IMDRF International Medical Device Regulators Forum

Japan Update

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MHLW Ministry of Health, Labour and Welfare of Japan

PMDA

Agenda

Outline of the Act Partially Amending the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Act No. 37 of 2025)

- **Revision of Performance Evaluation for IVDs**
- **Promoting RWD Use in Regulatory Applications**
- **Expansion of Conditional Approval System**

Agenda

Outline of the Act Partially Amending the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Act No. 37 of 2025)

- **Revision of Performance Evaluation for IVDs**
- **Promoting RWD Use in Regulatory Submissions**
- **Expansion of Conditional Approval System**

Revision of Performance Evaluation for IVDs

Background

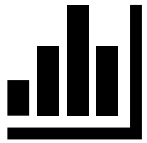
COVID-19 increased demand and supply of test kits.

Viral mutations can affect test accuracy over time. Even if performance is assured at approval, **false negatives** may occur later.

Ensuring **public trust** in IVDs become critical.

Revision of Performance Evaluation for IVDs

Outline of the Amendment



Ongoing Performance Monitoring

Manufacturers must collect, evaluate, and report post-marketing data.

Revocation of Approval

Approval can be revoked if performance cannot be assured .

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- Revision of Performance Evaluation for IVDs
- **Promoting RWD Use in Regulatory Applications**
- Expansion of Conditional Approval System

Promoting RWD Use in Regulatory Applications

Background

Why RWD Matters

RWD from registries and databases can streamline clinical development.

Current Actions

MHLW has issued guidance and supports reliable database.

development.

Next Steps

Further promotion and international harmonization are needed.

Promoting RWD Use in Regulatory Applications

Outline of the Amendment

RWD Is Acceptable

Submission structure clarifies to support RWD-based applications.

Flexible Evidence Requirements

Statutory requirement for clinical trial results are abolished.

Efficacy and safety data from RWD can be accepted.

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- **Expansion of Conditional Approval System**

Expansion of Conditional Approval System

Background

In Japan and U.S., medical devices for **rare and serious diseases** may be approved based on **exploratory studies** .

- Japan’s system **lacks a revocation provision**, so it's used only when:
  - **Clear effects** are confirmed, or
  - **Confirmatory trials** are ongoing.
- Compared to U.S., Japan has **fewer approvals** under this system.

Expansion of Conditional Approval System

Outline of the Amendment

Exploratory Trials-Based Approval

Approval is possible if clinical usefulness is reasonably predictable.

Post-Marketing Review

MHLW can revise conditions based on quality, efficacy and safety data.

Revocation of Approval

Approval can be revoked if efficacy and/or safety cannot be confirmed

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Thank you for your attention