Kazakhstan – June 2023

The Rules on Wholesale and Retail Sale of Medicines and Medical Devices have been amended and supplemented

The Rules on Wholesale and Retail Sale of Medicines and Medical Devices were amended by the Order of the Minister of Health of the Republic of Kazakhstan ("**RK**") No. 98 dated June 2, 2023 ("**Rules on Wholesale and Retail Sale**").

The main changes include:

- *Introduction of the possibility of returning medicines and a ban to sell medicines to children*. Subparagraph 1 of paragraph 1 of Article 30 of the Law of the RK "On Protection of Consumer Rights" introduced the provision that medicines and medical devices are not subject to exchange and return, except the cases where medicines and medical devices are sold with an expired date or deficiencies that are discovered by the consumer, as well as the provision that medicines cannot be sold to children;
- *Introduction of a provision on inadmissibility of wholesale and retail sale of bulk products of medicines or medical devices*. Wholesale and retail sale of bulk products of medicines or medical devices is not allowed except the case where wholesale of bulk products of medicines or medical devices are used by entities in the field of circulation of medicines and medical devices for the purposes of medicine manufacture. This novelty was previously adopted in the Code of the RK No. 360-VI ZRK dated July 7, 2020 "On Health of the Public and the Healthcare System" ("**Code**") and is now reflected in the Rules on Wholesale and Retail Sale;
- *Clarification of the concept of an online pharmacy*. A clarification has been introduced into the text of the Rules on Wholesale and Retail Sale that a pharmacy that sells via the Internet are considered as objects of retail sale of medicines and medical devices.

The rules for conducting pharmacovigilance and monitoring the safety, quality, and effectiveness of medical devices

The Order of the Minister of Health of the RK No. 99 dated June 2, 2023, introduces amendments and additions to the rules for conducting pharmacovigilance and monitoring the safety, quality, and effectiveness of medical devices ("**Rules for Conducting Pharmacovigilance**").

Major changes include:

- *A clarification on self-registration on the portal by the holders of the medicine registration certificate – market authorization holders ("**MAH**") for the purpose of transmitting messages*

on pharmacovigilance. In order to gain access to the portal in order to send messages to the expert organization, MAHs register their personal account independently on the Internet resource with a login and password (previously, MAHs had to submit to the expert organization the data on the authorized contact person for pharmacovigilance in the territory of Kazakhstan). In case there is an authorized person for pharmacovigilance in the territory of the EAEU countries, the presence of a contact person for pharmacovigilance in the territory of Kazakhstan is optional. Notification of the expert organization on the change of the contact information or the change of an authorized person (contact person) for pharmacovigilance must be sent immediately, within 30 calendar days;

- *Introduction of new grounds for making changes to the leaflet and the general characteristics of medicines*. Now, when new information on safety is revealed in international sources and based on the results of pharmacovigilance, the expert organization notifies MAHs through the information resources on the need to make appropriate changes to the instructions for medical use (leaflet) and the general characteristics of the medicine within 90 calendar days after making changes to the safety information instructions for the original product from the date of posting the information on the website of the expert organization;
- *Extending the grounds for revocation of the medicine registration certificate – market authorization ("**MA**")*. Now the state body in the field of circulation of medicines and medical devices can withdraw the MA in the prescribed manner based on the information of the expert organization (conclusion, report) on changes in the assessment of the "benefit-risk" ratio of medicine, as well as the results of the inspection of the pharmacovigilance system;
- *Setting the deadline for submitting reports on post-registration clinical monitoring for class 3 medical devices, as well as class 2b medical devices implanted in the human body*. Now, the manufacturer of the medical device or its authorized representative for class 3 medical devices, as well as class 2b medical devices implanted into the human body submits annually, for 3 years, the reports on post-registration clinical monitoring to the expert organization to assess the "benefit-risk" ratio.

The rules for organizing and conducting procurement of medicines, medical devices, and specialized medical products within the guaranteed volume of free medical care and (or) in the system of compulsory social health insurance were adopted in a new edition

By the Order of the Minister of Health of the RK No. 110 dated June 7, 2023 a new version of the rules for organizing and conducting procurement of medicines, medical devices and specialized medical products under the guaranteed volume of free medical care ("**GOBMP**"), an additional

volume of medical care for persons held in pre-trial detention centers and institutions of the penitentiary (penal) system, at the expense of budgetary funds and (or) in the system of compulsory social health insurance ("**OSMS**"), pharmaceutical services ("**Procurement Rules**").

General changes:

- *Removed:* the concept of an automated tender;
- *Introduced:* a provision that a single operator provides users with services for the use (access) of the web portal on a paid basis, the price for services for the use (access) of the web portal by users is set by a single operator.

➢ Procurement from a single source from domestic or foreign manufacturers, international organizations established by the United Nations.

