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Implications of the Accession of the Republic of Croatia to the European Union for Croatian Health Care System

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A B S T R A C T

The Republic of Croatia's accession to the European Union (EU) will affect all segments of economy and society, including the health care system. The aim of this paper is to establish the potential effects of joining the EU on Croatian health care, as well as to assess its readiness to enter this regional economic integration. The paper identifies potential areas of impact of EU accession on Croatian health care and analyzes the results of the conducted empirical research. In this research, a method of in-depth interviews was applied on a sample of 49 subjects; health professionals from public and private sectors, health insurance companies, pharmaceutical companies, drug wholesalers, and non-governmental organisations (patient associations). Once Croatia joins the EU, it will face: new rules and priorities in line with the current European health strategy; the possibilities of drawing funds from European cohesion funds; labour migrations; new guidelines on patient safety and mobility. From the aspect of harmonising national regulations with EU regulations in the area of health care, Croatian system can be assessed as ready to enter the EU. Croatia's accession to the EU can result in a better information flow, growth of competitiveness of Croatian health care system, enhanced quality, inflow of EU funds, development of health tourism, but also in increased migration of health care professionals, and potential increase in the cost of health care services. Functioning within the EU framework might result in adaptation to the EU standards, but it could also result in the concentration of staff and institutions in larger cities.

Key words: *European Union, implications, health care system, Republic of Croatia*

Introduction: The impact of the European Union rules on health care systems in member states

The Republic of Croatia's accession to the European Union (EU) will affect all segments of economy and society, including the health care system. EU accession has been set among Croatia's priorities for a number of years now. The official request to join the EU was submitted on 21 February 2003 and negotiations between EU member states and Croatia began in October 2005 at the first session of Intergovernmental Conference. After more than eight years following the submission of the request and almost six years of negotiations, accession negotiations were closed on 30 June 2011, and the Treaty of Accession was signed on 9 December 2011. Croatia is expected to join the EU on 1 July 2013 when it should become the 28th member of this regional economic integration.

The relationship between European legislation and health policy is a rather complex one, partially because health policy does not have a clear delimitation between the competences of member states and European institutions. Because of specific historical reasons, the systems of health and social welfare are for the most part not directly linked with the EU common policy and are consequentially not part of the acquis communautaire. However, indirectly, almost all chapters of the acquis affect

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health in one way or the other. Although health systems of member states are decentralised, there are still a number of guidelines that tend to streamline and coordinate them. Republic of Croatia must harmonise its legislation and practice with EU conventions and guidelines in the area of health.

Ever since the European Coal and Steel Community was established, considerable efforts have been invested in Europe to deepen its economic integration. There are several key documents of the EU that have established the rules on protection from influencing health care system and service provision:

- The Treaty of Rome[1] established the common market. As for health protection, Article 152 (5) of the Treaty of Rome says that Community actions in the field of public health must entirely respect the responsibilities of the member states for the organisation and delivery of health care services[2]. This way, the Treaty of Rome has established the principle of subsidiarity.
- The Treaty of Maastricht[3] established additional spheres within which European countries could undertake joint European actions on an intergovernmental basis. This Treaty gave the EU a more pronounced role in the development of health policy in Europe. Article 129 of this Treaty provided the EU with a mandate to encourage collaboration between member states and, if necessary, to support their actions in the public health domain. Furthermore, Article 129 empowered the EU to spend funds on the European level for health projects but forbade it to enact laws in terms of harmonising measures of public health in the member states[3].
- In 1997, Article 152 of the Treaty of Amsterdam[4], confirmed the affirmative responsibility of the EU in order to ensure a high level of protection for human health in defining and implementing all policies and activities, and to cooperate with member states to improve public health, prevent diseases, and reduce the sources of danger to human health. Moreover, the Treaty of Amsterdam points to the need of developing health policy at a supranational level.
- The Lisbon Treaty promotes dynamics that might result in a converging model through some forms of soft collaboration, especially through the initiatives whose aim is to establish guides and indicators, through the exchange of best practices, and by preparing all elements necessary for periodical monitoring and evaluation[5]. Article 192 (7) of the Treaty on the Functioning of the EU as amended by the Lisbon Treaty states that EU actions in the field of public health must fully respect the responsibility of the member states for defining their health policies and for organising and providing health services and protection, as well as for resource allocation[5].

