

HEALTHCARE AND MEDICAL EQUIPMENT IN CROATIA









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1. INTRODUCTION

GEOGRAPHY

The Republic of Croatia is located in Southeast Europe covering a total of 56,610 km². Croatia is bordering Slovenia, Hungary, Serbia, Bosnia-Herzegovina and Montenegro and has a long coastline 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, and has 124 towns.

POLITICAL OVERVIEW

Formerly a major constituent part of Yugoslavia, Croatia declared independence in June 1991. This lead to a prolonged war with Serbia, ostensibly over the fate of the areas of Croatia inhabited by Serbs.

The current president of Croatia is Ivo Josipović. Executive authority rests with the prime minister who is appointed by the president and is accountable to the parliament. The current prime minister is Zoran Milanović, the leader of the Social Democratic Party of Croatia (SDP). On July 1st 2013, Croatia became the 28th member of the European Union.

ECONOMIC OVERVIEW

GDP

Croatia boasts a larger economy than most of its immediate neighbours and in per capita terms, the country is similar to the CEE average. According to BMI, the economy contracted in 2009, 2010 and 2012. Growth of just 0.1% is expected in 2013 and modest average growth of 2.0% per annum is forecast for the 2014-2018 period. GDP is expected to reach US\$ 58.6 billion, or US\$ 13,534 per capita, by 2018. Inflation is expected to decrease slightly, averaging 3.2% in 2013.

GDP (I	GDP (mil. EUR)								
2003	2004	2005	2006	2007	2008	2009	2010	2011	2012
30.012	L 32.759	35.725	39.102	42.833	47.370	45.379	47.795	49.361	43647
	orconita								
GDP p	er capita	1							
2003	2004	2005	2006	2007	2008	2009	2010	2011	2012
6.759	7.380	8.043	8.807	9.656	10.682	10.245	10.820) 10.400	10.245

GDP –	GDP – yearly growth rate (%)									
2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	
5,0	4,2	4,2	4,7	5,5	2,4	-6	-1,2	0	-0,5	

Source: Croatian National Bank (HNB) <u>http://www.hnb.hr/;</u> Organization for Economic Co-operation and Development (OECD)

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, but also more recently in winter months, due to an increase in popularity of snow sports such as skiing. With over 10 million foreign tourists annually, tourism generates revenue in excess of \notin 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.

POPULATION

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

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

POPULATION BY AGE GROUP, ETHNICITY AND RELIGION

Age		65+	15-64	0-14
% o popula	of atior	15,7%	67,2%	17,1%

Croatia is inhabited mostly by Croats (89,6%), while minority groups include Serbs (4,5%), Bosniaks, Hungarians, Italians, Slovenes, Germans, Czechs, Roma 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%.

DEMOGRAPHICS

Principal Demographic Indicators

	2001	2006	2011
Live births	40,993	41,446	41,197
Rate/000 pop	9.2	9.3	9.4
Deaths	49,552	50,378	51,019
Rate/000 pop	11.2	11.3	11.9
Infant deaths	315	215	192
Life expectancy			
Male	71.1	n/a	73.9
Female	78.1	n/a	80,0

Source: http://www.hzjz.hr/publikacije/hzs ljetopis/, Croatian Health Service Yearbook 2012

According to the Croatian Central Bureau of Statistics (CBS), the most common causes of overall infant deaths were pathologic conditions from prenatal period and congenital malformations. As far as the total population is concerned, the leading causes of death in 2011 were circulatory diseases (24.841) and neoplasm (13.861). They represent ³⁄₄ of all deaths.

Others causes of disease are related to injuries and poisonings (62,8/100), digestive system (52,8/100), respiratory system (46,6/100).

2. HEALTHCARE AND MEDICAL EQUIPMENT SECTOR

FACILITIES INVOLVED IN HEALTH ACTIVITIES

Healthcare facilities 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 starting a process of merging due to which their number was reduced from 120 (in 2001) to 49 (in 2012). Out of 76 hospital institutions and sanitariums, nine special hospitals and five sanitariums were privately owned.

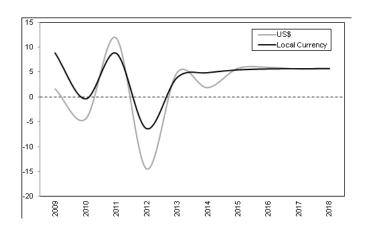
By the end of 2012, there were 5,792 private practice units (doctors' offices, laboratories, private pharmacies, private physical therapy practices and home care services) registered.

Out of these, 2,460 were private doctors' offices, 1,832 of which were rentals. There were 2,212 private dentists' offices; out of these 875 were rentals.

MEDICAL MARKET IN CROATIA

In 2013, the Croatian market for medical equipment and supplies is estimated at US\$ 232.1 million, or US\$ 53 per capita. It is expected that the market will expand at a rate of 5.0% per annum, reaching US\$ 295.6 million, or US\$ 68 per capita by 2018. 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.



Medical Device Market, 2009-18 (% Change)

Source: BMI Espicom

MEDICAL PERSONNEL

Croatia has fewer doctors per 100.000 inhabitants than the Central and Eastern European average.

64,255 health professionals and associates were employed in total on 31 December 2011 in the healthcare sector in Croatia.

Country	Doctors per 100.000 inhabitants in 2010
Croatia	227
Italy	350
Belarus	520
Norway	400
Spain	400
Belgium	380
Hungary	340
United Kingdom	270

Slovenia	250
USA	240

Source: http://www.hzjz.hr/publikacije/hzs_ljetopis/, http://data.worldbank.org/

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. BROJ ZDRAVSTVENIH DJELATNIKA ZAPOSLENIH U DRŽAVNIM ZDRAVSTVENIM USTANOVAMA PREMA VRSTI RADNOG ODNOSA I BROJ STANOVNIKA NA JEDNOG ZDRAVSTVENOG DJELATNIKA U HRVATSKOJ 2012. GODINE - Health workers employed in state and county institutions (permanent job and total) and population per one health worker, Croatia 2012

Zdravstveni djelatnici	Neodređeno	Broj stanovnika na 1 zdrav. djelatnika	Sveukupno a	 Broj stanovnika na 1 zdrav. djelatnika
Health workers	Permanent	Population per one health worker	Total	Population per one health worker
Doktori medicine - Medical doctors	9.705	442	10.397	412
Doktori dentalne med Doctors of dental. med	. 698	6.139	854	5.017
Farmaceuti - Pharmacists	1.165	3.678	1.235	3.470
Suradnici s visokom stručnom spremom				
 Other university degree staff 	854	5.017	995	4.306
Viša stručna sprema - Junior college education	7.081	605	7.981	537
Srednja stručna sprema - High school educatio	n 20.126	213	23.420	183
Niža stručna sprema - Semi-skilled	414	10.350	444	9.651
Ukupno - Total	40.043	107	45.326	95

Source: Croatian Health Yearbook 2012

Tablica - Table 14.

DOKTORI MEDICINE SPECIJALISTI PO GRANAMA SPECIJALNOSTI U PRIVATNOJ PRAKSI U HRVATSKOJ NA DAN 31.12.2012.

