



China's Drug Registration and Reimbursement Process

Current State and Future Outlook



Emerging Asia

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China's Drug Registration and Reimbursement Process: Current State and Future Outlook

It typically takes four to five years to register a drug in China, however, in the current environment this period could extend to longer periods due to backlogs and bureaucracy within the chief regulating body, the State Food and Drug Administration (SFDA). In order to reduce the registration time, it is very important for pharmaceutical companies to understand the registration process and build relationships with key relevant stakeholders.

Background

The drug registration process in China is centrally managed by the State Food and Drug Administration (SFDA) and its sub-organizations: the Center for Drug Evaluation (CDE) and the National Institute for the Control of Pharmaceutical and Biological Products (NICBP). The SFDA used to be an independent authority, but was incorporated into the Ministry of Health (MoH) in early 2008 because of several drug safety issues and internal corruption scandals. It is hoped that this change will strengthen the oversight of SFDA activities related to drug registration and subsequent safety investigations.

Rigorous Current Environment

The most recent drug registration regulation took effect in October 2007, introducing a far stricter and transparent registration process than previously existed. The recent scandals involving healthcare and food should ensure that the regulatory environment is tougher in the future. In particular, the regulations outline:

- More requirements and much stricter requirements in documents preparation, particularly for new products;
- More inspections at production and clinical trial (CT) sites;
- A feature allowing the status of applications can be checked online (ie, more transparency);
- Separate categories for generic and innovative drugs have been created in order to focus the evaluation of each, and the technical evaluation standards for both categories have been raised.

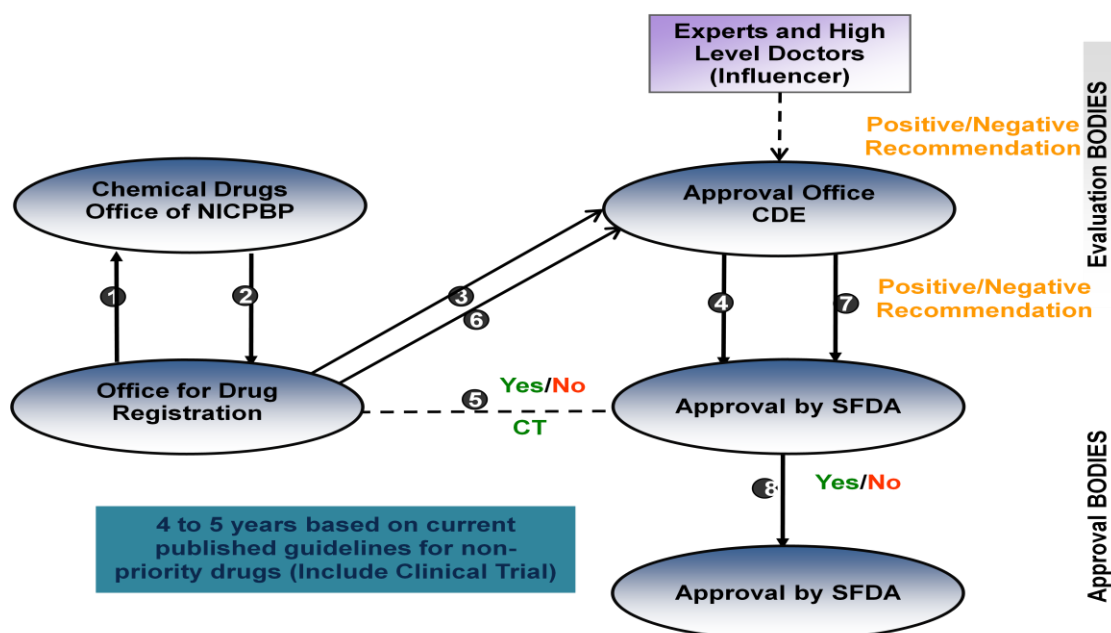
The government publishes a 'standard time' for each step of the drug registration process, but according to regulatory affairs managers at various pharmaceutical companies in China, the SFDA often delays the approval process. Some foreign companies indicated that the actual time taken for some steps could be twice as long or longer than the 'standard time'.



The delay of applications in the last 2 years is mainly due to an accumulated backlog. The SFDA and CDE have promised to process applications according to the 'standard time' from 1 January 2009. However, based on Emerging Asia's sampling of pharmaceutical companies in China, most believe that this is unlikely to happen. There is however, broad agreement that the registration process should become faster in 2009 than in 2008.

