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

<table>
<thead>
<tr>
<th>Language:</th>
<th>Latvian</th>
</tr>
</thead>
<tbody>
<tr>
<td>Link:</td>
<td><a href="http://www.vestnesis.lv">www.vestnesis.lv</a></td>
</tr>
<tr>
<td>Nature:</td>
<td>Official gazette of Latvia</td>
</tr>
<tr>
<td>Organisation responsible for the website:</td>
<td>Ministry of justice of Latvia</td>
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### Legal UHC start date

| 1991 |

### 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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Latvia


HSPM Members: Riga Stradins University, Department of Public Health and Epidemiology

Latvia: Regulation

2.8 Regulation

The Latvian health system is regulated through a mix of legislative (laws, regulations), administrative (licences, permissions) and market mechanisms (contractual relationships). In general, the parliament passes laws such as the “Medical Treatment Law” (Government of Latvia, 1997), which sets the framework for regulation of providers, pharmaceuticals and medical devices, while more specific regulations for each of these fields are defined by the Ministry of Health and approved by the Cabinet of Ministers.

Regulatory functions (standard setting, monitoring, enforcement) are predominantly concentrated in the hands of the central government, i.e. the parliament and the Ministry of Health and its agencies: the NHS with its five territorial branches, the HI, the SAM, the CDPC, the SEMS, the Centre for Forensic Medical Examination, the State Blood Donor Centre, and the Latvian Sports Medicine Agency. In addition, some regulatory functions in the area of education and accreditation of physicians have been delegated to the Latvian Medical Association. Municipalities no longer have a regulatory function in the health system.

National health plans and policy statements are discussed in section 2.4.

2.8.1 Regulation and governance of third-party payers (the NHS and VHI)

The NHS is the only third-party payer in the Latvian statutory health care system. It has to secure health services for the entire population (universal coverage) within the health budget approved by parliament. The main document regulating the activity of the NHS is the “Regulations on Organization and Financing of Health Care” (2006). The document determines almost all aspects of health care provision and financing, including the responsibilities of the NHS, the benefits package and the selection criteria for contracting of providers. The document is updated five to six times per year to take into account the introduction of new technologies, changes in the benefits package and modifications of service definitions and tariffs. These updates are always prepared in close collaboration between the Ministry of Health and the NHS.

As a result of the reform that established the NHS in 2011 (see section 6.1.3), the institution has come under direct control of the Ministry of Health and is directly responsible to the Minister of Health. This is different from its predecessor institutions: the SCHIA and the HPC (which existed between 2009 and 2011) were regulated through a “contract of administration and management” signed between the Minister of Health and the director of the SCHIA (or the HPC). Consequently, the NHS is more closely bound by instructions from the Ministry of Health, whereas the SCHIA had a greater degree of autonomy. The NHS implements health policies and strategies determined by the Ministry of Health and has to monitor and report on the processes and results of policy implementation.

The responsibilities of the director of the NHS are determined by Regulation No. 850 from 2011 (“Regulation of NHS”) and include:

- determining the appropriate volume of health services in accordance with the available financial resources, priorities and capacity of service providers;
- selecting providers and planning, concluding and monitoring the contracts; and
- informing the public about publicly funded health services and terms and conditions of accessibility.

The director of the NHS is formally employed by the Ministry of Health and has a description of work.

Activities of the territorial branch offices of the NHS are determined by the Central Office, which provides the framework contracts for contracting with providers and defines the services that have to be purchased as well as certain quality standards (NHS, 2012c).

VHI is offered in Latvia exclusively by private companies and provides primarily group coverage to
employer organizations although individual coverage is available as well (for more details see section 3.5). Each insurance company is free to define its benefits package and price without any external health-related regulation after having obtained a licence from the Financial and Capital Market Commission, which is concerned only with the financial viability of VHI companies.