- *Introduction of a provision on the term of a contract with a foreign manufacturer*. When procuring from a foreign manufacturer a Single Distributor concludes a contract for up to 3 (three) years;
- *Introduction of a provision that regulates cases of reduction of the marginal price for medicines and (or) medical devices*. When the authorized body in the field of healthcare reduces the marginal price for the international nonproprietary name ("**INN**") and (or) trade name ("**TN**") of medicines and (or) medical devices during the execution of the supply contract (agreement), the Single Distributor shall negotiate with the domestic or a foreign manufacturer reduction of the price of the contract. Disagreement to reduce the price or refusal to negotiate may serve as a basis for termination of the contract;
- *Possibility to submit additional applications by the ordering party.*

➢ Procurement from a single source through the Single Distributor's web portal, by the ordering party or the procurement organizer:

- *Notification of procurement by the method from single source can contain an unlimited number of procured items.*

➢ Conclusion and execution of supply contracts by a Single Distributor, the ordering party, or the procurement organizer:

- *Introduction of the provisions regarding changes in the marginal prices for medicines and (or) medical devices*. If the marginal price for INN and (or) TN of medicines and (or) medical devices changes upwards during the execution of the supply contract, the supply contract remains valid until the contract is fully executed at the previous price. When the marginal price changes downwards, the Single Distributor negotiates with the supplier reduction of the price of the contract for the supply of medicines and (or) medical devices. In case of disagreement in reducing the price of the supply agreement or refusal

by the supplier to negotiate, the Single Distributor has the right to terminate the supply contract.

- Competition for the conclusion of long-term supply contracts among potential suppliers who intend to create and (or) modernize medicine and (or) medical devices manufacturing through a web portal:
  - *Requirement to provide a new document to the competitive bid*. The competitive bid of a potential supplier for participation in the tender must now include a letter of guarantee on non-infringement of patent and other rights and claims of third parties related to the sale of medicines and (or) medical devices;
  - *Change in the number of points awarded*. Now, when applying the point system to the applications of potential suppliers, 2 (two) points are provided for confirmation of the ownership of a land plot to be used to start the manufacture of medicines and (or) medical devices, and 1 (one) point for having a land plot in lease, trust management, temporary land use (previously 1 (one) point was given regardless of the type of rights);
  - *Introduction of the deadline for submission of documents related to the manufacture of medicines and (or) medical devices*. The period of state registration in the RK, price registration, receipt of a certificate of origin of medicines, medical devices for internal circulation "CT-KZ" shall not exceed 3 (three) years;
  - *Setting the deadline for notification of the readiness to supply*. The supplier shall notify the Single Distributor of the readiness to supply medicines and (or) medical devices at least 6 months prior to the readiness to supply;
  - *Requirement to provide additional documents*. Now, during the period of supply of medicines and medical devices within 10 (ten) years, a domestic manufacturer submits to the Single Distributor documents confirming compliance with the criteria on a point scale (for example, research and development in the production of medicines and medical devices, increasing human resources, etc.). Documents shall be submitted no later than 5 (five) years from the date of the first supply. Failure to submit documents or failure to achieve criteria of at least 6 (six) points serve as the basis for termination of a long-term supply contract;
  - *Introduction of new grounds for termination of the contract*. New grounds have been added for termination of a long-term supply contract ("**LSC**"), including violation of the supply start date provided for in the LSC, violation of patent and other rights and claims of third parties related to the sale of medicines and (or) medical devices established in court; the ordering party's lack of need for medicines and (or) medical devices for 3 (three) years in a row, as well as the basis for not achieving the criteria of necessary sum of points;

- *Possibility to extend the LSC for 3 (three) years*. It is now allowed to extend the LSC for 3 (three) years pursuant to a new procedure, according to which the Single Distributor creates a commission to conclude an addendum.

➢ Conclusion of the LSC for original patented medicines with contract manufacturing customers ("**CMC**"):

- *Provisions on biosimilars are excluded*. The possibility of concluding an LSC for biosimilar medicines (bioanalogs, biosimilars) has been excluded;
- *Requirement of additional documents to be submitted by the applicant*. Now, when submitting an application to the Single Distributor, applicants shall additionally provide:
  - conclusion of an expert organization on the originality of the medicine indicating the INN or composition, dosage form, specific dosage and (or) concentration, unit of measure, TN, manufacturer;
  - conclusion of an expert organization acting on the basis of the Kazakhstan Patent Law on the existence of a valid patent for original medicines, indicating the period of its validity, or on its absence.
- *The list of documents for the conclusion of an LSC has been reduced*. For the conclusion of an LSC for the original medicines, the CMC presents a notarized copy of the contract for contract manufacturing with a manufacturer located on the territory of Kazakhstan;
- *Clarification on the deadline for the start of delivery.* Now, the period from the conclusion of the LSC to the date of the readiness to supply does not include the period for the inclusion of original patented medicines into the list of the Single Distributor;
- *Amendment to the list of documents for concluding an addendum to the LSC*. The requirements for the provision of a GMP certificate and a license for pharmaceutical activities are omitted. The requirement for the MA has been clarified, namely, it must indicate one or more stages of manufacturing at a manufacturing site located on the territory of Kazakhstan;
- *Introduction of a provision to suspend procurement from a domestic manufacturer until the expiration of the patent for the original medicine from the CMC*. The LSC with a domestic manufacturer is suspended from the date of signing an addendum to the LSC with the CMC for the period of validity of the patent for the original medicine.
- *Reduction of the list of the grounds for termination of the LSC.* The ground for termination of the LSC for the original patented medicines with the CMC now includes a violation of the of the obligations stipulated in the LSC;

- *Exclusion of the provisions on advance payment by the Single Distributor*. The rules on advance payment that existed in the previous version of the rules (for example, in the event of prevention and elimination of the consequences of emergencies) were omitted.

➢ Procurement of medical equipment:

- *Introduction of a procedure for the procurement of medical equipment ("**ME**") with an extended service period*. Such a procurement method is provided for specific ME, such as a CT scanner, magnetic resonance imaging scanner, angiograph, etc.;
- *No competition bid for procurement from potential suppliers who have the manufacturing of MEs within the LSC framework.* Instead of organizing a competitive bid, the commission reviews the documents of potential suppliers and negotiates provision of a conditional discount.

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