

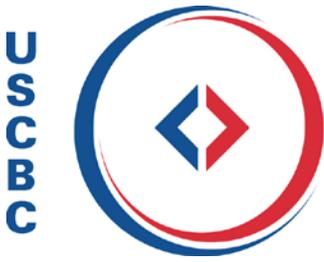


# THE PULSE

## of China's Healthcare

By the US-China Business Council

April 2017



## The Pulse of China's Healthcare

April 2017

### Introduction

The Chinese healthcare sector, which accounted for 6 percent of the country's GDP in 2016, is expected to capture a 10 percent share in the coming years. Racing to establish a modern system of coverage, services, and products to accommodate the world's largest population and fastest growing economy, China faces a number of development challenges. As China increasingly makes use of foreign products, services, and expertise to accomplish its reform goals, foreign companies are in a position to advance China's reform goals in the healthcare sector, if allowed market access.

Although China's development goals are broad, the recent release of several sector-specific 13th Five-Year Plans (13FYPs) outline priority themes and targets for China's healthcare reform through 2020. Seeking to expand the quality and reach of nationwide healthcare while controlling cost, the government crafted a variety of FYPs that [promote innovation, R&D, and entrepreneurship](#); [improve healthcare, hospital, and insurance systems](#); [tackle societal health challenges](#); and [build stronger citizen awareness around health issues](#).

These plans, which serve as a broad overview of China's evolving healthcare sector, offer scant details on how foreign companies can contribute to China's healthcare industry. Instead, foreign companies must continue to reference China's [Catalog on Guiding Foreign Investment \(CGFI\)](#) and [Catalog on Encouraged Imported Technology and Products](#), as well as specific policies portending national strategy for pharmaceutical and medical device sector development. While foreign technology could contribute to specific reform goals, these catalogs and policies are a guide to market restrictions for foreign firms.

### Leading industry issues and challenges

In addition to new market opportunities in China's growing healthcare industry, members will also encounter new and existing regulatory hurdles. Such challenges include China Food and Drug Administration (CFDA) [clinical trial requirements](#) that burden foreign companies selling products in China; a new [two-invoice policy](#) that limits foreign company negotiating power; [pricing restrictions](#) for foreign companies registering new products; and ongoing [anti-monopoly inspections](#) focusing on healthcare and medical device companies in China.

#### *Two-invoice system for pharmaceuticals*

China's new [two-invoice policy](#), announced by a number of agencies including the National Development and Reform Commission (NDRC) and National Health and Family Planning Commission (NHFP), seeks to reduce pharmaceutical prices by cutting wholesale markups in the distribution network. The current system permits invoices from the manufacturer and multiple distributors before a final sale to a hospital. This can result in numerous upcharges from distributors and sub-distributors – as many as 5-7 for products dispensed to more remote rural areas. However, the new system consolidates these invoices to only two: one from the manufacturer to the distributor and a second from the distributor to the hospital, in an effort to disclose distributor profits and [lower healthcare](#) costs for consumers. In addition to increasing transparency and lowering cost, the policy will accelerate

consolidation among pharmaceutical distributors, which could weaken competition, reduce negotiating power for producers, and inflate future prices. China will begin implementing this policy nationwide for pharmaceuticals in 2018.

#### *Two-invoice system for devices*

Although the central government has not announced an equivalent policy for medical devices, a 2016 [announcement](#) calls for provincial governments to pilot a two-invoice policy for medical devices. Provincial pilots have launched in Shaanxi, Shanxi, Qinghai, and Hainan, while others are under consideration in roughly 20 provinces, according to a recent AdvaMed survey. Unlike pharmaceuticals, medical devices include post-sale services such as repairs or hospital training, a significant additional charge included in the invoice from the distributor to the hospital. This is problematic as some provincial governments seek to limit gross margins in the second invoice without a thorough consideration of the overall value chain. Several companies report that provincial governments would like to reduce the roughly 200 distributors to an approved list of 15-20 distributors. This forced consolidation may negate efforts to confront and eliminate corruption, as designated guaranteed distributors will become gatekeepers for hospital tendering processes. Companies also report that some distributors are not equipped to train staff or install and service the devices.

