Overview of Drug Information Progress in Taiwan

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http://www.fda.gov.tw/
Outline

01 Regulations of drug labeling management in Taiwan

02 Progress of drug labeling management in Taiwan

03 Future prospects of drug labeling management in Taiwan
Important roles of drug labeling

01 Important Information from preclinical, clinical trial and post-marketing
  - Toxicology, PK/PD, Clinical trials, ADR reports, etc.

02 Direction of use
  - Indication
  - Contraindication
  - Warning and Precaution
  - Adverse reaction
  - Drug interaction
  - etc.

03 Tool of Risk Management
  - Risk communication
  - Routine risk management tool
Progress of drug labeling management in Taiwan

Easily Accessible

Easy to Read & Understand

Advanced Applications
Progress of drug labeling management in Taiwan

Search System for Drug License (including drug labelling)

Standardization of labelling format for non-prescription drugs

Before 2010

Drug Scan (Medicine Scan) APP

2015

2016
### Search system for drug license for the public

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Product name (Chinese)</th>
<th>Product name (English)</th>
<th>Dosage form</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>Applicant</th>
<th>Manufacture</th>
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<tbody>
<tr>
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<table>
<thead>
<tr>
<th>License No.</th>
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<tbody>
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</table>

<table>
<thead>
<tr>
<th>薪餘</th>
<th>醫療器材、特定用途化妝品許可證查詢</th>
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</thead>
<tbody>
<tr>
<td>許可證字號</td>
<td>License No.</td>
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<tr>
<td>許可證種類</td>
<td>口腔製品</td>
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<tr>
<td>薪餘</td>
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</tr>
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<td>醫療器材次分類</td>
<td>口腔製品</td>
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<tr>
<td>限制項目</td>
<td>口腔製品</td>
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<td>細(粗)</td>
<td>口腔製品</td>
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<tr>
<td>申請商名稱</td>
<td>適應症(藥品)</td>
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<tr>
<td>製造廠名稱</td>
<td>效能(醫療器材)</td>
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<tr>
<td>種別</td>
<td>用途(化妝品)</td>
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<td>藥品類別</td>
<td>單/複方別</td>
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<td>藥物治療分類(AHFS/D碼)</td>
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<td>成分</td>
<td></td>
</tr>
<tr>
<td>排序方式</td>
<td>許可證字號</td>
</tr>
</tbody>
</table>

[Image of a form with various fields for searching drug licenses]
Search system for drug license for the public

Drug labeling
Drug package appearance

PDF file
Medicine Scan (藥掃描) APP

- Smartphone-Based Barcode Scanning
<table>
<thead>
<tr>
<th>藥品條碼掃描 藥品資訊</th>
</tr>
</thead>
<tbody>
<tr>
<td>許可證號</td>
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<tr>
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<td>主成分</td>
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<td>申請廠商名稱</td>
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<tr>
<td>製造商</td>
</tr>
<tr>
<td>藥品有效日期</td>
</tr>
<tr>
<td>非藥品有效日期</td>
</tr>
<tr>
<td>劑型</td>
</tr>
</tbody>
</table>

請將鏡頭對準欲掃描的條碼掃描將會自動完成
Standardization of labelling format for non-prescription drugs

1. Standardized format
2. Easy to read & understand

Steven-Johnson syndrome
Skin rash, Itch, Blisters
Standardization of labelling format for non-prescription drugs-2

• Format of package
  – All the designated information need to be listed at the fixed location.
  – The manufacturers need to conform with the legal liabilities and direction of use, for example, the labeling contents should include “Restricted group” and “Contact information”
  – QR code linked to specific sound files that read the labelling contents aloud for visually impaired users.

Advantages for the QR code

- Alternatives for visual impairment groups
- More drug information provided
- More Cost-efficient than braille edition
- User-friendly for elderly and people with poor visions
Future prospects of drug labeling in Taiwan

- Structured product labeling
- Electronic data transmission
- Advanced functions of the electronic system

Benefits
1. Healthcare professionals can obtain the most up-to-date information with a minimum of search time.
2. Advance the searching system of package insert in response to user needs.
Structured drug labeling-1

- Transmission format convergence for e-labeling
- Establish machine-readable format for sharing drug information

Drug manufacture  Government  Healthcare, Hospital or Pharmacy Information System

Communication in identical language
Structured drug labeling-2

- Standardization of labelling format for prescription drugs
- Labeling information appears in hierarchical view (TreeView) on the website for designing a User-friendly search page

Click to open or close the tree branches.
Electronic data transmission

- **E-submission**
  - Drug License Holder
  - Build up platform for pharmaceutical manufacturers to upload the package insert.
  - Improve and Expend the system functions.

- **Structured Product Labeling Database**

- **Open data**
  - Gradually ask the pharmaceutical manufacturers to upload the package insert.

- **Accessible**
  - Healthcare, Hospital, Pharmacy Information System

2019-2020 Transition period

2021-2022 Phased implementation
Advanced functions for the electronic system

- Checking for drug interaction and repeated medication
- Responsive Web Design
- QR code scanning for Prescription drugs
- Drug package barcode
Conclusion

Government

Drug License Holders

Users
(Healthcare professionals and patients)
Thank you for your attention.