The Latest Developments of Drug Registration Administration in China (Translated)

Zhang Wei
Department of Drug Registration
State Food and Drug Administration
I. To see the current situation of drug development in China from the drug registration data

II. The latest developments and future of drug registration administration in China
The research & development of innovative drug is the only way for China to change from the pharmaceutical country to the leading pharmaceutical country.
The role of government in promoting the pharmaceutical innovation and the research & development of new drug

Government plays a vital role in promoting the pharmaceutical innovation and the research & development of new drug. We need new treatments to meet the unmet clinical demands.

Measures to support and promote the research & development of new drug from the global governments:

- Critical Path Plan (U.S. FDA, 2002)
- European Innovative Drug Plan (EU, 2007)
- Five-year Strategic Plan for Innovative Medicines and Medical Equipment (Japan, 2007)
- Specialized Plan of Major Drug Creation (China, 2008, 2011)
State 12th Five-year Scientific and Technological Development Plan

Specialized Plan for Major New Drug Creation:

- Develop 30 kinds of innovative drugs, transform about 200 categories of drug, develop 150 kinds of diagnostic reagents, put more than 10 new vaccines into clinical trials, and obtain 40 biological drugs with independent intellectual property right.
Opportunities for the innovation brought by growth expectation of pharmaceutical industry

IMS Health predicts:

- the pharmaceutical industry growth in 2011
- in the next 4-5 years, the domestic pharmaceutical industry will maintain the same growth rate (25-27%), exceeding 50 billion U.S. dollars
- the investment of specialized funds during 12th five years- the key role of promoting
Data about the gaps to the international new drug research

Proportion of the investment of new drug R&D to the sales revenue

Significant increase in the total output value of pharmaceutical industry
Slow growth in the R & D input indicator
Low proportion of R & D personnel to total employees in China
Drug Registration Approval
Situation 2010-2011
Drug Registration Data Analysis 2010

Drug Registration Acceptance Situation

<table>
<thead>
<tr>
<th>Internal Application Acceptance</th>
<th>Oversea Application Acceptance</th>
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</thead>
<tbody>
<tr>
<td>Chemical drugs</td>
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<tr>
<td>Traditional Chinese Medicines</td>
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<tr>
<td>Biological Products</td>
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<td>Supplementary Application</td>
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<tr>
<td>Quantity</td>
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<td>4734</td>
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</tbody>
</table>

Drug Registration Data Analysis 2010

Drug Registration Acceptance Situation

Acceptance quantity of various chemical drugs:
- New drug: 54%
- Dose form changing: 7%
- Generics: 39%

Acceptance quantity of various traditional Chinese medicines:
- New drug: 20%
- Dose form changing: 11%
- Generics: 69%
## Drug Registration Acceptance Situation

<table>
<thead>
<tr>
<th></th>
<th>Internal Application Acceptance</th>
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</thead>
<tbody>
<tr>
<td><strong>Quantity</strong></td>
<td>Chemical drugs</td>
<td>Traditional Chinese Medicines</td>
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<td>2678</td>
<td>144</td>
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<td><strong>Total</strong></td>
<td>2913</td>
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<tr>
<td><strong>Total</strong></td>
<td>6990</td>
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</tr>
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</table>
Drug Registration Data Analysis
2011

Drug Registration Acceptance Situation

Acceptance quantity of various chemical drugs

- New drug: 62%
- Dose form changing: 5%
- Generics: 33%

Acceptance quantity of various traditional Chinese medicines

- New drug: 15%
- Dose form changing: 11%
- Generics: 74%
In the past seven years, drug registration application and acceptance trends

<table>
<thead>
<tr>
<th>Year</th>
<th>Internal Application Acceptance</th>
<th>Oversea Application Acceptance</th>
<th>Supplementary Application</th>
</tr>
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<tr>
<td>2005</td>
<td>22166</td>
<td>518</td>
<td>3710</td>
</tr>
<tr>
<td>2006</td>
<td>16728</td>
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<td>2007</td>
<td>3245</td>
<td>603</td>
<td>3226</td>
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<td>2008</td>
<td>2634</td>
<td>593</td>
<td>3235</td>
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<tr>
<td>2009</td>
<td>2336</td>
<td>614</td>
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<tr>
<td>2010</td>
<td>2418</td>
<td>648</td>
<td>3228</td>
</tr>
<tr>
<td>2011</td>
<td>2913</td>
<td>766</td>
<td>3311</td>
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The declaration of antibiotics without new target or new mechanism is still accounted for a large proportion. The TKI antitumor drugs are the focus of R & D investment. The adefovir antiviral drugs are the concerns of R & D investment. The above information about the declaration of category 1.1 chemical drug of domestic enterprise reflect the expectations and judgments of the enterprise to the future market, mainly focused on tracking innovation, and supported by the combination of imitation and creation.
Drug Registration Data Analysis 2010

