MADE IN CHINA

IN HEALTHCARE INDUSTRIES:

REGULATORY FRAMEWORK AND WHAT IT MEANS FOR FOREIGN COMPANIES

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Introduction

With the continuous rise of healthcare needs in China, the market remains eager to welcome new medical devices from foreign companies. Although the FDA (Food and Drug Administration) and the EMA (European Medicines Agency) are recognized in the domain of benefit/risk ratio validation and registration, getting approval by the NMPA (National Medical Products Administration) in China is another challenge. In fact, besides requiring approval by the FDA or the EMA, the NMPA adds its own conditions to grant access to the market.

The imported product has to offer something new – be it to patients, to practitioners, to healthcare institutions, or to the healthcare chain as a whole e.g. medico-economic benefits – to keep a competitive status and good visibility. Otherwise, making a difference and being seen among the tens of makers offering solutions in the same domain will take much work, sometimes for uncertain rewards.

While overall faster than 5-10 years ago, the approval process is quite complex, depending on the device's characteristics and the market. We will go through different aspects and steps to give the best insights and advice leading to the smoothest approval process.

Local support for such projects is more than advised. Between local cultures, contacts in networks, and the number of stakeholders throughout the market entry process, a local team is necessary to follow up on the submission.

Classification

Medical devices are sorted into three classes:

Class	Description	Registration
I	**MD with the lowest risk, where safety and effectiveness can be ensured through routine administration**	**Filing Only**
II	**MD with moderate risk, where strict control and administration are required to ensure their safety and effectiveness**	**Registration Required**
III	**MD with the highest risk and must be strictly controlled and administered through special measures in respect to safety and effectiveness**	**Registration Required**

How to determine the classification?

- Search on NMPA Website: Need to know well the NMPA website is quite complex to find the most suitable and most accessible way.
- Query Classification Rules/Catalogue: According to the Class of the product, there are different ways to conduct the research
- Submit a Request for Official Classification – Duration 2-3 months.
- Submit Directly to the NMPA as Class III Product Innovative, Priority, and Drug-Device Combination Products ("Breakthrough" / "Green Channel" equivalents): specific approach

There is also the possibility to bypass this step by registering the device directly in Class III. However, the full validation for a class III device may require steps that are not necessary if the device is in a lower class. A higher class can also be selected to prepare for future evolutions of the device as a class change following an upgrade is very impractical.

The more this phase is anticipated, the more time and funds will be saved. As for example, required clinical trials for China may be alleviated thanks to clinical results submitted to FDA or EMA or to real-world clinical evidence collected overseas.

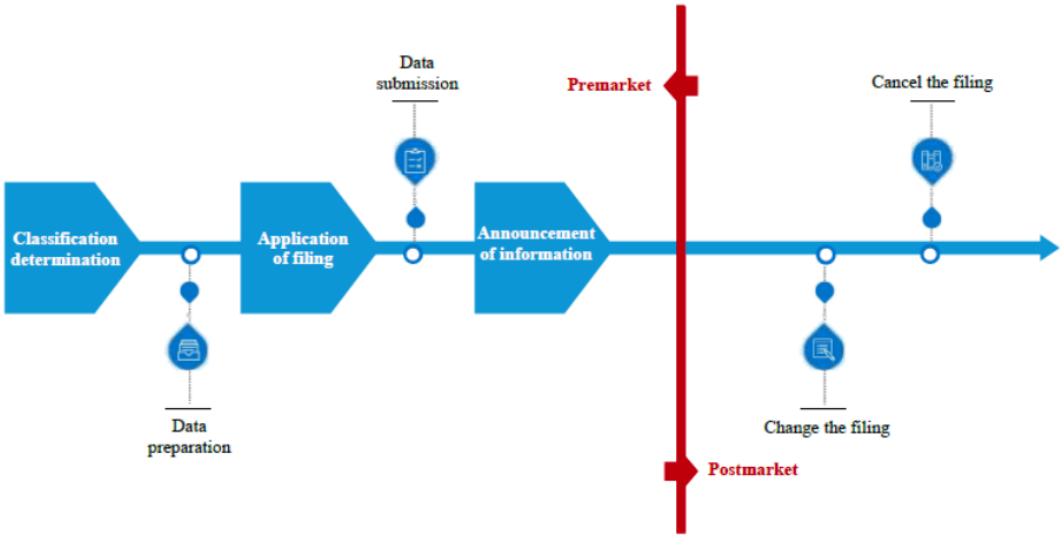
CLASS I FILING PROCESS

AS STRAIGHTFORWARD AS IT GETS, BUT ATTENTION TO DETAIL IS STILL REQUIRED

Class I concerns mainly simple mechanical devices (such as orthopedic braces, bandages for instance). Although the submission is only documents and reports, authorities will perform deep analysis. A very detailed approach is required.