- Croatia's private medical doctors by specialty, December 31, 2012

SPECIJALNOST	Broj	
Specialty	No.	
OPĆA MEDICINA - General medicine	398	
OBITELJSKA MEDICINA - Family medicine	482	(9)#
INTERNA MEDICINA - Internal medicine	45	(1)#
PNEUMOFTIZIOLOGIJA - Pneumophthisiology	9	
INFEKTOLOGIJA - Infectology	1	
NEUROLOGIJA - Neurology	5	
PSIHIJATRIJA - Psychiatry	50	(1)#
NEUROPSIHIJATRIJA - Neuropsychiatry	12	
DERMATOLOGIJA I VENEROLOGIJA - Dermatology and venerology	36	
PEDIJATRIJA - Pediatrics	186	
OPĆA KIRURGIJA - General surgery	4	
MAKSILOFACIJALNA KIR Maxillofacial surgery	1	
PLASTIČNA KIRURGIJA - Plastic surgery	1	
SPORTSKA MEDICINA - Sports medicine	2	
UROLOGIJA - Urology	2	
ORTOPEDIJA - Orthopedics	12	
OTORINOLARINGOLOGIJA - Otorhinolaringology	13	
OFTALMOLOGIJA - Ophthalmology	41	
OPSTETRICIJA I GINEKOLOGIJA - Obstetrics and gynecology	190	(1)#
ANESTEZIOLOGIJA I REANIMACIJA - Anesthesiology and resuscitation	5	
TRANSFUZIJSKA MEDICINA – Transfusiology medicine	1	
RADIOLOGIJA - Radiology	14	
RADIOTERAPIJA I ONKOLOGIJA – Radiotherapy and oncology	1	
FIZIKALNA MEDICINA I REHABILITACIJA - Physical medicine and rehabilitation	27	
MEDICINA RADA - Occupational health	144	
ŠKOLSKA MEDICINA - School medicine	69	
EPIDEMIOLOGIJA - Epidemiology	1	
MEDICINSKA MIKROBIOLOGIJA S PARAZITOLOGIJOM		
 Medical microbiology with parasitology 	2	
NUKLEARNA MEDICINA - Nuclear medicine	1	
KLINIČKA CITOLOGIJA - Clynical citology	7	
PATOLOŠKA ANATOMIJA – Anatomical pathology	2	
	1.764	

SPECIJALIZANTI - On specialty training

Source: Croatian Health Yearbook 2012

HEALTHCARE EXPENDITURES

Based on data from the World Health Organisation (WHO), Espicom estimates that Croatia spent 7.9% of GDP on healthcare in 2012, equal to US\$ 4.9 billion, or US\$ 1,118 per capita. Around 85% of this was in the public sector, worth US\$ 4.2 billion or US\$ 946 per capita. Compulsory health insurance accounted for 91% of public health expenditure in 2012.

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 dependants. Whilst the system has significantly reduced the number of unofficial payments made in the healthcare sector, out-of-pocket payments still accounted for almost all private health expenditure in 2012. Total private healthcare expenditure accounted for 15.4% of total spending in 2012, equal to US\$ 0.8 billion, or US\$ 172 per capita.

The public part on health expenditures is a bit lower than the three previous years (2% lower in comparison with 2007), showing the increasing role of private health expenditures in the total expenses. According to Business Monitor forecasts¹, this private part will continue to grow over the medium term, to raise 16 % of the total expenditures by 2014.

Concerning HZZO, 83% of its expenses are made on healthcare, and 17% are utilized for sick leave compensation². Hospital care, dental and other care and prescription medicaments accounted for three-quarters of HZZO expenditure. The detailed structure of its healthcare expenditures is as follows:

- 20% PRIMARY HEALTHCARE
- 21.3% DRUGS/MEDICATIONS
- 20% SPECIALIZED TREATMENT
- 35% HOSPITAL TREATMENT
- 3.5% ORTHOPEDIC AIDS

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 healthcare.

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 healthcare 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 healthcare 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 <u>exclusively</u> by the HZZO, and on a capitation basis³. 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 hospital 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 2007, the hospitals' and pharmacies' debt to suppliers together reached HRK 4 bn (\leq 530 m). Some of these institutions sometimes also subscribe to bank loans to compensate their deficits.

¹ Business Monitor, Croatia Pharmaceuticals & Healthcare Report Q3 2010.

² US Commercial Service, Croatia: Medical Equipment Market, Miroslav Nikolac, June 2006.

³ "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, <u>http://www.eridlc.com</u>).

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

HOSPITAL SERVICES

Tables Tabled

According to the Ministry of Health of Croatia, the country had 22 general hospitals in 2013. Most other facilities were small and specialist in nature. In 2013, the number of chronic disease hospitals fell to one and a further pulmonary T8 hospital came into use.

RAVSTVENE USTANOVE	BROJ USTANOVA
lealth institutions	No. of institutions
OM ZDRAVLJA - Health center	49
LINIČKI BOLNIČKI CENTAR - Clinical teaching hospital	5
LINIČKA BOLNICA - Clinical hospital	3
LINIKA - Clinic	5
PCA BOLNICA - General hospital	22
PECIJALNA BOLNICA - Special hospital	34
JEČILIŠTE - Health resort	7
AVOD ZA JAVNO ZDRAVSTVO - Public health institute	22
STALI DRŽAVNI ZAVODI - Other state institutes:	5
 ZAVOD ZA TRANSFUZIJSKU MEDICINU - Institute of transfusion medicine ZAVOD ZA ZAŠT. ZDRAVLJA I SIGURNOST NA RADU - Institution 	1 te for
 Health Protection and Safety at Work ZAVOD ZA TOKSIKOLOGIJU I ANTIDOPING - Institute of toxic 	
 and Antidoping ZAVOD ZA HITNU MEDICINU - Institute of emergency medicine 	1
 ZAVOD ZA TELEMEDICINU – Institute for telemedicine 	i
STANOVA ZA HITNU POMOĆ - Emergency care station	20
OLIKLINIKA - Polyclinic	362
STANOVA ZA MEDICINU RADA – Institution of occupational health	9
JEKARNA - Pharmacy	187
STANOVA ZA NJEGU-SKRB - Nursing care institution	187
RGOVAČKO DRUŠTVO ZA OBAVLJANJE ZDRAV. DJELATNOSTI	
- Health company	346
kupno - Total	1.263

TODAVCTVENE UCTANOVE U UDVATOKO IS OF 40 0040

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

Source: Croatian Health Yearbook 2012

HEALTH INSURANCE

The notion of compulsory health insurance was introduced in the 1993 Healthcare Act. Since then there have been many changes to this Act in an 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 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.

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 healthcare 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 neighboring countries.⁴

In case of sick leave, the cash compensations are payed 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 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 HRK 831,5 and HRK 4.257 (\leq 112,6 and \leq 576,6⁵).

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

MEDICAL DEVICE OUTLOOK

During the post-war reconstruction period, the renovation of health services was settled as a priority, helped by financial international institutions. 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 equipment is required to modernize ageing facilities and, as medical device regulations are in line with EU requirements, gaining access to the market, which should not be a problem for those familiar with EU legislation.

The Croatian market of medical devices is characterized by a low local production: between 85 and 90% of the demand is met by import⁶. The main import countries are the United States (around 25% of imports⁷), Germany, Italy, Japan, Austria, Switzerland, Slovenia. Germany, Italy and the US together provide more than 50% of the imports.

⁴ Croatia background data. Espicom 2006, Espicom Business Intelligence.

⁵ 1 € = 7,5171 (23/07/2013)

⁶ Business Monitor, Croatia pharmaceuticals & Healthcare report Q3 2010

⁷ Business Monitor, Croatia pharmaceuticals & Healthcare report Q3 2010

The Croatian market of medical devices is estimated to be worth around US\$ 220 m. The demand for medical equipment is expected to increase in the coming years, due to several factors, among which the healthcare modernisation, European Union requirements, private health sector's development, the economic development, and the ageing population. The government has promised to spend US\$ 90 m more on medical equipment purchases.

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. In 2004 and 2005, 227 devices were purchased by the Ministry of Health, for a tenders' value of US\$ 25 m. Some local subsidiaries of foreign manufacturers (for example S&T Croatia, Astra Tech, Drager) can participate to the tenders.

Medical devices expenditure projections in 2011 reached HRK 1.41bn (US\$ 264m) and HRK1.39bn (US\$ 255m) in 2012.

