



**AMERICAN CHAMBER OF COMMERCE
IN KAZAKHSTAN**

**IMPROVING KAZAKHSTAN'S
INVESTMENT CLIMATE:
BUILDING A WORLD-CLASS
HEALTHCARE SYSTEM IN KAZAKHSTAN**

AMCHAM WHITE PAPER

2018





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Introduction

The American Chamber of Commerce of Kazakhstan shares the goals of Kazakhstan in increasing the welfare of its citizens. AmCham and its member companies welcome efforts to reform the healthcare system and believe they can offer unique opportunities to help Kazakhstan achieve its objectives.

AmCham's member companies can help the Ministry of Health and other stakeholders introduce the world's leading technologies, pharmaceuticals, research, education, and approaches to managing both the overall healthcare system as well as individual facilities.

AmCham members active in and knowledgeable about healthcare issues and needs come from many different industries and international organizations. This diversity in the AmCham membership provides many different perspectives on healthcare development in Kazakhstan and offers many opportunities for the Government and Ministry of Health to utilize member resources and knowledge.

For Kazakhstan to take full advantage of the opportunities offered by the world's leading healthcare companies and institutions, AmCham has several general and specific policy recommendations.

In recent years, AmCham has devoted two full-length conferences to issues involved in Kazakhstan's healthcare reform strategy, supported by four years of pharmaceutical patent protection information to the Ministry of Health and *SK-Pharmacy* through the *AmCham Inter-Ministerial Working Group on Intellectual Property Protection*.

The more recent creation of an *AmCham Healthcare Reform Working Group*, an internal AmCham Group, provides a broader perspective on the current status of healthcare in Kazakhstan. AmCham has also devoted repeated sessions of the *Prime Minister's Council to Improve the Investment Climate* to dialogue on healthcare reform with those Cabinet Ministers responsible for Kazakhstan's healthcare policy and the economic and budgetary resources underpinning the country's healthcare system.

It is noteworthy that the annual AmCham Awards presented each year to members with outstanding achievements in a variety of fields always include a large number of awards for healthcare projects designed and funded by member companies themselves. This again demonstrates our members' commitment to the improving the well-being of the communities in which they live and operate, and to the future of Kazakhstan.

The recent invitation from the Ministry of Health to AmCham to participate in the Ministerial Working Group devoted to developing the new Health Code for Kazakhstan is very welcome, a recognition of the experience and knowledge readily available through AmCham members.

Together with its member companies, AmCham looks forward to an expansion of dialogue on how industry can help Kazakhstan achieve its ambitious healthcare goals.

Context

Kazakhstan will need to improve its healthcare provision if it is to achieve its high-level goals. The **100 Steps** announced by President Nursultan Nazarbayev includes several ambitious healthcare goals, including mandatory health insurance based on “the principle of mutual responsibility of the state, employers and citizens”, development of private healthcare, and introducing higher standards for healthcare. Kazakhstan’s *Strategic Development Plan 2025* sets the goal of accessible healthcare throughout the country, including in remote regions. *Strategy Kazakhstan-2050* discusses strengthening public health and several specific aspects, including digitization.

Against the backdrop of these larger strategies, a series of healthcare reform programs have increased access to coverage and introduced several innovations. The 2016-2019 strategy includes a range of new measures to improve education, healthcare delivery, universality and accessibility, including mandatory social health insurance. Prior and parallel programs as well have identified worthwhile goals. In fact as long ago as the landmark international *Alma-Ata Declaration of 1978* primary health care was identified as they key to healthcare universality.

Yet, despite, or perhaps because of, the multiple reform programs, AmCham has received feedback from a wide range of stakeholders that they do not perceive that a clear vision and strategy for healthcare reform that could rally citizens and healthcare providers has been articulated.

This perception results in a resistance to the Government strategy. Regarding mandatory social health insurance, the stated rational is that there should be mutual responsibility of the state, employers and citizen. However, experience from many other countries show that people buy insurance for themselves, not for others. They ask, “what’s in it for me?” and so far they appear to not know the answer.

