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DRUG POLICY IN CROATIA
ATTITUDES TOWARD DRUG EXPENDITURE RATIONALIZATION

CONTENT

INTRODUCTION

The *Croatian Association of Research-based Pharmaceutical Companies* (CARPC), founded in 1994, gathers today 21 innovative pharmaceutical companies, which employ 970 employees and have more than 50% of the market share in Croatia in value of the drugs. The CARPC strongly advocates timely access to innovative drugs, ethics and social responsibility in its members' business activities, and partnership with all stakeholders in the health care.
The CARPC is a member of the *European Federation of Pharmaceutical Industries and Associations* (EFPIA).

As active stakeholders in health care, we would like to express the attitudes of CARPC members toward the issues related to drug expenditure rationalization in the Republic of Croatia.

MACROECONOMIC INDICATORS

The key macroeconomic indicators, such as a negative growth rate of the gross domestic product (GDP), high unemployment rate, substantial state budget deficit, and high external debt, show that Croatia has been affected by the economic recession.

At the same time, Croatia is faced with the problem of aging population with two-sided consequences, one being the reduced revenue for the mandatory health insurance system and the other increased expenditures due to increased prevalence of chronic non-infectious diseases and malignancies.

Table 1. Macroeconomic indicators

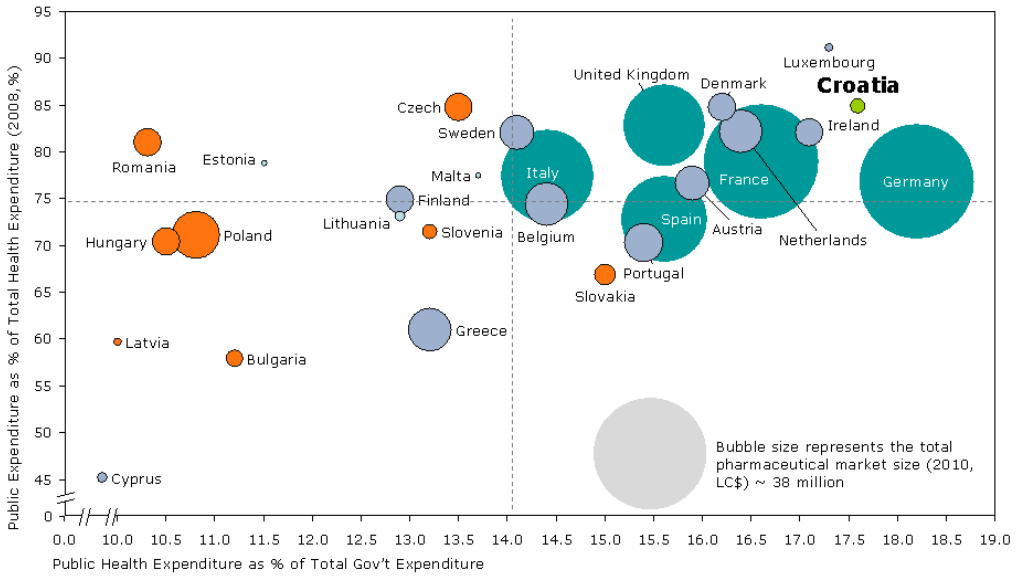
Basic Macroeconomic Indicators

	INDICATOR	2010	2011 (estimate)	EFFECT ON THE AREA OF DRUGS
Demographic data (Croatian Bureau of Statistics)	•Total population	4,429		– Ageing of the population
	•Average age	41.1		– Increasing incidence and prevalence of chronic non-infectious and malignant diseases
	•Life expectancy	75		– Increasing pressue on spending in health care
Economic growth (HNB, HGK 2010 reports; RBA analysis)	•GDP per capita (EUR)	10.393	10,812	– Slowed GDP growth directly affects the availability of money in health care sector
	•GDP growth (%)	-1.2%	0.5%	– Expected reduced spending through rationalization and reduced availability of some health care services I(including drugs)
	•Inflation (%)	1.1%	2.6%	
Employment rate (HGK)	•Unemployment rate (%)	17.6%		– Increase in unemployment rate /decrease in health care contributions without alternative forms of health care funding will result in worsened liquidity or reduced scope of health care services available through health insurance
Budget balance (HGK)	•Total deficit (mil EUR)	-1,923		– To reach the level 3 deficit (Maastricht criteria), a dramatic reduction in all forms of public spending is needed, including spending in health care
	•Total deficit (% GDP)	-4.2%		
Credit rating (HGK, srpanj 2011)	•Standard & Poor's		BBB-	– Without stronger fiscal consolidation, the credit rating would continue to be at risk
	•External debt (% GDP)		100.5%	– More difficult and expensive funding will limit the possibilities of economic recovery

