

CHAPTER 7. TOWARD GREATER ACCESS TO PHARMACEUTICALS IN AZERBAIJAN

7.1 Introduction

Public expenditure on pharmaceuticals in Azerbaijan is one of the lowest in the region. As a share of total healthcare expenditures, however, it is one of the highest. This seeming inconsistency is due to the fact that a very large proportion of pharmaceutical purchases are made out-of-pocket. Healthcare expenditures in Azerbaijan as a percentage of GDP are the lowest in the region, as are expenditures on pharmaceuticals (see Table 7.1). However, the data do not fully account for formal and informal private spending on healthcare and pharmaceuticals.

The decline in the GDP in the 1990s, together with decreasing public expenditures on healthcare, resulted in households bearing an increasing amount of their healthcare expenditures out-of-pocket (OOP), including for pharmaceuticals. In a 2004 national representative sample survey, annual household OOP expenditures for medical goods and dispensed drugs was estimated at AZM 242,875 per capita, or approximately 70.7 percent of total OOP health expenditures per capita. The annual per capita payment for medicines procured outside of health service providers was estimated at AZM 19,763, or 31.9 percent of total hospital per capita expenditures.¹⁶³ These estimates should be viewed in the context of a general deterioration of health due to increases in communicable diseases, environmental pollution, stress related to economic difficulties and a lifestyle characterized by high levels of alcohol consumption and smoking—all of which increase the need for healthcare and pharmaceuticals.

Another study estimated that purchases of pharmaceuticals comprised almost 61 percent of total healthcare expenditures, with a considerable proportion of such purchases made out-of-pocket.¹⁶⁴ Using information from a pharmaceutical wholesale company that has a 5 percent market share, it can be estimated that total pharmaceutical sales on the Azeri market are between US\$120 and US\$150 million. These figures are higher than U.S. State Department estimates of about US\$80 million,¹⁶⁵ computed on the basis of official government estimates of US\$37 million, an allowance for underreporting of import and customs data, and black market estimates. Although the actual size of the Azeri pharmaceutical sector is difficult to fully ascertain, especially the ratio of public to private spending, the latter is thought to account for most expenditures on medicines.

¹⁶³ G&G Consulting, “Health Financing Study,” 2005.

¹⁶⁴ G&G Consulting, “Health Expenditure Analysis,” 2004.

¹⁶⁵ U.S. and Foreign Commercial Services and U.S. Department of State, “Market Snapshot: Pharmaceuticals Market in Azerbaijan,” <http://www.bisnis.doc.gov/bisnis/bisdoc/011012AZPharm.htm>, 2003.

Table 7.1 Healthcare and Pharmaceutical Expenditures in Selected Countries, 2004

Region	Country	Total expenditure on health as % GDP, 2001 (1)	Total pharmaceutical expenditure as % of total healthcare expenditure, 2000 (2)	Total US\$ expenditure on pharmaceuticals (per capita at exchange rate), 2000 (2)
European Union	Austria	8.0	17.3	323
	Estonia	5.5	22.3	49
	France	9.6	20.4	421
	Germany	10.8	13.6	328
	Ireland	6.5	10.6	168
	Italy	8.4	22.2	336
	Lithuania	6.0	20.0	39
	Netherlands	8.9	10.1	202
	Spain	7.5	17.7	186
Western Europe	Albania	3.7	16.5	8
	Bulgaria	4.8	22.0	16
	Turkey	5.0	28.0	58
Eastern European Region	Belarus	5.6	11.9	7
	Republic of Moldova	5.7	12.2	1
	Russian Federation	5.4	17.8	12
	Ukraine	4.3	17.8	5
Caucasus Region	Armenia	7.8	52.6	12
	Azerbaijan	1.6	7.8	2
	Georgia	3.6	39.1	8
Central Asian Region	Kazakhstan	3.1	8.4	5
	Kyrgyz Republic	4	39.9	5
	Tajikistan	3.3	13.4	1
	Turkmenistan	4.1	26.7	7
	Uzbekistan	3.6	7.6	2

Sources: (1) WHO, *World Health Report*, 2004; (2) WHO, *World Medicines Situation*, 2004.

Since independence, the pharmaceutical sector in Azerbaijan has undergone considerable changes—from severe shortages to a rapidly maturing and consolidating market. Immediately following independence, economic conditions across the CIS deteriorated considerably, more so in Azerbaijan due to armed conflict, declining production of goods and services, rampant inflation and massive population movements across and into the country. Consequently, public sector outlays for healthcare in general and pharmaceuticals in particular were greatly reduced. Furthermore, the breakup of the Soviet Union led to the dissolution of centralized pharmaceutical supply, regulation and distribution systems. The immediate impact in Azerbaijan was a severe shortage of drugs because the country had very limited pharmaceutical manufacturing capacity. Supply shortages, combined with liberalization of the market, led to a rapid increase in imported drugs to meet demand. Given low supply and high demand, drug prices consequently skyrocketed.

