



# 2016 Top Markets Report **Pharmaceuticals** Country Case Study

## China

The pharmaceutical market in China is one of the most promising for U.S. exports in the long-term given its size and growth potential. Rising per capita incomes, an aging population, greater access to healthcare and regulatory reform are key drivers that will enhance the appeal of China's market to U.S. companies. Increasing price pressure and slowing economic growth, however, will impede sales in the near-term. Moreover, a number of serious regulatory concerns remain, including shortcomings in China's system for pharmaceutical registration and market approval. U.S. industry will continue to look to policy makers for assistance with these barriers.

Overall Rank

**20**

China is the second largest pharmaceutical market in the world, forecasted to grow from \$108 billion in 2015 to \$167 billion by 2020, representing an annual growth rate of 9.1 percent.<sup>1</sup> Total public and private healthcare expenditure reached \$640 billion in 2015 and is expected to almost double to \$1.1 trillion by 2020, as the Chinese government rapidly expands universal insurance coverage.

Pharmaceutical sales currently amount to 17 percent of total health expenditures, or \$78 per person. In terms of the market breakdown, generics dominate with a hefty 64 percent of total sales. Low per capita spending and government policies favor rapid growth in the generic market, which is expected to surpass the United States in sales by 2017, when it is projected to reach \$80 billion.

Patented drugs amount to only 22 percent of total sales. Over the past decade, patented drug sales enjoyed strong, double digit growth rates. In the last couple years, government policy changes regarding reimbursement, tendering, hospital financing and sales promotion have significantly hindered revenues.

### Figure 1: China Snapshot

- Population:** 1.38 billion
- Population over 65:** 131 million (9.6%)
- Total healthcare expenditure:** \$640 billion (5.9% of GDP)
- Government healthcare expenditure:** \$348 billion (54% of total)
- Private healthcare expenditure:** \$291 billion (46% of total)
- Total pharmaceutical sales:** \$108 billion (1% of GDP; 17% of total healthcare exp.)
- Per capita pharmaceutical sales:** \$78
- Generic sales:** \$68 billion (64% of total sales)
- Patented sales:** \$23 billion (22% of total sales)
- OTC sales:** \$16 billion (16% of total sales)
- U.S. pharmaceutical exports:** \$2 billion

### U.S. exports

U.S. pharmaceutical exports to China reached \$2 billion in 2015, up from \$617 million in 2010, representing an annual growth rate of 26.6 percent over the last five years. The United States is a leading source of pharmaceutical imports to China, comprising 11 percent of the total.

Importing drugs to China is complex endeavor. While domestic manufacturers can sell directly to consumers, importers face a daunting, complex and highly fragmented distribution system made up of thousands of local distributors and wholesalers. Transportation quality and regulations vary by locality, and markups at various stages push up a product's final cost. Moreover, depending on the product, duties on imported drugs are high. Regulatory delays, IP violations, counterfeit medicines, price controls and a lack of transparency remain some of the most commonly cited barriers to better penetration of the Chinese market by foreign producers.

#### Competitive environment

China's generic market is dominated by a large number of low-cost, domestic manufacturers. The fragmented industry includes around 5,000 drug manufacturers, with the top 100 comprising just one-third of the market. Going forward, government policies aim to reduce industry fragmentation by imposing regulatory requirements that the China Food and Drug Administration (CFDA) estimates will shut down hundreds of sub-par, small manufacturers for lack of compliance.<sup>2</sup>

Healthcare industries, particularly biopharmaceuticals, have been targeted by the Chinese government as a priority sector for industrial policies intended to create national champions.<sup>3</sup> While these trends may improve some aspects of market access and regulatory reform, government policy goals are likely to increasingly advantage domestic companies over foreign multinationals.<sup>4</sup>

#### Disease profile

In addition to China's large population and rising income levels, the chronic disease burden will remain a key driver of growth in the decades ahead. Changing diets and lifestyles, as well as air and water pollution, are contributing to staggering increases in the incidence of cancer, heart disease, diabetes and other chronic conditions. For example, China already has 110 million diabetics, three times the number in the United States, with many more undiagnosed.<sup>5</sup> In 2015, China reported 4.3 million new cancer cases, accounting for 20 percent of the worldwide total.<sup>6</sup> China's population over 65 will reach 170 million by 2020, creating immense demand for treatment and services for many years to come.