HEALTH CARE FUNDING

According to the World Health Organization data for 2008, the share of public spending in total health expenditures in Croatia was 84.9%, which makes it one of the countries with the highest share of public funding of health care in Europe. Also, public spending on health care accounts for 17% of the total government spending.[1, 2]

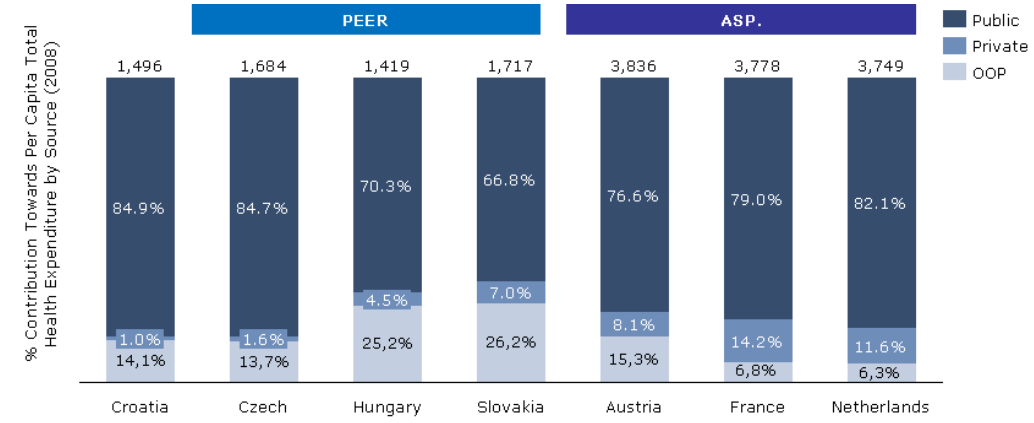
Figure 1. Share of public spending in total health expenditures and share of public spending on health care in the total government spending in European Union countries and Croatia



Source: WHO; IMS Market Prognosis

The share of private spending on health is relatively small (15.1%); however, in Croatia, private spending on health mostly refers to out-of-pocket expenses, because private health insurance coverage is underdeveloped. Thus, each time that financial burden is switched from the government to the citizens, it is immediately and directly felt by the citizens.[1, 2]

Figure 2. Comparison of health care funding sources in Croatia and countries of similar economic development *("peer"*) and economically more developed countries *("aspirational"*)



The figures at the top indicate the Total Health Expenditure Per Capita (PPP$, 2008)

In economically developed Western European countries, the share of private health care funding through different forms of private health insurance schemes is significantly higher than direct out-of-pocket funding, which makes these systems more flexible.

According to the analysis of possible scenarios for health care funding in Croatia carried out by the IMS, an international consulting group, with the present level of public health care funding, Croatia should significantly increase the private spending on health care either through direct out-of-pocket payments or through additional forms of health insurance, in order to achieve a comparable ratio between the public and private funding, such as the ratio in the countries of similar economic development *("peer"*) or economically more developed EU countries *("aspirational"*).