In a recent survey of companies conducted by Ernst and Young, 43 percent saw no advantage in introducing mandatory health insurance; 58 percent were concerned that there was no quality standard for medical services; and of companies that already provide private health insurance, 61 percent assumed they would continue to do so, given their lack of trust in the mandatory system. At a minimum, these results suggest the government has not made the case for social health insurance, including among companies that already insure their employees.

Health and development organizations note improvements are needed in nearly all areas of healthcare, while acknowledging that significant progress has been made, particularly in the last several years. The World Health Organization finds that Kazakhstan lags behind countries in the region with comparable GDP in key health indicators, including cardiovascular disease, cancers, infant mortality and life expectancy.

Despite this state of affairs, Kazakhstan spends nearly three times less on healthcare than the OECD average as a percentage of GDP, and the money that is spent could be done so more efficiently. The Soviet legacy carries with it many inefficiencies, including an emphasis on hospitalization and other practices that drain resources.

Although new reforms that target specific diseases will of course save lives, the question remains whether they are the most rational use of budget resources.

Digitalization may introduce efficiencies, but it is unclear whether it has been weighed against other priorities that may be addressed with less costly reforms. Reforms to better address cardiac illness are impressive, yet the disease rate for Kazakhstan is still six times worse than in the European Union, and more than twice that of Serbia, which has a slightly lower per capita GDP.

A somewhat different approach would be to organize healthcare around the needs of the patient. This patient-centric approach would give more authority to primary-care physicians, so that issues can be addressed in a single visit, rather than through referrals to multiple doctors. It would also address behaviors, i.e., diet, exercise and smoking, and attitudes about what citizens should reasonably expect from healthcare providers.

Fixing these long-standing problems are within Kazakhstan's reach, but AmCham believes there first needs to be a coherent vision around which a strategy can be built and the country can rally. Such a vision and strategy will address three key questions:

1. Universality. Will healthcare be available to all citizens, or only those who can prove they have insurance, or all patients regardless of citizenship?

Access to healthcare for all citizens is considered a fundamental human right in some countries and an unattainable luxury in others. The implementation issues evolving around universality mainly center on single payer system vs. multiple payer system and costs involved for each option.

2. Affordability. How much medical care will be provided, and how will costs be shared?

Affordability is multidimensional metric as well – ranging between individual affordability of direct and out of pocket expenses for healthcare for citizens to affordability of healthcare systems for taxpayers and country overall. The issues include conceptual differences between pre-funding and post-funding, disproportionate healthcare needs for various age groups and resulting inevitability of rationing care and capping procedures covered.

3. Quality. What are the standards, targets, and how will these be measured? What mechanisms will ensure a continuous learning process? How can fragmentation in the provision of services, financing, governance and resourcing be reduced?

Quality of healthcare includes such considerations as timeliness, perceived quality and health outcomes from infant mortality to life expectancy, focus on primary care vs. bearing costs for expensive treatments for serious illnesses.

The country's healthcare strategy should also have clear intermediate indicators showing whether reforms are on track between healthcare's present status and its end-point goal. These indicators might include patient wait times, decrease in chronic diseases, clearer financial modeling, and updated actuarial tables so that the government has a clearer sense of how much various reforms will cost, and where the money will come from.

Localization

AmCham is concerned that Kazakhstan is trying to kill two birds with one stone by both procuring necessary drugs and medical equipment and promoting economic diversification through the healthcare industry. While both are worthy goals, it may not always be wise to combine them.

AmCham members believe the government holds the point of view that companies should compete for market access in Kazakhstan, with the goal being support of local manufacture of drugs. While this may hold true for some types of products and services, it is less valid for patented drugs, medical devices and services, and it is not always clear that local production is more cost-efficient, given the relatively small size of the Kazakhstani market, and existing facilities in other countries of the Eurasian Economic Union.

From the firm-level perspective, Kazakhstan is competing with other countries that may offer higher return on investment. In other words, it isn't Company A competing with Company B for customers in Kazakhstan; instead, it is Country A competing against Country B for funds as decided by the company's investment board.

