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:** Ukrainian, Russian and English
- **Link:** [http://zakon.rada.gov.ua](http://zakon.rada.gov.ua)
- **Nature:** Official site of the Ukrainian government
- **Organisation responsible for the website:** The government of Ukraine

**Legal UHC start date**
- 1992

**Source:**

**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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Ukraine
HIT: 2015 - Lekhan VN, Rudiy VM, Shevchenko MV, Nitzan Kaluski D, Richardson E.
HSPM Members:
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Ukraine: Regulation

2.8 Regulation

2.8.1 Regulation and governance of third-party payers

Most health services are provided through government-owned health care facilities, and the relationship between purchasers and providers remains integrated, as it was in the Semashko system (see section 3.3.4). Different levels of government act as agents that ensure the maintenance of health care facilities within the limits of strict line-item budgets (see section 3.7). Health care facilities therefore do not generally have autonomy in managerial and financial decision-making. Although the Law on public procurement of goods, works and services was passed in February 2000 to regulate the purchase of health services with public funds on a contractual basis from both public and private providers, in practice this law has not been fully implemented (Lekhan & Rudiy, 2007). Since 2013, as part of the health reform programme, contractual relations have begun to be introduced in the primary care system in the pilot regions; however, these agreements are still more of a formality than a regulatory instrument as there are inadequate mechanisms for their enforcement (see section 3.3.4). Elsewhere in the country, the health system continues to function on the basis of hierarchical relations between the state (as third-party payer) and directly subordinated local authorities (as state property) and the public providers of health services.

2.8.2 Regulation and governance of providers

The public providers, which provide most of the population’s health services, are budgetary institutions financed on the basis of itemized estimates of expenditure agreed by the higher authorities. This conditions the very limited rights of public providers to make independent managerial and financial decisions, as does the compulsory use of strict Ministry of Health normative planning structures. At the same time, the Ministry of Health has been trying to increase the autonomy of providers. The aforementioned pilot regions have trialled reimbursement according to just two codes (ongoing and capital expenditure), since 2013 for primary care, and since 2014 for emergency and secondary care (see section 3.7.1). In one of the pilot reform regions (Kyiv) the providers have been changed from publicly owned health care facilities (providing both primary and secondary/specialist care) to communal non-commercial health enterprises.

State regulation of health care providers is concentrated at the national level, with few regulatory activities under the authority of local government. The Ministry of Health develops and approves state quality standards and clinical protocols, and is responsible for the organization and implementation of the mandatory accreditation of health care facilities and the issuing of licences to legal entities and individuals engaged in the delivery of medical services or the production and sale of pharmaceuticals and medical equipment (Lekhan & Rudiy, 2007). Accreditation was introduced on 15 July 1997 by Cabinet of Ministers Decree No. 765, On approving the procedure of state accreditation of a health facility, and is mandatory for all facilities regardless of their form of ownership. Assessment of the first stage of accreditation indicated that it has led to some improvement in material and technical resources, the qualification of medical staff and the quality of care. At present there are 27 accreditation commissions in Ukraine in the regional administrations (Lekhan & Rudiy, 2007). The accreditation process initiated the creation of preconditions for the realization of patients’ rights to medical care of adequate quality. However, the process has gradually become a formality and it has no real impact on the quality of care.

Public and private health care providers (individuals and legal entities) are licensed under the Law on licensing of specific types of economic activities, No. 1775-14 (2000) and a joint order of the State Committee of Ukraine for Regulatory Policy and Entrepreneurship and the Ministry of Health as of 16 February 2001, No. 38/63 On licensing conditions for economic activity relating to medical practice (Lekhan & Rudiy, 2007). The legislation is designed to ensure that professional staff and providers achieve minimum standards of competence and meet function-specific requirements regarding sanitation and safety, and technical standards of equipment. The licensing of medical practice has not assured the quality of health care. Many health care facilities, especially in rural areas, face severe structural problems; many buildings have become dilapidated, with equipment that is outmoded and in poor condition. Some of the
reasons behind this are the lack of modern standards for material and technical support, as well as a very liberal form of licensing for state and community health care facilities, which usually manage to keep their historically established range of services.

