Priority Review Program
for Medical Device Registration in Taiwan

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Outlines

- Medical Device Regulatory Framework & Pre-Market Approval Processes

- Brief Introduction of Priority Review Program
  - Purpose, Criteria & Application Procedure
  - Products Designated for Priority Review Program
Medical Device Regulatory Framework & Pre-Market Approval Processes
Basis of Medical Device Regulation

Pharmaceutical Affairs Act
Medical Care Act

Regulations for Governing the Management of MD
Regulation for Registration of MD
Pharmaceutical Good Manufacturing Practice Regulations (GMP)
   Good Clinical Practice (GCP)
   Good Laboratory Practice (GLP)
Regulations for Drug Safety Monitoring

Guidelines for Registration of In Vitro Diagnostic Medical Device
Guideline for Additive Manufactured Medical Devices
Recognized International standards
Definition of Medical Devices

◆ Article 13 (Pharmaceutical Affairs Act)

The term "medical device", as used in this Act, shall refer to any instruments, machines, apparatus, materials, software, reagent for in vitro use, and other similar or related articles, which is used in diagnosing, curing, alleviating, or directly preventing human diseases, regulating fertility, or which may affect the body structure or functions of human beings, and do not achieve its primary intended function by pharmacological, immunological or metabolic means in or on the human body.
Marketing a Medical Device Product in Taiwan

Manufacturing Facility
GMP/QSD Application

Product License Application

DAO Auditing

DAO: Designated Auditing Organization

TFDA

Class I / II / III

Review Center (Document Review)

Medical Device Advisory Committee (new devices)

GMP/QSD Compliance Letter

License Granting

Approval
Risk Based Regulation

Low risk

GMP/QSD

Class 1

Affidavit
(on-site registration)

➢ Technical Documents
➢ Pre-Clinical Testing Reports
➢ Clinical Reports (new devices only)

High risk

GMP/QSD

Class 2

➢ Technical Documents
➢ Pre-Clinical Testing Reports
➢ Clinical Reports (new devices only)

GMP/QSD

Class 3

➢ Technical Documents / EP-STED
➢ Pre-Clinical Testing Reports
➢ Clinical Reports (new devices only)

Technical Document: structure, materials, specifications, performance, intended uses, and drawings, etc.

Pre-Clinical Testing Reports: specifications, methods and test records

- Chemical properties
- Physical properties
- Biocompatibility test
- Chemical safety test
- Electrical safety test
- Electromagnetic compatibility test
- Software validation
- Performance test
- Sterility
- Shelf life

EP -- Essential Principles
STED -- Summary of Technical Documentation
Brief Introduction of
Priority Review Program
Purpose for Priority Review Program

to encourage the development of innovative medical devices

to take into account rare and life-threatening diseases, or serious disability

TFDA announced “Priority Review Program for Medical Devices” in 2017, and effective immediately

to benefit the life of patients and the public health
Criteria for Priority Review Program - I

◆ A medical device meets any of the following criteria is entitled to seek priority review designation:

Criteria 1

- used to prevent, diagnose, or treat life-threatening diseases or diseases that cause severe disabilities

- employs breakthrough technologies to substantially improve the safety and effectiveness over available products

- there exist no suitable drugs or alternative therapies in the domestic market
Criteria for Priority Review Program - II

◆ A medical device meets any of the following criteria is entitled to seek priority review designation:

Criteria 2

A medical device that the primary intended use, effectiveness, or indication is to prevent, diagnose, or treat a rare disease set forth in Article 3 of the Rare Disease and Orphan Drug Act*.

* The term "rare diseases" shall refer to diseases with prevalence rate lower than the standard announced by the central competent authority; or diseases recognized through review by the Review Committee, and designated and publicly announced by the central competent authority under special circumstances.
Criteria for Priority Review Program - III

- A medical device meets any of the following criteria is entitled to seek priority review designation:
  
  - Criteria 3

- **A**
  Approved to be supported with regulatory consultation or sponsorship in its research and development by a government agency

- **B**
  the safety and effectiveness of the medical device are validated by domestic clinical trials (including global multi-center clinical trials with at least one domestic site)

- **OR**
  the medical device is urgently needed by the domestic public health or medical treatments
Procedure for Priority Review Program

**Filling the Form**
- complete the **Self-Assessment Form** for Priority Review Program for Medical Devices

**Submission**
- submit the form with an inquiry letter, inquiry fee, and **supporting documentation** to TFDA to request a priority review designation

**Notification**
- TFDA will then notify the applicant with an **official letter** about the decision

**Registration**
- the priority review will apply to a registration application if the applicant submits the registration application with an official letter stating the priority review designation.
Characteristics of Priority Review Pathway

In Taiwan, there are three characteristics of the priority review pathway:

**Special Review Team**

- A review team consisting of experienced reviewers would be assigned to the priority review case.

**Advisory Panel**

- Scientific and clinical experts outside TFDA would contribute their recommendations from a professional point of view.
Supporting Strategies for Priority Review Pathway

- During the priority review period, TFDA provided some supporting strategies for this mechanism:

  I. Both the qualification identification and the subsequent priority reviewing registration were handled by specific assigned personnel without queuing.

  II. Specific assigned personnel counsel the manufactures on document preparation during the period of priority reviewing registration.

  III. Other supporting strategies (such as post-marketing surveillance, etc.) were also provided.

  IV. Priority meeting arrangement for the Advisory Panel consultation.
Termination for Priority Review Program - I

◆ In any of the following circumstances, TFDA has the right to terminate a priority review and the medical device under the priority review shall roll back to a regular review:

- The base to obtain the priority review designation no longer stands, due to a change of the applicable laws, regulations, or relevant facts.

- The applicant requests for termination.
In any of the following circumstances, the competent authority has the right to terminate a priority review and the medical device under the priority review shall roll back to a regular review:

- The materials provided by the applicant are found that they are untruthful or misleading.
- The competent authority identifies there to be substantial reasons that the continuation of priority review is no longer appropriate.
Examples of Product Designated for Priority Review

- GB HDV Ab
- Foam-type Dura Substitute
- Lung Perfusion System
- Retinal Prosthesis System
Review Considerations for Priority Review Program

- TFDA imposes the same requirements on the scientific and clinical evidence submitted for priority reviews and regular reviews, as well as the same requirements on study period and quality of data. A medical device must meet the safety, effectiveness, and quality requirements in order to obtain approval from the competent authority.
Reference

◆ The content of “Priority Review Program for Medical Devices” & the “Self-Assessment Form”

--- Chinese Version :


--- English Version :

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ご清聴ありがとうございました