The key principle of EU governance is solidarity. In line with this principle, the EU supports the development of social services for all residents of its member states and the realisation of the »European social model«. In 2000, EU member states articulated their social model in the Charter of fundamental rights of the European Union. As for health, the Charter claims that everyone is entitled to access preventive health care and medical treatment under the conditions established by national laws and practices. Furthermore, it is necessary to ensure a high level of health care when defining and implementing all EU policies and activities.

Although all EU member states have their own health systems and policies, these are directly affected by the rules and objectives of the EU. There are three distinguishable categories of EU measures[6]. The first category comprises the acknowledged measures for achieving free movement of workers, free provision of services, and free establishment of institutions. The second category refers to the measures that seek to ensure free movement of goods, especially pharmaceuticals and medical devices. The third category includes the measures that arise from other areas of EU policy, which can be directly related to health.

In the EU context, there is an issue of how citizens from one country can enjoy solidarity and provide their part of income to citizens in other countries[6]. Many meetings held between EU member states have revealed an interest in developing a common position in the area of financing of health systems and social protection in health[7].

As for the freedom of providing health services to patients within the EU member states, it is worthwhile pointing out that besides enjoying the emergency health care, which is secured through the European Insurance Card*, when moving across the EU member states they are also entitled to the following[6]:

- Clinical treatments in any member state of the EU and reimbursement of funds once they are back in their respective countries of origin, at prices applicable in that country. No prior authorisation for reimbursement is required in accordance with Article 49 of the European Community Treaty
- Treatment in any EU member state in an identical manner in which the service is provided to all other citizens of that country (the prices etc.) but with a prior authorisation by a local institution (Article 22, Regulation 1408/71)
- To require the abovementioned authorisation for the treatment abroad whenever such a treatment is objectively needed, depending on the patient's health status, or when the treatment is or will be otherwise unavailable in the country for a determinate period of

* European Health Insurance Card provides the citizens of EU27 + Island, Lichtenstein, Norway, and Switzerland with the access to health services, if these are required during the stay abroad. The card does not cover the costs related to treatments and injuries occurring before the trip, nor does it provide for the costs of private health care.

time (this right also derives from Article 49 of the European Community Treaty).

These rights can be exerted by all patients from the EU states, irrespective of whether their country of domicile applies the reimbursement system (as is the case in France, Germany, Luxembourg,…), the benefits-in kind system with contractual physicians and hospitals (as is the case in the Netherlands), or the system of benefits provided primarily through public institutions (as is the case in Great Britain and Italy). Although the laws ensure patient mobility, there has not been a reported increase in the number of patients who opt for a treatment in different member states of the EU.

Assuming that universal coverage with health services is the main objective, at least three variables are needed to define the general interest in the area of health services that truly belong to the category of common interest[6]. The first variable refers to the types of treatments and pharmaceuticals that the system provides for. These differ from one country to the other and so does the availability of treatments due to numerous factors. The most typical examples are the issue of abortion, cosmetic surgery etc. The second variable refers to the quality of treatment and varies according to the number and level of expertise of health professionals, development of health infrastructure, waiting lists etc. The third variable involves the quality of non-health services, such as cleaning and accommodation services etc. However, irrespective of legal regulations, standards, and all variables, these have rarely been described in detail in the EU and they fail to fully define the public interest in the area of health care. Therefore, it seems that the application of EU regulations requires introducing a concept of »services of public interest« or »public services« and their precise definition in the area of health care[6].

Although infrastructure and other fixed costs are primarily financed through public funds, of late, various countries have also attempted to attract private investment. The British initiative of private financing is now also looked into by other EU countries. It is important to underscore that the choice of private investors who will assist in the financing of public hospitals can only be made in line with the principles of public procurement.

