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Recent legal changes affecting pharmaceutical companies in the Republic of Kazakhstan

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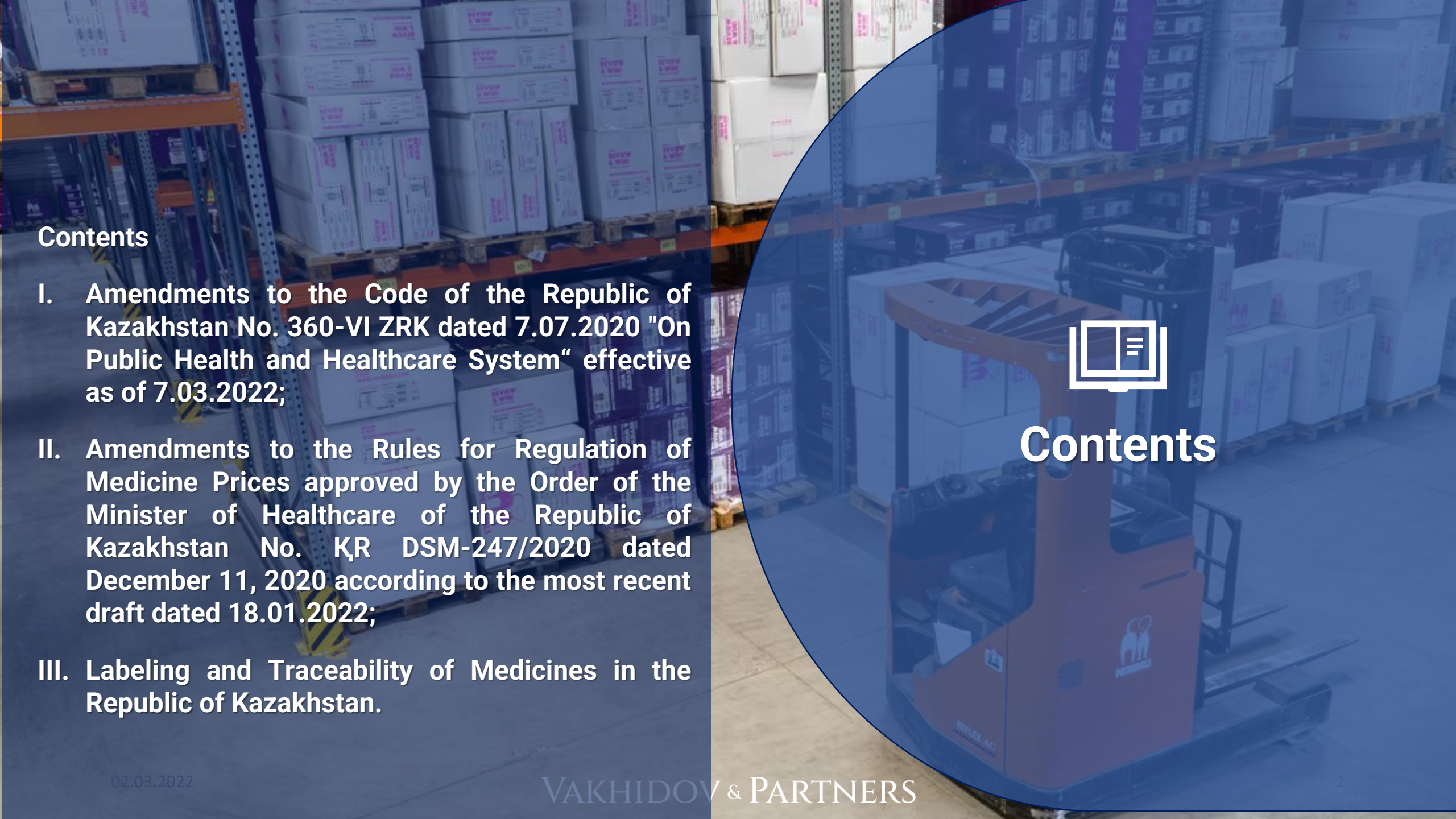

Contents

I. Amendments to the Code of the Republic of Kazakhstan No. 360-VI ZRK dated 7.07.2020 "On Public Health and Healthcare System“ effective as of 7.03.2022;

II. Amendments to the Rules for Regulation of Medicine Prices approved by the Order of the Minister of Healthcare of the Republic of Kazakhstan No. ҚR DSM-247/2020 dated December 11, 2020 according to the most recent draft dated 18.01.2022;

III. Labeling and Traceability of Medicines in the Republic of Kazakhstan.

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The Law of the RK No. 101-7 ZRK dated 3.01.2022 “On Amendments and Additions to Certain Legislative Acts of the Republic of Kazakhstan on the Development of Competition” (hereinafter – the **“Law”**), among other things, introduced amendments to the Code of the Republic of Kazakhstan No. 360-VI ZRK dated 7.07.2020 "On Public Health and Healthcare System“ (hereinafter – **“Health Code”**).

