GCP implementation status in China

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I A brief history

The followings are a brief developmental history of Chinese GCP:

In 1998 MOH "*Good Clinical Practice*" (Trial implementation)

In 1999 SDA "*Good Clinical Practice*"

In 2003 SFDA "*Good Clinical Practice*"

Accreditation of clinical trial bases (institutions) are divided into four stages:

- **Stage 1: Choosing from healthcare institutions with relatively better clinical and research capabilities, the Ministry of Health accredited 3 batches of clinical pharmacologic bases in 1983, 1986 and 1990, respectively. The 46 bases in total covered over 100 technical disciplines.**

- **Stage 2: Ministry of Health reaffirmed and published the list of clinical pharmacologic bases in February and April of 1998. The 113 bases in total covered 70 technical categories.**

- **Stage 3: The former State Drug Administration reaffirmed the original clinical pharmacologic bases in 1999 and renamed them as “National drug clinical research bases”. The number of reaffirmed bases reached 132 in total including 96 for Western medicine and 36 for traditional Chinese medicine.**

- **Stage 4: From year 2000 to present.**

II Rationale for implementation

"Drug Administration Law of the People's Republic of China"

- **Article 30: Non-clinical safety evaluation institutions and clinical trial institutions must implement the respective Good Laboratory Practice and Good Clinical Practice independently.**

- **Article 29: The procedures of accreditation of drug clinical trial institutions should be co-formulated by drug administration departments and health administration departments under the State Council.**

"Regulations for Implementation of the Drug Administration Law of the People's Republic of China"

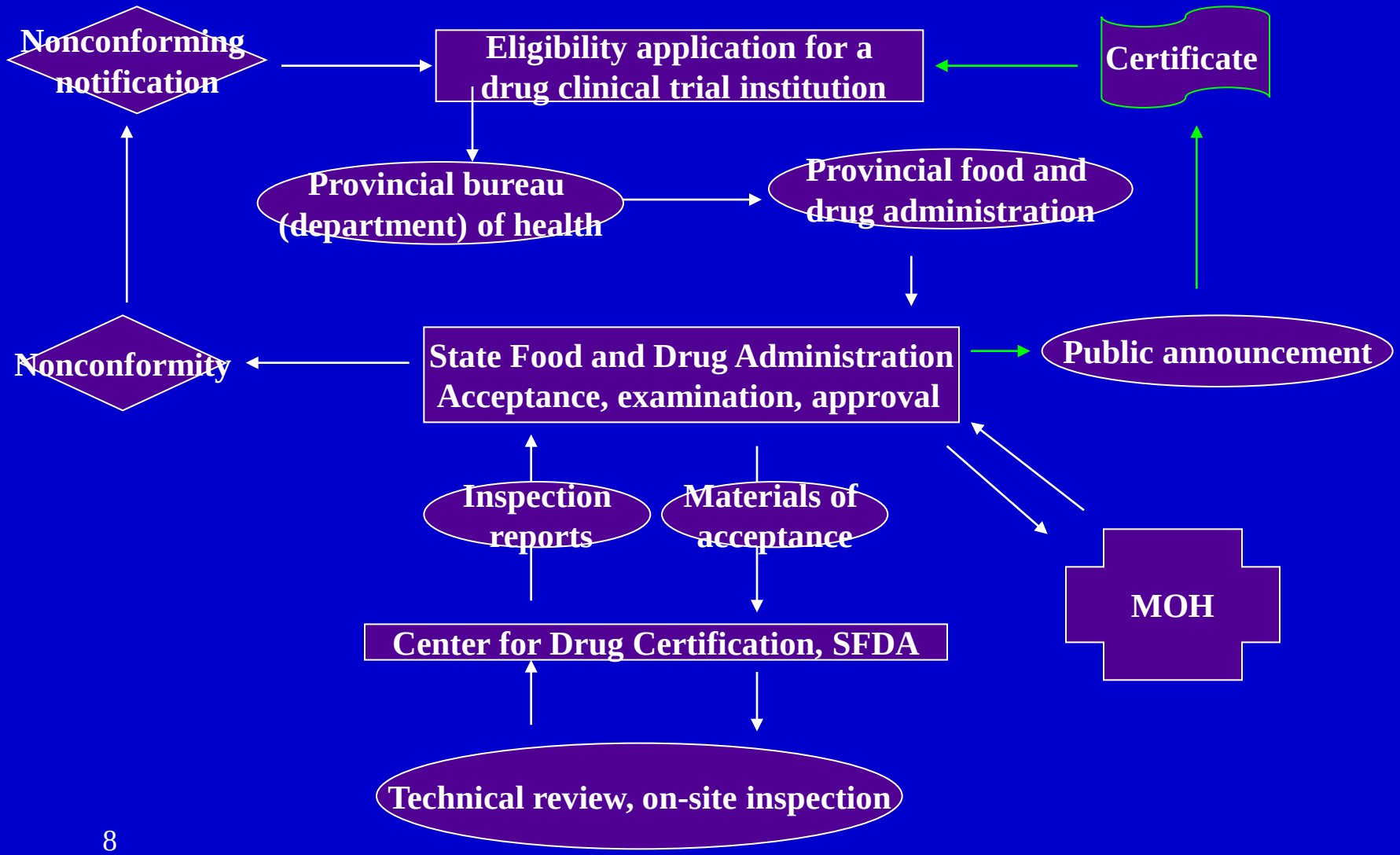
- **Article 30: Once a drug clinical trial application has been approved by a drug administration department under the State Council, the applicant should choose eligible drug clinical trial institutions from those accredited by the law.**

