Update on Medical Device and IVD Regulation in Japan

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Medical Device Regulations in Japan

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Post market safety (vigilance/surveillance)

PMDA and MHLW

In addition,
- Definition, Risk Classification and Essential Principles are aligned with GHTF/IMDRF guidelines.
- Nomenclature “JMDN” is based on GMDN.
IVD reagents are regulated under the rules based on the medical devices. 

- Risk based classification
- QMS requirements
- Essential principle
- Generic name etc.
Amendment of Pharmaceuticals and Medical Devices Act (PMD Act) in Dec. 2019

Following provisions are introduced for earlier and safer approval of medical devices and IVDs of high medical needs:

1. SAKIGAKE designation system
2. Priority review for specific uses, e.g. pediatric use
3. Conditional early approval system
4. Early realization of improvement in post-marketing
1. **SAKIGAKE Designation System**
   
   *pilot started in 2015*


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[Diagram showing the process of the SAKIGAKE Designation System including stages such as Consultation, Clinical Trial Phase I/II, Consultation on Clinical Trial, Clinical Trial Phase III, Review, Covered by Insurance, and Commercialization in market. The diagram also highlights key processes like Priority Consultation, Prior Review, Priority Review, and Review Partner.]
2. Priority review for specific uses, e.g. pediatric use

- Designation of “Specific use product” for highly unmet medical needs, e.g. pediatric use and AMR.
- Priority review and other supportive measures are applied to designated products for specific use.

Before
- PMD Act
- Priority review
  - Orphan drugs and devices
  - Others

"Others" category had been applied operationally.

After
- Priority review
  - Orphan drugs and devices
  - SAKIGAKE products
  - Specific use products
  - Others

Criteria of specific use
1. Products for pediatric use, AMR, etc.
2. Highly unmet medical needs
3. High effectiveness and/or safety
3. Conditional Early Approval for innovative MDs

Accelerate approval of MDs of high clinical needs by balancing the pre- and post-market requirements, based on the lifecycle management of the MDs.

**Ordinary review**

- Long period
- Collection of clinical data
- Review
- Approval
- Market - Use

**Conditional Early Approval for Innovative MDs**

- Collection of clinical data
- Review
- Approval
- Market - Use

- Partial change application (e.g. expanded indication, etc.)
- Cooperation with academia
- Planning **Post-market Risk Management**
- Post-market Risk Management Plan (draft)
- Implementation of **Post-market Risk Management Measures**
- Data collection to confirm use results, long-term performance
Possible type of Conditional Early Approval

Extrapolation of indication to other therapeutic areas based on the function

Conditions:
- For devices which performs physical function on human body, e.g. ablation, freezing and shielding
- Clinical evidence on a specific therapeutic area which can be extrapolated to other areas
- Clinical use standards and risk management plan developed in collaboration with academic society

Early realization of application of device to other organs and body parts based on the function by risk management measures in the post-marketing phase.

Collection of clinical data → Review → Approval → Market - Use

- Implementation of Post-market Risk Management Measures
- Data collection to confirm use results, long-term performance

"PHysical OpEratioN Items’ eXtrapolative and inclusive approval (PHOENIX)"
Post-Approval Change Management Protocol will be introduced for medical devices to enable continuous improvements.

4. Early realization of Improvement in Post-marketing

Current Process

Clinical data collection → review → Approval

Developing the change plan for application expansion → Data collection → Change request → review

Change of approval issues → Application expansion

New Process

Clinical data collection → review → Approval

Developing the change plan for application expansion → Submission of change plan confirmation → Data collection based on the plan → Request or submit of change → check

Change of approval issues → Application expansion

Objects for submit
- Change of sizes, components, performances
- Improvement of diagnostic accuracy by using post-marketing RWD

Check to ensure the predetermined results are obtained

Early realization of improvement

“Improvement Design within Approval for Timely Evaluation and Notice (IDATEN)”
Approval review process which enables continuous improvement of performance of SaMD using AI

- Changes of performance must be in one-direction (improvement) and be managed by MAH.
- MAH may develop a process which ensures such performance changes as “Improvement Process”, and submit in the approval review process.

Post-market changes in line with the Improvement Process can be made by minor change notification, which does not require approval process.

*Compliance is checked in QMS audits.

“IDATEN-AI”
International regulatory harmonization in medical devices

GHTF (1992-); IMDRF (2011-)


IN-JP MOC (2015-)

PMDA Asia Training Center (2016-)

Asian countries

Japan
Voices from Japanese industry experienced business in India

1. Harmonize to internationally recognized regulation/ rules/ standards as much as possible.
   • e.g. Classification rules, UDI based on GHTF/IMDRF

2. Conduct educational sessions for industry to sufficiently train the new regulation / requirements.
   • e.g. Seminar, Q&A, Consultation

3. Coordinated approach for the introduction of the new regulation / requirements.
   • e.g. Consultation process, Transition period
Summary

1. Japan enacted the amendment of PMD Act, which includes SAKIGAKE and other systems for earlier and safer approval of innovative products.

2. MHLW/PMDA is willing to share our knowledge and experience with India through IN-JP MOC and Asia Training Center for harmonization.

3. Japanese industry is also collaborative with India through business development and constructive discussion on the regulation.