China’s legal framework for pharmaceutical products: challenges and opportunities for EU companies

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Abstract: It is unanimously recognised in the literature that although the Chinese pharmaceutical market offers huge opportunities to European industry, it poses several challenges regarding compliance with the laws governing this sector. Because of the different legal traditions, a peculiar public health history and culture, and a different system of healthcare, EU companies have faced many barriers in accessing the Chinese pharmaceutical market over the years. In order to provide a better understanding of the China’s regulatory landscape and its emerging trends, the article focuses on three critical legal topics, which are relevant for the business of EU pharmaceutical companies in the Chinese market: drug registration, drug distribution system, and IP rights protection.

Keywords: China; drug registration; imported drug; new drug; generic drug; pharmaceutical distribution; wholesale; retail; pharmaceutical manufacture; cross border sales; patent; trademark; trade secret; foreign investment.


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1 Introduction

1.1 An overview on current market state

The Chinese pharmaceutical industry represents a perfect example of China’s impressive change over the last 30 years.

After opening up its policy, China started to change very fast. Its economy became the second largest in the world, making China one of the most attractive markets and making Chinese society an incubator of new demands.

Owing to years of family planning under the one-child policy, Chinese society can be nowadays defined as an ageing society, which means not only a greying population but also a new market of demands, especially in the healthcare sector.

New disease diagnoses have increased and consequently both personal and total national healthcare expenditure has risen (see Figure 1).

Aside from the dramatic meaning of these data, figures show the Chinese pharmaceutical industry has a strong growth potential. This has been confirmed by the 12th Five-Year Plan through which the Chinese Government has launched new policies directed toward strengthening the industry, an evident confirmation that the Chinese Government glimpses a promising market.

The current situation denotes that the Chinese healthcare sector is dominated by the pharmaceutical sub-sector and, even more important, also denotes that with a value estimation of US$83.3 billion (The Economist, 2014) (at the end of 2013) the Chinese
pharmaceutical market is expected to become greater than the parallel Japanese sector in next few years.

Figure 1  China’s healthcare expenditure 2000–2014

As briefly noted above, it can be said the fast and growing importance of the Chinese pharmaceutical sector in the economy is a result of a combination of macro-environmental and industry-driven factors.

The ageing population issue and the increase of new diseases represent mere examples and must be considered alongside the rapid domestic economic growth, Chinese policies reforming the entire healthcare industry (including pharmaceuticals), as well as all the global and national structural changes in the pharmaceutical industry (consider, for example, the pharmerging 3 markets phenomenon).

From a theoretical point of view, recent statistics on sales market value and forecasted data of ‘what next?’ For the Chinese pharmaceutical sector (Pharmaceutical Industry in China to 2020: An In Depth Analysis of Multinational and Chinese Biopharma Companies, Industry Trends, Environment, Regulation, Market Drivers, Restraints, Opportunities & Challenges, 2015) are undoubtedly very attractive. However, the practical experiences of many big multinational companies seem to suggest the Chinese pharmaceutical industry is actually very complex. 4 Therefore, success inevitably requires on one hand a deep knowledge of the market structure, and on the other hand a strong local presence.

Planning a business in China’s pharmaceutical industry – which could mean playing in the manufacturing and/or distribution industry – could be extremely problematic due to a multi-layered structure chain and a fragmented and complex regulatory legal framework.

1.2 A challenging legal framework

It is unanimously recognised in the literature that although the Chinese pharmaceutical market offers huge opportunities to European industry, it poses several challenges regarding compliance with the laws governing this sector (Schatz, 2015).

Owing to different legal traditions, a distinctive public health history and culture, and a completely different system of healthcare, European Union (EU) companies have faced
many barriers in accessing the Chinese pharmaceutical market over the years (European Commission, 2011). Foreign pharmaceutical firms operating in China have experienced many difficulties in the form of legal and regulatory hurdles, such as those stemming from the drug registration process – notoriously long and complicated compared to EU procedures – and from the drug distribution system, which is hampered by complex regulations. Other concerns regard intellectual property (IP) right issues, especially “the lack of proper data exclusivity protection, the absence of patent term restoration, counterfeiting, inconsistent administrative protection, and enforcement” [Griesar, (2006), p.23].

The existing legal framework on pharmaceutical products has been developed from the early 1980s, when the People’s Congress of China approved the Drug Administration Law. This Law, which still represents the basic legislation regulating the sector, marked a ‘new era’ for the administration of drugs in China, characterised by more attention to strengthening regulations and the safety and quality of pharmaceuticals. The Drug Administration Law has been enforced and implemented by several regulations aiming to “protect public health and promote economic development in the pharmaceutical sector by establishing a legislative process for the regulation of drug manufacturing, distribution and purchasing” [Yan et al., (2013), p.714]. Among these instruments, the Regulations for the implementation of the Drug Administration Law (hereinafter Regulations) is of primary importance.

The regulatory framework is completed by several technical guidance documents issued by the China Food and Drug Administration (CFDA), (formerly the State Food and Drug Administration and earlier the State Drug Administration), which is the ministerial-level authority (on the same level as the Ministry of Health) under the control of the State Council in charge of drafting, applying and enforcing drug regulation, as well as drug registration and other relevant functions concerning drugs (Tan et al., 2015). Moreover, it is necessary to take into consideration the special provisions reserved for foreign investors and the rules on IP rights, as explained hereafter.

China is continuously improving its pharmaceutical regulation, aiming to align it with EU and the USA standards in order to guarantee the safety, quality and efficacy of drugs, to foster the development of the domestic pharmaceutical industry and to encourage foreign investment in conformity with the ‘opening-up’ policy.

Against this background, this article aims to provide a better understanding of China’s drug regulatory framework and its emerging trends. For these purposes, it focuses on three critical legal topics, which are relevant to the business of EU pharmaceutical companies in the Chinese market: drug registration, drug distribution and IP rights protection. The paper is structured as follows: Paragraph 2 is focused on drug registration regulation. The evolution and the development of the distribution sector and the different investment channels and models to enter major segments of the Chinese market are described in Paragraph 3, while Paragraph 4 is about IP rights issues.

2 The drug registration regulation

EU companies can place their pharmaceutical products on the Chinese market only after having successfully completed a drug registration application with the CFDA. Unfortunately for them, “China currently has arguably the world’s most complex
requirements for the introduction of new drugs, second only, perhaps, to Japan” [Griesar, (2006), p.17]. Over the years, foreign companies have come up against many regulatory barriers, such as: requirements for the registration process that are unique for each drug and different from international guidelines; long CFDA review timelines for each step of the registration procedure compared to those of other countries; onerous clinical trial processes before the first step of registration, requiring the repetition of some clinical stage for pharmaceuticals and even the full development of vaccines; frequent and unexpected changes in registration procedures; limited dialogue with CFDA staff [Griesar, (2006), p.22; European Commission, 2011). One of the most critical elements of this complicated regulatory environment is the time required when a company decides to enter the Chinese market. Last year the CFDA reported a backlog of drug registration applications, which further hinders market entry. This situation is damaging not only to foreign companies, but also to Chinese patients who have to wait a long time to receive benefits from innovative drugs available abroad.