In this perspective, countries with larger markets, or those countries eligible for official development assistance, and/or those that are experiencing high GDP growth will jump to the head of the queue when a company's investment board is making its decisions. Moreover, countries that meet these conditions are in Kazakhstan's immediate neighborhood, making competition more acute.

As an example, one AmCham member company recently succeeded in launching a modest public-private partnership to reduce the incidence of a chronic disease in one *oblast* of Kazakhstan. The agreement includes consulting, doctor training and equipment. This scheme appears to be a win-win and is supported by the *oblast akim*. It could be replicated in other *oblasts*, however the local partner exhausted its resources on this one deal, and the multinational partner may not be able to provide the financing.

"We are competing globally for financing," a company representative said. "Just in our region, Russia is 80 percent of the market and Uzbekistan is just opening up with lots of donor financing, so it's hard to make the case to our investment committee." In Kazakhstan, available financing at commercial rates is likewise not attractive, when compared with other countries.

In this context, AmCham members suggest the government might consider preferential financing for social projects to stimulate investment in healthcare, thus supporting policy goals with financial resources.

Intellectual Property Rights

It goes without saying that intellectual property rights is a complex issue that many countries struggle with. In the *2018 AmCham Investment White Paper*, infringement of these rights was considered a major barrier to foreign investment in the technology, pharmaceutical, and consumer-product sectors.

Defending IPR is critical to establishing a welcoming investment environment. A potential investor will need to know that its product or service will not be undercut by counterfeits or generics that may infringe existing patents. This is also essential to establishing a modern society, where liability for the safety of products can be tied to a legitimate provider.

It is critically important that the public be protected by having only legitimate products under patent protection or legitimate generics distributed in the country's pharmacies and used for medical treatment in Kazakhstan's clinics and hospitals. Unfortunately, to date the status of medicinal and healthcare products is not well-protected, creating an uncertain and risky situation for patients and the general population who purchase drugs themselves or are treated with drugs in healthcare facilities. This situation requires critical and immediate attention.

AmCham has enjoyed constructive cooperation in IPR policy development via the *Inter-Ministerial Intellectual Property Rights Working Group* and *HealthCare Reform Working Group*, which addresses the concerns of the technology, pharmaceutical, and consumer products industries. AmCham members note a cooperative and active law-enforcement response concerning counterfeit drug imports and other obvious illegality. However, aside from clear criminal misconduct, the door remains open for violation of drug patents.

First, a generic version of a patented drug can be registered legally in Kazakhstan, assuming it passes clinical trials and other verifications, as the registration process does not take the presence of patents into account.

Second, the state procurement list and government tenders (or *SK-Pharmacy* on behalf of the government) use the international nonproprietary name (INN) of drugs. This may make sense for non-patented medicines, but where a drug is patented it opens the door for 'generic' versions, in violation of the patent, to be offered. If the non-patented version wins the tender, SK-Pharmacy or the Ministry believes the responsibility lies on the patent-holder to take legal action.

Intellectual property rights also risk infringements in the localization process. AmCham is aware of one case where a local company with no manufacturing experience received a ten-year contract to supply a 'generic' drug that is still under patent-protection with the legitimate manufacturer. The local company has been given four years to construct a facility and get the drug authorized despite the fact that the legitimate patent on the drug will still be valid in four years, and therefore the local 'generic' will be illegitimate.

Another area of IPR violation is the overuse of rules for drugs to treat orphan diseases. Orphan drugs treat conditions so rare that the standard approval process is fast-tracked to get the drug onto the market quickly. AmCham members are concerned that the orphan-drug exception may have been used to register bio-similar versions of patented drugs, although exceptions should only be granted when there is no proven drug on the market.

In addition to the legal issues involved in violating patents, illegitimate generic drugs may lead to health risks resulting from poor quality, and may lead doctors to prescribe off-label treatments when procurements are made based on the INN without taking into account clinical trials.

AmCham is aware of one case when a generic drug with the same active ingredient as a patented drug won a government tender. However, the patented drug had undergone clinical trials and had four indications. The generic version with the same active ingredient had just one indication, so if doctors need to prescribe for the other three, they will be presented with the conundrum of either prescribing the drug off-label or pursuing another path. This issue could be addressed if the tender includes not just the INN but the clinical indications as well.