Privatization of the pharmaceutical sector in Azerbaijan began after the enactment of the Law on Pharmaceutical Activity in 1997. Private importers, wholesalers and pharmacies began to enter the market, and a wider range of drugs were imported that resulted in gradual withdrawal of the state in providing pharmaceuticals, limiting its involvement to regulation and quality control of the market. As a result, the availability of drug supplies began to gradually improve. At present, some 70 domestic and foreign companies are supplying the Azeri market with 3,000 mainly generic drugs. An influx of unregistered and counterfeit drugs, particularly from Russia, Turkey and India, means that the drug quality control system must be modernized and efforts to monitor the drug supply strengthened, both of which are critical steps in tackling the problem of counterfeit drugs in the country.

7.2 Supply of, Access to and Quality of Pharmaceuticals

Affordability of drugs is a major concern. Although a wide range of pharmaceutical products is, in principle, available on the market, these drugs are not necessarily affordable. Public funding allocations for drugs cover only minimal needs and are limited either to inpatient care or diseases with public health consequences, such as tuberculosis, malaria or other chronic diseases. As a result, the burden of paying for almost all outpatient drugs falls squarely on the patient. Even people who are supposedly eligible for free drugs are often unable to access them.

In 2000, per capita expenditure on pharmaceuticals in Azerbaijan was estimated at US\$2.0, the lowest ranking in the region, only slightly above the worldwide average of US\$1.1 among low-income countries.¹⁶⁶ Even Georgia, which has a lower per capita income than Azerbaijan, spent US\$8 per capita on pharmaceuticals that same year, the average for middle-income countries. Turkey, on the other hand, spent US\$58 per capita on pharmaceuticals during that same period (see Table 7.1). European Union countries spent significantly more per capita than the rest of the world, ranging from a low US\$39 by new EU member Lithuania to a high US\$421 by France. Azerbaijan is now working with international donors to improve both access to and rational use of drugs.

Most drugs are imported and remain expensive by local standards. Imports are estimated to account for at least 60 percent of the local drug market in Azerbaijan. The perception that imported products are of higher quality than those produced domestically or in neighboring countries drove the shift to imported products. After the Russian currency crisis in 1998 and the devaluation of the Azeri Manat, imports of West European drugs decreased because they became prohibitively expensive. Subsequently, the market shifted to low-price suppliers from India and Turkey. A large share of the current supply of pharmaceuticals also comes from Russia, Ukraine and Iran. Products that enjoy a reputation for quality, such as those from the USA, France, Germany and other European countries, are often able to maintain higher prices. A growing number of foreign pharmaceutical firms have a local presence, often represented by a physician who promotes their drugs.

¹⁶⁶ WHO, *World Medicines Situation*, 2004.

Domestic production in Azerbaijan remains limited. While there are nominally two production facilities in Azerbaijan, only one plant is currently in operation. The functioning plant, Azerpharm (Farmsintez), was established in 2000. Shares of the company are held by MOH and private Azeri, Turkish and Iranian interests. The MOH acts on behalf of the Azeri shares. The Turkish partners supply technology and equipment, while the Iranian partners provide bulk raw materials for production.