2.8.2 Regulation and governance of providers

The “Law of Commerce”, which was passed by parliament in 2000, specifies that hospitals and polyclinics are capital companies (stock companies or companies with limited liability). Smaller hospitals and some bigger regional hospitals are usually owned by municipalities, while larger tertiary hospitals (university hospitals) and specialized (monoprofile) hospitals (e.g. psychiatric hospitals) are owned by the Ministry of Health. All hospitals are limited liability companies and are governed by a management board, which is directly responsible to the local municipalities (municipal hospitals) or the State Secretary of the Ministry of Health (state hospitals). Some outpatient clinics are organized as public–private partnerships (municipalities, along with private owners).

The 1997 “Law on Physician Practice” determined that primary care physicians have the status of independent professionals, which is a specific form of entrepreneurship existing only for primary care physicians. Some secondary ambulatory care providers (those who do not work in hospitals or as employees of health centres) work as self-employed individuals or as private sector agents, with the distinction between the two referring to legal and tax status according to Latvian legislation.

According to Article 55 of the 1997 “Medical Treatment Law”, all health service providers, regardless of their type and legal status, must meet compulsory requirements, which have most recently been defined by the Cabinet of Ministers in the “Regulations on Compulsory Demands for Health Care Institutions and their Structural Units”, in force since January 2009. These regulations determine structural (size, equipment, etc.) and staffing requirements (number and type of specialists) for the provision of specific services. However, since 2009, accreditation of health care institutions according to these requirements is no longer mandatory. Instead, conformity with the standards is only based on self-reporting principles as well as planned and random controls carried out by the HI.

Service provision is mostly regulated by contracts signed between health care providers and the NHS or its territorial branch offices. The NHS negotiates contracts depending on regional needs as specified in the “Regulations on Organization and Financing of Health Care”. Contracts with outpatient facilities are based on competitive tendering if additional services are needed.

For every health care institution, contracts indicate the number of patients to be treated per “health care programme”, which can be a specific type of hospitalization, a certain specialist consultation, or a diagnostic manipulation, etc. (see also section 3.7.1). In addition, the contracts define minimum technological and staffing requirements for institutions depending on the contracted “health care programme”.

If an institution has completed its obligations for the year (for example, it has performed the number of elective surgeries indicated in its contract with the NHS), it may offer patients surgery at full cost instead of waiting until the next year.

The mechanisms in place to ensure and monitor quality of care provided tend to be rather limited, although some quality control issues are included in contracts with the NHS. Primary care is the only area in which quality plays a more important role in the contracts between the NHS and providers as both voluntary and mandatory quality incentive schemes exist (see section 3.7.2).

The HI is the most important institution ensuring compliance of health care providers with the conditions of service provision determined in NHS contracts as well as adherence of providers to the mandatory requirements of health care institutions determined by the Ministry of Health. The HI audits service provision and informs the NHS if services are either not fully provided or provided with inappropriate medical technologies, which will lead to the NHS refusing payment or reducing payments to providers. In addition, the HI is entitled to impose penalties for inappropriate service provision or misreporting.

Until 2010, guidelines were mostly developed by medical specialist associations, often based on international guidelines but sometimes doubts existed regarding their quality. Since then, the NHS has
taken over responsibility for the development, evaluation, registration and implementation of clinical guidelines according to the 2010 Cabinet of Ministers "Procedures for the Development, Evaluation, Registration and Implementation of Clinical Guidelines". The regulation requests clear standards for clinical guidelines. By 2012, 11 guidelines had been registered and published on the webpage of the NHS. Treatment guidelines are recommendations including international best practice. However, the required treatments may be very expensive and are not necessarily entirely covered by NHS contracts.

