

Commentary

E-labeling and GS1 barcodes for patient safety: Traceability and access to drug information

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INTRODUCTION

In 2019, Pharmaceutical and Medical Device Act was amended in Japan. Most of all pharmaceuticals sold in Japanese market have been marked an international barcode, GS1 barcode, on their packages, however, these barcoding is going to be mandatory from December 2022. And another measure, e-package insert (digitized package insert) and access to the information via GS1 barcodes, has been executed from August 2021. Under the policy, paper leaflet will be abolished and all digitized package inserts are collected on the database of PMDA, the Pharmaceuticals Medical Devices Agency, linked to the relevant international product identifier, Global Trade Item Number (GTIN), that is encoded in a GS1 barcode. The latest package insert information is going to be available at any time by URLs (Uniform Resource Locators) containing GTIN. An application for mobile devices such as smartphones has been developed, and you will be able to see the information by scanning GS1 barcodes on pharmaceutical packages.

HISTORY OF PHARMACEUTICAL GS1 BARCODING IN JAPAN

GS1 barcode marking started in 2006 with the announcement from the Ministry of Health, Labor and Welfare (MHLW), from high risk products such as blood product and injections. Since 2015, all products including blister packs have barcoded. From

April 2021, secondary packages have to have a GS1 barcode encoding lot number and Expiration date in addition to GTIN.

In 2019, Japanese Pharmaceutical and Medical Device Act was amended. The Act is stronger force than the announcement of MHLW, and the barcoding on the pharmaceuticals is going to be mandate under the law from December 2022. (Figure 1)

EXAMPLES OF GS1 BARCODES ON PHARMACEUTICAL PACKAGES IN JAPAN

All of pharmaceutical packages excluding Over-the-Counter (OTC), from primary such as ampules or blister packs to tertiary, have GS1 barcodes. Under the amendment law, more accurate barcodes marking is required, and active use of those barcodes in medical institutions should be expected. (Figure 2)

DIGITALIZATION OF PACKAGE INSERTS

From August 2021, all pharmaceutical's package insert information has registered on website of PMDA with GTIN encoded to a GS1 barcode of every package. Healthcare providers can check the digitalized information with a specific App, Tenbun-Navi which was developed by GSI Japan, the Federation of Pharmaceutical Manufacturers' Associations of JAPAN, and the Japan Federation of Medical Devices Association. (Figures 3, 4)

DISCUSSION

For pharmaceuticals, GS1 barcodes are almost entirely displayed on every package in Japan. The barcodes can be used for many purposes and have provided a lot of benefits for healthcare providers. Especially the strategy in the digitalization of

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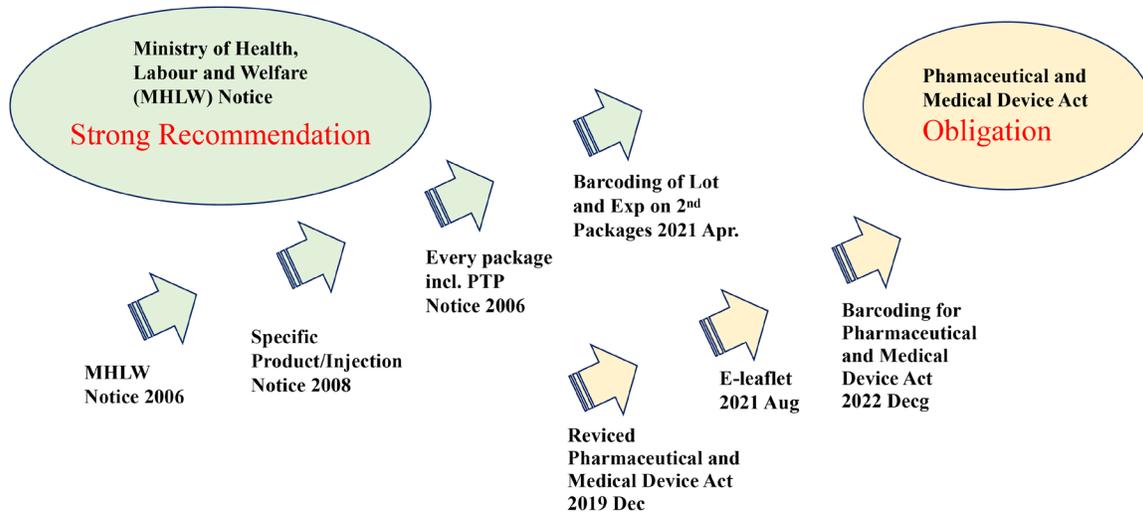


Figure 1. History of pharmaceutical GS1 barcoding in Japan



Figure 2. Barcode labeling on products

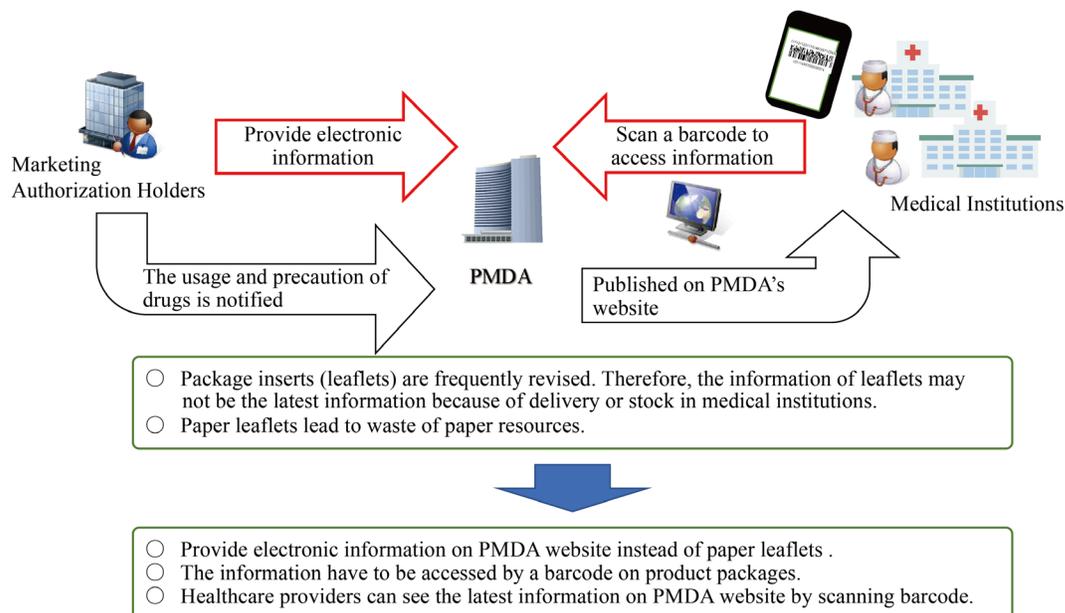


Figure 3. Digitalization of package inserts from August, 2021