REGULATORY ENVIRONMENT

The registration of medical devices in Croatia comes under the jurisdiction of the Agency for Medicinal Products and Medical Devices (<u>http://www.almp.hr/?ln=en</u>), 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 include the following:

Under Article 120 of Medicinal Products Act

- Granting of marketing authorization for medicinal products and homeopathic medicinal products;
- Maintaining the register of homeopathic medicinal products;
- Providing expert assessment of quality, efficacy and safety of medicinal products and homeopathic medicinal products;
- Conducting pharmaceutical testing of medicinal products and homeopathic medicinal products;
- Performing quality control of medicinal products and homeopathic medicinal products, issuing quality control certificates and approvals for the marketing of an imported batch of a finished medicinal product;
- Analyzing and assessing adverse drug reactions and safety of patients in clinical trials;
- Drawing up the Croatian pharmacopoeia;
- Issuing manufacturing licenses to manufacturers of medicinal products and homeopathic medicinal products;
- Issuing Good Manufacturing Practice (GMP) certificate;
- Granting licenses for the wholesale distribution of medicinal products and homeopathic medicinal products;
- Granting licenses for the retail sale of medicinal products in specialized retail shops;
- Issuing licenses for import and export of medicinal products;
- Giving approval for import and export of medicinal products;
- Monitoring adverse drug reactions and quality defects of medicinal products;
- Carrying out urgent recall procedures for medicinal products;

- Monitoring the consumption of medicinal products and promoting their rational use;
- Proposing measures to the Minister to supervise consumption of medicinal products;
- Engaging in waste management activities (for its own needs);
- Educating and providing information on medicinal products;
- Providing expert advice from its scope of activities;
- Proposing harmonization of medicinal products regulations 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;
- Maintaining the register of medical device manufacturers and the register of medical devices;
- Analyzing and assessing incidents and safety of patients in clinical trials of medical devices;
- Granting licenses for the retail sale of medical devices in specialized retail shops;
- Issuing licenses for import and export of medical devices;
- Giving approval for import and export of medical devices;
- Vigilance of medical devices
- Carrying out urgent recall procedures for medical devices
- Classification of a medical device
- Issuing certificate on registration of medical device in the medical devices register;
- Educating and providing information on medical devices;
- Establishing international cooperation in the field of medical devices;
- Proposing harmonization of medical device regulations with those of the European Union as well as with the regulations and guidelines of international institutions;
- Carrying out other tasks pertaining to medicinal products and homeopathic medicinal products in accordance with the Medicinal Products Act and the ensuing regulations as well as tasks pertaining to medical devices in accordance with 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 and the authorization has not been withheld, withdrawn or suspended in any of the EU member states.

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;
- 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 labeling 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;
- 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

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

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

¹⁰ www.almp.hr

On 1st January 2013, HALMED published a new price list for its services. The costs associated with obtaining manufacturing licenses and medical device registrations are listed below.

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.

EMERGENCY MEDICAL SERVICE

In some offices of the Institute for Emergency Medicine, and the locations of health facilities (generally, in area of 30,000 inhabitants) and health centers (total of 49) there has been a doctor provided on duty or standby during 24 hours.

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 permanent readiness medical teams.

In 2012, a total of 536 physicians has steadily worked in emergency medical services in Croatia (an increase of 10.3% compared to 2011).

WOMEN'S HEALTHCARE

The main objectives of the women health policy are not just to extend life expectancy, but also to improve the quality of life. In addition to the 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 2012 they were 1,548,638 women registered in the care of gynecologists in primary healthcare sector, which is 4.9% more than in 2011. According to the total number of women who have chosen their gynecologists in primary healthcare, 529,122 of them, or 34.2% used services, which is 2.7% less than it was the previous year.

The Croatian Bureau of Statistics announced that according to the latest research in 2011, they were 2,218,554 women registered, (51.8% percent of the total population). The number of women aged over 15, who are potential users of gynecologists in primary healthcare sector (1,900,851), as well as women of childbearing age (972,948 or 43.9%) is in decline.

DENTAL CARE

As far as dental care is concerned, according to received data from the annual report of teams and institutions, a total of 1,845 dental teams was active in 2012, out of which 1,722 medicine teams, 44 specialist teams of pediatric and preventive dental medicine and 79 other specialist

teams. These teams care about 3,877,543 insured persons (about 0.8% more than in 2011.), of which 1,334,971 benefit from healthcare. (An increase of approximately 6% compared to 2011.).

In addition to these teams services are provided. Concerning health insurance; from 683 teams of dental medicine without agreement with CIHI, 617 teams were dentists, 17 specialist teams - preventive and pediatric dentists and 49 teams from other specialties. During 2012, according to received reports, there have been 4,171,326 visitors recorded in contracting practices (an increase of 6.5% compared to 2011) and 787,342 visitors in offices without a contract with CIHI (an increase of 2% compared to 2011). The most common diagnosis was dental caries, followed by diseases of pulp and periapical tissues.

INFANT AND YOUNG CHILD CARE SERVICE

The children's healthcare has under its disposal 272 teams. The protection of children is implemented for 410,986 insured persons, of which 276,501 (67.3%) are pre-school children, while others present mostly the school-age children population. For 92.6% of pre-school children, the health protection is carried out through this sector.

OCCUPATIONAL HEALTH SERVICE

According to reports from the Occupational Health Service in 2012, there were 184 teams working full time (2 teams more than in 2011) and 8 teams working part time (4 teams less). The OHS consists of 186 occupational medicine specialists, 2 other specialists, and 23 doctors of general medicine.

At the beginning of 2011, change has occurred in the healthcare system especially in the field of occupational health services. The treatment of injuries and occupational diseases has returned to the care of general/family medicine and to specialists.

The Occupational Health Service, consisting of doctors from the Croatian Institute for Croatian Institute for Health Insurance (CIHI), is responsible for the implantation of preventive activities amongst the workforce.

HOME CARE SERVICE

The total number of recorded visits for the home care service in 2012 was 1,870,456.

In 2011 there were 1,492,355 registered visitors. Compared to the previous year, this showed a decrease in the number of employees by 2.1 % and an increase in the number of visits by 20.2%. The average number of yearly visits per nurse per year is 1,812 (an increase of 21% compared to 2011).

VISITING HEALTH SERVICE

		do 2012. godine u Hrvat Visitors Service	skoj - <i>i ne numb</i> e	er oi visits in Croatia 1990	0-2012, from the Health
GODINA	UKUPNO	POSJETI ŽENAMA	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
0010					1.005

334.928

937.093

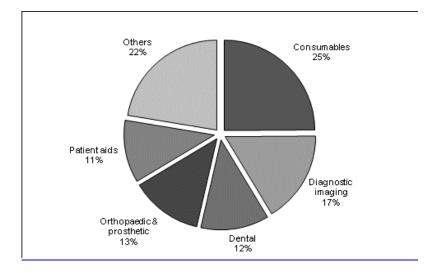
1.605

2012. 1.525.126 200.741 Source: Croatian Health Yearbook 2012

IMPORT

Medical Device Imports by Product Area, 2012

(% Distribution)



Source: BMI Espicom

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 and catheters amounted to US\$ 21.9 million in 2012, while bandages and dressings amounted to US\$ 12.0 million.

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 to 2011, with electrodiagnostic apparatus falling the most, by 29.2%. The figure does fluctuate widely 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.

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%, US\$ 25.0 million. Dental capital equipment fell by 7.1% to US\$ 3.5 million, while instruments and supplies increased by just 0.9% to US\$ 21.5 million.

ORTHOPAEDIC AND PROSTHETIC DEVICES

Imports of orthopaedic and 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, at 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.

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.

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.

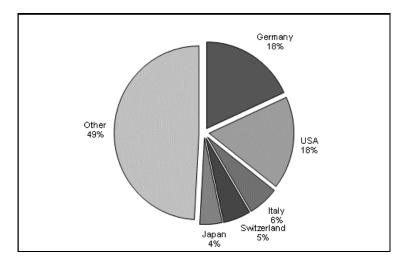
The USA was the second largest supplier in 2012, accounting for US\$ 39.2 million or 19.1% of the total.