The drug registration process is regulated by the *Drug Administration Law* and the *Regulations for implementation of the Drug Administration Law*, which set out the basic regulation for pharmaceutical registration. This basic regulation has been enhanced by the *Provisions for Drug Registration* (also known as *Measures of the Administration of Drug Registration or Drug Regulation Registration*, hereinafter *Provisions*),9 which detail the technical requirements and procedures for application, review and approval. Furthermore, the CFDA has issued several technical guidelines to support applicants at each step of the procedure.

According to these registration rules, there are five types of registration applications (*Provisions*, article 11):

1. new drugs applications
2. generic drugs applications
3. imported drug applications
4. supplementary applications
5. re-registration applications.

While the fourth and fifth respectively concern applications to modify an already registered drug and applications for licence renewal, the other types focus on the first pre-market approval. The choice among them depends on the drug category and class that the pharmaceutical product to be registered belongs to. In fact, the Chinese registration system classifies pharmaceuticals into three categories: chemical drugs, biological drugs, and Traditional Chinese Medicine (TCM). Each category is subdivided into several classes (6 classes of chemical drugs, 15 classes of biological drugs and 9 classes of TCM). For each class the *Provisions for Drug Registration* provides the registration application and the documentation for research and clinical trials.

In brief, a new drug application is needed for the registration of a pharmaceutical product that will be manufactured in China but not marketed in China yet (for example, class 1 for chemical drugs); a generic drug application is necessary for the registration of a pharmaceutical product to be manufactured in China but which is a generic version of the drug already approved by the CFDA according to national standards (for example, class 6 of chemical drugs); and an imported drug application is required for the
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registration of a drug manufactured abroad and already approved abroad (for example, class 3 of chemical drugs).

The registration process for the three applications is divided into several steps. The new drug and imported drug registration processes are pretty similar; their registration applications involve two approval procedures: approval for clinical trials and approval for new drug applications or for imported drug applications, and, accordingly, two applications – an application for clinical trials (CTA) and an application for new drugs (NDA) or for an imported drug licence (IDL) submitted upon completion of the clinical trials. Once issued, the New Drug Certificate (NDC) or the Imported Drug License (IDL) is valid for five years.

The thorniest step of the process is that of clinical trials. Their requirements are specified according the drug classification and application type. Generally, local clinical trials are mandatory and can be carried out only at CFDA-accredited hospitals, after obtaining CTA approval. “Even if a product is approved elsewhere in the world, the SFDA is still likely to require the foreign manufacturer to conduct at least one study in China before approval. Results from overseas trials can only be regarded as referential clinical data” [Zhang, (2011), p.165].

For instance, in the case of new chemical drugs, subject to a new drug application, a drug developer (i.e., a clinical trial sponsor) must conduct a three-phase clinical evaluation program (including Phases I, II and III of the clinical trials). For new chemical drugs, subject to an imported drug application, only a Pharmacokinetics study and abbreviated Phase III trial with 200 cases or an abbreviated Phase III trial with 100 cases for treatment arm only are requested.

For overseas applicants, when a drug has already been registered abroad or submitted to Phase II or Phase III clinical trials in another country, the Provisions (art. 44) provide the opportunity to conduct an international multicentre clinical trial – also known as multi-regional clinical trials (MRCTs) – a clinical trial performed simultaneously in multiple regions or countries following an identical protocol. Upon completion of the MRCT, which must be conducted in conformity with the clinical trials requirements of the Provisions, the applicant shall submit the complete report to the CFDA, “and then this regulatory procedure is over automatically” [Zhang, (2011), p.165].

Finally, it is worth noting that Chinese registration rules (specifically, the Rules on Special Approval for New Drug, issued by the CFDA in 2009) also set forth a special registration procedure for new drugs that meet certain requirements (also known as Green Channel). Substantially, this special channel provides fast-track review and approval, offering a shorter approval process and a preferential communication channel between applicants and the CFDA, as well as the facility to freely submit additional data during the review process [Yan et al., (2013), p.720].

The categories of drugs admitted to this special channel are:

1. new drugs involving active ingredients extracted from plants, animals or minerals, not yet marketed in China
2. chemical drugs, active pharmaceutical ingredients (APIs) or biological products that have not yet been approved in China or overseas
3. new drugs for the treatment of AIDS, cancer, and rare or orphan diseases
4. new drugs for the treatment of diseases without effective available therapy.

Such categories have been expanded recently, as noted below.
2.1 Drug development strategies: emerging trends for speeding up new drugs registration

Given this regulatory framework, Western companies have developed various strategies to bring their new drugs to China.\(^1\)

The most direct approach to the Chinese market consists of filing an imported drug application. In this case, as said above, the pharmaceutical shall be in possession of the drug marketing authorisation (demonstrated by the Certificate of Pharmaceutical Product, CPP) in the producing country where the overseas pharmaceutical manufacturer is located. However, drugs as yet without marketing authorisation may still be approved for importation if applicants can confirm their safety and efficacy through clinical trials. For chemical drugs, it is usually necessary that the drug has been in Phase II of the clinical trials conducted overseas. In this case, an entire local clinical trials program (in case of new chemical drugs, from Phase I to Phase III inclusive) is mandatory for progress to the imported drugs licensing stage. “This is an aggressive scenario for imported drugs not marketed anywhere in the world” [Zhang, (2011), p.167].

Conversely, in the case of imported drugs with a CPP, the imported drug application approach has a high probability of success, since the drug has already been approved abroad and its entire dossier can be submitted to the CFDA. Furthermore, “the new drug has been used in a fairly big study population overseas and had passed the high-risk stage of the early years” [Lu et al., (2015), p.517]. Moreover, “the imported drug registration study can be a miniature of the Pivotal Phase III trials and simply mimic the pivotal Phase III trials conducted overseas with a limited scope only in China. Therefore, the investment is relatively small” [Lu et al., (2015), p.517].

However, the other side of the coin is that there is a time lag of approximately five years between the initial approval overseas and the granting of Chinese approval.

An alternative strategy for overcoming such a limitation is the local developed strategy, i.e., the submission of a domestic new drug application. Obviously, in order to do this it is necessary that foreign companies have an established local manufacturing structure.

This strategy offers potential for the early launch of a drug in China, since it could be initiated before obtaining drug marketing approval overseas. Furthermore, the more extensive data collected during the local clinical trials (which is wider-ranging than in the aforementioned approach) and the correlated experience gained with the drug could become a competitive advantage in the marketplace [Su, (2013), p.21].

Moreover, there are advantages in terms of exclusivity. New drugs approved under this scheme are entitled to a ‘monitor period’ of up to five years from the date of marketing approval. During this period, the CFDA will not approve any manufacturing or import applications for the same drug or other formulations of the drug [Su, (2013), p.21]. Furthermore, new drugs with new chemical entities receive six years of data protection (see Regulations, art. 35). “Within this period, the CFDA will reject any application made by other applicants using undisclosed data of the approved drug without the original developer’s permission, unless the follow-on applicant generated the data independently” [PPD, (2013), p.7]. Finally, new drug applications that meet certain requirements can have access to the Green channel.