The integration of care across providers still remains limited in Latvia although some elements of integrated care pathways have been introduced in recent years, especially in the context of the Social Safety Net Strategy (see section 6.1.2). For example, the newly introduced home care service for the chronically ill is based on cooperation between GPs and home care providers (mostly the GP team with a nurse or a special home care team) and rehabilitation at home is now available based on a rehabilitation plan developed by physical medicine and rehabilitation specialists in hospitals. In addition, the status of “potential disability”, which is confirmed after assessment by the “State Medical Commission for the Assessment of Health Condition and Working Ability”, provides the possibility for patients to receive complex and problem-oriented care based on a rehabilitation plan written by a GP or other medical specialist.

There have been ongoing discussions for years about establishing new standards for accreditation of health care organizations but the outcome of these discussions remains uncertain.

2.8.3 Registration and planning of human resources

All health professionals (i.e. medical doctors and nurses) have to be certified by the applicable professional association, which are the Latvian Medical Association, the Latvian Nurses Association or the Latvian Confederation of Professional Organizations of Health Care Personnel (responsible for allied sciences, such as speech therapist, dental technician, dental prosthesis, laboratory assistant, etc.). Certification requirements are regulated by Article 26 of the “Medical Treatment Law” (1997) and specified in the “Regulations of the Cabinet of Ministers on Certification of Treatment Persons” (in force since 1997). The organizations determine examination programmes and establish examination committees for each specialty, subspecialty or subsidiary specialty. A certified practitioner is automatically recertified if he collects at least 250 education points during a five-year period for participation at seminars, conferences, courses, etc.

Besides certification through their professional organizations, all health care practitioners have to be entered into the uniform nationwide information system, the Register of Medical Persons, maintained by the HI in accordance with the Rules on the “Establishment, Fulfilment and Maintenance of the Register of Medical Persons” (in force since October 2005). Registered professionals receive the certificate of a “Treatment Person”.

The certificate has to be renewed once every five years and contains information about the particular health care profession in which the health care practitioner has the right to practise. Every health care practitioner has a personal registration number. To receive the registration certificate, the practitioner must provide proof of identity and documents proving the level of education.

Training of health professionals in Latvia conforms to EU standards for mutual recognition. The curriculum for medical education is defined by regulations of the Cabinet of Ministers but according to advice given by the Latvian Medical Association. Similarly, the number of training places at universities and for residencies (specialist training) is determined by the Ministry of Health. Latvian health professionals are free to live and work in any EU country without restrictions. The Latvian Medical Association monitors specialists moving to other countries and provides the Certificate of Conformity to physicians who are interested in working abroad.

Several policy documents have been adopted by the Cabinet of Ministers concerning planning in the Latvian Health Sector, such as the Master Plan (see section 2.5). In accordance with these plans, the Ministry of Health has defined targets for the number of primary care practices and secondary care providers in each municipality. In addition, for the period 2006–2015 the “Basic Statement on Development of Human Resources for Health Care” was adopted by the Cabinet of Ministers in 2006. The policy envisages the adoption of staffing requirements for physicians and nurses per bed and patient by specialty
in hospitals. In addition, the document suggests a unified model of postgraduate education, supervision and coordination and adjusted health care personnel remuneration levels to promote recruitment of new doctors and retain existing staff. However, as a result of financial constraints in the context of the economic crisis, salaries of health professionals have, in general, been reduced rather than increased in recent years.

2.8.4 Regulation and governance of pharmaceuticals

Legislation and policies in the field of pharmaceuticals are the responsibility of the Health Care Department of the Ministry of Health. Besides the Ministry of Health, the SAM and the NHS are the two most important institutions for regulation of pharmaceuticals.

Before entering the Latvian drug market, pharmaceuticals must have an authorization from the SAM or the European Medicines Agency. The SAM is the national authority for pharmaceuticals and assesses quality, safety and effectiveness of (human and veterinary) medicines and issues market authorizations. The SAM was founded in October 1996 and was reorganized following implementation of the "Law on Pharmaceuticals" (1998). The agency’s activity is financed from its own revenues (for example, administrative fees collected from pharmaceutical companies).

