This document contains links to websites where you can find national legislation and health laws. We link to official government legal sources wherever possible. Where we link to unofficial sources this is noted and users should take this into account before relying on these materials. We recommend checking with the relevant national government if you have questions about the currency or validity of any unofficial source of law.

**Legal system**

Civil law

**National law database**

*Language:* Kazakh, Russian and English  
*Link:* [www.adilet.zan.kz](http://www.adilet.zan.kz)  
*Nature:* Official law database  
*Organisation responsible for the website:* Ministry of justice of Kazakhstan

**The health system and policy monitor: regulation (PDF)**

As part of its Health Systems in Transition (HiT) series the European Observatory on Health Systems and Policies systematically describes the functioning of health systems in countries as well as reform and policy initiatives in progress or under development. The HiT health system reviews cover the countries of the WHO European Region as well as some additional OECD countries. This PDF includes information about the country’s regulation. To see the complete HiT report of this country go to: [http://www.euro.who.int/en/about-us/partners/observatory/publications/health-system-reviews-hits](http://www.euro.who.int/en/about-us/partners/observatory/publications/health-system-reviews-hits)
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Kazakhstan
HIT: 2012 - Katsaga A, Kulzhanov M, Karanikolos M, Rechel B.
HSPM Members:
HSPM Contributors:
Kazakhstan: Regulation

2.8 Regulation

The country’s health system is currently regulated by the Code on People’s Health and the Health Care System (President of Kazakhstan, 2009). The Code is a comprehensive legal document regulating a broad range of issues related to the functioning of the health system. While integrating and systematizing all existing health legislation and realigning it with the regulation of other economic sectors, the Code also cancelled outdated or more specific laws and acts that used to regulate various aspects of the health system. The development of the Code was a huge undertaking for the Ministry of Health and involved other ministries, the government, professional and public associations, and international experts. The Code went through several readings in Parliament.

The Code regulates relationships in the health system to ensure the constitutional right of the population to health protection, harmonize the health system with international norms and standards, and improve the quality of health services and provision of drugs, medical supplies and equipment (President of Kazakhstan, 2009). Adoption of the Code has driven the revision of lower-level legislation, including government decrees, orders of the Ministry of Health and legal acts of local executive bodies.

One of the priorities of health reforms was to improve the system of health administration and management, as envisaged by the National Programme for Health Care Reform and Development 2005–2010. Between 2005 and 2009 major improvements in the management of the health sector were made through a shift from administrative ways of regulation to a system of economic incentives, including the pooling of funds at oblast level, the creation of a single-payer, incentive-driven provider payment systems, greater autonomy of health care providers in managing their resources, and increasing the role of the population through free choice of providers.

2.8.1 Quality control

The current quality control system faces a number of challenges. Health workers and managers often have no incentive to improve their performance, and quality improvement proposals are not implemented. In addition, internal and external quality control measures are not interlinked, and the parallel health services linked to other ministries or agencies do not form part of the Ministry of Health quality control system.

The current quality control system started to emerge in 1996. As part of the implementation process of the mandatory health insurance in the period 1996–1998, a system of assessing the quality of health services was developed. It was mainly punitive, stipulating fines and penalties for poorly performing providers. Although the system of penalties was discontinued, the analysis and evaluation of health services continued, with increasing emphasis on patient satisfaction surveys and the compliance of health services with medical standards (Ministry of Health, 2004). The Ministry of Health Order No. 898 of 28 December 2004 established new rules for the quality control of services provided by health facilities. According to these rules, the Ministry of Health is responsible for:

- developing national policies on quality assurance and accreditation;
- developing the legislation for the accreditation of health organizations;
- developing the legislative basis for quality control of health services, including intra-hospital management and efficiency of health organizations; and
- overseeing adherence to licensing rules permitting medical practice.

The Medical and Pharmaceutical Activity Control Committee under the Ministry of Health was established by Ministry of Health Order No. 565 of 23 October 2009. The committee subsumed the Pharmaceutical Committee and the Committee for Health Services Quality Control, assuming their core functions. In the area of quality assurance and control, the Committee has the following key responsibilities:

- ensuring implementation of the national policy on health care quality and drugs, medical
supplies and medical equipment;

- accreditation of legal and physical entities involved in health services, irrespective of forms of ownership and departmental affiliation;
- licensing medical practice performed by republican organizations and private providers, as well as of organizations whose work extends beyond a single oblast (medical licensing for other health care providers is done by oblast health authorities);
- certification of managers of state institutions and organizations working in the health sector;
- controlling the level and quality of delivered health care;
- defining compliance of the different types of health care with existing licences; and
- dealing with complaints of citizens about low-quality care.