The main amendments affect the State’s Price Regulation of Medicines and Medical Devices:

- Only **the listed** Medicines will be subject to Price Regulation within the Wholesale and Retail Sales (the list is to be approved no often than once in a half-year);
- The ban on purchase and Co-payment of Medicines and Medical Devices registered in the Republic of Kazakhstan (hereinafter – **“RK”**) without a maximum price for a Trade Name within the Guaranteed Volume of Free Medical Care (hereinafter –“**GVFMC**”), and (or) in the System of Obligatory Social Medical Insurance (hereinafter –“**OSMI**”), remains in force.

These amendments will come into effect as of 7.03.2022.

II. Amendments to the Rules for Regulation of Medicine Prices approved by the Order of the Minister of Healthcare of the RK No. ҚR DSM-247/2020 dated December 11, 2020 according to the most recent draft dated 18.01.2022

II. Draft Amendments to the Rules of Regulation of Medicine Prices

(1/3) *General Information*

The introduction of the amendments to the Rules of Regulation, Formation of maximum Prices and the Markups for Medicines as well as Medical Devices within the GVFMC and (or) in the system of OSMI approved by the Order of the Minister of Healthcare of the RK No. ҚR DSM-247/2020 dated December 11, 2020 is being anticipated.

The draft Rules contain the following novelties:

- Only **the listed** Medicines will be subject to Price Regulation within the Wholesale and Retail Sales;
- Medicines will be included into the list of the Medicines that are subject to Price Regulation based on certain criteria, such as availability of several other Trade Name Medicines within the same INN;
- The draft list of the Medicines subject to Price Regulation within the Wholesale and Retail Sales was published for Public Discussion on 1.03.2022 on legalacts.egov.kz;
- The quality assessment costs, marketing costs, customs costs for the imported medicines etc. were united into a Single Markup;
- The requirement to compare the Price of the Generic Medicine with the Price of the Original Medicine during the Price Formation has been repealed;
- Armenia, Brazil, Georgia, Serbia were added to the list of Reference Countries.

II. Amendments to the Rules of Regulation of Medicine Prices

(2/3) Criteria for the inclusion in the list of Medicines subject to Price Regulation

- **The list of the Medicines for Wholesale and Retail Sales subject to Price Regulation is formed on the basis of Medicines registered as of January 15 and July 15.**

TN– Trade Name;
INN – International Non-Proprietary Name.

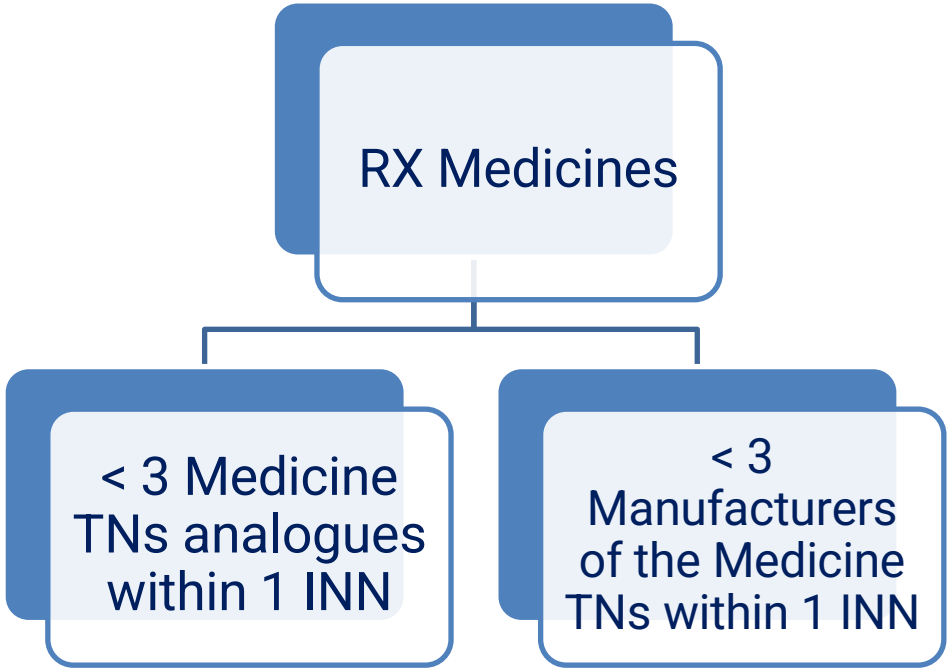


Figure 1

II. Amendments to the Rules for Regulation of Medicine Prices

(3/3) Proposed Single Markup values (likely to be abandoned)

FM – Foreign Manufacturers;
LM – Local Manufacturers.

