

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



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Ministry of Health, Labour and Welfare (MHLW)

- Secure & improve people's life
- Develop economy
- Cope with changes

Promote Integrally & Comprehensively

Improve & Promote

Public Health

Social-Security

Social Welfare

Maintain

Work environment

Secure & Train people

Profession

Changes

Aging with fewer children

Gender equality

Economic structure

Comprehensive Promotion

Social security policy



Labor policy

MHLW Organization

As of April 1, 2013

Ministry of Health, Labour and Welfare	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, Economic Affairs 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
	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

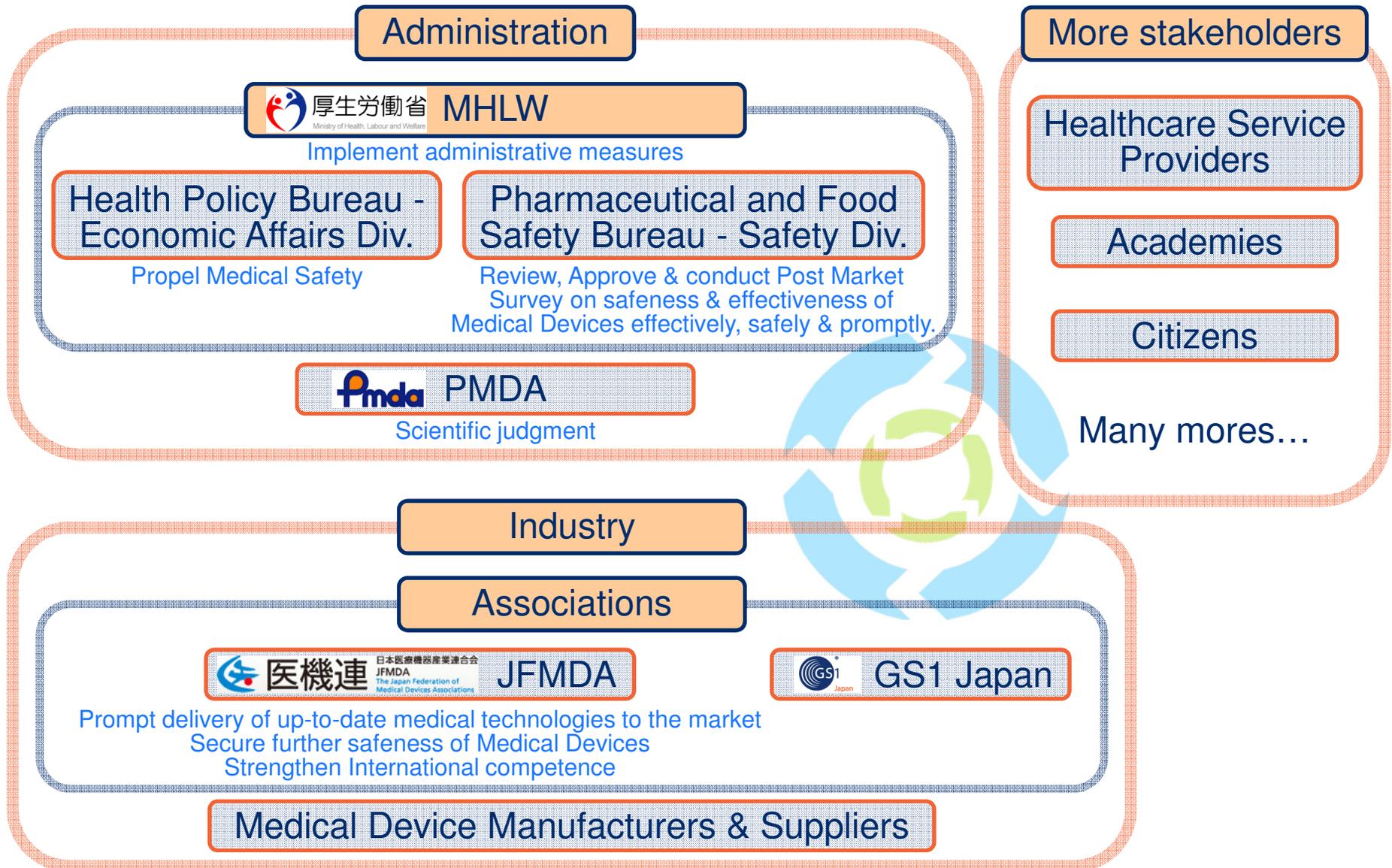
Economic Affairs Div., Health Policy Bureau

