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**

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**Source:**
- [http://www.who.int/countryfocus/cooperation_strategy/ccsbrief_hrv_en.pdf](http://www.who.int/countryfocus/cooperation_strategy/ccsbrief_hrv_en.pdf)
- [http://www.bmj.com/cgi/content/full/331/7510/223](http://www.bmj.com/cgi/content/full/331/7510/223)

**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:

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Regulation

Croatia

**HIT:** 2014 - Džakula A, Sagan A, Pavić N, Lončarek K, Sekelj-Kauzlarić K.

**HSPM Members:** Andrija Stampar School of Public Health

**HSPM Contributors:** Čivljak M, Džakula A, Lončarek K, Kovačić L, Pavić N, Sagan A, Sekelj-Kauzlarić K, Vajagić M.
Croatia: Regulation

2.8 Regulation

The Ministry of Health is the main regulatory body for the health care system. It regulates standards of health services; the training of health care professionals; and capital investments in public health care providers. General public health issues, such as food and environment safety, are regulated in cooperation with other Ministries. The regulation of health care financing is coordinated with the Ministry of Finance. Monitoring and enforcement of regulations are often delegated to other bodies, such as the Agency for Medicinal Products and Devices (HALMED) or the Agency for Quality and Accreditation in Health Care and Social Welfare.

Introduction of the National Programme for Rare Diseases, 2015–2020

By Aleksandar Džakula, Karmen Lončarek, Katarina Sekelj-Kauzičarić, Nika Pavić, Maja Vajagić

In February 2015, the Ministry of Health introduced the National Programme for Rare Diseases. It defines six main priorities for rare diseases in Croatia: improving access to information and knowledge about rare diseases, development of registries of rare diseases (and their permanent financing), improvement of the availability of health services and of the quality of healthcare services (diagnosis, treatment and prevention) for rare disease patients, improving the availability of drugs for rare diseases (“orphan drugs”), promotion of scientific research in the field of rare diseases and international networking and cooperation.

2.8.1 Regulation and governance of third-party payers

Mandatory health insurance

The CHIF is the single payer in the MHI system and is overseen by the Governing Council (see Section 2.3). In addition, the Ministry of Health monitors its activities and the State Audit Office performs regular audits. Mandatory health contributions are paid into the single State Treasury account and, as such, constitute the revenues of the State budget. The State is therefore responsible for any deficits incurred by the CHIF. Furthermore, the CHIF collects the complementary VHI premiums, which are then transferred to the State Treasury. Although the State supports supplemental insurance for socially vulnerable groups, it is not responsible for the deficits in the portion of the CHIF’s budget related to its complementary insurance activities.

Because there are no explicit positive lists of services and goods covered under the MHI scheme, the CHIF plays a key role in determining which basic health services are purchased and thus covered under the MHI scheme (see Section 3.3). All these decisions are made in cooperation with the Ministry of Health. The CHIF pays for services according to contracts agreed with health care providers. These contracts determine the services to be provided, their scope and quality. Privately owned providers can enter into contracts with the CHIF and become part of the publicly funded system. The CHIF does not differentiate between private and public providers as long as they meet the criteria for participation in the Health Care Network. The Health Insurance Standards adopted by the CHIF’s Governing Council in 2010 regulate, among others, the rights of insured persons to drugs and medical devices paid for by the CHIF under the MHI scheme (see also Section 2.8.2 for more information on Health Insurance Standards).

Voluntary health insurance

Provision of VHI, both by the CHIF and private insurers, is regulated by the Voluntary Health Insurance Act of 2006 (and its amendments). The CHIF must keep the funds for supplementary health insurance separate from the MHI funds. All private health insurers must be approved by the Ministry of Health and are supervised by the Croatian Financial Services Supervisory Authority (HANFA). For more information on VHI see Section 3.5.
2.8.2 Regulation and governance of providers

Organization

The key legal acts regulating the organization of health care provision are the Health Care Act of 2008, the Mandatory Health Insurance Act of 2013, the Voluntary Health Insurance Act of 2006, the Act on Safety and Health at Work of 1996, the Act on Institutions of 1993 (non-profit health care institutions), the Companies Act of 2011 (for profit) and the Concessions Act of 2012.