Data of Approved Drugs in 2010, (Chemical Drugs 1.96:1)

<table>
<thead>
<tr>
<th>Type</th>
<th>Quantity (by acceptance No.)</th>
<th>Involved number of varieties</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical drugs</td>
<td>794</td>
<td>369</td>
</tr>
<tr>
<td>Traditional Chinese Medicines</td>
<td>80</td>
<td>72</td>
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<tr>
<td>Biological Products</td>
<td>12</td>
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<tr>
<td>Total</td>
<td>886</td>
<td>451</td>
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## Drug Registration Data Analysis 2011

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</thead>
<tbody>
<tr>
<td>Chemical drugs</td>
<td>569</td>
<td>314</td>
</tr>
<tr>
<td>Traditional Chinese Medicines</td>
<td>47</td>
<td>47</td>
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<tr>
<td>Biological Products</td>
<td>25</td>
<td>19</td>
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<tr>
<td><strong>Total</strong></td>
<td><strong>641</strong></td>
<td><strong>380</strong></td>
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## Drug Registration Data Analysis 2010

### Data of Approved Drugs in 2010

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</thead>
<tbody>
<tr>
<td>New drug</td>
<td>Dose form changing</td>
<td>Generics</td>
</tr>
<tr>
<td>103</td>
<td>51</td>
<td>640</td>
</tr>
<tr>
<td>794 (19% of new drugs)</td>
<td></td>
<td></td>
</tr>
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</thead>
<tbody>
<tr>
<td>New drug</td>
<td>Dose form changing</td>
<td>Generics</td>
</tr>
<tr>
<td>103</td>
<td>35</td>
<td>431</td>
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<tr>
<td>569 (24% of new drugs)</td>
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<td>47 (89%)</td>
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641
Comparison of Approval Quantity between Different Registration Categories of Chemical Drugs 2010

<table>
<thead>
<tr>
<th>Category</th>
<th>I</th>
<th>II</th>
<th>II I</th>
<th>IV</th>
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<tbody>
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<td>1</td>
<td>46</td>
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</tr>
<tr>
<td></td>
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<td>1</td>
<td>22</td>
<td></td>
<td></td>
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</table>
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<table>
<thead>
<tr>
<th>Category</th>
<th>I</th>
<th>II</th>
<th>III</th>
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<th>V</th>
<th>VI</th>
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<td>2</td>
<td>1</td>
<td>35</td>
<td>431</td>
<td>2</td>
</tr>
</tbody>
</table>

Note: Categories I, II, III, IV, V, and VI represent different registration categories for chemical drugs.
Comparison of Approval Quantity between Different Registration Categories of Traditional Chinese Medicines 2010

- Traditional Chinese Medicines Category 5: 2
- Traditional Chinese Medicines Category 6: 10
Comparison of Approval Quantity between Different Registration Categories of Traditional Chinese Medicines 2011

<table>
<thead>
<tr>
<th>Category</th>
<th>Quantity</th>
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</thead>
<tbody>
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<tr>
<td>Category 5</td>
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</tr>
<tr>
<td>Category 6</td>
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</tr>
<tr>
<td>Category 8</td>
<td>24</td>
</tr>
<tr>
<td>Category 9</td>
<td>5</td>
</tr>
<tr>
<td>Category III</td>
<td>1</td>
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</tbody>
</table>
Data changes - the analysis of overall trend to the drug registration

- The proportion of new drug reporting is increased, indicating the implementation of the legislative ideas of encouraging innovation and improving imitation.
- With the constant improvement of the drug review and approval system, strengthen the on-site verification of drug registration, strictly control the drug review and approval standards, and effectively control the phenomenon of fraud, and purify the drug registration environment in a certain degree.
- The quantity and structure of drug registration application are gradually returned to normal, the overtime review and approval are improved in different degrees, and the public satisfaction to the drug registration administration is gradually increased.
## Approvals of Drugs Clinical Research in 2010