Figure 3. Sources of health care funding in Croatia – analysis of possible scenarios

Source of healthcare funding	Croatia current healthcare expenditure per capita ($)*	Increase in per capita spend ($ per person) needed to match OOP/Private insurance funding in...	
		... Peer	... Aspiration
Out of Pocket (OOP)	211	+138	+25
Private Insurance	15	+55	+420
Public	1,270	1,270	1,270

DRUGS

Drug expenditures

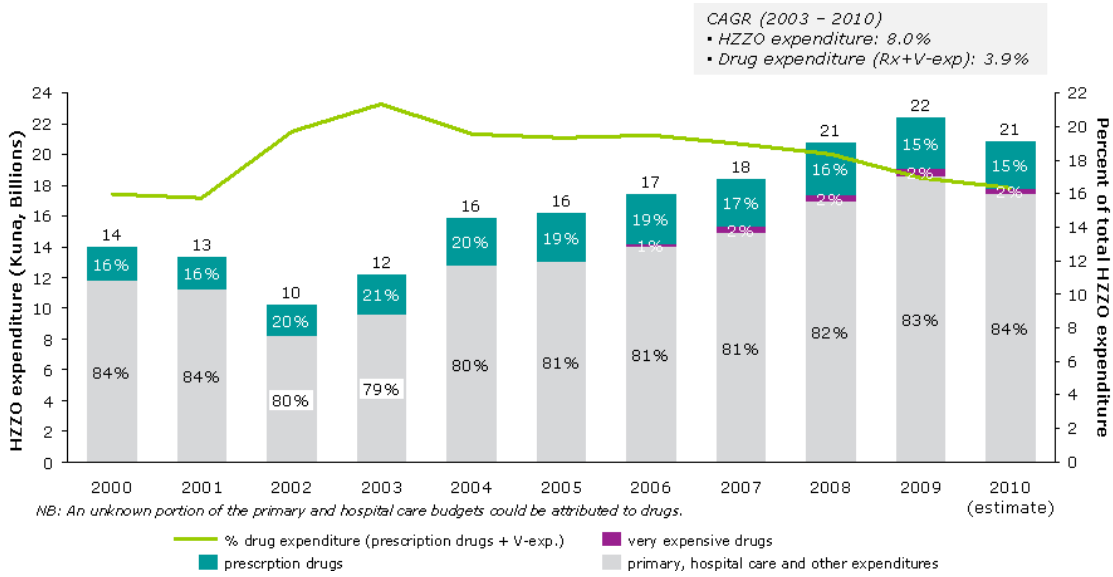
In Croatia, drug expenditures account for 19% of the total health expenditures. However, the total amount of 128€ per capita spent on drugs is relatively low in comparison with the amount spent in other countries of similar economic development *("peer"*) and economically more developed countries *("aspirational"*).[2]

Figure 4. Comparison of economic development indicators and health care and drug expenditures in Croatia and some EU countries

	Country	Population (million)	GDP (billion $)	GDP/Capita ($)	Total Health Exp. as % of GDP	Total Rx Pharma Exp. Per capita (LC €)
	Croatia	4.4	84	18800	7.8	128
Peer	Austria	8.3	334	41300	10.1	332
Peer	France	62.1	2180	34000	11.1	395
Peer	Netherlands	16.4	696	41800	9.1	185
Neighbour	Czech	10.4	268	26200	6.8	169
Neighbour	Hungary	10.1	201	20100	7.4	183
Neighbour	Slovakia	5.4	122	22400	7.8	187
Other	Germany	82.2	2998	36400	10.4	268
Other	Romania	21.5	253	11500	4.7	88
Other	Bulgaria	7.6	92	12800	7.3	85
Other	Poland	38.1	752	18800	6.6	118
Other	Turkey	70.6	958	12300	5.0	96