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



PMDA : Pharmaceuticals and Medical Devices Agency
JFMEDA : The Japan Federation of Medical Devices Associations

Administrative efforts on Medical Device cording

26 Dec. 2001	Ground design aiming at information revolution in Health Science field	
2002 – (Every year)	Statistics survey on Medical Device informatization progress	
31 Mar. 2003	Medical devices industrial vision	
	19 Sep. 2008	New medical devices and a medical technology industrial vision
	26 Jun. 2013	Medical devices industrial vision
22 Jun. 2007	Three-year deregulation program	
28 Mar. 2008	Guidelines for Placing Standard Codes (Barcode Marking) on Medical Devices	



Guideline from MHLW

Guidelines for Placing Standard Codes (Barcode Marking) on Medical Devices

医政経発第 0328001 号
平成 20 年 3 月 28 日

日本医療機器産業連合会会長 殿

厚生労働省医政局経済課長

医療機器等へのバーコード表示の実施について

医療機器等へのバーコード表示については、これまで関係団体における自主的な取り組みを基本として、その普及を推進してきたところです。

今般、「規制改革推進のための3か年計画」（平成19年6月22日閣議決定）において、医療材料への標準コード付与を整備推進することとされたことを踏まえ、医療機器等の流通の効率化及び高度化、トレーサビリティの確保、医療事故の防止並びに医療事務の効率化の観点から、医療機器等への標準コード付与（バーコード表示）の実施要項を別紙のとおり取りまとめたので、各製造販売業者等が本実施要領に従い適正にバーコード表示を行うよう、貴会会員企業に対する周知徹底をよろしくお願いします。

なお、本実施要項は、貴会の「医療機器商品コード・GS1-128バーコード標準化運用基準マニュアル」の基本方針を踏襲して策定したものであり、その具体的な運用に当たっては、貴会の更なるご協力をよろしくお願いします。

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)

① Marking on individual package (*4)

Type of medical device	Product code	Expiration date	Lot number or serial number
Specially controlled medical device, etc (*5) (including specially designated maintenance management required medical device)	◎	◎	◎
Designated insured medical material	◎	◎	◎
Medical devices other than the above	◎	○	○
In vitro diagnostics	◎	◎	◎

② Marking on inside box (*6) and outside box (*7)

Type of medical device	Product code	Expiration date	Lot number or serial number
Specially controlled medical device, etc (including specially designated maintenance management required medical device)	◎	◎	◎
Designated insured medical material	◎	◎	◎
Medical devices other than the above	◎	◎	◎
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.

Packaging unit	Product code	Expiration date	Lot number
Inside box and outside box	◎	○	○

(*1) "Medical devices" refers to the medical devices as stipulated in Article 2, Paragraph 4 of the Pharmaceutical Affairs Law. Any medical devices, etc used entirely in the home (including contact lens) are exempt from the marking requirement. "In vitro diagnostics" refers to the in vitro diagnostics as stipulated in Article 2, Paragraph 13 of the Pharmaceutical Affairs Law.

English translation available

History: BarCode Implementation

1980s

||

1999

Guideline Manual (JFMDA)

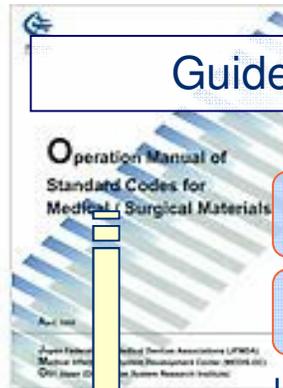
2000

2001

Database for All Healthcare Products (MEDIS-DC)

2002

Revised Pharmaceutical Affairs Law effectuated



Logistics & Usage report became mandatory.
Manufacturers & Wholesalers implemented GS1-128 traceability.



