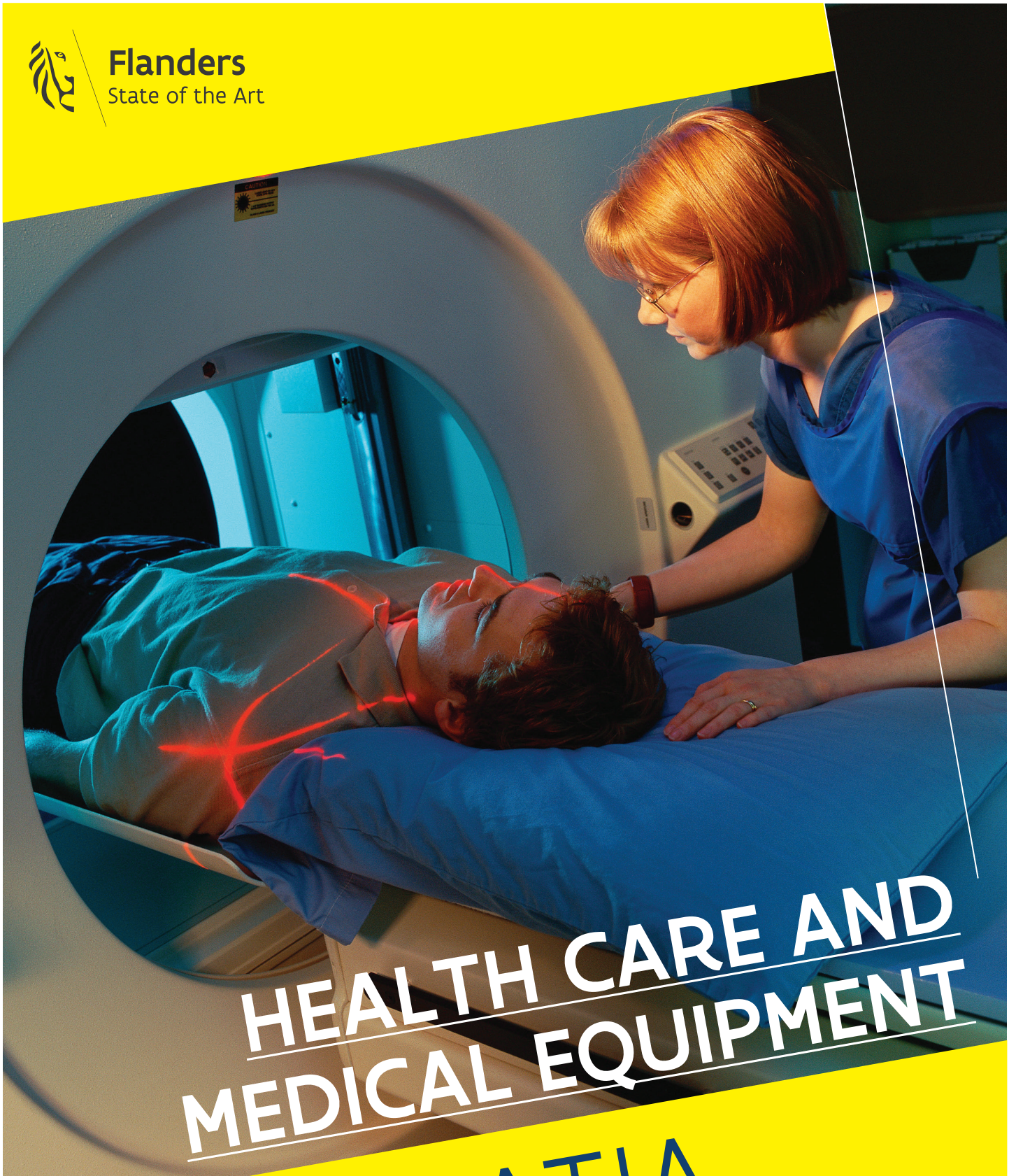




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HEALTH CARE AND MEDICAL EQUIPMENT

IN CROATIA

FLANDERS INVESTMENT & TRADE MARKET SURVEY



Health care and medical equipment in Croatia

February 2016

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1. Introduction

1.1. Geography

The Republic of Croatia is located in Southeast Europe covering a total of 56,610 km². Croatia is bordered by Slovenia, Hungary, Serbia, Bosnia-Herzegovina, Montenegro and Italy with which it shares a maritime border along the Adriatic Sea. The capital is Zagreb and other major cities are Split, Osijek, Rijeka, Zadar, Pula and Dubrovnik. The country is divided into 21 counties, which contain 124 towns.

1.2. Political overview

Formerly a major constituent part of Yugoslavia, Croatia declared independence in June 1991. Today, Croatia is a member of the European Union (EU), United Nations (UN), the Council of Europe, NATO, the World Trade Organization (WTO) and also the founding member of the Union for the Mediterranean. The current president of Croatia is Mrs. Kolinda Grabar Kitarović but the executive authority rests with the Prime Minister, Mr. Tihomir Orešković, who is appointed by the president and is accountable to the Parliament.

1.3. Economic overview

Before the global financial crisis of 2008-09, the Croatian economy grew at a healthy 4-5% annually, incomes doubled, and economic and social opportunities dramatically improved. The prolonged crisis put this progress, as well as Croatia's aspirations, to the test, as the country struggled with six years of recession. The latest economic forecast expects Croatia to have a GDP growth of 2.1% in 2016 and 2017 along with an inflation of 0.3% in 2016 and 1.6% in 2017. Moreover, there will be an improvement in the public budget balance (% of GDP) increasing from -3.9 in 2016 to -3.2 in 2017.¹

The highest contribution to this growth comes from exports of goods and services. Declining oil and food prices and the personal income tax cut helped with the recovery of domestic demand, especially the personal consumption.

¹ http://ec.europa.eu/economy_finance/eu/countries/croatia_en.htm

1.4. GDP

| | 2005 | 2006 | 2007 | 2008 | 2009 | 2010 | 2011 | 2012 | 2013 | 2014 |
|------------------------------------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|
| GDP (million €) | 36,508.4 | 40,197.8 | 43,925.8 | 48,129.8 | 45,090.7 | 45,004.3 | 44,708.6 | 43,933.7 | 43,487.1 | 43,019.8 |
| GDP per capita, PPP(\$) | 15535,49 | 17019,72 | 18923,49 | 20464,44 | 19399,37 | 18968,86 | 20571,25 | 21113,61 | 21314,12 | 21210,28 |
| GDP growth (annual %) | 4,16 | 4,78 | 5,15 | 2,05 | -7,38 | -1,70 | -0,28 | -2,19 | -1,06 | -0,36 |
| Inflation, GDP deflator (annual %) | 3,39 | 4 | 4,10 | 5,70 | 2,78 | 0,83 | 1,67 | 1,58 | 0,80 | 0,02 |

Source: World Bank Data <http://data.worldbank.org/> - Eurostat <http://ec.europa.eu/eurosta>

Croatia is a member of the IMF, the European Bank for Reconstruction & Development and the World Trade Organization. Croatia applied for EU membership in February 2003 and has worked hard to align its legislation with the EU acquis. The EU has provided Croatia with financial assistance in the areas of economic and social development, justice and home affairs, the building of administrative capacity and environmental protection, with a view to enable a smooth transition to European structures.

Tourism is a notable source of income, particularly during the summer months. With over 10 million foreign tourists annually, tourism generates revenue in excess of € 7 billion. Croatia is ranked amongst the top 20 most popular tourist destinations in the world, and was voted the world top tourism destination in 2005 by Lonely Planet. According to the site Best European Destinations, Zadar was voted best European destination in 2016, and Zagreb was voted for the best Christmas destination in 2015.²

1.5. Population

According to the Croatian Bureau of Statistics, the Croatian population is 4.284.889 million.

Zagreb City, the capital, is the country's largest region, with a population of 790.017 according to the 2011 census, which equals to 17,6% of the total population.

Population by age group, ethnicity and religion

| Age | 65+ | 15-64 | 0-14 |
|-----------------------|-------|-------|-------|
| % of total population | 15,7% | 67,2% | 17,1% |

² <http://www.europeanbestdestinations.com/>

Croatia is inhabited mostly by Croats (89,6%), while minority groups include Serbs (4,5%), Bosniaks, Hungarians, Italians, Slovenes, Germans, Czechs, Roma people and others (5,9%). The average [life expectancy](#) is 75,1 years, and the literacy rate is 98,1%. The main religions of Croatia are Roman Catholic 85%, Orthodox 5%, other Christian 0,4%, Muslim 1,3%, other and unspecified 0,9%, none 5,2%.

1.6. Demographics

Principal Demographic Indicators

| | 2001 | 2006 | 2011 | 2014 |
|------------------------|--------|--------|--------|---------------|
| Live births | 40,993 | 41,446 | 41,197 | 39,566 |
| Rate/000 pop | 9.2 | 9.3 | 9.4 | 9.3 |
| Deaths | 49,552 | 50,378 | 51,019 | 50,839 |
| Rate/000 pop | 11.2 | 11.3 | 11.9 | 12.0 |
| Infant deaths | 315 | 215 | 192 | 199 |
| Life expectancy | | | | |
| Males | 71.1 | n/a | 73.9 | 74,6 |
| Females | 78.1 | n/a | 80,0 | 80,5 |

Source: http://www.hzjz.hr/publikacije/hzs_ljetopis/, [Croatian Health Service Yearbook 2014](#)

According to the Croatian central bureau of statistics (CBS), the most common causes of death in 2014 were due to ischemic heart diseases (10.831), cerebrovascular diseases (7.300) and malignant neoplasms of trachea, bronchus and lung (2.827).

For the overall infant deaths, the most common were pathologic conditions from the prenatal period and congenital malformations. Regarding the total population, the leading causes of death in 2014 were circulatory diseases (24.112) and neoplasms (14.206). They represent $\frac{3}{4}$ of death. Other causes of death are injuries and poisonings (2.750), respiratory system diseases (2.227), of digestive system diseases (2.149).

2. Health care and medical equipment sector

2.1 Facilities involved in health activities

They are either state- or county-owned, or private. Teaching hospitals, clinical hospital centers and state institutes of public health are state-owned.

Health centers, polyclinics, general and special hospitals, pharmacies, institutions for emergency medical aid, home care institutions, and county institutes of public health are county owned.

During 2002 health centers began the process of merging due to which their number was reduced from 120 (in 2001) to 49 (in 2014). Out of 73 hospital institutions and sanatoriums, nine special hospitals and five sanatoriums were privately owned.

By the end of 2014, there were 5,399 private practice units (doctors' offices, laboratories, private pharmacies, private physical therapy practices and home care services) registered.

2.2 The medical market in Croatia

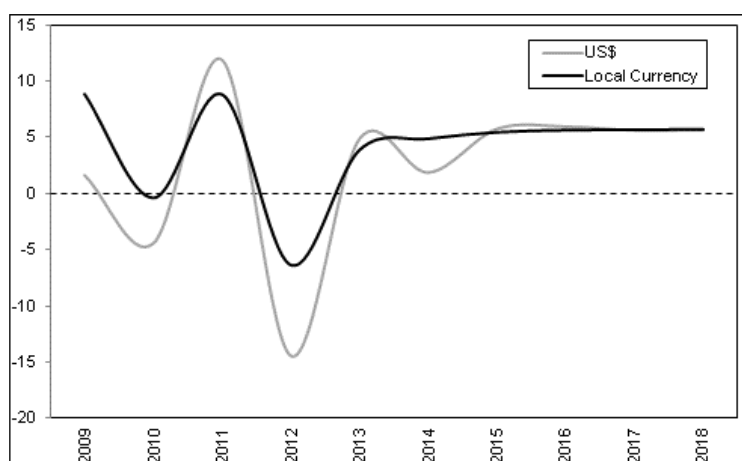
In 2014, around \$ 214.3 million, or \$50 per capita, was spent on medical equipment. The largest product area within the market was consumables, accounting for 27.7% of the overall total, followed by diagnostic imaging with a market share of 13.5%.

It is expected that the market will increase by a CAGR of 2.7% in USD terms along with a CAGR of 5.6% in local currency terms over the 2014-2019 period reaching \$295.6 million by 2018.³

The government aimed to bring the performance of the healthcare system into line with that of other EU member states through the National Health Strategy 2006-2011.

