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# China's medical device market: **New Policies, Higher Stakes**

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The recent introduction of the *Regulations on the Supervision and Administration of Medical Devices* (also known as State Council Order 650) has created significant impact in the medical device industry in China. The changes affect products at each stage of their life cycle. This paper offers analysis of the major changes, and provides insight into the organizational design and development of the regulatory affairs function at a medical device company in China.

**The biggest concern** for leaders of multinational medical device companies operating in China is regulatory change. A 2014 McKinsey survey revealed that the top item on executives' agendas—some way ahead of other critical issues such as talent attraction and retention, competitive intensity, and the sustainability of commercial models—is government-driven regulatory change *(see Exhibit 1 below)*.

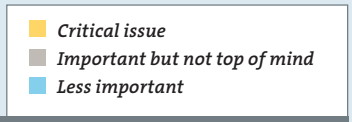
This reflects the fact that recent regulatory changes are affecting almost every aspect of companies' business models, from manufacturing, product registration, and go-to-market approach all the way to product pricing and commercial access to end users. Although the new policies have yet to be implemented in full, companies would be well advised to start planning their responses now. Businesses that adopt a "wait and see" approach risk incurring delays and extra costs in launching their products, failing to meet new standards for manufacturing and distribution, and harming their chances of success at a time when pricing pressures are intensifying.

In this paper, we examine the transformation under way in China's regulatory system for medical devices, look at what the changes mean for companies in the industry, and consider what leaders should do to achieve the regulatory excellence needed to create value in the new environment.

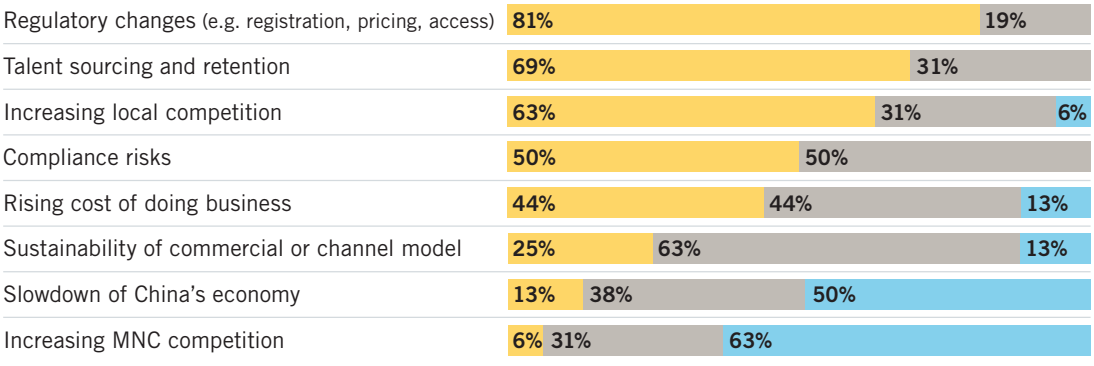
**Exhibit 1**

## Regulatory Changes are a Major Concern for Medical Device Leaders in China

McKinsey's survey collected views from **16 general managers** of top multinational medical device manufacturers, representing **40–50%** of MNC medical product revenues in China




*"What are your key worries about the China market?"*




SOURCE: McKinsey survey of medical device CEOs in China, 2014

## A REGULATORY TRANSFORMATION IS UNDER WAY

In March 2014, the Chinese Food and Drug Administration (CFDA) introduced State Council Order No. 650, with wide-ranging provisions affecting clinical trials, product approvals, manufacturing practices, product distribution, and post-launch supervision of medical devices. Some of the most important provisions for industry participants are:

### R&D: Guidelines for clinical trial waivers

Order 650 stipulates that all domestically produced and imported class II and III devices must undergo product registration trials within China unless they are listed in the CFDA's clinical trial waiver catalogue or meet certain other conditions. Clinical trials can be waived on a case-by-case basis if the safety and efficacy of a device can be demonstrated through non-clinical performance evaluations or through the analysis of data derived from clinical studies or clinical uses associated with the same type of device already approved in China. However, it is not yet clear how much equivalence needs to be established with the approved device. In addition, the guidelines for clinical trial waivers acknowledge the possibility of referencing foreign study data, although they do not stipulate whether it can completely substitute for local registration study data.

### Regulatory approval: Opportunities for fast-track registration

In February 2014, the CFDA issued guidance on a fast-track approval process for new medical devices. In this process, devices designated as innovative are given priority in the registration queue and afforded abundant opportunities for consultation with examiners and experts. Applications for innovative status can be made by any medical device manufacturer, domestic or foreign. So far, 34 products – two of them imported – have been designated for fast-track approvals. Anecdotal evidence suggests that these can reduce approval timelines significantly. For example, one domestic corneal implant was approved within 80 working days of submission, much faster than the typical timeline for an implant of six to nine months.