However, there are also downsides, such as the significant manufacturing investment and the complexity of managing a local manufacturing project [Su, (2013), p.21].
In order to solve these issues or at least to mitigate them, many major multinational pharmaceutical companies are arranging partnerships with Chinese domestic companies or contract research organisations (CROs) in order to collaborate on the local development of innovative pharmaceuticals (Spigarelli and Wei, 2014). These partnerships may take different forms: licensing deals, co-development/co-promotion relationships or even joint ventures [Su, (2013), p.21; Deloitte, 2015]. This ‘collaborative’ approach, which presents challenging aspects but also substantial benefits, is also expanding to take advantage of an emerging new drug development strategy.

In the past few years, another approach to the Chinese market has become more attractive for overseas companies wishing to accelerate new product registration: integration of Chinese clinical studies into MRCT. This pathway allows overseas companies to add China to their global development program for market approval, thus synchronising global market approval.

This approach is increasingly adopted by both overseas pharmaceutical companies with local manufacturing structures, applying for a new drug application, and by overseas pharmaceutical firms without manufacturing structures applying for an imported drug application. In both cases this strategy has several advantages in terms of speeding up the registration.

More specifically, in the case of an imported drug application supported by MRCT data, “since this path allows the clinical programme to start earlier and before the overseas market approval, submission of the NDA to the CFDA for approval could take place right after the overseas approval. An estimated timeframe reduction in China is roughly 1.5 years” [Lu et al., (2015), p.517].

For new drug applications, “one of the commonly accepted strategies is to initiate the clinical activities in China early, adopting the Class I category drug development strategy. Using this method, they can catch up with the western world global development speed. The success of this path could give global companies very early entry to the Chinese market compared to the traditional import drug pathway or the aforementioned IMCT pathways being implemented by multinational pharmaceutical companies without local manufacturing capabilities” [Lu et al., (2015), p.517].

For both applications, it is possible to take advantage of the Green Channel. This possibility may reduce the operational risk linked to this drug development model: in fact, the long CTA approval time established for the other registration channels may be an obstacle for China to join the global trials in time [Su, (2013), p.21].

Since there has been an increase in the number of recently registered MRCTs that integrate Chinese studies, the CFDA has issued appropriate official guidance (Guidance on Multi-Regional Clinical Trials, effective since 1 March 2015). The Guidance was preceded by several CFDA decisions resulting in regulatory delays or rejections of clinical trial applications for MRCT (CIRS, 2015), thus triggering alarm among foreign companies. Even if there is a strong interest in improving the participation of China in MRCT, there are accompanying concerns that the rush to MRCT for shorter approval could increase risks for patients, by omitting to consider potential differences in ethnicity. On the one hand, this document promotes MRCT for developing drugs for unmet medical needs and for serious life-threatening diseases; on the other, it provides new substantive procedural requirements for the design and implementation of an MRCT.
2.2 The recent drug registration reform

The issue of the Guidance on MRCT is part of a broader reform of the registration process begun in 2015 and officially announced in August by the State Council with its circular *Opinions concerning the Reform of the Review and Approval System for Drugs and Medical Devices* (Notice [2015] No. 44, 9 August), which is being implemented gradually by the CFDA. One of the most relevant CFDA implementation acts is the *Announcement on Several Policies Pertaining to the Review and Approval of Drug Registration* ([2015] No. 230, 11 November).

The main topics addressed by the reform include:

- **Simplifying and improving the drug registration process:**
  a. Eliminating the drug application backlog by 2016 thanks to more professional staff and financial resources for CFDA review and approval activities.
  b. Simplifying approval processes for clinical trials by the adoption of a one-time umbrella approval procedure for new drug clinical trials applications instead of a phase-by-phase approval, and by the introduction of a record-filing system instead of the review and approval system for bioequivalence studies on generics.
  c. Self-review and voluntarily withdrawal of applications by the applicants, inspection of clinical data by the CFDA and severe punishment for frauds in clinical data.
  d. Improving clinical trials permitting the conduct of parallel clinical trials in China for new drugs never marketed overseas and the use of data obtained from MRCT involving Chinese institutions in their applications.
  e. Expanding the Green Channel to include more types of drug such as: paediatric and geriatric drugs; drugs sponsored by national science and technology grants; foreign innovative drugs that will be manufactured in China; drugs with advanced technology, innovative treatment approaches, significant therapeutic advantages and that are urgently needed; drugs manufactured at a US or EU qualified facility and under review by US FDA or EMA for concurrent marketing authorisation; clinical trials applications for drugs under urgent clinical needs and whose originator’s patent is due to expire in three years; and production applications for drugs whose originator’s patent is due to expire in one year.

- **Redefining the classification of new drugs and generics:** New definition for new drugs, that are defined as drugs not yet been marketed worldwide and divided into sub-categories, innovative drugs and improved new drugs; and a new definition for generic drugs, i.e., drugs (already marketed either in the domestic market or overseas) whose quality and efficacy is equivalent to the originators’ drug.

- **Launching the Market Authorization Holder (MAH) pilot program for drugs:** Currently, only drug manufacturers are qualified to obtain regulatory approvals. A MAH pilot program to be carried out in ten provinces will allow both domestic research and development (R&D) institutions and scientific research personnel of Chinese nationality to apply for approvals for new drugs and completely outsource production to manufacturing organisations.
Undoubtedly, the ongoing reform will significantly impact the Chinese healthcare market and have profound implications for foreign companies, that should be prepared to redesign their strategies to seize the opportunity provided by the new regulatory framework.

3 The drugs distribution

Planning a business in China’s pharmaceutical industry – which could mean playing in the manufacturing and/or distribution industry – could be extremely problematic due to a multi-layered structure chain and a fragmented and complex regulatory legal framework.

3.1 Evolution and development of the distribution sector from the ’50s to present

The China’s pharmaceutical distribution system has experienced significant changes over the years, experiencing three stages of development:

3.1.1 The planned economy period, from 1950 to 1979

When the China’s pharmaceutical distribution was established for the first time, it was a State controlled allocation system. In this period all aspects related to pharmaceuticals (from production to pricing, R&D, and distribution) were centrally controlled by Chinese Government. The allocation of all pharmaceutical products passed mainly through three stages: the medical and pharmaceutical purchase and supply station, under the direct supervision of the central government; the wholesale station, supervised by provincial or municipal authorities; and wholesalers which were managed by local governments. In any case the structure of organisations was state-owned (Tang, 2009).

3.1.2 The reform and open period, from 1980 to 1989

In 1979, Deng Xiaoping launched the open door policy beginning an important era of economic changes for China. These were justified, regarding the pharmaceutical sphere as well as other economic sectors, by an essential lack of competition derived from the previous closed-market. The great economic transformation of this period also affected the distribution of pharmaceuticals, and marketisation was the primary goal for China in those years. For the pharmaceutical distribution sector this meant passing from a planned, closed and introverted economy to a market-oriented system characterised by an opposed decentralised structure, which progressively abandoned the three-stage organisation of the previous years. This left distributors and manufacturers the freedom to determine their preferred channels, after years with the State as the sole actors on the stage, having the full control of the market.

3.1.3 The market-oriented period, from 1990 to present

The opening up of policy caused several imported drugs, foreign investment, and privatisation in the Chinese market, embraced by Chinese Government since the early Reform and Open Period and even more evident during ‘90s, in which many
pharmaceutical state-owned companies transformed into private or collective ownership companies.

In this sense, you can say the key turning point was the *Guidance on Reform of the Medical Distribution System*, released in November 1999 by the former State Economic and Trade Commission.