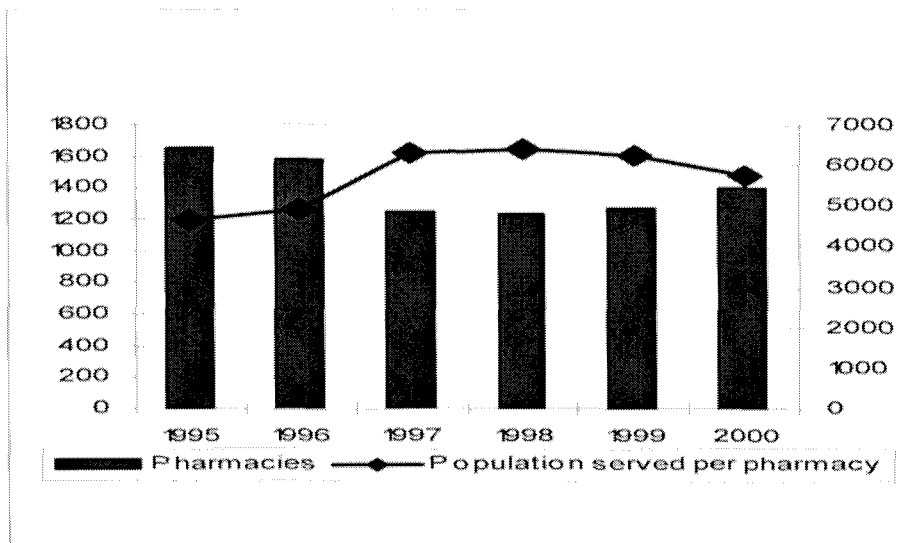
In its four manufacturing facilities, Farmsintez produces drugs in many formulations, including liquids, tablets, ointments and creams. The firm currently produces 86 generic products, some of which are well-known internationally, mostly in small volumes. None of these facilities is compliant with good manufacturing practices (GMP). Farmsintez sells its products mainly through the MOH and local wholesalers. The manufacturing facilities are currently operating at less than 25 percent of their capacity, with annual estimated sales of US\$450,000. The potential for export is limited as the company is not GMP-compliant. In addition, importation of expensive raw materials would make Azeri prices uncompetitive in international markets.

There is a large and unregulated informal market in pharmaceutical products in Azerbaijan. Sales of unregulated market traders are estimated to account for as much as 50 percent of market volume. Although several laws govern the import of pharmaceuticals and inspection of imports has improved, anecdotal evidence indicates that up to 70 percent of imports do not pass through customs or undergo inspection. Quality control has recently been instituted through the introduction of a “hologram seal of approval,” but pharmaceuticals without this seal are still widely available and distributed. The absence of the “hologram seal” is often explained by saying that retail drugs came from old stocks distributed prior to the new system, or that the seal was affixed only to the wholesale bulk package, not to retail packages. Thus, many drugs are easily available for purchase at numerous private outlets, but their quality is often dubious.

7.3 Distribution of Pharmaceuticals

Drug distribution in Azerbaijan was privatized for the most part following enactment of the Law on Pharmaceutical Activity in 1997. This law privatized most warehouse, distribution and retail pharmacy facilities in the country. During the Soviet era, state-owned wholesaling companies in Azerbaijan imported pharmaceuticals and distributed them to state-owned pharmacies. With most wholesale companies now transformed into private companies, these firms presently operate on a commercial basis independent of state control. There are an estimated 50 drug importers and/or wholesalers in the country.

Figure 7.1 Private Pharmacies in Azerbaijan, 1995–2000



Sources: SSC, 2002, as cited in Holley, Akhundov and Nolte, "Healthcare Systems in Transition," 2004; and World Bank, WDI, 2004.

Geographic access to pharmaceuticals is highly uneven. There are rural areas where drugs are not readily accessible simply because there are no pharmacies. However, most urban residents have good access to pharmacies. Outpatient drugs are purchased through a large number of private pharmacies, particularly in urban areas. Figure 7.1 shows that in 2000, there were an estimated 1,300 pharmacies in Azerbaijan. This is equal to just under 5,500 persons served per pharmacy as compared to the average in Western Europe of around 6,750 persons per pharmacy.¹⁶⁷

Numbers of pharmacies have continued to increase and there are now over 600 private pharmacies in Baku alone. Competition between pharmacies in Baku is so keen, especially in central areas, that pharmacies are sometimes located side by side. There are concerns that competition has driven trade in cheap, often counterfeit, drugs. Although it is likely that some pharmacies may fold because they are unable to compete, studies in other markets have shown that competition can bring quality improvements in the services provided by pharmacies, such as longer opening hours, home delivery, prescription monitoring and patient information programs.¹⁶⁸ In Baku, the positive effect of competition can be discerned in the modernization of more pharmacies run by professional staff.