These decentralized two-invoice system pilots pose other issues for device companies, such as provincial implementation discrepancies and undefined criteria for which entity – the manufacturer or affiliated dealer – qualifies as the first invoicer. Despite these challenges, however, the two-invoice policy could have positive implications for device and drug companies in the long term, as a better regulated and more simplified distribution system will improve supply-chain efficiency.

#### *Clinical trials*

For years, Chinese Food and Drug Administration (CFDA) clinical trial requirements have [burdened foreign companies](#) seeking to sell their products in China. Despite efforts to expedite an [inefficient registration process](#) for new drugs and devices, CFDA's Center for Drug Evaluation (CDE) and Center for Medical Device Evaluation (CMDE) still [do not accept clinical data certified by international regulatory bodies](#) for market approval. CDE/CMDE expectations that companies repeat costly and time-consuming trials in China also significantly delay time to market for products. CFDA has defended its [pharmaceutical](#) and [medical device](#) clinical trial requirements as necessary to reduce [falsified data and create fairer competition](#) for healthcare companies. However, these requirements may soon become less burdensome, at least for drug manufacturers, following the March 17 release of CFDA's [draft Decision for Adjusting the Administrative Regime for Import Drug Registrations](#). If finalized, these measures would considerably accelerate the process of approving foreign innovative drugs for the Chinese market.

#### *Registration pricing restrictions*

An August 2015 State Council [opinion](#) that limits drug prices in China to no more than the price in the originating country or neighboring countries continues to be of top concern to foreign pharmaceutical companies. China repeated these vaguely-worded requirements in a January 24, 2017 [announcement](#), causing distress among foreign companies about its impact on China's competitive environment, and potentially on other national markets that choose to implement a similar restriction. Medical device companies are watching the pharmaceutical industry and worry that China might apply a similar policy to the device industry.

#### *Anti-Monopoly Law investigations*

A recent influx of anti-monopoly inspections are expected to continue in China, causing growing concern among member companies. These investigations have primarily targeted the activities of companies in the pharmaceutical and medical device industries. Concerned with [monopolistic activities and restrictions on competitiveness](#), NDRC – along with China's State Administration for Industry and Commerce (SAIC) – have conducted investigations into companies suspected of violating fair market practices through price fixing and abuse of market dominance. As these investigations continue, USCBC will advocate in support of its members that foreign companies are not targeted disproportionately.

## 13FYP for the Development of the Medical Industry

The Plan for the Development of the Medical Industry, [issued](#) November 7, 2016, targets areas for development in the pharmaceutical and medical device sectors and compares goals with 12th Five-Year Plan (12FYP) outcomes, including:

- **Growth rate** China shifted its growth metric from industrial output during the 12FYP to corporate growth in the 13FYP to focus on the production value chain. Corporate metrics emphasize innovation and research, rather than manufacturing.  
*Key target:* Main operating revenue will grow 10 percent annually.
- **Investment** The research and development (R&D) investment requirement is ambitiously expanded from a limited government list of enterprises to “all enterprises above a designated size” within the industry, referring to companies with an annual operating revenue of more than 20 million RMB.  
*Key target:* All enterprises above the designated size must invest at least 2 percent of their revenue into R&D.
- **Entrepreneurial expansion** The 13FYP places more focus on entrepreneurial growth than product-based growth, suggesting the government’s long-term strategic view of the industry. Promoting market share growth of select medical companies will help them manufacture high-quality products and invest in innovation and environmentally-friendly production at a lower average cost.  
*Key targets:* More than 100 companies will pass international Good Manufacturing Practice standards; 100 companies will earn an aggregate revenue that makes up 10 percent of total medical industry revenue.
- **Green development** The 13FYP details technical targets for reduced emissions, stronger adherence to the environmental protection law, and greater focus on low-carbon, energy-efficient production.  
*Key targets:* Raise environmental standards in pharmaceutical manufacturing according to the Environmental Protection Law; reduce carbon emissions from the industry by 22 percent, water usage by 23 percent, and volatile organic compound emissions by 10 percent; strengthen clean production standards and mandatory reviews of production processes; and construct green manufacturing plants and parks to experiment with low carbon, energy-efficient production methods.
- **International competitiveness** The 13FYP reiterates 12FYP growth trajectory goals, prioritizing increased medical exports to improve international competitiveness.  
*Key target:* Exports will make up 10 percent of total sales revenue within the industry.