Hospital budgets have a very complex structure and differ from one country to the other. However, they have one thing in common: distinguishing between fixed (maintenance, heating, staff etc.) and variable costs (directly related to the volume of their activity). The manner of calculating variable costs has been under revision in the past few years in almost all EU member states. In order to maintain costs and rationalize treatments, there are three main approaches: (1) advance payments through the planned budget based on average costs of hospitals falling into the same category, (2) calculation of average costs based on Diagnoses Related Groups or equivalent units of measure where each specific medical condition is related to a specific treatment and/or length of stay and (3) allowing efficient hospitals to retain any surplus. Not only do these measures encourage hospitals to manage financial resources in a more efficient manner, but they also enhance transparency. State aid to hospitals must be precisely calculated in order to meet the economic requirements of this public service.

Of course, the EU keeps increasing its involvement in health care governance through the development of new governance tools. This development coincides with a growing interest in enhanced welfare, in particular, in respect of health care. The main criticism of new EU governance refers to its incapacity to protect what is »social« from what belongs to the »market«[8]. New mechanisms of governance include the open method of coordination, which represents a flexible and participative method of governance and is nothing like traditional top-down approaches that are based on rules, and governed and controlled methods. The process of the open method of coordination uses joint learning, benchmarking, best practices etc. In the context of social or welfare policy, there is a considerable scepticism in respect of this method, as it is seen as a way of orienting European welfare policies towards a non-liberal direction[8].

The majority of criticism is nothing but a fear that new governance is only liberalisation or privatisation of social institutions in disguise. In Europe, liberalisation or privatisation in the context of social policy can create a challenge for the concept of welfare. Some see these new methods of governance as an opportunity to defend and maintain these legally grounded social commitments in the future, whereas others feel that there will be a deviation from these legal commitments and a shift towards a more liberal orientation of welfare policy. To elaborate on this criticism, a difference should be made between »continental European capitalism«, which is based on restricted and socially controlled market economy, and »Anglo-Saxon capitalism«, which is based on market liberalism. It is much easier to move from continental European capitalism to the Anglo-Saxon one, as the restrictive elements of European capitalism are easier abandoned than implemented. However, in the context of health care policy, there are no arguments to support the idea that the open method of coordination in health serves the purpose of undermining continental European social paradigms or of moving towards the Anglo-Saxon or neo-liberal model[8].

Although formulating and implementing health care policies is still a task for national policies, the development of the internal EU market and the work of EU institutions (in particular the European Court of Justice) have transformed the legal environment so much so that health systems now employ people, purchase goods, finance services, and organise themselves[9]. Though it is difficult to establish a cause-effect relationship, enhanced European integration coincides with market orientation of service production, that is, with the transfer of services from public towards private sphere. Collectively organised and provided services related to transport, communications, education, and health care can be replaced with market production of these services with retention of public financing.

The EU does not have a political mandate to interfere with national systems of social security. There is no EU social model because the differences between member states are too large[10], but the EU can affect the habits of public expenditure through budgets and by stimulating growth, in line with the Lisbon strategy. There is a huge indirect impact exerted through deregulation of national markets. Furthermore, the influence of the European Court of Justice is occasional but significant.

Moreover, it can be stated that today there is a new strategic approach to healthcare as health is considered as one of integral parts of the EU development strategy. The concept of health must be included in all relevant policies. This particularly refers to social and regional development, taxation, education, environmental protection, and research and development policies. The approach of »health inclusion« must be applied when policies are drafted, irrespective of the area of interest. In addition, for it to be fully effective, it must be entirely respected when regional, national, and local policies are developed.

A new strategy of the European Commission was developed under the name »Together for health: A Strategic Approach for the EU 2008–2013«. Its objective was to enhance patients' safety, citizens' welfare and solidarity, and stimulate knowledge and dissemination of health information. This strategy underscores the importance of developing such a health care system that will be founded on common values and principles, reduce inequalities, and include all related policies such as environmental policy, research and development, regional cooperation, pharmaceutical and other policies. This strategy also points to the need of strengthening the EU voice on the global level through cooperation with international organisations[11]. In line with the abovementioned, the key principles that a health care system and a broader health strategy should be founded on are[11]:

- A strategy based on common values
- Underlining health as the greatest wealth
- Integrating health in all policies
- Strengthening the EU voice in the area of health and global health care.