Health care institutions

Several types of health care institution (university hospitals, university hospital centres, national institutes of health, specialist clinical hospitals) can only be established by the Ministry of Health. Counties can establish general and special hospitals (special hospitals may also be established by cities and other legal persons); primary health centres (there must be at least one primary health centre per county and at least three in the city of Zagreb); County Institutes of Emergency Medicine; County Institutes of Public Health; outpatient clinics; spas; health care facilities providing home care; palliative care institutions; and pharmacies.

Each institutional health care provider has a Governing Board (composed of representatives of the founders, e.g. a local council in the case of a general hospital, and employees); a director (appointed and dismissed by the Governing Board with the approval of the Minister of Health); and a deputy director – one of whom is required to be a medical doctor with at least five years’ clinical experience (directors and deputy directors have an obligation to attend Board meetings but have no right to vote). In addition, each health care institution has an Expert Council, composed of heads of organizational units, which advises on professional and technical issues related to the institution’s activities. Expert councils participate in the planning of health care provision and supervise the implementation of clinical standards. Furthermore, all health care institutions must have an Ethics Committee, a Committee for Medicinal Products and a Committee for Quality, functioning as advisory bodies to the director. Hospitals must also have a Committee for Hospital Infections.

The Ministry decides whether a health care institution meets the requirements with respect to premises, staff, and medical and technical equipment. Institutions that meet these criteria are included in the register of health care institutions.

Health care companies operating on a for-profit basis are regulated in the same way as all commercial companies. However, the following types of health care institution cannot operate for profit: pharmacies; university hospital centres; clinical hospitals; specialist hospital clinics; general hospitals; medical institutes; and health centres (however, for-profit companies may perform certain health care services performed by these institutions). For-profit companies are strictly prohibited from performing certain services, such as blood and tissue collections, and organ transplantations.

Private practice

The 1993 health reform (Health Care Act and Health Insurance Act) brought about the privatization of primary care provision. Privatization took two basic forms: private practice in privately owned facilities provided by self-employed doctors (contracted by the CHIF and financed mostly through capitation), and private practice in rented offices of county health centres (which used to have salaried employees and were the exclusive providers of primary care services prior to the reform).

The introduction of concessions in 2009, when the new Health Care Act entered into force, was aimed at reforming the existing solution of rental of premises under privileged conditions and privately contracted physicians (Bodiroga-Vukobrat, 2012). A ‘concession’ in the context of the Croatian health system is a model of PPP, whereby county governments organize tenders for the provision of primary health care services for the chosen types of primary care specialities, depending on county-specific needs (see also Section 2.4). Concessions may serve as grounds for performing the following types of health care service: family (general) medicine; dental health care; health care services for infants and children of preschool age and for women; laboratory diagnostics; pharmaceutical services; occupational medicine; and medical care in the home of the patient. Concessions are granted to primary care teams that operate within the National Health Care Network but outside of primary health care centres where doctors work as salaried employees. In 2012, the Health Care Act was amended to apply market prices to health care centre
premises rented by private physicians (until then, rental prices were uniform) (Bodiroga-Vukobrat, 2013). Prices of services provided in private practices are regulated by the relevant chambers. At the end of 2012, there were 5792 registered private practice units, including 2460 doctors’ offices. Out of these, 74% were in concession (Bodiroga-Vukobrat, 2013).

Privatization of pharmacies started at the end of 1990, when the first legislative act on private ownership within the health care system came into force. In 1996, legislation on the gradual privatization of the existing State-owned pharmacies was passed, involving leasing a pharmacy to all employed pharmacists who had continually worked in that pharmacy for at least three years (group practice) (Jakševac-Mikša, 2007). The majority of pharmacies in Croatia (66.5%) are privately owned; just over 21% of pharmacies are owned by the counties and the City of Zagreb (Government of the Republic of Croatia, 2012).

Quality

Regulation of quality standards in health care institutions (both public and private) is the responsibility of the Ministry of Health. The key legal act regulating quality is the Act on the Quality of Health and Social Care of 2007 (and its amendments) and the Ordinance on Health Care Quality Standards and their Application adopted in 2011 pursuant to this Act. According to this Ordinance, all health care providers must continuously evaluate and improve the quality of their clinical and nonclinical procedures. The Ordinance establishes the types and frequency of reviews (e.g. a systematic review of the use of antibiotics must be conducted every six months). It defines which performance indicators must be monitored by various types of providers (e.g. hospitals must track waiting times for certain procedures, duration of hospitalizations, unplanned readmissions, survival rates for patients with certain conditions). It also regulates other aspects of health care quality, such as patient and personnel safety, medical documentation, patient rights and experience, personnel satisfaction, infection control, deaths and autopsies, monitoring of drug side-effects and harmful events related to medical products.