Although the openness and marketisation should have pushed foreign investors toward the Chinese pharmaceutical market, we have to observe that the current market panorama is characterised mainly by local companies that work on a small scale with a low level of service.

Being rigorous, the current Chinese distribution system could not be considered particularly efficient and this is due to intrinsic high costs in the distribution chain, and to a price-set-logic based on a tendering system.

From the manufacturing point of view, if you compare local Chinese manufacturers with overseas’ standards, you will notice a more developed technical advancement in the latter, at all levels.

Local manufacturers suffer the weakness of their technology and this is confirmed by the fact that the Chinese pharmaceutical market is completely dominated by the production of generic drugs; in other words those no longer covered by patent (see Figure 2).

**Figure 2** China’s pharmaceuticals market

![Figure 2](China's pharmaceuticals market)

*Source: Leung et al. (2014)*

For this reason

1 very few players (principally local players) are emerging in the market and creating high competition

2 companies tend more often to integrate their *ab origine* main business, with other business activities, becoming big multinational holdings and developing pharmaceutical distribution chains on the side, often under the direct control of the State.
This was the experience, for example, of Sinopharm which can be considered the largest (see Figure 3) Chinese medical and healthcare group managed by the State, with the most complete industrial chain coverage including distribution, retail, import-export, scientific research and manufacture of healthcare-related products (from medicine and medical devices to TCM).

**Figure 3**  China wholesale and distribution market shares (%) 2014

By analysing the Chinese pharmaceutical market by licensing status, it can be seen that the branded off-patented pharmaceuticals are destined to become generic pharmaceuticals soon after, making the Chinese generic pharmaceutical market segment even more enormous and, thus, even more attractive for investors – both domestic and overseas. This is true both for pharmaceutical manufacturing and the distribution sector, very often part of the same business reality.

For this reason, representing the backbone of China’s pharmaceutical market, the generic sector should be taken into serious consideration. If the loss of a patent represents on one hand a turning down moment in one market (for example, from the US or Japanese pharmaceutical market), on the other hand it could represent an opportunity to enter the Chinese market through M&A operations with Chinese generic pharmaceuticals companies, to compensate their loss of income from the expired patent. This is no different to what happened in recent years between Simcere Pharmaceutical Company (better known as 先声药业 – Xiānshēng yàoyè) and Merck & Co. in 2012.19

Considering this point, it should be noted that the Chinese legal term for generic drug is – not by chance – 仿制药 fǎnzhìyào which literally means ‘copied’ or ‘imitated’ drugs.

Analysing actual possibilities, with specific respect to the pharmaceutical distribution industry, is to be remembered that joining by the WTO protocol (in 2001), China committed to gradually eliminate all limitations on market access for foreign investors. Before that moment China placed several restrictions on foreign investments,20 both in the wholesale and retail sectors.

The 2004 version of the *Foreign Investment Guidance Catalogue*21 (the *Catalogue*) classified wholesale and retail activities of pharmaceutical products under the *restricted foreign investment industries*. 

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*Source: Visiongain (2015)*
From the juridical point of view, things started to change in 2004 with the promulgation of the *Administrative Measures for Foreign Investment in Commercial Sectors* (briefly *Measures*, released by the Ministry of Commerce) in further lowering Chinese market barriers to foreigners, especially in those sectors where it was previously banned or limited.

Practically, the complete actualisation of all commitments signed by China with the WTO, then confirmed through those *Measures*, with reference to the pharmaceutical distribution industry, occurred only in 2015 when the *Catalogue* was revised and both wholesale and retail activities were removed from the *restricted* category, being this way elevated to *permitted* activities.

Nevertheless, up to 2015, investments in the wholesale and retail of pharmaceuticals industries were possible, but only limited in joint venture with a Chinese partnership.

Any wholly foreign-owned investment was not permitted.23

Regarding pharmaceutical manufacturing (intended as a strategic pre-phase of a more structured business up to distribution), one can observe the situation over the years was less rigid, indeed, it has been considered by the *Catalogue* mostly as an *encouraged* activity.24

In any case, as distributor or manufacturer, the *generic drug* sector remains the most attractive for foreign investor.

The following data (see Figure 4), suggests another important piece of information: the target sectors (for sales) that foreign investors should aim for are both the over-the-counter (OTC) and prescription drugs sectors.

**Figure 4**  China’s pharmaceuticals market sectors

In this way, comparing results (Figure 2 and Figure 4) it can be said that OTC and prescription drugs (both domestic and imported ones) – which could at the same time be defined as *generic drugs*, under the *Drug Administration Law of People’s Republic of China* – have a high chance of success in the Chinese pharmaceutical market.
3.2 Cross border sales, wholesale and retail, manufacturing as China’s pharmaceutical sector challenge

There are three main ways to enter the Chinese pharmaceutical market: cross border sales, wholesale and retail, and manufacturing. The choice between these three possible options strictly depends on the company structure (also in terms of patent and branded off-patent products expertise) and, even more importantly, on the investment capability of the company.

Foreign investors generally opt for one of the latter two ways, as seen through M&A operations or, in some cases, joint venture contracts which could both be considered as the best emerging models for smart growth.

- **Cross border sales:** Also known as country-to-country sales, can not be properly classified as an investment model. From a juridical point of view, sellers (from outside China) and buyers (based in China) engaging in cross-border-sales activities are doing nothing different from an import-export activity. With reference to pharmaceutical products, cross-border sales are permitted, but there are no special laws or regulations – with the exception of those regarding the import of goods into China (in this case medicines) such as the *Administrative Measures for the Import of Drugs* (2012) and the *Notice of the State Food and Drug Administration on the Issues concerning the Implementation of the Administrative Measures for the Import of Drugs* (2003, briefly the *Notice*).

  As stated in Article I of the *Notice*, imported drugs are allowed to enter China only through 18 port cities, namely, Beijing, Tianjin, Shanghai, Dalian, Qingdao, Chengdu, Wuhan, Chongqing, Xiamen, Nanjing, Hangzhou, Ningbo, Fuzhou, Guangzhou, Shenzhen, Zhuhai, Haikou, and Xi’an.

  On the foreign investors side, is not necessary to set up any foreign direct enterprise in China, because each part of the business relationship remains in its own home country. Therefore, potential trading issues are limited to administrative aspects such as, for example, port customs. However, do not forget the mandatory special licences required before importing pharmaceutical products into China, as well as drug registration steps (analysed above) (see paragraph 2), and quality analysis tests.

- **Wholesales and retails:** domestic distribution activity is ruled by a complex legal framework composed by the *Drug Administration Law* (as amended in 2015), the *Regulations for the implementation of Drug Administration Law* (2002), the *Measures for the Administration of Pharmaceutical Trade License* (2004), *Measures for the Supervision and Administration of Circulation of Pharmaceuticals* (2007) and the *Good supply practice for pharmaceutical products* (2015). Moreover, if the distribution activity is carried out by a foreign investor, you have to take into further consideration the special legal framework provided for foreign direct investments. In this case the reference is to joint venture laws (both Equity and Cooperative), the *Wholly Foreign-Owned Enterprise law and the Catalogue* (last version issued in 2015).

