Current and planned e-labeling initiatives in Japan

KURIHARA Sayaka

PMDA
Today’s Agenda

• Revision of PMD Act

• Benefits of E-labeling

• Future E-labeling
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Revision of Pharmaceuticals and Medical Devices Act

**Basic Policy**

1. To provide better medical products safely, promptly and efficiently.
2. To improve a pharmaceuticals provision system for patient's secure access in familiar community

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<th>Value of Community Pharmacies/Pharmacists</th>
<th>Prevention of Illegality</th>
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<td>➢ Increasing importance of appropriate treatment with medicines More concern about polypharmacy along with aging More outpatients suffering from cancer (thousand)</td>
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<td>➢ Unmet medical needs</td>
<td>➢ To recommend some of services To help patients choose his/her pharmacy</td>
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<td>➢ Introduction of new approval schemes into the Act SAKIGAKE Conditional early approval Priority review of unmet medical needs such as products for pediatrics modified scheme for a technology which requires continuous amelioration such as AI</td>
<td>➢ Recommendation of additional services Following up adherence and condition of a patient Information sharing with other healthcare professionals</td>
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<td>➢ Enrichment of governance structure of a company Levy system against profit stemmed from false/puffery advertising</td>
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<td>➢ To legislate a certification system for import</td>
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**Current Status**

- Evaluation Lag: Deference of total review time btw. Japan and EU/US (median)

**Issues**

- To facilitate patient access
  - To improve regulation in terms of predictability, international harmonization and efficiency.
  - To enhance safety measure

**Proposed Measures**

- Introduction of new approval schemes into the Act
  - SAKIGAKE
  - Conditional early approval
  - Priority review of unmet medical needs such as products for pediatrics
  - Modified scheme for a technology which requires continuous amelioration such as AI

- Safety measure
  - Electronic provision of package insert
  - Bar code display

**Value of Community Pharmacies/Pharmacists**

- Polypharmacy
  - More than 5 items/month
  - 3-4 items/month
  - 1-2 items/month

**Prevention of Illegality**

- Unfavorable events
  - Manufacturing through unapproved process
  - False/puffery advertising
  - Distribution of a falsified product
  - Fraudulent procurement of a certification to import a product

**Modernizing Regulatory System**

- Good performance in review process

**Surrounding change**

- Advanced technology
  - Needs for innovative products
- Globalization

**Unmet medical needs**

**Expectation of patients for improving their service**

- To recommend some of services
  - Following up adherence and condition of a patient
  - Information sharing with other healthcare professionals

- To enhance the safety measure
  - Electronic provision of package insert
  - Bar code display

**Number of cancer patients**

- Inpatient
  - 100
  - 2002
  - 2008
  - 2014

- Outpatient
  - 2017
  - 2019

**Polypharmacy**

- 75 yrs. old
  - 45%
  - 25%
  - 34%
- 15-39 yrs. old
  - 22%
  - 25%
  - 49%
Electronic Distribution of Package Insert Information

- Package inserts shall basically be distributed electronically instead of being enclosed in products.
- In addition to the electronic distribution, package inserts shall be provided in paper format at the initial delivery of drugs/medical devices under the responsibility of a Marketing Authorization Holder and in cooperation with a wholesaler, if needed. Also, a scheme shall be built to provide information to access the latest package insert information shown on the outer box of a product, and revised information is distributed to medical institutions/pharmacies without fail in paper format or other forms.
- For OTC drugs and medical devices for home use that are directly purchased by consumers, package inserts shall be continuously prepared in paper format and enclosed in products to make the information available at the time of use.

From 1 Aug, 2021
Bar Code Labeling of Drugs/Medical Devices

For securing medical safety, measures to improve traceability from manufacturing/distribution to clinical settings are important, such as managing product information, tracking of usage records, preventing mix-ups. With an aim to enhance safety by these measures, bar code labeling based on the international standards shall be required for immediate containers/wrappings/retail packages of drugs/medical devices.