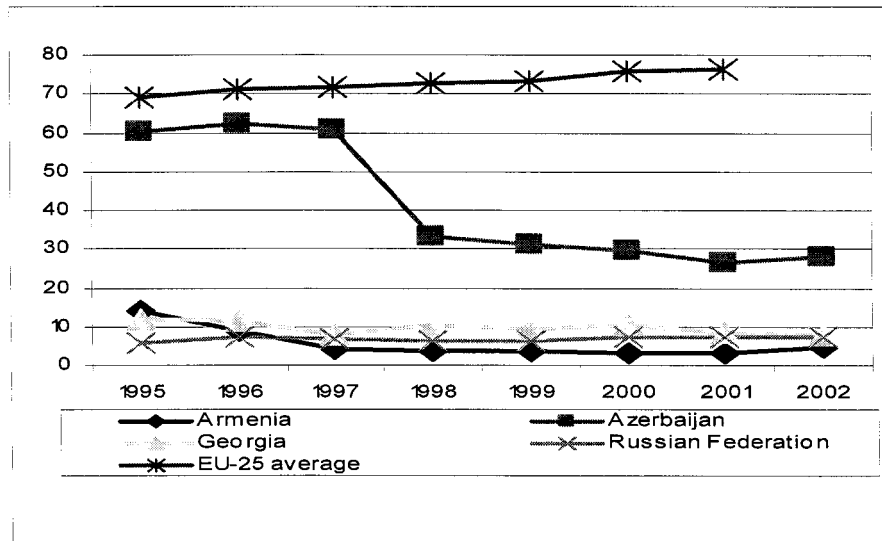
Some public pharmacies remain, mainly as part of the polyclinic of a given district. Such pharmacies are responsible for dispensing subsidized drugs to the underprivileged. Public pharmacies often have simple infrastructure (with open displays) and are managed

¹⁶⁷ WHO, "Health for All" database, 2005.

¹⁶⁸ Office of Fair Trading, *The Control of Entry Regulations and Retail Pharmacy Services in the UK*, Volume 2 (London: Office of Fair Trading, 2003).

by pharmacists who are reportedly properly qualified. There are also about five public warehouses for medicines, but these facilities are in poor condition and do not have proper stock management tools, save those located in Baku. Despite poor conditions, the distribution system continues to function with the support of MOH.

Figure 7.2 Pharmacists per 100,000 Population in Selected Countries, 2004



Source: WHO, "Health for All" database, 2004.

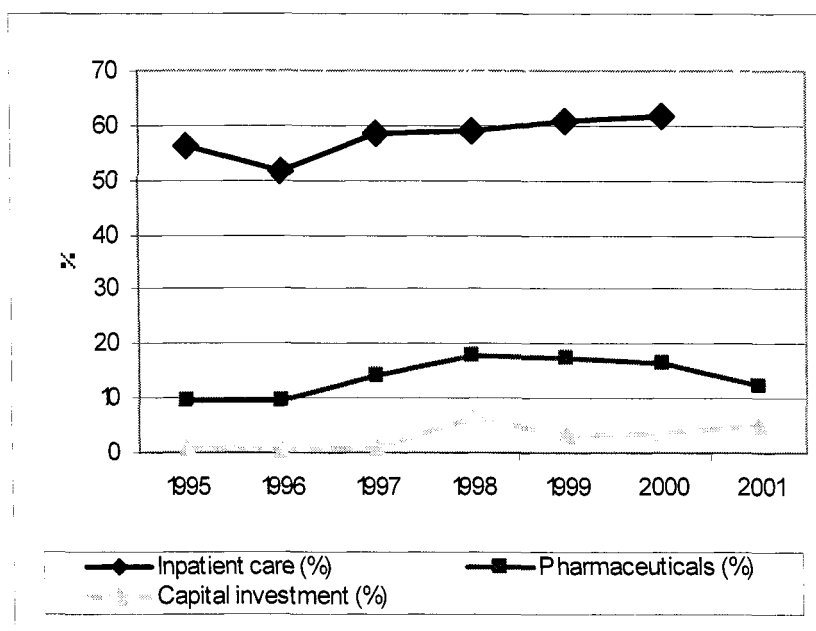
The number of pharmacists per 100,000 population in Azerbaijan is better than that of neighboring countries, including Russia, given the sizeable drop in the number of pharmacies resulting from privatization (see Figure 7.2). However, an area of concern is the potential shortage of hospital pharmacists, who are paid less than their colleagues in private pharmacies.

7.4 Financing

The burden of pharmaceutical financing has shifted to a great extent from the state to households. Public spending on pharmaceuticals is thought to account for just over 10 percent of all healthcare expenditures (see Figure 7.3). A similar breakdown exists at the district level, where expenditures of AZM 23.2 million in 2002 accounted for 13 percent of total district healthcare spending.¹⁶⁹ Although recent allocations for pharmaceuticals were estimated to represent about 20 percent of all public healthcare expenditures, given the current level of financing, it is likely that only a limited range of inpatient drugs and certain outpatient drugs for underprivileged groups are covered by public funds. This trend marks a significant shift away from full government pharmaceutical coverage for inpatient medicines and free or highly subsidized outpatient prescriptions in the FSU. Lower levels of public financing and higher drug prices have certainly affected access to needed medicines.

¹⁶⁹ G&G Consulting, "Health Expenditure Analysis," 2004.

