The summary of Partial revision of Regulation for Enforcement of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices

The government of Japan is planning to amend the Ordinance for Enforcement of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (hereinafter referred to as "the Ordinance"), in order to specify the details of the system that Marketing Authorization Holders (hereinafter referred to as "MAHs") basically use electronic methods when providing information on pharmaceuticals and medical devices.

Background

- The amendment to the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices was established in December 2019.
- The amendment to the Act introduced the system in Japan according to which MAHs basically use electronic methods when providing information on pharmaceuticals and medical devices. In response to the amendment above, the Ordinance will be amended to specify the details of the system.
- Amendment to the Ordinance will be adopted in February 2021 and will entry into force in August 2021.

Outline of the amendment

Attaching package inserts to the products is abolished. Instead, MAHs basically use electronic methods such as barcodes when providing information on pharmaceuticals and medical devices.

MAHs put barcodes on product containers to allow access online to the latest information.

MAHs need to build a mechanism to reliably provide the information to medical institutions.

- Barcodes on product containers, which allow access online to the latest information on pharmaceuticals and medical devices, are Global Trade Item Number (GTIN) (planned).

- MAHs need to publish the latest information via the website of the

Pharmaceuticals and Medical Devices Agency's (hereinafter referred to as "PMDA"), which can be accessed with the barcodes on product containers.

○ If product containers are too small to put barcodes, MAHs can put barcodes on the package inserts attached to the products.

○ In the case of over-the-counter drugs and medical devices for general consumer, MAHs need to continue to provide the information by attaching package inserts to their products and are not obliged to publish the latest information via the PMDA's website.

○ MAHs need to build a mechanism to reliably provide the information to medical institutions at the time of initial delivery.

○ MAHs need to build a mechanism to reliably provide the information to medical institutions when the information is revised

(end)