2005

Revised Guideline Manual (JFMDA)

2006

Followed by Dental Trade Association

Direct Marking Guideline

2007

2008

Guideline (MHLW)

(Issued in March 2008)

2009

2010

2011

Implementation required (time limit)

2012

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



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 >

GS1-128

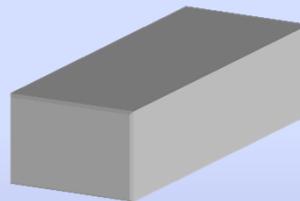
2D Barcode
standardized by ISO



< Inside Box >

< Secondary Packaging >

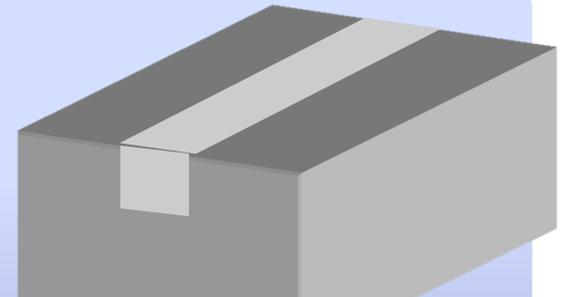
GS1-128



< Outside box >

< Shipping Container >

GS1-128



AI (01) GTIN

(Partly required)

AI (17) Expiry Date

(Partly required)

AI (10) Lot No. or AI (21) Serial No.

BarCode Marking: Example

(Individual Package ≈ “Primary Packaging” by GS1)



AI (01) GTIN

AI (17) Expiration Date

AI (10) Batch/Lot No.

BarCode Marking: Example

(Inside Box ≈ “Secondary Packaging” by GS1)

承認番号 [REDACTED] 管理医療機器 EOG滅菌済
 機械器具 [REDACTED] 再使用禁止
 単回使用クラスII処置キット

アキオキット [REDACTED] (腹部)

1.	[REDACTED]	1本
2.	[REDACTED]	1本
3.	[REDACTED]	2本
4.	[REDACTED]	1本
5.	[REDACTED]	1個
6.	[REDACTED]	20枚
7.	[REDACTED]	1個
8.	[REDACTED]	2個
9.	[REDACTED]	1枚
10.	[REDACTED]	1枚
11.	[REDACTED]	1枚
12.	[REDACTED]	1枚
13.	[REDACTED]	1枚

GS1-128

使用期限 2015年6月
 LOT.No [REDACTED]
 5 キット

(01) 145 [REDACTED] 9 (17) 150600 (10) 1 [REDACTED]

直射日光、水滴れ、高温・多湿を避けて保管し、破損品はご使用しないで下さい
 粘着テープ部があるトレイを使用の際は、万が一かゆみ、発赤等の症状を起こした場合は直ちに使用を中止し、適切な処置を施してください。

Selling Agency: Company A Manufacturing and Distribution by: Company B

AI (01) GTIN

AI (17) Expiration Date

AI (10) Batch/Lot No.

BarCode Marking: Example

(Outside box ≈ “Shipping Container” by GS1)

[Redacted]	
一般的名称	植込みポート用医薬品注入器具
認証番号	[Redacted] 滅菌済み 管理医療機器
加印番号	[Redacted] 単回使用
ロット番号	[Redacted]
使用期限	170131
包装	[Redacted]
針	[Redacted]
チューブ	[Redacted]
Yサイト	[Redacted]
<p>注意事項</p> <ol style="list-style-type: none"> 1. 「再使用禁止。」 2. 「本品に異常や破損がある場合は使用しないこと。」 3. 「包装の開封や汚損がある場合は使用しないこと。」 4. 「水濡れに注意し、高温、多湿、直射日光を避けて保管すること。」 5. 「蛍光灯下やオゾンが発生する器械の周辺等に保管しないこと。」 6. 「記載されている使用期限までに使用すること。」 	
使用前には添付文書を必ず読むこと	
Selling Agency:	
GS1-128	Company AA

AI (01) GTIN

AI (17) Expiration Date

AI (10) Batch/Lot No.