**Figure 7.3 Composition of Healthcare Spending, 2004
(as % of total)**



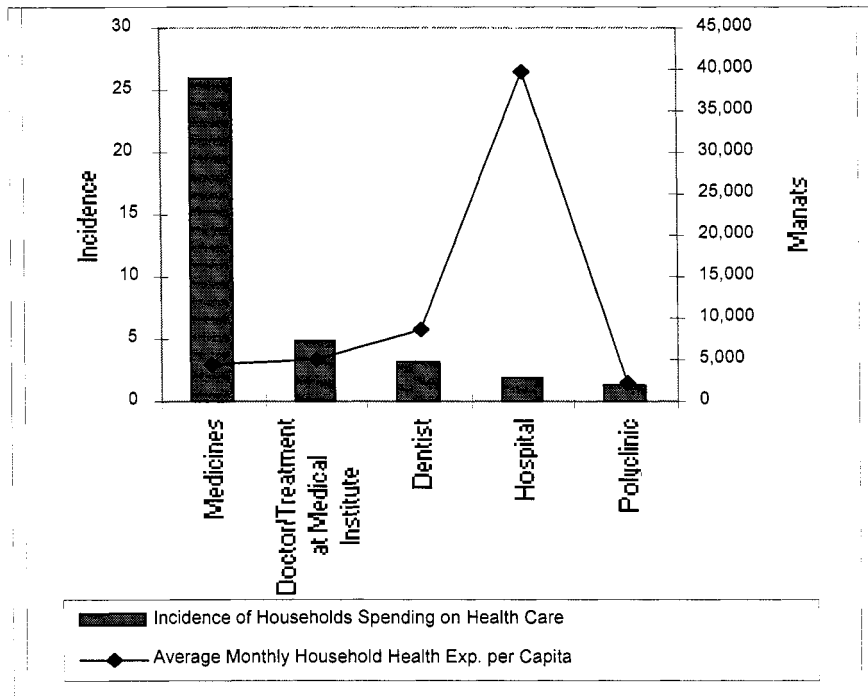
Source: Holley, Akhundov and Nolte, "Healthcare Systems in Transition," 2004.

Given current funding arrangements, historic expenditure patterns continue to determine current allocations, including those for pharmaceuticals. Hospitals often attempt to increase the amount requested for pharmaceuticals and other areas of expenditure, but little if any increase is seen from year to year. Most hospital budgets go to staff salaries and benefits. In some cases, even a portion of the meager budget allocation for pharmaceuticals is reallocated toward salaries. Patients are often requested to purchase the drugs they will need in hospitals out-of-pocket from private pharmacies. Although MOH does have a central supply system, there has been little effort to systematically and competitively leverage scale through bulk procurement of basic drugs. At present, such purchases are estimated to cover only about 6 to 8 percent of the hospital market.

The shortfall in public healthcare budgets has reduced the number of people eligible for public drug coverage, as well as the number of products covered. Although private pharmacies are supposed to supply drugs free to certain defined vulnerable groups, they rarely do so. Private pharmacies generally turn away subsidized patients because of delays in government reimbursement. Community-based health councils, moreover, determine which families are exempt, leading to large variations in their number. Some districts have been reluctant to identify too many exempt families so as not to spend too much money. Humanitarian donations played a role in meeting this demand, particularly during the early stages of the transition, but few such initiatives remain. Some rehabilitated primary-care facilities financed by donors have been stocked with basic drugs. However, given limited budgets, restocking these facilities will be difficult.

Due to current levels of public funding, patients currently pay for most or all of their pharmaceutical needs out-of-pocket. The 2002 Household Budget Survey of the State Statistical Committee estimated that pharmaceuticals were one of the main areas of out-of-pocket health expenditure.¹⁷⁰ According to the survey, almost one-quarter of all household expenditures on healthcare are for medicine. Although average per capita monthly household expenditures on medicines were less than expenditures in other areas of healthcare, the incidence of expenditures on medicines far exceeded that for other areas of treatment (see Figure 7.4). Of note, the richest Azeri households spend four times more per month on medicines than do the poorest households (see Figure 7.5). This finding indicates that there are wide disparities in households' ability to secure needed medicines. The need for affordable drugs thus continues to drive demand for counterfeit drugs, despite concerns about their quality.

