

# 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 I T infrastructure survey in medical device industry**

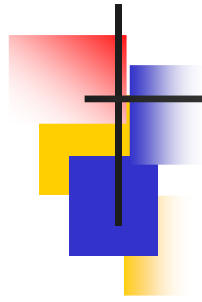
**Sep. 2006; Notification of GL for Bar Coding on Prescription Drugs**

**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

	<b>As of September 2007</b>			<b>Comparison : as of Sep 2006</b>
	<b>Medical materials</b>	<b>Medical device</b>	<b>Total</b>	
<b>Number of Items</b>	<b>463,306</b>	<b>104,652</b>	<b>567,958</b>	<b>611,832</b>
<b>Number of Items with GTIN-13</b>	<b>448,312 (96.8%)</b>	<b>80,370 (76.8%)</b>	<b>528,682 (93.1%)</b>	<b>550,000 (89.9%)</b>
<b>Number of Items Registered to MEDIS-DC Database</b>	<b>305,618 (66.0%)</b>	<b>39,083 (37.2%)</b>	<b>344,701 (60.7%)</b>	<b>344,379 (56.3%)</b>
<b>Number of Barcoding Items</b>	<b>408,387 (88.1%)</b>	<b>44,831 (42.8%)</b>	<b>453,218 (79.8)</b>	<b>429,497 (70.2%)</b>
<b>Number of Items of which Smallest Package (could be unit of use) barcoding</b>	<b>316,039 (68.2%)</b>			<b>267,259 (55.4%)</b>

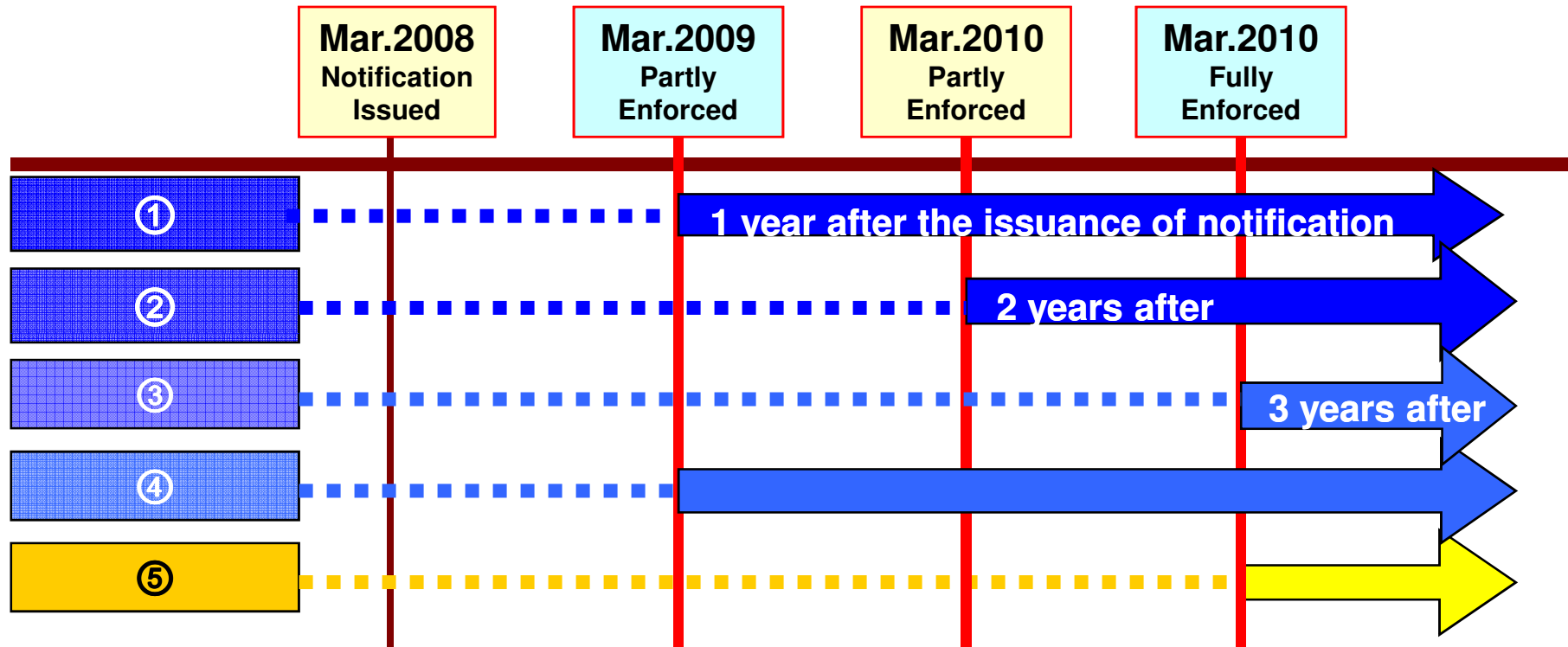


## Guidelines for Bar-coding on Medical Devices

- 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<<<



- 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