The new National Healthcare Development Strategy 2012-2020 will expand health-related IT systems in the country and see a restructuring of the hospital sector. Some of the goals have already been achieved - the implementation of a prescription system, followed by an e-waiting list, and a centralized information system. Even though informatization of healthcare has been in place for 10 years, it is expected that it will be speeded up with use of EU structural funds now available to Croatia. The strategy also anticipates the reorganization of health institutions, integrating local clinics, family practitioners, hospitals and specialized hospital services.

Medical Device Market, 2009-18 (% Change)



Source: BMI Espicom

³ US Commercial service, *Healthcare Resource Guide: Croatia*, Nina Radicevic, November 2015

2.3 Medical personnel

65,757 health professionals and associates were employed in total on 31 December 2014 in Croatian health care which translates to 65 inhabitants per health worker.

Tablica - Table 2. UKUPAN BROJ ZDRAVSTVENIH DJELATNIKA SA ZAPOSLENJEM U ZDRAVSTVENOM SUSTAVU TE BROJ STANOVNIKA NA JEDNOG ZDRAVSTVENOG DJELATNIKA U HRVATSKOJ 2014. GODINE - Health workers employed in health system (permanent job and total) and population per one health worker, Croatia 2014

| Zdravstveni djelatnici | Sveukupno | Udio (%) | Broj stanovnika na 1 zdrav. djelatnika |
|---|---------------|---------------------|---|
| <i>Health workers</i> | <i>Total</i> | <i>Proportion %</i> | <i>Population per one health worker</i> |
| Doktori medicine - <i>Medical doctors</i> | 14.057 | 21,4 | 305 |
| Doktori dentalne med. - <i>Doctors of dental. med.</i> | 3.545 | 5,4 | 1.209 |
| Mag. farmacije - <i>Pharmacists</i> | 2.744 | 4,2 | 1.562 |
| Medicinski biokemičari - <i>Medical biochemists</i> | 478 | 0,7 | 8.964 |
| Ostali zdravstveni djelatnici visoke obrazovne razine - <i>Other university degree health workers</i> | 874 | 1,3 | 4.903 |
| Suradnici s visokom obraz. razinom - <i>Other university degree staff</i> | 631 | 1,0 | 6.791 |
| Viša - <i>Junior college education</i> | 10.457 | 15,9 | 410 |
| Srednja - <i>High school education</i> | 32.529 | 49,5 | 132 |
| Niža - <i>Semi-skilled</i> | 442 | 0,6 | 9.694 |
| Ukupno - Total | 65.757 | 100 | 65 |

Source: http://www.hzjz.hr/publikacije/hzs_ljetopis/

Compared to the European average, Croatia has one of the lowest rates of doctors per 100.000 citizens. Due to this, the Ministry of Health has taken an active role in the management of human resources, especially in the segment of PhDs in medicine. The plan is to provide quality medical care for all citizens of Croatia no matter where their place of residence is.

Tablica - Table 2. UKUPAN BROJ ZDRAVSTVENIH DJELATNIKA SA ZAPOSLENJEM U ZDRAVSTVENOM SUSTAVU TE BROJ STANOVNIKA NA JEDNOG ZDRAVSTVENOG DJELATNIKA U HRVATSKOJ 2014. GODINE - Health workers employed in health system (permanent job and total) and population per one health worker, Croatia 2014

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| Niža - <i>Semi-skilled</i> | 442 | 0,6 | 9.694 |
| Ukupno - Total | 65.757 | 100 | 65 |

Source: Croatian health Yearbook 2014

Tablica - Table 4. DOKTORI MEDICINE SPECIJALISTI PO GRANAMA SPECIJALNOSTI SA ZAPOSLENJEM U ZDRAVSTVENOM SUSTAVU U HRVATSKOJ U 2014. GODINI - Medical specialists in Croatia's health system by specialty 2014

| SPECIJALNOST <i>Specialty</i> | UKUPNO <i>Total</i> | SPECIJALIZANTI <i>On specialty training</i> | SPECIJALISTI <i>Specialists</i> |
|---|-------------------------------|---|---|
| OBITELJSKA/OPĆA MEDICINA - Family practice | 1.235 | 113 | 1.122 |
| INTERNA MEDICINA - Internal medicine | 1.357 | 178 | 1.179 |
| OPĆA INTERNA MEDICINA - General internal medicine | 15 | 14 | 1 |
| KARDIOLOGIJA - Cardiology | 35 | 35 | - |
| PULMOLOGIJA - Pneumophthsiology | 28 | 28 | - |
| GASTROENTEROLOGIJA - Gastroenterology | 17 | 17 | - |
| NEFROLOGIJA - Nephrology | 15 | 15 | - |
| HEMATOLOGIJA - Hematology | 21 | 21 | - |
| LABORATORIJSKA IMUNOLOGIJA - Laboratory immunology | 4 | 1 | 3 |
| ENDOKRINOLOGIJA I DIJABETOLOGIJA - Endocrinology | 10 | 10 | - |
| INTERNISTIČKA ONKOLOGIJA - Internal medicine oncology | 10 | 10 | - |
| ALERGOLOGIJA I KLINIČKA IMUNOLOGIJA - Allergy and clinical Immunology | 1 | 1 | - |
| PNEUMOFITZILOGIJA - Pneumophthsiology | 83 | - | 83 |
| INFEKTOLOGIJA - Infectology | 142 | 39 | 103 |
| PEDIJATRIJSKA INFEKTOLOGIJA - Pediatric Infectology | 16 | 4 | 12 |
| NEUROLOGIJA - Neurology | 409 | 76 | 333 |
| PSIHIJATRIJA - Psychiatry | 634 | 115 | 519 |
| DJEČJA I ADOLESCENTNA PSIHIJATRIJA - Child and adolescent psychiatry | 8 | 8 | - |
| NEUROPSIHIJATRIJA - Neuropsychiatry | 34 | - | 34 |
| DERMATOLOGIJA I VENEROLOGIJA - Dermatology and venerology | 212 | 32 | 180 |
| PEDIJATRIJA - Pediatrics | 826 | 119 | 707 |
| OPĆA KIRURGIJA - General surgery | 730 | 84 | 646 |
| KARDIOTORAKALNA KIRURGIJA - Cardiothoracic surgery | 5 | 5 | - |
| VASKULARNA KIRURGIJA - Vascular surgery | 9 | 9 | - |
| ABDOMINALNA KIRURGIJA - Abdominal surgery | 21 | 21 | - |
| NEUROKIRURGIJA - Neurosurgery | 86 | 25 | 61 |
| DJEČJA KIRURGIJA - Child surgery | 65 | 20 | 45 |
| MAKSILOFACIJALNA KIR. - Maxillofacial surgery | 40 | 6 | 34 |
| PLASTIČNA KIRURGIJA - Plastic surgery | 12 | 7 | 5 |
| HITNA MEDICINA - Emergency medicine | 213 | 82 | 131 |
| UROLOGIJA - Urology | 192 | 35 | 157 |
| ORTOPEDIJA I TRAUMATOLOGIJA - Orthopedics and traumatology | 230 | 51 | 179 |
| OTORINOLARINGOLOGIJA - Otorhinolaryngology | 275 | 52 | 223 |
| OFTALMOLOGIJA I OPTOMETRIJA - Ophthalmology and optometrics | 412 | 78 | 334 |
| OPSTETRICIJA I GINEKOLOGIJA - Obstetrics and gynecology | 791 | 105 | 686 |
| ANESTEZIOLOGIJA I REANIMACIJA - Anesthesiology and resuscitation | 824 | 224 | 600 |
| TRANSFUZIJSKA MEDICINA - Transfusiology medicine | 126 | 15 | 111 |
| KLINIČKA RADIOLOGIJA - Clinical radiology | 617 | 125 | 492 |
| RADIOTERAPIJA I ONKOLOGIJA - Radiotherapy and oncology | 110 | 24 | 86 |
| NUKLEARNA MEDICINA - Nuclear medicine | 95 | 24 | 71 |
| FIZIKALNA MEDICINA I REHABILITACIJA - Physical medicine and rehabilitation | 398 | 45 | 353 |
| REUMATOLOGIJA - Rheumatology | 2 | 2 | - |
| MEDICINA RADA I SPORTA - Occupational and sports medicine | 266 | 22 | 244 |
| ŠKOLSKA I ADOLESCENTNA MED. - School and adolescent medicine | 226 | 23 | 203 |
| SOCIJALNA MEDICINA S ORGANIZ. ZDR. ZAŠTITE - Social medicine and health administration | 12 | - | 12 |
| JAVNO ZDRAVSTVO - Public health | 30 | 3 | 27 |
| EPIDEMIOLOGIJA - Epidemiology | 171 | 21 | 150 |
| MEDICINSKA MIKROBIOLOGIJA S PARAZITOLOGIJOM - Medical microbiology with parasitology | 172 | 10 | 162 |
| KLINIČKA MIKROBIOLOGIJA - Clinical microbiology | 5 | 5 | - |
| PATOLOŠKA ANATOMIJA - Anatomical pathology | 138 | 22 | 116 |
| PATOLOGIJA - Pathology | 9 | 9 | - |
| KLINIČKA CITOLOGIJA - Cytirical citology | 118 | 14 | 104 |
| SUDSKA MEDICINA - Forensic medicine | 5 | - | 5 |
| ZDRAVSTVENA EKOLOGIJA - Medical ecology | 4 | - | 4 |
| KLINIČKA FARMAKOLOGIJA - Clinical pharmacology | 20 | 4 | 16 |
| SPORTSKA MEDICINA - Sports medicine | 3 | - | 3 |
| POMORSKA MEDICINA - Maritime medicine | 2 | - | 2 |
| UKUPNO - Total | 11.546 | 2.008 | 9.538 |

Source: Croatian health Yearbook 2014

2.4 Health care expenditure

Based on data from the World Health Organisation (WHO), Espicom estimates that Croatia spent 7.8% of GDP (6.6% from public sources and 1.2% from private ones) on healthcare in 2014, which equals to US\$3.99 billion, or US\$900 per capita. Around 85% of this was in the public sector, worth US\$3.39 billion, and 15% in the private sector (US\$600 million).

The compulsory health insurance system, which provides treatment for approximately 4 million people, had a budget of US\$3.85 billion. The insurance system was introduced in 1993 and is operated by the Croatian Institute for Health Insurance (HZZO). The HZZO collects contributions from the working population and the government makes payments on behalf of those exempt, such as the elderly, the unemployed and dependents. From the last figures, the total private healthcare expenditure accounted for 14% of total spending in 2013.

Concerning HZZO, 88,71% of its expenses are made on healthcare, 9,54% on reimbursements and 1,75% on other expenditures. The detailed structure of its healthcare expenditures is the following:

- 33% hospital care
- 20% drugs/medications
- 15% primary healthcare
- 10% renovation of health institutions
- 6% health care abroad
- 4% orthopedic aids
- 4% emergency medical health and transport
- 3% secondary health care

HZZO is financed through payroll contributions as well as subsidies from the central budget. In turn it funds hospitals and pharmaceuticals. HZZO has a monopoly on the Croatian market and the majority of the population is dependent on the organization for health care.

The payroll contributions are perceived by the central government as part of the central annual budget for healthcare (determined each year by the Ministry of Health and Social Welfare and the Ministry of Finance) and partly allowed to the HZZO fund in function of the planned budget decisions. The HZZO has contracts with health care providers all around the country, and allocates the financial resources among the counties according to the needs (determined by several criteria: mortality, demographic characteristics, etc.). The government controls the Croatian health care sector through the HZZO funding and the ownership of the main hospitals and health institutions.

Most of the main healthcare providers (mainly hospitals) are funded exclusively by the HZZO, and on a capitation basis⁴. The cost of providers' workforce represents between 60% and 90% of the providers funding. Furthermore, the renewing of equipments and facilities are not financed by the HZZO but by providers' owners, resulting in insufficient hospitals improvements.

As a consequence of all these issues, a lot of providers face an increasing debt. This deficit situation is also faced by the HZZO, whose budget increase is utilized to pay previous debts to suppliers, helped by additional loans. In 2013, the Hospitals and pharmacies debt to suppliers together reached 4 billion Kuna. Some of these institutions sometimes also subscribe to bank loans to compensate their deficit.

Finally, 95% of HZZO's revenues come from the taxes, while only 5% comes from its own assets.