The USA was particularly strong in the supply of orthopaedic products, accounting for 24.8%.

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.

Leading Medical Device Suppliers, 2012

(% Distribution)



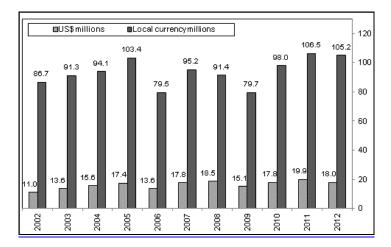
Source: Espicom

EXPORT

Croatia is not a major medical equipment exporter. In 2012 it exported for a total of US\$ 18.0 million, around half of which 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

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 and catheters amounted to US\$ 460,000 million, equal to 2.6% of total exports and a decrease of 20.1% compared with 2011.

Diagnostic Imaging Apparatus

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

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.

Orthopaedic and Prosthetic Products

Exports of orthopaedic and 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.

Patient Aids

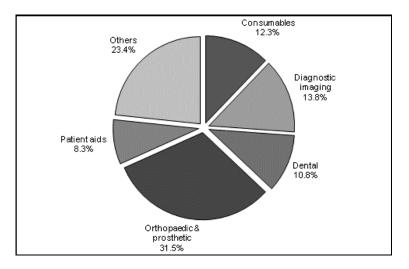
Exports of patient aids amounted to US\$ 1.5 million in 2012, equal to 8.3% of the total. This was the best performing sector in 2012, increasing by 24.4% over 2011. Exports of other portable aids reached US\$ 860,000 and mechano-therapy apparatus US\$ 487,000.

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 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 another 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.

THE PHARMACEUTICAL MARKET

The Croatian pharmaceutical market continues to pose a challenging environment to domestic and international drug makers. The economy is expected to contract in 2012 with weak growth returning in 2013 on the anticipation of capital inflows from the EU. The implementation of a claw back tax at the start of the year will increase pricing pressures. VAT rises and inflation suggest growth seen in 2012 will not be due to increased drug consumption.

According to Espicom, the forecast weak growth in the pharmaceutical market for the next decade is due to the prevailing economic conditions in Europe. Healthcare and medical devices spending is projected to rise significantly over the next 10 years owing to a rapidly ageing population. But even after EU accession the country will still represent a modest opportunity for foreign firms.

The Headline Expenditure Projections for the pharmaceuticals market are HRK 7.38bn (US\$ 1.38bn) in 2011 to HRK 7.55bn (US\$1.39bn) in 2012; 2.2% in local currency and 0.1% in US dollar terms.

Pharmacies

Type of pharmacy						
	Nonhospital	Hospital				
Pharmaceutical technology	6	6				
Drug testing and control	2	7				
Medical biochemistry	2	0				
Pharmaceutical informatics	4	0				
Clinical pharmacology	0	2				
Sanitary chemistry	1	0				
Pharmacists	2.374	98				
Pharmaceutical technicians	1.609	189				
Nurses-technicians	1	2				
No. of pharmacies	1.199	57				

Table 1 - Health workers at	hospital and	nonhospital pharma	cies. Croatia 2012
		nonnoopreen prienner	0.00, 0.00000 = 0 = =

Medicines are prescribed and issued pursuant to the regulations on the prescription and dispensing of prescription drugs, the prescription of drugs are prescribed by doctors of medicine and dental medicine primary care, with the permission of the Health Institute, for the implementation of healthcare.

Latest news from the field of pharmacy.

The Agency for Medicinal Products and Medical Devices has published its first list of drugs that can be bought without prescription in stores, which came into force in June 2013. If some products want to be sold in ordinary stores, dealers must comply with the regulations prescribed by the Ministry of Health, which require strict regulations on transport, warehousing and storage of these products.

Pharmaceutical wholesalers

List of biggest pharmaceutical wholesalers active in the country:

- Medika d.d (leading pharmaceutical wholesaler in Croatia in 2012 with a turnover of 2.100.200.000 kn/€ 278m)
 http://www.medika.hr/hr/
- Phoenix Farmacija d.d, since the German company Phoenix aquired Farmacija in the mid 2000s. Second largest pharmaceutical wholesaler in Croatia with a turnover of 1.886.900.000 kn/€ 250m)
 http://www.phoenix-farmacija.hr/

- Medical Intertrade, one of the largest Croatian wholesalers (turnover of 1.160.000.000 kn/€ 153,7m in 2011) http://www.medical-intertrade.hr/
- Oktal Pharma (49 % share owned by the German company Andrae-Noris Zahn AG and a turnover of 1.324.500.000 kn/€ 175,5m in 2011)
 http://www.oktal-pharma.hr/
- Belupo, since July 2009 part of the company Podravka, with a turnover of 643.300.000 kn/€ 85,3m in 2011
 http://www.belupo.hr/

The sector of the pharmaceutical wholesalers is very concentrated: the 4 largest wholesalers together account for around 90% of the market¹⁰.

Pharmaceutical retailers

Since the beginning of the 1990s, when the first privatizations were allowed by law in Croatia, 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.

In 2010, the number of qualified pharmacists in Croatia was around 2,900, employed in stateowned community pharmacies (75%), state-owned hospital pharmacies (4%), wholesalers (5%), representative offices of the domestic and foreign pharmaceutical companies (10%), and other private pharmacies and institutions (6%)¹¹.

In 2007, there were 970 community pharmacies and 50 hospital pharmacies: 60% were private, around 25% were state-owned, and the remainder were private-leased (around 15%). The retail sector is also concentrated, since around 60% of the total pharmacies are group-owned.

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

MEDICAL TECHNOLOGY, OPERATION THEATRES AND MEDICAL PROCEDURES

In 2012, 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 in 2012.

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)

¹⁰ Business Monitor, Croatia Pharmaceuticals & Healthcare Report Q3 2010.

¹¹ Business Monitor, Croatia Pharmaceuticals & Healthcare Report Q3 2010.

- Special hospitals and spas (9 institutions did not submit information)
- Part of the office specialist healthcare clinics and companies for health services (data submitted by 102 institution of 721 contacted).

Tablica – Table 2. Operacijske dvorane – Operation Theatres

	• •		
	U bolničkim ustanovama - In	U ostalim zdravstvenim ustanovama - In other health care	
	hospitals	facilities	Ukupno - Total
Operacijske dvorane - Operation theatres	403	26	429