BarCode Marking: Progress

[Annual Survey by MHLW in Sep. 2012]



≈ GS1: < Primary Packaging >

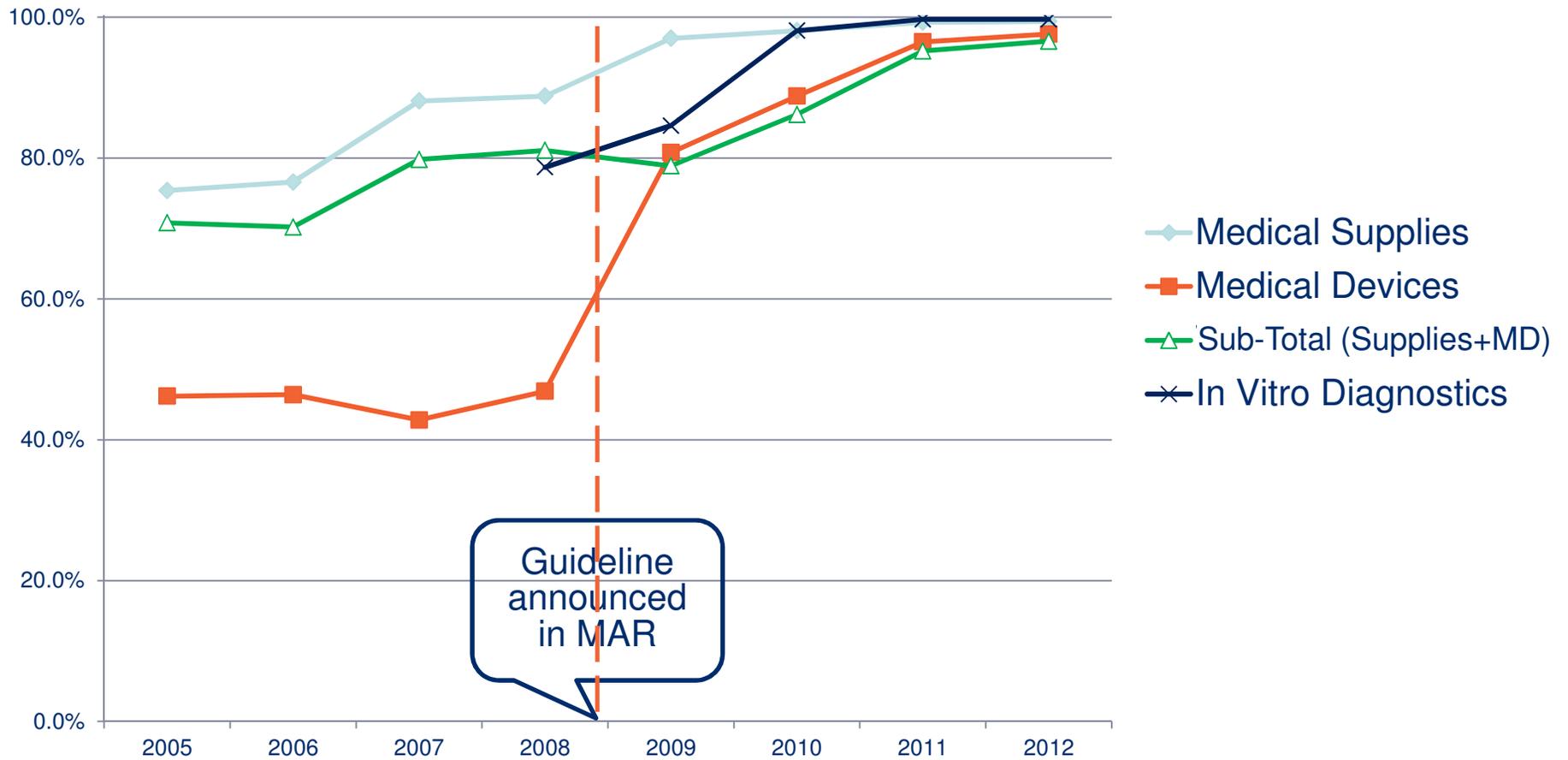
< Secondary Packaging >



	GTIN-13 (JAN) Acquired	Individual Package Labeled	Inside Box Labeled	Registered to MEDIS-DC Database
Medical Devices	99.1%	81.1%	97.6%	80.0%
<i>In Vitro</i> Diagnostics	100.0%	92.5%	99.7%	65.7%
Consumable Supply	96.8%	-	88.4%	65.0%