2.5 Hospital services

According to Ministry of Health of Croatia in 2014 Croatia had 20 general hospitals. Most other facilities were small and specialist in nature.

⁴ "A health insurance payment method whereby a fixed amount of money is paid per person to cover all services, without regard to the number or nature of services rendered to each person within a set period of time. It is the provider who bears the financial responsibility to coordinate patient care within the fees or capitated rate for all patients" (Distance Learning Centre, <http://www.eridlc.com>)

Tablica - Table 1. ZDRAVSTVENE USTANOVE U HRVATSKOJ* 31.12.2014. - Health institutions in Croatia, December 31, 2014

| ZDRAVSTVENE USTANOVE | BROJ USTANOVA |
|--|----------------------------|
| <i>Health institutions</i> | <i>No. of institutions</i> |
| DOM ZDRAVLJA - Health center | 49 |
| KLINIČKI BOLNIČKI CENTAR - Clinical teaching hospital | 5 |
| KLINIČKA BOLNICA - Clinical hospital | 3 |
| KLINIKA - Clinic | 5 |
| OPĆA BOLNICA - General hospital | 20 |
| SPECIJALNA BOLNICA - Special hospital | 33 |
| LJEČILIŠTE - Health resort | 7 |
| ZAVOD ZA JAVNO ZDRAVSTVO - Public health institute | 22 |
| OSTALI DRŽAVNI ZAVODI - Other state institutes: | 5 |
| • ZAVOD ZA TRANSFUZIJSKU MEDICINU - Institute of transfusional medicine | 1 |
| • ZAVOD ZA ZAŠT. ZDRAVLJA I SIGURNOST NA RADU - Institute for Health Protection and Safety at Work | 1 |
| • ZAVOD ZA TOKSIKOLOGIJU I ANTIDOPING - Institute of toxicology and Antidoping | 1 |
| • ZAVOD ZA HITNU MEDICINU - Institute of emergency medicine | 1 |
| • ZAVOD ZA TELEMEDICINU - Institute for telemedicine | 1 |
| USTANOVA ZA HITNU POMOĆ - Emergency care station | 21 |
| POLIKLINIKA - Polyclinic | 350 |
| USTANOVA ZA MEDICINU RADA - Institution of occupational health | 9 |
| LJEKARNA - Pharmacy | 181 |
| USTANOVA ZA NJEGU-SKRB - Nursing care institution | 198 |
| TRGOVAČKO DRUŠTVO ZA OBAVLJANJE ZDRAV. DJELATNOSTI - Health company | 411 |
| Ukupno - Total | 1.319 |

* Ustanove bez obzira na vrstu vlasništva - Institutions regardless of the type of ownership

Source: Croatian health Yearbook 2014

2.6 Health insurance

The notion of compulsory health insurance was introduced in the 1993 Health Care Act. Since then there have been many changes to this Act in the attempt to balance the supply of resources and the demand for services.

Under the social insurance system, a number of benefits are available including Cash Sickness Benefit, Workers' Medical Benefits and Dependents' Medical Benefits. The latter consists of a range of treatments that are partly funded by the patient, including hospitalization, orthopedic aids, dental care, specific pharmaceuticals, maternity care and emergency aid. Services are free for children under 18 years of age, citizens of low income, disabled people in need of constant assistance and disabled veterans.

Citizens who have compulsory insurance and are also paying for supplementary insurance, have all medical costs covered for them by HZZO. Supplementary insurance is not obligatory and one can choose to pay it or not (70kn per month).

Patients are required to make co-payments for services such as primary care consultations, home visits and transportations by ambulance. Charges are also made for hospital stays. However, a large proportion of the population is exempt from co-payment, including children, poor and war veterans, which means that this source of health care funding adds little to the total health budget. Certain illnesses also excuse people from making the payment, such as contagious disease, occupational injuries and mental illness. The incidence of unofficial payment is also very low, especially in comparison with neighbouring countries.⁵

In case of sick leave, the cash compensations are paid by the employer during the first 42 days and by the health insurance during the following days (one year maximum). The daily compensation amount is calculated on the basis of the patient's average net wage of the last 6

⁵ Croatia Background data. Espicom 2006, Espicom Business Intelligence

months (70% of this average wage for the first 6 months of the sick leave, and 80% for the following six months). The compensation can be complete (100%) in some cases. The monthly allowances are comprised between 831,5 kuna and 4.257 kuna (108,6€ and 556,2€ ⁶)

After joining the EU on July 1st 2013, Croatia was able to withdraw funds from the EU structural funds for development of the health care sector. This is supposed to financially strengthen the Croatian health care system by extra funding intended for improvement of the health care sector and rendering health services to Croatian citizens.

2.7 Medical device outlook

During the post-war reconstruction, helped by financial international institutions, the renovation of health services was referred to as a priority. These renovations, as well as reforms in the Croatian social security system, have apparently been conducted well so far.

However the medical device industry in Croatia suffers from a lack of high-tech companies. New equipments are required for the modernization of ageing facilities and as medical device regulations are in line with EU requirements, gaining access to the market should not be a problem for those familiar with EU legislation.

The demand for medical equipment is expected to increase in the coming years, due to several factors, among which the healthcare modernisation, the European Union requirements, private health sector's development, the economic development, and the aging population.

Currently the Croatian market of medical devices is characterized by a low local production. Moreover, the main import sources are the United States (around 25% of the imports⁷), Germany, Italy, Japan, Austria, Switzerland, and Slovenia. Germany, Italy and the US together provide more than 50% of the imports. However, Croatia possesses a small domestic production sector and manage to supply the Croatian market and the countries from former Yugoslavia.

The purchases of medical devices are made directly by hospitals and local health authorities, or centralized by the Ministry of Health (through tenders) for large procurements. The total amount of money that Croatian hospitals (primarily Clinical centres in Zagreb and Rijeka as the most active purchasers) spent on medical equipment, surgical instruments, accessories, laboratory equipment and various supplies in 2014 amounts to \$208 million (\$45 million was spent on medical equipment). Additionally, orthopedics and prosthetics, diagnostic imaging, and consumables are considered to be the most prospective product areas of the medical device market.

⁶ 1 € = 7,6535 (09/02/2016)

⁷ Business Monitor, *Croatia pharmaceuticals & Healthcare report Q3 2010*

| Projected Medical Device Market, 2014-2019 | | | | | |
|--|---------------|------------------|---------------------------|-----------------------------|------------------------------------|
| | Total (USDmn) | Per Capita (USD) | Total (Local Currency mn) | Per Capita (Local Currency) | Exchange Rate (Local Currency/USD) |
| 2014 | 257.5 | 60.3 | 1,466.0 | 343.2 | 5.7 |
| 2015 | 211.5 | 49.7 | 1,479.7 | 347.7 | 7.0 |
| 2016 | 213.8 | 50.4 | 1,551.3 | 365.9 | 7.3 |
| 2017 | 226.6 | 53.6 | 1,652.0 | 391.0 | 7.3 |
| 2018 | 252.0 | 59.8 | 1,789.3 | 424.9 | 7.1 |
| 2019 | 294.5 | 70.2 | 1,921.7 | 457.8 | 6.5 |

Source: BMI

2.8 Regulatory environment

The registration of medical devices in Croatia comes under the jurisdiction of the Agency for Medicinal Products and Medical devices (<http://www.halmed.hr/en/>) based in Zagreb. The agency was established in October 2003, following the merger of the Croatian Institute of Medicines Control and the Croatian Institute of Immunobiological Preparations Control. The Agency's activities, which are mentioned by MoH, include the following:

Under Article 122 of Medicinal products Act

- granting of marketing authorisations for medicinal products and homeopathic medicinal products
- carrying out registration procedures for traditional herbal medicinal products and homeopathic medicinal products
- granting of authorisations for parallel imports of medicinal products
- making expert assessments of quality, efficacy and safety of medicinal products
- performing laboratory analyses of medical devices
- performing tasks of the official laboratory for quality control for the Republic of Croatia
- performing quality control of medicinal products and homeopathic medicinal products, and issue certificates of quality control
- analysing and assessing adverse reactions and safety of subjects in clinical trials
- preparing the Croatian Pharmacopoeia
- issuing the Croatian Pharmacopoeia and other expert publications from its scope of work
- performing pharmacovigilance tasks
- granting manufacturing authorisations to manufacturers and importers of medicinal products and investigational medicinal products
- keeping the register of manufacturers, importers and wholesale distributors of active substances and excipients
- granting of authorisations for wholesale distribution of medicinal products

- granting of authorisations for retail sale of medicinal products in specialized retail sale outlets
- granting of authorisations for brokering of medicinal products
- giving approval for entry and importation of medicinal products
- giving approval for emergency entry and importation of medicinal products
- monitoring adverse reactions and defects of medicinal products
- initiating procedures for the suspension marketing medicinal products and make product recalls
- monitoring the supply of medicinal products
- monitoring the consumption of medicinal products and promote their rational use
- proposing measures to the Minister to supervise the consumption of medicinal products
- engaging in waste management activities (for its own needs)
- ensuring education and provide information on medicinal products
- providing expert advice from its scope of activities
- providing expert guidelines from its scope of activities
- proposing harmonisation of regulations on medicinal products with those of the European Union as well as with the regulations and guidelines of international institutions
- establishing international cooperation in the field of medicinal products
- carrying out inspection of the production of medicinal products, investigational medicinal products, active substances or excipients and the inspection of pharmacovigilance
- keeping the register of manufacturers of medical devices, the register of medical devices and the register of the wholesale distributors of medical devices
- analysing and evaluating adverse events in clinical trials of medical devices
- granting of authorisation for the retail sale of medical devices in specialized retail sale outlets -keeping the register of medical devices marketed in the Republic of Croatia
- operating a vigilance system for medical devices, and monitor safety of medical devices
- carrying out the procedure for emergency recall of medical devices
- carrying out the procedure for classification of medical devices
- issuing certificates of free sale of medical devices
- ensuring education and provide information about medical devices
- establishing international cooperation in the field of medical devices
- proposing harmonisation of regulations on medical devices with those of the European Union as well as with the regulations and guidelines of international institutions

- performing other tasks in the field of medicinal products in line with this Act and the ensuing regulations and in the field of medical devices in accordance with the Medical Devices Act and the ensuing regulations.

Croatia's medical device regulations are in line with the EU medical devices directives. Medical devices may only be marketed in Croatia if they have received authorization for marketing in the EU countries and the authorization has not been withheld, withdrawn or suspended in any of the member states.

2.9 Medical device registration

The Mission of the Agency for Medicinal Products and Medical Devices is to contribute actively to protection and promotion of public health by:

- Mobilizing expert resources in order to achieve high quality assessment of medicinal products, medical devices and homeopathic products, promoting research and development programs, as well as providing clear and useful information to the public and healthcare professionals;
- Developing effective and transparent procedures aimed at providing the public with a prompt access to medicinal products;
- Supervising safe use of medicinal products and medical devices by monitoring adverse reactions and quality of medicinal products and medical devices marketed in the Republic of Croatia;
- Collaborating with international authorities competent for medicinal products and medical devices; and
- Developing bilateral collaboration with national regulatory authorities and international institutions. ⁸

The Agency for Medicinal Products and Medical Devices (HALMED) is responsible for placing medical devices on the Medical Devices and Homeopathic Products Register. In order to register a medical device, manufacturers should submit a written application to the Agency, accompanied by the following documentation:

- Name, brief description and intended use of the device;
- Details of qualitative and quantitative composition of the device;
- Description of the manufacturing process;
- Quality specifications for medical device and control methods;
- Clinical documentation or clinical trial results (for implants);
- Specimen;
- Packaging information including the form, type of material and composition;
- Proposed outer and inner labelling of the packaging (in Croatian) and the original packaging for devices manufactured abroad;
- Package leaflet containing instructions for use (proposal in Croatian) and the original package leaflet for devices manufactured abroad;

⁸ Sophie Delvaux, *Croatie, le marché des équipements médicaux*, Wallonia export & investment, 2007

- Proposed shelf life and storage conditions;
- Evidence that the medical device has been authorized for marketing in the EU Member States and the list of countries in which the medical device concerned is authorized for marketing (for devices manufactured abroad);
- Details of agency registration, or the decision on entry in the foreign subsidiary register, if the application has been submitted by the agent or local subsidiary of a foreign manufacturer;
- Manufacturing license;
- Liability insurance policy;
- Proof of payment of administrative fee.⁹

On 14th January 2014, HALMED published a new price list for its services. The costs associated with obtaining manufacturing licenses and medical device registrations are listed below¹⁰.