	Stacionarno - Inpatient cases		U dnevnoj bolnici - Day cases		Ambulantno - Outpatient cases	
Medicinski postupak - Medical Procedure	Plaćanje HZZO - Paid by HZZO	Plaćanje ostalo - Paid by others	Plaćanje HZZO - Paid by HZZO	Plaćanje ostalo - Paid by others	Plaćanje HZZO - Paid by HZZO	Plaćanje ostalo - Paie by others
Ekstirpacija, ekscizija i uklanjanje intrakranijalne lezije - Extirpation, excision and destruction of intracranial lesion	816	1	0	0	0	0
Evakuacija subduralnog hematoma i intrakranijalnog krvarenja - Evacuation of subdural haematoma and intracranial haemorrhage	647	6	0	0	0	0
Discektomija - Discectomy	2.632	13	0	0	0	0
Tiroidektomija - Thyroidectomy	2.336	7	0	0	0	0
Operacija katarakte - Cataract surgery	19.353	33	1	0	1.604	1.560
Implantacija umjetene pužnice - Cochlear implantation	73	0	0	0	0	0
Tonzilektomija - Tonsillectomy	5 4 4 8	20	ŏ	ŏ	ŏ	ž
Pulmektomija - Pulmectomy	305	0	ŏ	ŏ	ŏ	ō
Dijagnostička bronhoskopija s ili bez biopsije - <i>Diagnostic</i>		-	-		-	-
bronchoscopy with or without biopsy	8.026	36	636	1	11.905	160
Transluminalna koronarna angioplastika - Transluminal coronary angioplasty	7.734	55	0	0	8	27
Koronarna aortna premosnica graftom - Coronary artery bypass oraft	2.280	0	0	0	0	0
Karotidna endarkterektomija - Carotid endarterectomy	889	1	0	0	0	0
Rekonstruktivna terapija infrarenalne aneurizme aorte - Infrarenal aortic aneurysm repair	313	0	0	0	0	0
Femoro-poplitealna premosnica - Femoropopliteal bypass	511	1	0	0	0	0
	211	-	U	U	0	U
Transplantacija matičnih stanica (stem cell) - Stem cell transplantation	157	2	0	0	0	0
Kolonoskopija s ili bez biopsije - Colonoscopy with or without biopsy	11.446	8	1.211	0	27.602	2.055
Otvorena kolektomija - Open colectomy	2.502	0	0	0	0	0
Laparoskopska kolektomija - Laparoscopic colectomy	708	0	0	0	0	0
Otvorena apendektomija - Open appendectomy	2.928	42	0	0	0	0
Laparoskopska apendektomija - Laparoscopic appendectomy	1.562	24	0	0	0	0
Otvorena kolecistektomija - Open cholecystectomy	2 157	11	0	0	0	0
Laparoskopska kolecistektomija - Laparoscopic cholecystectomy	7.278	29	ŏ	ŏ	ŏ	3
Otvorena reparacija ingvinalne kile - Open repair of inguinal hernia	7.435	23	1 1	Ő	Ő	9
Laparoskopska reparacija invinalne kile - <i>Laparoscopic repair of</i> inguinal hemia	482	2	0	0	0	0
Transplantacija bubrega - Kidney transplantation	296	0	0	0	0	0
Otvorena prostatektomija - Open prostatectomy	934	8	0	0	0	0
Transureteralna prostatektomija - <i>Open prostatectomy</i> Transureteralna prostatektomija - <i>Transurethral prostatectomy</i>	1.472	6	0	0	0	0
Otvorena histerektomija - Open hysterectomy	4.221	11	0	0	0	0
	235	0	0	0	0	0
Laparoskopska histerektomija - <i>Laparoscopic hysterectomy</i>			-	-		
Carski rez - Caesarean section	8.209	213	0	0	0	0
Artroskopska ekcizija meniska koljena - Arthroscopic excision of meniscus of knee	5.437	46	471	196	0	2
Endoproteza kuka - Hip replacement	5.064	93	0	0	0	0
Zamjena endoproteze kuka - Secondary hip replacement	574	41	0	0	0	0
Totalna endoproteza koljena - Total knee replacement	1.990	59	0	0	0	0
Parcijalna mamektomija - Partial excision of mammary gland	2.578	0	0	0	0	6
Totalna mastektomija - Total mastectomy	1.540	ŏ	Ŏ	ŏ	ŏ	9
CT pregled - CT exams	162.528	521	4.574	35	135,774	5.041
MR pregled - MR/ exams	23.258	50	1,135	1	102.874	15.614
PET pregled - PET exams	0	0	0	0	6.825	401

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

	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	49	17	66
1.1.	s jednim ili dva reda detektora	26	4	30
1.2.	sa 6 redova detektora	1	1	2
1.3.	s 8 redova detektora	1	0	1
1.4.	sa 16 redova detektora	15	3	18
1.5.	s 32 reda detektora	2	1	3
1.6.	sa 64 reda detektora	4	8	12
2.	MR uređaj - MR unit	25	17	42
2.1.	0,3 T	1	2	3
2.2.	0,5 T	4	0	4
2.3.	1,5 T	20	15	35
3.	Mamograf - Mammograph	50	24	74
8.1.	klasični	36	20	56
3.2.	digitalni	14	4	18
1.	Gama kamera - Gamma camera	22	0	22
5.	SPECT/CT uredaj - SPEC/CT scanner	4	1	5
8. 8.	Angiosala - DSA - Angiography unit	26	0	26
5.1.	digitalizirana	13	0	13
5.2.			-	
	digitalna DTC use fair Dadiaseratus mit	13	0	13
	RTG uređaj - Radiography unit	286	30	316
.1.	uređaj za radiografiju	185	26	211
.1.1.	konvencionalni/klasični sa snimanjem na film	101	13	114
.1.2.	konvencionalni/klasični s digitalizatorom	50	7	57
.1.3.	digitalni	34	6	40
.2.	dijaskopski uređaj	101	4	105
.2.1.	klasični	55	1	56
.2.2.	kombinirani/višenamjenski	46	3	49
).	Litotriptor - Lithotriptor	30	0	30
).	Denzitometar - Densitometer	36	12	48
0.	Ultrazvučni uređaj - Ultrasound unit	689	175	864
0.1.	kardiološki	93	37	130
0.2.	ainekološki	115	61	176
0.3.	ostali (NE uključuje uređaje za UZV fizikalnu terapiju)	481	78	559
1.	Gamma knife	35	0	35
2.	Anesteziološki uređaj - Anaesthetic machine			
		478	12	490
3.	Defibrilator - Defibrilator	589	74	663
4.	Respirator - Medical ventilator	654	2	656
5.	Uređaj za dijalizu - Dialysis machine	779	165	944
6.	Uređaj za ekstrakorporalnu cirkulaciju - Heart-lung machine	31	0	31
7.	ECMO uredaj - Extra corporal membrane oxigenation machine	5	0	5
7.1.	s cirkulacijskom pumpom (duža cirkulacijska potpora, do 60 dana)	5	0	5
7.2.	s cirkulacijskom pumpom (kraća cirkulacijska potpora, do 7 dana)	0	0	0
8.	EEG	105	14	119
9.	EMG	62	14	76
0.	Linearni akcelerator - Linear Accelerator	14	0	14
0.1.	s klasičnim/konvencionalnim simulatorom	3	0	3
0.2.	s CT simulatorom	11	0	11
1.	Urođaj za brahiterapiju - Brachytherapy system	5	0	5
1. 1.1.	s niskom brzinom doze - LDR			
		2	0	2
1.2.	s visokom brzinom doze - HDR	3	0	3
	Ergometar - Ergometer	67	28	95
3.	Inkubator - Incubator	263	8	271
4.	Set za gastroskopiju - Gastroscopy set	127	23	150
5.	Set za kolonoskopiju - Colonoscopy set	101	21	122
	Set za rektoskopiju - Rectoscopy set	57	9	66
5.	Set za artroskopiju - Arthroscopy set	64	1	65
		-		
1.		148	6	154
6. 7. 8.	Set za cistoskopiju - Cistoscopy set	148	6 20	154
7.		148 38 103	6 20 1	104 58 104

Tablica – Table 1. Medicinska oprema – Medical Technology

HEALTH REFORMS

To rein in spending, Croatia was cautiously considering the issue of health reforms. The National Health Strategy 2006-2011 was to align Croatia with other EU member states, with a focus on health delivery and public health, alongside financing.

Over the next three to five years, the government is planning to introduce a system requiring individuals to contribute around 15% of their income to the cost of health, close to the EU average of 20%. However, this may not prove possible given that more than a million people in the country earn less than EUR 150 per month.

In early 2009, local press reported that the Croatian Ministry of Health stated that healthcare reform in Croatia is moving at a fast pace. According to official information from the HZZO, 83.45% of practitioners working in gynecology and dentistry are already charging co-insurance fees. Around the same time, the Ministry of Health indicated that the Croatian healthcare system will receive an additional HRK 5.5bn (USD 1.13bn) from the state budget in 2009 compared to the previous year. He added that the HZZO can be expected to receive around HRK 23,5bn (USD 4,82bn), which will be utilized for internal reforms of the Croatian healthcare system.

In monetary terms, the scheme initially offers limited foreign investment opportunities for large private healthcare firms, with local healthcare providers likely to compete for the service contracts. Nevertheless, BMI believes private healthcare will play an increasingly important role over the coming years. While the recently announced outsourcing will still originate from government funds, private expenditure will rise as out-of-pocket payments become increasingly important to help cope with escalating costs.

