Regulatory Updates on Medical Devices in Japan

- Amendment of Pharmaceuticals and Medical Devices Act (PMD Act) -

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Overview of Amendment of Pharmaceuticals and Medical Devices Act (PMD Act)

- Enacted in November, 2019
  Implemented in September, 2020
- Following provisions are introduced:
  1. SAKIGAKE designation system
  2. Priority review for specific uses, e.g. pediatric use
  3. Conditional early approval system
  4. Post-Approval Change Management Protocol (PACMP) for Medical Devices
1. SAKIGAKE Designation System

【Ordinal Review】

Consultation → Non-clinical research/clinical research → Clinical Trial Phase I/II → Consultation on Clinical Trial → Clinical Trial Phase III → Review → Covered by Insurance → Commercialization in market

1. Priority Consultation

【Review under SAKIGAKE Designation System】

Consultation → Designation as SAKIGAKE → Prior Review → Review → Covered by Insurance → Commercialization in market

2. Prior Review

Prior Review → Clinical Trial Phase I/II → Consultation on Clinical Trial → Clinical Trial Phase III → Review

3. Priority Review

4. Review Partner

Practical application of innovative medical products

NOTE: SAKIGAKE was originally introduced as a pilot program based on the administrative notification in 2015.

Administrative notification No.0831-6, August 31, 2020
Criteria and Advantage of SAKIGAKE Designation

➢ Criteria
  • innovativeness
  • severity of disease
  • prominent effectiveness or/and safety
  • willingness and framework to first development in Japan

➢ Advantage
  • Prioritized Consultation: waiting time; 2 months → 1 month
  • Pre-application Consultation: de facto review before application
  • Prioritized review: targeting total review time; 12 months → 6 months
  • Review Partner: assignment of PMDA manager as concierge
Approved Products under SAKIGAKE Designation

_products designated as SAKIGAKE

- Medical devices: 12
- In Vitro Diagnostics (IVDs): 2

Approved Products under SAKIGAKE system

<table>
<thead>
<tr>
<th>Category</th>
<th>Product name</th>
<th>Company</th>
<th>Indication</th>
<th>Date of designation</th>
<th>Approval date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical Device</td>
<td>TITANBRIDGE</td>
<td>Nobelpharma Co. Ltd.</td>
<td>Adductor spasmodic dysphnia</td>
<td>Feb. 10, 2016</td>
<td>Dec. 15, 2017</td>
</tr>
<tr>
<td>Medical Device</td>
<td>Boron neutron capture therapy(BNCT) system</td>
<td>Sumitomo Heavy Industries, Ltd.</td>
<td>Head and neck cancer</td>
<td>Feb. 28, 2017</td>
<td>Mar. 11, 2020</td>
</tr>
<tr>
<td>IVD</td>
<td>OncoGuide NCC Oncopanel System</td>
<td>Sysmex Corporation</td>
<td>Solid tumors</td>
<td>Feb. 28, 2017</td>
<td>Dec. 25, 2018</td>
</tr>
</tbody>
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NOTE: These were approved as a pilot program based on the administrative notification in 2015.
2. Priority Review for Specific Uses

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

Administrative notification No.0831-5, August 31, 2020
Criteria for Specific Use Products Designation

Criteria

- use for diagnosis, treatment or prevention of illness for children
- highly unmet medical needs
- excellent effectiveness and safety

Advantage

- Prioritized Review: targeting review time; 12 months → 9 months
- Tax benefits and grants of subsidy for product development

IMDRF Stakeholders Forum, March 23, 2021
3. Conditional Early Approval System

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

Administrative notification No.0831-2, August 31, 2020

- 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
  - 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)
PACMP is introduced for medical devices to enable continuous improvements through product lifecycle.

Regular Approval Process

Clinical data collection → Application → Review → Approval

Plan for application expansion → Data collection → Change request

Approval Process using PACMP

Clinical data collection → Application → Review → Approval

Plan for application expansion → Submission of PACMP → Confirmation → Data collection based on the protocol

Change request → Change approval or Change notification

Check to ensure the predetermined results are obtained in accordance with the planned change

Early realization of improvement

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

Administrative notification No.0831-14, August 31, 2020
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.

PACMP for AI medical devices

Approval review process which enables continuous improvement of performance of SaMD using AI

Performance continues to be changed and improved.
Thank you for your attention!