

E-labeling initiative and pilot project for pharmaceuticals in the Republic of Korea

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Agenda

- 1. Current Status of e-labeling implementation**
- 2. Pilot project of pharmaceuticals in 2023**
- 3. Future plan**

1. Current status of e-labeling implementation

- Increased demand(need) for for electronic information(e-labeling) of pharmaceuticals as the information accessibility environment such as mobile and electronic devices changes rapidly
- "E-labeling" was selected as one of the 100 priority tasks of the MFDS regulatory innovation in 2022
- The process of collecting opinions is carried out through the operation of a consultative group consisted of consumers ,healthcare experts , pharmaceutical companies , and related stake holders
- The Pilot project for prescription drugs from 2023 to 2024 by impact assessment

1. Current status of e-labeling implementation

➤ Promotion of Pharmaceutical Affairs Law Amendment

The National Assembly proposed an amendment to the Pharmaceutical Affairs Act('23.1.6, 1.17)

<Main contents of Pharmaceutical Affairs Act amendment>

- ❖ (Article 56) Barcodes, QR codes, etc. for electronic provision of drug information can be written on drug containers or packages
- ❖ (Article 58) Electronic information for prescription drugs

2. Pilot project of pharmaceuticals in 2023

- **(target drugs)** A total of 27 products, injections only used in medical institutions from 10 manufacturers(licence holders)
- **(Method)** Exemption from the provision of paper insert when providing electronic information(e-labeling)
- **(Provider)** Link to the website of the licence holders
- **(Considerations for vulnerable population)** Prepare an alternative way to provide paper insert or document if medical institutions request
 - * For instance, paper attachments, photos, e-mail, faxes, etc.
 - if necessary printable electronic forms such as files (documents, PDFs) are also can be utilized

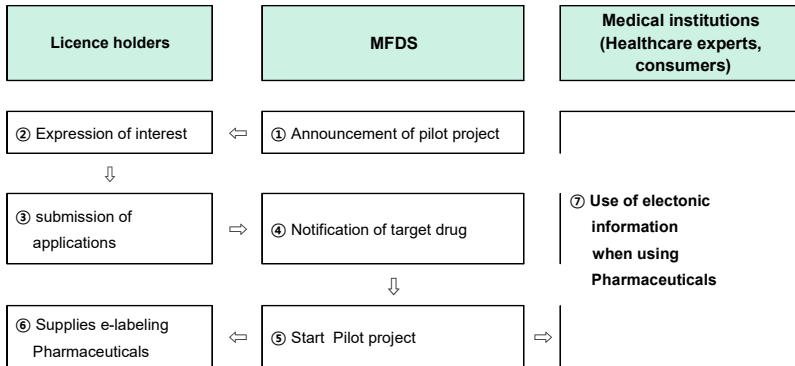
2. Pilot project of pharmaceuticals in 2023

<Schedule of pilot project (draft)>

Announcement of pilot project	Application received	Eligible products/ preparations notice	commencement of a pilot project	Assessment of pilot projects
'22.12.5.	'22.12.19. ~'23.1.31.	'23.2.10.	'23.4.~	'23.10.~

2. Pilot project of pharmaceuticals in 2023

<Promotion System of Pilot Project>



3. Future plan

- 2nd round of e-labeling pilot project in 2024
- Keep working on the Amendment of Pharmaceutical Affairs Act
- Review of step-wise progress of the initiative from prescription drugs to non- prescription drugs

Thank you all