In March 2013, HALMED informed the holders of medical device registrations that as of June 1st 2013, it will cease to accept applications for the registration of medical device manufacturers from legal entities in Croatia who represent manufacturers with headquarters in the EU or EEA, as well as manufacturers with headquarters outside the EU or EEA territory, that already have an authorised representative in the EU/EEA.

In addition, HALMED will no longer accept applications for Class I medical devices to be entered into the registry.

2.10 Emergency medical service

It is estimated that about four fifths of the population is covered by activities of professional EMS units, while the remaining fifth is covered by doctors on duty or through medical teams. In 2009 the Croatian government started a national reform process of the emergency medical system with a goal of improving the availability and boosting the quality of EMS throughout Croatia. Today every Croatian county has its own unique emergency medical institute with a central medical call centre unit that tracks, co-ordinates and organizes the work of all the teams in the county area.

In 2014, a total of 641 physicians have steadily worked in emergency medical services in Croatia (decline of 4.7% compared to 2013). Also, there's an average of 7.094 inhabitants per EMS team (decline of 3.2% compared to 2013). The number of interventions in the field has increased by 16,3% in comparison to 2013 (183), as well as the number of interventions at home which have increased with 2,7% (312).

2.11 Women's health care

The main objectives of the woman health policy are not only to extend life expectancy, but also to improve the quality of life. In addition to the further improvement and development of health services this objective involves the promotion of healthier lifestyles, reduce or eliminate health risks that can prevent and improve the quality of life of chronically ill and disabled people.

During the 2014 1,672,864 women were followed-up by gynecologists in the primary health care sector, which is almost the same as in the 2013. According to the total number of women who

⁹ Croatia Medical Device Market Medical Intelligence Report, Quarter IV 2007, Espicom Business Intelligence

¹⁰ http://www.halmed.hr/en/O-HALMED-u/Usluge-i-cjenik/Cjenik-usluga-Agencije/#Annual_fees

have chosen their gynecologists in primary health care, 620,270 of them, or 37%, used their services.

According to the latest research of the Croatian Bureau of Statistics (2014), there were 2,192,588 women registered (51.7% of the total population). The number of women aged over 15, who are potential users of gynecologists in the primary health care sector (1,889,226), as well as women of childbearing age (945,333 or 43.1%) is in decline.

2.12 Dental care

The oral health care in Croatia ensures almost all basic dental procedures (restorative, endodontic, basic periodontal, oral surgery, oral diseases, orthodontics up to 18 years, and some prosthodontics) and emergency dental care. According to the figures from the Croatian Statistical Yearbook in 2014 there were 1 858 dental therapists, 1 853 doctors of dental medicine, 3 dentists with non-university college degree, 90 dental technicians and 1 723 dental auxiliaries. Those dental specialists received 4 646 000 visits in 2014. In which we can find that 2 230 431 were for fillings, 445 418 were there for an extraction, 1 118 391 for treatment of soft tissue and 288 460 came for prostheses.

2.13 Infant and young child care service

Primary health care for children in Croatia is mostly provided by primary pediatricians (PP) in the urban areas and by family doctors in rural areas.

Childrens health care had at its disposal 273 medical doctors in 2014. Protection is implemented for 409,053 insured persons, of which 275,749 (67.4%) are pre-school children, while others present mostly the school-age children population.

2.14 Occupational health service

Occupational health service is carried out through 145 occupational medicine specialists, 3 other specialists and 7 doctors of general medicine.

At the beginning of 2011, change has occurred in health care system especially in the field of occupational health services. The treatment of injuries and occupational diseases returns to general/family practitioners and to specialists. The Croatian Institute for Health Insurance (CIHI) licenses doctors for implementing preventive activities.

2.15 Home care service

In the home care service in 2014 there were 123 nurses with college education, 169 bachelors of physical therapy, 831 nurses with high school education and 168 physical therapists with high school education. According to the data on the number of the insured persons in primary health care, one health professional had on average 3,518 insured persons in care, wherein the average registered number of procedures per health professional was 1,706 per year. The total number of recorded procedures for the home care service in 2014 was 2,202,523 and 25.2% was in the age group 75-84 years.

2.16 Visiting health service

Tablica - Table 2. Usporedni prikaz broja posjeta u PATRONAŽNOJ ZDRAVSTVENOJ DJELATNOSTI od 1990. do 2014. godine u Hrvatskoj - The number of visits in Croatia 1990-2014, from the Health Visitors Service

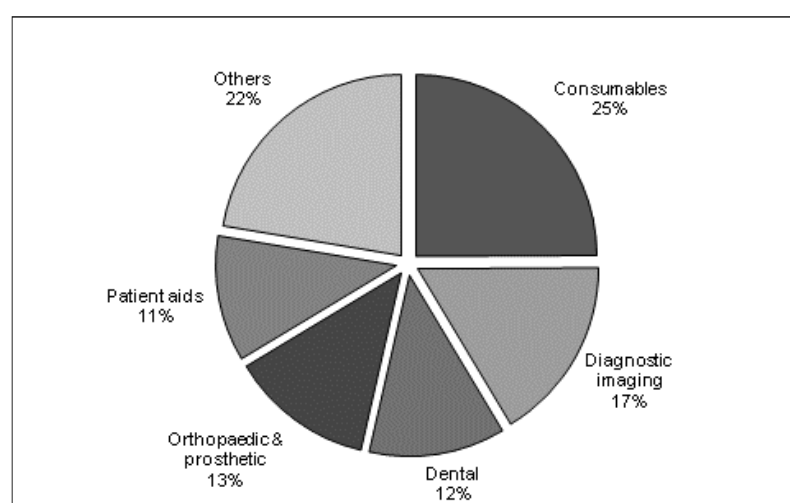
| GODINA | UKUPNO | POSJETI ZENAMA | POSJETI DJECI | POSJETI DOMAĆINSTVIMA | POSJETI ŠKOLAMA |
|--------|-----------|-----------------|--------------------|-----------------------|-------------------|
| Year | Total | Visits to women | Visits to children | Visits to households | Visits to schools |
| 1990. | 1.035.737 | 134.100 | 292.929 | 608.346 | 362 |
| 1991. | 837.829 | 108.278 | 218.782 | 510.448 | 321 |
| 1992. | 707.679 | 101.971 | 180.651 | 424.973 | 84 |
| 1993. | 698.675 | 100.411 | 177.051 | 413.074 | 8.139 |
| 1994. | 720.905 | 91.334 | 151.439 | 475.946 | 2.186 |
| 1995. | 976.010 | 133.331 | 226.806 | 613.755 | 2.118 |
| 1996. | 1.085.963 | 162.341 | 264.012 | 656.860 | 2.750 |
| 1997. | 1.221.618 | 179.702 | 293.467 | 745.882 | 2.567 |
| 1998. | 1.259.912 | 194.054 | 309.457 | 753.438 | 2.963 |
| 1999. | 1.177.853 | 192.236 | 301.346 | 662.427 | 2.029 |
| 2000. | 1.217.396 | 203.432 | 306.614 | 696.685 | 1.100 |
| 2001. | 1.286.021 | 206.182 | 311.100 | 758.006 | 1.652 |
| 2002. | 1.284.247 | 197.579 | 294.514 | 781.764 | 920 |
| 2003. | 1.420.394 | 205.818 | 312.107 | 889.760 | 919 |
| 2004. | 1.356.668 | 199.437 | 294.059 | 851.771 | 1.155 |
| 2005. | 1.315.052 | 196.008 | 274.077 | 832.865 | 1.134 |
| 2006. | 1.296.498 | 199.371 | 267.707 | 818.286 | 1.687 |
| 2007. | 1.398.229 | 213.506 | 296.166 | 879.018 | 756 |
| 2008. | 1.287.722 | 172.711 | 287.377 | 782.937 | 669 |
| 2009. | 1.318.260 | 172.790 | 288.272 | 813.738 | 1.210 |
| 2010. | 1.414.578 | 178.136 | 303.020 | 880.419 | 880 |
| 2011. | 1.465.526 | 180.799 | 309.446 | 924.012 | 1.419 |
| 2012. | 1.525.126 | 200.741 | 334.928 | 937.093 | 1.605 |
| 2013. | 1.346.088 | 177.433 | 296.627 | 821.097 | 864 |
| 2014. | 1.356.837 | 182.121 | 293.808 | 830.296 | 597 |

Source: Croatian Health Yearbook 2014

2.17 Import

As said earlier, the medical equipment in Croatia are mainly imported. In fact, 92% of the medical devices come from abroad and were valued at \$210 million in 2014. We can observe a 6% increase compared to 2013. ¹¹

Medical Device Imports by Product Area, 2012 (% Distribution)



Source: BMI Espicom

¹¹ US Commercial service, *Healthcare Resource Guide: Croatia*, Nina Radicevic, November 2015

2.17.1 Consumables

Imports of medical consumables amounted to US\$51.1 million in 2012, a decrease of 9.6% compared with 2011. This amounted to 24.9% of total imports in 2012. Imports of syringes, needles & catheters amounted to US\$21.9 million in 2012, while bandages & dressings amounted to US\$12.0 million.

2.17.2 Diagnostic imaging

Imports of diagnostic imaging equipment amounted to US\$33.9 million in 2012, or 16.5% of the total. This was a fall of 24.3% compared with 2011, with electrodiagnostic apparatus falling the most, by 29.2%. The figure does fluctuate strongly from year to year; the Compounded Annual Growth Rate (CAGR) for the 2007-12 period was -9.3%.

Imports of electrodiagnostic apparatus amounted to US\$14.3 million in 2012, while X-ray and related apparatus fell to US\$6.5 million.

2.17.3 Dental products

The import growth in the dental products sector has been uneven in recent years; the CAGR in 2007-12 was 0.8%. In 2012, the sector decreased by -0.3% to US\$25.0 million. Dental capital equipment fell by 7.1% to US\$3.5 million, while instruments & supplies increased by just 0.9% to US\$21.5 million.

2.17.4 Orthopaedic & prosthetic devices

Imports of orthopedic & prosthetic products amounted to US\$26.3 million in 2012, equal to 12.8% of the total. This sector had the highest 2007-12 CAGR (7.0%). Fixation devices fell by 14.7% to US\$7.6 million and artificial body parts fell by 10.6% to US\$11.4 million.

2.17.5 Patient Aids

Imports of patient aids amounted to US\$23.1 million in 2012, a decrease of 17.9% compared with 2011.

Portable aids fell by 9.5% to US\$15.6 million, although within this, imports of other portable aids increased by 8.4% to US\$8.9 million. Imports of therapeutic appliances fell by 31.4% to US\$7.4 million.

2.17.6 Other Medical Products

Imports of other medical products amounted to US\$45.9 million, or 22.4% of the total. The most important products in this category were other instruments & appliances (US\$33.9 million) and medical/surgical furniture (US\$4.0 million). In the previous year, kidney dialysis apparatus (US\$5.6 million), and endoscopy apparatus (US\$3.2 million) were also important categories, although no data was reported for these products in 2012.

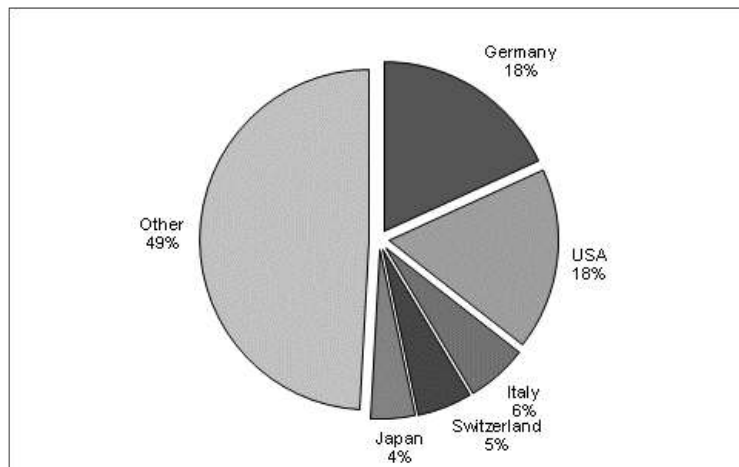
The largest supplier to Croatia in 2012 was Germany, accounting for US\$41.0 million or 20.0% of the total.

