Kyrgyz Republic

Cabinet of Ministers of the Kyrgyz Republic

DECISION No. 53
Dated February 09, 2023

On the implementation of the traceability system for medicines in the Kyrgyz Republic

In order to implement the decrees of the President of the Kyrgyz Republic "On urgent measures to develop the healthcare sector and improve the quality of life and health of the population in the Kyrgyz Republic" dated February 8, 2021 No. 23, "On the National Development Program of the Kyrgyz Republic until 2026" dated October 12, 2021 No. 435, in accordance with Articles 13 and 17 of the constitutional Law of the Kyrgyz Republic "On the Cabinet of Ministers of the Kyrgyz Republic", the Cabinet of Ministers of the Kyrgyz Republic decides to:

1. Launch a phased introduction of a traceability system for medicines manufactured, imported and sold on the territory of the Kyrgyz Republic.

2. Approve the Procedure for ensuring the traceability of medicines (hereinafter referred to as the Procedure) in accordance with the Appendix.

3. Assign to the Department of Medicines and Medical Products under the Ministry of Health of the Kyrgyz Republic (hereinafter - the Department of Medicines and Medical Products) the functions of implementing and maintaining a traceability system for medicines.

4. To the Department of Medicines and Medical Products by the time this regulation comes into force
1) Approve:
- a phased plan for the implementation of medicine traceability system;
- list of medicines to be traced;
- methodological recommendations on the use of the information system "Electronic Database of Medicines and Medical Products" (hereinafter - IS EDB) by participants in the turnover of medicines;
2) Carry out appropriate information and explanatory work.

5. Define that
- from the moment of the deadlines stipulated by the phased plan for the implementation of the medicine traceability system, it is prohibited to wholesale and retail sales of medicines included in the list of medicines subject to traceability without registering digital marking codes in the IS EDB;

- medicines imported into the Kyrgyz Republic or manufactured in the Kyrgyz Republic before the deadlines provided for by the phased plan for the implementation of the traceability system for medicines remain subject to their expiration date without registration of digital marking codes in the IS EDB;
- the requirements of this Decision do not apply to medicines, the selling price of which when manufactured in the territory of the Kyrgyz Republic or the delivery price when imported into the territory of the Kyrgyz Republic does not exceed 100 KGS per package (such medicines can be traced on a voluntary basis).

6. Introduce the following amendments to the Decision of the Government of the Kyrgyz Republic "On approval of the Procedure for assessing the quality of medicines" dated July 5, 2018 No. 312:
in the Procedure for assessing the quality of medicines, approved by the above resolution:
- Clause 33 shall be supplemented with the second clause of the following content:
"It is allowed until December 31, 2025 to assess the quality of medicines subject to mandatory traceability in packaging other than registered, with a traceability code."

7. Impose control over the execution of this resolution on the control over the execution of decisions of the President and the Cabinet of Ministers of the Administration of the President of the Kyrgyz Republic.

8. This resolution comes into force after fifteen days from the date of official publication.

Chairman of the Cabinet of Ministers of the Kyrgyz Republic: A. U. Zhaparov

Seal:
/Kyrgyz Republic/
*/Cabinet of Ministers * No. 1/*

Appendix

The procedure for ensuring the traceability of medicines

Chapter 1. General Provisions

1. This Procedure for Ensuring the Traceability of Medicines (hereinafter referred to as the Procedure) defines the requirements for the process of traceability of medicines manufactured, imported and sold in the territory of the Kyrgyz Republic, for participants in the turnover of medicines and their functions, the procedure for registration of participants in the turnover of medicines in the Information system "Electronic database of medicines and medical products" and information exchange of participants in the turnover of medicines, the procedure for providing digital marking codes to participants in the turnover of medicines in the Information system "Electronic Database of Medicines and Medical Products", requirements for applying a digital marking code to medicinal products subject to traceability, the procedure for providing information in the Information System "Electronic Database of Medicines and Medical Products" on the introduction of medicinal products into turnover, being in turnover and withdrawal from turnover, and making changes to them.

