Regulations for Approval of Specific Medical Products' Manufacturing or Importing as a Special Case

Article 1

These regulations are promulgated pursuant to the Paragraph 3 of Article 48-2 of the Pharmaceutical Affairs Act (hereafter "the Act").

Article 2

Teaching hospitals which are higher level than regional hospital or psychiatric teaching hospitals may submit the following documents when applying to the central competence authority for approval of specific medical products' manufacturing or importing as a special case in accordance with Subparagraph 1 of Paragraph 1 of Article 48-2 of the Act:

1. Diagnosis certificate;
2. Verification of the approval of the application for the specific medical products from the IRB of the submission hospital;
3. A complete therapy protocol and related references;
4. The patient's informed consent form;
5. The amounts of the medical products and the calculation basis;
6. Instructions of the medical products; and
7. Medical products' certificates of the market approval or a photocopy of the reference country's pharmacopeia.

Contents in Subparagraph 1 and Subparagraph 2 of preceding Paragraph shall include the intention that it is for the purpose of prevention, diagnosed as life-threatening, severely disability diseases, and there is no domestic appropriate drug or alternative treatment.

Whereas the drug applying in accordance with Paragraph 1 and cannot submit documents listed in Subparagraph 7 of Paragraph 1, it shall submit product's manufacturing and quality control documents, the animal safety test report, human body usage data and risk-benefit assessment report as the substitution.

Whereas the medical device applying in accordance with preceding Paragraph is made by domestic manufacturer, it can submit documents with the product's construction, specification, efficacy, purpose, drawing, manufacturing and quality control documents, the animal safety test report, human body usage data and risk-benefit assessment report as the substitution of documents listed in Subparagraph 7 of Paragraph 1.

Article 3

Whoever applies to the central competence authority for approval of specific drug's manufacturing or importing as a special case in accordance with Subparagraph 2 of Paragraph 1 of Article 48-2 of the Act shall submit the following documents:

1. A complete prevention or therapy protocol and related references; The contents of the protocol shall include the application purpose of responding the emergency public health circumstances and documents to show the benefits will greater than the risks.
2. The amounts of the drug and the calculation basis;
3. Instructions of the drug; and
4. The drug's certificates of the market approval in foreign countries or a photocopy of the reference country’s pharmacopeia.

Whereas the drug applying in accordance with the preceding Paragraph and cannot submit documents listed in Subparagraph 4 of the preceding Paragraph, it shall submit product's manufacturing and quality control documents, the animal safety test report, human body usage data and risk-benefit assessment report as the substitution.

Article 4

Whoever applies to the central competence authority for approval of specific medical device’s manufacturing or importing as a special case in accordance with Subparagraph 2 of Paragraph 1 of Article 48-2 of the Act shall submit the following documents:

1. The explanatory document of responding the emergency public health circumstances.
2. The amounts of the medical device and the calculation basis;
3. Instructions of the medical device; and
4. The medical device's certificates of the market approval in foreign countries.

Whereas the medical device applying in accordance with preceding Paragraph is made by domestic manufacturer, it can submit documents with the product's construction, specification, efficacy, purpose, drawing, manufacturing and quality control documents, the animal safety test report, human body usage data and risk-benefit assessment report as the substitution of documents listed in Subparagraph 4 of preceding Paragraph.

Article 5

While the central competence authority reviews the application in accordance with the preceding three articles, shall take the situation,

risk and benefit, and amounts calculation methods listed in Paragraph 1 of Article 48-2 of the Act into consideration, and consult with scholars or professionals when necessary, and then make the decision of approval or disapproval.

Article 6

The central competent authority may approve the validity duration of the special case based on the situation of individual case.

Article 7

If necessary, the central competent authority may order the approved special case's manufacturer or importer to submit the safety or medical efficacy assessment report of the medical product of the approved special case within a time limit. If it fails to submit in the due time, the central competent authority may annul the approvement.

Article 8

These regulations shall be effective as of the date of promulgation.