Market Access

AmCham members believe the transparency and efficiency of the process for bringing drugs onto the market could be improved. Currently, the process is as follows: 1) a new drug's price is registered (to be discussed further below), 2) it is included in the *Kazakhstan National Formulary*, 3) and it is then added to a list of recommended medicine. Only then is it eligible for state procurement via *SK-Pharmacy*.

At each stage, AmCham members report lack of transparency and clarity about what information they should provide, for example, clinical trials in other countries, pharmacological data and related matters. As well, members report they are not always informed of appeals procedures if a drug is excluded.

As a first step, AmCham suggests the government consider removing or merging either the national formulary or the list of recommended medicines. This would reduce the steps to eligibility.

Drug Pricing

Drug pricing is a complex process, with a wide range of ethical and economic arguments in play. To manage this process, Kazakhstan until recently followed a methodology similar to other countries in the region and across the globe, by comparing a drug's price across a range of countries. However, Kazakhstan used 39 referent countries, more than any other in the region, and it relied on the drug seller to provide the prices from these countries. This system presented corruption risk – which was borne out in 2017 -- since it was so difficult to verify prices across such a large sample size, and since it relied on self-reporting.

To reduce corruption potential, Kazakhstan in March 2018 adopted an Ex-Works methodology for drug pricing, ie pricing based on an assumed price for selling drugs straight from the manufacturing facility. This has struck drug makers as an unusual and impractical policy. As almost no countries use Ex Works for drug pricing, and as most companies do not sell drugs straight from the manufacturing facility, producers have had to develop Ex Works price offers without industry standards.

In other words, producers are having to create pricing methodologies just for the Kazakhstani market. Moreover, it is not a certainty that an Ex Works mechanism will lead to lower prices in all cases, and the process for appealing price disputes is not yet clear.

An approach that would address these difficulties while aligning with international practice would be to use a smaller number of referent countries in the same region with similar demographics. It was not the underlying method of using a basket of referent countries that presented the risk, but the high number and the way it was overseen.

By comparison, Russia uses 22 countries; Azerbaijan 10; Ukraine 5 and Serbia 3; in all these cases, the countries are in Eurasia and the latter two are neighboring countries. By using a smaller number of referent countries, Kazakhstan could more easily verify the information provided by the suppliers.

The above applies to prescription medicines and medical devices that are reimbursable by the state. These will become more significant when mandatory social health insurance is introduced.

A separate issue is over-the-counter (OTC) medicines. While price regulation for prescription, patented medicines are common, very few countries - none in the OECD - regulate OTC medicines, with some exceptions for medicines that are reimbursable. AmCham would caution against introducing such price regulation, as it could force some drugs out of the market. On the other hand, price competition for non-patented medicines could provide a market mechanism to stimulate the type of local economic diversification sought by the government.

Opportunities for Efficiency

Current budget management does not make available multi-year procurement contracts. With some drugs, Kazakhstan could realize economies of scale with multi-year orders. In particular, many types of vaccines require lengthy preparation processes. Yet Kazakhstan has very precise demographic data on how many people will need vaccines and when the vaccines will be needed, thus allowing for multi-year orders.

Citizen Involvement

Healthcare is a fundamental part of national identity in many countries across the world. It is also an area that requires the entire society to be involved. The Red Crescent of Kazakhstan, an AmCham member, has two areas where it believes a partnership with the government could produce much-needed results.

The first area is blood banks. The Ministry of Health's blood-bank network works relatively well, but has some weaknesses. For example, blood is often collected by friends and family of a patient to replace the blood that person used. This leads to a higher percentage of contaminated blood than should otherwise be the case, as donors may be unlikely admit they have a contraindication. The Red Crescent suggests that it partner with the blood banks to establish a database of volunteer donors. Such an approach would ensure a more reliable supply of blood while also encouraging citizen responsibility, a stated goal of healthcare reform.

