

# From Innovation to Commercialisation 2007

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# China: developing and commercialising life sciences innovations

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The life sciences industry incorporates a number of sub-sectors. This article focuses on the pharmaceuticals and medical devices sub-sectors of the life sciences industry. Investment in the life sciences (both domestic and foreign) is growing exponentially in China. The pharmaceutical market in China is expanding at a faster rate than the more mature markets. China has 1.3 billion people (ie, one-quarter of the world's population) and its growing middle class is the key driver behind this exponential growth. In 2005, the total production value in the pharmaceuticals and medical devices industry was RMB450.8 billion (approximately US\$58 billion), which is almost double the number in 2000.

China is increasingly becoming an ideal location for research and development. There are sufficient well-trained medical researchers in China and the cost of research is relatively low. In China, the cost of bringing a new drug to market is US\$6.5 million, compared with US\$800 million in the West, and the cost of conducting clinical trials is one-third of the cost in the US. Overall, Chinese spending in R&D in 2004 was US\$24.2 billion (1.2% of GDP). In February 2006, the Chinese government announced that it plans to increase the ratio of R&D spending to 2% of GDP by 2010 and 2.5% by 2020.

There are 500 to 1,000 small and medium-sized biotech companies in China, many of which are privately owned. Foreign investment plays an important role in the life sciences industry in China. By the end of 2004, more than 250 medical trials (which increased by 15% in 2002) were in progress, most of which were directly or indirectly sponsored by multinational companies.

Three key factors determine the attractiveness of China to potential investors

in the life sciences industry:

- Strong patent protection of innovations.
- Proper administration and regulation of the life sciences industry.
- Governmental support for investment in life sciences.

## Patent protection for life sciences innovations

In China, patents are the most important and useful tool in protecting innovations in the life sciences. Drugs, medical devices and the processes for manufacturing these are typically patentable as invention patents. Medical devices are usually protected as utility model patents.

## Specific rules for patentability

Most medical innovations are patentable. Under the PRC Patent Law, however, there are several types of unpatentable innovation, which include, among others, methods for diagnosis and treatment of diseases. These innovations are not patentable for ethical reasons.

A diagnostic method is one which is applied to living human beings or animals (including substances separated from them, such as blood samples), and used for the determination and understanding of disease or health status.

Methods for treatment of disease include physical operations, immunisation and the administering of medication (eg, injections), as well as other ancillary methods such as anaesthetics.

It should be noted, however, that despite the unpatentability of methods for diagnosis and treatment of diseases as such, the equipment and materials used in diagnosis and treatment are of course patentable, provided that novelty, creativity and utility can be demonstrated.

## Patent eligibility

An innovation is eligible for patent protection

under the PRC Patent Law if the criteria of novelty, creativity and utility are met.

Novelty requires that the innovation to be patented has not been published within or outside the PRC, or used within the PRC, prior to the date of application for patent protection. Simply speaking, the innovation must be new. In the context of new usage of known drugs, the novelty requirement is satisfied if the newly found usage is substantially different from the known usage and the new usage affects the manufacturing process of the existing drug.

In other words, a new usage alone is not patentable; in order to satisfy the novelty requirement, the new usage must be reflected in the manufacturing process, rather than in the actual effect on humans or the purpose of administering the drug.

Creativity requires that the innovation must be a substantial improvement over the prior art. In other words, the inventive step must not be obvious to technical personnel within the same field. In the pharmaceutical industry, creativity may be reflected in the structure of the compound as well as in its usage. For example, sulphanilamide is a kind of antibiotic; sulphonylurea is similar to sulphanilamide in its structure (ie, the structure of sulphonylurea is not creative), but is used to treat diabetes, resulting in sufficient creativity for it to be separately patentable.

Utility requires that the innovation must be capable of industrial use – ie, it delivers a benefit and the usage of the patent can be repeated in practice. Innovations which rely on unique conditions that cannot be repeated or result from incidental events, whose use will place humans in danger or which have no known industrial usage (eg, target gene fragments) are not eligible for patent protection.

#### Protection of foreign innovations and technology importation

Foreign nationals may either develop medical innovations in China or develop such innovations overseas and then import them into China.

China is a signatory to all major intellectual IP treaties, including the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs), the Paris Convention for the Protection of Industrial Property and the Patent Cooperation Treaty, all of which require China to provide equal protection to innovations made by foreign nationals (whether in China or in foreign jurisdictions) as is provided to PRC nationals. As such, China grants protection

to foreign innovations – assuming patents are applied for in China – within a grace period of up to 30 months from the first application for foreign patents on the same innovation.