Registration Process

According to the published standard procedures for drug registration, there are around 8 steps, which take around 4 to 5 years in total. See flow Chart below:



1. Application for drug license submitted to Office for Drug Registration (ODR), who check the dossier content / format of the application documents then forward submissions to the NICBPB
2. Samples testing of raw materials and / or finished products and national standards verification by the NICBPB; testing results are then returned to the ODR
3. ODR forwards the application documents and testing results to the CDE
4. Technical evaluation by CDE; Positive/negative recommendations are then given to the SFDA
5. SFDA reviews the document and decides whether to issue the license for clinical trial; Applicants conduct the clinical trial (CT) and send the clinical data to ODR



6. ODR checks the dossier content / format of the clinical data, organizes a CT on-site inspection and forwards them to CDE
7. Technical evaluation by CDE and positive / negative recommendations are given to SFDA
8. SFDA review the document and decide whether to issue the drug license

Fast Track Registration Process

According to the official list (within the Chinese drug registration law), four kinds of medicines are eligible for 'fast-track' approval:

- Effective ingredients and preparations extracted from natural medicines;
- Chemical compounds and biological drugs never launched in China or overseas;
- New (to China) drugs with obvious benefits for treatment of cancer, AIDS, and some rare diseases;
- New (to China) drugs for diseases without a current effective curable method

In some extreme crises and disasters such as SARS (2004) and the Sichuan earthquake (2008), essential drugs considered helpful in treating a public health crisis have been approved very quickly.

When the SARS outbreak occurred, one Chinese medicine was approved by CDE in one day and after the 2008 earthquake, some drugs for maintaining the freshness of blood were approved very quickly.

According to the new drug registration law, the term for 'fast-track approval procedures' has been changed to 'special approval procedures' but the details of these new procedures are still at a consultative stage whereby opinions from key leaders and provincial authorities are being sought. The new registration law is expected to take effect in early 2009.

Reimbursement Lists

There are two types of drug reimbursement lists in China known as the A List and the B List. The A List includes 315 commonly used western drugs (mostly generics), which receive 100% reimbursement. The B List includes 712 western drugs including innovative and patented drugs. Both lists are compiled by Central Government authorities, but provincial government authorities can add or subtract up to 15% of List B.

Currently the process for approving drugs for the reimbursement lists is dominated by the Ministry of Human Resources and Social Security (MoHRSS), while the SFDA, National Development and Reform Commission (NDRC), Ministry of Health, Ministry of Finance and State Administration of Traditional Medicine (SAOTM) are also involved to varying degrees. Every four years, the ad-hoc team that creates the reimbursement list is drawn from bureaucrats from these agencies.