Companies answered: 581/756 = 84.4%

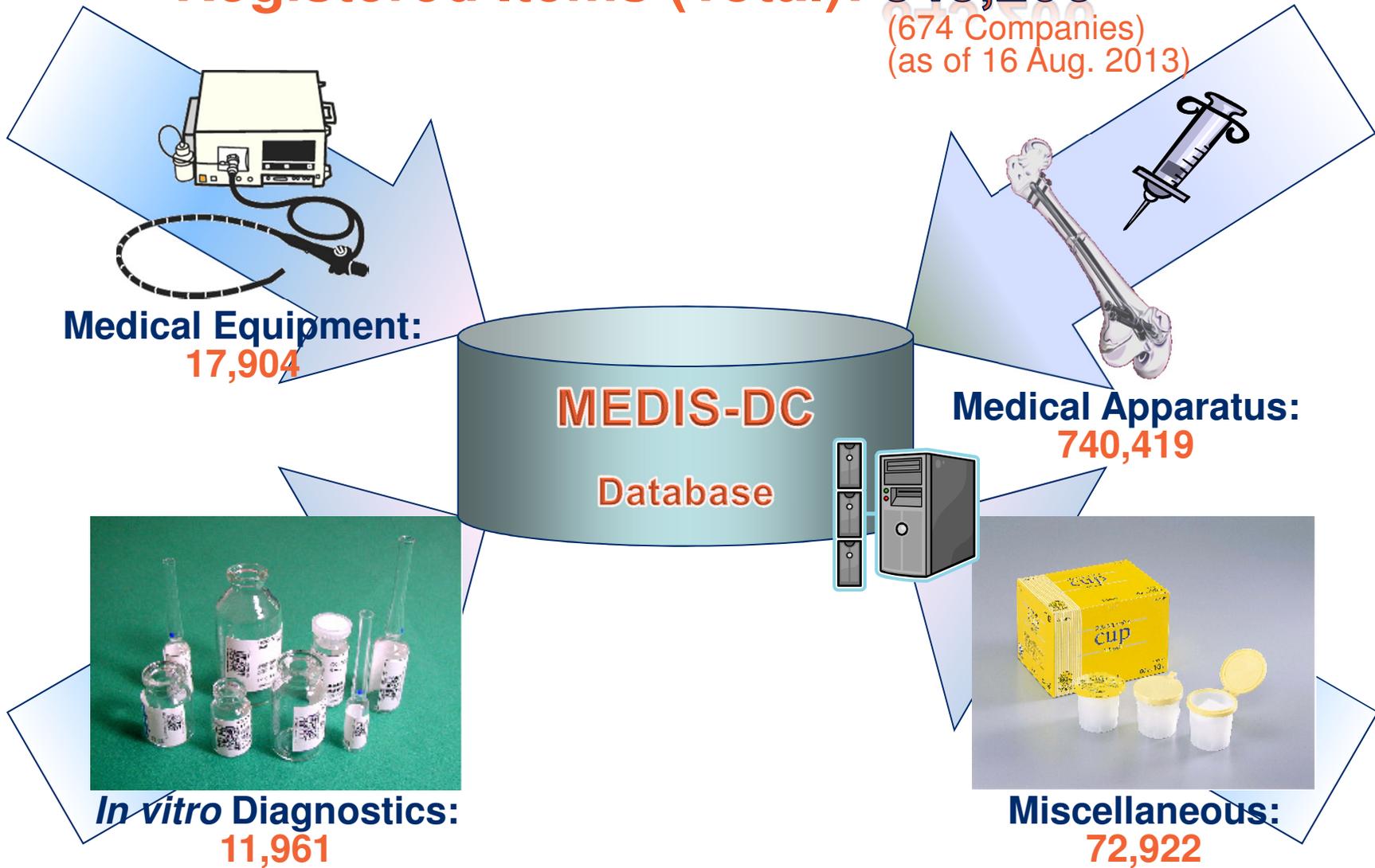
GTIN-13 Acquiring Efforts on Individual Units