#### Healthcare reform

To meet these demands, China's healthcare reform program, which began in 2009, includes expanding insurance coverage to its enormous rural population and building thousands of community healthcare centers. Today, over 95 percent of citizens are enrolled in various public health insurance plans, which aim to achieve universal health insurance for the population.<sup>7</sup> Although coverage remains shallow, the central government is massively increasing its funding and continuing rapid reforms, including the merger of China's new rural cooperative medical scheme with its urban residents basic medical insurance scheme.<sup>8</sup> Ultimately, the long-term impacts of such developments should be positive for U.S. companies by expanding the depth of coverage for patients, particularly in lower-tier markets. The government's need to focus on cost savings and cut prices, however, is also increasing, creating uncertainty over reimbursement policies. Although the extent of China's macroeconomic problems remains unknown, the economy will likely continue to face significant headwinds and volatility over the next few years. The resulting budgetary constraints will inevitably produce further pricing pressure on drugs, particularly as frustrations over corruption, cost and access to healthcare continue to mount.

To be eligible for reimbursement under the national health insurance system, and therefore be affordable to the mass market, products must be on the National Reimbursement Drug List (NRDL). The NRDL has not been updated since 2009, however, and the process for inclusion on the list, as well as pricing policies, remains opaque and chaotic.<sup>9</sup> Moreover, new processes include the introduction of a bidding system in which branded generics compete directly on price with domestically-produced generics. Such bidding systems, which vary on a provincial and local level, are driving U.S. companies out of this market segment.<sup>10</sup>

China's healthcare reform is also geared toward rooting out corruption by reducing the reliance of hospitals on a 15 percent mark-up on drug sales as a source of revenue. Until recently, this mark-up generated around 50 percent of hospital revenue, creating incentives for doctors to prescribe high-value medicines. While the gradual prohibition of this practice is positive for the industry in the long-run, it is causing a major drag on pharmaceutical company revenues.<sup>11</sup>

In China, U.S. companies have long been reliant on selling more expensive, patented and branded generic drugs. Although patients predominantly pay out-of-pocket for medicine, they often ask for foreign brand products, partly due to perceptions of superior manufacturing quality. In addition, doctors in China have considerable prescribing power. As such, firms have relied heavily on promotional efforts among healthcare professionals to drive sales.

In 2013, UK-based GSK was fined \$489 million, a record criminal penalty in China, for allegedly bribing doctors and health officials to prescribe its medicines.<sup>12</sup> The fallout has caused industry-wide reputational damage and increased scrutiny of promotional practices. Although foreign multinationals have largely ceased egregious sales tactics, domestic companies generally have not appeared to follow suit. Because doctors are extremely overworked and poorly paid, getting their attention for education on new therapies is difficult and corruption remains pervasive. Regardless, foreign companies are vulnerable to further crackdowns in this area and will need to develop strategies for selling drugs that avoid such risks.

The issues listed above are squeezing U.S. pharmaceutical companies in China, with revenue growth for many multinationals slowing from around 24 percent to under 5 percent over the last three years.<sup>13</sup> To remain profitable, companies urgently need to bring new products to the market.<sup>14</sup> Unfortunately, the China Food and Drug Administration's (CFDA) infrastructure and staff remain unable to approve products in a reasonable timeframe. The extent to which China will bolster CFDA funding, harmonize with global standards and enact necessary regulatory reforms in ways that benefit foreign as well as domestic companies remains to be seen.