There are three main objectives arising from the strategy »Together for Health«[11]: (1) promoting health for all citizens and its sustainability in a climate of unfavourable demographic conditions of an ageing population, (2) improving the system of monitoring and responding to health threats, and (3) stimulating dynamic health systems, development and implementation of new health technologies, fostering care and safety of patients, and regulating patients' cross-border rights.

Attempts are made to find new and sustainable ways of financing and pointing to health as to a priority area for investment, as well as of stimulating equality and prevention among EU citizens. There are various initiatives within the framework of the European Health Programme for the period 2008–2013 that promote disease prevention and health care, raise awareness, and disseminate information and experience[12]. To meet the objectives of this scheme, the funds in the amount of 321.5 million euros have been earmarked for this purpose. The scheme represents the main instrument of the European Commission for implementing its health strategy.

In November 2011, a proposal for a new health programme for the period 2014–2020 entitled »Health for Growth« was adopted. This programme will continue to promote health as an integral part of a sustainable and inclusive economic growth, and will follow the broader EU development strategy. The new programme covers four objectives through which it can positively affect economic growth and citizens' health[13]: (1) addressing the problem of insufficient financial and human resources and stimulating innovation to ensure innovative and sustainable health systems, (2) providing an access to information and medical expertise within and outside national borders to ensure an access to better and safer health care for all EU citizens, (3) recognising, disseminating and promoting best practices in the area of prevention to prevent disease outbursts and promote good health, and (4) developing common approaches for better preparedness and coordination in emergencies to protect citizens from cross-border health threats.

The new programme intends to help EU countries to effectively face demographic and economic challenges and create an environment in which cooperation, coordination, and innovative solutions for quality, efficiency, and sustainability improvement are promoted. The budget allocated for the programme »Health for Growth« amounts to 446 million euros.

Besides the strategies whose only focus is health, the umbrella strategy for Europe's development, »Europe 2020«, also contains health, which is indirectly represented through several different initiatives. A particular emphasis is placed on innovation arising from the past activities of research and development, stimulation and development of telemedicine and similar services, and stimulation of personalised medicine that could provide patients with better care and supervision of health[14]. Improving health and safety of workers is also stimulated. The European Agency for Safety and Health at Work was founded in 1996 with the aim of enhancing occupational safety in EU countries. Each year, there are more than 5.500 serious workplace accidents in the EU, and millions of workers regularly sustain minor injuries or endanger their health[15]. It is necessary to raise awareness of workers and employers on the need to protect their health at work.

Furthermore, WHO Regional Office for Europe rendered a decision on new health care policy for the period until 2020. The purpose of this new policy known as »Health 2020« is to strengthen health systems, build infrastructure and public health institutions, develop coherent and founded policies and solutions for potential health threats, and achieve sustainable improvements. As the umbrella policy, it will cover and coordinate all actions undertaken by the World Health Organisation and European countries[16]. The main objectives of "Health

2020" include[16]: joining forces of all European member states to promote health and welfare; creating better conditions of living, increasing life expectancy, reducing inequities in health, and coping with demographic changes; improving health governance; creating common strategic objectives; speeding up innovation and knowledge--sharing and increasing participation of all members of civil society.

European cohesion policy aims at reducing regional inequalities by granting financial support from structural funds. Health and health care have been recognised as significant elements of welfare and competitiveness and have been included in the programmes of regional financing. Three investment priorities have been highlighted: two refer to direct and indirect investments in health, and the third refers to investments that are outside the health sector but are somehow related to it. The first two areas involve investments in health infrastructure, e-health, providing access to health care for the most vulnerable groups, emergency health care, medical equipment, occupational health and safety, health promotion and disease prevention, and education and training for health workers. Other investments refer to information technology, cross-border cooperation etc. The effective use of structural funds for improving skills and competences of labour in health and health infrastructure development may contribute to improved working conditions and growing quality of medical services, reducing thus health differences and strengthening cohesion between EU member states[17].

There are three main funds within the framework of the European cohesion policy, which are beneficial to health care[18]:

- European Regional Development Fund, which mostly focuses on financing investments in health infrastructure and medical equipment, can also provide financing for investment projects in the area of energy, investments in the strengthening of institutional infrastructure etc.
- European social fund most often finances those health projects that are related to national strategic priorities: for example, increasing employment, reducing sick leaves, promoting health etc.
- Cohesion fund is one of structural instruments aimed at reducing regional economic and social differences between member states. This fund can finance projects that are directly or indirectly related to health care: for example, road building, environmental protection etc.

