E-labeling
Current status and Future

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Pharmaceuticals Medical Devices Agency (PMDA)

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E-labeling around the world
**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

### Modernizing Regulatory System
- **Good performance in review process**
- **Surrounding change**
  - Advanced technology
  - Needs for innovative products
  - Globalization
- **Unmet medical needs**

### Value of Community Pharmacies/Pharmacists
- **Expectation of patients for improving their service**
- **Increasing importance of appropriate treatment with medicines**
  - More concern about polypharmacy along with aging
  - More outpatients suffering from cancer

### 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

### Current Status

<table>
<thead>
<tr>
<th>Year</th>
<th>Value of Community Pharmacies/Pharmacists</th>
</tr>
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<tbody>
<tr>
<td>1996</td>
<td>&lt;polypharmacy&gt;</td>
</tr>
<tr>
<td>2002</td>
<td>&lt;number of cancer patients&gt;</td>
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<tr>
<td>2008</td>
<td>&lt;number of cancer patients&gt;</td>
</tr>
<tr>
<td>2014</td>
<td>&lt;number of cancer patients&gt;</td>
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</tbody>
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### Issues

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

### Proposed Measures

- To recommend some of services
- To help patients choose his/her pharmacy
- **Recommendation of additional services**
  - Following up adherence and condition of a patient
  - Information sharing with other healthcare professionals
- To establish a display system related to pharmacy’s feature
- To set countermeasures

- Enrichment of governance structure of a company
- Levy system against profit stemmed from false/puffery advertising
- To legislate a certification system for import
- 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 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.
Benefit of e-labeling

- **Accessibility**
  - Latest version
  - Anywhere and anytime
    - If it is not adopted at own medical institution

- **Arrangeability**
  - For own drug formulary
  - Converting to other languages

- **Searchability**
  - Drug/food interaction, contraindication etc.
English Version of Japanese Labeling in PMDA Website

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

- PMDA International Strategic Plan 2015, 26 June, 2015
- Revision of “Basic Policy for the Asian Health Initiative”, for the achievement of Universal Health Coverage, 2018
English translation guidance for prescription drugs

第2章 各記載項目における留意事項

添付文書英訳中、記載項目毎の必須留意事項は以下の通りである。なお、添付文書及び英訳は英語に従っての標準用語とし、それぞれ以外は参考用語とする。

ア．作成又は改訂年月

（例）(1) 新規作成の場合：2019年4月作成
   □Prepared: April 2019
(2) 改訂の場合：2020年7月改訂（新様式第2版）
   □Revised: July 2020 (2nd version of new form)

イ．日本標準商品分類番号 □Standard Commodity Classification Number of Japan

日本標準商品分類番号等

・日本標準商品分類番号 □Standard Commodity Classification No. of Japan
・承認番号 □Approval No.

（例）(1) 承認番号：22300AMX12345678
   • Approval No.: 22300AMX12345678
   承認番号
   番12.5mg: (63AM) No.512
   番25mg: (63AM) No.513
   • Approval No.: 12.5 mg: (63AM) No.512
   25 mg: (63AM) No.513
(2) 承認番号に漢字が含まれる場合はローマ字で音訳する。
   承認番号：(阪東) 1613
   • Approval No.: HAN-YAKU No.1613

ウ．承認番号、販売開始年月 □Approval Number, □Date of Initial Marketing in Japan

・販売開始年月 □Date of Initial Marketing in Japan

エ．貯法、有効期間等 □Storage, □Shelf Life

・貯法 □Storage

Expectation to e-labeling

- Updates by timely manner and fast dissemination
- Accessibility
- Arrangeability
- Searchability

Labeling is a living document!
Thank you for your attention!

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