Kazakhstan– November 2022

What should you know about digital labelling of medicines in Kazakhstan

1. What is digital labelling of medicines?

Digital labelling of a medicine means assigning each medicinal package a unique Data Matrix code, which is a two-dimensional matrix barcode in black and white applied in the form of a square, intended for encoding information about the product suitable for machine reading.

The uniqueness of the Data Matrix codes allows to track medicine's full history from the moment of production to withdrawal from circulation.

Generated digital labels include the following information:

(1) Data Matrix code;
(2) GTIN[1]; and
(3) unique serial number of the medicine[2].

Digital labelling in the Republic of Kazakhstan ("**RK**") is regulated by the Rules on Marking and Traceability of Medicines and Marking of Medical Devices ("**Rules**")[3].

2. Participants of the digital labelling

The digital labelling process is organized and managed by the unified operator for digital labelling, Kazakhtelecom JSC, through their Information System for Marking and Traceability of Goods ("**ISMTG**")[4]. Thus, in order to engage into the process of digital labelling, the Participants shall register in the ISMTG with its EDS[5] key and sign standard contracts to use the ISMTG and its services.

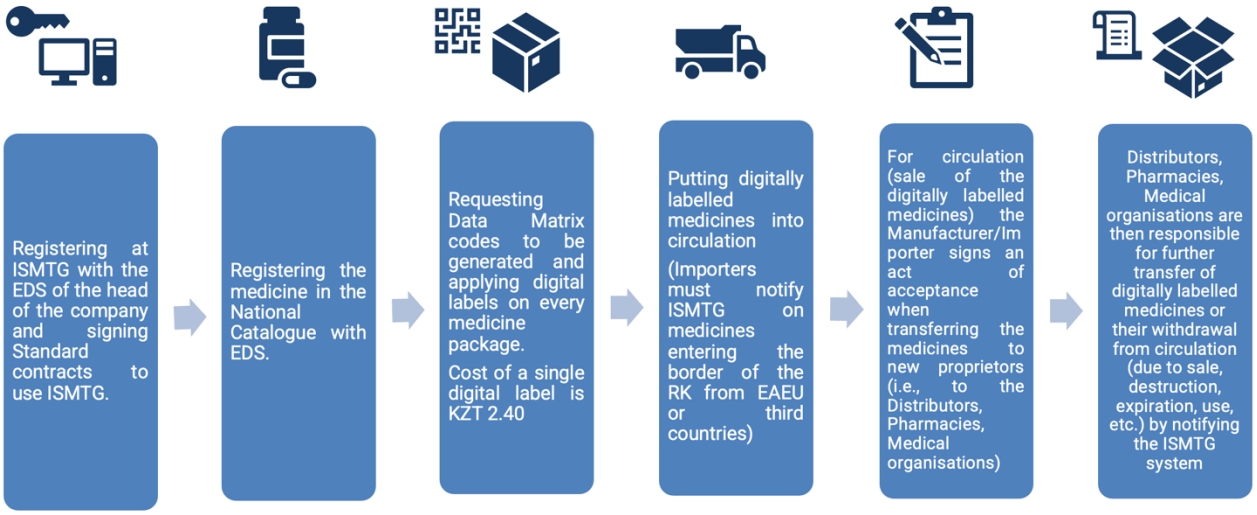
Participants of the digital labelling process:

- Local and foreign manufacturers, MAHs[6]
- Importers of medicines
- Distributors

[1] GTIN – Global Trade Item Number
[2] sp. 13) of p.2, p. 32 and p. 49 of the Rules
[3] Order of the Minister of Health of the RK dated 27 January 2021 No. ҚР ДСМ-211 "On Approval of the Rules Marking and Traceability of Medicines and Marking of Medical Devices"
[4] Decree of the Government of the RK dated 3 March 2020 No. 95 "On the Appointment of a Unified Operator for Marking and Traceability of Goods"
[5] EDS – Electronic Digital Signature
[6] MAH – Marketing Authorization (Registration Certificate) Holder

- Pharmacies or pharmacy chains
- Medical organizations

3. Key steps of the digital labelling process



4. Registration at ISMTG of local and foreign manufacturers and importers

- Local manufacturers register in ISMTG with their regular EDS key used for everyday activities.
- Foreign manufacturers or MAHs can register in the ISMTG through their representative offices and / or branches or subsidiaries (subject to review from the tax perspective). In this case, their representative office / branch / subsidiary registers with their regular EDS key used for everyday activities.
- If a foreign manufacturer does not have a representative office / branch / subsidiary, the foreign manufacturer needs to obtain its own EDS key as a non-resident.
- Importers of the medicines in the RK can register in ISMTG with their regular EDS key used for everyday activities.

