An update on the bar code guideline for medical devices in Japan

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Ministry of Health, Labour and Welfare (MHLW)

Promote Integrrally & Comprehensively

Improve & Promote
- Public Health
- Social-Security
- Social Welfare

Maintain
- Work environment
- Profession

Secure & Train people

Changes
- Aging with fewer children
- Gender equality
- Economic structure

Comprehensive Promotion
- Social security policy
- Labor policy

- Secure & improve people’s life
- Develop economy
- Cope with changes
### MHLW Organization

- **Minister’s Secretariat**
  - Personnel Division, General Coordination Division, Finance Division, Regional Bureau Administration Division, International Affairs Division, Health Sciences Division

- **Statistics and Information Department**
  - Policy Planning Division, Vital, Health and Social Statistics Division, Employment, Wage and Labour Welfare Statistics Division, Information System Division

- **Health Policy Bureau**
  - General Affairs Division, Guidance of Medical Service Division, Medical Professions Division, Dental Health Division, Nursing Division, Research and Development Division, National Hospital Division

- **Health Service Bureau**
  - General Affairs Division, Cancer Measures and Health Promotion Division, Specific Disease Control Division, Tuberculosis and Infectious Diseases Control Division, Environmental Health Division, Water Supply Division

- **Pharmaceutical and Food Safety Bureau**
  - General Affairs Division, Evaluation and Licensing Division, Safety Division, Compliance and Narcotics Division, Blood and Blood Products Division

- **Department of Food Safety**
  - Policy Planning and Communication Division, Standards and Evaluation Division, Inspection and Safety Division

- **Labour Standards Bureau**
  - General Affairs Division, Working Conditions Policy Division, Inspection Division, Workers’ Life Division

- **Occupational Safety and Health Department**
  - Policy Planning Division, Safety Division, Industrial Health Division, Chemical Hazards Control Division

- **Workers’ Compensation Department**
  - Workers’ Compensation Administration Division, Labour Insurance Contribution Levy Division, Compensation Division, Compensation Operation Division

- **Employment Security Bureau**
  - General Affairs Division, Employment Policy Division, Employment Development Division, Employment Insurance Division, Labour Market Center Operation Office

- **Employment Measures for the Dispatched and Fixed-term Workers Department**
  - Policy Planning Division, Demand and Supply Adjustment Division, Foreign Workers’ Affairs Division

- **Employment Measures for the Elderly and Persons with Disabilities Department**
  - Employment Measures for the Elderly Division, Employment Measures for the Persons with Disabilities Division

- **Human Resources Development Bureau**
  - General Affairs Division, Human Resources Development Division, Vocational Training Promotion Division, Vocational Ability Evaluation Division, Overseas Cooperation Division

- **Equal Employment, Children and Families Bureau**
  - General Affairs Division, Equal Employment Policy Division, Work and Family Harmonization Division, Part-time Work and Home Work Division, Family’s Welfare Division, Child-rearing Promotion Division, Day Care Division, Maternal and Child Health Division

- **Social Welfare and War Victims’ Relief Bureau**
  - General Affairs Division, Public Assistance Division, Community Welfare and Services Division, Welfare Promotion Division, Planning Division of War Victims’ Relief, Relief Division, Record Division

- **Director-General for Policy Planning and Evaluation**
  - Policy Planning Division, Welfare Division for Persons with Disabilities, Mental Health and Disability Health Division

- **Department of Health and Welfare for Persons with Disabilities**
  - Policy Planning Division, Welfare Division for Persons with Disabilities, Mental Health and Disability Health Division

- **Health and Welfare Bureau for the Elderly**
  - General Affairs Division, Long-term Care Insurance Planning Division, Division of the Support for the Elderly, Promotion Division, Division of the Health for the Elderly

- **Health Insurance Bureau**
  - General Affairs Division, Employees’ Health Insurance Division, National Health Insurance Division, Division of the Health Services System for the Elderly, Medical Economics Division, Actuarial Research Division

- **Pension Bureau**
  - General Affairs Division, Pension Division, International Pension Division, Corporate Pension and National Pension Fund Division, Actuarial Affairs Division, Pension Service Planning Division, Pension Service Management Division

- **Director-General for Policy Planning and Evaluation**
  - Counsellor, Counsellor for Policy Evaluation
Economic Affairs Div., Health Policy Bureau
For both Pharmaceutical & Medical Device Industries

- Window as administration function
- Plan promotion
- Take various measures
- Consultation on insurance reimbursement price
- Instruct on distribution improvement
Collaborations for Medical Device Policies

- **Administration**
  - **MHLW**
    - Implement administrative measures
  - **Health Policy Bureau - Economic Affairs Div.**
    - Propel Medical Safety
  - **Pharmaceutical and Food Safety Bureau - Safety Div.**
    - Review, Approve & conduct Post Market Survey on safeness & effectiveness of Medical Devices effectively, safely & promptly.