These medical sector growth targets strongly emphasize innovation, R&D, and entrepreneurship, signaling China’s desire to drastically improve product quality and competitiveness. Such goals pressure manufacturers to achieve higher production standards within a largely underdeveloped market. Although China is pushing to develop its domestic medical industry and create greater independence from foreign products, it will remain dependent on international industry expertise, technologies, and products during the current development period. USCBC member companies are in position to play a leading role in the industry as CFDA and other regulatory bodies seek foreign assistance to achieve these ambitious targets.

## 13FYP on Deepening Medical and Health Reform

This [circular](#), released by the State Council on January 9, 2017, serves to enhance medical reform during the 13FYP period, particularly for health insurance and hospitals, including:

- **Hierarchical healthcare system** More than 85 percent of cities should start implementing hierarchical diagnosis and treatment—a system that uses [varied tiers of hospitals](#) to allocate medical resources to grassroots institutions—by 2017; optimize distribution of medical resources; clarify roles of medical institutions at different levels; promote the sharing of resources and diagnoses; improve town and community health center capacity for diagnosing common diseases; and guide public hospitals to make use of the hierarchical system in treating complicated and serious diseases.
- **Hospital reform** Establish an efficient management system that separates business operations as independent legal entities from government administration; adjusts medical service prices to reduce operational costs of public hospitals; curbs the unreasonable rise of medical expenditures; launches an efficient human resource management and payment system; and provides performance-based competitive salaries to hospital employees.
- **Health insurance** Establish an efficient national healthcare insurance system that includes sustainable revenue streams and a reimbursement ratio of about 75 percent; reaches a nationwide medical insured rate

of 95 percent and promotes an integrated national insurance and payment network this year; strengthens coverage for those with critical diseases, enabling critical illness insurance to target poverty-stricken people; and encourages diversified coverage of commercial health insurance.

- **Doctors** Expand the pool of family doctors to cover the entire population; ensure that every country-level region has at least two qualified doctors for every 10,000 people and at least 300,000 general doctors in the country.

As China uses new reforms to bolster its healthcare, hospital, and insurance systems, USCBC member companies that develop hospital and health clinic equipment, as well as digital payment technologies, should seek new market opportunities. China's growing emphasis on extending resources and networks to rural regions means that USCBC members should prioritize cultivating new or existing relationships with provincial and local governments to accommodate the specific product and technology needs of various regions.

## 13FYP on Hygiene and Health

The State Council recently [issued](#) the 13FYP on Hygiene and Health, targeting various demographic groups to promote healthier habits and lifestyles. The plan, announced January 10, 2017, highlights the following targets and groups for the five-year period ending in 2020:

- **General life expectancy** Raise average life expectancy by one year; lower premature death rate caused by major diseases – such as cancer, chronic respiratory diseases and cardio-cerebrovascular diseases – by 10 percent.
- **Smoking** Reduce the smoking rate among people older than 15 years to less than 25 percent; and launch programs that promote health education, nutrition, and tobacco control.
- **Women and children** Improve health conditions for women, infants, and teenagers; lower death rates to less than 18 per 100,000 among pregnant women and 7.5 per 1,000 among infants; continue the two-child policy; and crack down on sex-selective abortion to address gender imbalance.
- **Elderly, poor, and disabled** Distribute government subsidies to eligible poor and disabled residents to subsidize basic healthcare insurance.
- **Grassroots services** Offer more support to grassroots clinics and general practitioners and encourage patients to visit grassroot clinics to reduce crowding at large hospitals.
- **Standards** Enhance supervision of healthcare services, including food and drugs; establish more than 300 national food safety standards; and modify several medical standards.
- **Finance** Encourage an influx of private capital, as well as social and scientific research institutions to provide healthcare services and develop new medicines and medical facilities; and promote commercial insurance.

China's growing insistence on tackling widespread societal health challenges by expanding nationwide health clinic and R&D capacities presents important opportunities for USCBC members. China will call on US industry experience and expertise to more efficiently achieve its ambitious reform agenda. As China takes steps to launch and improve these institutions and accompanying products, services, and technologies, USCBC members should work with provincial and local governments to play a leading role in assisting China's sector development.