The EU as a whole supplied US\$110.7 million, equal to 54.0%. Other major EU suppliers included Italy and the UK.

The USA was the second largest supplier in 2012, accounting for US\$39.2 million or 19.1% of the total. The USA was particularly strong in the supply of orthopedic products, accounting for 24.8% of these.

The other major non-EU supplier in 2012 was Switzerland, which accounted for US\$11.8 million or 5.7% of the total. Patient aids accounted for a quarter of this.

Leading Medical Device Suppliers, 2012 - (% Distribution)

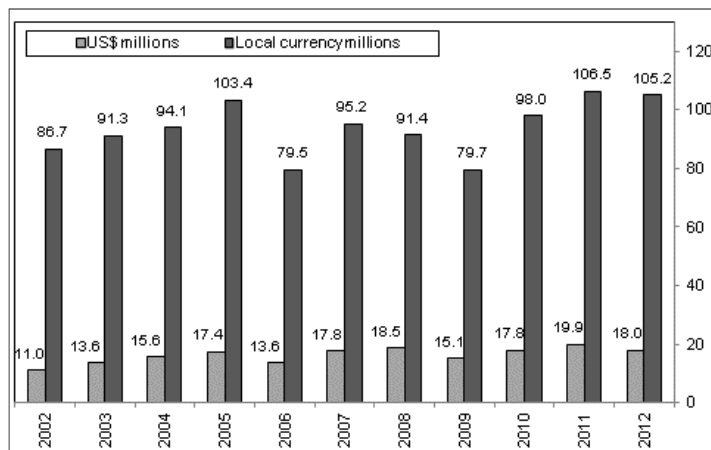


Source: Espicom

2.18 Export

Croatia is not a major medical equipment exporter; the total was US\$18.0 million in 2012, around half of which was sent to other former Yugoslav countries. Growth in exports was strong until 2005, but the level has since stabilised between US\$13 million and US\$20 million.

Medical Device Exports - 2002-2012



Source: Espicom

2.18.1 Consumables

Exports of medical consumables amounted to US\$2.2 million in 2012, equal to 12.3% of the total. This represented a decrease of 6.0% compared with 2011. Adhesive dressings and blood-grouping reagents accounted for all of the growth in 2012. Non-adhesive medical dressings accounted for the bulk of consumable exports; these were worth US\$919,000 in 2012, equal to 5.1% of total exports.

Blood grouping reagents represented 3.8% of exports in 2012, worth US\$675,000. Exports of syringes, needles & catheters amounted to US\$460,000, equal to 2.6% of total exports and a decrease of 20.1% compared with 2011.

2.18.2 Diagnostic Imaging Apparatus

Exports of diagnostic imaging equipment were valued at US\$2.5 million in 2012, a decrease of 51.0% compared with 2011 and equal to 13.8% of the total. Of this, US\$1.2 million was composed of electrodiagnostic apparatus.

2.18.3 Dental Products

Exports of dental products amounted to US\$1.9 million in 2012, or 10.8% of the total. The sector has performed poorly over the last few years and fell by 16.0% in 2012. Instruments and supplies accounted for the majority of exports, at US\$1.7 million in 2012.

2.18.4 Orthopaedic & Prosthetic Products

Exports of orthopedic & implantable products amounted to US\$5.7 million in 2012, equal to 31.5% of the total. This was one of the better performing sectors in 2012, growing by 5.9%. Fixation devices had the highest growth, increasing by 36.9% to US\$2.1 million.

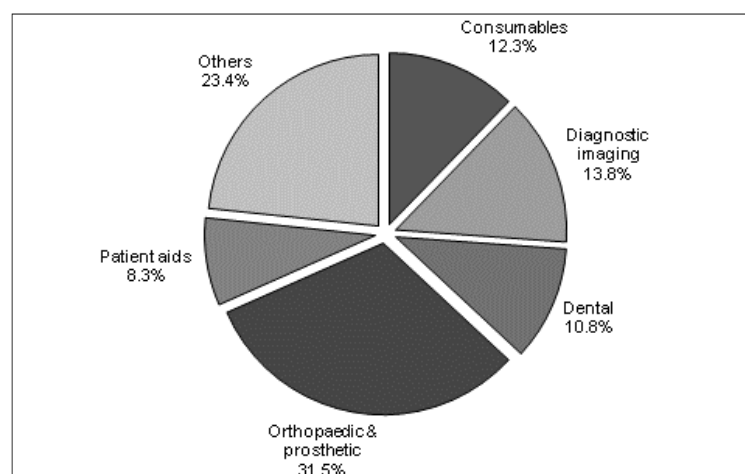
2.18.5 Patient Aids

Exports of patient aids amounted to US\$1.5 million in 2012, equal to 8.3% of the total. This was the best performing sector in 2012, increasing by 24.4% over 2011. Exports of other portable aids reached US \$860,000 and mechano-therapy apparatus US\$487,000.

2.18.6 Other Medical Products

The other major export categories for Croatia were medical/surgical furniture (US\$1.6 million) and wheelchairs (US\$239,000).

Medical Device Exports by Product Area, 2012 - % Distribution



Source: BMI Espicom

Other former Yugoslav countries remain the major destinations for Croatian exports. Bosnia-Herzegovina was the leading destination in 2012, accounting for US\$5.4 million or 29.8% of the total. Slovenia accounted for US\$1.6 million (8.9%) and Serbia for US\$982,000 (5.5%).

Germany was the other major destination in 2012, accounting for US\$2.9 million or 16.0% of the total. Germany was the destination for 37.3% of diagnostic imaging equipment and 23.9% of dental products.

2.19 The pharmaceutical market

The presence of generic products is very important in Croatia. However, we are able to observe an important increase of innovative medicines since 2012.

Despite the cuts made by HZZO by removing some drugs from the reimbursement list, repayment had generated most of the \$1.2 billion pharmaceutical sales in 2014. The total drugs expenditures had only known a small increase compared to \$1.19 billion in 2013.

The expenditures per capita for pharmaceuticals is similar in to other Central & Eastern European countries. Furthermore, the ranking of drugs by expenditures is: cardiovascular drugs representing 25% of all spending, the second are drugs for the nervous system, followed by immune system/cancer treatment drugs and gastro-intestinal drugs.¹²

2.19.1 The different Health institutions including pharmacies

29-1. ZDRAVSTVENE USTANOVE HEALTH INSTITUTIONS

| | 2010. | 2011. | 2012. | 2013. | 2014. | |
|---|-------|-------|-------|-------|-------|---|
| Zavodi za javno zdravstvo | 22 | 22 | 22 | 22 | 22 | <i>Institutes of public health</i> |
| Opće bolnice | 22 | 22 | 22 | 22 | 20 | <i>General hospitals</i> |
| Klinike | 10 | 12 | 13 | 13 | 13 | <i>Clinics</i> |
| Specijalne bolnice | 39 | 40 | 41 | 41* | 40 | <i>Special hospitals</i> |
| Domovi zdravlja | 49 | 49 | 49 | 49 | 49 | <i>Health centres</i> |
| Ljekarne | 181 | 184 | 187 | 187 | 181 | <i>Pharmacies</i> |
| Poliklinike | 352 | 363 | 362 | 360 | 350 | <i>Polyclinics</i> |
| Ustanove za njegu | 157 | 167 | 187 | 199 | 198 | <i>Care organisations</i> |
| Ustanove za medicinu rada ¹⁾ | 12 | 9 | 9 | 9 | 9 | <i>Institutions of occupational medicine¹⁾</i> |
| Zavodi za hitnu medicinu | ... | 13 | 20 | 21 | 21 | <i>Institutes of emergency medicine</i> |
| Ostale zdravstvene ustanove | 8 | 5 | 5 | 5 | 5 | <i>Other health institutions</i> |
| Trgovačka društva za obavljanje zdravstvene djelatnosti ²⁾ | 264 | 300 | 346 | 383 | 411 | <i>Health companies²⁾</i> |

¹²Source: Country commercial guide for U.S. companies, doing business in Croatia, 2015, <http://photos.state.gov/libraries/croatia/231771/PDFs/Croatia%202015%20Country%20Commercial%20Guide.pdf>

2.19.2 Health workers in the different pharmacies

Tablica – Table 1. ZDRAVSTVENI DJELATNICI I BROJ IZVANBOLNIČKIH I BOLNIČKIH LJEKARNI U HRVATSKOJ U 2013. GODINI - Health workers at hospital and nonhospital pharmacies, Croatia 2013

| ZDRAVSTVENI DJELATNICI <i>Health workers</i> | VRSTA LJEKARNE - <i>Type of pharmacy</i> | |
|---|--|-----------------------------|
| | IZVANBOLNIČKA <i>Nonhospital</i> | BOLNIČKA <i>Hospital</i> |
| FARMACEUTI SPECIJALISTI - <i>Pharmaceutical specialists</i> | | |
| UKUPNO - <i>Total</i> | 12 | 17 |
| • FARMACEUTSKA TEHNOLOGIJA - <i>Pharmaceutical technology</i> | 6 | 6 |
| • ISPITIVANJE I KONTROLA LIJEKOVA - <i>Drug testing and control</i> | 1 | 7 |
| • FARMACEUTSKA INFORMATIKA - <i>Pharmaceutical informatics</i> | 4 | 0 |
| • KLINIČKA FARMACIJA - <i>Clinical pharmacology</i> | 0 | 4 |
| • SANITARNA KEMIJA - <i>Sanitary chemistry</i> | 1 | 0 |
| FARMACEUTI - <i>Pharmacists</i> | 2.354 | 87 |
| • MEDICINSKA BIOKEMIJA - <i>Medical biochemistry</i> | 1 | 3 |
| FARMACEUTSKI TEHNIČARI - <i>Pharmaceutical technicians</i> | 1.640 | 161 |
| MEDICINSKE SESTRE - TEHNIČARI - <i>Nurses-technicians</i> | 1 | 2 |
| BROJ LJEKARNI - <i>No. of pharmacies</i> | 2.115 | 57 |

It's important to know that the Agency for Medicinal Products and Medical Devices is the main Croatian institution responsible to contribute to the safety and quality of medicines and medical devices through effective risk management and market surveillance but also the risk-based regulatory framework. For instance, it has published its first list of drugs that can be bought without prescription in June 2013. If some products are to be sold in ordinary stores, dealers must comply with the regulations prescribed by the Ministry of Health, which require strict regulations about transport, warehousing and storage of these products.

2.19.3 Pharmaceutical wholesalers

List of biggest pharmaceutical wholesalers active in the country:

- Medika d.d., the leading pharmaceutical wholesaler in Croatia in 2014 with an income of € 291.050.100
<http://www.medika.hr/hr/>
- PHOENIX Farmacija d.d, the second largest pharmaceutical wholesaler in Croatia with a turnover of € 219.157.600 in 2014.
<http://www.phoenix-farmacija.hr/>
- Medical Intertrade, one of the largest Croatian wholesalers (turnover of € 202.136.600 in 2014)
<http://www.medical-intertrade.hr/>
- Oktal pharma, 49% owned by the German company Andrae-Noris Zahn AG had a turnover of € 154.102.800 in 2014
<http://www.oktal-pharma.hr/>

The sector of the pharmaceutical wholesalers is very concentrated: the 4 largest wholesalers account together for around 90% of the market.

2.19.4 Pharmaceutical manufacturers

- PLIVA HRVATSKA d.o.o. is the main pharmaceutical producer in Croatia with a turnover in 2014 of € 495.794.700
<http://www.pliva.hr/>
- BELUPO d.d. is the challenger and came at the second place in term of turnover with € 83.023.500 in 2014
<http://www.belupo.hr/>
- JGL d.d. completed the podium with a turnover of € 82.805.600
<http://www.jgl.hr/hr/naslovna/>

2.19.5 Pharmaceutical retailers

Since the beginning of the 1990s, when the first privatizations were allowed, a lot of state pharmacies have been privatized, more particularly since 1996. The law determines the minimal distance authorized between each pharmacy, and the minimal number of insured persons that each pharmacy has to cover.