Foreign innovations may be imported into China by way of licence or assignment, whether such innovations are under patent protection or are simply “know-how”. Basically, the PRC government encourages the importation of advanced technological innovations in the life sciences sector and beyond. The royalties and assignment fees paid for the imported technology innovations may, upon approval, be exempt from PRC business tax in certain circumstances.

However, the PRC government is concerned about the misuse of technology monopolies held by foreigners and has thus set out a series of restrictions to use by PRC licensees which cannot be included in technology import contracts. The prohibited restrictions are provisions:

- Requiring the technology recipient to accept additional conditions that are not indispensable to the technology.
- Requiring the technology recipient to pay consideration for unprotected technology.
- Restricting the improvement or use of the subject technology.
- Restricting the technology recipient's right to obtain similar or competing technology from other sources.
- Unreasonably restricting the sources from which the technology recipient may purchase raw materials or equipment.
- Unreasonably restricting the export channels, variety or sale price of the products manufactured using the subject technology.

These prohibited restrictions will be held invalid and unenforceable if they are included in a technology import contract. In the context of domestic technology transfers between two onshore PRC legal persons, similar rules apply.

#### Compulsory licences

Medical innovations are important to human lives and public health. Therefore, in compliance with the Doha Declaration on the TRIPs Agreement and Public Health, the State Intellectual Property Office (SIPO) may issue compulsory licences for drugs used to treat infectious diseases in a public health crisis.

There are three types of compulsory licence. First, if manufacturers in the PRC have the capacity to manufacture the patented drug, SIPO may issue a compulsory

licence to manufacture the patented drug to the extent necessary to overcome the crisis. Second, if manufacturers in the PRC do not have the capacity to manufacture the drug, SIPO may issue a compulsory licence to import the patented drug. The drug manufactured or imported under this compulsory licence may not be exported. In addition, however, SIPO may issue compulsory licences to manufacture and export patented drugs if a least developed country is experiencing an infectious disease crisis and sources drugs from the PRC according to the stipulated WTO mechanism.

To date, however, the PRC government has not issued (or threatened to issue) any such compulsory licences, despite the fact that more than 800,000 citizens are carriers of the AIDS virus and, in some areas, malaria and phthisis have reached epidemic proportions.

#### **Administrative procedures for drug production**

China is an ideal place to research new drugs, as it has sufficient well-trained medical researchers and the cost of research is relatively low – the cost of bringing a new drug to market is US\$6.5 million in China, compared with US\$800 million in the US. In order to ensure the efficacy and safety of drugs, the PRC government has imposed a series of regulations to control each stage of the R&D process: pre-clinical research, clinical research and trial production. With the exception of pre-clinical research, the commencement of each stage of the development process, as well as the commencement of normal production, requires approval from the State Food and Drug Administration (SFDA).

#### **Pre-clinical research**

Pre-clinical research includes all kinds of research on a compound that take place prior to clinical research. Most importantly, it includes research on the safety of the compound, which is termed “non-clinical research” under PRC law.

The SFDA requires that a series of requirements and conditions be observed by “responsible persons”, researchers and laboratories of non-clinical research institutes. These requirements – except for those concerning the educational backgrounds of responsible persons and researchers – appear quite discretionary. For example, the institute must have reasonable and suitable facilities for raising animals to

be used in testing, the researchers must have sound vocational ethics and responsible persons must be competent to carry out their work. The SFDA has the authority to examine the qualifications of non-clinical research institutes from time to time.

#### **Clinical research**

Clinical research includes clinical trials and biological equivalence testing. In addition, the drugs used for clinical research must be inspected. The commencement of clinical research must be approved by the SFDA.

As clinical trials directly involve humans, this area is heavily regulated by the SFDA. Upon approval of the commencement of clinical trials, the applicant must engage a qualified institute to conduct the trials. The SFDA website includes a list of these qualified institutes; most are large or specialised hospitals.

In order to ensure the safety of volunteers, the institute in charge of the clinical trials must strictly follow the SFDA's ethical and procedural rules, and must report any serious side effects to the applicant and the SFDA within 24 hours of their occurrence. The SFDA has the authority to stop the clinical research in the event of any serious side effects. The SFDA will decide whether to approve the manufacture of the new drug on the basis of the data generated from the clinical research.

Further, drugs used in clinical research must be inspected according to the procedures specified by the SFDA. The inspection may be conducted by the applicant or by an institute designated by the SFDA.