Items registered in the Public Data Base

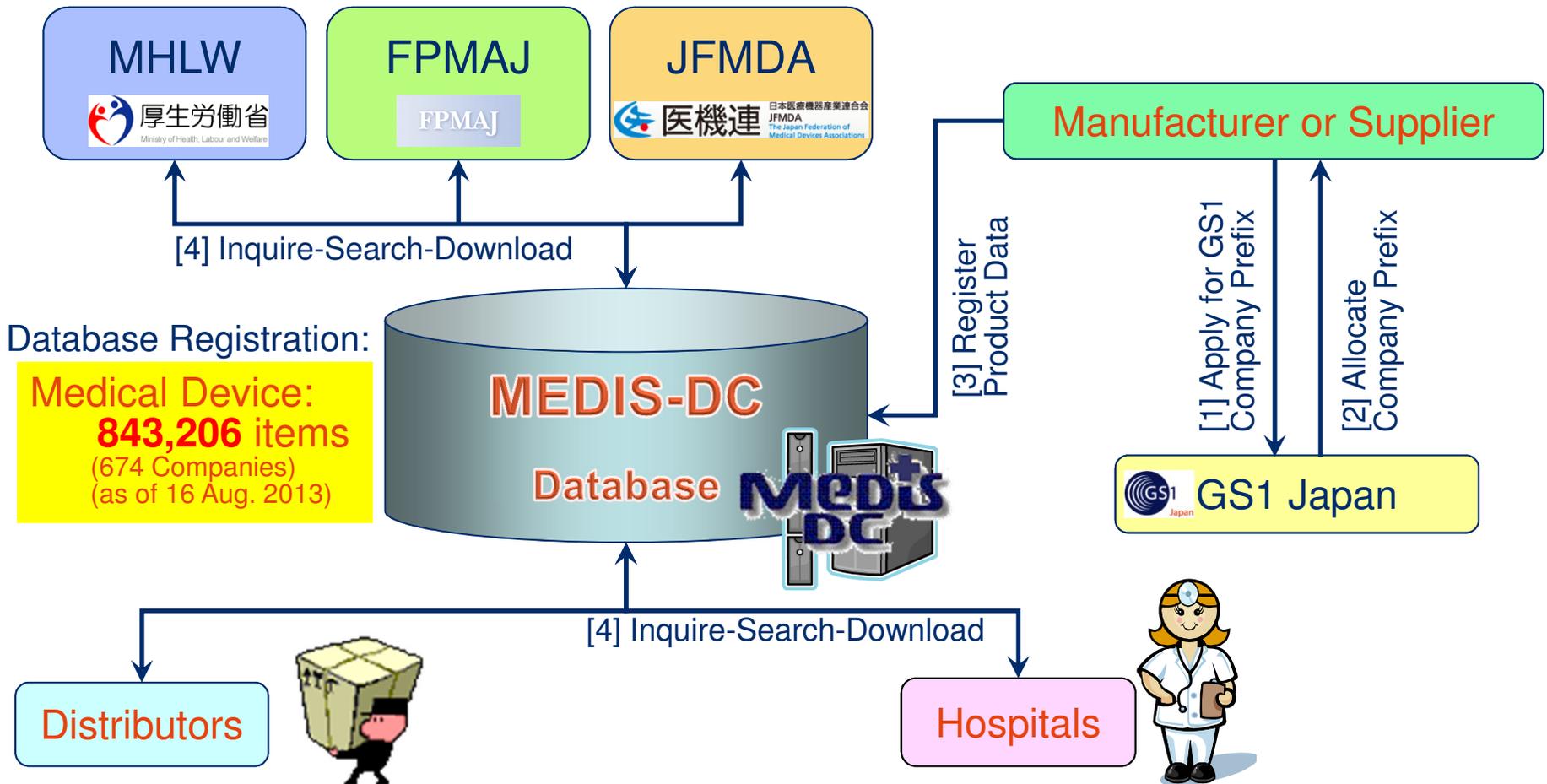
Registered Items (Total): 843,206

(674 Companies)
(as of 16 Aug. 2013)



Healthcare Products Database

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



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

Administration



Industries



- 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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