Requirements:

- Seven documents to file, containing:
  - Product Technical Requirements
  - Test reports
  - Manufacturer info
- Lead time: 2-3 months
- Administrative Cost: 0



CLASS II-III REGISTRATION PROCESS

It looks tedious on paper, but is highly optimizable in both preclinical and clinical phases. For instance, almost 90% of the new Class II medical devices registered in 2021 did not require any local clinical trials. Of note, the vast majority of digital health medical devices belong to one of those two classes.

Local support is necessary for these classes. The required investment will be justified by savings made throughout the process, not only in terms of registration documentation contents, but also in terms of time, particularly during the preclinical testing phase.

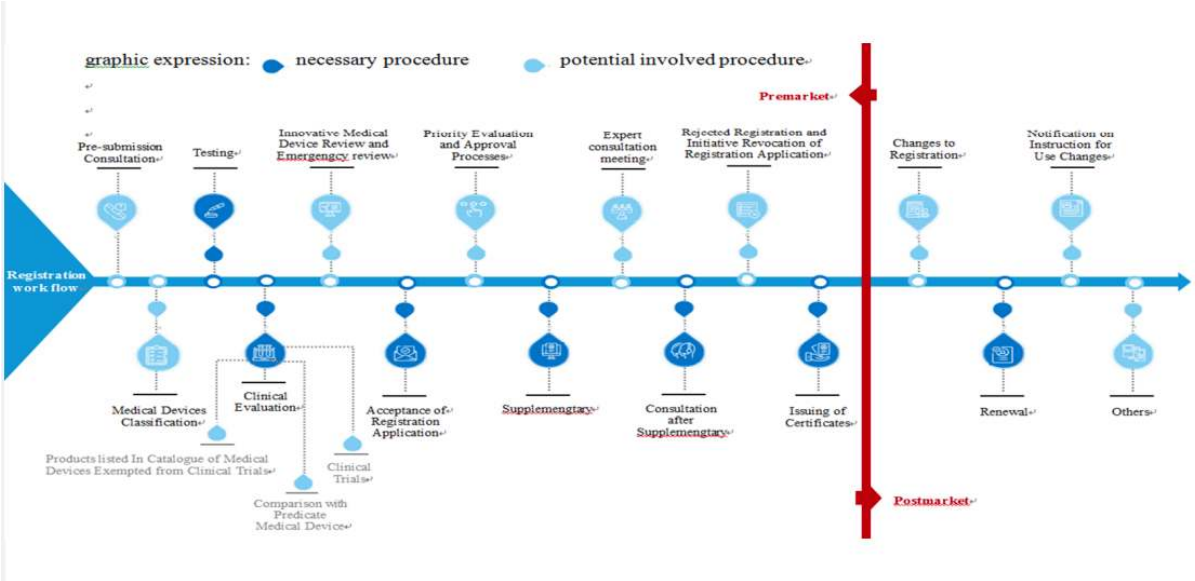
Requirements:

- **ISO13485 certificate**
- **Risk analysis report**
- **Product Technical Requirements**
- **Test reports**
- **Manufacturer info**
- **Clinical Evaluation Reports**
- **Etc.**

Lead time: 1-2.5 years

Administrative Costs excluding Clinical Studies

- **Testing 3~15k EUR**
- **NMPA submission 30-45k EUR**



IMPORTATION VS DOMESTIC ASSEMBLY/MANUFACTURING

In 2013, 75% of medical devices in China were imported. Between the rise of this market, legal adaptations, and projection, the target is 75% locally produced, and even 100% in defined product ranges. Having the device produced in China may be a solution to avoid the disadvantages of importation, and deep analysis is required to make the decision.

In terms of regulatory submission, process lead time gap will vary depending on the device class. Some steps and documents are indeed optional for domestic manufacturing. In theory, it looks simpler and faster. However, considering the complexity of the device and technology, several crucial questions to explore before making any decision:

- Quality control
- Protection of technology/knowledge
- Time required for technology transfer
- Balanced business relationship
- Territory of influence

A thorough manufacturing partner search and/or audit is absolutely required prior to choosing this route. However, especially for medium- to high-sales volume devices, local assembly / manufacturing is becoming more and more popular.

