VAKHIDOV & PARTNERS

IQVIA Power Breakfast 2022
Executives Discussion Spot

28 September 2022 –
Villa Dei Fiori, Almaty, Kazakhstan

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About us

About us

- Vakhidov & Partners is the first legal consultancy boutique in Central Asia focused on life sciences and retail.
- Our lawyers have worked at leading international law firms, major pharmaceutical and other companies, Big 4 consultancies and government agencies.
- For over 17 years we have been advising and representing foreign investors in Uzbekistan, Kazakhstan and other Central Asian countries on a wide range of issues, including corporate, pharmaceutical, anti-corruption, competition, labor, compliance, telecommunications and intellectual property.
- Members of our team provided legal support to various major international pharmaceutical, FMCG, telecom, manufacturing and other companies in their day-to-day business, resolving complex regulatory issues, analysis and mitigation of legal and compliance risks in Kazakhstan and Uzbekistan. We have also assisted numerous international companies on M&As and corporate restructuring projects in Central Asia.
- For many years we have been leading specialized legal committees to proactively serve the industry and have participated in determining and providing legal and GR support to achieve the development strategy of major companies in the local markets.
- Our efficient team is here to use the wealth of our experience, expertise and resources to lead your business to its goals in compliance with highest ethical standards.

Digital labelling of medicines in Kazakhstan. What, When and How?

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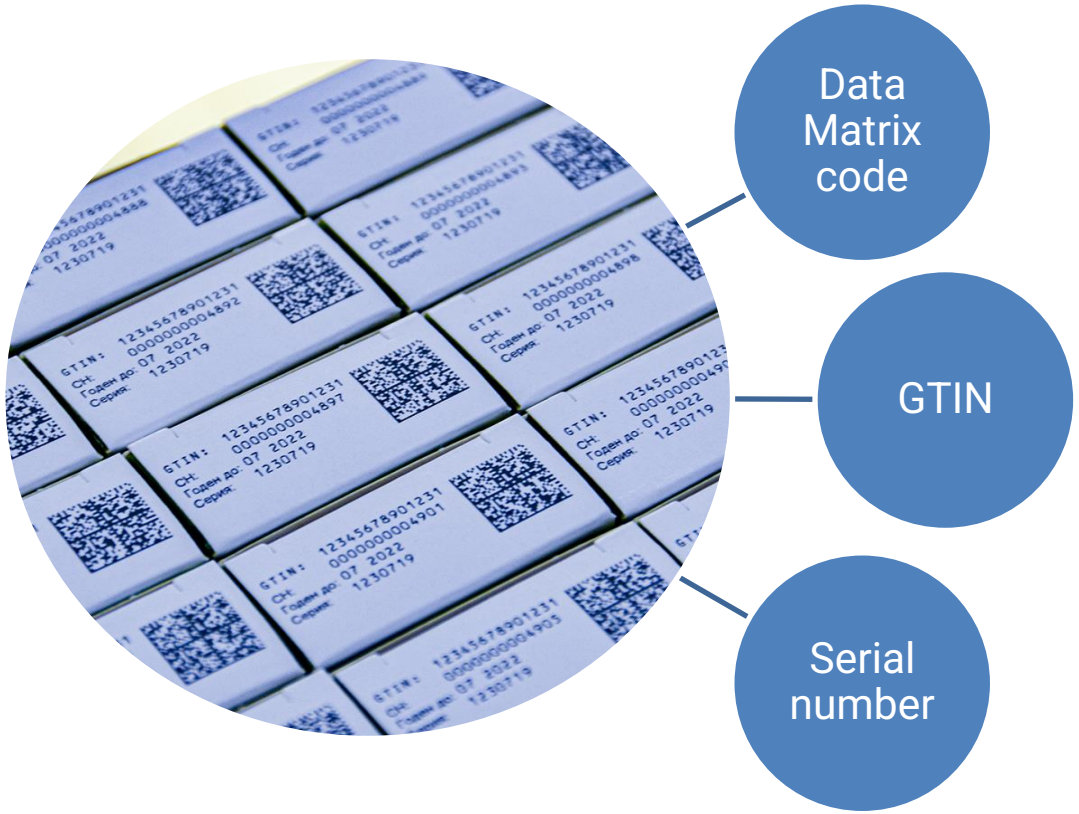
1. What is digital labelling?

1. What is digital labelling
1.1. General information

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. What is digital labelling
1.2. Purpose of the digital labelling

What is the purpose of the digital labelling?

The purpose of introduction of the digital labelling of medicines is to track them and protect consumers from falsified, low-quality and/or counterfeit medicines circulating in the Kazakhstan market.

This is achieved through the process where the Participants* and subjects in the field of circulation of medicines and medical devices provide information on putting into circulation, sale and/or transfer, as well as withdrawal from circulation of digitally labelled medicines.

*** Participants** – participants in the circulation of medicines, i.e., subjects in the field of circulation of medicines and medical devices, representative offices and/or branches of foreign manufacturers of medicines, authorized individuals and legal entities representing foreign manufacturers, registration certificate holders and foreign manufacturers of medicines, as well as subsidiaries of foreign medicine manufacturers.