<table>
<thead>
<tr>
<th>Registration type</th>
<th>Chemical drugs</th>
<th>Traditional Chinese Medicines</th>
<th>Biological Products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical trials</td>
<td>600</td>
<td>55</td>
<td>81</td>
</tr>
<tr>
<td>Bioequivalence test</td>
<td>180</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Total</td>
<td>780</td>
<td>55</td>
<td>81</td>
</tr>
<tr>
<td>Total (32 new compounds, 168 international multi-centers clinical)</td>
<td>916</td>
<td></td>
<td></td>
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</tbody>
</table>
## Drug Clinical Trial Approval Situations

### Approvals of Drugs Clinical Research in 2011

<table>
<thead>
<tr>
<th>Registration type</th>
<th>Chemical drugs</th>
<th>Traditional Chinese Medicines</th>
<th>Biological Products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Innovative drugs clinical research</td>
<td>159</td>
<td>47</td>
<td>62</td>
</tr>
<tr>
<td>Verification clinical research</td>
<td>185</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Generics clinical research</td>
<td>121</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>574</td>
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</tr>
</tbody>
</table>
International multi-center clinical trials conducted in China

- Our involvement in the synchronization research of global new drug development and research is increased year after year.
- In 2009, it approved 320 clinical trials of foreign applicants, of which there were 132 international multi-center clinical trial applications; In 2010, it approved to put a total of 32 new compounds into clinical trials, and it approved 168 applications of international multi-center clinical trials.

Changes of the Number of International multi-center clinical trials application since 2005
Declaration and review of the international multi-center clinical trials in China

Review conclusion:

The above declared varieties, 168 applications of international multi-center clinical trials have been completed the technical review, as follows:

- 138 registrations were approved accounting for 82.1%
- 23 applications were canceled by the companies accounting for 13.7%
- 7 applications were not approved accounting for 4.2%

Disapproved reasons: the program had security problems, the drug test report was disqualified, and the information was too simple to be evaluated.
The international multi-center clinical trials Conducted in China

1. With the rapid social and economic development of China, the wide distribution of diseases, the abundant clinical resources, and the relative less costs of research and development, China becomes one of the important options for the global R & D.

2. China aims for gradual integration to the international standards & criterion and inter-coordination, so we are constantly refining and improving the legal system, the approval system and regulatory capacity.

3. In the face of the general trend of the global synchronization R & D, China shall have the courage to meet the challenges and grasp the opportunity to further optimize the allocation of review resources and improve the capability, quality and efficiency of review.

4. Actively participate and response to the profound changes in subjects protection system, the Ethics Committee setting, the clinical trials supervision mode brought by global R & D.
Trends of the new drugs R&D in China

- Implement and build the strategy of “innovative country”, increase the support from the “major new drugs” and other policies
- Implement the intellectual property strategy of “encouraging innovation, effectively use, protect according to law, scientific management”

1. Achieve the leap transfer of drug R&D
   - Focus on imitation ➔ Combine with imitation and creation ➔ Focus on creation
2. R & D investment entities
   - Focus on national investment ➔ Focus on the national support and enterprise investment.
3. Actively participate in the globalization of drug development and research
The level and stage of the innovation and R & D

1. Research about high-level imitation
   • Resolve the problem of availability.

2. Tracking innovation based on the original target (me-too, me-better)
   • Resolve the problem of intellectual property and availability.

3. Brand-new innovation of new target with clinical value
   • Provide the therapeutic means for the clinical demands

From the view of category 1.1 accepted situations, our country still focus on the innovation of the first and second levels.
The level of innovation is in the stage of imitation to the combination of imitation and creation.
The Latest Developments and Future Prospects of Drug Registration Administration in China
Learn from the scientific supervision concepts of FDA

Definition of supervise science by FDA

• Development
  • New tools, new standards, new methods

• Evaluation
  • Security, effectiveness, quality and performance

Ensure that FDA has prepared for the evaluation of innovative technology, which is one the eight prior fields.
Learn from the scientific supervision concepts of FDA

Two important ideas:

1. Scientific advances has caused essential changes to the development and use of medical treatment and diagnostic methods—bringing new challenges to the review.

2. The FDA must prepare the necessary tools and methods in advance to reliably assess the safety and efficacy of these products generated under these new scientific advances.
Learn from the scientific supervision concepts of FDA

- New drug approvals of FDA

- The quantity of approved new drugs by FDA is increasing in the first half of this year, thanks to pharmaceutical companies have changed the development strategy of new drugs, from the me-too drugs with recognized better effects to the development of new drugs in unknown therapeutic areas.

