Kazakhstan – July 2024

Amendments to the Rules for Labelling and Traceability of Medicines have been introduced

The main change concerns the list of goods subject to digital labelling, which was approved by the Resolution of the Government of the Republic of Kazakhstan ("**Kazakhstan**") dated June 28, 2024, No. 516 ("**Resolution**").

According to this Resolution, the requirement for mandatory labeling of medicines from July 1, 2024, applies to all medicines manufactured after July 1, 2024. Thus, medicines produced before the specified date can be imported and circulate without labelling.

The resolution comes into force after the day of its first official publication and applies to relations arising from July 1, 2024.

The Order of the Minister of Healthcare of Kazakhstan dated June 19, 2024, No. 22 (the "**Order No. 22**") introduces other amendments to the Rules for Labelling and Traceability of Medicines and Labeling of Medical Devices ("**MD**") which were approved by the Order of Minister of Healthcare of Kazakhstan dated January 27, 2021, No. KR DSM-11 ("**Labelling Rules**"), including the following:

- Now labelling of medicines with identification means when importing the medicines is carried out, among other places, in customs warehouses, which are pharmacy (distribution) warehouses, before placing them under customs procedures for release for domestic consumption or re-import, *or* in pharmacy (distribution) warehouses, *after* placing them under customs procedures for release for domestic consumption or re-import (herein they removed the requirement of compliance of the warehouses with the standards of good distribution practice, and also introduced a clarification that in this case, labeling is carried out after the medicine is placed under customs procedures)[1];
- As a form of completion for the second group of marking code data, a special separator character GS, having the code 29 in the ASCII character table (ASCII) or the function 1 character, FNC, having the code 232 in the ASCII character table (ASCII) is used (in the previous edition - special ASCII separator character (ASKII) 29)[2]. As a form of completion for the third group of data, a special separator character GS, having the code 29 in the ASCII character table (ASCII) or the function character 1, FNC, having the code 232 in the

[1] Clause 6.2. and 6.3 of the Labeling Rules as amended by the Order No. 22 and the Order of the Minister of Healthcare of Kazakhstan dated May 30, 22 No. KR DSM-49;
[2] Clause 32 of the Labeling Rules as amended by the Order No. 22 and the Order of the Minister of Healthcare of Kazakhstan dated May 30, 22 No. KR DSM-49;

ASCII character table is now used (in the previous edition - a special separator character ASCII (ASKII)[3];

- Aggregation. Participants in the circulation of medicines carry out aggregation of packages before putting medicines into circulation on the territory of Kazakhstan[4], and also on the territory of Kazakhstan aggregation of medicine packages with one or more GTIN (GTIN) product codes is carried out into transport packaging, as well as aggregation of medicines transport packages into higher-level transport packaging with the creation of a new transport packaging identification code, as well as a higher-level transport packaging identification code.
- Further the participants in the circulation of medicines on the territory of Kazakhstan aggregate medicine packages by removing or inserting medicine packages that have one or more GTIN product codes (GTIN) into transport packaging, as well as medicines' transport packages into higher-level transport packaging preserving the identification code of the transport packaging and information about the relationship between the identification codes of each included package and the identification code of the created package[5].
- Now, when participants in the circulation of medicines provide information on the circulation or withdrawal from circulation of part of the labeled medicines located in transport packaging to the Information System for Labeling and Traceability of Goods ("**ISLTG**"), in the absence of aggregation, the disbandment of the transport package containing seized medicines is registered automatically, not within 3 (three) business days as before[6].
- Clauses 71-1, 71-2, and 71-3 regulating the procedure for submitting information to ISLTG were added:
  - when transferring labeled medicines between geographically distributed divisions of the participant in the circulation of medicines with one BIN;
  - when selling and/or transferring labeled medicines to the Single Distributor ("**SD**"), as well as from the SD to a medical organization within the framework of the guaranteed volume of free medical care ("**GVFMC**") and (or) in the system of obligatory social health insurance ("**OSHI**");
  - when transferring labeled medicines between branches and (or) representative offices of logistics companies providing medicines' storing and transportation services to SD[7].

[3] Clause 32 of the Labeling Rules as amended by the Order No. 22 and the Order of the Minister of Healthcare of Kazakhstan dated May 30, 22 No. KR DSM-49;
[4] Clause 57 of the Labeling Rules as amended by the Order No. 22 and the Order of the Minister of Healthcare of Kazakhstan dated May 30, 22 No. KR DSM-49;
[5] Clause 57-1, Clause 57-2 of the Labeling Rules as amended by the Order No. 22;
[6] Clause 58 of the Labeling Rules as amended by the Order No. 22;
[7] Clause 71-1, Clause 71-2, Clause 71-3 of the Labeling Rules as amended by the Order No. 22;

- In addition to the above, appendices 6, 7, 8, 9, and 10 of the Labeling Rules were set out in a new edition, and were supplemented with appendices 11, 12, 13, 14, 15 and 16[8].

Order No. 22 comes into force after 10 (ten) calendar days after the day of its first official publication, namely July 5, 2024. The official publication of the document took place on June 24, 2024.