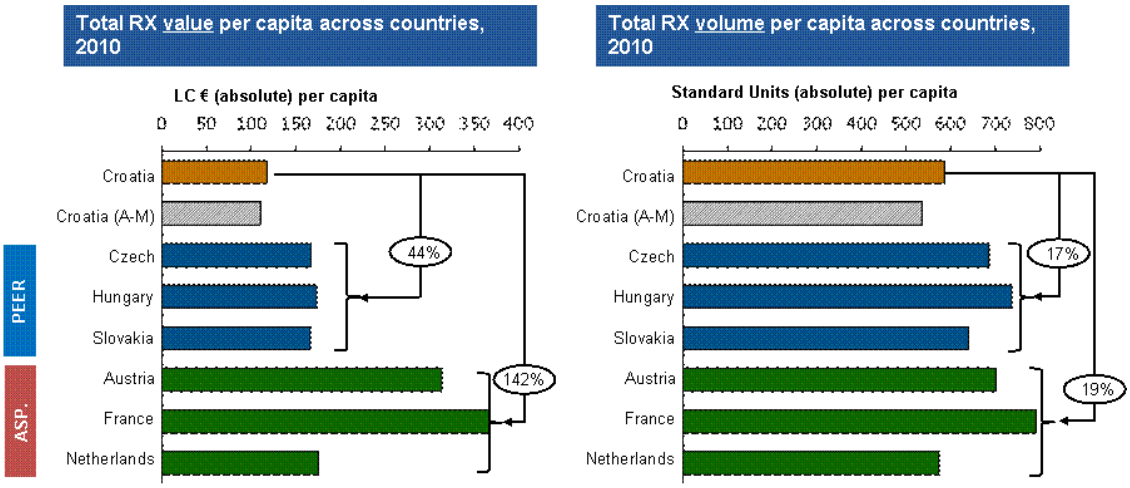
Health care expenditures have visibly increased since 2003, but the drug spending share in total health expenditures has been continually decreasing, because of reduced drug prices and slow and limited accessibility to new innovative drugs.[2]

Figure 5. Drug expenditures and total health care expenditures in Croatia in 2000-2010



In comparison with other countries of similar economic develpment *("peer"*) and economically more developed countries *("aspirational"*), drug expenditures in Croatia are lower in terms of value and volume.

Figure 6. Drug expenditures in Croatia and other countries of similar economic development *("peer"*) and economically more developed countries *("aspirational"*)



In all countries market defined as 'total Rx excluding TAs not of interest';
***Croatia (A-M)**: Total Croatia Analysis Market (i.e. with non-HZZO covered products also excluded)*

Drug Prices

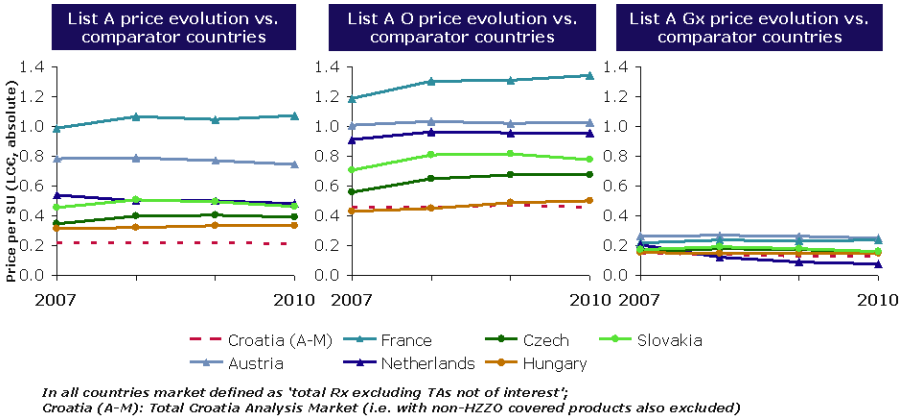
Drug prices in Croatia equal 73% of average drug prices in EU-25 countries, irrespective of whether or not the drugs are included in the Positive List of drugs partly or fully reimbursable by the CIHI.[3]

The reasons are as follows:

a) The highest drug prices, which are regulated by the *Ordinance establishing the criteria for wholesale pricing of medicinal products and the method for reporting wholesale prices* (Official Gazette 155/2009), do not match average prices in comparator countries but are calculated by using a discount factor (90%, i.e. 65%), which is why the prices are, by definition, among the lowest in Europe*;
b) New drugs enter the market slowly and to a limited extent, which is why their average price per unit is low; and
c) Drug manufacturers' efforts to reduce the price paid by the insured (co-payment) as much as possible in order to improve the accessibility of drugs in the setting where private health insurance is non-existent.