In the period 2007–2012, 5 billion euros have been earmarked from the European Regional Development Fund for investments in health infrastructure. The European Social Fund finances activities in the area of e-health, health promotion and other similar priority areas[19].

Aiming at streamlining member states and providing assistance in the area of financing, all in line with cohesion policy, the European Commission has prepared a Common Strategic Framework – CSF for the period 2014–2020[20]. This document consists of guidelines for preparing financing, which should add to a better use of available funds and maximise investment effects. The Common Strategic Framework will replace the present guidelines for the Cohesion Fund, the European Rural Development Fund, the European Regional Development Fund, the European Social Fund, and the European Maritime and Fisheries Fund and will combine these into a single set of guidelines that will strengthen coherent financial planning. The objective is to direct investments into development sectors and develop programmes for better combining and coordinating of the available funds. National and regional authorities will use this set of guidelines when developing project applications or applying for funding from CSF funds. When preparing, implementing, supervising, and assessing a programme, all member states, potential beneficiaries of CSF funds, must ensure cooperation and coordination between national authorities and ministries that are competent for implementing the allocated funds. The available funds are intended for the implementation of specific structural reforms needed to achieve the objectives of EU 2020 development strategy. It is therefore necessary to ensure the consistency between actions and programmes financed through CSF funds and the umbrella strategy for EU development.

Empirical research in this paper was conducted with the purpose of gaining an insight into potential effects of Croatia's accession to the EU on Croatian health care system.

Research Methods

Methods of research implementation

This research was implemented in the period between June and October 2011 within the framework of a broader research whose scope was to provide a better understanding of the situation and perspectives for future development of health care in Croatia. The selected method of research was a semi-structured interview, which can be audio recorded, carried out online (chat, e-mail…), and/or by phone[21]. The main advantage of the method of in-depth interviews is that they provide more detailed information than what is possible to collect through other methods[22]. In-depth interviews provide an opportunity to subjects to express themselves. Many people are flattered to be able to express their opinions and life experiences and that someone listens to them with interest[23].

The research on the state of play and perspectives for a future development of health care system in Croatia was conducted in three main stages:

1. Background research: investigating the problem by reviewing the available literature.
2. Construing the main research.
3. Main research that covered 49 subjects.
   3.1. Step one: synthesising main topics.
   3.2. Step two: analysing.

3.3. Step three: interpreting results.

3.4. Step four: verifying and reporting.

In line with the objective of this research, we asked the following research question: How do national health care systems function in EU member states and what are the implications of Croatia's accession to the EU? Research problems were analysed against today's situation (year 2011) and against the perspective on development and potential future state of play (year 2030). Account was taken of the research conducted at the EU level on the development of national health care systems in member states by 2030[24]. Besides, analysing both the current state of play and future perspectives allows for high quality results to be obtained, which is significant, as these will later be used to develop recommendations for implementing policies that will minimise potential negative effects and stimulate potential positive developments.

Participants and Data Processing

The main research involved subjects that were relevant for the established research problems. In-depth interviews were conducted with 49 subjects in the period from the beginning of June until the end of September 2011: 23 of them were health professionals, 8 were representatives of health insurance companies, 10 were representatives of pharmaceutical companies and suppliers, and 8 were representatives of patients' associations among which there was a coalition of associations that covered 70 patients' associations. As for the choice of subjects, account was taken of the bias, that is, impartiality was ensured; subjects had to be relevant for the area of research, and their knowledge had to be such that it could contribute to determining the implications of Croatia's accession to the EU for health care in Croatia. Ethical issues are always present in all types of research[25] and all subjects must be informed on the objectives and main points of the research[26]. The main ethical issues that were taken into account during this research were: (1) subjects' consent, (2) privacy, and (3) data confidentiality. Each participant in the research was assigned a letter »I« and an adequate ordinal number.