2. For the purposes of this Procedure, the following concepts are used:

1) aggregation - documentary confirmation of the hierarchical relationship between the outer packaging, which has a unique identification code, and the manufactured products contained in it, also has a unique identification code, in order to improve workflows related to serialization and involving the exchange of data and / or compliance with regulatory requirements;
2) serialization - the process and results of determining, assigning and applying unique codes to product packaging;
3) putting medicinal products into turnover - primary registration of the digital marking code for medicinal products in the traceability system;
4) withdrawal from turnover of medicinal products - termination of the registration of the digital marking code of medicinal products in the traceability system in relation to a specific unit of the medicinal product upon reaching the end user or destruction;

5) primary (inner) packaging - packaging that is in direct contact with the medicinal product;

6) secondary (outer or consumer) packaging - packaging in which the medicinal product is placed in primary and intermediate packaging;

7) group package - a package that combines sets of homogeneous (within one package code of a medicinal product, also called GTIN (Global Trade Item Number) is applied to the packaging of goods according to standardized rules in the form of a bar code) of secondary (and in case of its absence, primary) consumer packages of medicines used for storage and transportation in order to protect them from damage during transportation, and forming an independent transport unit. The aggregation code is applied to the group packaging. Group packaging may include transport packages of a smaller size (volume);

8) individual package number (serialization code) a sequence of characters that uniquely identifies the secondary packaging of the medicinal product within one product code;

9) drug packaging code (GTIN) - a code assigned by the GS1 association (GS1 is the leading international organization that manages a multi-industry product numbering system. GS1 develops barcoding standards and solutions aimed at improving the efficiency and transparency of supply chains worldwide) for a medicinal product in accordance with the rules established by GS1, ensuring the registration of a medicinal product in the national drug registry and the GS1 global catalog;

10) digital marking code - a unique sequence of characters in a machine-readable form, presented in the form of a two-dimensional barcode Data Matrix (Data Matrix code - a two-dimensional matrix barcode representing black and white elements or elements of several different degrees of brightness, usually in the form of a square, placed in a rectangular or square group);

11) aggregation code of a sequence of characters, which is a unique copy of the group package;

12) digital marking application of the digital marking code on the medicinal product packaging;

13) data transfer protocol - a formalized set of requirements for the structure of information messages and the algorithm for exchanging messages between programs and / or devices;

14) the status of the digital marking code, the state of the traceability code, determined by the Information System "Electronic Database of Medicines and Medical Products", which changes during the implementation of the processes provided for by this Procedure;

15) participants in the turnover of traceable medicinal products (hereinafter - the participant in the turnover) - legal entities and individuals engaged in pharmaceutical or medical activities in the territory of the Kyrgyz Republic;

16) sticker - an information carrier intended for applying a digital marking code to the packaging of medicines in a way that does not allow its separation from the packaging without damaging it;

17) Information system "Electronic Database of Medicines and Medical Products" - an information system that provides accounting for the movement of medicines and medical products;

18) operator of the Information system "Electronic Database of Medicines and Medical Products" - an authorized state body in the field of turnover of medicines and medical products.

3. The effect of this Procedure - applies to medicines that are in turnover on the territory of the Kyrgyz Republic and are subject to traceability.

4. This Procedure does not apply to medicines:

1) being in temporary storage or placed under the customs procedure of a customs warehouse;

2) placed under the customs procedure of customs transit for transportation (transportation) through the customs territory of the Eurasian Economic Union of foreign products from the customs authority at the place of arrival to the customs authority at the place of departure;

3) placed under the customs procedure of customs transit for transportation (transportation) through the customs territory of the Eurasian Economic Union of foreign medicines from the customs authority at the place of arrival to the internal customs authority;

4) placed under customs procedures for the purpose of further export outside the customs territory of the Eurasian Economic Union;

5) produced for the purpose of export to the territory of the member states of the Eurasian Economic Union;

6) placed under the customs procedure of a free warehouse;

7) intended for testing for the purpose of registration and quality assessment;

8) imported into the territory of the Kyrgyz Republic or produced in the territory of the Kyrgyz Republic by the organizers and participants of international exhibitions and fairs as samples and exhibits and not intended for sale (sale);

9) imported into the Kyrgyz Republic by individuals and acquired by them for personal use;

10) intended for use by diplomatic missions, consular offices, international, interstate and intergovernmental organizations, their representative offices, as well as representative offices of states attached to them;

11) in the cases provided for by Article and of the Agreement on the marking of goods with means of identification in the Eurasian Economic Union, ratified by the Law of the Kyrgyz Republic "On ratification of the Agreement on the marking of goods with means of identification in the Eurasian Economic Union, signed on February 2, 2018 in the city of Almaty".

5. The traceability of medicines is ensured by transferring data to the Information System "Electronic Database of Medicines and Medical Products" (hereinafter - IS EDB) on the introduction of medicines into turnover, with the subsequent reading and recognition of digital marking codes by the participants in the turnover during the movement of medicinal products from one participant to another participant in the turnover until the withdrawal of medicinal products from turnover.

6. IS EDB is an information system that provides accounting for the movement of medicines on the territory of the Kyrgyz Republic. The operation of the IS EDB is provided by the operator of the IS EDB.