In order to deregulate commercial activities, from 2011 the process of getting a licence for enterprises has been gradually simplified by the introduction of a licence to practise medicine, as in other fields. This is reflected in the new licensing conditions for private medical practices. It was assumed that deregulation would be combined with the responsibility for the accuracy of the data being firmly with the licensee, but this mechanism still has problems.

2.8.3 Registration and planning of human resources

The Ministry of Health establishes the requirements for professional staff; for the training and development of health and pharmaceutical workers; uniform qualification standards for people engaged in medical or pharmaceutical activities; the list of medical specializations; and the classification of types of health care facility. Practising doctors are subject to recertification every five years, but there is no system of registration for doctors.

Current practices in human resource planning and management of the state-run health system do not follow a coherent model or correspond to organizational goals. Overall, the current system lacks any coherent approach to ensuring appropriate levels of health care workers. Staffing levels for outpatient care providers are determined according to norms approved by the Ministry of Health (see section 2.5) and the use of rigid standards provides few opportunities for effective management at facility level. At the time of writing, the Ministry of Health was in the process of developing new approaches to norm-setting for the workload of health care workers, which are expected to fundamentally change the approach to norm-setting around both the overall number of health care workers required as well as how many are needed for different specialties.

2.8.4 Regulation and governance of pharmaceuticals

The main regulatory functions in pharmaceuticals are currently split between two bodies: the State Expert Centre (until 27 September 2010 called the State Pharmacological Centre) and the State Administration of Ukraine on Medicinal Products (SAUMP), both of which are under the Ministry of Health. The State Expert Centre is a specialized organization which covers: the registration and quality control of pharmaceutical products; preclinical, clinical and postclinical research; monitoring adverse drug reactions (although adverse drug reaction reporting by physicians is very low); developing the list of pharmaceuticals that may be bought over the counter and submitting it for approval to the Ministry of Health; authorizing the import and use of unregistered pharmaceuticals; and advising on the content of the National Drug Formulary. Moreover, the Centre has the task of standardizing medical services, including pharmaceutical services. The State Expert Centre is completely funded through fees and charges for services, with no contribution from the state budget.

According to Article 9 of the Law on medicines, drugs are permitted for use in Ukraine after registration by the state (No. 123/96BP, 4 April 1996). To ensure the quality and safety of pharmaceuticals, the registration process requires the presentation of preclinical examinations and clinical trial results. From 2008, the registration process for generics also requires proof of their bioequivalence to their brand-name counterpart. State registration of medicinal products is carried out by the State Expert Centre on the basis of a submitted application, which, since 2014, has included a good manufacturing practice (GMP) certificate along with a plethora of other specific information. Upon registration, the applicant receives a certificate that states the term for which the drug is licensed for use in Ukraine. According to the Ukraine National Register of Medicines, as of 12 May 2014, there were 12 811 medicines registered, including 3673 domestic (29%) and 9138 foreign (71%) products. In the structure of retail sales by value the market is dominated by imported medicines but by volume domestic medicines predominate (see section 5.6).

Ukrainian law provides for intellectual property protection for the developers of medicines. A state registration applicant must provide a patent copy or a licence and letter indicating that the patentee’s rights are not violated by registration. Moreover, the Law on pharmaceuticals, which was passed when Ukraine joined the WTO (with several amendments in 2006–2007), prohibits the registration of generics using registration data from another pharmaceutical for a period of five years, regardless of the lifetime of the
patent. In linking the registration of generics to the expiration of a patent and giving a five-year exclusive right to the original brand name, Ukraine undertook commitments that are quite stringent in comparison with the WTO and Trade-Related Aspects of Intellectual Property Rights (TRIPS) requirements, and contradictory to the Bolar Provision, which allows manufacturers of generics to submit their products for regulatory approval before the expiry of a patented intervention. Implementation of these commitments may make pharmaceuticals less accessible to the population and create problems for the pharmaceutical industry of Ukraine and therefore for the country (Polyakova, 2006; Sur, 2006).