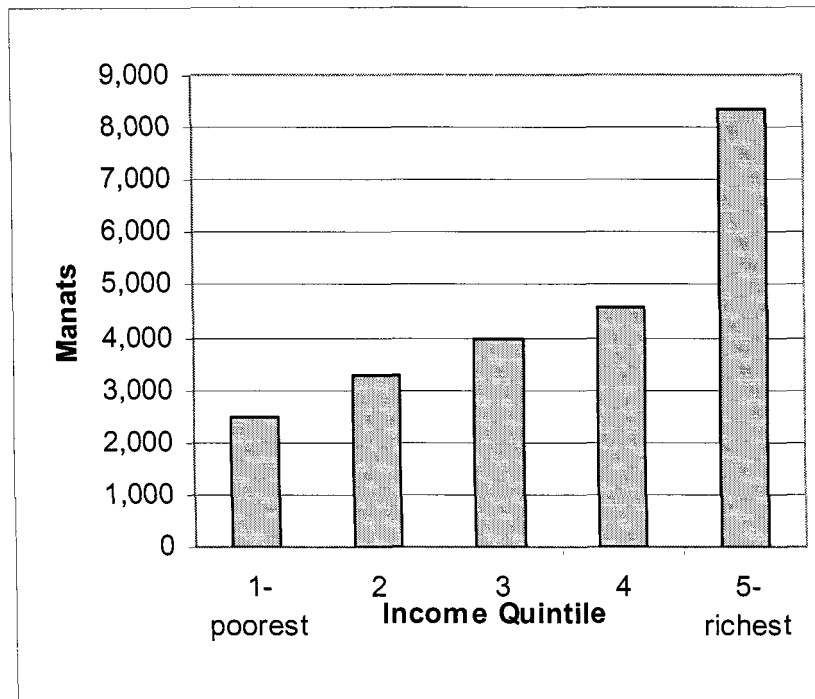
Figure 7.4 Household Spending on Medicines and Healthcare, 2002



Source: SSC, Household Budget Survey, 2002.

¹⁷⁰ World Bank, PA, 2003.

Figure 7.5 Average Monthly Household Expenditure on Medicines per Capita



Source: SSC, Household Budget Survey, 2002.

A more recent national sample survey carried out in 2004 reported similar trends in household incidence of pharmaceutical expenditures.¹⁷¹ Approximately 31.9 percent of OOP per capita expenditures for hospital treatment are for drugs procured outside of the providing facility. Annual per capita outpatient expenditures for prescribed and over-the-counter (OTC) medicines are approximately 52 percent of total outpatient expenditures.

An earlier study estimated that direct drug payments range from 46.2 to 49.8 percent of OOP health expenditures of households.¹⁷² The relatively high incidence of expenditure on pharmaceuticals by Azeri households seems consistent with the estimate of local experts that the current level of public coverage of pharmaceuticals is approximately 10 percent of demand.

7.5 Rational Drug Use (RDU)

Irrational prescribing of drugs continues to undermine the quality of healthcare in Azerbaijan. This practice is an inheritance of the former Soviet health system, in which all treatments were free and consultations created the expectation of a prescription. Anecdotal evidence points to a high number of prescribed products per visit, over-use and irrational prescribing of antibiotics and overuse of injections (for example, Vitamin C injections). Antibiotics are among the top-selling drugs in Azerbaijan, along with

¹⁷¹ G&G Consulting, "Health Financing Study," 2005.

¹⁷² G&G Consulting, "Health Expenditures Analysis," 2004.

analgesics, cardiovascular drugs and gastrointestinal products.¹⁷³ This trend raises concerns about antibiotic resistance, as well as the cost and safety of drugs that are being prescribed (oral formulations are not only safer, but less expensive than injectable formulations).

While there have been limited efforts to promote rational prescribing practices among physicians, many factors inhibit wider adoption of these practices. The rapid influx of previously unavailable medicines has, moreover, impeded the development of rational prescribing because physicians often lack independent, unbiased information needed to prescribe rationally. As a result, physicians often have to rely on the manufacturers for information.

Since many drugs are available over-the-counter, people often bypass physicians and go directly to the pharmacy. Potent pharmaceuticals, including antibiotics, can be purchased without a prescription. Drugs available by prescription in Europe are often available over-the-counter in a number of CIS countries. Even if a requirement stipulates that a drug be dispensed only by physician prescription, the requirement may not be strictly enforced. Patients, for example, often go directly to a pharmacist in order to avoid paying a physician consultation fee.

The development of drug monitoring and evaluation systems for both prescribing and dispensing is essential to improve rational drug use. Physicians, however, lack the tools for adequate prescribing: guidelines, a formulary, recent and unbiased drug information, plus other supporting tools. Furthermore, health centers often reflect the preferences of their chief physician rather than basing prescriptions on evidence-based practice. Rational drug use training of primary-care physicians between 2002 and 2004 reportedly led to better compliance with modern prescribing principles, compared to that of physicians who did not undergo such training.