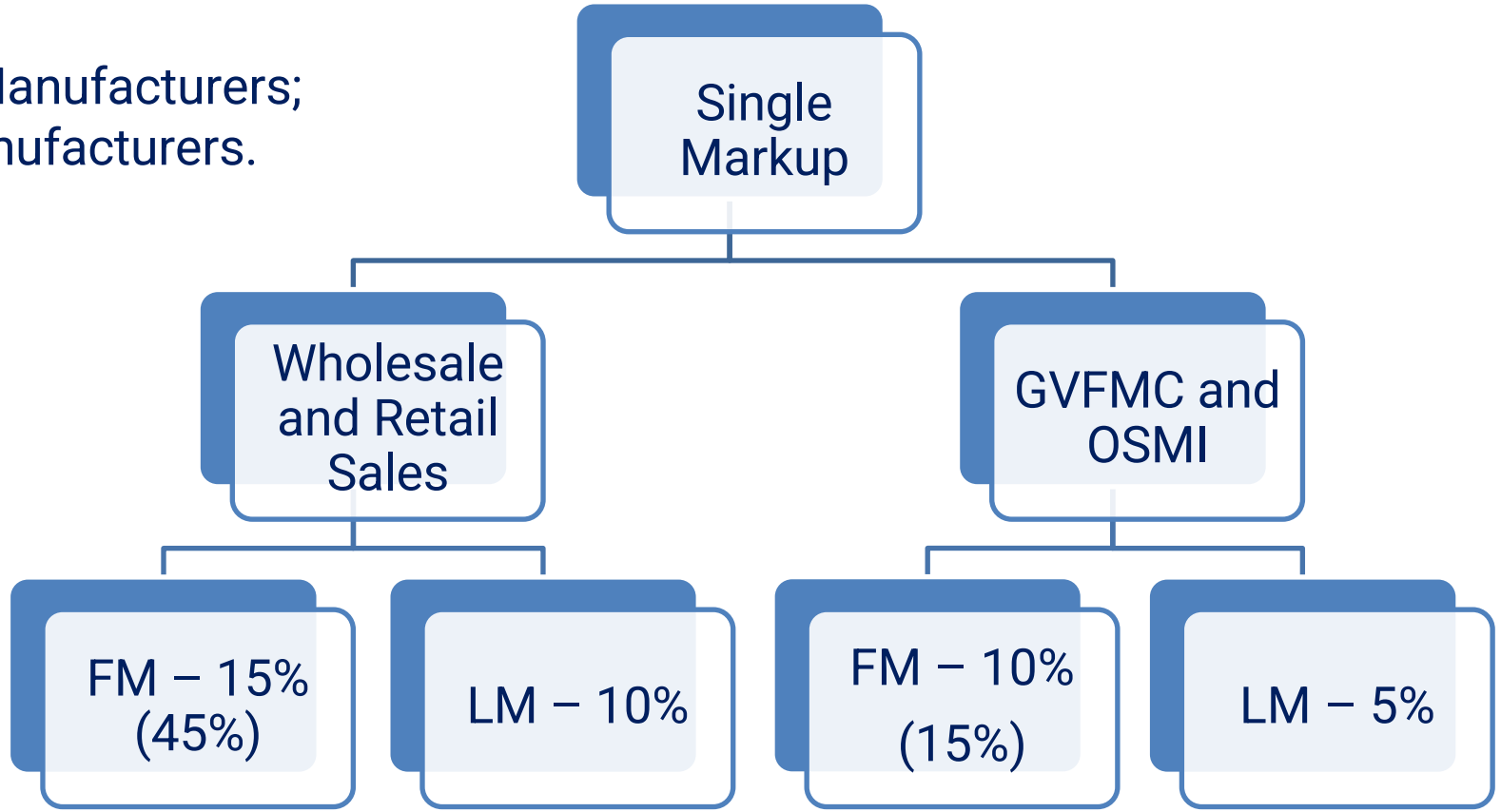


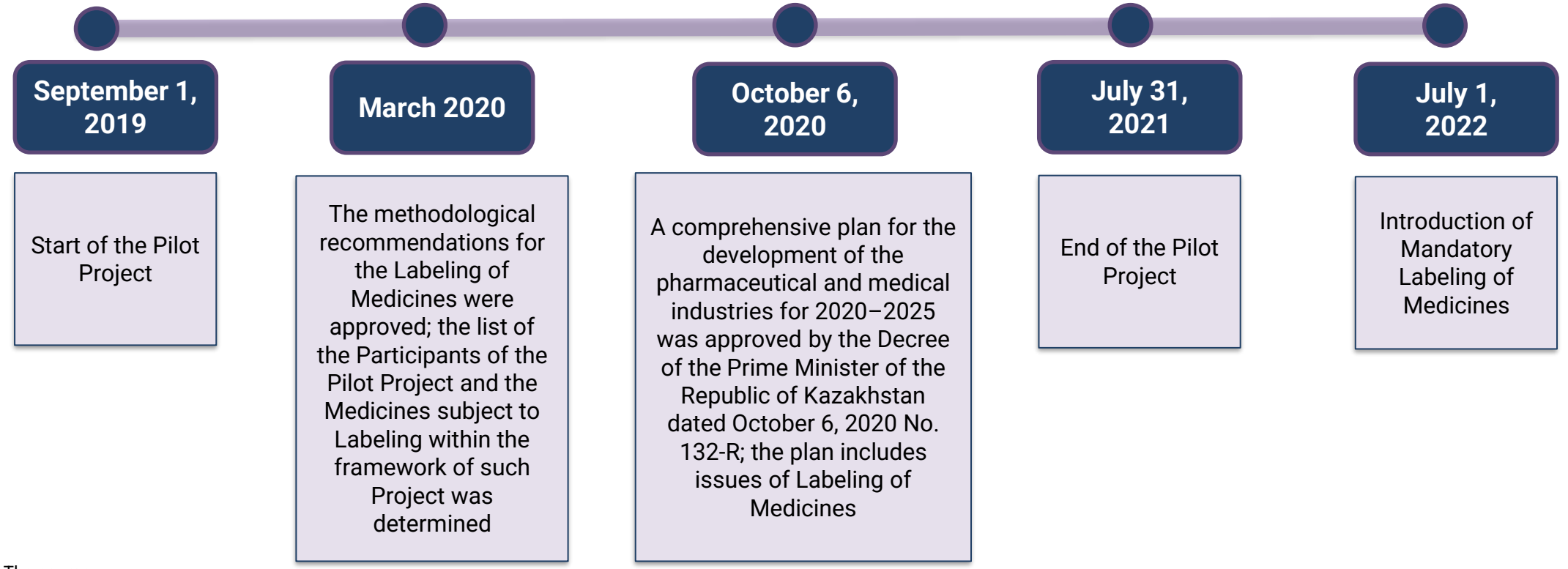
Figure 2

I. Labeling of Medicines in the RK

III. Labeling and Traceability of Medicines in the RK

(1/7) Pilot Project

Pilot Project



The source:
https://www.ismet.kz/ru/main/business/product/medicine

Figure 3

III. Labeling and Traceability of Medicines in the RK

(2/7) Planned implementation of Labeling in the Republic of Kazakhstan

Discussed phased implementation of Labeling in the Republic of Kazakhstan

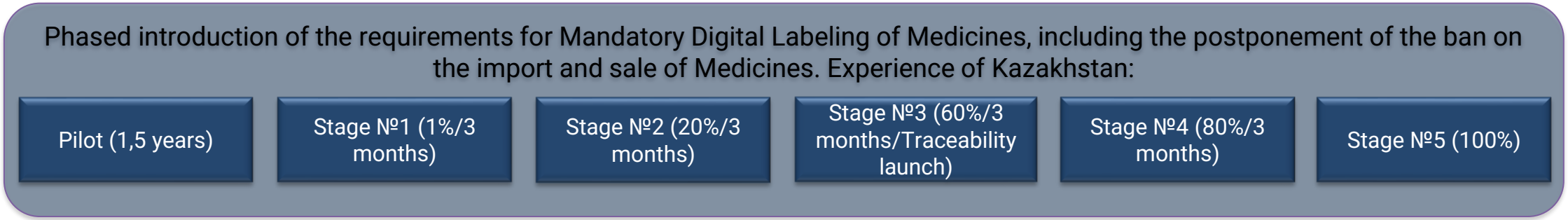


Figure 4

The Participants of the Pilot Project are:

1. Committee for Medical and Pharmaceutical Control of the Ministry of Healthcare of the RK (hereinafter - the **“Committee”**);
2. National Center for Expertise of Medicines and Medical Devices;
3. «SK-Pharmacy» LLP single distributor;
4. Republican Center for e-Health of the Ministry of Healthcare of the RK;
5. Subjects in the field of circulation of Medicines and Medical Devices according to the approved list;
6. A Single Operator for Labeling and Traceability of goods (JSC Kazakhtelecom) (hereinafter - the **"Operator" or "ISMET"**);
7. fiscal data operators.

