IMDRF International Medical Device Regulators Forum

UDI Implementation in Japan

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Timeline for UDI Implementation

2000s
MHLW began medical device code standardization efforts

2006
Notification regarding barcode labeling for prescription pharmaceuticals

2008
Notification regarding barcode labeling for medical devices

2019
Legal revision

2022
Legal enforcement of mandatory barcode labeling

Article 68-2-5 of the PMD Act*

2025
Legal revision

*Related notification: https://www.pmda.go.jp/files/000248333.pdf

Products and Data to Be Labeled

Type of medical devices	Individual packaging		Packaging to be sold		Original packaging	
	Product code	Manufacturing identifier	Product code	Manufacturing identifier	Product code	Manufacturing identifier
(1) Medical devices that fall under special treatment materials	◎	◎	●	●	◎	◎
(2) Medical devices that fall under specially controlled medical devices or specially designated maintenance-and-management-required medical devices other than (1)	○	○	●	●	◎	◎
(3) Medical devices other than (1) and (2)	○	○	●	●	◎	◎
(4) *In vitro* diagnostics	○	○	●	●	◎	◎
(5) Consumable materials used repeatedly for medical care exclusively at medical institutions, which are other than (1) - (4).	○	○	◎	○	◎	○

●: Information that shall always be labeled in accordance with Article 68-2-5 of the Act
◎: Information that shall always be labeled in accordance with this notification
○: Optional labeling

Compliance Rate

	Database registration rate	Barcode labeling rate	
		Individual packaging	Packaging to be sold
(1)Medical devices that fall under special treatment materials	**98.1%**	**99.5%**	**99.1%**
(2)-1 Specially designated maintenance-and-management-required medical devices	**93.2%**	**92.3%**	**97.9%**
(2)-2 Specially controlled medical devices	**82.7%**	**92.3%**	**97.9%**
(3) Other medical devices	**91.0%**	**84.8%**	**98.8%**
(4) *In vitro* diagnostics	**76.1%**	**99.1%**	**99.7%**
(5) Consumable materials	**60.5%**	**-**	**89.4%**

Results of the “Survey on the Progress of Digitalization in Medical Devices, etc.” conducted by MHLW (as of September 2023)
https://www.mhlw.go.jp/content/10807000/001442481.pdf

Upcoming Regulatory Changes

< Basic purpose of UDI labeling >

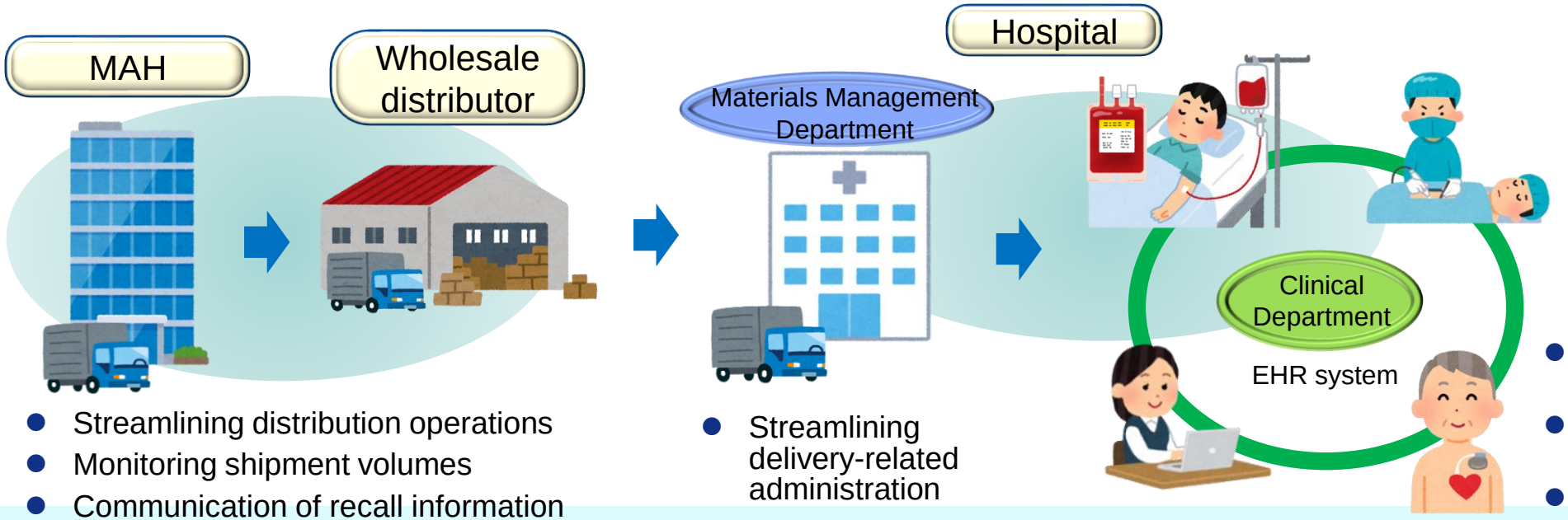
- Prevention of medical device mix-ups
- Ensuring traceability
- Promoting distribution efficiency

< New Challenge >

- Currently, product data registration is requested at shipment stage
  - at the notification level (using private databases)
- Legal revision in 2025 will mandate registration by manufacturers
- Public database under development; specifications under review

Key Points for Effective UDI Utilization

- Barcodes are only useful when both labeling and database registration are in place
- Limited use by few stakeholders reduces overall impact
- Active participation from all stakeholders is essential



- Streamlining distribution operations
- Monitoring shipment volumes
- Communication of recall information

- Streamlining delivery-related administration

- Storage of implantation records
- Streamlining insurance claim processes
- Response to recall