## Healthy China 2030

Healthy China 2030, a plan [released](#) by China's Central Committee and State Council on October 25, 2016, touches on many of the themes in the 13FYP on Hygiene and Health. Promoting broader national goals for healthier lifestyles and living environments in China, this campaign [includes 29 sections](#) covering health and medical services, food and drug safety, and environmental management.

[President Xi Jinping](#) heavily promoted Healthy China 2030 as a guideline for policymakers across sectors as China moves to [stabilize its economy](#), shaken by years of rapid industrialization, urbanization, population aging, and other environmental and lifestyle changes. Methods include:

- Improve drug inventory and emergency supply.
- Construct a modern pharmaceutical supply network for rural areas.

- Change drug pricing by strengthening the link between price, health insurance, and procurement.
- Strengthen the innovative capabilities of manufacturers of generic drugs, Chinese medicine, new reagents, and high-end medical devices.
- Commercialize important medications and hasten the upgrade of medical devices.
- Reach international standards for drug and medical device quality.
- Increase the international market share of new domestically produced medical and clinical devices that adhere to intellectual property rights standards; and raise the domestic production rate of high-end medical devices.

Healthy China 2030 [targets](#):

	2015	2020	2030
<b>Life expectancy</b>	76.34	77.3	79
<b>Rate of infant mortality</b>	8.1 per 1,000	7.5 per 1,000	5 per 1,000
<b>Rate of premature death caused by chronic conditions</b>	19.1%	10% lower than 2015	30% lower than 2015
<b>Personal financial contributions as percent of total cost of healthcare</b>	29.3%	Roughly 28%	Roughly 25%

Healthy China 2030 reflects China’s steadfast goals to greatly enhance its domestic healthcare sector. Championed by the country’s highest leaders, this major public campaign encourages healthier and better aware lifestyle habits among Chinese citizens. China has reaffirmed many of these goals, outlining strategies for achieving proposed development and targets through these various healthcare FYPs. As the Chinese government signals a determined effort to improve lifestyles by strengthening healthcare systems across the country, USCBC member companies have an opportunity to help usher in this development.

## Prioritized medical products in the 13th FYP

The 13FYP identifies products necessary for domestic market development and policies and reforms intended to create regulatory efficiency in the Chinese medical sector.

### *Pharmaceuticals*

China’s pharmaceutical market, the [second-largest in the world](#), is expected to grow 9.1 percent annually from \$108 billion in 2015 to \$167 billion in 2020. The 13FYP prioritizes innovative drugs and manufacturing technology for drugs, such as biomedicines. The government has also called on the industry to develop: drugs with less side effects, new drug intake methods, and technology to treat biohazardous waste. Categories of prioritized drugs include:

- Antibody drugs for treating cancer and cardiovascular diseases
- Vaccines for major contagious diseases such as tuberculosis, malaria, dengue fever, Ebola, AIDS, MERS, and Zika
- Recombinant protein drugs to treat diabetes and viral infections
- Ingredients for protein-free and serum-free mediums, as well as protein separation and purification mediums
- Other innovative drugs for treating rare diseases, malignant tumors, diabetes, neurodegenerative diseases, mental illnesses, autoimmune diseases, and drug-resistant bacterial infections.

China's recent policies and programs facilitate the development and provision of prioritized drugs and technologies. To improve its backlogged review and approval system, CFDA implemented a series of policies during the past two years that lay out reform plans:

- **Clinical trial reform** Generic bioequivalence switched from an approval to a notification system, shortening the approval process for generic drugs by three to four years. Also, approvals for imported drugs were adjusted to accept simultaneous clinical trials, instead of only those drugs in phase II and III clinical trials.
- **Market authorization holder pilot program** Prior to reform, only manufacturers were allowed to apply for a drug approval number (DAN), leading to overcapacity and less incentives in the pharmaceutical sector. A November 2015 National People's Congress decision on market authorization holder (MAH) reform instituted a three-year pilot program in 10 provinces that removed the need for manufacturing licenses for drug approval numbers. China expects these changes to offer opportunities for contract manufacturing organizations and reduce pharmaceutical overcapacity.
- **User fee reform** In 1995, user fees for domestic new drug applications (NDA) were between 10,000 and 25,000 RMB – about 0.07-1.18 percent of fees in the United States. Despite a drastic increase in fees during the 20 years since, China's user fees are still only about 3 percent of US fees. Imported NDA fees were raised from 45,300 RMB in 1995 to 600,000 RMB in 2015.
- **Human resources reform** CFDA pledged to recruit 300 new reviewers by the end of 2016 and adopt a competitive payment system to recruit international talent. CFDA also signed a memorandum of understanding (MOU) with the Gates Foundation in mid-2016, in which Gates agreed to provide international talent and support to CFDA.
- **Drug procurement catalog expansion** The Ministry of Human Resources and Social Security (MOHRSS) announced in September an update to the [Catalog of Pharmaceutical Products for National Basic Health Insurance, Work Injuries Insurance, and Reproductive Insurance](#), which will add 300 drugs to the catalog for public hospital procurement. Foreign companies offering "high-value and urgently needed drugs" should see benefits from this change. The government [claims](#) that drug selection will be impartial, data-based, and subject to the "full authority" of an expert panel to readjust the catalog, as no government authority will intervene in evaluation and selection procedures. However, this claim may be problematic, as the first step of the drug selection procedure involves government issuance of a pre-approved drugs list, which is then presented to the expert panel for selection into the catalog. This feature allows the government to discriminate against imported drugs through preliminary filtering.

CFDA's reforms are expected to cause short-term setbacks for domestic Chinese companies, but yield long-term benefits. Multinational corporations stand to benefit as China becomes part of their global launch strategy for new drugs. Consumers will have greater access to higher quality drugs in a more timely manner.

### *Medical devices*

The Chinese medical device market is forecast to grow by 8.7 percent annually. The [fourth-largest market globally](#), sales are expected to rise from \$17.8 billion in 2015 to \$27 billion in 2020. As with the pharmaceutical sector, the 13FYP provides a list of medical devices China aims to develop based on growing market demand. They are:

- High-end scanning equipment such as PET-CT, PET-MRI, and DSA
- In-vitro diagnostic equipment such as TLA, POCT, and blood cell analyzers
- Implantation equipment including heart valves, orthopedic 3D printing, cochlear, dental, and intraocular implants
- Mobile treatment equipment for elderly care and at-home therapy

As China emphasizes medical device sector development, it seeks to speed up the review and approval process for devices as they enter the market. CFDA has created new provisions that prioritize certain devices to reform the market entry process.

- **Breakthrough devices** CFDA issued the [Rules for Prioritizing Review and Approval for Medical Devices](#) on October 25, which offers a priority review and approval pathway for high-end, "breakthrough" medical devices. These rules came into effect on January 1, 2017:

- Class II and III imported devices and Class III domestic devices can be prioritized for registration application if the technology is urgently needed for clinical use and differs from existing registered products
- Devices may also obtain priority status if the product is proven to have therapeutic advantages in diagnosing or curing rare diseases or malignant tumors; or diagnose or cure elderly-specific or children-specific diseases that cannot be effectively diagnosed or cured with current methods.

Only [four of the 67 devices](#) approved for priority review from February 2014, when the CFDA trial began, through July 2016 were foreign manufactured. This imbalance suggests CFDA is using the priority review pathway to favor Class III domestic devices over Class II and III foreign devices.

- **Automated manufacturing** China will build at least 10 pilot plants specializing in automated manufacturing of medical devices, replacing existing plants in which devices are fitted and produced. Quality evaluation will also be automated.
- **Quality standards** China is upgrading quality standards for medical devices, to support industry efforts to improve manufacturing quality, and will begin clinical trials for product reliability and stability.

China is calling for the development of various advanced pharmaceutical and medical device products as it moves to modernize the domestic healthcare sector during the present five-year period. USCBC member companies that manufacture these drugs and devices can help China achieve market targets, particularly during the development phase. China will continue to depend on foreign industry expertise, technology, and equipment to fulfill its goals of establishing quality medical infrastructure managed by a high standard of regulatory oversight.