For medical products belonging to the 'Software as a Medical Device' (SaMD) category, the distinction between domestic and import registration is less clear-cut, which gives specific market entry opportunities but also requires deeper ad hoc analysis to determine the optimal regulatory pathway.

No.	Difference	Class I		Class II		Class III	
		Imported	**Domestic**	Imported	**Domestic**	Imported	**Domestic**
1	Department	NMPA Beijing	Municipal	NMPA Beijing	Provinces	NMPA Beijing	
2	Registration numbers	Marked as "G."	Abbreviation of the place	Marked as "G."	Abbreviation of the province	Marked as "G."	
		-	-	Marked as "J."	Marked as "Z."	Marked as "J."	Marked as "Z."
3	Relevant documents	Overseas certification documents	-	Overseas certification documents	-	Overseas certification documents	-
4	Administrative Cost (RMB/EUR)	-	-	210,900 /~30,000	**Formulated by provincial price and financial departments**	308,800 /~45,000	**153,600 /~22,000**
5	Indicative Timeline	2-3 months	**2-3 months**	1-2 years	**~6-15 months**	1.5-3 years	**~9-24 months**

MADE IN CHINA FOR CHINA: EVOLUTION OF LEGAL FRAMEWORK

Decisions on the legal side create new opportunities easing up controls and validations.

March 2020: Decree 9

Extend the possibility for Class II and Class III overseas medical devices to use Real World Evidence clinical data instead of running local clinical trials

This decree brought that the trials and reports produced out of China are better recognized during validations, leading to a reduced pre-submission workload.

September 2020: Notification 104

Allows direct transposition of an import Market Authorization towards a domestic Market Authorization without full resubmission under certain conditions

The purpose of this update was to ease the transition from imported to locally manufactured devices. A simple technical file allows transition in months – or even weeks in certain provinces – rather than years. Local authorities actively promote this process and sometimes even dedicate specialized teams to accompany the manufacturers.

Beyond this, the State Council Decree 739 (9 February 2021) further emphasizes this trend.

THE NEW REALITY OF THE MARKET: VOLUME BASED PURCHASING (VBP)

In order to limit buying costs and facilitate the distribution of medical devices across China, groups of provinces have begun to aggregate their consumption to buy with higher volumes. Purchasing committees have tremendously more weight on negotiations of prices as well as volumes. As VBP is becoming the new trend, unless the device is high-end or very innovative, primary range products – and in particular high-end consumables – are absorbed into VBP volumes.

How do multinationals cope with VBP?

Already established multinational companies face a serious profit decrease due to the large discount generated through VBP. Most of those discounts are higher than 50% discount, usually reaching 70 to 80%. Thus the profitability of the healthcare business in China is to be considered again. Manufacturing their "basic range" in China is a possibility to participate in the game but due to large investment required to manufacture in China, how could you expect a ROI if prices are down by 50 to 70%? Quality and high volumes of some simple products are put to advantage, but this is mostly true for disposables in Medical Devices. High-end, or high technology and innovative products are, meanwhile, still manufactured out of China, thus leading to the question of their future in the post VBP Chinese healthcare market.

They may sometimes mix domestic (basic range) and latest, imported, innovative products to VBP bidding to offer bundle packages. This allows them to propose one-stop-shopping solutions, thereby maintaining volumes and market shares. But profitability is to be considered anyway on a global mid-term perspective as VBP is only one of the potential threat in front of healthcare business in China

"Made In China For China" also impacts medical devices.

This new policy impacts the business of medical devices in several aspects, with volume as a root. Hospitals are required to buy China-made equivalents of existing MD when available. Chinese authorities accepted in October 2021 that multinational companies manufacturing in China could be authorized to participate to public tender for equipment with a similar status than a Chinese manufacturer. Innovative products need some time to ramp up, and even though the private clinic market is on a solid rise, the volumes generated by public hospital purchases (more and more via VBP) are an important factor of long-term success. Another solution is to cooperate with specialized distributors, with access to higher volumes than just a few clinics. This, however, may limit market footprint and brand awareness across the country.