The SAUMP (previously the State Pharmaceuticals Quality Control Inspectorate) is responsible for quality control once drugs are on the market and it has a network of 27 laboratories across the country to facilitate this; all have completed sector certification and comply with ISO 17025. The SAUMP Central Laboratory has completed the WHO Prequalification Programme, is accredited with the European Directorate for the Quality of Medicines (EDQM) and included in the Europe-wide General European OMCL (official medicines control laboratories) Network (GEON). Moreover, since 2013, Ukraine has been party to the European Pharmacopoeia (as per the Law on the ratification of the Convention on the development of a European Pharmacopoeia as amended by its protocol, No. 5441-VI, 16 October 2012) and, since 2011, SAUMP has been a member of both the Pharmaceutical Inspection Convention and the Pharmaceutical Inspection Cooperation Scheme (PIC/S). GMP inspection, as well as the inspection of pharmacies and distributors, is also the responsibility of SAUMP and, as of 2009, the licensing of production, distribution and retail sales has also fallen under its remit. There is no difference in the legal provisions for the licensing of public and private pharmacies (WHO, 2013). Wholesalers and distributors are required to comply with good distributing practices. Since 15 February 2013, it has been illegal to put on sale any pharmaceutical product that has not been manufactured in compliance with GMP.

Ukraine’s Law on medicines was amended on 5 September 2014, adding a category of products subject to simplified marketing authorization procedures. The new procedure applies to medicinal products that are intended to treat TB, HIV/AIDS, cancer and rare (orphan) diseases. It authorizes fast-track registration for medications that have been approved by competent authorities of the United States of America, Swiss Confederation, Japan, Australia, New Zealand, Canada, the EU or Israel (countries with “high regulatory standards”).

The advertising of prescription medicines direct to the general public is prohibited, but this ban is frequently violated. There are also guidelines for the promotion and advertising of over-the-counter medicines. People purchase pharmaceuticals over the Internet, which is illegal; however, this is not widespread, because of relatively limited access to the Internet nationwide.

In Ukraine there is a negative list of 3430 medicines that can be sold without a prescription; by default, all other medicines are nominally prescription-only. Around a third of drugs dispensed in Ukraine between 2004 and 2013 were retail prescriptions for privileged categories (people belonging to disadvantaged or vulnerable populations, and people with socially significant or especially serious illnesses). For these beneficiaries, medicines included on the list approved by the government are dispensed free or with a discount. The costs associated with subsidized drug provision account for 3% of the total government expenditure on pharmaceuticals, but in practice beneficiaries often still need to pay out of pocket for medications they are prescribed. As most pharmaceuticals are purchased by either outpatients or inpatients, the scope for influencing prescribing patterns is rather limited and is further hampered by the de facto liberal pharmacy dispensing procedures (see section 5.6). A list of prescription-only drugs has been developed by the Ministry of Health, but most of these can nonetheless be bought over the counter. At the same time, pharmacies do maintain strict controls on the supply of psychotropic drugs and hormonal preparations, even though many others, such as antibiotics, can usually be bought without a prescription.

Clinical protocols can have some influence on prescribing patterns as long as they contain a very clear definition of the medical indications for the use of a specific drug. There is no national programme promoting generic drugs. Pharmaceutical companies have a significant influence on prescribing patterns: they operate aggressive marketing policies; actively advertise pharmaceuticals in the mass media; hold free seminars for medical specialists; and reward doctors who prescribe their products (Lekhan, Rudly & Richardson, 2010). There is a high level of over-prescription among physicians, who often prescribe expensive brand-name pharmaceuticals instead of less expensive generics and, in certain cases, disregard rational prescribing policies in favour of more tailored approaches (Bazylevych, 2009). In practice, doctors only prescribe generic drugs from the National Essential Drugs List to patients who are
exempted from co-payments or who pay reduced prices for pharmaceuticals, which the patient then obtains from their local community pharmacy (see section 5.6). Pharmacists also offer their customers substitutes for indicated medications without consulting the prescribing physician and some will reward physicians who advise their patients to choose a particular treatment (Richardson, Sautenkov & Bolokhovets, 2014).

In order to improve pharmaceutical provision, a national programme was developed for 2004–2010, which outlined the selection of safe and efficient pharmaceuticals using pharmaco-economic analysis (Cabinet of Ministers Decree No. 1162, 25 July 2003). The programme also introduced a formulary-based drug procurement system to improve tender procedures for state purchases of medications and to identify state priorities for pharmaceutical purchasing. The formulary-based system was designed to improve the quality of treatment and provide clinicians with access to information on the use of pharmaceuticals registered in Ukraine (their pharmacological properties, contraindications and distribution methods). The first National Drug Formulary of Ukraine for the supply of pharmaceuticals in health care facilities was published in 2009 and the sixth edition was published in 2014 (Ministerial Order No. 252, 8 April 2014). The programme also introduced the state registration of wholesale prices, as well as the introduction of appropriate laboratory, clinical, industrial and distribution practices based on such standards as GMP and good laboratory practice (GLP). A list of essential pharmaceuticals and medical devices was approved in accordance with the programme.