### Manufacturing: New GMP regulations

The CFDA recently replaced the 2011 good manufacturing practice (GMP) regulations for medical devices with an updated version that came into effect in March 2015. All device manufacturers are expected to meet China's GMP standards throughout their product development and manufacturing cycles, whether they manufacture in China or overseas. The priorities and areas of concern set out in the Chinese GMP can differ from those under ISO 13485, so the manufacturers of imported devices will need to carefully evaluate their quality management systems and ensure compliance with the new standards.

### Distribution and post-market surveillance: New GSP regulations

The CFDA issued its first-ever good supply practice (GSP) document for medical devices in December 2014 to tighten controls over distribution. This heightened level of post-market surveillance brings additional concerns. China's inventory of imported devices may not always carry up-to-date information on product licenses, and can be challenged by local enforcement authorities. Changes in the regulatory approach for certain

devices could also leave room for ambiguity. For instance, local enforcement authorities may interpret the removal of explicit references to research-use-only IVDs (in vitro diagnostics) in the registration rules as meaning that these devices are no longer allowed under the new regulatory regime unless they have been converted into registered products.

### ■ COMPANIES FACE HIGHER STAKES AND GROWING COMPLEXITY

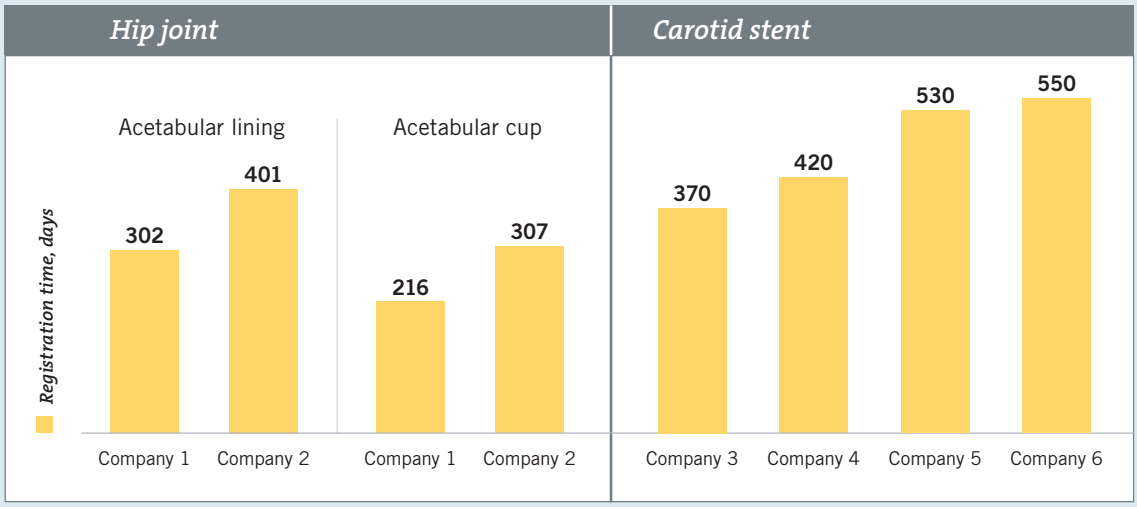
All of these developments have implications for how companies operate in the new regulatory environment.

Past cases show that the speed of registration varies significantly between similar products, which may reflect differences in regulatory affairs practices between companies. Exhibit 2 *(below)* shows that one company was able to bring a product to market almost 100 days faster than a competitor, giving it a first-mover advantage in capturing the market opportunity. By contrast, products launched as followers face challenges in securing market access because of limited procurement quotas and irregular tendering cycles at public hospitals. Latecomers also face difficulties in building a leadership position among physicians. The gap between top performers and the rest is likely to widen as regulatory changes increase the complexity of developing, trialing, manufacturing, and launching new medical devices.

The new environment will bring a number of additional factors into play:

**Exhibit 2**

## Registration Timelines Can Differ Substantially for the Same Product




SOURCE: CFDA

### Clinical trial waivers: Highly desirable, but fraught with uncertainty

A company's ability to make a case for its new product's equivalence to an already approved device can determine whether or not it is able to obtain a clinical trial waiver. In turn, this has a huge effect on approval timelines and cost: a typical trial for a medical device takes one to two years and costs 100,000 to 500,000 RMB. Under the new regulatory regime, the requirements for a clinical trial waiver are to be interpreted and substantiated by examiners on a case-by-case basis. It is hardly surprising, then, that all the regulatory affairs leaders who took part in our survey expressed a degree of uncertainty about the likelihood of obtaining clinical trial waivers.

### Fast-track approval process: Limited take-up so far

The average processing time for CFDA approval is between 11 months and two years, and a substantial majority of respondents to our survey felt that approval lead times had yet to show any signs of shortening. The fast-track approval process – or so-called "green channel" – for medical devices designated as innovative gives them priority in the registration queue and provides extensive opportunities for evaluation and consultation, helping them to secure a more favorable market position. Yet among the respondents to our survey, only a minority said they considered taking advantage of the fast-track protocol. Some cited intellectual property risks and unproven savings in launch time as deterrents.