https://www.ismet.kz/ru/main/business/product/medicine

III. Labeling and Traceability of Medicines in the RK

(3/7) Draft normative legal acts under discussion

The following drafts are currently under discussion:

- Draft Rules for Labeling and Traceability of Medicines
- Draft methodological recommendations for Labeling and Traceability of Medicines
- Draft Decree "On determining the maximum value of the cost of the Control (Identification) Mark, Means of Identification used in the Labeling of Medicines"

III. Labeling and Traceability of Medicines in the RK

(4/7) Draft normative legal acts under discussion

Draft Order of the Minister of Healthcare "On approval of the Rules for Labeling and Traceability of Medicines“

Manufacturers of Medicines carry out Labeling of Medicines produced in the territory of the RK with Identification Means in accordance with the requirements of the Rules.

In the case of the production of Medicines outside of the RK (foreign production), Labeling of Medicines with Identification Means is provided in accordance with the requirements of the Rules by:

- Representative Offices or Branches of Foreign Medicine Manufacturers in the territory of the RK;
- Subsidiaries of the Foreign Medicine Manufacturers that import Medicines into the territory of the RK;
- Importers importing Medicines into the territory of the RK, if the Foreign Manufacturer does not have a Representative Office or Branch, or a Subsidiary in the territory of the RK.

Medicines labeled with the Means of Identification are the Medicines, which are labeled with the Means of identification in compliance with the requirements of the Rules; and the reliable information about which (including information about the Means of Identification applied to them or material carriers containing Means of Identification) is contained in the **IS LTG** (Information System for Labeling and Traceability of Goods).

III. Labeling and Traceability of Medicines in the RK

(5/7) Draft normative legal acts under discussion

Draft Order of the Minister of Healthcare "On approval of the Rules for Labeling and Traceability of Medicines“

IS LTG (markirovka.kz) is not integrated with the Virtual Warehouse. The latter is a component of the e-Invoice system. IS LTG transmits information regarding Acceptance Certificates to the e-Invoice system, then the e-Invoice system processes this data in its systems.

The scanning of Labeled Medicines is carried out by means of devices that read 2D Data Matrix codes.

With the full integration of the information systems (1C) with the IS LTG, there is no need to keep records in several systems.

The ISMET platform is a part of the Digital Kazakhstan Integrated Program implemented by Kazakhtelecom JSC and is aimed at improving the standard of living of every citizen of the country through the use of digital technologies.

Digital Economy Development Center LLP was established on April 10, 2020.

The Sole Founder of the company is Kazakhtelecom JSC.

Sources:
https://atameken.kz/ru/news/43706-markirovka-lekarstvennyh-sredstv-atameken-publikuet-otvety-na-chastye-voprosy-o-markirovke
https://www.ismet.kz/ru/main/business/product/medicine

III. Labeling and Traceability of Medicines in the RK

(6/7) Requirements for Medicine circulation Participants

Draft Order "On determining the maximum value of the cost of the Control (Identification) Mark, Means of Identification used in the Labeling of Medicines"

- Status: Under the public discussion
- Draft Version: Version 1
- Type of Normative Legal act: Decree
- Creation date: 03/12/2021.
- Public discussion until: 21/12/2021

1. The maximum cost of the Control (Identification) Mark, Means of Identification used in the Labeling of Medicines is determined at 2.68 KZT per unit without value added tax.
2. This Decree comes into force on July 1, 2022 and is subject to official publication.

III. Labeling and Traceability of Medicines in the RK

(7/7) Rules for the functioning of the Traceability of goods mechanism in RK

Order of acting Minister of Finance of the RK dated January 27, 2022 No. 88 "On approval of the Rules for the functioning of the mechanism for the traceability of goods"

The Rules for the functioning of the Traceability of goods mechanism were adopted in accordance with the Tax code of the RK and the Agreement on the Traceability of Goods Mechanism with respect to the goods imported into the Customs Territory of the Eurasian Economic Union concluded in Nur-Sultan on 29.05. 2019.

Electronic Invoice Information System ("IS e-Invoice") is designated as the National Traceability System in the RK.

According to the Rules the persons involved in the circulation of goods subject to Traceability must issue the electronic Accompanying Documents with some exceptions to use Virtual Warehouse etc.


Any questions?

About us

About us

- Vakhidov & Partners is the first legal consultancy boutique in Central Asia focused on life sciences, retail and IT/Telecom.
- 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, 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.
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Thank you for your attention!

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