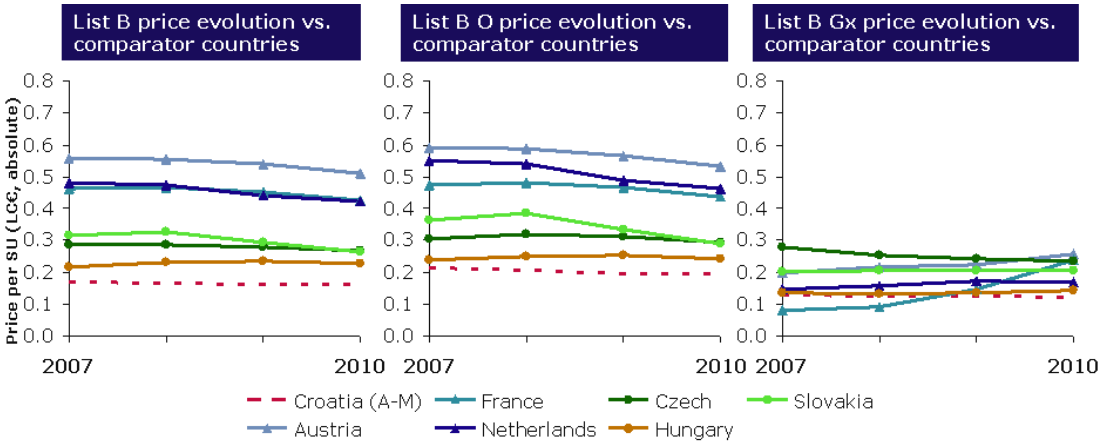
The current price referencing system, which determines the prices of drugs covered by the CIHI per pharmacotherapeutic groups (ATC classification level 3), does not take into account different mechanisms of action of different drugs or additional value of innovative drugs in comparison with generic and original drugs whose patents have expired. Such a price referencing system favors higher reimbursement prices for generics and brand name drugs whose patents have expired, while the authorization holders of patent-protected innovative drugs cannot achieve such a low price; therefore, innovative drugs are included in the list of drugs co-paid by the insured. Since no additional forms of health insurance exist to cover the co-payment for drugs, patients in Croatia have a limited access to new innovative drugs.

Figure 7. Price levels of drugs included in the Positive (basic) list ("List A") compared with prices of the same drugs in countries of similar economic development *("peer"*) and economically developed countries *("aspirational"*): **(a)** prices of all drugs; **(b)** prices of innovative manufacturers' drugs ("O") including patent-protected drugs and drugs whose patents have expired; **(c)** generic drug prices ("Gx")



* The ordinance establishing the criteria for wholesale pricing has not been consistently applied in practice due to the requirement that 90% discount factor be applied to comparator prices of patent-protected drugs.

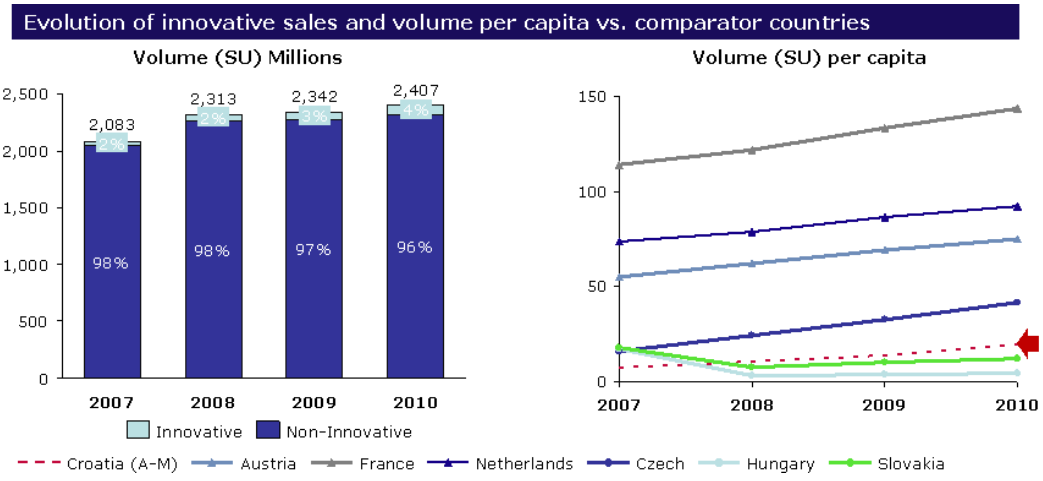
Figure 8. Price levels of drugs included in the Additional drug list ("List B") compared with the prices of the same drugs in other countries of similar economic development *("peer"*) and economically more developed countries *("aspirational"*): **(a)** prices of all drugs; **(b)** prices of innovative manufacturers' drugs ("O") including patent-protected drugs and drugs whose patents have expired; **(c)** generic drug prices ("Gx")