The Health Insurance Standards adopted by the CHIF’s Governing Council in 2010 regulate standards such as educational requirements for medical staff and the number of people per medical team. The standards are monitored by the Governing Council of the CHIF and by the Ministry of Health. They are amended every year. Teams of health inspectors from the Ministry of Health visit health institutions to monitor whether health care services are provided in accordance with the relevant regulations on organizational and professional standards; inspections are usually carried out following complaints. Inspections may also be carried out by the professional chambers and the sanitary inspection units in the counties.

The Department for Accreditation of the Agency for Quality and Accreditation in Health Care and Social Welfare sets accreditation standards for health care institutions and health care companies and also conducts accreditation assessment and manages accreditation databases. So far, accreditation standards have only been developed for hospitals (the Ordinance on Accreditation Standards for Hospital Health Care Institutions was issued in 2011). They cover the following areas: quality assurance; hospital governance; staffing requirements; patients’ rights; documentation and statistics; health care services (the requirement to have an organized nursing service operating 24/7); hospital infection control; and safety control. These standards are monitored by the Agency’s Working Council. Accreditation is voluntary.

Although the introduction and implementation of external evaluation of the quality of health care institutions is proclaimed as one of the goals of the National Health Care Strategy 2012–2020, as of December 2013, no hospital has been accredited (Poslovni dnevnik, 2013a). It was announced that this process will start in 2014. This is mainly because of insufficient staff capacity at the Agency for Quality and Accreditation in Health Care and Social Welfare and insufficient provisions in the labour law and collective agreements for rewarding high quality and sanctioning poor quality of work. Moreover, there seems to be no clear link between the financing of health care institutions and the quality of the care they provide, while accreditation standards are still not validated.13

There are many quality improvement programmes for health care institutions in Croatia. The most prominent among them is the WHO European Region PATH, launched in Croatia in 2008 and conducted in 2009 in hospitals that have voluntarily decided to be involved. This offers hospitals a comprehensive and standardized tool (a set of indicators) to evaluate their own performance and development of measures for quality improvement.
European centres of reference for patients with rare diseases\textsuperscript{14}

There is currently no official strategy or plan in Croatia regarding rare diseases. However, special funding is available for orphan medicinal products; there is a “list of especially expensive drugs” that are eligible for reimbursement; and, since 2008, steps have been taken towards the development of a national plan for rare diseases (e.g. in 2008, the Croatian Society for Rare Diseases was established as part of the Croatian Medical Association and, in 2010, the National Commission for Rare Diseases was set up).

Currently, there is no national registry for rare diseases in Croatia, nor a national committee dedicated to registries for rare disorders (see Section 2.7). However, many patients are registered through three referral centres for rare diseases acknowledged by the Ministry of Health (for Birth Defects, Rare Diseases and Metabolic Disorders, and Medical Genetics and Metabolic Diseases in Children).

Since 2006, there is a dedicated Orphanet team in Croatia, currently hosted by the Zagreb University School of Medicine. This team is in charge of collecting data on resources related to rare diseases (specialized clinics, medical laboratories, ongoing research, registries, clinical trials and patient organizations) for entry into the Orphanet database. Apart from the national Orphanet team there are no official information centres on rare diseases in Croatia.

\textsuperscript{14} And their amendments.

\textsuperscript{15} Clinics, spas, health care facilities providing home care, palliative care institutions and pharmacies can also be established by other legal and natural persons.

\textsuperscript{16} Some other health institutions are accredited either by the Croatian Accreditation Agency (CAA) or by international agencies.

\textsuperscript{17} Based on the European Union Committee of Experts on Rare Diseases (EUCERD, 2012).

2.8.3 Registration and planning of human resources

All medical professionals in Croatia have to be registered, licensed and relicensed by their respective professional chamber. Eight categories of medical profession are regulated by medical chambers in Croatia: medical doctors; dentists; pharmacists; nurses; midwives; medical biochemists; physical therapists; and other health care professionals (sanitary monitoring staff, radiology technical staff, occupational therapists, medical laboratory staff). The chambers regulate registration, licensing and continuous medical education (CME), controlling whether CME requirements are being met and imposing sanctions if not (see Section 4.2). They also promote professional ethics.