The Committee aims to adopt a systematic approach and to use objective indicators and independent experts. The quality control system makes use of the following procedures:

- comprehensive planned investigations, conducted not more than once a year;
- unplanned investigations based on complaints of citizens, conducted at the request of health care authorities, other state authorities or the Parliament;
- targeted investigations, conducted continuously throughout the year based on specified goals; and
- joint investigations, conducted by several state authorities to ensure compliance of health service providers with health legislation.

The Committee aims to promote the development of independent medical expertise and has the power to accredit individuals or organizations with the status of independent experts.

New certification rules for health workers were approved by Ministry of Health Order No. 660 of 6 November 2009. The rules were developed in compliance with the new Code on People’s Health and the Health Care System. Heads of oblast health administrations, heads and deputies of republican administrations, and heads of public health facilities are subject to mandatory certification. In order to ensure an unbiased and competent certification, attestation committees have been established. These committees have a minimum of seven members, including representatives of state bodies, health facilities, medical science and NGOs. The certification process includes a computer-based test with 100 questions and an interview with the Attestation Committee.

Within the framework of implementing the Concept on the Unified National Health Care System, in 2009 the Ministry of Health initiated a national accreditation system for health organizations. Ministry of Health Order No. 103 of 26 February 2009 approved the respective accreditation standards. Within the World Bank Health Sector Technology Transfer and Institutional Reform Project, a new Accreditation Centre has been established under the Health Care Development Centre. In 2010, 1319 health organizations applied for accreditation and 1205 were accredited.

2.8.2 Regulation and governance of human resources

The Code on People’s Health and the Health Care System (President of Kazakhstan, 2009) regulates all aspects of the health system, including human resources. According to this document, the government is responsible for developing the major strategic directions in the health sector. The Ministry of Health is responsible for implementing these strategies. In terms of human resources, it is charged with:

- developing an overall human resource policy in the health sector;
- organizing undergraduate and postgraduate training, continuous education and retraining of medical and pharmaceutical personnel;
- defining standards for the training of specialists with higher and postgraduate education, for continuous education and the retraining of health professionals;
- organizing and conducting the attestation of health organizations and managers; and
- approving forms and training programmes for medical specialties, and developing and approving staffing standards of health organizations.
Oblast health departments are responsible for:

- approving oblast health care programmes and ensuring their implementation;
- ensuring that health organizations in the public sector have adequate staffing;
- ensuring the provision of human resources in health organizations and assessing the expertise of health workers;
- when necessary, determining and ensuring additional staffing of health organizations in the public sector above minimum rates approved by the Ministry of Health;
- determining and ensuring social support plans for medical personnel and pharmacists allocated to work in rural areas; and
- implementing undergraduate and postgraduate training, and the continuous education and retraining of medical personnel, including pharmacists.

### 2.8.3 Regulation and governance of pharmaceuticals

The main actors in the pharmaceutical market of Kazakhstan are the Ministry of Health, the Medical and Pharmaceutical Activity Control Committee under the Ministry of Health, the Medical Industry Committee, and the National Centre of Pharmaceutical Expertise. The Code on People’s Health and the Health Care System regulates functions and responsibilities of all participants of the pharmaceutical system.

The Ministry of Health is the highest administrative body, implementing the following key functions:

- developing the national drug policy;
- approving the Essential Drugs List;
- organizing intra- and intersectoral coordination with regard to pharmaceuticals;
- developing and approving a list of diseases and population groups eligible for free or discounted drugs, baby formula and diet food products;
- approving standards in the pharmaceutical area, including pharmaceutical education; and
- approving the State Pharmacopoeia and the State Drugs Registration List.

The Pharmaceutical and Medical Control Committee under the Ministry of Health is responsible for:

- implementing the national policy on the distribution of drugs;
- carrying out the registration, re-registration and withdrawal of registration of drugs, and granting permissions for the use of drugs in medical practice;
- carrying out control and surveillance of pharmaceutical activities of individuals and organizations in the area of drugs circulation;
- granting licences and supervising adherence to legislation of licence holders;
- issuing permissions for advertisement of drugs;
- coordinating the import and export of drugs, medical equipment and medical supplies; and
- overseeing international cooperation in the area of drugs distribution.

