

Updates on e-Labeling in South Korea

23 April 2024

Yeonhae Han

Deputy Director

Pharmaceutical Management Division



Ministry of Food and
Drug Safety

Contents

1. Legislative Updates
2. E-labeling Pilot Project: 2023 Overview
3. Expanded E-labeling Pilot: 2024 Progress
4. Challenges and Future
5. MFDS Platform Integration



Legislation

- **Amendment to the Pharmaceutical Affairs Act (PAA)**
 - Key provisions: article 56 and article 58 revised
 - Proposed on **6 Jan. 2023** → amended and **enforced on 2 Jan. 2024**
 - Summary of the amendment: **Electronic provision** of information through barcodes or equivalent means is **permitted** as a **substitute for paper inserts** for **prescription drugs designated by the Minister of MFDS**



Before the Pilot in 2023

- E-labeling practically in use preceding the pilot project
 - Applied to **COVID-19 vaccines** according to **special exemption**
 - However, the explicit term ‘e-labeling’ was not used in the case
- ✓ **Pandemic to endemic: COVID-19 crisis level to downgrade from “Alert” to “Attention”, the lowest tier effective on 1 May 2024 in Korea**

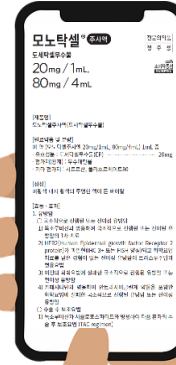
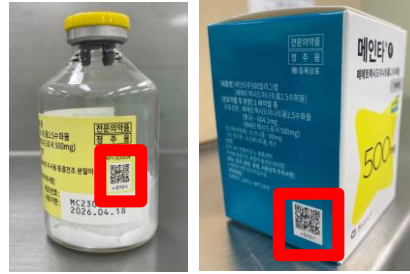


Pilot in 2023

- Participation of 10 companies (MAHs), **27 products** (18 locally manufactured and 9 imported)
 - Products **designated by MFDS** among those applied for by **interested MAHs**
 - Anti cancer agents, X-ray contrast agents and anti-biotics, etc.
- Product selection limited to **injections administrated by healthcare professionals** within **medical institutions**
- Option to **retain** or **remove paper** inserts:
 - 6 products provided with both e-labeling and paper inserts, 21 products with e-labeling only
- **Contingency plans** should be prepared to address unexpected disconnections



Pilot in 2023 – Example



- Access to up-to-date information
- Improved readability
- Keyword searchability
- Reduced carbon footprint



Carton height reduced to prevent vial movement within due to excess space



Pilot in 2023 – Survey

- Despite **low overall awareness levels (33%)**, users' **satisfaction rates high (72.7%)**
- **HCPs** showed higher expectation for benefits of e-labeling expansion compared to general consumers, while **consumers** favored more cautious and conservative approach
- **Industry** suggested **expanding the scope of products under the pilot projects** is necessary for a **comprehensive evaluation** of its effectiveness
 - include self-administrated prescription drugs such as self-administrating injections and inhalers, etc.



Expanded Pilot in 2024

- **Total of 109 products** (from 27 MAHs), including 27 ongoing since 2023
 - Scope limited to **injections administrated by healthcare professionals within medical institutions, consistent with 2023**
 - Biopharmaceuticals newly included
 - With exclusions for products used in emergency and those (potentially) administrated outside medical institutions
- Option to either **remove** or **retain paper** inserts enclosed with products
- **Platform by MAHs** (vendors' platforms also allowed)
- **XML formats** and **PDFs** are both accepted



Challenge & Future plans

- More than 1 different barcodes/QR codes?
 - Codes for **e-labeling**
 - Codes for **audio/sign** language videos
 - Barcodes mandated by Ministry of Health and Welfare for **distribution** information
- ✓ Another amendment PAA mandates **braille** and codes for conversion into **audio/sign** language videos (enforced on 21 July 2024), initially focusing on commonly used OTC drugs
- Common platform for all (by MFDS'?) versus MAHs' own platform
- Prioritization of product types or categories for implementation



MFDS Platform Integration



19:50 LTE 63

의약품상세정보

모노탁셀주사액(도세탁셀무수물)

기본정보

제품명 | 모노탁셀주사액(도세탁셀무수물)
 성상 | 미황색 내지 황색의 투명한 액이 든 바이알
 업체명 | 동아에스티(주)
 위탁제조업체 | 전문의약품
 전문/일반 | 전문의약품
 허가일 | 2010-01-28
 품목기준코드 | 201000987
 표준코드 | 8806425061709, 8806425061716, 8806425061723, 8806425061808, 8806425061815, 8806425061822
 회수폐기이력 | 회수폐기이력조회
 제조업체/제조 | 동아에스티(주) 천안

19:51 LTE

원료약품 및 분량

이 약 1mL 중

순번	성분명	분량	단위	규격	성분정보	비교
1	도세탁셀무수물	20	밀리그램	EP		

첨가제 : 폴리소르베이트80, 시트르산, 무수에탄올

효능효과 + [PDF] [XML] [Globe] 변경이력

용법용량 + [PDF] [XML] [Globe] 변경이력

사용상의주의사항 + [PDF] [XML] [Globe]

의약품 적정 사용 정보 (DUR) ?



의약품 적정 사용 정보 (DUR) ? **DUR**

단일/복합 | 재심사, RMP, 보험, 기타정보 **Re-examination, RMP, Health Insurance, etc.**

DUR성분(-) | 저장방법 | 밀봉용기. 2~25°C 차광하여 보관

DUR유형 | 사용기 | 생산실적 (단위: 천원) **Production/Import**

년도	생산실적
2022	
2021	
2020	
2019	
2018	

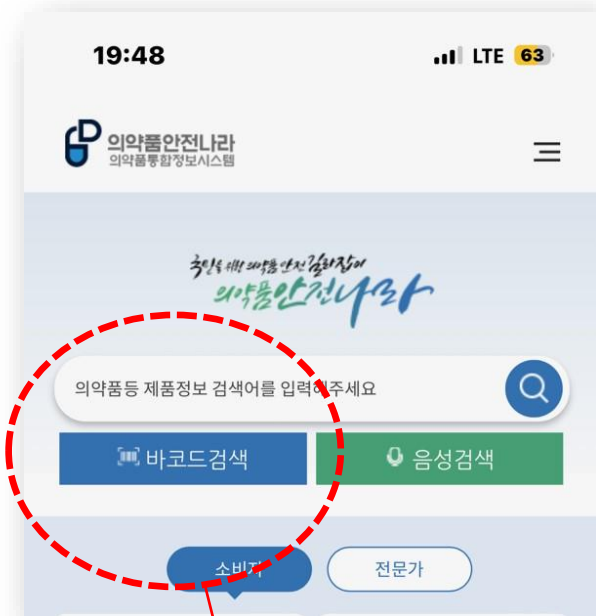
변경이력 + [PDF] [XML] [Globe] **Revision History**

관련검토서정보 **Review Summary**

1
 모노탁셀주사액
 모노탁셀주(2010.4.28)-안전성유효성요약서.pdf



MFDS Platform Integration



Barcode scan



Audio/sign language video



E-Labeling in Other Areas of Korea

- **Risk Management Plan (RMP) Materials (Pharmaceuticals):**
 - Electronic provision of materials for HCPs and patients initiated since Mar. 2023
- **Cosmetics:**
 - Pilot project launched on 25 Mar. 2024
 - Using platforms developed by **individual companies**
- **Food:**
 - Pilot project launched in 2022 and continues to expand; Preparing legislation
 - Using platform provided by **MFDS**

Thank you for your attention!