Japan Regulatory Update

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Kanako Sasaki
Ministry of Health, Labour and Welfare (MHLW)
Agenda

1. Overview of regulation on medical devices in Japan

2. Amendment of the Pharmaceutical and Medical Device Act (PMD Act)
- Regulatory Authorities in Japan -

**MHLW**
(Ministry of Health, Labour and Welfare)
- Final Authorization of applications
- Publishing Guidelines
- Supervising PMDA Activities

**PMDA**
(Pharmaceuticals and Medical Devices Agency)
- Scientific Review
- Consultation on Clinical Trials etc.
## Medical Device Regulations in Japan

<table>
<thead>
<tr>
<th>Classification</th>
<th>Class I</th>
<th>Class II</th>
<th>Class III</th>
<th>Class IV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Category</td>
<td>General MDs</td>
<td>Controlled MDs</td>
<td>Specially controlled MDs</td>
<td></td>
</tr>
<tr>
<td>Premarket regulation</td>
<td>Self-declaration</td>
<td>Third party certification</td>
<td>MHLW approval (PMDA review)</td>
<td></td>
</tr>
<tr>
<td>Example</td>
<td><img src="image1" alt="Example Image" /></td>
<td><img src="image2" alt="Example Image" /></td>
<td><img src="image3" alt="Example Image" /></td>
<td><img src="image4" alt="Example Image" /></td>
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</tbody>
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**Post market safety (vigilance/surveillance)**: PMDA and MHLW
Agenda

1. Overview of regulation on medical devices in Japan

2. Amendment of the Pharmaceutical and Medical Device Act (PMD Act)
Overview of Amendment of the Pharmaceuticals and Medical Device Act

• Enacted on Nov., 2019; to be implemented within 1 year

• 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
# Overview of Amendment of the Pharmaceuticals and Medical Device Act

<table>
<thead>
<tr>
<th>Type</th>
<th>Designation requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expedited review</td>
<td>NOT Required</td>
</tr>
<tr>
<td>Priority review</td>
<td></td>
</tr>
<tr>
<td>Orphan</td>
<td>Required</td>
</tr>
<tr>
<td>Sakigake (innovative)</td>
<td>Required</td>
</tr>
<tr>
<td>Specific use (pediatric, AMR)</td>
<td>Required</td>
</tr>
<tr>
<td>Conditional Early Approval ※</td>
<td>NOT Required</td>
</tr>
</tbody>
</table>

※These reviews are currently operated based on the administrative notification.
SAKIGAKE Designation System

[Diagram showing the process of Ordinal Review and Review under SAKIGAKE Designation System.]

• Practical application of innovative medical products
• Strengthening post-marketing safety measures (re-evaluation period)
Priority Review for Specific Uses

- Designation of “Specific use product” for highly unmet medical needs (e.g. pediatric use and AMR).
- Priority review (9 months) and other supportive measures are applied to designated products for specific use.

Priority review

- Orphan drugs and devices
- Others

Amendment of PMD Act

Priority review

- Orphan drugs and devices
- SAKIGAKE products
- Specific use products
- Others

“Others” category had been applied operationally.
Conditional Early Approval System

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

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

Conditional Early Approval for Innovative MDs

Collection of clinical data

Review

Approval

Market - Use

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

Cooperation with academia

Planning Post-market Risk Management

Post-market Risk Management Plan (draft)

Partial change application (e.g. expanded indication, etc.)
Early Realization of Improvement in Post-marketing

Post-Approval Change Management Protocol is introduced for medical devices to enable continuous improvements.

Current Process
- Clinical data collection
- Application
- Review
- Approval
- Developing the change plan for application expansion
- Data collection
- Change request

New Process
- Clinical data collection
- Application
- 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 to ensure the predetermined results are obtained
- Early realization of improvement

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

“Improvement Design within Approval for Timely Evaluation and Notice (IDATEN)"
Summary

- Following items are introduced by the amendment of the Pharmaceuticals and Medical Device Act in 2019
  - SAKIGAKE designation system
  - Priority review for specific uses, e.g. pediatric use
  - Conditional early approval system
  - Early realization of improvement in post-marketing

- MHLW/PMDA is encouraging development of innovative products
Thank you for your attention!!

MHLW Website
https://www.mhlw.go.jp/english/

PMDA Website