All health care workers and associates\textsuperscript{15} are also registered in the Croatian Health Manpower Registry, established in 1991 at the CNIPH. Every health care provider (including private providers) is obligated to submit information on all the health workers it employs, including their name, age, profession, entry or departure from service, and any change of position or professional level. This information is analysed and then published annually by the CNIPH in the Health Service Yearbooks, and special analyses may be performed upon request from different users (e.g. the CHIF, ministries, Parliament). The Registry is an important tool for human resources planning that reveals trends and points to areas where changes may be needed. The main challenges in maintaining the Registry are to keep it up to date, and that health institutions provide the requested data.

Higher educational institutions and study programmes offered in the Republic of Croatia are subject to a mandatory accreditation procedure. Accreditation applications are submitted to the Ministry of Science, Education and Sport and decisions are taken by an expert commission within the National Council for Higher Education, in collaboration with the Agency for Science and Higher Education.

According to the National Health Care Strategy 2012–2020, the field of nursing education is insufficiently regulated in Croatia, with unclear qualifications and competences acquired in various existing forms of education. For certain health professions (medical laboratory, medical radiology, environmental and public health, and occupational therapy) there are significant discrepancies when compared to EU countries in terms of educational standards, as well as of vertical and horizontal educational mobility. Namely, due to insufficiently developed or unavailable formal higher education, these health workers improve their competences only through informal education, or go abroad in order to acquire additional knowledge and skills (Government of the Republic of Croatia, 2012).
2.8.4 Regulation and governance of pharmaceuticals

The key act regulating pharmaceuticals in Croatia is the Act on Drugs of 2013. It regulates issues such as drug production, registration and marketing, labelling, classification, supervision, pharmacovigilance, and so on.

Wholesalers and pharmacies

The HALMED issues licences for the wholesale and retail distribution of medicinal products. The Croatian Chamber of Pharmacists gives an opinion on whether a pharmacy can be established in a given geographical area and the Ministry of Health decides where a pharmacy is to be established. Pharmacies can be owned by individual persons or institutions. Mail order or Internet trading of pharmaceuticals is not permitted, with the exception of non-prescription pharmaceuticals.

Pharmaceutical products

The HALMED, established as an independent agency at the end of 2003 and supervised by the Ministry of Health, is responsible for granting marketing authorizations for medicinal products and homeopathic medicinal products. The official timeline for the Agency to issue marketing authorization approval for a new medicine is 210 days, with an average length of marketing authorization approval procedure, including clock stops, of 365 days. Marketing authorization approvals for medicines already authorized in the EU following the Centralized or Mutual Recognition Procedure are largely simplified since the implementation of the nCADREAC\textsuperscript{16} regulatory procedures as of 10 January 2006. Since Croatia’s EU accession, all marketing authorization approvals following the Centralized Procedure in the EU automatically apply to Croatia as well (Innovative Health Initiative, 2012).

The Agency is also responsible for overseeing the quality, efficacy and safety of medicinal products and for monitoring adverse drug reactions (ADRs) and quality defects (of finished products and products in clinical trials). If necessary, it may carry out urgent recall procedures. It also indirectly controls the quality of medicines by issuing manufacturing licences to manufacturers, and granting good manufacturing practice (GMP) and licences for the import and export of medicinal products.

Pharmacovigilance

According to the Medicinal Products Act of 2008, pharmacovigilance activities are part of the HALMED mandate. Marketing authorization holders are legally required to continuously monitor the safety of their products and to report to the HALMED. There are also laws regarding the monitoring of ADRs in Croatia. All physicians who observe ADRs in patients are required to report them to the HALMED. An official standardized form for reporting ADRs is used in Croatia and information pertaining to ADRs is stored in a national database. Every year, reports on ADRs in Croatia are published by the HALMED.

A number of steps are being considered in order to enhance the pharmacovigilance system. These include: various forms of reporting for patients and health care professionals; the provision of safety information for patients on the HALMED’s website; and strengthening of periodic safety update report (PSUR) and risk minimization plan (RMP) analysis by the HALMED staff (Ministry of Health and Social Welfare, 2011).

Patent protection

Legal provisions granting patents to manufacturers cover pharmaceuticals, laboratory supplies, medical supplies and medical equipment. Intellectual property (IP) rights are managed and enforced by the State Intellectual Property Office. National legislation implements the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) as Croatia is a member of the WTO.