III Organizational structures

The current supervision of GCP implementation concerns the following organizations primarily:

- **Department of Drug Registration, SFDA**
- **Department of Medical Administration, MOH**
- ***Center for Drug Certification*, SFDA**
- **Various provincial drug administration agencies under SFDA**
- **Various provincial departments of medical administrations under MOH**

IV Procedures for examination and approval



V Implementation status

By June 1 of 2009, SFDA had published 21 "Bulletins of accreditation of drug clinical trial institutions" and approved:

- **A total of 276 drug clinical trial institutions that covered 1700 technical departments and laboratories and scattered in 27 provinces (regions, cities) nationwide;**
- **Three hospitals (Prince of Wales Hospital, Queen Mary Hospital, Hong Kong Eye Hospital) in Hong Kong special administrative region;**
- **Specific list is available at SFDA website at www.sfda.gov.cn**

The approved drug clinical trial institutions are able to meet contemporary needs of clinical trials essentially except for the following specific disease categories:

- **AIDS**
- **Pediatrics**
- **Vaccines**
- **“Orphan drugs”**

Contemporary implementation of the Chinese GCP is characterized by the followings after development over a decade:

- **Firstly, there are clear legal and regulatory requirements for supervision of GCP implementation;**
- **Secondly, there are well-defined procedures and criteria for eligibility accreditation of medical institutions;**
- **Thirdly, awareness of GCP by personnel of medical institutions, pharmaceutical product manufacturing companies and various levels of drug administrative agencies are improving apparently;**
- **Fourthly, the number of international multicenter clinical trials is increasing gradually every year;**
- **Fifthly, regulatory and administrative requirements for GCP are brought in line with international standards gradually.**

Comparison between Chinese GCP and GCPs of other countries

- **Similarity**

1. **Consistent with basic spirits and principles of international GCPs**
2. **Being essentially in line with international GCPs**
3. **Compliance with Chinese laws and regulations for drug administration**
4. **Accordance with Chinese national conditions and achievable by diligent efforts**

VI Key tasks

- **2. Reinforce sampling and random inspection diligently, punish all illegal and rule-violation behaviors seriously.**
- **3. Strengthen training of GCP inspectors to build a highly competent inspector team.**

Thank you