GUIDELINE ON EXAMINATION AND REGISTERATION OF NEW CHINESE MEDICINES

1. Foreword

On June 29, 1998, Department of Health published the "Guideline on Examination and Registration of New Chinese Medicines". Since then, the field of drug development and clinical evaluation has evolved significantly. As a consequence, and according to comments submitted by the scientific community, industry and others, Committee on Chinese Medicine and Pharmacy Department of Health has revised these guidelines in the following document, where the requirement for qualification of hospitals conducting clinical trials is amended. The documents also open registration of new raw materials, new administration routes, and new combinations to the public so as to encourage manufacturers to develop new Chinese medicines, and to internationalize their products in the near future.

2. Guideline for Examination and Registration of New Chinese Medicines

2-1. Chinese medicines listed in classical Chinese pharmacopoeias

(A) Chinese medicines with new therapeutic efficacy

(1) Qualification of hospitals and investigators conducting the clinical trials

i. Hospitals:

Hospitals conducting clinical trials should be teaching hospitals accreditated by Department of Health and Ministry of Education.

ii. Investigators:

Investigators should be visiting staffs of Chinese medicine or specialists in related fields of declared efficacy with the assistance from some Chinese medicine doctors.

(2) Applications for clinical trials are required to contain the following information:

i. Related information of the prescription, formula constitutes and their germ plasms' identities
ii. Related information (including academic literature) of pharmacodynamic studies on the declared efficacy
iii. Specifications of the finished products required for the current rules, and quantitatives data of the main principal involved with the declared efficacy (If multiple principals are involved, quantitative data of two, at least, have to be provided).
iv. Reference information of non-clinical pharmacology/toxicology studies
v. A protocol of the clinical trial (The trial design should be randomized placebo-controlled. A double-blind trial is preferred. If a open-label trial is required, the applicant should submit an explanation along with the protocol)

(3) Applications for registration are required to contain the following information:

i. One copy of the application form of registration

ii. One copy of the pilot batch production record
iii. A report of the accelerated stability test for more than 3 months
iv. A report of the clinical trial conducted in Taiwan

(4) The clinical trial should be conducted in accordance with GCP (Good Clinical Practice) published by the Department of Health on September 2002.

(5) Safety surveillance of newly approved Chinese medicines:
The newly approved Chinese medicine with a new therapeutic effect will be subjected to a safety monitoring for five years from the date the license is issued. During this period, agents and manufacturers, in applying for either the manufacturing or importation of the same medicine with
identical efficacy, must submit reports of domestically conducted clinical trials equivalent to that of the original manufacturer and other required documents.

(B) Chinese medicines with new administrating routes (the guideline on injections will be described in other places)

(1) Qualification of hospitals and investigators conducting the clinical trials

i. Hospitals:

Hospitals conducting clinical trials should be teaching hospitals accreditated by Department of Health and Ministry of Education.

ii. Investigators:
Investigators should be visiting staffs of Chinese medicine or specialists in related fields of declared efficacy with the assistance from some Chinese medicine doctors.

(2) Applications for clinical trials are required to contain the following information:
i. Related information of the prescription, formula constitutes and their germ plasms' identities
ii. Related information (including academic literature) of pharmacodynamic studies on the declared with new administrating route, and its safety.
iii. Specifications of the finished product required for the current rules, and, quantitative data of at least two main provided
iv. A report of the accelerated stability test for more than 3 months
v. Reference information of non-clinical pharmacology/toxicology studies
vi. A protocol of the clinical trial (The trial design should be randomized placebo-controlled. A double-blind trial is preferred. If a open-label trial is required, the applicant should submit an explanation along with the protocol)

(3) Applications for registration are required to contain the following information:
i. One copy of the application form of registration
ii. One copy of the pilot batch production record
iii. A report of the accelerated stability test for more than 6 months

iv. A report of the clinical trial conducted in Taiwan

(4) The clinical trial should be conducted in accordance with GCP (Good Clinical Practice) published by the Department of Health on September 2002..

(5) Safety surveillance of newly approved Chinese medicines:
The newly approved Chinese medicine with a new administrating route will be subjected to a safety monitoring for five years from the date the license is issued. During this period, agents and manufacturers, in applying for either the manufacturing or importation of the same medicine with an identical administrating route, must submit reports of domestically conducted clinical trials equivalent to that of the original manufacturer and other required documents.

2-2. Chinese medicines not listed in classical Chinese pharmacopoeias

(A) Chinese medicines used outside Taiwan area and listed in the pharmacacopeias of their countries, or recognized by their central competent health authority, and intended to be introduced into Taiwan by local companies.

(1) Qualification of hospitals and investigators conducting the clinical trials
i. Hospitals:

Hospitals conducting clinical trials should be teaching hospitals accreditated by Department of Health and Ministry of Education.

ii. Investigators:

Investigators should be visiting staffs of Chinese medicine or specialists in related fields of declared efficacy with the assistance from some Chinese medicine doctors.