- **PMDA**
  - Scientific judgment

- **Industry**
  - **Associations**
    - **JFMDA**
      - Prompt delivery of up-to-date medical technologies to the market
      - Secure further safeness of Medical Devices
      - Strengthen International competence
    - **GS1 Japan**

- **Medical Device Manufacturers & Suppliers**

- **More stakeholders**
  - **Healthcare Service Providers**
  - **Academies**
  - **Citizens**
  - **Many mores…**

**PMDA** : Pharmaceuticals and Medical Devices Agency
**JFMDA** : The Japan Federation of Medical Devices Associations
<table>
<thead>
<tr>
<th>Date</th>
<th>Event Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>26 Dec. 2001</td>
<td>Ground design aiming at information revolution in Health Science field</td>
</tr>
<tr>
<td>2002 – (Every year)</td>
<td>Statistics survey on Medical Device informatization progress</td>
</tr>
<tr>
<td>31 Mar. 2003</td>
<td>Medical devices industrial vision</td>
</tr>
<tr>
<td>19 Sep. 2008</td>
<td>New medical devices and a medical technology industrial vision</td>
</tr>
<tr>
<td>26 Jun. 2013</td>
<td>Medical devices industrial vision</td>
</tr>
<tr>
<td>22 Jun. 2007</td>
<td>Three-year deregulation program</td>
</tr>
<tr>
<td>28 Mar. 2008</td>
<td>Guidelines for Placing Standard Codes (Barcode Marking) on Medical Devices</td>
</tr>
</tbody>
</table>
Guidelines for Placing Standard Codes (Barcode Marking) on Medical Devices

Guidelines for placing standard codes (barcode marking) on medical devices have been established as below to promote efficient and sophisticated distribution systems, efficient medical administration, and securing traceability as well as prevention of medical accidents by refining distribution management from licensed marketing approval holders and manufacturers to medical institutions. As these guidelines are standards to be promoted cooperatively by the medical devices industry and the administration, barcode marking should be promoted to this effect.

1. Marking Subjects and Data to be Placed

1) Medical Devices, etc.

Marking subjects are medical devices and in vitro diagnostics (*1). Depending on the type of product, the product code, expiration date (*2) and lot number or serial number should be placed as shown in the following table. (*3)

<table>
<thead>
<tr>
<th>Type of medical device</th>
<th>Product code</th>
<th>Expiration date</th>
<th>Lot number or serial number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specially controlled medical device, etc (*5) (including specially designated maintenance management required medical device)</td>
<td>☒</td>
<td>☒</td>
<td>☒</td>
</tr>
<tr>
<td>Designated insured medical material</td>
<td>☒</td>
<td>☒</td>
<td>☒</td>
</tr>
<tr>
<td>Medical devices other than the above</td>
<td>☒</td>
<td>☒</td>
<td>☒</td>
</tr>
</tbody>
</table>

In vitro diagnostics | ☒ | ☒ | ☒ |

2) Consumable Supplies other than Medical Devices (*8)

Marking subjects are consumable supplies other than medical devices which are repeatedly used entirely at medical institutions. Product code, expiration date and lot number should be placed on the inside box and outside box as shown in the following table.

<table>
<thead>
<tr>
<th>Packaging unit</th>
<th>Product code</th>
<th>Expiration date</th>
<th>Lot number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inside box and outside box</td>
<td>☒</td>
<td>☒</td>
<td>☒</td>
</tr>
</tbody>
</table>

(*1) "Medical device" refers to the medical devices as stipulated in Article 2, Paragraph 3 of the
Medical Devices Law, except for the medical devices listed in Paragraph 4 of the same Article.

(*2) "Expiration date" refers to the expiration date of the product or the date of expiry of the medical device.

(*3) The placement of the lot number or serial number is optional.

(*5) Specially controlled medical devices include special approval medical devices, medical device for the management of medical waste, blood products, and medical products for use in clinical trials.