  First of all, in setting up a new supply company (either wholesale or a retail), the enterprise itself must comply with requirements stated by the *Drug Law*. In other words:
it shall demonstrate itself to be staffed with legally certified pharmaceutical technical personnel
it shall have business premises, equipment, storage facilities and a sanitary environment suitable for the pharmaceuticals in which it trades
it shall have a quality control unit or personnel
it shall have rules and regulations to ensure the quality of the pharmaceuticals (Article 15 of the Drug Law).

If all pre-conditions for the establishment are fulfilled, the investor can apply for the Trade Licence from the department of Food and Drug Administration at the appropriate level (depending on the activity and where the enterprise to be established is located) submitting documents required by Article 8 of the Measures for the Administration of Pharmaceutical Trade Licence.

The appropriate local authorities observed the fulfilment of requirements for the regular setting up, and checked documentation to decide whether to issue a Trade Licence or not (Article 14 of the Drug Law).

This is a mandatory step, in fact, Drug Law prohibits any trade distributor from engaging in the pharmaceutical distribution industry without a Trade Licence. The Trade Licence contains important information such as the scope of trade and its period of validity, renewable upon the deadline.

Moreover, all pharmaceutical distributors are required to establish a comprehensive quality control system. For this reason they must guarantee that all pharmaceutical products (to be distributed) meet Standards for Quality Control of Pharmaceutical Trading in conformity with the Good supply practice for pharmaceutical products (briefly the GSP).

As a proof, the legal framework on pharmaceutical distribution provides a ‘licensing system’ for all drugs to be distributed. As seen in the event of cross-border sales, even in wholesale and retail activities, drugs to be distributed must be previously registered. Moreover, the distributor must have received a valid, aforesaid, drug Trade Licence and, last but not least, the distributor must have GSP certification.

Generally, the distribution of pharmaceuticals could be divided in two macro categories:

prescription drug distribution
non-prescription drug distribution (or OTC distribution) further divided into OTCTypeA and OTC-TypeB.

The Trade Licence reports the list of drugs that distributors can trade. Contrary to wholesalers, retailers can sells medicines straight to patients, for this reason the Chinese system provides a larger protection (Article 15 of the Regulations). Retailers can sell prescription drug to consumers only if

the consumer present a written prescription issued by a licensed physician or other pharmaceutical technicians whose qualifications are legally recognised
the drug falls within the category of drugs that can be distributed in the light of the Trade Licence
3 the pharmacist shall review, sign and keep the prescription of the drug.

OTC drugs are usually sold by retailers entitled by a pertinent Trade Licence, which reports the list of non-prescription drugs the retailer sells.

If the investor in a distribution activity is foreigner a larger legal framework has to be considered, in addition to the basic regulations. Moreover, the Trade Licence shall be deemed as an integrative licence beyond the ordinary Business Licence (released form SAIC or AIC) allowing legitimate investors to legally operate in China.

- **Manufacturing:** Even if the planning a business in the pharmaceutical distribution sector did not mean necessarily passing through a manufacturing structure, case-histories suggest manufacture and distribution activities are often part of the same project structure of many enterprises, both local and foreign.

For an analysis example, recall the Sinopharm and the Sincere-Merck & Co experiences. On one hand, a local investor (Sinopharm) started as a distributor then integrated its industrial chain with other activities including pharmaceutical manufacture. And on the other hand, a sino foreign joint venture between a pure distributor of pharmaceutical products later became a leading manufacturer and supplier of drugs in China (Simcere) and a multinational leader (Merck & Co) in full phase of expansion in the Chinese market.

In both experiences distribution business activities were in someways linked with the manufacturing activity.

Actually this is not particularly strange, considering the features of the Chinese pharmaceuticals market. As already seen, it is characterised by sectors, by the predominance of the OTC and generic-drugs sales which make completion higher, by market shares, and by the overall control of Chinese enterprises, often state-owned or state-participated which leaves a poor business environment.

The multi-layered system of distribution, then, is not helpful and, for locals, the inadequate advancement in technologies has increased the need to improve skills and expertise, which only foreign R&D enterprise can contribute and compensate.

It is not by chance that the current situation describes (Wang and Zedtwitz, 2005) a predominance of foreign companies in R&D rather then in distribution or manufacture.

In many cases the local presence in China begins with R&D collaborations (as happened in joint venture between Simcere and Merck & Co) which can represent at the same time a larger sales platform for the foreign part, and a broader collaboration in research addressed to technology advancement for the Chinese one.

As well as for wholesales and retail activities, Chinese legislation also provides a licence system for manufacturing activities, a part from the Trade Licence eventually released for an ‘extensive’ distribution activity.

To start a manufacturing business, both domestic and foreign, the company needs to apply for a manufacturing licence. Generally, the licence includes the ‘green-light’ for distribution, but limited to drugs the manufacturer have produced. For the distribution of an ‘extensive’ list of drugs (produced elsewhere) the investor must
obtain a Trade Licence. The legal framework mainly refers to the Drug Law, to the Regulations, and the Good Manufacturing Practice for Pharmaceutical Products (2011). Also, if the activity in this sector is carried out by foreigners this – basic – legal framework shall be integrated by the special provisions reserved for overseas investors.

3.3 Models and multi-layered structure of China’s distribution industry

M&A operations and joint ventures currently represent preferred ways to enter the Chinese pharmaceutical sectors. Besides the weakness of Chinese companies and their considerable generic drug-market market share, reasons which further make M&A and joint ventures the main channel of entrance in China’s pharmaceutical distribution segment are found in its multi-layered complex structure.

Most drug manufactures are not allowed to sell pharmaceuticals directly to retailers (hospitals and pharmacies). Generally, they must go through state-owned wholesalers. For this reason, it is quite obvious, thus, being a local manufacturer or simply being in China (through a sino-foreign joint venture or a M&A operation) could mean being favoured in the complex distribution context.

To better understand, it is worth noting Chinese hospitals have been traditionally the principal distributors of drugs to patients and this practice finds its origin in the country’s economic development.

During the Deng Xiaoping Era (from 1979 onwards) China launched its economic reform aimed at boosting its economic growth; the organisation and the management of the Chinese healthcare framework changed radically, to fall in line with most other Chinese economic sectors.

With the policy shift towards the introduction of the market economy in the early 1980s, state-owned enterprises could no longer meet the financial costs of social security.

All medical institutions of all types and levels were made responsible for their own well-being with the consequence of a renewed profit-seeking healthcare system, often too expensive for patients (especially those in rural areas, where insurance programs were weak).

The commonly heard phrase among people 看病难, 看病贵 (kànbìng nán, kànbìng guì, which means “seeing a doctor is hard and expensive”) clearly summarises the healthcare situation in that period. An interesting study (Meng et al., 2004) conducted in 2004 demonstrates that awareness of this phenomenon is common among the people, whose frequent complaints (about public doctors in public medical structures) concern over-prescription cases. People (in that study mainly coming from Guangdong, Shanxi and Sichuan provinces) said: “The [public] doctor prescribes more drugs for you because their bonus is related to the volume of the drugs they prescribe”.

This explains clearly two important things: first of all why hospitals have historically been the main way of retailing of drugs in China (they were traditionally public), and second why over the years patients started to fear hospital services (they tend to over-prescrive drugs).