1. What is digital labelling
1.3. Legal acts regulating digital labelling of medicines in Kazakhstan

Legal acts regulating digital labelling of medicines in Kazakhstan

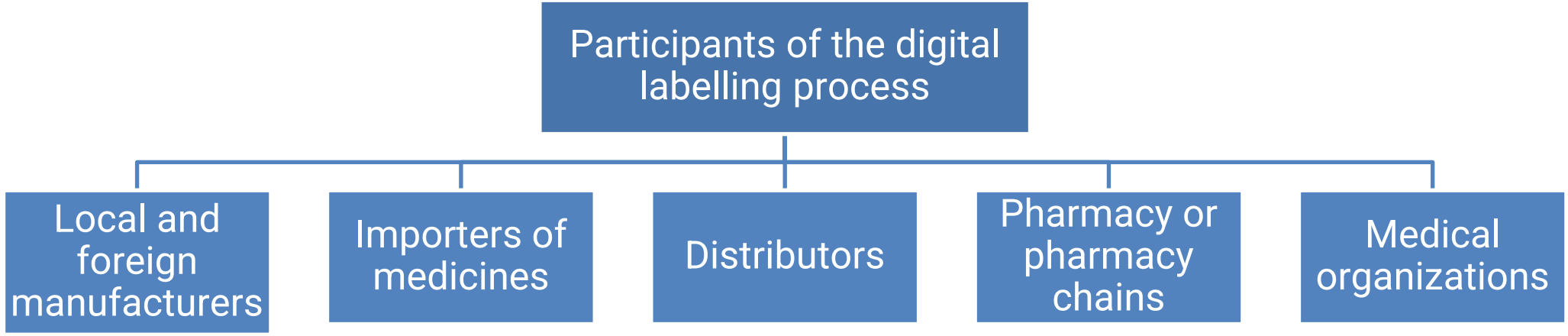
- Code of the Republic of Kazakhstan ("**RK**") dated 7 July 2020 No. 360-VI ZRK "On Public Health and Healthcare System"
- Order of the Minister of Health of the RK dated 27 January 2021 No. ҚР ДСМ-211 ""On Approval of the Rules of Marking and Traceability of Medicines and Marking of Medical Devices» ("**Rules**")
- Order of the Minister of Health of the RK dated 30 May 2022 No. ҚР ДСМ-49 "On amendments to the Rules"
- 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"
- 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"
- Decree of the Government of the RK dated 10 September 2020 No. 568 "On Determining of the List of Goods Subject to Digital Labelling"

II. How does digital labelling work?

2. How digital labelling works
2.1. Participants of the digital labelling of medicines

Participants of the digital labelling

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

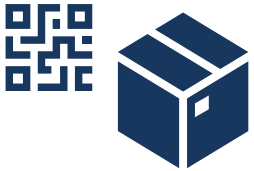


* EDS - Electronic Digital Signature

2. How digital labelling works
2.2. Key steps of the digital labelling process

Registering at ISMTG with the EDS of the head of the company and signing Standard contracts to use ISMTG.

Registering the medicine in the National Catalogue with EDS.



Requesting Data Matrix codes to be generated and applying digital labels on every medicine package.

Cost of a single digital label is KZT 2.40

Putting digitally labelled medicines into circulation

(Importers must notify ISMTG on medicines entering the border of the RK from EAEU or third countries)

For circulation (sale of the digitally labelled medicines) the Manufacturer/Importer signs an act of acceptance when transferring the medicines to new proprietors (i.e., to the Distributors, Pharmacies, Medical organisations)

Distributors, Pharmacies, Medical organisations are then responsible for further transfer of digitally labelled medicines or their withdrawal from circulation (due to sale, destruction, expiration, use, etc.) by notifying the ISMTG system

2. How digital labelling works
2.3. Registration at ISMTG system

Registration at ISMTG of local and foreign manufacturers and importers

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

2. How digital labelling works
2.4. Registration at ISMTG system for non-residents

If a foreign manufacturer does not have a rep.office / branch / subsidiary in the RK, the foreign manufacturer needs to obtain its own EDS key as a non-resident

1. Obtaining IIN for the director of the foreign manufacturer company
2. Obtaining EDS key for the director of the company
3. Obtaining BIN for the foreign manufacturing company
4. Obtaining EDS key for the foreign manufacturing company
5. Registration at ISMTG with the obtained EDS key of a non-resident

2. How digital labelling works
2.5. Application of the digital labelling

Application of the digital labelling

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* states) or at special customs warehouses in Kazakhstan that comply with the GDP** standards – when importing medicines from non-EAEU countries;
- ✓ outside the state border of the Republic of Kazakhstan – when importing medicines from the EAEU member states.

* EAEU - Eurasian Economic Union
** Good Distribution Practice

3. What are the timelines?

3. What are the timelines

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 stage, how many stages there will be, and when these stages are going to be introduced.
- 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.

What about coordination of digital labelling of medicines within the EAEU states?

- Pursuant to Art. 7 of the Agreement on Digital Labeling of Goods in the EAEU, Member States shall notify the Eurasian Economic Commission ("**EEC**") of their intentions to introduce in their territories digital labelling of goods that are not subject to digital labelling within the Union and provide information on such goods and, if possible, on the means of identification, methods of their application and the date of introduction of such labelling.
- According to the Order of the Board of the EEC dated 17 May 2022 No.80 approving a draft Decision of the Council of the EEC, Member States will not impose a ban on the circulation of not digitally labeled goods before 1 January 2024.

The basis of and the use of the presentation materials

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- The information contained in the presentation materials 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 in this presentation.

Any questions?

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Thank you for your attention!

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