(*8) Consumable supplies include, but are not limited to, surgical supplies, medical instruments, and medical supplies.
History: BarCode Implementation

1980s

1999

Guideline Manual (JFMDA)

2000

Database for All Healthcare Products (MEDIS-DC)

2001

Revised Pharmaceutical Affairs Law effectuated

2002


2005

Revised Guideline Manual (JFMDA)

2006

Followed by Dental Trade Association

2007

Direct Marking Guideline

2008

Guideline (MHLW)

(Issued in March 2008)

2009

2010

Implementation required (time limit)

2011

(Step-by-step by March 2009 / March 2010 / March 2011)

2012
**MHLW Barcode Guideline: Outlines**

- **Objective**
  - Promote Efficient supply chain
  - Efficient medical office works
  - Secure Traceability
  - Prevent Medical error

- **Implementation**
  - Applied to Medical Devices, *in vitro* Diagnostics & Consumable Supplies
  - Contents
    - Product code, Expiry Date & Lot or Serial #
  - Product Codes
    - GTIN recommended
  - Symbol
    - GS1-128 recommended
  - Database
    - Open source DB opened to public
  - Implement by
    - 1 to 3 years after the issuance of the guideline

MHLW Barcode Guideline: Key points

- Not a legal regulation
  - An administrative notification (no legal penalty)

- Following JFMDA Guideline Manual
  - First edition issued in 1999

- Package level marking on the Medical Device packages
  - Direct Part Marking (DPM) is not yet required

- Harmonized with GS1 standards

- Promote registration to the Data Base opened to public
  - Making manufacturers aware of the Data Base for registration
MHLW Barcode Guideline: Practical

MHLW: <Individual Package>
≈ GS1: < Primary Packaging >

< Inside Box >
< Secondary Packaging >

< Outside box >
< Shipping Container >

GS1-128
2D Barcode standardized by ISO

Al (01) GTIN
(Partly required)

Al (17) Expiry Date
(Partly required)

Al (10) Lot No. or Al (21) Serial No.
BarCode Marking: Example
(Individual Package ≈ “Primary Packaging” by GS1)
BarCode Marking: Example
(Inside Box ≈ “Secondary Packaging” by GS1)
**BarCode Marking: Example**

*(Outside box ≈ “Shipping Container” by GS1)*

<table>
<thead>
<tr>
<th>AI (01) GTIN</th>
<th>AI (17) Expiration Date</th>
<th>AI (10) Batch/Lot No.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## BarCode Marking: Progress

[Annual Survey by MHLW in Sep. 2012]

<table>
<thead>
<tr>
<th></th>
<th>&lt; Primary Packaging &gt;</th>
<th>&lt; Secondary Packaging &gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>GTIN-13 (JAN) Acquired</td>
<td>Individual Package Labeled</td>
<td>Inside Box Labeled</td>
</tr>
<tr>
<td>Medical Devices</td>
<td>99.1%</td>
<td>81.1%</td>
</tr>
<tr>
<td><em>In Vitro</em> Diagnostics</td>
<td>100.0%</td>
<td>92.5%</td>
</tr>
<tr>
<td>Consumable Supply</td>
<td>96.8%</td>
<td>-</td>
</tr>
</tbody>
</table>

≈ GS1:

Companies answered: 581/756 = 84.4%
GTIN-13 Acquiring Efforts on Individual Units

Guideline announced in MAR
Items registered in the Public Data Base

Registered Items (Total): **843,206**
(674 Companies)
(as of 16 Aug. 2013)

**Medical Equipment:** 17,904

**Medical Apparatus:** 740,419

**In vitro Diagnostics:** 11,961

**Miscellaneous:** 72,922

MEDIS-DC Database
Healthcare Products Database

GTIN-13 Acquired Rate (September, 2012):
Medical Device - 99.1%

Database Registration:
Medical Device: 843,206 items (674 Companies) (as of 16 Aug. 2013)

MEDIS-DC Database

[1] Apply for GS1 Company Prefix
[3] Register Product Data
[4] Inquire-Search-Download

Manufacturer or Supplier

GS1 Japan

MHLW
FPMAJ
JFMDA

Distributors
Hospitals

FPMAJ: The Federation of Pharmaceutical Manufacturers' Associations of Japan
Next Step

• UDI Patio
  • Talking how the BarCode labeling in Japan should be
    – Discussion on issues about UDI
  • Members

• DPM on Medical Devices
  • Current : Not required in the Guideline
  • Future : Study when to enact DPM provision watching followings,
    » International trends
    » Technology development and its validation

• Expansion of the scope of marking data
  • Current : Some data are left to the discretion of companies.
  • Future : Shall be considered in the future by studying how such data are actually displayed and used.
Thank you so much for your kind attention and wish you a happy stay in San Francisco!

See us Next Time!
Contact Details

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