The second area is first-aid training. Responsibility levels of the population for their health is very low in Kazakhstan, which leads to a heavy burden on the healthcare system. Preparedness of the population to respond to crisis situations and the ability to provide timely first-aid can significantly reduce mortality and improve the quality of life of the affected.

The Red Crescent suggests partnering in teaching first-aid skills among key population demographics (railway and aviation staff, educational employees, security, catering, recreation, entertainment, and commercial workers) under government financing.

Recommendations

1. *Healthcare should be viewed from the perspective of the patient.*
Does the patient need to visit multiple doctors and offices to get treated, or are primary care teams (doctors, nurses) able to address issues during simple office visits?
This approach will help to reduce fragmentation in the delivery of services, generate efficiencies, and promote a holistic view of *health* rather than of diseases. Indicators such as avoidable hospitalizations, wait times, number of visits needed for the same episode of care, and change in the number of patients visiting doctors will reflect this patient-centric approach.
2. *Update actuarial tables to allow for strategic decision-making in procuring services and medicines.*
3. *Separate economic diversification goals from healthcare goals.*
The desire for innovative multinational companies to open joint ventures in Kazakhstan is understandable; however, Kazakhstan is a relatively small market for healthcare companies and the government needs to be realistic in understanding how they evaluate their investment decisions.
4. *Consider preferential financing to support public-private partnerships and similar goals.*
5. *Simplify market access for new drugs and devices. Decision-making should be made more transparent, and the multi-step process can be rationalized.*
6. *Return to drug pricing based on referent countries, as is the practice in most other countries.*
To manage corruption risk, select a smaller pool of countries that are similar to Kazakhstan and where data can be easily verified. Ex Works pricing for drugs was introduced to address corruption risk, but it is not clear that this will in fact be the effect, and it introduces a new set of problems for both suppliers and purchasers.
7. *Do not introduce price controls on over-the-counter medicines.*
This is not a practice in OECD countries and carries clear risks of some drugs becoming unavailable.
8. *Do not allow 'generic' versions of patented medicines onto the market.*
 - a. Such drugs should not be included in the Kazakhstan National Formulary.
 - b. In government-funded tenders (via SK-Pharmacy and others) specify both INN and indications; and verify that the supplier holds the legitimate patent or a license.
 - c. Review the use of orphan-drug rules to ensure they are not used as a backdoor to patent violation.
9. *Consider legislative changes that would allow for multi-year purchases - in particular for vaccines, where demographic data are well known.*
10. *Consider partnerships with NGOs, including the Red Crescent, that will promote citizen responsibility for public health and will introduce strategies proven throughout the world with positive effects on public health.*
11. *Engage AmCham and its member companies in dialogue.*
Consulting with companies responsible for the world's best healthcare innovations will bring perspectives and expertise that can help Kazakhstan meet its ambitious goals.

Conclusion

Kazakhstan has the potential to transform its healthcare system, but it needs to define a path that its citizens, health personnel, healthcare companies, charitable organizations and employers fully embrace. With this, they will be able to take on the responsibilities and burden-sharing that are rightly considered essential to a successful reform. But, this buy-in can only be achieved through increased communication and dialogue, so that these stakeholders believe that the reform takes into account what they need and what they can offer.

Kazakhstan will also need to increase its spending on healthcare if it is to reach OECD standards, and it will need to do this as efficiently as possible, to close the gaps that remain from the stagnation of the last years of the Soviet Union. Yes, technology is part of the answer, but positive changes to approaches and attitudes, both from healthcare providers and from patients, must also be supported.

AmCham and its member companies, who represent not only employers and healthcare providers, but also users of the healthcare system, share the sense of urgency and importance of healthcare reform, and they can assist in promoting the two-way communication, in achieving efficiencies and in introducing the cutting edge medicines and technologies that can help make it one of the world's greatest success stories in improving the welfare of its people.

AmCham is always ready to continue the excellent dialogue in the *Council to Improve the Investment Climate* to the Ministry of Health to allow for more detailed discussion of the Ministry's priorities and vision.

The American Chamber of Commerce in Kazakhstan thanks its Member Companies and the International Institutions that contributed to this White Paper, presented to the Government of Kazakhstan in July 2018.

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