

# Overview of Introduction of UDI Regulation in Japan

IMDRF-DITTA Workshop

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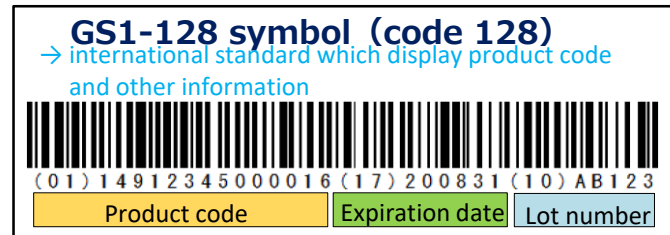
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# Improving Traceability of Medical Device

- by displaying a barcode on a package of medical device, product traceability system is established and utilization of barcode in logistics site and clinical environment is expected. Recently, standardized barcode display and its utilization has been promoted in Japan and internationally.
- To improve traceability of medical devices, displaying traceability barcode became compulsory by the amendment of the Pharmaceuticals and medical devices act (PMD Act) , which will be enforced in December, 2022.

## <Display GSI barcode on package of medical device>



## <Register product information on database>

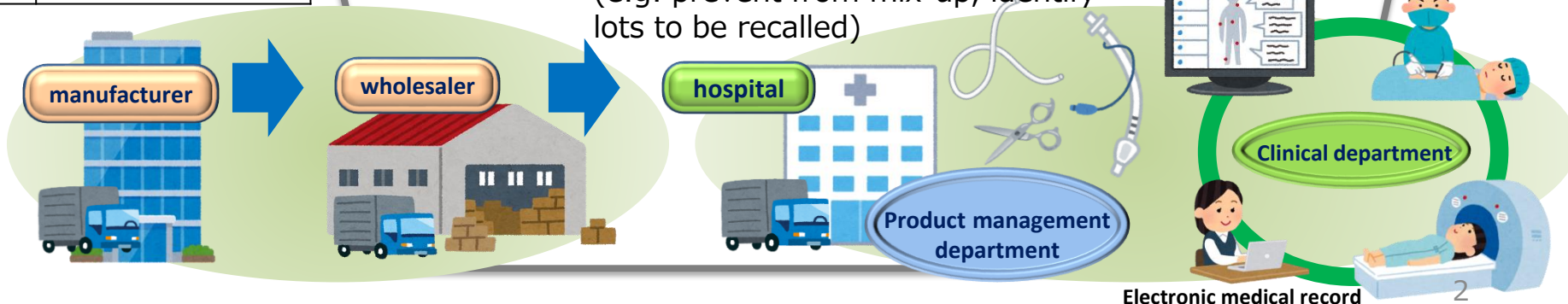


## Utilize barcode in logistics site and clinical environment

- streamline logistics management and product inventory management
- improve clinical safety  
(e.g. prevent from mix-up, identify lots to be recalled)

Main information indicated in GS1-128

(01)	Product code (GTIN/JAN)
→ specific code for manufacturer, product and package	
(11)	Date of manufacture
(17)	Expiration date
(10)	Lot number
(21)	Serial number
(30)	Quantity



# Example of barcode display

GS1 barcode display on a label sticker  
on an inner box of a medical device