- Effective/stepwise implementation according to the type of drugs/medical devices and the current status of use of coding including OTC drugs shall be considered in the Bar code labelling requirement.
- Also, safety measures using bar code labeling at clinical settings shall be promoted, as well as registration of production information in the database by MAHs, along with mandatory bar code labeling.

Expected use of bar codes in clinical settings

- Identifying patients who used a particular drug/medical device
- Preventing mix-ups of drugs during preparation/dispensing
- Electronically recording OTC drug sales/purchases
- Confirming hospital inventory of recalled medical devices
- Utilizing drug/medical device use records as Big Data
- Link with electronic version of Medicine notebook

Manufacturing company ➔ Wholesale ➔ Hospital ➔ Medical care

Using bar codes in logistics/clinical settings

<GS1 bar code labeling on drugs/medical devices>

From 1 Dec, 2022
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• Benefits of E-labeling

• Future E-labeling
Benefits of e-labeling

- Accessibility
- Efficiency
- Ecological
- Searchability
- Arrangeability
Benefits of e-labeling

• **Accessibility**

• **Efficiency**

• **Ecological**

• **Searchability**

• **Arrangeability**
Use an app to scan the barcode

Select the document

Packaging Inserts

Related Documents

* The actual visual image shown on the smartphone will vary depending on the app used.

Show the latest version of the package insert from the PMDA website.

Show the PMDA web page with links to the related documents. (Example for human drugs shown here)
Benefits of e-labeling

- **Accessibility**
- **Efficiency**
- **Ecological**
- **Searchability**
- **Arrangeability**
Efficiency and Ecological
Benefits of e-labeling

• Accessibility
• Efficiency
• Ecological
• Searchability
• Arrangeability
Searchability
-Labeling format in Japan-

Labeling (PDF, XML)

- DATE OF PREPARATION OR REVISION
- STANDARD COMMODITY CLASSIFICATION NUMBER OF JAPAN
- APPROVAL NUMBER, DATE OF INITIAL MARKETING IN JAPAN
- STORAGE, SHELF LIFE
- THERAPEUTIC CATEGORY
- REGULATORY CLASSIFICATION
- NAME OF PRODUCT
- WARNINGS
- CONTRAINDICATIONS (This drug is contraindicated to the following patients.)
- COMPOSITION AND PRODUCT DESCRIPTION
- INDICATIONS
- PRECAUTIONS CONCERNING INDICATIONS
- DOSAGE AND ADMINISTRATION
- PRECAUTIONS CONCERNING DOSAGE AND ADMINISTRATION
- IMPORTANT PRECAUTIONS
- PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS
- INTERACTIONS
- ADVERSE REACTIONS
- INFLUENCE ON LABORATORY TESTS
- OVERDOSE
- PRECAUTIONS CONCERNING USE
- OTHER PRECAUTIONS
- PHARMACOKINETICS
- CLINICAL STUDIES
- PHARMACOLOGY
- PHYSICOCHEMICAL PROPERTIES
- PRECAUTIONS FOR HANDLING
- APPROVAL CONDITIONS
- PACKAGING
- REFERENCES
- REFERENCE REQUEST AND CONTACT INFORMATION
- PRECAUTION CONCERNING HEALTH INSURANCE BENEFITS
- MARKETING AUTHORIZATION HOLDER, etc.

https://www.pmda.go.jp/PmdaSearch/iyakuSearch/ (Only in Japanese)
Benefits of e-labeling

• **Accessibility**

• **Efficiency**

• **Ecological**

• **Searchability**

• **Arrangeability**
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Notification on English translation
English translation guidance for prescription drugs, PSEHB/PSD Notification No. 0329-8, 29 March, 2019

- In order to promote regulatory harmonization and international collaboration, MHLW and PMDA declare to disseminate regulatory information to the other countries.

- To share knowledge and experience on proper use of medicines to Asia

(Only in Japanese)

(Only in Japanese)
Information Update
Future E-labeling
Conclusion

E-labeling can be utilized for each regulatory authorities in the world.

Patient access faster!
Thank you for your attention!