Just think in 1980, in the early economic opening phase, Chinese hospitals already accounted for about 95% of all drug sales (Pharma Handbook, 2007) and in 2003 the percentage of hospitals sales increased approximately at 85% (Von der Hagen et al., 2002).
Although things seem to change (Wang, 2015), the current situation demonstrates that hospital reliance on drugs is still very high (see Figure 5).

**Figure 5** Hospital revenue composites in 2011

Source: Citi Research (2012)

Sales from hospitals or pharmacies to patients are only the last link in the chain.

As already underlined, the Chinese distribution chain is extremely complex and it is characterised by a hierarchical multi-layered structure at a national, regional and local level. In many cases, before drugs arrive at hospitals and/or pharmacies, it takes three, four or even more steps through a long chain of intermediaries and sub-distributors which increase prices.

Returning to the above point, having a physical presence in China could help foreign investors to succeed in the market.

Remember that hospitals purchase most of their pharmaceutical products through a price-set-logic based on a tendering system and, even with poorer quality products, local companies are more favoured in this distribution-chain step.

The tendering system was originally developed, by the Chinese Government, as a pilot project between 2001 and 2002, then extended nationally to contain drugs’ costs, quickly becoming a price-competition moment between manufacturers.

The bidding price, determined as the ‘winner price’, represents the starting point for hospitals (or other medical institutions) to determine the final price (for the patient, often for medicines not covered by the social insurance scheme and for this reason not reimbursed) with higher profit margin possibilities.

Once or twice per year each province issues a call for proposals, so running for a specific province call does not guarantee approval in another province.

After the call, all local and foreign manufacturers are invited to submit offers and, after a qualification inspection, provinces or administrations which launched the call, decide whether to admit the bid or not. Once the prices are determined they will be reported to the local bureau of the Ministry of Health for the public announcement of the bid winners.

Because of the country size, even distributors who are professional and well-funded are not able to operate in all regions of China or toward to all hospital’s typologies. Therefore foreign companies tend to establish more relationships with multiple distributors to guarantee themselves a wider distribution across China.
4 Pharmaceutical innovations and IP rights

Intellectual property rights (IPRs) are the key elements in the promotion of pharmaceutical innovations. Among all types of IPRs, the most important bases for the commercial business models of pharmaceutical industry are patents, trademarks and trade secrets. In the last 30 years, China has established a comprehensive IP system on the protection of pharmaceutical products.

4.1 Patent

The revisions of Chinese Patent Law are mostly accompanied with the change of the rules on pharmaceutical patents. In the first version of Chinese Patent Law enacted on April 1, 1985, article 25 stated that “patent will not be provided for drug or new chemical entity.” In the next version revised on January 1, 1993, the scope of patent protection extended to include drug and new chemical entity and products, mainly to keep it consistent with the TRIPS. Revisions in 2000 confirmed the 1993 patent law, clearly providing all drugs in China with patent protection. In the last revision in 2008, Bolar exemption was officially introduced into the Patent Law (Yin, 2012).

Nowadays in China, if pharmaceutical products could meet the patentability standards set out in the patent law, patent rights should be granted. Pharmaceutical product related invention is equally treated with the invention in other fields during patent examination. It has to meet the requirements, such as novelty, non-obviousness, capable of industrial application, sufficient disclosure, provided in the Guidelines for Patent Examination.

In the meantime, to balance the relationship between IPRs, R&D incentives, pricing and access to medicines, some regulations that are specific to the pharmaceutical sector, such as Bolar exemption, public health related compulsory licensing, were established in Chinese Patent Law.

Bolar exemption, named after the US case Roche Products v. Bolar Pharmaceutical, permits generic manufactures exempted from infringement for certain acts relating to the development and submission of testing data to a regulatory agency. Article 69 (5) of the current Patent Law stipulates that “None of the following shall be deemed an infringement of the patent right: (5) where for the purposes of providing information needed for the regulatory examination and approval, any person makes, uses or imports a patented medicine or a patented medical apparatus, and where any person makes, imports the patented medicine or the patented medical apparatus exclusively for such person.”

According to this provision, not only the generic manufacture and R&D organisation, but also the third party manufacturer could be exempted from infringement of patented rights. Medical apparatus also forms part of the exempted subject-matter.

Compulsory licensing is the method a country can use to circumvent the traditional process of requesting permission to use patented material [Lewis, (2014), p.1056]. “China has never granted any compulsory licence, nor does it seem likely that it will in the near future. But on February 3, 2010, at a State Intellectual Property Office (SIPO) press conference regarding the announcement of the new Implementing Regulations for the Patent Law, a SIPO spokesperson stated that, if China were to begin granting compulsory licence, it would likely start with pharmaceutical patents relating to public health” (Ma, 2011).
The basic compulsory licensing mechanism has existed in the *Patent Law* for over a decade. Chapter VI of the *Patent Law* provides that a compulsory licence may be awarded by SIPO when an applicant can establish one of the following circumstances:

1. A patentee has failed to exploit a patent without reasonable justification for more than three years from the date of grant and four years of the date of filing (Article 48.1).
2. A patentee’s patent use is determined to be monopolistic and a compulsory licence would remove or reduce the anticompetitive effects of such patent use (Article 48.2).
3. Public interest, extraordinary circumstances, or national emergency requires a compulsory licence (Article 49).
4. Public health interests require that a compulsory licence on patented medicine is granted to export the medicine to underdeveloped countries when such countries conform to the provisions of relevant international treaties (Article 50).
5. Major technical improvements with significant economic impact are dependent on earlier patents (Article 51).


It has to be emphasised that, supplementary protection certificate (SPC), which is introduced as a means to extend the patent term of protection for medicinal products to compensate brand name manufactures for the time period required to obtain regulatory approval, does not exist in Chinese Patent Law [Tang, (2005), p.45]. However, six years of data exclusivity, a SPC alike non-patent related right, which is also serves the purpose of encouraging the development of new medicines, is provided by *Regulations for Implementation of the Drug Administration Law*, and *Provisions for Drug Registration in China*.

### 4.2 Trademark

In China, pharmaceutical trademarks are governed by *Trademark Law* and *Drug Law*. Both *Trademark Law* and *Drug Law* seek to prevent potential confusion in the relevant business circles due to similarities between conflicting trademarks. There are three types of names associated with drugs: trademark, generic name and drug product name.

The use of registered trademark is a compulsory requirement to put the drug into the market. Article 27 of the *Provisions on the Administration of Drug Directions and Labels* provides that it is prohibited to use any unregistered trademark or any other pharmaceutical name not approved by the CFDA on drug directions and labels. Article 6 of the *Trademark Law* stipulates “with respect to the commodities that the state has designated as requiring the use of a registered trademark, an application for trademark registration must be filed; the commodities may not be sold on the market before the registration is granted.”
A generic name is a standard legal name generated by Chinese Pharmacopoeia Commission for a pharmaceutical product using the same active ingredient or formula in China, which is officially called China Approved Drug Name (CADN). It is usually the transliteration of an International Non-proprietary Name (INN) generated by the WHO for the product. The generic name of drugs shall not be applied as a trademark.

A drug product name is generated by drug producer itself, mostly for originators’ drugs, but has to be approved by CFDA. Now, the CFDA will not approve an originator’s use of a specific drug product name unless the product name is registered as a trademark (He et al., 2015).