Manufacturing costs could be reduced if multinational companies come to manufacture in China, but China is no longer a low-cost country and fully automated plant in Western countries have limited the impact of lower labor costs. Importation costs could disappear if you ar lucky to find good quality raw materials in China but that is not easy and fast process. Then investments in terms of industrial equipment, processes and systems to implement local manufacturing require important funding to start. But VBP lowering selling prices and profits will increase the difficulty to finance the development costs to manufacture in China. At the end, the fruits of the final outcome will be a great advantage for Chinese companies. But for foreign investors that have been present in China, the large investment requested with the much lower profitability, might represent a high risk of disappearance of Chinese market in a near future..

However, the higher the technology value will be, the higher the chances will be to keep a strategic position on the market. China still needs high technology products, and, as long as patents and IP are well protected, a multinational company with high technology products has a strong chance to be successful in China. Companies with products that have comparable Chinese products could still consider China as a long-term potential interesting market due to the large size of this market.

How do established players cope with "Made In China For China"?

If we don't consider the ROI such as discussed previously, already established companies could use their position to reinforce partnerships and participate in the concept of locally manufactured in China. Partnerships can be developed with carefully selected, trustworthy distributors for local device assembly, but if the equipments are not patented, companies must be very careful of the potential local competitors that could be launched very fast with similar products. Some even engage in China-specific new product development with their existing partners. Some other companies focus exclusively on private clinics but this is still a very small market compared with public hospitals.

Companies specializing in consumables have an interest in working with VBP process, even if due to the large discount required, the profitability has to be considered very closely.. Consumables fit very well with high volumes: easy to produce with scalable productions and volumes, as they are originally designed for their purposes. China has a strategic experience when it comes to building up volumes in production and distribution, and current policies continue to incentivize new manufacturing implantations, but they are mostly provided to Chinese entities. But for healthcare companies providing large equipments or high-end technology, the Made in China policy will make things more complicated to reach Chinese market.

Conclusion

Although China is adapting its strategy to encourage local production and purchase, the importation of medical devices might still have a future but it is uncertain.

Historically, almost every medical device well-established and tested in Europe, the USA, or Japan was able to find its place in the Chinese market, from consumables to high-technology.

Today, consumables and devices in lower regulatory classes (I-II) tend to be locally produced, especially large and high technology equipment. Western Industries already adapted their manufacturing equipment to fit with large volumes, thus labor cost are negligeable in their manufacturing costs. Thus, due to large investments expected to be done, even with lower labor costs, but with also lower profitability, they might need to consider that the most preferable solution is to partner with Chinese manufacturers. But then what is the mid-term outcome for Western multinational healthcare companies? At the same time, more technical devices which are required to be produced in China for the Chinese market face a serious dilemma of their capacity to fit with such requirement.

Foreign companies wishing to develop these projects with local partners have to invest in the efficient transfer of technology to ensure the quality and brand image, protecting the knowledge that they have been developing for years to reinforce their strategic position in the global market. But not every product has patented rights that makes this transfer of technology possible and for all those products the road to the Chinese market is now more tiny than it used to be few years ago.

Thank you for reading

Since its founding in 2013, The French Healthcare Alliance in China has sought to develop the best healthcare solutions for the Chinese society and the strongest collaboration in this field between France & China. As a French organization, our objectives are to promote French Healthcare excellence with the introduction of innovative companies, to organize meetings between experts and to create joint business synergies. The French Healthcare Alliance is the union of more than 150 companies & institutions from various fields such as chronic diseases, infectious diseases, rare diseases, ageing industry and digital health. Our members already have impressive track records and are developing innovative solutions in China, for China.

With the support of the French Embassy and Business France, our organization aims to enhance the relationship and understanding between French and Chinese stakeholders by organizing:

- Medical conferences, such as the Sino-French medical seminars on diabetes in Beijing in 2019 and the French Medical Day in Shenzhen in 2020 with focus on rare diseases, infectious diseases and elderly care. Oncology will be the focus of this year's edition, in Shanghai this November.
- French Pavilions at professional fairs such as CMEF for medical devices and China Aid on the silver economy.Webinars every month since 2020 on several topics such as vaccines, hypertension, infectious diseases, silver economy, E-health, etc.
- Delegations in major Chinese cities to expand the relationship between local companies and French ones and create business opportunities. Platform of information and discussions between industry specialists. We hope that this website will provide an interesting insight into French Healthcare excellence and encourage you to come and join us.