## Foreign investment in China's healthcare

The recent release of the [Catalog Guiding Foreign Investment \(CGFI\)](#) and [Catalog of Encouraged Imported Technology and Products](#) reaffirms China's desire to incorporate foreign technologies as it develops the domestic medical sector. Given existing domestic technological gaps, these encouraged products and investments indicate opportunities for companies. These products are listed as follows:

### *Catalog Guiding Foreign Investment: Pharmaceuticals*

China's most recent negative list is largely welcoming to imported medical products, with the exception of investments in medical institutions restricted to joint ventures or cooperatives, as well as traditional Chinese medicine production technologies. As USCBC member companies seek opportunities to invest and contribute to the development of the Chinese medical sector, they should pay particular attention to following CGFI provisions:

- New types of compound medicine or medicine with active ingredients
- Amino acids, including fermented tryptophan, histidine, and methionine
- Development and manufacture of new anti-cancer medicines; new heart, brain, and blood vessel medicines; and new neurology medicines;
- New medicines using bio-engineering technology
- AIDS vaccines, hepatitis-C vaccines, contraceptives, and new vaccines such as those for cervical cancer, malaria, and hand-foot-and-mouth disease
- Oceanic/marine medicines
- Pharmaceuticals, including new forms of pharmaceuticals and new products that use technologies and delivery mechanisms such as slow release, controlled release, targeting, and absorbing through surfaces
- New pharmaceutical adjuvants
- New diagnostic reagents
- New technology and equipment that control medicine quality
- New technology for analysis of effective ingredients in natural medicines, new techniques for extraction, and new equipment for these purposes

### *Catalog Guiding Foreign Investment: Medical Devices*

The CGFI negative list is also welcoming to medical devices, including:

- Key elements of medical imaging equipment (high-field superconducting magnetic resonance imaging equipment, X-ray computed tomography imaging equipment, and digital color ultrasound diagnostic equipment)
- Supersonic energy converters (3D) for medical applications

- Boron neutron capture therapy (BNCT) equipment
- Image-guided, intensity-modulated radiation therapy system
- Hemodialysis and blood-filtering machines
- Fully automated biochemical monitoring devices, five-category blood cell analyzers, fully automatic chemiluminescence immunoassay analyzers, high-throughput gene sequencing systems
- Multi-layer water-cooled film blow molding equipment with non-PVC medical intravenous infusion bags

#### *Catalog of Encouraged Imported Technology and Products: Medical Devices*

China's [Catalog of Encouraged Imported Technology and Products](#) also reveals China's openness toward foreign medical device imports, including the following products:

- Technology for developing clinical therapeutic equipment
- Manufacturing of electronic medical products
- New model diagnostic medical equipment
- Minimally invasive surgery and interventional therapy instruments
- Emergency and mobile medical equipment
- Rehabilitation devices
- Household medical equipment
- Contraceptive devices (third generation IUD)
- New model medical materials
- Artificial organs and other crucial parts
- Medical imaging product digitization and medical information technology development and use

In addition to the CGFI and Catalog of Encouraged Imported Technology and Products, recent regional policies issued by provincial governments also encourage foreign investment in the medical sector:

- **Yunnan** The [Yunnan Province 13FYP of Science and Technology Innovation](#) indicates government support toward foreign companies that seek to set up R&D institutions or centers in the province.
- **Shanghai** The [Shanghai three-year action plan](#) includes interest in attracting top multinational enterprises and R&D institutions to set up headquarters in Shanghai.

Drugs and devices listed in recent investment and import catalogs shed light on the medical products China will prioritize during the current five-year period. China will seek to overcome limitations and advance its goals as quickly as possible, making use of imported products in the short term. As China targets foreign industry products and related expertise, USCBC companies that manufacture these drugs and devices should seek to play a direct role in assisting China's sector development.

## Conclusion

China has made healthcare a top priority for enhancing citizen quality of life. New commitments to improve regulatory standards and efficiency, product and service quality, infrastructure capacity, and nationwide scope of coverage are a signal of China's long-term goal of high-standard universal healthcare for the world's largest population. China has taken an important first step toward these broad medical sector development goals through outlining an array of healthcare industry 13FYPs, investment and import catalogs, and other sector-specific policies. These documents are intended to indicate Chinese government strategies for advancing the safety and scale of its domestic pharmaceutical and medical device industries.

However, they also shed light on ways in which foreign companies can assist China in meeting its healthcare reform targets. USCBC healthcare companies are among those leading global industry efforts to develop products and services that improve the human condition. As China takes steps toward tackling its reforms, USCBC members should leverage their expertise, technologies, and experience, partnering with China to help turn goals of improving citizen health into a reality.