4.3 Trade secret

China’s rules defining and regulating trade secrets are scattered among a series of laws and regulations. In 1985–2002, over 130 trade secret related laws and regulations were issued, and the most important of these is the Anti-Unfair Competition Law (AUCL), which was released in 1993 [Shan, (2004), p.81].

AUCL defines trade secret as “any technology information or business operation information which is unknown to the public, can bring about economic benefits to the obligee, has practical utility and about which the obligee has adopted secret-keeping measures.”

The following actions are taken as infringement of trade secret under AUCL:

1. obtaining an obligee’s trade secrets by stealing, luring, intimidation or any other unfair means
2. disclosing, using or allowing another person to use the trade secrets obtained from the obligee by the means mentioned in the preceding paragraph
3. in violation of the agreement or against the obligee’s demand for keeping trade secrets, disclosing, using or allowing another person to use the trade secrets he possesses.

Moreover, obtaining, using or disclosing another’s trade secrets by a third party who clearly knows or ought to know that the case falls under the unlawful acts listed in the preceding paragraph shall be deemed as infringement upon trade secrets.

Additional aspects of trade secret protection and management are covered in other laws and regulations, including Article 43 of the Contract Law, Article 62 of the Company Law, Article 22 of the Labor Law, Article 23 of the Labor Contract Law and Article 219 of the Criminal Law.

5 Concluding remarks

Investing in the pharmaceutical sector still remains very challenging because of the fragmented structure of the healthcare management overall and, with reference to pharmaceutical distribution chain, due to the multilayered structure.

The comprehension of the China’s pharmaceutical market, in fact, can not exclude the analysis and the deep consideration of socio-economical factors (for instance, the population ageing, the increase of new diseases) and the ongoing juridical edification of the Chinese pharmaceutical legal framework.
Up to date China, indeed, has been strengthening its pharmaceutical legislation toward a better and more comprehensive healthcare environment. From the perspective of foreign companies, the interest in refining legislation represents a positive trend towards the removal of legal and regulatory hurdles affecting their business. However, this process of ‘never-ending changes’ tends to generate legislative instability and lack of legal certainty. Thus, foreign investors have been forced to continuously update their knowledge of the complex and fast-changing Chinese pharmaceutical legal landscape, and their ability to “develop sound regulatory strategies and navigate the Chinese regulatory system” has become one of the most “important success factors” [Su, (2013), p.23].

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References


China’s legal framework for pharmaceutical products


Notes

1 Sub-paragraph 1.1, within the Paragraph 1 is credited to Federica Monti; 1.2 to Pamela Lattanzi. Paragraphs 2 and its subparagraphs are credited to Pamela Lattanzi; Paragraph 3 and its subparagraphs are credited to Federica Monti; Paragraphs 4 and its subparagraphs are credited to Zhao Xu. Conclusion is credited to Federica Monti and Pamela Lattanzi.

2 According to the China statistical yearbook, the leading causes of death (crude mortality) in the last ten years, both in urban and rural areas, are respectively: malignant tumours, heart diseases, cerebrovascular diseases, diseases of the respiratory system, trauma and toxicosis.

3 The term Pharmerging markets refers to those markets which have rank high-growth and power to conquer a global considerable market share. The industry consultancy IMS Health (2010) has pinpointed 17 Pharmerging Markets, among them and beside China there are countries such as Brazil, Russia, India, South Korea, Turkey and others.

4 In this sense could be read the Novartis case history (Festel, Kreimeyer, Oels, Zedtwitz, 2005).

5 The Drug Administration Law of the People’s Republic was first published on September 20, 1984. It was revised at the 20th Meeting of the Standing Committee of the Ninth National People’s Congress on February 28, 2001 and became effective on December 1, 2001. The Law saw a substantive update in 2015, effective as of April 24.

6 The first comprehensive drug regulation of the People’s Republic of China was published in 1963: Provisions for Pharmaceutical Administration, followed in 1965 by Interim Provisions of New Drug Administration. Both regulations were not enforced because of the Cultural Revolution, lasting from 1966 to 1976. In the late 1970s the State Council adopted the Pharmaceutical Regulation (1978) concerning clinical trials and new drug approvals, implemented by the New Drug Regulation (1978). Under these regulations, market authorisations for most new drugs were issued by provincial health departments without commissioning scientific experiments to prove the quality and efficacy of the drugs, with the result that local pharmaceutical manufacturers could easily receive approval (Yan et al., 2013; Zhang, 2013).

7 The Regulations were approved by the State Council and became effective on September 2002.

8 According to CFDA Drug Review Annual Report 2014, more than 18,500 drugs applications were waiting for approval at the end of 2014.

9 The latest version of the Provisions for Drug Regulation (SFDA Issue no. 28) was issued by the SFDA on 10 July 2007 and enacted on 1 October 2007. The Provisions are currently under review.

10 A drug is defined as an article that is used in the prevention, treatment, or diagnosis of diseases in humans and that is intended for the regulation of the physiological functions of humans (see Drug Administration Law, article 100).
The main difference between the two procedures concerns the submission of the registration application, which in the case of a new drug application, must be submitted to the CFDA through its local counterparts (Provincial Food and Drug Administration); but for an imported drug, the application must instead be submitted directly to CFDA. Moreover, the procedure of this latter application demands that a sample of the drug be tested at the National Institute for the Control of Pharmaceutical and Biological Products (NICPBP) or at a test institute designated by the NICPBP. Finally, all documents need to be in Chinese [Yan et al., (2013), p.719]. Because a registration application can be carried out only by a Chinese legal entity, foreign manufacturers can apply for product registration through their Chinese branch or an entrusted agency within Chinese territory if they are without legal representation in China (see Provisions, article 10).

MRCTs are forbidden for preventive vaccines not yet registered overseas.

“For an imported generic drug, even if the CPP is available at the beginning of the CTA submission, the CFDA will regulate it as a generic drug application with the requirement of dossier, clinical trial, and timeline” [Zhang, (2011), p.164].

“Since the drugs control system of in China is based on the manufacturer’s location, the transfer of final product manufacture to a subsidiary or a joint venture, or to a third party in China means that the CTA from this entity is regarded as the first stage of a domestic NDA, regardless of whether the subsidiary or joint venture is 100 percent owned by a foreign company” [Zhang, (2011), p.167].

“A partnership approach presents unique benefits, as 18 local companies tend to be more efficient operationally due to familiarity with the local R&D and regulatory environment. They also capitalize on policy incentives that lead to shortened approval times and reduced development costs” [Deloitte, (2015), p.4]. However, it is notable that foreign investors must take into consideration the complexity of identifying and working with the partner and correctly managing IP issues that may arise during the development process and other legal and business matters [Su, (2013), p.23].

The reference is to the 关于印发《深化医药流通体制改革的指导意见》的通知 (1999) 1055号.

The former State Economic and Trade Commission (SETC) in 2003 was incorporated in the Ministry of Commerce.