On the table below, we can see the different classification of pharmaceutical specialists, pharmacists, pharmaceutical technicians, nurses-technicians and the number of pharmacies owned by the state or not in 2013.

Tablica – Table 1. ZDRAVSTVENI DJELATNICI I BROJ IZVANBOLNIČKIH I BOLNIČKIH LJEKARNI U HRVATSKOJ U 2013. GODINI - Health workers at hospital and nonhospital pharmacies, Croatia 2013

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|---|--|-----------------------------|
| | IZVANBOLNIČKA <i>Nonhospital</i> | BOLNIČKA <i>Hospital</i> |
| FARMACEUTI SPECIJALISTI - <i>Pharmaceutical specialists</i> | | |
| UKUPNO - <i>Total</i> | 12 | 17 |
| . FARMACEUTSKA TEHNOLOGIJA - <i>Pharmaceutical technology</i> | 6 | 6 |
| . ISPITIVANJE I KONTROLA LIJEKOVA - <i>Drug testing and control</i> | 1 | 7 |
| . FARMACEUTSKA INFORMATIKA - <i>Pharmaceutical informatics</i> | 4 | 0 |
| . KLINIČKA FARMACIJA - <i>Clinical pharmacology</i> | 0 | 4 |
| . SANITARNA KEMIJA - <i>Sanitary chemistry</i> | 1 | 0 |
| FARMACEUTI - <i>Pharmacists</i> | 2.354 | 87 |
| . MEDICINSKA BIOKEMIJA - <i>Medical biochemistry</i> | 1 | 3 |
| FARMACEUTSKI TEHNIČARI - <i>Pharmaceutical technicians</i> | 1.640 | 161 |
| MEDICINSKE SESTRE - TEHNIČARI - <i>Nurses-technicians</i> | 1 | 2 |
| BROJ LJEKARNI - <i>No. of pharmacies</i> | 2.115 | 57 |

The pharmaceutical sector has been suffering from the health debts and payment delays of the HZZO, which accentuated the already low budget of the sector.

2.20 Medical Technology, Operation Theaters and Medical Procedures

In 2014, HZJZ (Croatian Institute for Public Health) has collected and processed data on the following subjects: medical equipment, operating rooms and conducted medical procedures in Croatia.

The data were collected from the following institutions:

- Clinical centers, teaching hospitals and clinics (1 institution did not submit data)
- General hospitals (all institutions have to submit data)
- Special hospitals and health resorts (1 institution did not submit)
- Health centers
- Institute for Emergency Medicine
- Part of the office specialist health care, clinics and companies for health activity (data delivered by 115 institutions from 450 contacted).

Tablica – Table 2. Operacijske dvorane – Operation Theatres

| | U bolničkim ustanovama - <i>In hospitals</i> | U ostalim zdravstvenim ustanovama - <i>In other health care facilities</i> | Ukupno - Total |
|---|---|---|-----------------------|
| Operacijske dvorane - Operation theatres | 412 | 30 | 442 |

Tablica – Table 3a. Provedeni medicinski postupci ukupno – Medical Procedures Total

| Medicinski postupak - Medical Procedure | Stacionarno - Inpatient cases | | U dnevnoj bolnici - Day cases | | Ambulantno - Outpatient cases | |
|--|-------------------------------|------------------|-------------------------------|-------------------|-------------------------------|-------------------|
| | Plaćanje HZZO - | Plaćanje ostalo | Plaćanje HZZO - | Plaćanje ostalo - | Plaćanje HZZO - | Plaćanje ostalo - |
| | Paid by HZZO | - Paid by others | Paid by HZZO | Paid by others | Paid by HZZO | Paid by others |
| Ekstirpacija, ekscizija i uklanjanje intrakranijalne lezije - <i>Extirpation, excision and destruction of intracranial lesion</i> | 789 | 4 | | | | |
| Evakuacija subduralnog hematoma i intrakranijalnog krvarenja - <i>Evacuation of subdural haematoma and intracranial haemorrhage</i> | 755 | 11 | | | | |
| Discektomija - <i>Discectomy</i> | 2.588 | 43 | | | | |
| Tiroidektomija - <i>Thyroidectomy</i> | 2.476 | 10 | 75 | | | |
| Operacija katarakte - <i>Cataract surgery</i> | 19.333 | 21 | 1.297 | 1.600 | 530 | 2 |
| Implantacija umjetne pužnice - <i>Cochlear implantation</i> | 85 | | | | | |
| Tonzilektomija - <i>Tonsillectomy</i> | 4.619 | 22 | 152 | | 466 | |
| Pulmektomija - <i>Pulmectomy</i> | 664 | | | | | |
| Dijagnostička bronhoskopija s ili bez biopsije - <i>Diagnostic bronchoscopy with or without biopsy</i> | 14.213 | 81 | 127 | | 14.436 | 142 |
| Transluminalna koronarna angioplastika - <i>Transluminal coronary angioplasty</i> | 10.898 | 124 | 20 | | 162 | 37 |
| Koronarna aortna prenosnica graftom - <i>Coronary artery bypass graft</i> | 2.274 | 7 | | | | |
| Karotidna endarterektomija - <i>Carotid endarterectomy</i> | 881 | 1 | | | | |
| Rekonstruktivna terapija infrarenalne aneurizme aorte - <i>Infrarenal aortic aneurysm repair</i> | 243 | | | | | |
| Femoro-poplitealna prenosnica - <i>Femoropopliteal bypass</i> | 510 | 1 | | | | |
| Transplantacija matičnih stanica (stem cell) - <i>Stem cell transplantation</i> | 208 | 4 | | | | |
| Kolonoskopija s ili bez biopsije - <i>Colonoscopy with or without biopsy</i> | 12.176 | 8 | 1.189 | 36 | 28.225 | 1.198 |
| Otvorena kolektomija - <i>Open colectomy</i> | 2.553 | 9 | | | 1.077 | |
| Laparoskopska kolektomija - <i>Laparoscopic colectomy</i> | 81 | | | | | |
| Otvorena apendektomija - <i>Open appendectomy</i> | 3.284 | 29 | | | | |
| Laparoskopska apendektomija - <i>Laparoscopic appendectomy</i> | 1.784 | 16 | | | | |
| Otvorena kolecistektomija - <i>Open cholecystectomy</i> | 2.039 | 24 | | | | |
| Laparoskopska kolecistektomija - <i>Laparoscopic cholecystectomy</i> | 7.046 | 19 | | | | |
| Otvorena reparacija ingvinalne kile - <i>Open repair of inguinal hernia</i> | 7.620 | 29 | | | 6 | |
| Laparoskopska reparacija ingvinalne kile - <i>Laparoscopic repair of inguinal hernia</i> | 475 | 1 | | | | |
| Transplantacija bubrega - <i>Kidney transplantation</i> | 275 | 2 | | | | |
| Otvorena prostatektomija - <i>Open prostatectomy</i> | 1.114 | 12 | | | | |
| Transureteralna prostatektomija - <i>Transurethral prostatectomy</i> | 1.466 | 8 | | | | |
| Otvorena histerektomija - <i>Open hysterectomy</i> | 4.068 | 20 | 1 | | 16 | |
| Laparoskopska histerektomija - <i>Laparoscopic hysterectomy</i> | 248 | | | | | |
| Čarski rez - <i>Caesarean section</i> | 7.333 | 245 | | | | |
| Artrioskopska ekscizija meniska koljena - <i>Arthroscopic excision of meniscus of knee</i> | 4.369 | 108 | 232 | | | |
| Endoproteza kuka - <i>Hip replacement</i> | 5.601 | 28 | | | | |
| Zamjena endoproteze kuka - <i>Secondary hip replacement</i> | 662 | | | | | |
| Totalna endoproteza koljena - <i>Total knee replacement</i> | 2.332 | 23 | | | | |
| Parcijalna mamektomija - <i>Partial excision of mammary gland</i> | 2.519 | | | | 367 | |
| Totalna mastektomija - <i>Total mastectomy</i> | 1.669 | 1 | | | | |
| CT pregled - <i>CT exams</i> | 150.599 | 681 | 4.866 | 262 | 179.963 | 2.411 |
| MR pregled - <i>MRI exams</i> | 23.393 | 100 | 1.268 | 11 | 95.120 | 3.591 |
| PET pregled - <i>PET exams</i> | 30 | | | | 2.024 | 25 |

Tablica – Table 1. **Medicinska oprema – Medical Technology**

| Vrsta opreme - Type of technology | | U bolničkim ustanovama - In hospitals | U ostalim zdravstvenim ustanovama In other health care facilities | Ukupno - Total |
|-----------------------------------|---|--|--|----------------|
| 1. | CT uređaj - CT scanner | 50 | 14 | 64 |
| 1.1. | s jednim ili dva reda detektora | 23 | 3 | 26 |
| 1.2. | sa 6 redova detektora | 2 | 1 | 3 |
| 1.3. | s 8 redova detektora | 1 | 0 | 1 |
| 1.4. | sa 16 redova detektora | 17 | 6 | 23 |
| 1.5. | s 32 reda detektora | 1 | 0 | 1 |
| 1.6. | sa 64 reda detektora | 6 | 4 | 10 |
| 2. | PET CT uređaj - PET CT scanner | 1 | 4 | 5 |
| 3. | MR uređaj - MR unit | 25 | 19 | 44 |
| 3.1. | 0,3 T | 1 | 1 | 2 |
| 3.2. | 0,5 T | 3 | 0 | 3 |
| 3.3. | 1,5 T | 21 | 18 | 39 |
| 4. | Mamograf - Mammograph | 47 | 75 | 122 |
| 4.1. | klasični | 37 | 61 | 98 |
| 4.2. | digitalni | 10 | 14 | 24 |
| 5. | Gama kamera - Gamma camera | 22 | 0 | 22 |
| 6. | SPECT uređaj - SPECT scanner | 4 | 0 | 4 |
| 7. | SPECT/CT uređaj - SPECT/CT scanner | 5 | 1 | 6 |
| 8. | Angiosala - DSA - Angiography unit | 34 | 0 | 34 |
| 8.1. | digitalizirana | 20 | 0 | 20 |
| 8.2. | digitalna | 14 | 0 | 14 |
| 9. | Dijagnostički RTG uređaj - Radiography unit | 297 | 214 | 511 |
| 9.1. | uređaj za radiografiju | 203 | 184 | 387 |
| 9.1.1. | konvencionalni/klasični sa snimanjem na film | 114 | 89 | 203 |
| 9.1.2. | konvencionalni/klasični s digitalizatorom | 45 | 38 | 83 |
| 9.1.3. | digitalni | 44 | 57 | 101 |
| 9.2. | dijaskopski uređaj | 94 | 30 | 124 |
| 9.2.1. | klasični | 37 | 13 | 50 |
| 9.2.2. | kombinirani/višenamjenski | 57 | 17 | 74 |
| 10. | Litotriptor - Lithotripter | 26 | 1 | 27 |
| 11. | Denzitometar - Densitometer | 35 | 24 | 59 |
| 12. | Ultrazvučni uređaj - Ultrasound unit | 763 | 406 | 1169 |
| 12.1. | kardiološki | 122 | 61 | 183 |
| 12.2. | ginekološki | 117 | 164 | 281 |
| 12.3. | ostali (NE uključuje uređaje za UZV fizikalnu terapiju) | 524 | 181 | 705 |
| 13. | Gamma knive | 1 | 0 | 1 |
| 14. | Anestezioološki uređaj - Anaesthetic machine | 489 | 55 | 544 |
| 15. | Defibrilator - Defibrillator | 660 | 744 | 1404 |
| 16. | Respirator - Medical ventilator | 708 | 191 | 899 |
| 17. | Uređaj za dijalizu - Dialysis machine | 807 | 156 | 963 |
| 18. | Uređaj za ekstrakorporalnu cirkulaciju - Heart-lung machine | 16 | 0 | 16 |
| 19. | ECMO uređaj - Extra corporal membrane oxygenation machine | 31 | 1 | 32 |
| 19.1. | s cirkulacijskom pumpom (duža cirkulacijska potpora, do 60 dana) | 28 | 0 | 28 |
| 19.2. | s cirkulacijskom pumpom (kraća cirkulacijska potpora, do 7 dana) | 3 | 1 | 4 |
| 20. | EEG | 117 | 34 | 151 |
| 21. | EMG | 68 | 15 | 83 |
| 22. | Linearni akcelerator - Linear Accelerator | 15 | 0 | 15 |
| 22.1. | s klasičnim/konvencionalnim simulatorom | 3 | 0 | 3 |
| 22.2. | s CT simulatorom | 12 | 0 | 12 |
| 23. | Uređaj za brahiterapiju - Brachytherapy system | 5 | 0 | 5 |
| 23.1. | s niskom brzinom doze - LDR | 2 | 0 | 2 |
| 23.2. | s visokom brzinom doze - HDR | 3 | 0 | 3 |
| 24. | Uređaj za radioterapiju kobaltom 60 - Cobalt-60 radiotherapy units | 0 | 0 | 0 |
| 25. | Uređaj za radioterapiju cezijem 137 - Caesium-137 radiotherapy units | 1 | 0 | 1 |
| 26. | RTG uređaj za radioterapiju | 6 | 0 | 6 |
| 27. | Ergometar - Ergometer | 70 | 53 | 123 |
| 28. | Inkubator - Incubator | 290 | 7 | 297 |
| 29. | Set za gastroskopiju - Gastroscopy set | 166 | 33 | 199 |
| 30. | Set za kolonoskopiju - Colonoscopy set | 132 | 34 | 166 |
| 31. | Set za rektoskopiju - Rectoscopy set | 37 | 20 | 57 |
| 32. | Set za artroskopiju - Arthroscopy set | 50 | 3 | 53 |
| 33. | Set za cistoskopiju - Cystoscopy set | 99 | 12 | 111 |
| 34. | Set za kolposkopiju - Colposcopy set | 37 | 29 | 66 |
| 35. | Set za bronhoskopiju - Bronchoscopy set | 121 | 0 | 121 |
| 36. | Set za laparoskopiju - Laparoscopy set | 116 | 3 | 119 |