Table 1 shows the main research question and definitions used in its elaboration. The metacode used in the process of research implementation was designated as H9. Following the multilevel principle, the pertaining codes were presented in the same way (Table 1): potential positive effects of the accession of Croatia to the EU on Croatian health care and potential negative effects of the accession of Croatia to the EU on Croatian health care.

Results

Based on the subjects' opinion, the analysis of potential effects of Croatia's accession to the EU on Croatian health care underscored numerous potential positive and negative effects and resulted in the recommendations for maximising positive and minimising negative effects.

There are several potential positive effects; from better information flow (I15), growth of Croatian health care competitiveness (I27, I18) and consequential growth of service quality, growth of transparency (I27, I2, I47), introduction of clear benchmarks (I27, I37), improved monitoring and evaluation (I2), equalisation of quality and standards (I2, I18, I37, I42, I47), reduced room for nepotism (I26), to ensured EU funding (I6, I45), faster registration of innovative and generic drugs (I6), that is, centralised registration of drugs (I18), increased number of generics (I46), further integration into pan-European health care (I5), facilitated exchange of professionals (I28), improved administrative and political rules of behaviour (I36), more control (I41), better organisation (I47), improved certain segments of health through knowledge and experience exchange (I8), and further development of those segments in which Croatia has a comparative advantage (I8). Croatia's accession to the EU will allow Croatia to participate in EU projects, drug investigations, training programmes etc. (I10).

One of potential advantages is also the possibility of providing health care services to insured persons from other EU countries (I22), as we boast the advantages of being a tourist destination and can therefore focus on further development of health tourism. I45 states the following as a potential advantage: »in the long-term, processes of integration of health care will follow the direction of resource and activity specialisation. This is where we could find several health niches and exploit the tourist destination aspect of our country…«.

Furthermore, another advantage is a greater availability of treatments for rare diseases »because due to high costs for treating such diseases, specific centres will be organised that will cover the entire EU area« (I28).

TABLE 1
INDEX OF THEME CODES USED IN THE RESEARCH AND THE FREQUENCIES OF SUB-CODES

theme	metacode	sub-codes	frequencies	relative share of sub-codes in the metacode
implications of the Republic of Croatia's accession to the EU	H9		139	
potential positive effects of the accession of Republic of Croatia to the EU (2011/2030)		$H91_{2011}/H91_{2030}$	56/35	40%/25%
potential negative effects of the accession of Republic of Croatia to the EU (2011/2030)		$H92_{2011}/H92_{2030}$	29/19	21%/14%

When Croatia joins the EU, it will gain an insight into a good example of health care informatisation (I5). Another advantage of accession is seen in the harmonisation of rules with other EU member states (I9). I30 hopes that Croatian health care will be able to take over the positive aspects of national health care systems of EU member states, such as for example opening hospices, enhancing the quality of palliative care, and investing more in prevention and in the training of health staff.

In terms of negative effects of the accession of Republic of Croatia to the European Union on Croatian health care, subjects most frequently gave the following examples: medical doctors and nurses leaving for the EU (I1, I16, I31, I4, I5, I2, I6, I12, I8, I13, I22, I33, I42, I45), importing health staff (I4, I2, I12, I22) from third non-EU countries into Croatia (I31), patient outflow, that is, using health services in other EU countries while the costs are admitted in the country of origin (I8) (this is, on the other hand, underlined as a positive effect of the accession by some – I25), implementing EU decisions that are not favourable to us (I38, I48), higher costs of health services for a large number of citizens (I44), and coping with a number of insufficiently regulated health care systems in the EU (I28).

I13 points out that: »upon joining the EU, the patients will not automatically see improvements, as health care systems remain under the competence of member states«, and I19 states that »it is up to us to decide which health care system we will have«. In this regard, a number of subjects are of the opinion that there will be no greater changes once Croatia joins the EU (I23, I32, I33). The status of pharmaceutical institutions will be uncertain, as this kind of a model is not either known or recognised in the EU (I46) and the possibility of turning these into another ownership model will be open for discussion.

If Croatian economy improves, potential negative effects will be minimal (I1). It is necessary to undertake »due diligence of the system and measures that must be taken before joining the EU so that we are not taken aback when the time comes to join the Union« (I3). The pharmaceutical industry seems to be the most prepared of all to join the EU (I9).

