportunities have started to emerge for some funding pools targeting a large population—for example, Thailand's National List of Essential Medicines (NLEM) and Badan Penyelenggara Jaminan Sosial (BPJS), Indonesia's national health-insurance system—and some pharmaceutical companies are already attempting to access these new pools.

Thailand has three main areas of potential opportunity: CSMBS for civil servants, NLEM for universal healthcare, and the self-pay/private health-insurance markets. Traditionally, CSMBS has been the main funding source for innovative drugs. With universal healthcare providing coverage for all of Thailand's approximately 60 million citizens, NLEM represents the largest potential opportunity for pharmacos. However, this is also the most difficult area to access with a stringent process, increasing pricing pressure, and efforts to control budgets by the government—including several recent measures introduced by government, such as median pricing and medical-bill audit. Nevertheless,

with appropriate market-access strategies, many innovative drugs have managed to gain access to the funding pool—for example, Glivec, Herceptin, and Sprycel.

There are other funding pools across Southeast Asia that are in various stages of implementation. In Malaysia, the Voluntary Health Insurance Scheme was announced in late 2017, but without much information being disclosed to date. In the Philippines, Philippine Charity Sweepstakes Office and the Philippine Health Insurance Corporation are the two main public funding sources, although their future direction with regard to innovative drugs remains unclear. Indonesia's BPJS was formed in 2011 with the goal of providing universal healthcare by 2019 and continues to require significant price cuts.

#### 4. Rise of local biotech in China

A combination of support from policy makers, an influx of high-quality talent, and capital injection has seen China's innovation system start to come together, with many quality local biotech players emerging.

Growing interest from capital. In the first half of 2017, China's local biotech companies attracted twice as much venture-capital investment as in the same period in 2016 (up from \$2.7 billion to \$5.6 billion). Approximately 30 IPOs were completed in the 12 months to November 2017, with a combined value of \$2.8 billion (including the \$150 million IPO of Zai Lab), and many more IPOs are in preparation (for example, Hua Medicine and Innovent). Moreover, compared with their US peers, China biotech companies showed significantly higher market value last year. In a recent survey McKinsey conducted among biotech innovation leaders in China, around two-thirds shared their optimism concerning the biotech ecosystem. Leaders believe double-digit growth in invested funding will likely continue over the coming five to

ten years and are expecting some three to five IPOs each year.

**Expanding portfolio.** Among local biotech companies in China, there are approximately 800 innovative molecules in the pipeline, among which 70–80 are in phase III. Among these late-stage assets, many are aiming for applications beyond China. Chinese companies are now conducting trials for a quarter of their innovative assets beyond China, either alone or through partnerships. For example, as part of a strategic collaboration, BeiGene is now working with Celgene to initiate several programs for its PD-1 monoclonal antibody product (BGB-A317) in Europe, Japan and rest of the world outside Asia, and the United States.

**Active partnerships.** Biotech companies are actively partnering with leading global biopharmaceutical companies on both the R&D and commercial fronts. Asset-level partnership remains very active: for example, Fosun's collaboration with Kite Pharma to develop CAR T therapy in China, and the alliance between Janssen and Legend on their CART partnership. This year, however, we have seen an interesting development beyond asset R&D—as local biotech companies start to build commercial presence with new-product launches, we are seeing new partnerships emerge on the commercial front. This includes Celgene's collaboration with BeiGene on commercial operations in China, in addition to their partnership on the global development of immune-oncology therapy mentioned above.<sup>3</sup>

## 5. Acceleration of digital and advanced analytics in healthcare

Digital channels and big data have been buzzwords for years but now we are seeing real uptake.

Government policies are being designed to support this type of innovation. Various state-level policies have been formulated that are designed to promote the application of artificial intelligence

(AI) and big data in China. In 2016, the State Council issued a guideline to promote the development of healthcare big data, and the following year it issued a guideline on developing AI, with specific emphasis on its application to healthcare. Similarly, in Japan, the MHLW is actively driving digital adoption through its support for a holistic database that will ultimately link (among other things) claims data, the national database, and Kaigo data by 2020. The Law of Next Generation Healthcare Platform certifies vendors that can anonymize and make use of personal health data; it also allows medical institutions to provide the data in opt-out systems. Shiharai Kikin (the payer foundation that reviews and pays all corporate-based payer claims) is embarking on a transformation designed to streamline claims reviews by increasing the level of automation and introducing artificial intelligence to the process.