- Compared with the clinical drugs, the newly approved drugs have distinct advantages in the action mechanism and therapeutic effects.
Learn from the scientific supervision concepts of FDA

- The core power to the innovation growth in - the clinical value

  - Clinical value  Example 1: the approval of first drug to extend the survival of melanoma
  - Clinical value  Example 2: the first drug to cure the lupus in the past 50 years
  - Clinical value  Example 3: 2 kinds of hepatitis C drugs with better treatment effects than existing drugs

The full clinical value also has a good market expectation: there will be over 20 kinds of innovative drugs with the annual sales of more than one billion U.S. dollars to be approved.
Thinking about the future domestic pharmaceutical R & D and innovation

- Change the domestic cognitive environment of clinical trials of innovative drugs (change the mind of mouse)

- For the R & D direction, it is still targeted at the category with good market reaction, most of which are generic and me-too categories.

- The R & D investment is significantly less than the level of industrial growth, the R & D team is accounting for small proportion of employees

- Emphasize the intellectual property rights, neglect the clinical value, resulting in a high level repeat of R & D (TKI explosive phenomena)
Thinking about the future domestic pharmaceutical R & D and innovation

- For the R & D direction, it is still targeted at the category with good market reaction, most of which are generic and me-too categories.

- The R & D investment is significantly less than the level of industrial growth, the R & D team is accounting for small proportion of employees.

- Emphasize the intellectual property rights, neglect the clinical value, resulting in a high level repeat of R & D (TKI explosive phenomena)
Progress in the legal construction of drug registration administration and the reform of institutional mechanism in China
General mode for the international drug registration approval:

(1) internal audit-based
(2) external audit-based
(3) combined the internal and external audit

Chinese mode: internal audit-based, consulting to the external
Expert advices
Changes in the Policy of Drug Review and Evaluation

Innovative drugs IND: lenient entry, stringent exit, concern about the clinical value

CHEAP EARLY / FAIL EARLY

Generics: stringent entry and exit, concern about the availability (attainability and affordability), and promote the internationalization
Progress in the drug registration administration mechanism of China
The reform of institutional mechanisms of review and approval

Several considerations to accelerate the institutional reform of drugs review, evaluation and approval

- The objects are to reduce the unnecessary procedures and improve the efficacy, to actively explore the scientific dividing to the rights of technical review and administrative review.
- The objects are to enhance the risk control, to improve the predictability of review processes, to actively explore the reform to the clinical review and production review and the adjustment to the management strategies.
- The objects are to establish the united, high-efficient, coordinated and flexible review system, to further optimize the resources allocation of drugs registration review and approval (central and local, internal of state bureau, management of experts).
- Research and develop the encouraging and binding strategy to the drugs registration review and approval.
The reform of institutional mechanisms of review and approval

Several measures to optimize the system of drugs registration review and approval

• 1. Develop the overall plan for the right divisions of supplementary applications and carry out the pilot practices.
2. Research and develop the specific measures to encourage the innovation to actually reflect encouraging innovation.
3. Accelerate the promotion to develop and implement Drugs Registration Quality Management Practices and GRP, the draft of GRP of China has been formed primarily.
4. Explore to build the expert consulting committee for the drugs registration management
5. Explore to build the internal and external control system for the review and approval
The reform of institutional mechanisms of review and approval

- Focus on the working system, review quality and efficacy
- Establish the system for the review correction, academic supervision and quality evaluation
- Professionalize and specialize the duty system of review
- Released the Principles and Guidelines to the Technical Review
- Communication and Exchange—the key to the efficacy of review and decision-making
According to the review task classification and the level of risk, respectively develop the appropriate review procedure for the IND, NDA, ANDA:

- New drug applications for clinical and marketing - Parallel review
- Chemical generic drug application - single specialized review
- Category for supplementary application or single specialized review - simple review
- If the category of single specialized review is met many multi-disciplinary problems - sequential review
The institutional reform of Center for Drug Evaluation of SFDA

- Procedures of Technical Review and Evaluation of Center for Drug Evaluation of SFDA (Trial)
- Principles and procedures of Drug Technical Review and Evaluation
- Review and Evaluation Task Management Standards of Center for Drug Evaluation of SFDA (Trial)
- Technical Review and Evaluation Decision-making Path Management Standards of Center for Drug Evaluation of SFDA (Trial)
Take the international multi-center clinical research application as example