## **Challenges and Barriers to U.S. Exports**

### Regulatory approval delay

Approval delays for pharmaceutical products have become the most pressing impediment to market access for foreign companies, creating enormous uncertainty over product launches and chipping away years of patent validity. From 2011 to 2014, CFDA concluded an average of around 5,000 application reviews annually, yet it accepted between 7,000 and 9,000 annually.<sup>15</sup> As a result, the accumulated backlog of applications is now estimated at around 17,000, and

the approval timelines for both innovative and generic drugs can take more than seven years. To help address the problem, CFDA has successfully discouraged and thrown out a large number of deficient applications coming from substandard domestic manufacturers, and they have hired more review staff. Review efficiency has recently increased as a result. In 2015, CFDA completed reviews on 9,600 applications, compared to 5,260 in 2014.<sup>16</sup>

Through various engagement opportunities, such as the U.S.-China Joint Commission on Commerce and Trade (JCCT), U.S. industry has raised with China its concern with long wait times for approval. At the 2014 JCCT, China made commitments to streamline its approval process and eliminate the application backlog within 2 to 3 years.

Since then, China has rolled out a series of reforms and programs to reduce the current drug lag. Ongoing reforms signal national treatment concerns where foreign companies and imported products are treated differently than domestic products. For example, in a recent change in the CFDA review policy, innovative medicines manufactured locally in China are granted expedited priority review. Biosimilars from foreign companies remain blocked from the multi-regional clinical trial pathway and can only apply for clinical trials in China after receiving approval in the United States or European Union. This puts foreign biosimilar producers at a disadvantage to domestic firms and can result in additional market access delays of five years or more.

### Regulatory data protection

During its WTO accession in 2001, China agreed to provide six years of regulatory data protection. Because of lack of clarity in its definition of “new chemical entity” (NCE) in its drug registration system, however, China interprets this commitment as only applicable when the drug is “new” to the world, as opposed to “new” to the regulatory authority. As such, Chinese domestic companies have been able to use U.S. innovators’ data to apply for marketing approval for drugs first developed by U.S. companies, often before they are able to bring the drug to the Chinese market. At the 2012 JCCT, China committed to define NCE in a manner consistent with international research and development practices, but it has yet to do so.<sup>17</sup>

### Definition of “new drug”

The definition problem resurfaced again in the August 2015 State Council Drug Reform Opinion and the November 2015 CFDA reform plan, which went into effect in March 2016 to revise the definition of “new drug” as an entity “new to the world” for regulatory approval purposes. This policy creates the possibility that a drug approved or marketed first outside of China may receive slower regulatory pathways and no market exclusivity in China. The “new drug” definition may also have implications regarding pricing, reimbursement and tendering decisions.

### Patent linkage/enforcement

China lacks patent linkage rules to resolve disputes before infringing products are launched on the market. Chinese law requires that a product must actually be sold in the market before a patent holder can even bring an infringement action. Further, although China’s laws theoretically allow for injunctive relief, in practice injunctions are rarely, if ever, granted in pharmaceutical cases due to procedural and practical barriers. Moreover, monetary damages awarded by Chinese courts have proven far insufficient to cover lost revenue or discourage infringement.

### Data supplementation

Starting in 2001, China's State Intellectual Property Office (SIPO) disallowed patent applicants to file supplemental data and began denying patent protection to applicants that had been granted patents in the United States and elsewhere. China's Patent Re-examination Board then applied the change retroactively and invalidated existing drug patents that had been granted when supplemental data was allowed. At the 2013 JCCT, China agreed that they would allow filing of supplemental data and would note that this is their practice in their representations with the courts. In spite of this, recent court cases appear to violate the spirit of this commitment, and uncertainty remains on when supplemental data will be accepted.

### Patent term restoration

The lack of patent term adjustment or restoration provisions to compensate for regulatory review and patent office delays is a serious problem given the review backlogs at SIPO and CFDA.

### Transparency

Lack of transparency in Chinese regulatory development is widespread. U.S. pharmaceutical companies have had little opportunity to provide feedback or comment on unpublished process changes and new regulations. Even major amendments to its Drug Administration Law (DAL) have not been consistently released for public comment. At the 2014 and 2015 JCCT, China made commitments to publish relevant pharmaceutical regulations and measures in advance for public comment.