Retraining of physicians in some districts has led to some degree of success, particularly among physicians working in hospitals. Those working in remote areas with little access to drugs often continue to write extensive prescriptions to be fulfilled in private pharmacies. A multifaceted approach is needed to combat such practices, including formulation of a standard drug list, revision of treatment standards and education of physicians and patients. Progress in this area will greatly benefit the poor, who cannot afford the cost of extra prescriptions. Altering these practices will also improve the quality of healthcare by reducing the number of unnecessary drugs. However, such efforts will require a systematic, coordinated process at the national level.

With the support of the World Health Organization (WHO) and the World Bank, ***MOH has started to develop treatment protocols for selected common diseases, linked to modifications of the essential drug list.*** At present, the only standardized drug list is that used for patients who are eligible for free care. Even that list contains a range of drugs that do not meet WHO standards. An essential drug list (EDL) is being finalized by MOH and may be adopted before the end of 2005. A modern national drug formulary

¹⁷³ U.S. and Foreign Commercial Services, "Market Snapshot," 2003.

that uses internationally recognized drug classifications (ATC/DDD) is also expected to be adopted, together with revised standard treatment protocols (STP).

Even with such efforts, additional strategies will still be needed. Addressing the problem of irrational drug use requires well-defined communication with the general public to address patient expectations. The formulary is a useful source of information and can become a useful tool in prescribing practices and training. Based on available information, a drug utilization study could be conducted to create the basis for continual monitoring of prescribing practices. It is a well-known fact that confronting physicians with their own prescribing data is one of the most effective tools in changing prescribing patterns.

7.6 Legal and Regulatory Framework

The National Law on Pharmaceutical Activity of 1997 is the main legislation related to the pharmaceutical sector in Azerbaijan. This law provides the legal basis for registration, licensing and renewals, and a code of practice for the Central Drug Control Laboratory (CDCL). Certain other technical details are defined by the MOH on an ongoing basis.

Quality control and assurance need to be further strengthened. Despite the 1997 law, the process of developing a national drug policy has only commenced recently. Poor regulatory monitoring and law enforcement contributes to the problems of drug quality and the availability of unregistered drugs. In the Soviet Union, product registration and quality control was undertaken by Moscow. Equivalent institutions in Azerbaijan are therefore newly established. The country has taken steps to bring its national drug legislation and market authorization process in line with internationally accepted standards. However, the situation is complicated by an ineffective judicial system and limited financial resources, which lead to inadequate salaries for enforcement staff. Concerns over product quality and safety extend to the locations where drugs are sold. It is not uncommon for drugs to be traded in unlicensed pharmacies, where prescription requirements are often overlooked.

The Central Drug Control Laboratory of Azerbaijan was extensively modernized in 2003 and now has four functional units for: (i) medicine quality control; (ii) examination of medicines; (iii) food safety; and (iv) sanitary and epidemiological surveillance. Drug registration takes approximately 36 months for new drugs; registrations must be renewed every 5 years. If a drug is the generic equivalent of one already on the market and is registered in Western Europe, a copy of the existing registration certificate can be used. The cost of registering a drug is US\$500. As a way to combat corruption, fees were increased in 2003 to increase staff salaries. However, there is still scope for strengthening the inspection function.

With the rising number of drugs in the country, it has been a challenge for the CDCL to keep pace with drug registration. At the end of 2004, there were approximately 2,602 drugs officially registered. However, anecdotal evidence suggests that almost 50 percent

of current supply remains outside of legal channels. This finding raises considerable concern about the quality and effectiveness of the drug supply.

Experts from MOH and the AMU's Department of Pharmacology have concluded that it is imperative to improve the present system of drug registration to make it understandable and effective. The new National Drug Register will systematize the use of International Non-proprietary Names (INN) for pharmaceuticals and differentiate brand names from INN, as well as generic drugs from brand products.

To improve public confidence in the quality of drugs, the CDCL has introduced several measures to tackle unregistered drugs sold on the market. First, it has instituted a requirement for testing each batch of drugs put on the market. Hologram stickers are affixed to the packages of drugs that pass inspection. The idea is to indicate to the patient that the drug has been approved by quality control. In theory, these stickers are supposed to be very difficult to copy, but CDCL also has introduced a hotline that enables patients to call and check whether a given batch number has passed quality control. Since their introduction, these efforts have been responsible for stopping some of the trade in counterfeit products. Although these are important steps in tackling counterfeit drugs, the magnitude of the problem and the insufficient capacity of the CDCL make it unlikely that CDCL adequately controls the entire market.