Business Management Department

Mark the sequence of review task
Mark the difficulty coefficient

Review and Approval Department-Review and Approval Personal

Pharmacy:1
Pharmacology and toxicology:2
Clinical:2

Each review department

Business Management Department

Reviewed by director

Month plan

Professional review and approval

Reviewed by director

Comprehensive review and approval

Reviewed by director

Conclusion

Reviewed by center

Manage the review task

Public notification

Manage the decision-making path
The progress of the construction of drug registration laws and regulations
Drug Registration Administration Method and Supporting Documents

Drug Registration Administration Method

- Supplementary regulations for the registration administration of traditional Chinese medicines
- Administration Methods for the on-site review of drugs registration
- Administration regulations for the special review procedures of drugs registration
- Administration regulations for the transfer of pharmaceutical technology
Revise and update progress of the drug registration laws and regulations

- DMF - medicinal raw and auxiliary materials record management regulations
- Pharmaceutical standards management regulations
- Guiding principle for the registration of natural pharmaceutical products
- Drugs research supervision and management regulations and the series of supporting normative documents
- GRP (drug registration / review quality management practices)
- Electronic submission and CTD General Technical Document
The whole process GXP of drugs (management practices)

- actively explore GRP for the field of drug review and evaluation
- actively explore GUP for the use link of a drug
- Promote the information exposure of each public part of review and evaluation
Construction for the system of technical guidelines of pharmaceutical research
The role of technical guidelines of pharmaceutical research

- Guide the pharmaceutical R & D activities, regulate the R & D of drugs, and improve the overall level of R & D
- Introduce the essence of the ICH guidelines to deal with the global simultaneous development of drugs and promote the international mutual recognition of drug registration and the standards coordination
- Unify the scale of pharmaceutical review and evaluation, reflecting the fair and justice
The composition of technical guidelines for pharmaceutical research

- Officially released: 81
- Chemical drugs: 30
- traditional Chinese medicine: 12
- Biological products: 26
- Comprehensive disciplines: 6
- General principles: 5
Technical guidelines for pharmaceutical research

- To standardize the clinical trials research is very important to encourage the innovation
- The level and conclusions of clinical trials is directly related to the clinical significance of the innovation
- 18 technical guidelines based on clinical trials have been released recently.
The progress of pharmaceutical research supervision
Changes in supervision philosophy and management style

- Emphasize the approval, and enhance the supervision

- Strengthen the supervision and inspection to the clinical research process, and manage the whole process of pharmaceutical research and development.

- Combine the institutional supervision and the supervision to different varieties

- Make the internal quality assurance system of administrative counterpart play more important role

- Implement the classification and grading management to the clinical trials institutions
Changes in supervision philosophy and management style

- Emphasize the approval, and enhance the supervision
  - Encourage the administrative counterpart to strengthen the self-discipline, and strengthen the main responsibility and consciousness for the re-evaluation of drugs after marketed
  - Establish the integrity files to the drug R & D institutions, and explore to establish the on-site review mechanism linked with the integrity in the drug registration site.
  - Use the information technological means to strengthen the supervision of the clinical trials of drugs
Strengthen to manage the whole process of drug registration

- **Earlier stage of registration**
  - Policy guidance, early intervention

- **Middle stage of registration**
  - Emphasize the risk-benefit assessment
  - Require the new drug to reflect the innovative features
  - Require the dosage form changing to reflect the superiority
Strengthen to manage the whole process of drug registration

- Later stage of registration
  - Strengthen the supervision to the clinical research process
  - Strengthen the verification to the production site before marketed
  - Strengthen the interface before and after marketed
  - Require the generics to reflect the consistency
Construction to the supervision and management system of drug research

- Develop the Pharmaceutical Research Supervision and Management Methods and the supporting documents.
  - Clear the legal responsibility to each parties involved in the pharmaceutical research
  - Enhance the management of undertaker, research institutions and ethic committee to the clinical trials
  - Enhance the supervision and inspection of the administration authorities to the pharmaceutical research institutions and the processes of pharmaceutical research

Enhance the protection to the subjects
- Explore the force responsibility insurance of drugs clinical trials and related relieving system, independent ethic committee system and the inform consent system.