The digital labels are applied on a packaging by direct printing or stickering:

- at the manufacturing sites – if it is a local manufacturer responsible for applying;
- on the territory of third countries (non-EAEU[7] states) or at special customs warehouses in Kazakhstan that comply with the GDP[8] standards – when importing medicines from non-EAEU countries;

[7] EAEU – Eurasian Economic Union
[8] GDP – Good Distribution Practice

- outside the state border of the RK – when importing medicines from the EAEU member states[9].

5. What are the stages of digital labelling of medicines in Kazakhstan?

The digital labelling of medicines is to be introduced in stages. At the moment, the Decree of the Government of the Republic of Kazakhstan dated 10 September 2020 No. 568 "On Determining of the List of Goods Subject to Labeling" includes *90 (ninety) medicines manufactured from 1 July 2022 that are subject to digital labeling*.

However, there is no certain information as to what medicines are going to be in each of the next stages, how many stages there will be, and when these stages are going to be introduced.

On 26 October 2022, the unified operator for digital labelling suggested the following timelines for introduction of the next stages of the digital labelling and traceability:

1 July 2022 (1 October)	digital labelling for manufacturers/importers in relation to the list of medicines approved for the 1st stage (90 products)
1 April 2023	traceability of medicines for participants of wholesale and retail sale in relation to the list of the medicines approved for the 1st stage (90 products)
1 July 2023	digital labelling and traceability for manufacturers and participants of wholesale and retail sale in relation to the medicines in the secondary packaging (Customs Codes 3003, 3004)
1 October 2023	digital labelling and traceability for manufacturers/importers, participants of wholesale and retail sale of the medicines in the primary packaging (Custom Codes 3003, 3004), followed by mandatory drafting and circulation of all documentation on traceability and withdrawal from circulation of such medicines through ISMTG system
1 January 2024	digital labelling and traceability for manufacturers/importers, participants of wholesale and retail sale of the medicines in the primary packaging (Customs Codes 3003, 3004), followed by mandatory drafting and circulation of all documentation on traceability and withdrawal from circulation of such medicines through ISMTG system
1 July 2024	Traceability for medical organisations of all medicines followed by mandatory drafting and circulation of all documentation on traceability and withdrawal from circulation of all medicines through ISMTG system

Please note that the abovementioned timeline is a mere unofficial suggestion that is not yet effective.

[9] p. 6 of the Rules

Apart from the above timelines presented on the forum, the online portal of draft regulatory legal acts shares two draft legal acts for public discussion, one of which is related to postponing *traceability* of medicines until 1 July 2024[10] (postponement of the traceability may not mean postponement of the digital labelling itself), and the second one suggests the Data Matrix codes for medicines with the manufacturer's maximum price of up to 500 (five hundred) tenge to be issued by ISMTG free of charge[11].

It is expected that at the end of introduction of all the stages, all medicines produced in Kazakhstan or imported into the country will be subject to mandatory digital labelling.

6. Legal acts regulating digital labelling of medicines in Kazakhstan

1. Code of the RK dated 7 July 2020 No. 360-VI ZRK "On Public Health and Healthcare System"
2. Order of the Minister of Health of the RK dated 27 January 2021 No. ҚР ДСМ-211 ""On Approval of the Rules of Marking and Traceability of Medicines and Marking of Medical Devices»
3. Order of the Minister of Health of the RK dated 30 May 2022 No. ҚР ДСМ-49 "On amendments to the Rules"
4. Decree of the Government of the RK dated 3 March 2020 No. 95 "On the Appointment of a Unified Operator for Marking and Traceability of Goods"
5. Decree of the Government of the RK dated 18 July 2022 No. 498 "On Determining the Maximum Value of the Cost of the Digital Labels Used in the Marking of Medicines"
6. Decree of the Government of the RK dated 10 September 2020 No. 568 "On Determining of the List of Goods Subject to Digital Labelling"

The information contained herein reflects the main information on digital labelling in Kazakhstan but does not cover all the details and specific cases.

The firm is not responsible for damages caused to any person as a result of actions or, on the contrary, failure to act on the basis of the information contained herein.

Please do not hesitate to contact us for further assistance with the process of initiation of digital labelling in Kazakhstan.

[10] https://legalacts.egov.kz/npa/view?id=14259720
[11] https://legalacts.egov.kz/npa/view?id=14259806