The new health reform includes five core tasks:

- Reducing the waiting list for medical services (e-waiting and ordering list).

This reform has the task to insure medically acceptable time limits for delivering individual diagnosis, this will be done through creating waiting lists according to the degree of urgency based on the health condition of the patient, which will include an emergency procedure within 24 hours, a fast procedure whose term is three months and regular procedures whereby it is necessary to provide health services within six mounts. The conducted analysis has shown mixed results of the reform implementation procedure and demonstrates the need for further action, because the waiting lists for some procedures have become smaller, while for others they have become even larger.

- The law on Medically Assisted Human Reproduction.

The new law on artificial insemination has reversed one of the most restrictive laws in Europe in that field, allowing, among other things freezing of embryos, which as a result makes Croatia one of the most liberal countries in Europe in this respect.

- Reform of the emergency medical assistance.

By 2013, there should be at least one emergency medical team every 25 km. This is stated in the reform. The program costs \in 90 million, with the main goal of reorganizing the system of emergency medical services, which started in 2009. The reform should provide safer, more accessible and better emergency assistance to the patient, while for health professionals it implies a secured specialization and better education. The reform started with the foundation of the Emergency Medicine Office, which would be present in every Croatian county by the end of 2013. Croatia will have 21 specialized institutions for performing outpatient medical services. In practice, this means less wandering and waiting for patients.

- Abolition of private monopolies in public health.

The Croatian Institute for Health Insurance has a contract with private clinics in order to carry out certain medical tests (such as PET/CT, one of the most expensive tests) that previously could not be carried out in public hospitals due to lack of medical equipment. Now the government plans to reduce the amount of funds for 50 % to private clinics in order to save and make changes in the health system. Because of the customization process, the Croatian government has extended the contract with private clinics until 30th June 2013. Reform is not yet fully operational.

- Elimination of health insurance contributions for pensioners.

This reform measure was abandoned because of large debts building up in the health system.

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. The main areas of application are: computerization of primary health services, introduction of an integral information system for hospitals, computerization of the Croatian Institute for Health Insurance with the introduction of multifunctional smart cards. One of the main tasks of this project is to establish the standards of interoperability of these information systems by introducing online appointments for examinations by specialists.

The Ministry of Health and Social Welfare conducted evaluations of the Computerization of Primary Health Services (PZZ) projects, and the Computerization of the Hospital Information System (IBIS). In the meantime, the implementation of the project on the computerization of Primary Health Services was initiated. The development of functional and technical specification has been completed, as well as the creation of a health information system. Equipment was acquired and the system and application software implemented. Preparations for the production of application solutions for offices for primary health service were completed. In addition to that, a new call for tender for computerization of hospital information systems was prepared.

The Croatian Institute for Health Insurance (HZZO) initiated the HZZO Portal project, harmonious to the project of computerization of primary health service. The HZZO Portal ensures a secure electronic exchange of data with subjects within the health system of the Republic of Croatia. The first phase of the pilot project of introducing smart cards into the system of health insurance has been completed. The initiation of the project for the computerization of hospitals was

realized in 2006, as well as linking the same into the health information system in order to improve the level of service which the patient receives, and to enable rationalization of business.

In the continuation of the project, when the technical-technological basis for the application of electronic signatures, a secure electronic identification of a HZZO insured person (application of the smart card), is secured, all the activities for which insured people today have to visit one of the 130 networked HZZO locations, can be done via the Internet.¹²

CHRONIC DISEASES REGISTRIES

CROATIAN REGISTRY OF TREATED PSYCHOACTIVE DRUG ABUSERS

The Information on persons treated for addiction are collected in the Croatian National Institute of Public Health. During 2012, 7,855 persons were registered in the Croatian Health Institutions for addiction on psychoactive drugs. Compared to 2011 the total number of addicts increased by 2.5%. The most evident abuse of opiates is registered in Istria County (514.8:100,000). The male population has the largest share (82.5%) in the number of treated patients. The opening of a center for needle and syringe exchange and consulting and free testing for hepatitis B and C and HIV contributed to a more responsible behavior of addicts and a better compliance.

CROATIAN NATIONAL CANCER REGISTRY

The Cancer Registry was founded in 1959 in order to collect data for processing and analyzing 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 important cause of death in Croatia, representing the death cause of every fourth inhabitant. Compared with other European countries, Croatia is a country with high incidence, but also with a high rate of mortality from cancer.

CROATIAN COMMITTED SUICIDES REGISTRY

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

Since 1999, there is a downward trend of suicides, according to the received data until April 2013, were 692 cases of suicide were registered. With regard to gender in the same period, the proportion of suicides in males and females ranged from 2.2 to 3.6:1.The most common method of committing suicide was by hanging.

¹²The Central State Administrative Office for e-Croatia <u>http://www.e-hrvatska.hr/sdu/en/ProgramEHrvatska/Provedba/e-Zdravstvo.html</u>

CROATIA'S DISABILITIES REGISTRY

In order for 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, as well as the years without disease and disability are increased. The important data for the registry are collected in the field of Health and Social Welfare, Education, in the Ministry of Family, in Croatian Pension Fund and the Ministry of Sea, Tourism, Transport and development .The total number of persons with disabilities is 522,459, with a greater proportion of the male population (314,059).

The highest percent of persons with disabilities is located in the city of Zagreb.

CROATIAN PSYCHOSES REGISTRY

The group of mental and behavioral disorders ranks 7th in the list of hospitalization 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 22.9% in the total number of disease treatments.

NATIONAL DIABETES REGISTRY - CRODIAB

The National Diabetes Register is important for planning preventive actions and reducing the costs of healthcare, and plays a role in improving and ensuring quality care for patients. The CroDiabNET application program or the CroDiab WEB online system is used as a tool to register persons with diabetes. Every medical worker has to report on patients with diabetes in his practice and under his therapy. This system serves as the optimal information needed for monitoring and improving quality diabetes care. In 2011 the data sharing program has connected with the central database of medical information system in Croatia. In accordance with these data 234,457 adults diagnosed with diabetes were registered.

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 an official registry there can be an estimation of the number of patients with acute coronal syndrome, in order to determine survival rates and mortality, to determine which tests and treatments work and which complications occur during hospitalization.

PHARE

The PHARE programme was the main financial instrument of the European Union pre-association strategy for Croatia, established by Council Regulation 3906/1989/EC.

A major proportion of the funds were intended to strengthen the institutions and human capacity in the process of harmonization of national legislation with the European Union *acquis* and its implementation and enforcement. Another part of the funds is intended for support of economic and social cohesion actions.



The PHARE funds helped Croatia make the following changes:

- Increasing fiscal budgetary discipline in the health and health insurance sector;
- Lowering the costs of public healthcare to a maximum of 6% of GDP;
- Paying the already existing debt of the healthcare sector;
- Lowering the costs of hospital care and the costs of prescription medicaments;
- Lowering the time needed to register the medicaments;
- Increasing the amount of generic medicaments on the Croatian Institute of Health medicaments list by 50%;
- Lowering hospital deficits by making the hospitals board of directors directly responsible for the hospitals budget;
- Imposing a system of payment based on accomplished results;
- Rebuilding of the supplementary health insurance.

INSTRUMENT FOR PRE-ACCESSION ASSISTANCE (IPA)

IPA offers assistance to countries engaged in the accession process to the European Union for the period 2007-2013. The aim of IPA is to enhance the efficiency and coherence of the aid by means of a single framework in order to strengthen institutional capacity, cross-border cooperation, economic and social development and rural development. Pre-accession assistance supports the stabilization and association process of candidate countries and potential candidate countries while respecting their specific features and the processes in which they are engaged.