The Rules for the Formation of the Procurement List of Medicines for the GVFMC and OSHI have changed in Kazakhstan

By Order of the Minister of Health of Kazakhstan dated May 24, 2024 No. 19 (**"Order No. 19"**) amendments were introduced to the Rules for the Formation of the Procurement List of Medicines and MD within the framework of the GVFMC and/or in the OSHI system approved by Order of the Acting Minister of Health of Kazakhstan dated December 24, 2020 No. КР ДСМ-324/2020 (**"Rules for the Formation of the List"**).

Order No. 19 introduced the following main changes:

- Now the Procurement List includes Medicines and Medical Purpose Devices (**"MPD"**) intended for the *prevention* and treatment of socially significant diseases, diseases which pose a danger to others, diseases which predominate in the structure of morbidity and mortality in Kazakhstan, *for free and/or preferential outpatient care of certain categories of citizens of Kazakhstan with certain diseases (conditions) as well as those supplied under long-term contracts*[9].
- Now Medicines and MPD (in the previous version – MD) are included in the Procurement List without considering subparagraphs 1), 2), 3), 4) of paragraph 4 of the Rules for the Formation of the List, when there is[10]:
  - a decision of the Formulary Commission on inclusion into the List of Medicines and MPD for free and/or preferential outpatient care of certain categories of citizens of Kazakhstan with certain diseases (conditions);
  - readiness to supply Medicines and MPD within the framework of long-term contracts with domestic manufacturers or *customers of contract manufacturing of original patented medicines located in the territory of Kazakhstan*;
  - the presence of a *registered price for the trade name (**"TN"**)* of a Medicine or MPD produced under long-term contracts with domestic manufacturers or *customers of contract manufacturing of original patented medicines located in the territory of Kazakhstan and* the estimate of or the maximum price for the international non-proprietary name (**"INN"**) of a Medicine or technical characteristics of a MPD within

[8] Order No. 22.
[9] Clause 3 of the Rules for the Formation of the List as amended by Order No. 19 and as amended by the Order of the Acting Minister of Healthcare of Kazakhstan dated 12.08.22 No. КР ДСМ-80;
[10] Clause 5 of the Rules for the Formation of the List as amended by Order No. 19 and as amended by the Order of the Acting Minister of Healthcare of Kazakhstan dated 12.08.22 No. КР ДСМ-80;

the framework of the GVFMC and/or in the OSHI based on the information provided by the state expert organization.

- Now, during the professional examination for the purpose of inclusion of Medicines or MPD into the List for Procurement of Medicines and MPD within the framework of the GVFMC and/or in the OSHI system, a subordinate organization of the authorized body, whose competence includes the issues of health technology assessment ("**Center**"), inter alia conducts an analysis to verify that the Medicine is listed in the Kazakhstan National Medicine Formulary ("**KNF**"), approved by the Order of the Minister of Health of Kazakhstan dated May 18, 2021 No. ҚР ДСМ-41 *and the List of Medicines and MD for free and/or preferential outpatient care of certain categories of citizens of Kazakhstan with certain diseases (conditions) approved by the order of the Minister of Health of Kazakhstan dated August 5, 2021 No. ҚР ДСМ-75*[11];
- The requirements for the Center to conduct research on the following matters during the professional examination for the inclusion of Medicines or MPD in the list of Medicines and MD for purchase within the framework of the GFVMC and/or in OSHI system have been omitted[12]:
  - the availability of an Anatomical Therapeutic Chemical (ATC) classification code or a Global Nomenclature of Medical Devices (GMDN);
  - compliance of the INN of the Medicine and its form and dosage or the technical characteristics of the MD and its configuration and performance characteristics with the information in the State Register of Medicine and MD;
  - compliance of the indications for medical use of the Medicine or MD with clinical protocols and instructions for medical use of the Medicine or MD;
- Now the decision to exclude Medicines and MPD from the Procurement List is considered by the Formulary Commission at the initiative of the authorized body inter alia based on the following grounds[13]:
  - exclusion of Medicines from the KNF *and/or the List of Medicines and MD for free and/or preferential outpatient care of certain categories of citizens of Kazakhstan with certain diseases (conditions);*
  - absence of the application for purchase of a Medicine or an MPD for 3 (three) years based on the information provided by the SD.
- A provision has been added stating that the applicant's proposals regarding the agreement on sharing costs or risks as well as possible discounts and/or schemes which ensure accessibility for the patient are sent by the authorized body to the SD[14].
- Annexes 1, 2, 3 and 4 to the Rules for the Formation of the List have been updated[15].

[11] Sub-clause. 1, p. 10 of the Rules for the Formation of the List as amended by Order No. 19 and as amended by the Order of the Acting Minister of Healthcare of Kazakhstan dated 12.08.22 No. ҚР ДСМ-80;
[12] Clause 10 of the Rules for the Formation of the List as amended by Order No. 19 and as amended by the Order of the Acting Minister of Healthcare of Kazakhstan dated 12.08.22 No. ҚР ДСМ-80;
[13] Clause 14 of the Rules for the Formation of the List as amended by Order No. 19 and as amended by the Order of the Acting Minister of Healthcare of Kazakhstan dated 12.08.22 No. ҚР ДСМ-80;
[14] Clause 15 of the Rules for the Formation of the List as amended by Order No. 19;
[15] Order No. 19.

Order No. 19 entered into force on June 11, 2024.

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