**Customers are ahead of the digital offering.** This comes at a time of increasing constraints on commercial access to physicians and rising ethical and professional standards among doctors in both China and Japan. For example, policies issued by the State Council in China aim to restrict pharma sales-rep activities, while hospitals increasingly require scheduling appointments for specific days in Japan. At the same time, data is becoming available showing that digital engagement actually works, delivering a positive return against both educational and commercial metrics. In Japan, over half of physicians have already shifted away from pharmaceutical sales reps as their primary information source, while 40 percent use digital channels as their primary source of information—less than 15 percent of physicians are still reliant on sales representatives as their sole source of information. Today, the vast majority—85 percent—of physicians use digital sources as their primary or secondary source of information in Japan. Moreover, in-person detailing effectiveness is declining and, in many physician segments, e-detailing effectiveness

## The market in India

Any perspective on Asia that does not mention India would be incomplete. The pharma market in India is expected to grow by over a 10 percent compound annual growth rate in the coming three to five years. However, the market is still underweight because of low healthcare spend per capita with a high out-

of-pocket component. Generics dominate the drug market (at 75–80 percent) and will likely remain dominant in the near term. Meanwhile, intellectual property continues to be a challenge within innovative pharmaceutical markets. Overall, India remains an important market.

is approaching or overtaking in-person effectiveness. In China, doctors spend on average more than two hours of their working day online and have switched from computers to smartphones for many of their professional activities. Platforms such as DXY.cn have moved on from being the preserve of a few cutting-edge practitioners to become a regular part of the job for many physicians. Such changes in physicians' communication preferences are driving a need for companies to embark on an adaptive multichannel engagement strategy using microsegmentation to ensure better targeting and messaging.

Technology and platforms are catching up. China is a hotbed for innovation relating to digital and analytics. The past two years have been marked by the rising aspiration of BAT (Baidu-Alibaba-Tencent) and nontraditional healthcare players such as Ping An insurance. In Japan, the pharma industry is moving toward a multichannel commercial model, of which the sales force is only one part. Digital information (such as alerts and notifications) delivered to physicians at trigger points, remote detailing, online knowledge portals, and apps are all tools to complement face-to-face interactions with physicians. Further, a new generation of digital platforms is challenging the traditional prominence of M3, an early and very successful digital platform.

### Four key things to consider for pharmaceutical-company executives

#### 1. Look east for innovation—integrate Asia into the global innovation road map

Increase the weight of Asia in your global development strategy

Positive regulatory trends that are seeking to integrate China into global markets have ignited interest from pharmaceutical companies in bringing innovative products to China—and, against a backdrop of broadening access, they are becoming a more and more appealing business opportunity.

In recognition of the overall commercial importance of the Asian market, Asia, and especially China and Japan, needs to be elevated within companies' global development strategies and frameworks—whether this be incorporating Asia in a product's early development stage or enrolling Asia patients in global phase III pivotal trials for simultaneous development in the region. This requires an integrated strategy framework, which can be enabled by setting up an Asia development team to drive therapeutic-area strategy and portfolio prioritization, while providing better coordination of development needs across the Asian markets.

Beyond participating in global programs, companies should also consider investment—for example, in



the format of an Asia innovation center—to develop assets to address diseases that are highly prevalent in Asia, such as lung, gastric, and liver cancer. Such programs could enable companies to adapt their platform technologies in order to address specific clinical needs within the Asian population.

#### Tap into Asia innovation systematically

With the innovation boom in Asia and many early-stage assets emerging, now is the time to consider establishing a mechanism capable of consistently and systematically tapping into Asia's innovation potential for global impact.

Effective asset-level sourcing requires a fully integrated business development effort between Asia and global. The assessment of individual asset-level deals in Asia should be approached holistically to take into consideration potential global impact—and this approach requires an appropriate structure and governance. Beyond the asset level, pharma executives should consider bigger bets as a way to tap into local innovation—for example, investment and associated strategic partnerships with China's local biotech companies.

Some healthcare companies have already started doing this in a systematic way. Various companies have set up funds designed to bridge the innovation community across continents, and thereby accelerate and expand the commercialization opportunities for innovation. Such funds serve a dual purpose: not only bringing innovative assets or solutions from Asia to Europe and the United States, but also in the opposite direction.

### 2. Change the approach to talent acquisition and retention—new competition and value propositions for Asia's talent

A decade ago, multinational pharmaceutical companies were a very attractive career choice for many new graduates in China. The brand reputation, attractive compensation, systematic training, and

career outlook all made working in these companies an exciting opportunity. However, over the past year or two, we have seen talents in China switch from multinational companies to become leaders of new biotech companies. In addition to their international experience, these individuals know the local system well and have proven communication skills, strategic thinking ability, and deep technical and domain expertise. Historically, many local biotech management teams have been comprised of R&D leaders who are veterans of multinationals (for instance, CStone and Hua Medicine). However, we are also starting to see talent flow out from multinational companies to local firms on the commercial side, as leading local biotech companies start to launch their first products.

The outflow of talent from MNCs is inevitable given the attraction of local biotech companies, which offer what employees—especially millennials—value: local innovative companies that provide an exciting entrepreneurial experience with reasonable risk. And they promise a handsome financial return after an IPO—not to mention the national pride afforded by building a homegrown global biopharma industry leader.