#### **Trial production**

In order to begin production of a new drug, an application for a New Pharmaceutical Certificate must be filed with the SFDA.

A new drug will remain subject to SFDA supervision for up to five years from the date of first production. During this supervision period, the SFDA will not accept any applications for production of the same drug. However, if the new drug under supervision is not produced within two years of approval, the SFDA may approve production of the drug by other manufacturers. The new drug manufacturer enjoys the exclusive right to manufacture the drug during the five-year supervision period, in addition to the monopoly protection granted by the Patent Law.

The first two years in which the new drug is manufactured constitute a trial period (ie, the approval for manufacture is temporary). Three months before the end of this trial

period, the manufacturer must apply to the SFDA to upgrade from trial to formal production status. If the manufacturer fails to do so, or if the SFDA rejects the application to upgrade, the manufacturer must stop manufacturing the new drug.

#### Foreign investment in the life sciences industry

The PRC government encourages foreign investment in the life sciences industry and funding for the commercialisation of medical innovations.

#### Catalogue of medical industry

In the PRC, all industries are divided into four categories with respect to foreign investment: encouraged industries, permitted industries, restricted industries and prohibited industries.

The manufacture of the following medical products falls within the category of encouraged industries:

- Patented material drugs or chemical material drugs required for import.
- Niacin.
- Serine, tryptophan, histidine and other aminophenols.
- Analgesic-antipyretic drugs produced with new techniques or new equipment.
- New varieties of anticarcinogens, as well as cardiovascular and cerebrovascular drugs.
- New, effective and economical contraceptive drugs and devices.
- New genic or biological drugs.
- Vaccines produced through genetic engineering technology (especially vaccines against AIDS and hepatitis C, contraceptive vaccines, etc).
- Drug extracts from marine plants or animals.
- Diagnostic reagents for AIDS and radioimmunity diseases.
- New products and new dosage forms adopting new techniques such as slow release, controlled release, target preparation and skin absorption.
- New adjuvant medicines.
- Traditional Chinese medicine, traditional Chinese medicine abstracts and prepared traditional Chinese medicine.
- Biological medical materials and products.
- Veterinary antibiotic material drugs.
- New veterinary antibiotic medical, anthelmintic, insecticide and anti-coccidiosis drugs.

Foreign investment in encouraged industries enjoys the following benefits:

- Foreign investment may take the form of a wholly foreign-owned enterprise.
- The investment is more readily approved.
- Imported equipment for the foreign investment (with some exceptions) is exempt from customs duty and import value added tax.
- Domestically sourced equipment for the foreign investment (with some exceptions) is exempt from domestic value added tax.

The manufacture of the following medical products falls within the category of restricted industries:

- Chloramphenicol, penicillin G, lincomycin, gentamicin, dihydrostreptomycin, amikacin, tetracycline hydrochloride, oxytetracycline, medemycin, kitasamycin, ilotyin, ciprofloxacin and ofloxacin.
- Analgin, paracetamol, Vitamin B1, Vitamin B2, Vitamin C and Vitamin E.
- Immunity vaccines, bacterins, antitoxins and anatoxin (especially the BCG and DPT vaccines, and vaccines for poliomyelitis, measles, type-B encephalitis and epidemic cerebrospinal meningitis).
- Material medicines for narcotic and psychoactive drug addiction.
- Blood products.
- Non-self-destructible expendable injectors, transfusion systems, blood transfusion systems and blood bags.

It is relatively difficult to acquire approval for foreign investment in the above sectors.

## Tax incentives

The PRC government encourages the development and commercialisation of innovations in the life sciences and in medical engineering technology. Foreign invested enterprises engaged in the commercialisation of medical innovations may, upon approval, qualify as high/new technology enterprises and as advanced technology enterprises, and thus enjoy certain beneficial income tax treatment. Commencing from the first profit-making year, the rate of state income tax for such companies is:

- 0% for the first and second profit-making years.
- 7.5% for the third through seventh profit-making years.
- 15% thereafter.

These companies are also completely exempt from local income tax.

Beneficial tax treatment is also available for R&D spending. If the funds allocated by an enterprise for R&D increase by 10% on those in the previous year, up to an additional 50% of those funds may be deducted from the taxable income, upon approval by the tax authority.

The PRC government also encourages the flow of technological achievements. Royalties or assignment fees generated from licensing or the assignment of innovations may be exempt from business tax, upon approval by the tax authority.



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