Promoting IT Utilization in Healthcare in Japan

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Policy Making for IT Utilization in Healthcare

Dec. 2001; Grand Design for IT Utilization in Insured Medical Services

Oct. 2002; to begin annual IT infrastructure survey in medical device industry

Sep. 2006; Notification of GL for Bar Coding on Prescription Drugs

Jun. 2007; 3-year Plan for the Promotion of Regulatory Reform” decided by the cabinet

Dec. 2007; Grand Design for IT Utilization in Medical Service, Healthcare, Nursing and Welfare

Mar. 2008; Notification of GL for Bar Coding on Medical Devices

Sep. 2008; Industrial Vision for New Medical Devices and Medical Technologies
### IT Infrastructure Survey in Medical Device Industry

<table>
<thead>
<tr>
<th></th>
<th>As of September 2007</th>
<th>Comparison: as of Sep 2006</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Medical materials</td>
<td>Medical device</td>
</tr>
<tr>
<td>Number of Items</td>
<td>463,306</td>
<td>104,652</td>
</tr>
<tr>
<td>Number of Items with GTIN-13</td>
<td>448,312 (96.8%)</td>
<td>80,370 (76.8%)</td>
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<tr>
<td>Number of Items Registered to MEDIS-DC Database</td>
<td>305,618 (66.0%)</td>
<td>39,083 (37.2%)</td>
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<tr>
<td>Number of Barcoding Items</td>
<td>408,387 (88.1%)</td>
<td>44,831 (42.8%)</td>
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<tr>
<td>Number of Items of which Smallest Package (could be unit of use) barcoding</td>
<td>316,039 (68.2%)</td>
<td></td>
</tr>
</tbody>
</table>
Guidelines for Bar-coding on Medical Devices

- Not a legal regulation but Guidelines to be promoted cooperatively by the medical devices industry and the administration.
- Guidelines for marking on the package of medical devices (Marking on product body is not yet required.)
- Harmonized with GS1 Specification.
- GS1 product code (GTIN) is recommended to use whereas other codes are not excluded.
- Registration in a public Data Base is encouraged.
Guidelines for Bar-coding on Medical Devices

Date of Marking Requirement

Mar. 2008
Notification Issued

Mar. 2009
Partly Enforced

Mar. 2010
Partly Enforced

Mar. 2010
Fully Enforced

1 year after the issuance of notification

2 years after

3 years after

1. Designated insured medical material
2. Specially designed maintenance management required medical device and Specially controlled medical device (Excluding ① above)
3. Medical devices excluding ① & ② above
4. In vitro diagnostics
5. Consumable supplies other than medical devices