Amendments to industrial and IP legislation introduced between 2003 and 2011 harmonized Croatia’s IP laws with EU law. The provisions on supplementary protection certificate (SPC) patent protection were

\textsuperscript{16}The difference between health care workers and health care associates is that the former complete medical school degrees, such as medicine, pharmacy, dentistry and nursing, while the latter complete other (nonmedical) degrees, such as psychology, but are allowed to perform diagnostic and therapeutic procedures and work with patients.
introduced by the Patent Law in 2004 and came into force on the day of Croatia’s EU entry. Currently, the effective period of market exclusivity in Croatia is six years plus the time it takes to register and market the generic drug – minimum one year but typically one to three years. Three years from Croatia’s EU accession, the data exclusivity period will be extended to eight years (Patent Lawyer Magazine, undated).

**Classification of pharmaceuticals and OTC drugs**

Prescription pharmaceuticals are classified into the following categories: prescription drugs (Rp), prescription drugs for restricted use, including prescription drugs containing narcotic or psychotropic substances (Rps), and drugs used exclusively in hospital treatment under direct medical supervision. Over-the-counter (OTC) drugs are classified into those that can be sold in pharmacies only (not approved for the general market) (Br) and those that are approved for general sale (e.g. in a supermarket) (B rx).

**Advertising**

All applicants to the reimbursement lists are obliged to enter into a uniform Agreement on Ethical Promotion of Medicines and risk substantial financial penalties for unethical promotion (Vončina et al., 2012). Direct advertising of prescription medicines to the public is prohibited. The pharmaceutical inspection department of the Ministry of Health supervises adherence of advertising to the national legislation (Ministry of Health and Social Welfare, 2011).

**Generic substitution**

Substitution of generic equivalents of the same price or lower than paid by the national insurance company at the point of dispensing is allowed in public and private sector facilities but it is not mandatory (Ministry of Health and Social Welfare, 2011). Incentives for generic promotion are not considered necessary since the CHIF pays the reference prices and, as a consequence, most manufacturers lower their prices to avoid co-payments (Vogler et al., 2011).

**Clawback systems**

In 2009, the CHIF introduced various types of financial risk-sharing agreements, particularly for expensive products, in order to enable market access for new medicines but keep control over expenditure. In the case of innovative medicinal products, the CHIF usually proposes (a) pay-back agreements in order to meet the maximum price requirement, but also (b) cross-product agreements by which the marketing authorization holder is obliged to decrease the price of another of its products in order to ensure unchanged expenditures for the CHIF (Innovative Health Initiative, 2012).

**Cost-effective use of pharmaceuticals**

Cost-effective use of pharmaceuticals is strongly supported by the CHIF through its reimbursement lists. All generic drugs approved for reimbursement are automatically included in the basic list of drugs (100% reimbursement). On the other hand, if an original drug has a generic substitute, it will be included in the supplemental list and will only be eligible for a partial reimbursement. Overall, most drugs included in the basic list are generics. Because of differences in reimbursement levels, patients have a financial incentive to purchase generics. For original drugs included in the basic list, there are also clear guidelines on their application (they should be prescribed only for certain conditions and adherence to these guidelines is controlled by the CHIF).

**Pricing of prescription pharmaceuticals**

In 2009/2010, Croatia reformed its pricing system for medicines. Maximum prices for reimbursed products are determined at the wholesale selling price level (including wholesaler margin of up to 8.5%) by the CHIF and revised annually based on international price referencing. Calculation of the maximum price for the reimbursed product takes into account prices (original products and generics) in five reference countries. The average wholesaler selling price is calculated from the first three reference countries where the price is available (or at least two reference countries) in the given order: Italy, France, Slovenia, Spain and Czech Republic (or Spain and Czech Republic if no reference prices are available in the former) (Innovative Health Initiative, 2012). Specific pricing policies are applied for generics: the first generic available will have the price set at 30% below the original drug and each subsequent generic will be 10% below the previous generic on the Croatian positive list (Vogler et al., 2011).
Public reimbursement of pharmaceuticals

The CHIF decides on the reimbursement of prescription pharmaceuticals. The official timeline for the CHIF to issue a decision on reimbursement is 180 days, with the shortest real length of the procedure being 365 days. The CHIF sets reimbursement limits for most prescription medicines through therapeutic price referencing. Thirty-eight therapeutic groups are established at the 3rd, 4th or 5th Anatomical Therapeutic Chemical (ATC) classification levels and the therapeutic reference price for each product is subsequently determined based on the price of the cheapest product within the therapeutic group having at least 5% of the market share over a 12-month period (measured in terms of defined daily dose (DDD)) – with the aim of avoiding market shortages.

