Fact sheet

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1. Introduction

The practice clinical trial data is applicable to the registration of various new drugs and biologics for human use in China. The National Medical Products Administration (NMPA) has been regulating new drugs and biologics to ensure the safety, quality, and efficacy of these products for the benefit of patients. The NMPA has also been working on the establishment of a regulatory framework for the approval of new drugs and biologics to promote innovation and access to new therapies.

2. Acceptance criteria of clinical trial data

In China, the acceptance criteria for clinical trial data are quite stringent. The data must meet specific requirements to be considered for registration. The following are some of the key acceptance criteria:

- The clinical trial must be conducted under Good Clinical Practice (GCP) guidelines.
- The data must be scientifically sound and robust.
- The data must be comprehensive and cover all relevant endpoints.
- The data must be presented in a clear and concise manner.
- The data must be consistent with the sponsor's confidentiality requirements.

3. Global clinical trial (MRCT) on drug registration

MRCT (Multi-Centre Registration Trial) is a type of clinical trial that is conducted in multiple countries to support the registration of a new drug or biologic. MRCTs are used to collect additional data to support the registration of a new drug or biologic, especially when the data from a single country trial is not sufficient to support the registration.

4. Expansion of Special Review process

The Special Review process is designed to expedite the review of new drugs and biologics that meet specific criteria. The following are some of the key criteria for expansion of the Special Review process:

- The drug is intended for the treatment of a serious life-threatening condition.
- The drug is intended for the treatment of a serious life-threatening condition in children.
- The drug is intended for the treatment of a rare disease.
- The drug is intended for the treatment of a disease that has significant unmet medical needs.

5. Sponsorship system

The sponsorship system in China involves the participation of multiple parties, including the sponsor, regulatory authorities, and ethics committees. The sponsor is responsible for the design, conduct, and reporting of clinical trials, while the regulatory authorities are responsible for the review and approval of new drugs and biologics. The ethics committees are responsible for ensuring the ethical conduct of clinical trials.

6. Review system

The review system in China involves a series of steps to ensure the quality and safety of new drugs and biologics. The key steps in the review process include the submission of a New Drug Application (NDA), the review of the NDA by the regulatory authorities, and the final approval of the drug or biologic.

7. Evaluation system

The evaluation system in China involves the review of new drugs and biologics to ensure their safety, quality, and efficacy. The evaluation system is designed to identify potential risks and address them through regulatory actions.

8. Drug Registration

Drug registration is the process by which new drugs and biologics are approved for marketing in China. The registration process involves a series of steps, including the submission of a New Drug Application (NDA), the review of the NDA by the regulatory authorities, and the final approval of the drug or biologic.

9. Procedures

The procedures for the registration of new drugs and biologics in China are outlined in the guidelines issued by the NMPA. The procedures include the submission of a New Drug Application (NDA), the review of the NDA by the regulatory authorities, and the final approval of the drug or biologic.

10. Reconsideration

The reconsideration process in China involves the review of applications that have been previously rejected. The reconsideration process is designed to address any issues that may have been overlooked during the initial review and to ensure the quality and safety of new drugs and biologics.

11. Conclusion

The registration of new drugs and biologics in China is a complex process that involves multiple parties and regulations. The NMPA has been working to improve the registration process to ensure the safety, quality, and efficacy of new drugs and biologics for the benefit of patients.
<table>
<thead>
<tr>
<th>Country</th>
<th>Pharmacopeia</th>
<th>Additional requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>India</td>
<td>JP, EP, USP, BP</td>
<td>Acceptance for special review procedure, but not yet officially implemented.</td>
</tr>
<tr>
<td>Indonesia</td>
<td>JP, EP, USP</td>
<td>Risk Management and Implementation plans (RMP) are required for IND submission.</td>
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</tbody>
</table>

**Summary of Issues and Information**

- **Risk Management and Implementation (RMP)**
  - RMP is required for IND submission for New Chemical Entities (NCEs) and New Biological Products (NBP).
  - The RMP Guidance was released by PMDA in April 2012. It is mandatory to all NCEs or New biological products.
  - The data of the communication of drug information (DCI) is requested as an additional work and cost for artwork and packaging management, etc.
  - There is no exclusivity in terms of PI and Label of generic drug.
  - The PIL requirement was extended to a grace period (0 or 1 month) change, MFDS accepts short change, importing and managing the label is clarified, and there is no clear management policy of DMF.
  - The content of the description to PI and Label is clarified, and there is no clear management policy of DMF.
  - The content of the description to PI and Label is clarified, and there is no clear management policy of DMF.

- **Harmonization with USP/EP**
  - The required contents are described in Article 50 of the Pharmaceutical Affairs Act. The required contents are described in Article 50 of the Pharmaceutical Affairs Act. The required contents are described in Article 50 of the Pharmaceutical Affairs Act.

- **Technical Documents**
  - Technical documents was requested and approval was decided by the DS manufacturer to HA. The applicant is reviewed on a case-by-case basis by the experts.
  - The experts case by case.
  - The experts case by case.
  - The experts case by case.

- **Labeling of Pharmaceutical Products**
  - The required contents are described in the Cosmetic Rules 1945. The required contents are described in the Cosmetic Rules 1945. The required contents are described in the Cosmetic Rules 1945.
  - The required contents should be within the PI and Label of generic drug.
  - The required contents should be within the PI and Label of generic drug.
  - The required contents should be within the PI and Label of generic drug.

- **Language and Documents**
  - Language: English. The contents should be written in English. The contents should be written in English. The contents should be written in English.
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- **Product Approval**
  - The required contents are described in the PI and Label of Clinical Trial Application (CTA) Application and the leaflet is written in English. The required contents are described in the PI and Label of Clinical Trial Application (CTA) Application and the leaflet is written in English. The required contents are described in the PI and Label of Clinical Trial Application (CTA) Application and the leaflet is written in English.
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- **Regulatory Guidelines**
  - There are often country-specific statements to the PI and Label of generic drug.
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- **Application and Decision**
  - There is no exclusivity in the communication of drug information (DCI) for different products except for the DCI.
  - The required contents should be written in English. The required contents should be written in English. The required contents should be written in English.
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- **Pharmacopoeia**
  - The required contents are described in the Chinese Pharmacopoeia (8th Ed., 1985) and the Pharmacopoeia of the Philippines. The required contents are described in the Chinese Pharmacopoeia (8th Ed., 1985) and the Pharmacopoeia of the Philippines. The required contents are described in the Chinese Pharmacopoeia (8th Ed., 1985) and the Pharmacopoeia of the Philippines.
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The FDA is still working on

Electronic submission is going

Implementation of electronic submission

Rapid submission is under

In Thailand, the applicant need

In Malaysia as an ASEAN member state is

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