Standardize and enhance the supervision and inspection
- Develop and issue the standard documents to manage the record and extent the supervision to the register, CRO, SMO and pharmacy research institutions, etc.
- Develop the guidelines for supervision and inspection to guide the activities
Construction to the supervision and management system of drug research

• Establish the inspector team in the drugs supervision system
  Complete the selection, appointment, evaluation and management of inspector, improve the management to the expert team.

On-site approval system and the supervision and inspection of clinical trials
Establish the scientific on-site approval system for the clinical trials and the supervision and inspection system of clinical trials based on the technical review and supported by the on-site inspection.

Requirements and standards of supervision and inspection
Subdivide and improve the requirements and standards to the supervision and inspection of clinical trials, standardize the on-site inspection of clinical trials, enhance to guide the implementation and management of the clinical trials in each province.

Risk management and Process supervision
Establish the scientific reasonable united standard supervision processes and coordinated working system based on the information system, focused on risk management and processes supervision.
Carry out overseas on-site inspection

- develop the overseas on-site inspection pilot program to the imported drugs and the procedures for the overseas production site inspection to the imported drugs

- organize six working groups to go 7 countries to carry out on-site inspection to 7 varieties
Preliminary practice situation of electronic supervision to the pharmaceutical research

- It has carried out the pilot electronic supervision to the clinical trials in Tianjin, and obtained the preliminary experiences.
- It has developed and published a unified information construction data standards and management practices.
- Goals: to establish a unified national information platform to the supervision of drug clinical trials.
| Problems in technical review | • Quality and efficacy of technical review  
|                            | • Incomplete technical guidelines system  
|                            | • Obvious conflict in the human resources of registration review |
| Problems in the applicants | • The applicant has poor research basis and deficiency of the test data.  
|                            | • The researcher and reporter do not learn enough laws and technical requirements.  
|                            | • The declaration materials are not sufficient, so it can not conduct the evaluation of security and effectiveness. |
| Problems in clinical research | • Insufficient protection to the subjects  
|                               | • Lower level of ethic review  
|                               | • Problems in the research plan design, risk control of research.  
|                               | • The problem of trueness in the research |
Planned Measures

- The institutional reform of Center for Drug Evaluation of SFDA and the adjustment of review procedures and principles
  Scientific classification for innovative drugs and generics
  The review of innovative drugs is focused on security, while the review of generics is focused on the quality control level.

Communication and exchange between the reviewer and applicant
Important measure to improve the quality and efficacy of review
Have significant meaning to improve the quality and efficacy of registration review

Optimize the drugs registration processes and assign the tasks
Further promote the improvement of the quality and efficacy
Fully use the existing resources through the institutional reform

Electric submission of CTD format materials
Fully use the information tools to scientifically classify the technical data and lay the basis for electric review.
| Table of difficulty coefficient of each specialty under different tasks sequence |
|---------------------------------|---------------|---------------|----------------|
|                                 | Pharmacy      | Clinical      | Pharmacology and toxicology |
| New drugs clinical trials application | New drugs 2.5 | 3             | 5                          |
|                                 | Special dosage form 3.5 | 3 | 2                          |
| New drugs marketing application | Registration category 1,2 5 | 5 | 2                          |
|                                 | Registration category 3,4 3.5 | 3 | 1                          |
|                                 | Special dosage form 3 | 3 | 3                          |
| Verification clinical trials application | Registration category 3 (first reporting) 3.5 | 2 | 2                          |
|                                 | Registration category 3 (not first reporting) 2.5 | 1 | 0.5                        |
|                                 | Registration category 3,4 0.5 | 2 | 2                          |
|                                 | Registration category 4 3.5 | 2 | 4                          |
| Generics and dosage form changing application | First generics 3 | 2 | 0.5                        |
|                                 | Others (clinical application) 2 | 0.5 | 0.5                       |
|                                 | Others (production application) 2.5 | 0.5 | 0.5                       |
| Re-registration                 | 1 | 0.5 |               |
| Supplementary application       | 1(exclude 3, 4) | 2(exclude 3, 4) | 0.5                       |
Outlook the policies to encourage the innovation

Simplify the requirements to the clinical trials reporting materials, and adjust the focus of technical review

Parallel mode for the innovative drugs review and approval processes

Separate the focus of the innovative drugs review from that of generics, the critical factor of innovative drugs clinical program is security, while that of generics is quality control and verification test.

Optimize the human resources allocation, and enhance the supervision capacity and level of clinical trials
END Thanks!