The SAM maintains the Register of Human Medicines, classifies medicinal products into prescription and over-the-counter (OTC) drugs, monitors prices, manages consumption statistics and is responsible for pharmacovigilance, including management of adverse event reports. It issues licences to manufacturers and supervises manufacturing, wholesaling, retailing and importing and exporting of pharmaceuticals. The SAM authorizes clinical trials and monitors good clinical practice in trials. In addition, it assesses and monitors compliance of advertising materials – permitted only for OTC drugs – with statutory requirements. The SAM cooperates with the European Medicines Agency, the European Directorate for the Quality of Medicines and Health and other international organizations and it assists the Ministry of Health in the translation of EU directives into national law.

Reimbursement decisions

The NHS is the responsible institution for making decisions regarding the reimbursement of pharmaceuticals by including a medicine on the positive list. Regulation No. 899 (on the Reimbursement of Expenditures for Medicinal Products and Medicinal Devices, Government of Latvia, 2006a) determines the conditions for reimbursement. To be included on the positive list, pharmaceutical companies have to submit an application to the NHS containing comparative effectiveness data for the pharmaceutical; clinical information (about the intended patient group, indication, etc.) and pharmaco economic information (i.e. existing economic evaluations), price, etc. The NHS evaluates the application on the basis of the provided information and its own research, and makes a decision for or against including a pharmaceutical in the positive list depending on clinical and economic criteria. Clinical criteria include: (1) burden of disease and (2) the therapeutic value of a pharmaceutical and correspondence to treatment schemes. Economic criteria include: (1) impact on the health care budget and (2) results of a cost–effectiveness assessment according to the Common Baltic Guidelines on Economic Evaluation of Pharmaceuticals, which were approved by regulations of the Cabinet of Ministers and came into force in 2002.

All medicines (new and old) on the positive list are classified into one of three reimbursement categories (100%, 75% or 50%) depending on the illnesses for which they have been approved. For example, all medicines on the positive list for the diagnosis of schizophrenia are fully (100%) reimbursed by the NHS, while anti-hypertension medicines fall into the 75% reimbursement category and anti-depressive medications are only covered at 50% by the NHS, with the remaining part having to be covered by patients as OOP payments. In addition, the positive list consists of three parts, i.e. List A, List B and List C.

- List A is a reference price list with groups of interchangeable pharmaceutical products, for which the NHS used to pay the same “reference” price (until 2012 – see “pricing decision” below). The groups consist of either (a) products with the same active ingredient or (b) certain products within one pharmacotherapeutic group that have the same efficacy and side-effects, the same route of administration and the same patient target groups. There are 1092 medicines on the list (in 2012).
- List B consists of 327 non-interchangeable products.
• List C contains 30 pharmaceutical products with annual treatment costs exceeding LVL 3000 (€4300). The decision on reimbursement for these products is made on an annual basis, depending on the available budget and the number of patients for whom reimbursement is required.

In certain extraordinary cases, the NHS may also provide reimbursement for medicines that are not included in the positive list if it has been determined by a physicians’ case conference that the medicine (not exceeding LVL 10 000) is necessary for saving the life of the patient.

Furthermore, a reform of Regulation No. 899 (on the Reimbursement of Expenditures for Medicinal Products and Medicinal Devices) in September 2012 has introduced 50% reimbursement for all nationally registered prescription medicines (beyond those listed in the positive list) for children up to 24 months and 25% reimbursement for all pregnant women (plus until 42 days after childbirth).

Pricing decisions

Pricing of pharmaceuticals in Latvia is regulated by the “Regulations regarding the Principles for the Determination of the Price of Medicinal Products” (Government of Latvia, 2005). To commence the distribution of medicinal products in the territory of Latvia, holders of marketing authorizations must provide the SAM with the ex-factory price of the product.