In all countries market defined as 'total Rx excluding TAs not of interest';
Croatia (A-M): Total Croatia Analysis Market (i.e. with non-HZZO covered products also excluded)

Market share of innovative drugs (still patent-protected original drugs) in Croatia is low and accounts for approximately 4%.[2]

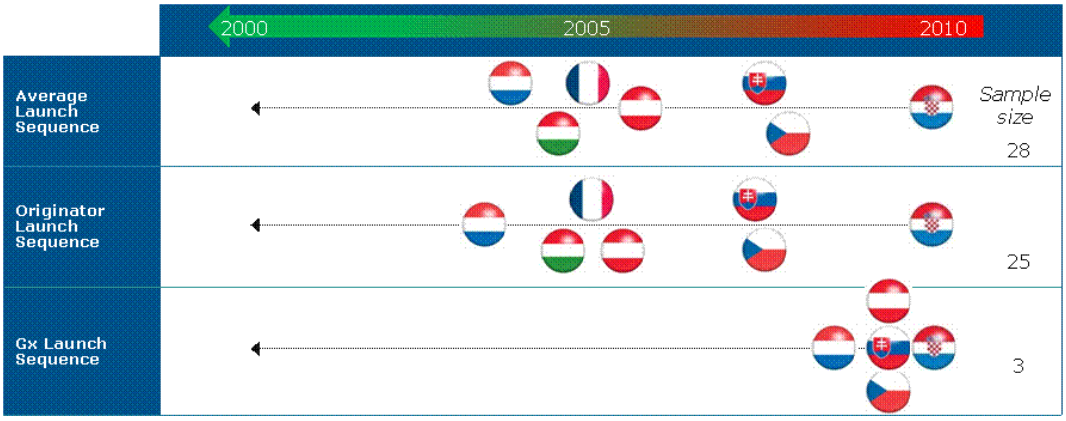
Figure 9. Market share (by volume) of innovative drugs in the overall drug market in Croatia and other European countries of similar economic development and economically more developed countries.



Availability of New Innovative Drugs

According to the IMS study, new innovative drugs become available in Croatia after 2-6 years of being available on the markets in EU countries.[2]

Figure 10. Availability of innovative and generic drugs in Croatia in comparison with their availability in the neighboring countries and Western European countries.



The reasons for delayed availability of innovative drugs in Croatia are (1) the fact that the registration process of innovative drug in Croatia can be started only after the drug has been authorized for marketing in other EU countries (the registration procedure at the Croatian Regulatory Agency lasts 12-14 months on average) and (2) the long duration of the decision making process regarding reimbursement/inclusion of innovative drugs into the CIHI Positive List due to restrictive rules for determining drug prices, which are most often inapplicable in case of innovative drugs.

At the same time, the process of inclusion of new drugs into the CIHI list of drugs is not in line with patient rights to equality and comparative assessment of health technologies and has not shown to value innovation according to the WHO guidelines (Italian Declaration) and European Commission criteria.