In order to join the European Union, Croatia had to meet the standards issued by Brussels. The response to this pressure has given rise to many reforms between 2006 and 2013, particularly in the financial stabilization of the health care system. The Ministry of Health has taken important measures between 2008 and 2011 in order to reach the objectives. Mostly in the diversification of public revenue, changes in co-payment policy and measures to resolve accumulated arrears.

Table 6.1
Financial stabilization measures of the 2008–2011 reform

| Measure | Specific actions |
|---|---|
| Diversification of public revenue | <ul style="list-style-type: none"> • MHI contributions for the retired with pension under the average salary paid from general taxation: rate 1% of gross pension • retired with pension over the average salary pay MHI contributions: rate 3% of gross pension • MHI contributions for the unemployed paid from general taxation: rate 5% of fixed sum • MHI contributions for pupils, students, war veterans, soldiers, asylum-seekers, etc. paid in bulk from the State budget • hypothecated cigarette taxation: 32% of excise duty • tax on mandatory car insurance premiums: 7% (to cover the cost of health care provided due to traffic accidents) • MHI contributions for 100% disabled, organ donors, multiple blood donors, pupils, students and all individuals with income per household member under the national poverty census threshold: paid from general taxation • CHI contributions: price increase from HRK 50 to HRK 80 per month for the retired and HRK 80 to HRK 130 for the employed with high salaries |
| Changes in co-payment policy | <ul style="list-style-type: none"> • inpatient and outpatient hospital services: 20% of price (previously 15–50%) • dentistry: 20% of price (previously 15–50%) • primary care family medicine and gynaecology: deductible of HRK 15* per visit • prescriptions – deductible of HRK 15* per prescription • price cap for all co-payments (maximum): HRK 3000** per episode of illness • reduced number of people exempt from co-payments |
| Measures to resolve accumulated arrears | <ul style="list-style-type: none"> • stringent control of expenditure on all levels of the system • monitoring of debts and arrears • ban on increasing arrears for health care providers |

Source: Vončina et al. (2012).

Notes: *HRK 10 (€1) from 1 October 2013; **HRK 2000 (€264) from 1 October 2013; CHI = complementary health insurance; MHI = mandatory health insurance.

The financial stabilization was mostly focused on the improving of the position of public hospitals divided in 2 parts: the joint hospital procurement and the financial restructuring of public hospitals.

After the economic crisis, one of the measures to increase state savings was the implementation of a joint hospital procurement programme for public hospitals. The principle was based on the grouping of hospitals for a purchasing order to reduce costs such as for drugs, medical devices and energy. Hospitals that had made orders with the best value for money have become a central purchasing for different hospitals and thus permitting decentralized logistics. Central procurement was launched for 15 groups of goods and services in October 2012.

Because of low funds of some hospitals, an Act on Financial Restructuring of Public Institutions was launched in 2012 to reduce the debts of the state and improve the efficiency of public institutions. The theory was based on a management transfer from hospitals to the Ministry of Health during financial reorganization and for two years following the end of this procedure. This centralization of the administration has been financed from the State budget.

For the last 2 years, the reforms have been oriented to the improving and development of EMS (emergency medical service) but also the improving access to public health services, development

and standardization of the infrastructure, investment in human resources and e-health and improvement of telemedicine¹³

2.21 E-health

The computerization of health is a priority area of the e-Croatia program which expects to improve the quality of service to citizens with considerable financial savings and it's in constant evolution such as for example for e-prescription. Thanks to the computerization of the entire health care system, Croatia is a huge IT canvas with more than 17,000 users in the Central Health Care Information System in Croatia (CEZIH) including all different medicine offices (family medicine, pediatric, gynecological, dentist, pharmacies, primary health care laboratories, school medicine, out-of-hospital specialist-consiliary health care). All members put data into the central database and in return receive advanced reports on the functioning of the health care system.

The ultimate purpose of computerization of health care is:

- To contribute directly to the improvement of the health care service quality, safety and consistency.
- To provide better communication between all participants in the health care through central management of patients' data, in primary, secondary and tertiary care (electronic medical record), centralised managing of processes in the health care system (e.g. e-appointment) and connecting all health care registers
- To achieve a complete availability of health care to patients through quick and secure access to their own health record, as well as to information on health services and the quality of health care.
- To enhance efficient administration and better management in the health care system by building an advanced reporting system including all data in the health care system, which would make a reliable support to health care authorities and decision makers and allow more efficient spending of resources.
- To align the health system with the political goals of digitalisation of the public sector and provision of electronic services to the population, in coordination with other state administration bodies and in accordance with the strategy of the Republic of Croatia and eCroatia.¹⁴

2.22 Chronic Diseases Registries

2.22.1 Croatian Registry of Treated Psychoactive Drug Abusers

The Information on persons treated for addiction are collected by the Croatian National Institute of Public Health. In 2014, 7,812 persons were registered in the Croatian Health Institutions for addiction on psychoactive drugs, compared to 2013 the total number of addicts decreased by 0,57%. The most evident abuse of opiates is registered in the Zadar County, with a rate of 486.3 per 100.000 inhabitants. The male population represent the largest share (82.5%) of treated patients. The younger population of reported users being treated for cannabis, is send to Juvenile Court in order to avoid criminal proceedings, but is implemented by true measures which include imposed treatments. The opening of the center for needle and syringe exchange and consulting and free testing for Hepatitis B and C and HIV contributed to responsible behaviour of addicts and better compliance.

¹³ Source: Health Systems in Transition, Croatia, Health system review, 2014

¹⁴ Source: Ministry of Health of the Republic of Croatia, National Health Care Strategy 2012-2020

2.22.2 Croatian National Cancer Registry

The Cancer Registry was founded in 1959 in order to collect data for processing and analysing records of cancer. From 1994 the Croatian Cancer Registry is a full member of the International Association Registry on Cancer (IARC). Cancer is the second most influential cause of death in Croatia, representing the cause of death of every fourth inhabitant. In 2013, 13,788 people died of cancer including 7,888 men and 5,900 women. Overall mortality rates for cancer were 321.8/100,000 (381.7/100,000 for males and 265.9/100,000 for women). Compared with other European countries, Croatia is a country with high incidence, and also a high rate of mortality from cancer.

2.22.3 Croatian Committed Suicides Registry

There have been an oscillating number of completed suicides during the years in Croatia.

Since 1999, there is a downward trend of suicides, according to the datas on the 2000 and 2014 period, 1.156 cases of suicides were registered. The most common method of committing suicide is by hanging.

2.22.4 Croatia's Disabilities Registry

In order for the appropriate precautionary measures to be adopted the program for people with disabilities must be well organized and always improved, so that the health level of the population and the years of life, and the years without disease and disability be increased. The important data for the Registry are collected by Ministries of Health and Social Welfare, Education and Family, the Croatian Pension Fund and the Ministry of Sea, Tourism, Transport and development. The total number of persons with disabilities is 507.645 in 2014, with a greater proportion of the male population (306.181).

The highest percentage of persons with disabilities is located in the city of Zagreb (90.684).

2.22.5 Croatian Psychoses Registry

The group of mental and behavioural disorders is on the seventh place for the hospitalizations reasons in Croatia. According to the number of days spent in the hospital on care, mental disorders are on the first place with a share of 23.9% in the total number of disease treatments.

2.22.6 National Diabetes Registry CroDiab

The National Diabetes Register has a great importance for the planning of preventive actions and reducing the costs in health care, and plays an important role in improving and ensuring quality care for the patients. The CroDiabNET application program or the CroDiab WEB online system is used as a tool to register a person with diabetes; it is obliged for every medical worker to report about patients with diabetes in his practice and under his therapy, which serves as the optimal column information needed for monitoring and improving quality diabetes care. In 2014 the data sharing program has connected with the central database of medical information in the Republic of Croatia in accordance with these data 254,296 adults diagnosed with diabetes were registered.

2.22.7 Zagreb City Acute Myocardial Infarction and Acute Coronary Syndrome Registry

Cardiovascular diseases are the leading cause of death in Croatia and represent a major health, economic and social problem. With the development of the official Registry there can be an estimation on the number of patients with acute coronal syndrome, in order to determine survival rates and mortality due to treatment, to determine which tests and treatments work and which complications occur during hospitalization.

3. Specific questions that could be of general interest

Which are the useful contacts and different institutions regarding the health care system in Croatia?

Ministry of Health in Croatia

Address: Ksaver 200a
10000 Zagreb, Croatia
Tel: +385 1 46 07 555
Fax: +385 1 46 77 076
Web: <https://zdravlje.gov.hr>
Contact: pitajtenas@miz.hr

Croatian Health Insurance Fund

Address: Margaretska 3
10000 Zagreb, Croatia
Tel: + 385 1 644 90 90
Web: <http://www.hzzo.hr/>
Contact: ncp-croatia@hzzo.hr

Agency for Medicinal Products and Medical Devices

Address: Ksaverska cesta 4
10 000 Zagreb, Croatia
Tel: +385 1 4884 100
Fax: +385 1 4884 110
Web: <http://www.almp.hr/en/>
Contact: halmed@halmed.hr

Croatian Institute of Public Health

Address: 7 Rockefeller Street
HR-10000 Zagreb, Croatia
Tel: +385 1 4863-222
Web: <http://www.hzjz.hr/english>
Contact: hzjz@hzjz.hr

Croatian Institute of Telemedicine

Address: Ksaver 211
10000 Zagreb, Croatia
Tel: +385 1 5496-086
Fax: +385 1 5496-099
Web: <http://ztm.hr/?q=en>
Contact: info@ztm.hr

Croatian Institute of Emergency Medicine

Address: Planinska 13, Zagreb, Croatia

Tel: +385 1 4677 390
Fax: +385 1 4677 180
Web: <http://www.hzhm.hr/english/>
Contact: info@hzhm.hr

How many certified laboratories for prenatal and neonatal screening are there in Croatia?