In 2012, the Council for National Security and Defence noted problems with meeting the needs of the population, government and health care facilities for medicines of good quality in the appropriate assortment, and the lack of any effective mechanism to counter the production and circulation of counterfeit drugs in the country (Decision of 25 May 2012, implemented by Presidential Order No. 526/2012 of 30 August 2012). It was therefore decided that it was necessary to make it mandatory for the state to: register the bioequivalence, therapeutic efficacy and cost–effectiveness of generic medicines; coordinate actions to combat fake and substandard medicines; and introduce a modern system of price controls using reference pricing or similar. As a result, a raft of legislative acts aimed at increasing the administrative and criminal penalty for the falsification or supply of fake medicines in the country and strengthening the capacity for monitoring imports was introduced. On 20 October 2014, with the aim of bringing procedures for the registration of pharmaceuticals into line with EU standards, the government introduced amendments to the Law on medicines (No. 1707-VII, 20 October 2014). However, this will not bring legislation into full alignment with EU Directive 2001/83/EC and this could lead to the appearance of substandard medicines on the market in Ukraine.

Price regulation for pharmaceuticals in Ukraine is based on the Law on prices and price regulation. The main direct mechanism of state price regulation was delegated to regional authorities by government decree in 1996 and consists of establishing maximum retail surcharges for pharmaceuticals and medical devices. Decentralized regulation, however, resulted in substantial regional differences in retail surcharges, as well as in wholesale and retail prices for pharmaceuticals. Sometimes the prices differ by two to three times, even in the same region (Lekhan, Rudý & Richardson, 2010). Prior to 2008, the list of medicines subject to state price regulation included 149 international nonproprietary names of medicines from various clinical and pharmacological groups that made up 21% of the Essential Drugs List. The Cabinet of Ministers Decree on amendments to certain decrees of the Cabinet of Ministers (No. 1499, 16 November 2001) established a maximum limit of retail surcharges at the national level for these pharmaceuticals: 35% of the manufacturer’s wholesale price (customs cost) distributed through the pharmacy network; and 10% for products that are purchased by publicly owned health care facilities with funds allocated from the budget.

Since the beginning of the global financial crisis in 2008, pharmaceutical prices have increased considerably (by 40–70%), largely as a result of currency devaluation. To stabilize the situation in the pharmaceutical market, the government adopted a number of potential solutions to curb rising pharmaceutical prices by significantly expanding the list of pharmaceuticals subject to state price regulation to cover almost the entire Essential Medicines List – 903 generic drugs (or 85% of all registered drugs in Ukraine). The mark-up limits were set at no more than 10% of wholesale prices and 25% of retail price; for drugs purchased through the budget the mark-up limit was set at 10% of wholesale and 10% of retail price, according to Cabinet of Ministers Decree No. 955 of 17 October 2008, On measures to stabilize the price of medicines. This approach reduced the range of medicines available in pharmacies, pushed up prices and, as a consequence, increased social tension. These moves were also met with
resistance from the pharmaceutical industry, which argued that they faced bankruptcy. The government reacted by softening the price controls by taking currency fluctuations into account in Cabinet of Ministers Decree No. 333 of 25 March 2009, On the issue of state price controls on medicines. This was later transformed into a mechanism for controlling the wholesale prices for medicines purchased through the state and local budgets by the Cabinet of Ministers Decree No. 1012 of 1 November 2010, On the wholesale and retail prices for medicines bought through national and local state budgets.