Key issues of IPA financial assistance in the health sector:

- Capacity building and institutional reform of the healthcare system and services of the beneficiary country;
- Improving the regulatory and management capabilities of healthcare institutions and authorities;
- Increasing access and inclusion of vulnerable groups in the healthcare system;
- Supporting fight against drug abuse and AIDS/HIV;
- Improving preventive health services with an emphasis on screenings;
- Promoting mutual recognition of health professional qualification;
- Further revision of the national law in the light of the *acquis communautaire* (e.g. laws on health protection, health insurance and the role of various chambers).

EXECUTIVE AGENCY FOR HEALTH AND CONSUMERS

The Executive Agency for the Public Health Programme (PHEA) of the European Commission was established in 2005 to improve the implementation of the public health programme. In 2008, the European Commission transformed PHEA into the Executive Agency for Health and Consumers. The agency was entrusted with new tasks in the field of consumer protection and food safety training, and its mandate was extended until the end of 2015. It is a temporary EU agency, and it reports to the Health and Consumer Protection Directorate General. It is located in Luxembourg.

There are various funding possibilities under the EU Health Programme 2008-13, these include:

- Grants for action (projects)
- Operating grants for organizations or specialized networks
- Co-financing of conferences
- Joint actions by the Community and Member States as well as other (third) countries participating in the Programme
- Tendering of actions to achieve the Programme's objective¹³

STRUCTURAL FUNDS AND THE COHESION FUND

Structural Funds are an instrument of the EU Cohesion Policy. The Cohesion Policy is financially the second most important common EU policy. From 2007 to 2013, the amount made available equals EUR 347.41 billion, i.e. 35.7% of the total EU budget for that financial period.

The goals of the Cohesion Policy are aimed at achieving the balanced development within the European Union and strengthening the global competitiveness of the European economy.

The structural instruments have been made available to the member states of the European Union that need additional investments in balanced and sustainable economic and social development.

The structural instruments are as follows:

- European Social Fund (ESF)
- European Regional Development Fund (ERDF)
- Cohesion Fund (<u>CF</u>)

Croatia is entitled to participate in the above instruments after accession to the European Union.

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¹³ <u>http://ec.europa.eu/health_eu/index-en.htm</u>

At its meeting of June 30th 2008, the Government of the Republic of Croatia made the Decision on the Strategic and Institutional Framework for the Use of EU Structural Instruments in the Republic of Croatia.

3. ANNEX 1: SPECIFIC QUESTIONS BY A BELGIAN FIRM THAT COULD BE OF GENERAL INTEREST

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

The laboratories mentioned are certified to conduct prenatal and neonatal screening in Croatia.

Name	Adress	N° Tel	Fax	E-Mail	Website
	Šalata ulica 2,				
Klinički bolnički centar Zagreb	10000, Zagreb	01 4920 019		kbc-zagreb@kbc-zagreb.hr	http://www.kbc-zagreb.hr/
	Ulica Sveti Duh 64,				
Klinička Bolnica "Sveti Duh"	10000, Zagreb	01 3712 111		<u>kb@kbsd.hr</u>	http://www.kbsd.hr/
	Zajčeva 19, 10000				
Klinička bolnica "Merkur"	Zagreb	+385 (0)1 24 31 390	+385 1 24 31 402	ravnateljstvo@kb-merkur.hr	http://www.kb-merkur.hr
	Srebrnjak 100, HR -				
Specijalna bolnica "Srebrnjak"	10000 ZAGREB	(01) 6391 100	+385 1 6391 188	info@bolnica-srebrnjak.hr	http://www.bolnica-srebrnjak.hr/
	SPINČIĆEVA 1,				
Klinički bolnički centar Split	21000, Split	021 390 444	+385 21 556 020	centar.narucivanja@kbsplit.hr	<u>www.kbsplit.hr</u>
Klinički bolnički centar Rijeka	Krešimirova 42	051 658 111	+385 51 337 536	info@kbc-rijeka.hr	http://www.kbc-rijeka.hr/
	J.Huttlera 4, 31000				
Klinički bolnički centar Osijek	Osijek	(031) 511-511	+385 31 512 221	curzik.darko@kbo.hr	http://www.kbo.hr
Klinika "Vuk Vrkovac"	Dugi dol 4a, 10000				
	Zagreb, Croatia	+385 (1) 2353 800		<u>SKVV@idb.hr</u>	http://www.idb.hr

Source: Mario TROŠELJ E-mail: <u>Mario.troselj@hzjz.hr</u> Tel: + 385 1 48 63 273 Fax: + 385 1 48 63 011 Croatian National Institute of Public Health <u>www.hzjz.hr</u>

2. Where are pathologies actually screened?

Pathology screenings:

Clinic for pathology and pathological anatomy

Address:	Braće Branchetta 20, 51000 Rijeka, Croatia
Telephone:	+385 51 325 800
Fax:	+385 51 325 810
Web:	http://www.medri.hr/katedre/Patologija
Contact:	Prof. dr. sc. Nives Jonjić, professor nives@medri.hr

Clinic for Pathology and Cytology

Address:	Clinical Hospital Center, Zagreb, Kišpatićeva 12, 10 000 Zagreb, Croatia
Telephone:	+385 1 2388 365
Web: Contact:	<u>http://www.kbc-zagreb.hr/</u> rradman@kbc-zagreb.hr

Clinic Hospital Mercur

Address:	Zajčeva 19, Zagreb 10000, Croatia
Telephone:	+385 1 2388 365
Fax:	+385 1 234 3500
Web:	http://www.kb-merkur.hr/
Contact:	prof. dr. sc. Mara Dominis, dr. med.

General Hospital Sveti Duh

Address:	Opća bolnica Sveti Duh, Sveti Duh 64, 10000 Zagreb, Croatia
Telephone:	+385 1 3712 111
Web:	http://www.obsd.hr/
Contact:	Mladen Busic <u>ob@obsd.hr</u>

General Hospital Dubrava

Address:	Avenija Gojka Šuška 6, 10000 Zagreb, Croatia
Telephone:	+385 1 2902 444
Web:	http://www.kbd.hr/
E-mail:	kbd@kbd.hr

Clinical Hospital Osijek

Address: Josipa Huttlera 4, Osijek, Croatia
Telephone: +385 31 511 857
Fax: +385 31 512 196
Web: <u>http://www.kbo.hr/</u>
Contact: Luka Tomasic
E-mail: <u>tomasić.luka@kbo.hr</u>

General Hospital Pula

Address:	Zagrebačka 30, Pula Croatia
Telephone:	+385 52 376 000
Web:	http://www.obpula.hr/
Contact:	prim. Lems Jerin, dr. med.

General Hospital Zadar

Address:	Bože Peričića 5, 23 000 Zadar, Croatia
Telephone:	+385 23 211 070
Web:	http://www.bolnica-zadar.hr/

General Hospital Karlovac

Address:	Andrije Štampara 3, 47000 Karlovac, Croatia
Telephone:	+385 1 608 078
Web: Contact:	http://www.bolnica-karlovac.hr/site/ Mira Mlinac-Lucijanić, dr. med.
contact.	wind winnde Edeljanie, dr. med.

General Hospital Vukovar

Address:	Bolnička 5, 32000 Vukovar, Croatia
Telephone:	+385 32 452 111
Web: Contact:	<u>http://www.ob-vukovar.hr/</u> Mr. Sc. Anto Blažanović

General Hospital Vinkovci

Address:	Zvonarska 57, 32100 Vinkovci, Croatia
Telephone:	+385 32 349 246
Web:	<u>www.obvk.hr</u>
E-mail:	opca-bolnica-vinkovci@vk.t-com.hr

General Hospital Sisak

Address:	J.J.Strossmayera 59, 44000 Sisak, Croatia
Telephone:	+385 44 553 100
Web:	http://obs.hr/
Contact:	Dražen Janković, dr.med. spec. patolog

General Hospital Varaždin

Ivana Meštrovića b.b., 42000 Varaždin, Croatia
+385 42 393 500
http://www.obv.hr/
Ivan Herman, dr. med.
iherman@obv.hr

General Hospital Šibenik

Address:	Stjepana Radića 83, 22000 Šibenik, Croatia
Telephone:	+385 22 246 201
Web:	http://www.bolnica-sibenik.hr/
Contact:	Željko Burić, dr. med.