For pharmaceuticals not included in the reimbursement system, prices are based on an unregulated manufacturer’s price with limited mark-ups for wholesalers and pharmacies. For pharmaceuticals included in the positive list, prices are negotiated between the NHS and the holders of marketing authorizations. One general principle of the NHS is that prices should not exceed the prices in other Baltic countries and the third lowest price in other EU member states. In addition, information from the economic evaluation performed by the NHS is used to determine the price. If the result of the economic evaluation for a particular product indicates that the incremental cost–effectiveness ratio (ICER) is above a certain threshold, the pharmaceutical company will be asked to lower the price so the drug falls below the ICER threshold. In addition, the NHS has implemented a pay-back system, where pharmaceutical companies (depending on their market share) have to compensate the NHS to a certain degree if the annual drug budget is exceeded. This pay-back system amounted to LVL 4 million (€5.6 million) in 2011.

In 2012, after hard and controversial discussions, new regulations were put in force by the government to rationalize pharmaceutical care provided by the NHS. Under the old reference pricing system for pharmaceuticals in the reference list (List A), pharmacists or patients could choose one of the products belonging to the reference group and, if the pharmaceutical product was more expensive than the reference price, patients could pay the difference between the reference price and the actual price as an OOP expense (in addition to the regular drug co-payment). The new regulations determine that there is only one pharmaceutical product in a reference group (the one with the cheapest price), which is awarded the status of “reference medicine”. Prescriptions for newly diagnosed patients now have to be made by the active ingredient and the NHS will only pay for the reference medicine. In addition, when the active ingredient is prescribed, pharmacists always have to dispense the reference medicine.

The new system stimulates competition between pharmaceutical companies because they have to rapidly decrease their prices in order to receive the status of reference medicine. Internal estimates by the NHS suggest that this has resulted in savings of about LVL 3.7 million (€5.3 million) in 2012. However, pharmaceutical companies and medical professionals strongly opposed the reform because of the limitations it imposes on patient choice.

The NHS monitors physician prescription practices every quarter. It sends out a report to service providers (outpatient clinics, GPs, etc.) if prescriptions of a physician working at the institution are on average 30% more expensive (for a group of similar diagnoses) than the average in the country. In addition, this information is also forwarded to the HI, which will more closely monitor prescription practices at the concerned health care institutions, and which can verify the appropriateness of prescriptions by accessing patients’ medical information. However, in the absence of strong penalties, there is a feeling that the system is not particularly effective at discouraging inappropriate prescriptions.

2.8.5 Regulation of medical devices and aids
Medical devices and goods in Latvia are regulated by the “Regulation on Registration, Conformity Assessment, Distribution, Use and Technical Surveillance of Medical Devices”, which came into effect in 2005. The SAM is the sole body responsible for the registration, use, surveillance and distribution of medical devices.

The purchase of most medical devices and goods is undertaken by health care providers in accordance with the "Law on Purchases for the Needs of State and Local Governments", adopted by parliament in April 2006 (this legislation applies to all government purchases, not just in the area of health care).

Procedures for centralized purchases of medical devices and vaccines are defined by “Regulations on Organization and Financing of Health Care” (2006). These purchases are undertaken by the NHS, on behalf of all institutions with which it has agreements (i.e. all statutory health care providers). From 2013 the NHS will purchase devices together with other Baltic countries in order to have a larger purchasing power.

2.8.6 Regulation of capital investment

In general, the owners of all health care institutions (hospitals as well as primary care institutions or practices) are responsible for financing investments (see section 4.1.1). The state as the owner of larger hospitals provides funding for all larger hospitals, while municipalities provide investment funding for their municipal hospitals and PHC centres. Investments in private hospitals or other private health care institutions (e.g. private practices) are financed entirely by the private owners, implying that they have to recover investment costs from the revenues generated through reimbursements for service delivery.

However, the government usually guarantees for credits of capital investments and assumes the risk if providers fail to pay back their credits. In addition, EU Structural Funds are sometimes available for large-scale investments for institutions listed in the Master Plan (see section 2.5).