These are the public laboratories certified to conduct prenatal and neonatal screening in Croatia.

| Name | Address | N*Tel | Fax | E-mail | Website: |
|---------------------------------|----------------------------------|---------------|----------------|--|---|
| Klinički bolnički centar Zagreb | Kišpatićeva 12, 10000 Zagreb | +38512388 888 | | kbc-zagreb@kbc-zagreb.hr | http://www.kbc-zagreb.hr/ |
| Klinička bolnica "Sveti Duh" | Ulica Sveti Duh 64, 10000 Zagreb | +38513712 111 | +385 13712 308 | kb@kbsd.hr | http://www.kbsd.hr/ |
| Klinička bolnica "Merkur" | Zajčeva 19, 10000 Zagreb | +38512431390 | +38512431402 | ravnateljstvo@kb-merkur.hr | http://www.kb-merkur.hr |
| Klinička bolnica "Srebrnjak" | Srebrnjak 100, 10000 Zagreb | +38516391100 | +38516391188 | bolnica@bolnica-srebrnjak.hr | http://www.bolnica-srebrnjak.hr/ |
| Klinički bolnički centar Split | Spinčićeva 1, 21000 Split | +38521556517 | +38521556 020 | office@kbsplit.hr | http://www.kbsplit.hr/ |
| Klinički bolnički centar Rijeka | Krešimirova 42, 51000 Rijeka | +38551337536 | +38551658898 | info@kbc-rijeka.hr | http://www.kbc-rijeka.hr/ |
| Klinički bolnički centar Osijek | Josipa Huttlera 4, 31000 Osijek | +38531511511 | +38531512221 | ravnateljstvo@kbcos.hr | http://www.kbo.hr |
| Klinika "Vuk Vrhovac" | Dugi Dol 4a, 10000 Zagreb | +38512353800 | +38512331515 | SKVV@idb.hr | http://www.idb.hr |

Source: Mario TROŠELJ

E-mail: Mario.troselj@hzjz.hr
 Tel: + 385 1 4863 273
 Fax: + 385 1 4863011
 Croatian National Institute of Public Health
www.hzjz.hr

Private laboratories certified to conduct prenatal and neonatal screening in Croatia:

| Name | Address | N*tel | Fax | E-mail | Website: |
|----------------------------------|-------------------------------|--------------|--------------|--|---|
| Poliklinika Harni | Bukovačka 1/III, 10000 Zagreb | +38512923648 | +38512921603 | info@poliklinika-harni.hr | http://www.poliklinika-harni.hr/ |
| Poliklinika Breyer | Ilica 191, 10000 Zagreb | +38513775092 | +38513730932 | lab@breyer.hr | http://www.lab-breyer.com |
| Rodilište i poliklinika Podobnik | Sveti Duh 112, 10000 Zagreb | +38516398000 | +38516398010 | podobnik@podobnik.hr | http://www.podobnik.hr/ |

Where are pathologies actually screened?

Pathology screenings:

Clinic for pathology and pathological anatomy

Address: Braće Branchetta 20, 51000 Rijeka, Croatia

Tel: +385 51 325 803

Fax: +385 51 325 810

Web: <http://www.medri.uniri.hr/hr/fakultet/katedre/patologija.html>

Contact: Prof. dr. sc. Nives Jonjić, professor
nives.jonjic@medri.uniri.hr

Clinic for pathology and cytology

Address: Clinical Hospital Center, Zagreb, Kišpatičeva 12, 10 000 Zagreb, Croatia

Tel: +385 1 2388 365

Fax: +385 1 2376 029

Web: <http://www.kbc-zagreb.hr/>

Contact: Prof. dr. sc. Damir Babic
predstojnik.zpa@kbc-zagreb.hr

Clinic Hospital Merkur

Address: Zajčeva 19, Zagreb 10000, Croatia

Tel: +385 1 2431 410

Web: <http://www.kb-merkur.hr/>

Contact: izv. prof. dr. sc. Slavko Gasparov, dr. med.
slavko.gasparov@kb-merkur.hr

Are there already tenders made for neonatal and prenatal screening in Croatia? If yes, who is the contracting authority? Do you have other general information regarding this (type of kit, quantity, schedule, etc.)?

For general information regarding neonatal and prenatal screening please refer to the following link:
<http://www.hzjz.hr>

Or contact the **Croatian Ministry of Health:**

Mrs. Zdravka Šindik

E-mail: zdravka.sindik@miz.hr

Tel: +38514607669, +38514607591, +38514607571

The tenders are published on the following Webpage of HZZO (Croatian Institute for Health Insurance): <http://www.hzzo.hr/natjecaji>

HZZO, Margaretska 3, 10 000 Zagreb

Which pathologies are screened in the frame of national screening campaigns or will shortly be part of those campaigns? Do you have information regarding those screening campaigns?

In the Republic of Croatia national screenings are available for the following:

Early detection of cancer of the large intestine

Address: Ksaver 200a, 10000 Zagreb

Contact: prof. dr. sc. Nataša Antoljak, dr. med.

Tel: +385 4863 352

Fax: +385 1 4863 271

Web: <http://www.preventivniprogrami.hr>

Early detection of breast cancer

Address: Ksaver 200a, 10000 Zagreb

Contact: prof. dr. sc. Nataša Antoljak, dr. med.

Tel: +385 4863 352

Fax: +385 1 4863 271

Web: <http://www.preventivniprogrami.hr>

Anonyms and free testing for HIV/AIDS

Hrvatski zavod za javno zdravstvo

Rockefellerova 7

Služba za epidemiologiju zaraznih bolesti - Savjetovalište za HIV/AIDS na adresi Rockefellerova 12

Tel: +385 1 48 63 345

E-mail: hiv.savjet@hzjz.hr

Web: <http://www.hzjz.hr/sluzbe/sluzba-za-promicanje-zdravlja/odjel-za-promicanje-odgovornog-spolnog-ponasanja-sa-savjetovalistem/savjetovaliste-za-hiv-spolno-zdravlje>

Early detection of cervical cancer in women

Address: Ksaver 200a, 10000 Zagreb

Contact: prof. dr. sc. Nataša Antoljak, dr. med.

Tel: +385 1 4863 352

Fax: +385 1 4863 271

Web: <http://www.preventivniprogrami.hr>

Do you know the contracting authorities in the frame of prenatal and neonatal pathologies? Do you perhaps have some contacts? Do you know how the tenders are published? Is it a single authority who is opening the tenders or can each certified laboratory do it?

Regarding the neonatal and prenatal sector in Croatia, the following contacts could be of use:

Laboratory Breyer

Address: Ilica 191, Zagreb

Tel: +385 1 3775 092

Fax: +385 1 3730 932
Web: <http://www.lab-breyer.hr/>
E-mail: lab@lab-breyer.hr

Hospital of 'Sestre Milosrdnice' Laboratory

Address: KBC Sestre milosrdnice
Vinogradska cesta 29
10000 Zagreb

Tel: +385 1 37 87 111
Web: <http://www.kbcm.hr/>
E-mail: kbcm@kbcm.hr

For further information about medical instruments and distributors in Croatia please contact the following companies:

OKTAL PHARMA d.o.o.

Utinjska 40, 10020 Zagreb Hrvatska
Tel: +385 1 6595 777
Fax: +385 1 6595 701
E-mail: oktal-pharma@oktal-pharma.hr
Web: <http://www.oktal-pharma.hr/>

MEDICAL INTERTRADE

Sveta Nedelja – Zagreb
Dr. Franje Tuđmana 3
10431 Sveta Nedelja
Tel: +385 1 3374 010
Fax: +385 1 3374 002
E-mail: uprava@medical-intertrade.hr
Web: <http://www.medical-intertrade.hr/>

Are there rules in Croatia imposing the publishing of tenders depending on the amount concerned? If so, is there a website summarizing all published tenders?

According to the Public Procurement Act there is no rule imposing the publishing of a tender depending on its amount. However, as procurement notices are issued for every single purchase it might depend on the suppliers.

In some countries (for example France) the validation of the kit is mandatory. Is it also the case in Croatia? If so, do you know who is in charge of this and can you give us its coordinates?

The medical equipment law of Croatia requires the validation of all medical kits.

Here you can find information on the medical devices registered in the Medical Devices Register of the Agency for Medicinal Products and Medical Devices.

A medical device (under Article 2 of the Medical Devices Act, [Official Gazette No. 67/08](#)) (<http://narodne-novine.nn.hr/clanci/sluzbeni/339714.html>) is any instrument, apparatus, appliance, software, material or other product for human use which does not achieve its principal intended action by pharmacological, immunological or metabolic means, whether used alone or in combination with the software necessary for its proper application.

A medical device is to be used for the purpose of:

Diagnosis, prevention, monitoring, treatment and alleviation of disease;

Diagnosis, monitoring, treatment, control, alleviation or compensation for an injury or handicap;

Investigation, removal or replacement or modification of the anatomy or of a physiological process;

Control of conception.

Medical devices data are classified in two databases such as:

- registered before 1st July 2013, accessible for search via form '[Database search \(before 1 July 2013\)](#)'
- database comprising class I medical devices registered after 1st July 2013 and medical devices for which we received a notification after 1st July 2013 on placing on the Croatian market, accessible for search via form "[Database search according to subjects \(after 1st July 2013\)](#)" i "[Database search by medical device \(after 1st July 2013\)](#)".

There will be changes to the legislation above, but these changes will only refer to Croatian companies and citizens. Foreign companies will not be affected by the new regulations and will not have to comply with them.

Agency for medical products and medical devices

Ksaverska cesta 4

10000 Zagreb

Tel: +385 1 4884 100

Fax: +385 1 4884 110

E-mail: halmed@halmed.hr

Web: <http://www.almp.hr/>

All medical equipment has to undergo registration at the Croatian Agency for Medical Products and Medical Devices.

[Is it possible to send documentation regarding our products to the adjudicators so they can already register us in their data base?](#)

It is not possible for anybody to send documentation to adjudicators because this would cause a conflict of interest.

[Who could you recommend to contact regarding the tender system in Croatia?](#)

The Croatian Institute for Health and Insurance can provide more information on the tender system.

DIREKCIJA HZZO-a

Margaretska 3

10000 Zagreb

Tel: 0800 7999

Fax: +385 1 4812 606

<http://www.hzzo.hr/>

Is there any possibility of being registered in the database of the contracting authorities so as to be directly contacted when a tender is called?

No, but we advise you to contact distributors in Croatia and form a local partnership with distributors which will enable your company to know when a tender is called. The following companies could be interesting for you:

OKTAL PHARMA d.o.o.

Utinjska 40, 10020 Zagreb Hrvatska
Tel: +385 1 6595 777
Fax: +385 1 6595 701
E-mail: oktal-pharma@oktal-pharma.hr
Web: <http://www.oktal-pharma.hr/>

MEDICAL INTERTRADE

Sveta Nedelja – Zagreb
Dr. Franje Tuđmana 3
10431 Sveta Nedelja
Tel: +385 1 3374 010
Fax: +385 1 3374 002
E-mail: uprava@medical-intertrade.hr
Web: <http://www.medical-intertrade.hr/>

PHOENIX FARMACIJA d.d.

Ozaljska ulica 95
10000 Zagreb
Tel: +385 1 3650 111
Fax: +385 1 3650 110
Web: <http://www.phoenix-farmacija.hr/>
E-mail: info@phoenix-farmacija.hr

MEDIKA d.d.

Capraška 1, 10000 Zagreb, Croatia
Tel: +385 1 2412 555
Fax: +385 1 2371 441
E-mail: medika.uprava@medika.hr
Web: <http://www2.medika.hr/en/>

ASTRA INTERNATIONAL ZASTUPANJE INOZEMNIH TRVTKI

Trg Dražena Petrovića 3
10000 Zagreb, Croatia
Tel: +385 1 484 36 24
Fax: +385 1 484 36 68
E-mail: direktor@astazit.hinet.hr

BAN-PROMET

Lascunski Borovac 32
10000 Zagreb, Croatia
Tel: +385 1 232 55 85
Fax: +385 1 234 75 22
Web: www.ban-promet.hr
E-mail: info@ban-promet.hr

BISERNICA

Kestereanekova 1
10000 Zagreb, Croatia
Tel: +385 1 242 15 76
Fax: +385 1 242 15 81
Web: www.bisernica.hr
E-mail: bisernica@bisernica.hr

CROLAB

Berislavićeva 6
10000 Zagreb
Tel: +385 1 6111 570
Mobile: +385 91 4111 570
Web: <http://www.crolab.hr/>
E-mail: tajnistvo@crolab.hr

HILUS MEDICAL

Makrsimirska 96/III
10000 Zagreb, Croatia
Tel: +385 1 233 97 21
Fax: +385 1 233 97 23
Web: www.hilus.hr
E-mail: hilus@hilus.hr

MEDIAL

Ulica grada Vukovara 237B
10000 Zagreb, Croatia
Tel: +385 1 611 63 93
Fax: +385 1 615 44 55
Web: www.medial.hr
E-mail: medial@medial.hr