In 2006, the government introduced internal reference pricing, setting limits to the reimbursement level for all drugs for which lower-priced generic drugs were available on the market. The reference price for all generically equivalent drugs was fixed at a level that the authorities regarded as acceptable. If the price of any product was higher than the reference price, payment or reimbursement would only be granted up to the level set by the government, and the difference would have to be paid by the patient (Vončina et al., 2012).

For new products applying for reimbursement, there are three maximum reimbursement price levels:

- 100% of the average reference price for innovative drugs with a significant impact on recovery and without a pharmacologically similar (at 3rd ATC level) product registered in Croatia;
- 90% of the average reference price for innovative drugs with a pharmacologically similar (at 3rd ATC level) product already reimbursed by the CHIF; and
- 65% of average reference price for generics (every newly reimbursed generic 10% below the cheapest reimbursed generic) (Innovative Health Initiative, 2012).

The new Regulation on Reimbursement introduced in 2009 (Official Gazette 155/09) has significantly increased the reimbursement requirements. Transparency, timeliness and methodology of decision-making by the CHIF’s Committee for Medicines in the reimbursement procedure have all been improved. The new requirements include:

- budget impact analysis undertaken according to strict criteria that largely adhere to International Society for Pharmacoeconomics and Outcomes Research (ISPOR) principles of good practice for budget impact analysis;
- cost–effectiveness analysis (voluntarily);
- a report of scientific evidence, particularly demonstrating the advantages of the medicinal product for the suggested indication over comparator treatments, mainly over the medicinal products already included in the basic or supplementary reimbursement lists of the CHIF; and
- comparison of the reimbursement status and financing of the product in all EU Member States.

The final decision on granting reimbursement is primarily driven by the impact of inclusion of the new medicine on the CHIF’s budget.

Very expensive medicines are financed from funds for especially expensive products (separate CHIF funds that are excluded from hospital budgets). In 2010, the CHIF defined financial limits to the funds that can be spent on especially expensive products within each therapeutic indication and entered into multilateral volume-cap agreements with the marketing authorization holders supplying such expensive products. Any new product proposed for financing from funds for especially expensive products should first be added to the existing volume-cap agreement with a condition that its price is lower than the price of the cheapest product listed in the existing agreement (Innovative Health Initiative, 2012).

2.8.5 Regulation of medical devices and aids
The HALMED is responsible for granting licences for wholesale distribution of medical devices, retail sale in specialized retail shops, and import and export. It also maintains a register of medical device manufacturers and a register of medical devices, analyses and assesses incidents and safety of patients in clinical trials of medical devices and may carry out urgent recall procedures.

Medical devices can be marketed or put into service only if they fulfil the essential requirements that take into account their intended use (with conformity assessment conducted by a laboratory or independent body appointed by the Ministry of Health), bear the marking of conformity with these criteria and have been entered into the register of medical devices.

Importers may supply medical devices only to wholesalers. Wholesale distribution of medical devices may be carried out only by legal persons holding the HALMED’s wholesale distribution authorization. Retail sale of medical devices may be carried out by legal and natural persons with authorization to engage in pharmacist activities, as well as specialized retail stores holding authorization for the retail sale of medical devices. Supervision of the implementation of the provisions of the Medical Devices Act of 2013 and the ensuing regulations is carried out through pharmaceutical inspection by the Ministry of Health.

2.8.6 Regulation of capital investment

The amendments to the Health Care Act of 1993 that came into power on 1 July 2001 decentralized the financing of medical institutions: responsibility for the financing of certain health care institutions (general and special hospitals and primary health care centres) was transferred to the counties and the city of Zagreb (i.e. their owners since 1993). The amendments to the Law on Financing of Units of Local Government and Regional Self-Government (Official Gazette 59/01) determined the sources of funds for decentralized capital investment expenses for institutions in the health care sector and the way they are allocated. Decisions on “minimal financial standards for decentralized functions for medical institutions” issued by the Ministry of Health in 2001–2003 enabled the use of decentralized funds for the maintenance of working premises; medical and nonmedical equipment and means of transportation in medical institutions; and new investments. The allocation of funds to various decentralized functions, including capital investments, is described in Section 4.1.