### Counterfeit medicines

According to industry estimates, annual revenue losses to U.S. pharmaceutical companies due to counterfeit products in China run between 10 percent and 15 percent of the market, although the percentage could be higher. In the past few years, China has been stepping up enforcement efforts to combat fake medicines through regulatory reforms and enforcement. Still, criminal penalties remain insufficient, thresholds for wrongdoing are too high, and law enforcement is slow to act and is often protective of local industries. The production, distribution and sale of counterfeit medicines and unregulated active pharmaceutical ingredients (APIs) will continue to pose a threat to its trading partners for the foreseeable future.

Under current laws, China lacks effective regulatory control over the manufacture and distribution of APIs, creating regulatory loop-holes that endanger drug supply chains around the world. Chemical manufacturers only register with the CFDA if their product is intended for medical use. If they declare otherwise, CFDA has no authority to regulate them. Furthermore, CFDA does not monitor or inspect APIs intended for export, leaving importing countries and companies responsible for conducting due diligence.

<sup>1</sup> Figure 1: China Snapshot:

Pharmaceutical sales, Pharmaceutical sales per capita, Generic drug sales, Patented drug sales: Southern Medicine Economic Institute (SMEI), Association of the European Self-Medication Society (AESGP), local news sources, BMI

OTC medicine sales: Association of the European Self-Medication Society (AESGP), BMI.

Health spending, Govt. health spend, Private health spend: World Health Organization (WHO), BMI

Population data, Population over 65: World Bank/UN/BMI

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<sup>5</sup> Financial Times, Andrew Ward and Patti Waldmeir, *China healthcare: Missing a beat*, December 2015,

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<sup>6</sup> CA: A Cancer Journal for Clinicians, Wanqing Chen et al., March/April 2016,

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<sup>7</sup> China Briefing – Business Intelligence from Dezan Shira & Associates, *China's Commercial Healthcare Insurance Industry on the Fast Track*, December 2015 <http://www.china-briefing.com/news/2015/12/24/chinas-commercial-healthcare-insurance-industry-on-the-fast-track.html>

<sup>8</sup> For more on healthcare reform: Health Intel Asia, Jung Huang, *What Should We Know about the Merger of China's Urban and Rural Resident Basic Medical Insurance Schemes?*, February 2016, <https://healthintelasia.com/know-merger-chinas-urban-rural-resident-basic-medical-insurance-schemes/>

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<sup>10</sup> Wall Street Journal, *China Healthcare Reform Sparks Feud Between Foreign Drug Firms, Hospital*, January 2016,

<http://blogs.wsj.com/chinarealtime/2016/01/18/china-healthcare-reform-sparks-feud-between-foreign-drug-firms-hospital/>

<sup>11</sup> Bain & Company, Philip Leung, Grace Shieh and Ellon Xu, *Embracing China's Brave New Pharmaceutical World*,

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<sup>12</sup> U.S.-China Economic and Security Review Commission, Benjamin A. Shobert, *Market Access for U.S. Medical Goods and Services in China*, April 2014, [http://www.uscc.gov/sites/default/files/Shobert\\_testimony.pdf](http://www.uscc.gov/sites/default/files/Shobert_testimony.pdf)

<sup>13</sup> Financial Times, Andrew Ward and Patti Waldmeir, *China healthcare: Missing a beat*, December 2015,

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<sup>14</sup> Forbes, Benjamin Shobert, *Reforms To China's Drug Approval Process Are More Important Than Ever*, November 2015, <http://www.forbes.com/sites/benjaminshobert/2015/11/11/reforms-to-chinas-drug-approval-process-are-more-important-than-ever/#16e53d15629e>

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<sup>16</sup> CFDA Center for Drug Evaluation (CDE), *Review of Chinese Drug Evaluation and Registration in 2015*,

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