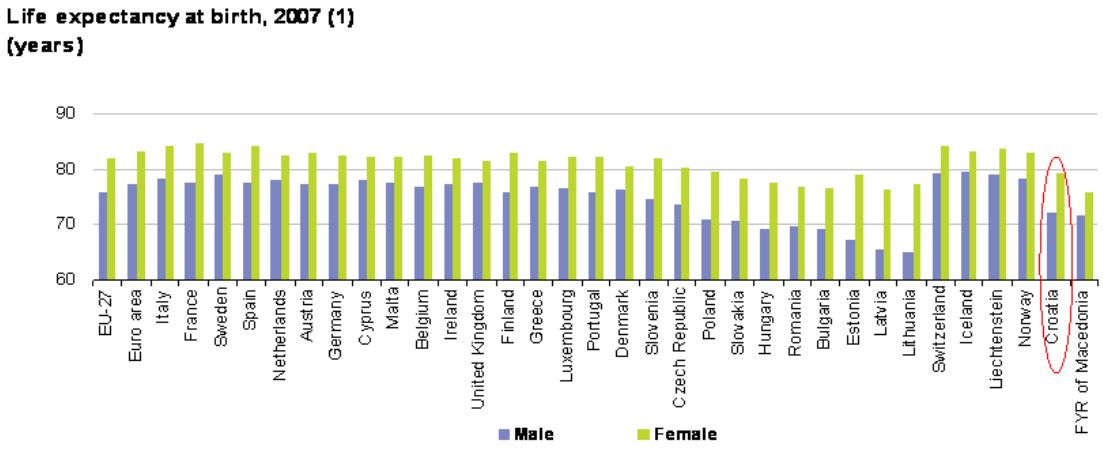
HEALTH OUTCOMES

Since 1960, the life expectancy at birth in the member countries of Organization for Economic Cooperation and Development (OECD) has increased by more than 10 years *(OECD, 2009.).*

The analysis of the contribution of pharmaceutical innovation in Germany in 2001-2007 has shown that approximately 1/3 (32%) of the increase in life expectancy is a result of the replacement of old drugs with new ones.[4]

According to the 2010 Eurostat data, the life expectancy at birth in Croatia is significantly lower than EU-27 average. In Croatia, the life expectancy at birth is 72.3 years for men (EU-27 average is 75.8 years) and 80 years for women (EU-27 average is 82 years).[5]

Figure 11. Life expectancy at birth in Croatia and EU-27 countries



Source: Eurostat (tps00025)

Mortality rates from ischemic heart disease and malignancies in Croatia are among the highest in Europe, i.e. in comparison with EU-27 countries.[5]

The use of newer drugs is associated with lower total treatment costs and improved health outcomes.[6, 7]

DRUG EXPENDITURE RATIONALIZATION

In the light of current economic situation in Croatia, it is necessary to rationalize health care expenditures in order to achieve a financially sustainable system and improve health outcomes.

Regarding the drug expenditure rationalization, the following measures to limit expenditures are considered acceptable:

<u>Competition-based pricing</u> of drugs whose patents have expired i.e., <u>generic</u> drugs (ATC classification level 5).

Increasing the price competition for the ATC level 5 drugs whose patents have expired rather than introducing the measures promoting the prescription of generic drugs as replacements for still-patent protected molecules

To ensure the effective systems allowing that savings created by direct generic competition are not kept in distribution channels but transferred to insurers and patients.

National price referencing for active substances
(e.g. originator after patent expiry and generics)

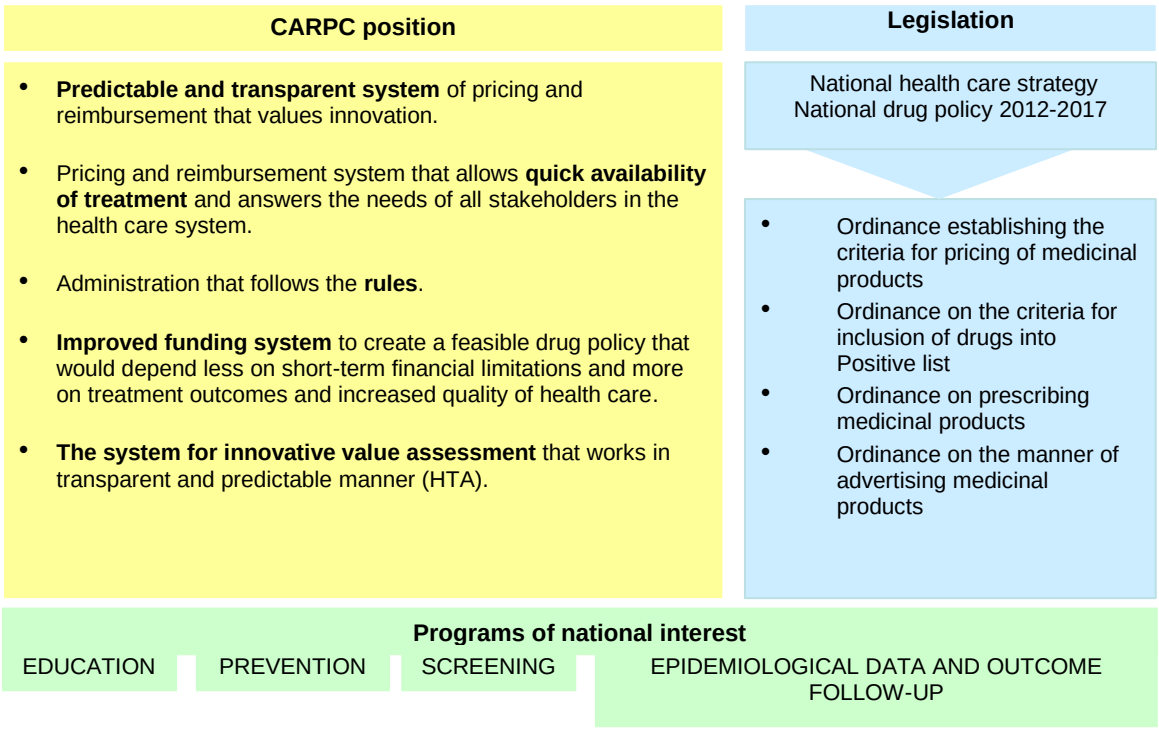
Contract-defined allocation of risks between the Institute and manufacturers (drug funding risk, health outcome risk) while new innovative drugs are introduced into the market.