7. The operator provides the possibility - registration and storage in the IS EDB of the following information:

1) about the participants in the turnover;

2) on medicinal products subject to mandatory traceability;

3) on digital marking codes of medicinal products provided to participants in the turnover;

4) on violations of the requirements for the traceability of medicines by consumers;

5) on putting into turnover, on the movement of traceable medicinal products and their withdrawal from turnover;

6) on the current status of traceable medicinal products, including:

- availability of state registration of the medicinal product;

- availability of a conclusion on the quality of the medicinal product;

- information about the withdrawal of the medicinal product from the market;

- information on the use of the medicinal product, including instructions for medical use in the state and official languages.

8. Information interaction of participants in the turnover of medicines with the IS EDB is carried out using data transfer protocols by exchanging messages, the format of which is posted on the official website of the EDB on the Internet.

9. Participants in the turnover must be registered (have an account) in the IS EDB and have equipment for applying, reading and recognizing digital marking codes.

10. Registration of participants in the turnover of medicines in the IS EDB and granting them access to a personal account are carried out on the basis of a valid license for pharmaceutical or medical activities, or on the basis of accreditation.

The turnover participant is provided with an account, which is used to work with a personal account, as well as to connect information systems for the purpose of messaging (integration).

The participant in the turnover undertakes to provide an e-mail address and a telephone number. The turnover participant is responsible for access to the account, including adding users and changing their access rights to the IS EDB functions, managing passwords and other actions.

11. Responsibility for the completeness, reliability and timeliness of the information sent to the IS EDB is borne by the participants in the turnover that provide information.

12. The access of the turnover participant to the IS EDB is terminated if one of the following bases exists:

1) termination of the license for pharmaceutical or medical activities;

2) withdrawal of accreditation;

3) termination of activities of a legal entity or an individual entrepreneur.

13. The release of digital marking codes is carried out by drug manufacturers or the IS EDB operator. If digital marking codes are issued by the IS EDB operator, the issuance of codes from the IS EDB is free of charge.

Chapter 2. The procedure for applying digital marking codes

14. The application of digital marking codes is provided by holders of registration certificates of medicines, manufacturers of medicines, authorized representative offices of foreign manufacturers and (or) branches or subsidiaries in the territory of the Kyrgyz Republic, or importers importing medicines into the territory of the Kyrgyz Republic, if a foreign manufacturer does not have a representative office or a branch, or a subsidiary in the territory of the Kyrgyz Republic.

15. The entities listed in clause 14 of this Procedure must ensure compliance with the requirements for the composition and application of the digital marking code provided for in the Appendix to this Procedure.

16. The digital marking code is applied to the package using one of the following methods:

a) direct application of the digital marking code during production;

b) indirect application (stickering) - is carried out using a digital marking code on self-adhesive paper in the form of a sticker.

Chapter 3. Procedure for traceability of medicines labeled with digital identification codes

17. Medicinal products with digital marking codes are put into turnover:

1) when manufacturing medicinal products in the territory of the Kyrgyz Republic - by sending a notification on the production of a medicinal product to the IS EDB, in the form approved by the authorized body, with confirmation of the digital marking codes when transferring the manufactured medicinal products to the warehouse of finished products;

2) when importing medicines from the territory of states that are not EAEU member states, by sending a notification to the IS EDB with the import of medicines for domestic consumption into the Kyrgyz Republic, in the form approved by the authorized body after release by the customs authorities of the Kyrgyz Republic;

3) when importing medicines from the territory of the EAEU Member States - by sending a notification to the IS EDB with acceptance of the imported medicines into the warehouse in the form approved by the authorized body, with confirmation of traceability codes.

18. Accounting for the movement of medicines with digital marking codes on the territory of the Kyrgyz Republic is carried out by registering in the IS EDB notifications from participants in the turnover on the transfer and (or) sale of medicines.

19. When transferring and (or) selling medicines with digital marking codes to another participant in the turnover, the sender of medicines forms a notice of their shipment in the form approved by the authorized body and sends it to the IS EDB at the time of their actual transfer and (or) sale.

20. The participant in the turnover that accepts medicines ensures the transfer to the IS EDB of the notification of acceptance of the medicine in the form approved by the authorized body at the time of actual acceptance.

21. If discrepancies are identified when accepting medicines, the recipient of medicines shall form a notice of the discrepancies found in the form approved by the authorized body and send it to the sender who transferred and (or) sold the medicines in order to make changes to the previously sent notice of shipment.

22. Withdrawal of medicinal products from turnover with digital marking codes is carried out by the participant in the turnover during sampling, dispensing, retail sales, issuance for medical use, export, re-export, loss, destruction, confiscation by sending a notification to the IS EDB at the time of the actual performance of the above operations.