### New GMPs: Affecting local and global manufacturing

With a number of production sites in China expecting to be challenged or closed for failing to meet the higher bar for quality management, the new GMP standards have become a source of increasing concern for local manufacturers. In future, audits of foreign manufacturing sites may also run into difficulties because of differences in quality systems, standards, and priorities between China and other countries.

### Post-market compliance: Need for consistency in interpretation

Post-market compliance is becoming increasingly challenging because of a lack of consistency in local enforcement authorities' interpretation of statutory requirements. These authorities are allowed to exercise a degree of discretion in identifying misconduct, especially if it extends before and after Order 650 came into effect. How the misconduct is characterized affects the scale of the penalties imposed on the manufacturer. The regulatory affairs team plays an important role in communicating their organization's position and bridging the gap in the understanding of regulatory standards between their company and the local enforcement authorities.

Given the high stakes of clinical trials, approval timelines, manufacturing quality standards, and enforcement risks, medical device manufacturers will need to put great efforts into understanding the new regulations and implementation rules. This task is complicated by the fact that the regulations are still evolving and are imprecise in places, while at the same time the CFDA is undergoing changes in its senior leadership.

## NOW IS THE TIME TO PLAN A RESPONSE

To navigate these changes in the medical device industry in China, executives should act quickly to build excellence in regulatory affairs by:

### Developing seamless interactions between local regulatory affairs and the global team

Companies should seek to establish a close working relationship between the local regulatory affairs team and the global teams for R&D, regulatory affairs, quality assurance, and operations. The goal is to establish a shared understanding of China's new policy requirements and what they imply for the company's product development and manufacturing. Global teams and business units need to involve regulatory affairs in developing business plans for new products and throughout the R&D process, rather than near the end of it or when problems occur.

### Becoming a valuable partner to regulatory bodies

Constructive partnerships between manufacturers and regulators will add value to regulatory efforts and improve healthcare outcomes. With this in mind, companies should consider carving out a position as a thought leader. This might involve hosting workshops on cutting-edge technology for examiners from the Center for Medical Device Evaluation, for instance, or supporting research projects led by the CFDA, third-party thinktanks such as the China Society for Drug Regulation, or other bodies to analyze regulatory practices internationally, identify best practices, and advise on future policies for China.

For multinational corporations, it will be important to show a willingness to work towards what the industry needs at its current state of development in China. Chinese regulators will appreciate their efforts to adapt their regulatory philosophy to local conditions rather than simply transplanting approaches from the US or Europe. Local regulatory affairs professionals play a critical role in bridging any gaps in understanding between corporate leaders and Chinese regulators. To be effective, these professionals must not only fully comprehend statutory requirements and translate them into practical business terms for internal purposes, but also clearly articulate the company's aspirations in China, and be prepared to explain to local authorities any need for special considerations under the medical device regulations. The best companies will work towards long-term two-way partnerships with regulators that allow them to explain the benefits of western approaches and the CFDA to make its regulatory philosophy better known to foreign regulators.

### Building the capabilities of the regulatory team

As regulatory affairs evolves from a support function to a driver of business value, companies need to ensure their regulatory teams are equipped with all the competencies they need to fulfill their enhanced role.[1] In practical terms, this begins with a comprehensive grasp of domestic and international laws, regulations, and guidance on medical devices across the full market cycle of a product. Regulatory teams need to understand and

[1] For more details, see Sandra Shire, Charles H. Swanson, Daniela Drago, and Jean E. Feagin, "Core competencies provide a roadmap for strengthening regulatory education," Regulatory Focus, September 2014.

implement quality systems and standards for ensuring compliance with GMP. They also need to understand the regulatory requirements for clinical trials, recognize the factors that influence regulatory policy making both nationally and globally, and help bring their company's product-development priorities into line with customer demand in China.

In addition, regulatory teams need strong analytical and communication skills to interact successfully with people from a range of specialist and non-specialist backgrounds, including regulatory, medical, engineering, business, and marketing. Finally, they need to work closely with other functions across the organization to reduce internal lead times for regulatory submissions and develop a good working relationship with regulators.

All this implies a profound evolution in the role of regulatory affairs leaders. From its original largely back-office function, the role will expand beyond deep content expertise to include the ability to engage local regulators and the leadership capabilities and executive-level influence to work with global stakeholders and drive the China agenda in a forward-looking, strategic fashion.

Company leaders will also need to foster the right environment for attracting and retaining the best regulatory talent, since top professionals are in high demand and often difficult to locate in local talent pools.

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As China's regulatory landscape becomes more complex and demanding, the value at stake for medical device companies will grow sharply over the next five to ten years. Regulatory excellence will become an important component of commercial success. To build competitive advantage, companies need a team of professionally capable and culturally sensitive regulatory affairs professionals. To overcome the challenges and capture more value, leaders must ensure that regulatory affairs has the capabilities, relationships, and status to evolve from a purely functional role to a strategic value-adding role in the business.

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