Since 2012, a pilot project which introduced state price regulation for essential antihypertensive medications, using reference pricing mechanisms and reimbursement, has been running in accordance with a Cabinet of Ministers Decree (No. 340, 25 April 2012). All pharmaceuticals registered as antihypertensives are divided into three groups: those reimbursed at 90% of the reference price; those reimbursed at up to 90%; and those that are not reimbursed. The medicines covered in this pilot project are all generics manufactured in compliance with GMP and are priced at or below the maximum wholesale price level. Under this pilot project, prescribed antihypertensive medicines are dispensed by health care facilities and pharmacies listed by the regional health authorities. The patient then pays the difference between the actual retail price and the reference price as approved by the Ministry of Health. The pharmacy sends the record of subsidized drugs dispensed in one month under the scheme and they are reimbursed from a subvention from the state budget, which is held in the local budget. However, these measures did not control retail prices, which have increased above the rate of inflation. In 2012, the antihypertensives budget was US$ 5 million and in 2013 it was US$ 24 million. The scheme did reduce the price of antihypertensive drugs on the market by 9.3% and increased consumption by 24%, primarily because it was the cheaper generics produced locally that were reimbursed. However, locally produced generics account for only 31% of those antihypertensives dispensed, which is much lower than in other European countries. The Parliamentary Committee on Health Care was highly critical of the pilot project as it did not reimburse the full cost of the drugs (Decision No. 04-26-4-31.3/1, On the realization of a pilot project to introduce state regulation of pharmaceutical prices for people with hypertension).

Prices in the pharmaceuticals market have stabilized somewhat, but the government system for price controls remains an inefficient aspect of the pharmaceuticals supply chain. There are four price control lists: the National List (Government Resolution of 25 March 2009, No. 333); the list of drugs that can be purchased through local or state budgets (Government Resolution of 5 September 1996, No. 1071); the mandatory minimum range of socially important pharmaceuticals and medical products (Order of Ministry of Health No. 1000 of 29 December 2011); and the list of drugs covered by the pilot project on hypertension (Government Resolution of 25 April 2012, No. 340). Just the administration of so many lists, given that there is a significant amount of duplication, leads to additional resource costs to the state regulatory bodies and suppliers, which are then passed on through higher prices. Also, the declared price system (Government Resolution of 13 August 2012, No. 794), provides formal declaration procedures for the manufacturers/importers, but at the same time accurate and objective information on the prices declared by the state are not checked. The state control of compliance with the mandated mark-up levels is ineffective where as much as 76% of the cost of a medicine goes directly to the manufacturer/importer.

A more indirect method of price regulation was the introduction of certain tax privileges. For example, sales of pharmaceuticals and medical devices registered in Ukraine used to be exempt from value added tax (VAT). However, in 2014, in connection with the worsening economic situation in Ukraine, emergency measures introducing 7% VAT on pharmaceuticals and medical products were brought in (Law on preventing financial catastrophe and preparing the foundations for economic growth in Ukraine, No. 1166-VII, 27 March 2014). This once again led to price increases and reduced access to pharmaceuticals (see section 5.6).

2.8.5 Regulation of medical devices and aids

There is no licensing system for medical equipment in Ukraine, but according to the Cabinet of Ministers Decree No. 1497, issued 9 November 2004, On approving the order of state registration of medical equipment and devices, as amended by Cabinet of Ministers Decree (No. 548, issued 20 June 2012), all domestic and imported medical equipment and devices are subject to mandatory state registration by SAUMP. Registration is based on a review of the appropriate set of documents presented by an applicant – an individual or a legal entity responsible for the production, safety and effectiveness of medical devices. The applicant takes part in choosing the appropriate agencies to review the documents. Based on the outcome of this review, the State Expert Centre may require the medical equipment to be tested before
registration.

2.8.6 Regulation of capital investment

There is only minimal budgetary financing of capital costs in the state health system and there is a consequent lack of planning in prospective development (construction, renovation) of publicly owned health care facilities. Both central and regional authorities are responsible for capital investment decisions, but these decisions are made in the light of available resources, which are generally very limited. From 2010, there was some small-scale, relatively centralized planning of capital investment in some priority areas under the health reform programme. Most often these investments were for the development of emergency, primary and perinatal care – allocations were made for the creation of a centralized emergency call centre, a network of perinatal centres and the re-equipping of primary care facilities in the pilot regions. However, overall strategic planning of capital investment is not sufficiently developed.

Strategic development planning and investment in the private medical sector depend on several factors. The main factor is the profitability of potential investments as well as identifying problem areas in the state health system. Consequently, most investments are made in the capital and other large cities. Diagnostic services, dentistry, gynaecology and a few other fields attract the most investment. Another important factor in private investment planning is the focus of high public officials on certain areas of the health system. However, private medical providers remain a very small proportion of all health providers in Ukraine (see section 4.1).