(2) Applications for clinical trials are required to contain the following information:

i. Certificates which show the medicine is incorporated in pharmacacopeias of its country, or approved by its central competent health authority.
ii. Related information of the prescription, fomula constitutes and their germ plasms' identities
iii. Related information (including academic literature) of pharmacodynamic studies on the declared efficacy
iv. Specifications of the finished product required for the current rules, and quantitative data of at least two main principals
v. Reference information of non-clinical pharmacology/toxicology studies
vi. A protocol of the clinical trial (The trial design should be randomized placebo-controlled. A double-blind trial is preferred. If a open-label

trial is required, the applicant should submit an explanation along with the protocol)

(3) Applications for registration are required to contain the following information:
   i. One copy of the application form of registration
   ii. One copy of the pilot batch production record
   iii. A report of the accelerated stability test for more than 3 months
   iv. A report of the clinical trial conducted in Taiwan

(4) The clinical trial should be conducted in accordance with GCP (Good Clinical Practice) published by the Department of Health on September 2002.

(5) Safety surveillance of newly approved Chinese medicines:
The newly approved Chinese medicine will be subjected to a safety monitoring for five years from the date the license is issued. During this period, agents and manufacturers, in applying for either the manufacturing or importation of the same medicine, must submit reports of domestically conducted clinical trials equivalent to that of the original manufacturer and other required documents.

(B) Chinese medicines, simple or complex recipe, with new raw materials (pharmaceuticals) or new parts of raw materials

(1) Qualification of hospitals and investigators conducting the clinical trials

   i. Hospitals:

      Hospitals conducting clinical trials should be teaching hospitals accreditated by Department of Health and Ministry of Education.

   ii. Investigators:

      Investigators should be visiting staffs of Chinese medicine or specialists in related fields of declared efficacy with the assistance from some Chinese medicine doctors.

(2) Applications for clinical trials are required to contain the following information:
   i. Habitats, growth conditions, and cultivation techniques of the raw material
   ii. Related information of formula constitutes and their germ plasms' identities
   iii. Related information (including academic literature) of pharmacodynamic study on the declared efficacy.
   iv. Specifications of the finished products required for the current rules, and quantitative data of at least two main principles
   v. A report of the accelerated stability test for more than 3 months
   vi. Reference information of non-clinical pharmacology/toxicology studies
   vii. A protocol of the clinical trial (The trial design should be randomized placebo-controlled. A double-blind trial is preferred. If a open-label trial is required, the applicant should submit an explanation along with the protocol)

(3) Applications for registration are required to contain the following information:
   i. One copy of the application form of registration
   ii. One copy of the pilot batch production record
   iii. A report of the accelerated stability test for more than 6 months
   iv. A report of the clinical trial conducted in Taiwan

(4) The clinical trial should be conducted in accordance with GCP (Good Clinical Practice) published by the Department of Health on September 2002.

(5) Safety surveillance of newly approved Chinese medicines:
The newly approved Chinese medicine will be subjected to a safety monitoring for seven years from the date the license is issued. During this period, agents and manufacturers, in applying for either the manufacturing or importation of the same medicine with a identical administrating route, must submit reports of domestically conducted clinical trials equivalent to that of the original manufacturer and other required documents.

(C) Chinese medicines with new complex recipe

(1) Qualification of hospitals and investigators conducting the clinical trials
   i. Hospitals:

      Hospitals conducting clinical trials should be teaching hospitals accreditated by Department of Health and Ministry of Education.
   ii. Investigators:

      Investigators should be visiting staffs of Chinese medicine or specialists in related fields of declared efficacy with the assistance from some Chinese medicine doctors.

(2) Applications for clinical trials are required to contain the following information:
   i. Related information of the prescription, formula constitutes and their germ plasms' identities
   ii. Related information (including academic literature) of pharmacodynamic studies on declared efficacy.
   iii. Specifications of the finished product required for the current rules, and, quantitative data of at least two main principles
   iv. A report of the accelerated stability test for more than 3 months
   v. Reference information of non-clinical pharmacology/toxicology studies
   vi. A protocol of the clinical trial (The trial design should be randomized placebo-controlled. A double-blind trial is preferred. If a open-label trial is required, the applicant should submit an explanation along with the protocol)

(3) Applications for registration are required to contain the following information:
   i. One copy of the application form of registration
   ii. One copy of the pilot batch production record
   iii. A report of the accelerated stability test for more than 6 months
   iv. A report of the clinical trial conducted in Taiwan

(4) The clinical trial should be conducted in accordance with GCP (Good Clinical Practice) published by the Department of Health on September 2002.

(5) Safety surveillance of newly approved Chinese medicines:
The newly approved Chinese medicine will be subjected to a safety monitoring for seven years from the date the license is issued. During this period, agents and manufacturers, in applying for either the manufacturing or importation of the same medicine must submit reports of domestically conducted clinical trials equivalent to that of the original manufacturer and other required documents.

3. This document does not include guidelines for injections.
4. A copy of the application form of the clinical trial is attached.