Contracts reduce the insurer's risk when making the decision on insuring new technologies. Contracts should remain a discretionary right of manufacturers in their relationship with the insurer.

Prices/savings resulting from negotiations in individual cases should not be used for other drugs on the list.

All listed measures are exclusively aimed at short-term goals of expenditure reduction.

In order to achieve long-term goals of improved health outcomes and quality of care, we suggest a partnership between innovative pharmaceutical industry and the Ministry of Health on several levels that would allow us to approach the following issues in a concerted fashion:



It is important to establish registries of diseases, defined as the main generators of morbidity and mortality in Croatian citizens, to modernize therapy accordingly and to monitor drug use and effectiveness of therapy.

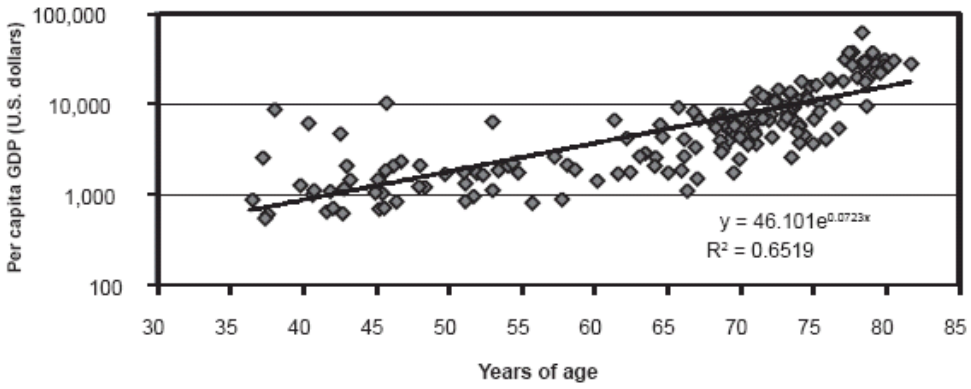
CONCLUSION

CARPC as an active stakeholder in the health care system would like to have a partner relationship with health administration in creating a financially sustainable and effective health care system in which innovative drugs would be timely and equally available to all patients.

The financial benefit that innovative drugs bring to the society significantly exceeds their price. The benefit consists of reduced total health expenditures, increased work capability and capability to perform other activities, and increased contribution to the quality of life and life expectancy.[8]

Investments in health and drugs are directly associated with the increase in life expectancy and quality of life and, consequently, with the increase in work capacity and productivity of the population, which leads to the economic growth and well-being of the entire society.[9]

HEALTH EQUALS WEALTH: LIFE EXPECTANCY VS. PURCHASING POWER PARITY PER CAPITA GDP



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