23. To re-enter the turnover of medicines that were previously withdrawn from turnover for the reasons specified in clause 22 of this Procedure, namely when exporting, re-exporting and returning confiscated medicines, the participant in the turnover sends a notification to the IS EDB about the re-introduction of medicines into turnover in the form approved by the authorized body.

Chapter 4. Access to information placed in the IS EDB

24. In the IS EDB, consumers have the opportunity to check, via a mobile application, the following information about the medicinal product using the applied digital marking code:
- status of the medicinal product (in turnover, withdrawn from turnover);
- information about the manufacturer;
- release conditions;
- expiry date;
- existence of the conclusion about quality;
- instructions for medical use in the state and official languages.

Appendix to the Procedure for Ensuring the Traceability of Medicinal Products

Requirements for the composition and application of traceability codes

1. Requirements for the composition of medicine traceability codes

In the Information system "Electronic Database of Medicines and Medical Products" digital marking codes of various composition can be loaded, provided that they meet the following minimum requirements:

- elements (blocks) of the digital marking code comply with the GS1 Application Identifier standard www.gs1.org/standards/barcodes/application-identifiers (GS1 application codes);

- the first element of the digital marking code is the drug code (GTIN), which consists of 14 digits and is specified in the medicine register of the IS EDB. The application code for this element (AI) in accordance with the GS1 standard is "01". When using EAN codes (13 digits), they are supplemented with 0 on the left;

- the element of the digital marking code is the individual serial number of the package. The application code for this element (AI) in accordance with the GS1 standard is "21". The package serial number is unique to the drug code. The final character of the second element is the separator character with code 232 (FNC1) or 29 (GS) in the ASCII character table;

- Other code elements can be anything (including digital signature) provided that they comply with the GS1 standard and are marked with the appropriate application codes.

When target labeling medicines for sale in the Kyrgyz Republic, it is recommended to adhere to the following composition of digital labeling codes:

AI (application code)	Content	Format	Explanation	Example
	FNC1 (Code word 232) or GS (ASCII 29)		Indicates that the code complies with the GS1 Data Matrix standard.	
01	GTIN	14-digit product code	GTIN product code. In the case of a 13-digit code (EAN), it is supplemented on the left with zero (0) up to 14 characters.	08699536090115
21	Unique package number	Variable length block (recommended minimum length is 14 characters) consisting of digits [0-9] and/or uppercase Latin letters [A-Z]. The use of only letters or only numbers is acceptable.	The unique package number is provided by the IS EDB or is generated by the manufacturer.	5UNDALD3W 6K44YIH
	FNC1 (Code word 232) or GS (ASCII 29)		Indicates the end of the unique number data block.	
17	Expiry date	Fixed length block of 6 digits	Last day of expiration date in the YYMMDD format.	270131
10	Batch number (series)	Variable length block (recommended minimum length is 14 characters) consisting of digits [0-9] and/or uppercase Latin letters [A-Z].	Production batch number (product series)	22262012

2. Requirements for applying medicine traceability codes

1. For digital labeling of medicines, a code printed on the package is used, presented in the form of a two-dimensional bar code GS1 Data Matrix, suitable for machine reading.

To facilitate visual control of the correct reading, along with a two-dimensional bar code, human-readable information (HRI) is applied, including the elements:
— GTIN (required);
— unique package number (required);
— expiration date of the packaging (optional);
— number of the production batch (series) of the medicinal product (optional).
Printed designations (labels) of the above elements when applying human-readable information are not regulated.

2. The two-dimensional and bar code printed on the package meets the following technical requirements:
a) compliance with ISO/IEC 16022:2006 (Data Matrix barcode symbology specification);
b) applied with quality class level C or higher in accordance with ISO/IEC 15415:2011, ISO 22742:2005;
c) the function of recognition and error correction is used not lower than the Data Matrix ECC200;
d) applied to a flat white surface with sufficient contrast;
e) the seal is resistant to fading until the end of the shelf life of the medicinal product, provided that the storage conditions are observed;
f) when using stickers, it is impossible to separate the sticker from the package without damaging it.

3. Equipment for reading two-dimensional bar codes must be able to read codes printed in accordance with ISO/IEC 15415:2011, ISO 22742:2005.

4. The digital marking code printed on the medicinal product packaging cannot be used (generated) again.

5. The code for digital marking of a group package is formed by a participant in the turnover that aggregates (combines) consumer packages of medicines into a group package, independently, in the form of a linear bar code that meets the standard of the international organization in the field of standardization of accounting and bar coding of logistic units GS1-128, with a unique identifier of the group package in the form of a serial code, presented as a digital number SSCC code, and is identified by the application code AI = "00".

6. The digital marking code of the group package is applied to the front or side of each individual group package at the discretion of the participant in the turnover in order to facilitate and simplify the aggregation of goods.

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