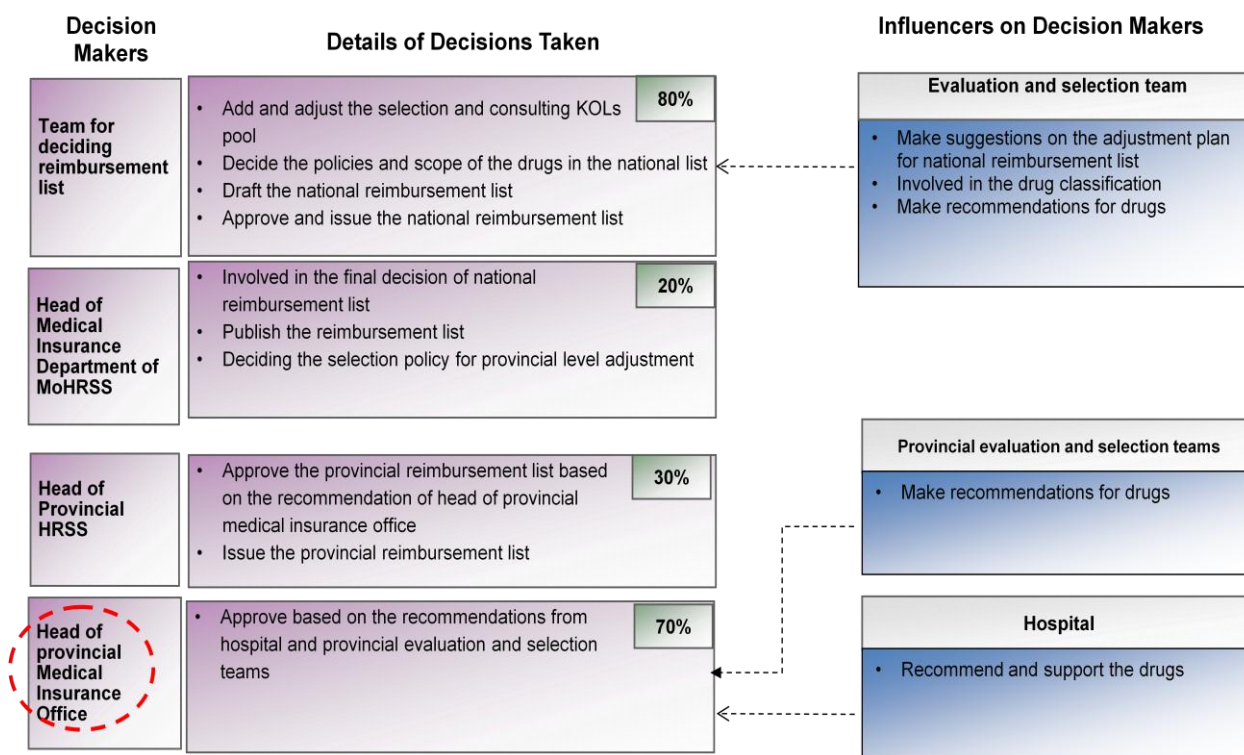


Local level (provincial, city, county) Human Resources and Social Security (HRSS) agencies are responsible for reimbursing hospitals, but the payment system varies significantly by region. Depending on each region, the medical fund is controlled and managed by city, county or provincial-level authorities. The city level HRSS follows the provincial level list – ie, all cities have the same reimbursement list, but cities can exercise their discretion in deciding what percentage of a drug should be reimbursed. Patients and the local level HRSS share the drug expense.

According to published standard procedures for drug registration, there are around 6 steps in total, which take around 5 to 6 months each at the national level and then provincial level. In total, the process will take just under a year.

Role of Key Stakeholders in Approving Drugs for Reimbursement

Drug pricing is centrally led but locally managed. Local governments can set a lower price than the ceiling set by the NDRC. The team responsible for determining the reimbursement list, the Head of Provincial HRSS and the Head of provincial Medical Insurance Office are the three most important decision makers, who play a leading role in this process. The importance of each decision maker is represented in the following table:



Key Criteria for the Drug Reimbursement Selection Process

1. *Essential Drugs.* Drugs to treat common diseases, widespread life threatening diseases such as high blood pressure, cardiovascular and cerebrovascular diseases and diabetes etc, are prioritized.



2. *Price.* According to official documents, price is the third most important criteria. However, many KOLs (key opinion leaders) and other physicians believe that in order to control the financial burden of the government, the price of drugs is a primary factor for selecting drugs for the reimbursement lists.
3. *Clinical efficacy.* An expert's (KOL's) support for a drug to be listed on the reimbursement list, should be based on the availability of clinical evidence. Companies that can provide strong overseas and Chinese clinical evidence to doctors and KOLs to influence them into supporting when/if asked to advise on a reimbursement list.

Trends for Future Drug Reimbursement Lists

The updated National Reimbursement Drug List has been effective since 2004, but it hasn't been updated within the last 4 years. However, provinces have flexibility in reviewing their discretionary portion of the List B, although some provinces may decide not to make any changes for several years.

The 'Essential Drug List,' which used to be the basis for the reimbursement list is likely to be published in 2009. According to KOLs and regulators, the changes to this list will include: a reduction in the number of drugs, which will be reduced from ~2000 to ~500; all drugs in this list will get 100% reimbursement; much stricter price control; and much stricter supervision of quality, logistics, etc.

There is some concern that a new, shorter version of the Essential Drug List may translate into a shorter National Reimbursement List. There is pressure on the government from state think-tanks to 1) shorten the Essential Drug List, and 2) to consolidate the Essential Drug List and the National Reimbursement List into a single list. If this happens, it may lead to a drastic change in the reimbursement scenario.



Research Methodology for this Study

Emerging Asia's consultants conducted over 100 in depth interviews as original, primary research across China. Interviewees included sales and registration staff in pharmaceutical companies, regulators of drug registration and reimbursement bodies, healthcare physicians and other key opinion leaders. This was in addition to leveraging any existing on-line secondary research from government reports, journals, etc.

About Emerging Asia

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