As already seen above, a rough classification of Chinese pharmaceuticals could be obtained reading the Article 100 of the Pharmaceutical Administration Law of People’s Republic of China which seems to want to classify drugs into three macro groups: Traditional Chinese Medicine – TMC – (such as raw TCM materials – 包括中药材 –, TMC prepared in ready-to-use portion – 中药饮片 – or prepared TMC – 中成药–); chemical drugs (such as medicinal chemicals and their preparations – 化学原料及其制剂 –, antibiotics – 抗 生素 –, biochemical medicines – 生化药品 –, radioactive drugs -放射性药品 –); Biological products (such as serum – 血清 –, vaccines – 疫苗 –, blood products – 血液制品 –). A partially different classification is provided by the article 11 of the Provision for Pharmaceutical Registration which provides pharmaceutical products divided as: new drugs – 包括新药 –, generic drugs – 仿制药 –, import drugs – 进口药 – and their supplementaries.

Merck & Co. is an US-based pharmaceutical company, among the biggest in the world. It is known as an international developer, manufacturer and distributor of pharmaceuticals. Simcere is a well-known Chinese manufacturer and distributor of generic drugs. In 2012, the two companies decided to set up a Joint Venture (JV) merging their expertise and resources (51% was left to the foreign partner and the remaining to the Chinese part). In that case, clauses of JV contract provided the exclusive right of the JV to sell some metabolite and cardiovascular drugs, before the blockbuster of the foreign company then off-patented. The JV permitted to Simcere to enjoy massive advantages from off-patented drugs of the Merck & Co. In this case Merck & Co. did not use the JV with Simcere to enter the market (Merck & Co. had already entered the market in 1994, in Hangzhou) but to expand its market, taking
advantages to its off-patented drugs. Another similar, and most recent case history, is represented by the JV set up by Pfizer Chinese and Zhejiang Hisun Pharma.

For example, previous 2004 foreign retailers could operate only in major cities and special economic zones.


In this sense, can be read Article 3 of the Administrative Measures for Foreign Investment in Commercial Sectors provides.

Provisions provided for the distribution of general goods was quite different form those which provides on the distribution of drugs. For the first one the measures allowed foreign investors to provide retail services through Joint Ventures or, indifferently, Wholly Foreign-Owned Enterprises.

Under Catalogue (2007 version) manufacture industry provided: 16 types of products and 10 types of equipments as encouraged, product such as immunity vaccines, psychotropic, blood products as restricted and stem cells, gene therapy as prohibited. So permissions in doing business in that sector were strongly linked on the nature of the drugs to be manufactured. Moreover with the amendment occurred in 2007 for special pharmaceutical and healthcare products manufacturing, industries structured as Wholly Foreign-Owned, were allowed to operate only on a pilot zones. Further enhancements came after the launch of the new edition of the Catalogue in 2015 and medical and pharmaceutical activities, previously restricted, became permitted.

As you can see, the Notice’s date of issue is previous than the main Administrative Measures for the Import of Drugs, which represent the main legal reference for imported drug. This happened because the first version for the Measures for the Import of Drugs (then amended in 2012) were promulgated in 2003 and entered in force in 2004. Contextually were issued also Notice for the proper implementation. Although the Measures for the Import of Drugs amendment previous Notice shall be still deemed as effective.

For wholesale activities the competent level of the Food and Drug Administration, is the provincial one whereas for retail activities the municipal or county level one.

Good supply practice for pharmaceutical products was issued for the first time in July 2000 and it was implemented by the Promulgating Provisions for the Administration of Drug GSP Certification promulgated in 2003. The Ministry of Health, after several years of drafting and public consultation, had replaced the Good supply practice for pharmaceutical products on 22 January 2013 and then further amended in 2015, strengthening even more the quality management of drug distribution in China.

You have to remember the registration for an imported drug is not the same as for domestic drug (see paragraph 2).

The distinction in OCT-TypeA AND OTC-TypeB depends on the level of hazardousness (or safety) of a drug for which Government could have provided, depending of the cases, a flexible or a more strict regulation. For example, OTC-TypeA can be sold only by retain pharmacies with a in-store licensed pharmacist or pharmacy technician, whereas OTC-TypeB can be sold by regular business enterprises, which means, enterprise with at least one full-time well-skilled and trained employee, or can be sold in ordinary shops such as supermarket, grocery stores and so on.

For example, Shanghai Pharma enjoy higher ratio of direct hospital sales, Jointown has nations coverage whereas Nanjing pharma is mainly a regional players. About this see more on Changing landscape of China’s Pharmaceutical distribution Industry, retrieved from: http://www.strategyand.pwc.com/media/file/Changing_Landscape_of_China’s-Pharmaceutical_Distribution_EN.pdf. You have to take in further consideration even not all distributor are at the same level, you can have in fact general distributor or special distributors
(for special classes of drugs), their distinction will be made on the basis of their respective Trade Licence.

31 Here, the ‘data’ means safety and efficacy related information of a new medicine collected by a brand name manufacture through pre-clinical and clinical trials. Submission of these data, where the generation takes considerable time, effort, expense and economic risk, is required by the regulation agency to get a marketing authorisation. Data exclusivity provides limited period during which the generic manufacture may not refer to the data of an originator to apply for a marketing authorisation.

32 Article 43 of the Contract Law stipulates that “Neither party may disclose or inappropriately exploit business secrets obtained in the making of a contract no matter the contract is executed or not. The party that disclose or inappropriately exploits the said business secrets causing thus loss to the other party shall hold the liability for the loss.”

33 Article 62 of the Company Law stipulates that “Unless required by law or consented to by the shareholders’ committee, a director, supervisor, or the general manager may not disclose the company’s confidential information.”

34 Article 22 of the Labor Law stipulates that “The parties to a labor contract may stipulate in the labor contract matters concerning keeping business secrets of the employing unit.”

35 Article 23 of the Labor Contract Law stipulates that “An employing unit and a worker may have such terms stipulated in the labor contract as keeping business secrets of the employing unit and keeping confidential the matters relating to its intellectual property right. With regard to a worker who has a confidentiality obligation, the employing unit may stipulate in the labor contract or confidentiality agreement competition restriction and payment of financial compensation to him on a monthly basis during the term of the competition restriction after the labor contract is revoked or terminated. If the worker breaches the stipulation on competition restriction, he shall pay penalty to the employing unit as agreed upon.”

36 Article 219 of the Criminal Law stipulates that “40 Whoever commits any of the following acts of infringing on business secrets and thus causes heavy losses to the obligee shall be sentenced to fixed-term imprisonment of not more than three years or criminal detention and shall also, or shall only, be fined; if the consequences are especially serious, he shall be sentenced to fixed-term imprisonment of not less than three years but not more than seven years and shall also be fined:

(1) obtaining an obligee’s business secrets by stealing, luring, coercion or any other illegitimate means

(2) disclosing, using or allowing another to use the business secrets obtained from the obligee by the means mentioned in the preceding paragraph; or

(3) in violation of the agreement on or against the obligee’s demand for keeping business secrets, disclosing, using or allowing another person to use the business secrets he has. Whoever obtains, uses or discloses another’s business secrets, which he clearly knows or ought to know falls under the categories of the acts listed in the preceding paragraph, shall be deemed an offender who infringes on business secrets. ‘Business secrets’ as mentioned in this Article refers to technology information or business information which is unknown to the public, can bring about economic benefits to the obligee, is of practical use and with regard to which the obligee has adopted secret keeping measures.

‘Obligee’ as mentioned in this Article refers to the owner of business secrets and the person who is permitted by the owner to use the business secrets.”