General Hospital Dubrovnik

Address:	Dr. Roka Mišetića 2, 20000 Dubrovnik, Croatia
Telephone:	+385 20 431 777
Web:	http://www.bolnica-du.hr/

Clinical Hospital Split

Address:	Spinčićeva 1, Split, Croatia
Telephone:	+385 21 556 111
Web:	http://draft.gideon.hr/kbcsplit/index.php?stil=1

Clinical Hospital center Zagreb

Address:	Šalata 2, 10000 Zagreb, Croatia
Telephone:	+385 1 2388 888
Web:	http://www.kbc-zagreb.hr/

3. 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 ...)?

For general information regarding neonatal and prenatal screening please refer to the following link: <u>http://www.hcjz.hr/pr.php?id=12519&rnd</u>=

Or contact the Croatian Ministry of Health:

Vibor Delić, dr. med.

E-mail: vibor.delic@mzss.hr

The tenders are published on the following Webpage of HZZO (Croatian Institute for Health Insurance).

Address:	Margaretska 3, 10 000 Zagreb, Croatia	
Telephone:	+385 1 4806 333	
Web:	http://www.hzzo-net.hr/dload/natjecaji/35	
	20090605 Natjecaj spec OM za akad 2009 10.pdf	

4. 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

Contact: Prof. dr. sc. Marija Strnad Zagreb, Al. A. Augustinčića 11 E-mail: prof.marija.strnad@gmail.com

Early detection of breast cancer

Udruge žena lječenih od bolesti dojke Kralja Tomislava 1 44000 Sisak Telephone: +385 44 510 042 E-mail: <u>udruga-zena@net.hr</u> Web: <u>http://www.rak-dojke.hr/index.php?page=news</u>

Anonymous 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 Telephone: +385 1 48 63 237 E-mail: <u>hiv.savjet@hzjz.hr</u> Web: http://www.hzjz.hr/epidemiologija/hiv_cent.htm

Pilot project of early detection of cervical cancer in women of PGŽ

Contact: Emina Grgurević-Dujmić, dr. med. E-mail: <u>emina@zzjzpgz.hr</u> Telephone: +385 1 98 259 041

5. Do you know who are 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 that 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:	llica 191, Zagreb
Telephone:	+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:	Clinic for Ontology and nuclear medicine	
	Klinička bolnica 'Sestre milosrdnice' Vinogradska 29, 10000 Zagreb, Croatia	
Telephone:	+385 1 3787 163	
Web:	http://www.endolabor.kbsm.hr/	
E-mail:	<u>endolab@kbsm.hr</u>	

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

OKTAL PHARMA D.O.O.

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

MEDICAL INTERTRADE

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

6. 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.

7. 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, <u>Official Gazette No. 67/08</u>) (<u>http://narodne-novine.nn.hr/clanci/sluzbeni/339714.html</u>) 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.

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;

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- Control of conception.

Database updated on: 12.08.2013:

http://www.almp.hr/?In=en&w=med proizvodi

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 Telephone: +385 1 4884 100 Fax: +385 1 4884 110 E-mail: <u>almp@almp.hr</u> Web: <u>http://www.almp.hr/</u> Contact: Krunoslav Kranjčec, <u>krunoslav.kranjcec@almp.hr</u>

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

8. Is it possible to send documentation regarding our products to the adjudicators so they can already register us in their database?

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

9. 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 Telephone: +385 1 4806 333 Fax: +385 1 4812 606 http://www.hzzo-net.hr/dload/natjecaji/35 20090605_Natjecaj_spec_OM_za_akad_2009_10.pdf

10. 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 these distibutors which will enable your company to know when a tender is called. The following companies could be of interest to you:

OKTAL PHARMA d.o.o.

Utinjska 40, 10020 Zagreb Hrvatska

Telephone: +385 1 6595 777 Fax: +385 1 6595 701 E-mail: <u>oktal-pharma@oktal-pharma.hr</u> Web: <u>http://www.oktal-pharma.hr/</u>

MEDICAL INTERTRADE

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

PHOENIX FARMACIJA d.d.

Ozaljska ulica 95 10000 Zagreb Telephone: +385 1 3650 111 Fax: +385 1 3650 110 Web: <u>http://www.phoenix-farmacija.hr/hr3_a/01/index1.php?url=abaout</u> E-mail: <u>v.babic@phoenix-farmacija.hr</u>

MEDIKA d.d.

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

ASTRA INTERNATIONAL ZASTUPANJE INOZEMNIH TRVTKI

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

BAN-PROMET

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

BISERNICA

Kestereanekova 1 10000 Zagreb, Croatia Telephone: +385 1 242 15 76 Fax: +385 1 242 15 81 Web: <u>www.bisernica.hr</u> E-mail: <u>bisernica@bisernica.hr</u>

CROLAB

Papandopulova 21 2100 Split, Croatia Telephone: +385 21 465 699 Fax: +385 21 465 699 E-mail: <u>crolab@st.htnet.hr</u>

HILUS MEDICAL

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

MEDIAL

Ulica grada Vukovara 237B 10000 Zagreb, Croatia Telephone: +385 1 611 98 41 Fax: +385 1 615 44 55 Web: <u>www.medial.hr</u> E-mail: <u>medial@medial.hr</u>

4. ANNEX 2: ADDRESS LIST

PUBLIC HEALTHCARE FACILITIES

Klinički bolnički centri

Klinički bolnički centar Zagreb

Šalata ulica 2, 10000 Zagreb Website: <u>http://www.kbc-zagreb.hr/</u> E-mail: <u>kbc-zagreb@kbc-zagreb.hr</u>

Klinički bolnički centar Rijeka

Krešimirova 42, 51000 Rjieka Website: <u>http://www.kbc-rijeka.hr/kontakt.php</u>

Klinička bolnica Split

21000 Split Website: <u>http://kbcsplit.newvibrations.net/index.php?stil=1</u> E-mail: <u>ocna.klinika@kbsplit.hr</u>

Kliničke bolnice

Klinička bolnica Osijek

31000 Osijek-Donji Grad Website: <u>http://www.kbo.hr/</u> E-mail: <u>enarucivanje@kbco.hr</u>

Klinička bolnica "Sestre milosrdnice"

Vinogradska cesta 29, 10000 Zagreb Website: <u>http://www.kbcsm.hr/</u> E-mail: <u>kbcsm@kbcsm.hr</u>

Klinička bolnica Merkur

Zajčeva 19, 10000 Zagreb Website: <u>http://www.kb-merkur.hr/</u>

Klinička bolnica Dubrava

Avenija Gojka Šuška 6, 10000 Zagreb Website: <u>http://www.kbd.hr/</u> E-mail: <u>Webmaster@kbd.hr</u>

<u>Klinike</u>

Klinika za ortopediju Lovran Šetalište maršala Tita 1, 51415, Lovran Website: <u>http://www.orto-lovran.hr/</u>

E-mail: narucivaje.lovran@gmail.com

Klinika za tumore Ilica 197, 10000 Zagreb Website: <u>http://www.kbcsm.hr/hr/klinike/klinika-za-tumore/</u> E-mail: <u>narucivanje.vinogradska@kbcsm.hr</u>

Klinika za dječje bolnice Klaićeva 16, 10000 Zagreb Website: <u>http://www.kdb.hr/</u> E-mail: <u>kdb.narudzbe@kdb.hr</u>

Sveučilišna klinika za dijabetes, endokrinologiju i bolesti metabolizma Vuk Vrhovac

Dugi dol 4A, 10000 Zagreb Website: <u>http://www.idb.hr/</u> E-mail: <u>SKVV@idb.hr</u>

Klinika za plućne bolesti Jordanovac

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