The National Centre of Expertise on Drugs, Medical Supplies and Medical Equipment under the Ministry of Health has the following responsibilities:

- certification of drugs
- control of quality and bioequivalence of drugs
- registering side-effects.

The Committee for the Control of Drug Trade and Trafficking under the Ministry of Interior is responsible for:

- implementation of the state policy on drug trade and trafficking
- licensing of activities related to narcotic drugs
- coordinating the control of the illegal use of narcotic drugs, psychotropic substances and precursors.
In order to implement the Code on People’s Health and the Health Care System, basic regulatory legislation has been introduced, governing the circulation of drugs, medical supplies and medical equipment. In response to the problems of the pharmaceutical sector, the Ministry of Health has recently approved a Concept on Drug Policy, envisaging:

- an annual growth of the assortment and volumes of local pharmaceutical products
- the reinstatement of a vertical structure of public administration in the pharmaceutical sector
- the organization of appropriate control systems for drugs, medical supplies and equipment
- the transition of drug certification functions to government bodies
- regulation of registration and advertisement procedures for food supplements.

Government measures aim to stimulate the domestic production of high-quality pharmaceutical products. The registration, certification and quality assurance of drugs, medical supplies and medical equipment, as well as their advertising, have been streamlined, and a National Drug Information Centre established. The government has also initiated a harmonization of legislative procedures with EU standards; Kazakhstan became an official observer of the Commission of European Pharmacopoeia and a full member of the WHO international programme for monitoring adverse side-effects in drugs. Two volumes of the State pharmacopoeia of Kazakhstan have been developed and approved. Price regulation of drugs purchased through the state budget reduced their price by an average of 30%. A drug formulary system has also been introduced, with the aim of ensuring rational drug use, based on therapeutic efficacy, pharmaco-economics and the monitoring of side-effects.

The creation of a unified system of drug distribution has been initiated. The system enables significant savings in public expenditure and an increase in the share of domestically manufactured drugs. Long-term contracts are agreed with domestic manufacturers, including for high-tech products (such as vaccines, insulin or blood products). This allows the upgrading of existing facilities and the construction of new ones, in accordance with international standards of good manufacturing practice, at an estimated cost of more than 30 billion tenge (US$ 206 million). It is expected that these investments will ensure an increase in the share of domestically produced drugs to 50% by 2014.

The introduction of a drug formulary system in 2009 (Ministry of Health, 2009f) allows the procurement of drugs for hospitals based on drug formulary lists that are compiled by physicians of all specialties within a hospital and approved by oblast health departments. Drug formularies are based on the principles of evidence-based medicine, with the aim of guaranteeing quality, effectiveness, safety, rational drug use and accessibility.

The Outpatient Drugs Benefit Package, introduced in 2005, was a major step in strengthening primary health care. The package has been gradually expanding since 2005 to cover more groups of patients, and diseases such as acute respiratory infections and acute diarrhoea in children, arterial hypertension, pneumonia, ulcers and other diseases. Surveys conducted by the Karaganda Drug Information Centre in 2006 and the NGO Aman Saulyk in 2008 have shown that the Outpatient Drugs Benefit Package is in high demand both with patients and physicians, but that the range of drugs, their accessibility in pharmacies, and the distribution and logistics are inadequate. Other challenges are that the mechanism of planning and financing the Outpatient Drugs Benefit Package is not flexible enough, and that the methods used for assessing demand at oblast level are inadequate. The results are irrational consumption of purchased drugs and a limited choice for patients, who depend on a small number of pharmacies and a limited range of drugs purchased within the programme.

In February 2009 the national company Samruk Kazyna Pharmatsiya was created under the National Welfare Fund Samruk Kazyna to assume the function of a single national distributor responsible for the procurement and distribution of drugs within the State Guaranteed Benefits Package. The institution of a single distributor was created with the aim of improving the provision of drugs for the population within the State Guaranteed Benefits Package, and supporting the development of the domestic pharmaceutical industry through a closer collaboration of the private and public sectors.

The new single distributor is responsible for the following main areas of activity:
- organization of open tenders for drug procurement within the State Guaranteed Benefits Package;
- organization of drug storage in line with good distribution practices and national legislation;
- organization of the logistic processes for the provision of drugs to state health organizations; and
- creation of an information system that aims to integrate logistic processes between the single distributor, clients and suppliers, and compiles up-to-date information on drug turnover and supplies.