For multinational pharma leaders, it is time to reassess the value proposition presented by the typical global MNC and to make appropriate adjustments in order to compete in the increasingly competitive talent war.

### 3. Invest in digital locally—fund at least one large digital program at scale

Asia has the potential to leapfrog in the digital-health segment. If we look at the level of digitization in the consumer world (for instance, WeChat in China or smartphones in South Korea), Asia is clearly embracing the new digital world with enthusiasm. Similarly, in the healthcare industry, Asia has an opportunity to take the lead in developing big data/advanced analytics solutions

and technology platforms, with the potential to contribute to the global healthcare ecosystem.

At the same time, we observe that, while pharmaceutical companies have many subscale pilots to “test the water,” few seem to have the vision and aspiration for substantial transformations. Understandably, pharmaceutical executives are skeptical and risk averse when it comes to making significant investment decisions. Yet, evidence is now available showing that digital customer engagement can deliver real business impact, and we believe now is the time for companies in Asia to invest at scale in digital transformations. Such moves may be greeted by customers eager to engage with the same convenience, participation, and added value as they have come to expect from other areas of their personal and professional lives.

For pharmaceutical companies, two seemingly contradictory elements are critical when embarking on a digital transformation: a sound digital strategy backbone at the global and/or regional level, and running digital programs at scale with fast iteration at a local level. While both are important, pharma companies should embrace an agile mind-set and approach when it comes to digital and adopt a test-and-learn approach rather than spend too much time planning. Experience shows that overall speed, quality, and impact are greater when running such agile iterative initiatives in the market, as opposed to classical big company projects.

#### 4. Unlock a market of three billion people—invest in expansion at the right time to unlock a broad patient base effectively

By any macroeconomic metrics, Asia is key for pharmaceutical executives: population base, disease burden, overall healthcare expenditure—the list goes on. However, concrete business opportunities in Asia can still seem relatively small, considering the accessibility and affordability challenges faced by many innovative pharmaceutical companies.

When thinking about Asia, be mindful of the scale of business opportunity, as well as the time and investment required to reach scale. Understanding the challenges faced by the Asian healthcare system and taking the pulse of the markets can help executives to define the right strategy for broadening their outreach to patients in Asia.

In China, for innovative products that normally come with a high price tag, the traditional focus has been “big-city big hospitals,” targeting mainly patients who can afford to pay out of pocket, supported by some patient access programs. Now, however, with recent progress on the access front, innovative products have started to be listed in the NRDL with significant price cuts. Cheaper prices, combined with a substantial reimbursement ratio from the public payer, are leading to a dramatic increase in affordability and widening of the applicable patient base. Pharma executives looking for success in this new landscape should consider a broader market strategy encompassing how to reach patients beyond the tier-one and tier-two cities and class III hospitals. Setting up the right commercial model to expand coverage to lower-tier cities and hospitals requires new thinking especially around potential partnerships. Companies such as AstraZeneca, Pfizer, and Sanofi, which started their market-expansion journey for their less pricy innovative products some years ago, have adopted various approaches ranging from pure own sales force to partnerships with distributors and contract sales organizations—we expect more and more companies will join hands with an increasing number of brands in exploring new territories in China.

Equally, among developing countries in Southeast Asia, the focus for pharmaceutical companies has historically been on the top five to ten cities—for a number of reasons, not least affordability and the readiness of the healthcare infrastructure. Looking ahead, developing healthcare infrastructure and introduction of multiple health-insurance



schemes offering greater affordability to the overall population mean that pharmaceutical companies should now consider options for expanding outreach to the broader patient pool. To extend their reach to the wider population in Southeast Asia, pharmaceutical companies should consider investing in three main areas: medical education to raise standards of care, access to public funding pools, and self-pay enablement. Moreover, many traditional areas of pharma activity can now be enabled digitally, given the high penetration of smartphones in the region. In this context, several pharmaceutical and medical-device companies have started pilots trialing digitally enabled diagnosis, as well as patient-management solutions, while some companies are even considering microfinancing and payment for healthcare services enabled via digital tools to reach the broader population in Southeast Asia.



While it is challenging to capture the essence of a broad range of market developments in Asia, this paper offers an overview of what we see as

several material changes underway along with their potential implications for pharmaceutical companies operating in the region. We are available to provide more details and specifics on each of these trends, as well as other market dynamics not covered in this paper. ■

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<sup>1</sup>"Building bridges to innovation," presentation at BioCentury China Healthcare Summit Report, Shanghai, November 14–15, 2017, McKinsey & Company, biocentury.com.

<sup>2</sup>*Yakkasa* means dispenser margin, the difference between the list price and the market price at which medical institutions and pharmacies purchase drugs.

<sup>3</sup>"Building bridges to innovation," presentation at BioCentury China Healthcare Summit Report, Shanghai, November 14–15, 2017, McKinsey & Company, biocentury.com.

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