7.7 Key Issues, Options and Recommendations

While Azerbaijan appears to spend a low amount on drugs, expenditures on pharmaceuticals constitute a significant percentage of all health expenditures. This discrepancy can partly be explained by relatively low wages in the healthcare system, relative to other types of expenditures, including pharmaceuticals, which are influenced by international prices. Most important, insufficient evidence exists to assess whether the amounts spent on pharmaceuticals buy good value and produce better health. Further economic studies are needed to document the extent to which drug use is appropriate, safe and cost-effective in the country.

On the production side, availability of pharmaceuticals has greatly improved, and the market has matured in terms of pricing, importation, wholesale, distribution, retail and quality control functions. However, there is a need for further action by the state to improve access to, and the safety and quality of, pharmaceuticals, as well as the appropriate use of drugs. Based on available data and dialogue with key stakeholders in the healthcare sector, the following recommendations are offered:

Azerbaijan needs a comprehensive national drug policy, the objective of which would be to improve the population's access to high-quality, safe and effective drugs in accordance with the burden of disease and the priorities of the national health sector. Areas of emphasis include pricing of brand and generic drugs, an essential drug list and standard treatment protocols for most common diseases.

Such a policy document should review progress to date on legislation and regulation, identify areas where further legislation and regulation is needed, as well as weaknesses in existing institutional and human resources for enforcement, quality assurance and control. More specifically, such a policy document should: (i) maintain and improve the quality, safety and efficiency of pharmaceuticals production in the country; (ii) establish efficient pricing and reimbursement policies; (iii) secure the uninterrupted supply of and access to drugs in critical therapeutic classes in accordance with disease prevalence, morbidity rates and available financial resources; and (iv) build a system for the rational use of medications.

Crucial goals include the pricing of brand and generic drugs, creation of an essential drug list and standard treatment protocols for most common diseases. Present efforts to develop and adopt an EDL suitable to Azerbaijan should be pursued to completion. In addition to an EDL, work on a national drug formulary and standardized treatment protocols (STP), together with a program for rational drug use (RDU), should be completed as expeditiously as possible. Expansion of STPs to cover additional areas should be on the immediate horizon, using present momentum to update the body of medical knowledge in the country. Ongoing work to improve the National Drug Register must be maintained to ensure systematic documentation that meets international standards. Training (pre and in-service) for all practitioners also needs to be conducted on a regular basis. Most importantly, a public education and information campaign should be carried out on the EDL, STPs and RDU.

Quality control and assurance need to be further strengthened. Despite a great deal of progress, especially with regard to licensing and the use of holograms, good manufacturing practices and good laboratory practices (GLP) in the manufacture and testing of both imported and locally produced drugs need to be introduced. Effective law enforcement to prevent importation or manufacturing of counterfeit or low-quality drugs should be scaled up. All these initiatives require significant investment in human resource development, as well as in production and testing facilities, not to mention the education of the general public.

Affordability of drugs can be improved under current circumstances. While the adoption of an EDL would be a step in the right direction, the government also needs to review the pricing of drugs on the EDL and its own payment and reimbursement policies so as to better target the poor and chronically ill. These changes would lead to the revision of state budgetary allocations for pharmaceuticals procurement. Targeting mechanisms used for social assistance could also be used for this purpose. Another method of potential cost containment is for the state to become an active bulk purchaser of, at the very least, drugs used in public facilities or distributed free (or at low cost) to eligible patients. Albania introduced precisely such a mechanism, resulting in lower prices and a higher quality of publicly procured drugs.

Appropriate use of drugs begins with good prescribing practices of physicians. While the introduction of STP would be a step in the right direction, it is unrealistic to expect that all medical practice could be covered by such protocols. While a more holistic

family medicine model is likely to increase time spent with patients, and consequently decrease both the number of prescriptions and the number of drugs per prescription, in-service physician training could, in the short run, result in more appropriate prescribing, as seen in pilot districts of the World Bank-financed health project in the country. Current training efforts must be, however, scaled up considerably.

A monitoring and evaluation system (M&E) is urgently needed. Admittedly, the amount, reliability and validity of data on pharmaceuticals remain very limited for sound policymaking and regulation in a sector known for its dynamism, private-sector involvement and consequences for health and safety. In its ever increasing stewardship role, MOH should build its own M&E system to collect timely and accurate data on the production, importation, distribution, pricing, quality control and retailing of pharmaceutical products, as well as the prescribing patterns of providers. In addition, feedback mechanisms should be put in place, such as the Central Drug Control Laboratory hotline for user complaints, to improve the quality of pharmaceuticals sold in the country.