

Legal Alert: Pharma Sector

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We hereby inform you of the **changes to the healthcare legislation** in Kazakhstan in February, 2022:

1. The Order of the Minister of Health of the Republic of Kazakhstan dated February 1, 2022 **invalidated** the previous order, dated April 11, 2018. Now, the Order No. 166 "On approval of the list of open data posted on the open data Internet portal" **is no longer valid**.

2. By the Order of the Minister of Health of the Republic of Kazakhstan dated February 3, 2022, **the following amendments are introduced** to the Rules for the provision of the public service "Issuance of a license for the **import into** the territory of Kazakhstan and (or) **export from** the territory of Kazakhstan of **organs (parts of organs) and (or) human tissues, blood and its components.**" Thus,

- The **rules will apply to the import and export of human organs** (parts of organs) and (or) tissues, blood and its components from and to countries that are not members of the Eurasian Economic Union;
- The **service will be provided by the Committee for Medical and Pharmaceutical Control** of the Ministry of Health of the Republic of Kazakhstan. Before, this was handled by the Committee for Quality and Safety Control of Goods and Services of the Ministry of Health;
- The services will be provided to individuals. Prior to this, the services were only available to legal entities;
- Revision of submitted documents will be provided **within one working day** from the date of filing (*it took two days before*).

The document is effective **on March 5, 2022**.

3. The Order of the Minister of Health of the Kazakhstan Republic dated February 4, 2022 **introduced the following amendments to the rules of pharmaceutical inspections of good pharmaceutical practices**. According to the new wording, the issuance of a certificate of good manufacturing practice (GMP) is carried out without inspection for manufacturers of medicines of the Republic, which have a license for pharmaceutical activities related to the production of medicines. The inspection is not needed only based on the application and the letter of guarantee on submission of documents **before July 1, 2021**. In case the subject of inspection fails to submit within six months from the date of certificate issue, the application in accordance with clause 12 of the Rules, the certificate issued by this clause shall be withdrawn. Another change was **an additional ground for revocation of the certificate** by a state body or its territorial subdivision. Thus, if critical non-compliances are detected during an inspection carried out with the manufacturers, having a certificate for compliance with GMP without an inspection, the certificate shall be withdrawn.

4. New Sanitary Rules "Sanitary and Epidemiological Requirements for Industrial Facilities" were approved and the Order of the Minister of National Economy of the Kazakhstan Republic dated March 20, 2015 № **236** with a similar name in accordance with the Order of the Minister of Health of February

11, 2022 **was invalidated**. Thus, 5 Annexes to this document approved sanitary and epidemiological requirements for facilities of **ferrous metallurgy, coal industry, non-ferrous metallurgy and mining industry, chemical industry**, as well as sanitary and epidemiological requirements for **technological and associated facilities and facilities engaged in oil operations**.

The Order is effective **on March 1, 2022**.

5. The Order of the Minister of Health of February 16, 2022 **approved a list of severe forms of certain chronic diseases**, effective **on March 1, 2022**.

6. The drug "**Ketorol® Express, dispersible pills, 10 milligrammes**", serial number V090025 **was withdrawn from circulation** by the Order of the Chairman of the Medical and Pharmaceutical Control Committee (Kazakhstan Ministry of Health) dated February 10, 2022.

7. A Decree of the Chief State Sanitary Inspector dated 11 February 2022 expanded the list of countries whose vaccination certificates or passports are valid in Kazakhstan. Thus, **Belize, Bolivia, Ecuador, the Republic of Indonesia, the Democratic Socialist Republic of Sri Lanka and the United Kingdom** vaccination passports or certificates **are valid** in Kazakhstan.