When asked how they felt Croatian health care was going to function within the EU framework until 2030, the subjects listed similar potential problems and benefits to those Croatia would face upon joining the EU next year. Some subjects were of the opinion that by 2030 Croatian health care: would be similar to the systems in other EU member states (I11, I34); would be fully in line with EU standards (I2, I3), or be a part of the EU system (I27, I5, I7, I37); would be determined by EU laws (13), but this would not affect the rest of the EU given Croatia's size (I4). I28 expressed a concern that the effect of unsuccessful national reforms would still be felt in 2030.

Some subjects hope that Croatian health care will not experience the problems of »brain drain« of health care professionals (I1, I15). I12 believes that the »brain drain« will occur but there will also be an inflow of health staff that can stir up some positive changes. I19 feels that »…if we start solving our problems responsibly and immediately, we can reach the EU golden mean quite soon. Unfortunately, today we are at the very end, aren't we?«. I28 warns of »nonmedical and other homeopathic impacts on poorly educated and insufficiently informed population«. Moreover, I36 believes that except for a few exceptions, Croatian health care system »has nothing to offer to the EU«.

Health tourism is seen to become a comparative advantage over other EU member states (I7, I23, I25). As a main objective of Croatian health care within the EU until 2030, I8 states the following: »to become a health care system recognised for its particular segments, which will make Croatia the country of choice for a number of EU patients«. Harmonisation with EU health care is seen as one of positive effects, as it will bring about more order (I9), the implementation of preventive programmes (I28), and the achievement of solidary and equally accessible health care (I33). I47 says: »joining the EU will doubtlessly help Croatian medicine to develop and higher standards to be introduced«.

Some subjects trust that 2030 will reveal poor implementation of EU acquis in practice (I38, I41, I48) and that staff and institutions will be concentrated in larger cities (I38, I48). Table 2 summarises the main expected effects of Croatia's accession to the EU on national health care today and in two decades.

Discussion and Conclusion

The systems of health care and health policies in EU member states are intertwined in several ways, some of

TABLE 2
EFFECTS OF THE ACCESSION OF CROATIA TO THE EU ON NATIONAL HEALTH CARE

joining the EU	long-term membership in the EU
• better information flow	• harmonisation with EU standards
• growth of Croatian health care competitiveness	• further development of health tourism
• increased quality	• concentration of staff and institutions in larger cities
• inflow of EU funds	
• development of health tourism	
• increased migration of health care professionals	
• increased costs of health services	

them being: the mobility of patients who are in search of health care services outside their country, migration of health care professionals, and new findings in the area of health technologies. The Republic of Croatia's accession to the European Union will affect all segments of economy and society, including the health care system. When Croatia joins the EU, it will face new rules and priorities in accordance with the current European health strategy. This strategy emphasizes the importance of developing such health care system that will be based on common values and principles, reducing thus inequalities. The concept of health must be included in all relevant policies, especially in the policy of social and regional development, taxation, education, environmental protection, and research and development. It is also important that the EU voice is strengthened on a global level through cooperation with international organisations.

Furthermore, Croatia will have the possibility to draw funds from European cohesion funds. The priority areas for investment are: health infrastructure, e-health, providing access to health care for the most vulnerable groups, emergency medicine, medical equipment, health and safety at workplace, promotion of health and prevention of diseases, education and training for health professionals, information technology, cross-border cooperation etc. Aiming at streamlining member states and providing assistance with strategic planning in the area of financing, and in accordance with cohesion policy, the European Commission prepared the Common Strategic Framework (CSF) for the period 2014–2020. National and regional authorities will use this framework of guidelines when developing project applications, that is, when applying for CSF financing.

The potential problem of labour migration has also been pointed out. Free movement of persons within the EU is one of fundamental rights guaranteed by Community law. Free movement of workers within the EU is permitted pursuant to Article 39 of the European Community Treaty. Potential advantages of Croatia's accession to the EU related to human resources refer to the possibility of providing health services to insured persons from other EU countries, exploiting thus the advantage of our tourist destination (that is, the advantages refer to the development of health tourism). Negative consequences of the accession might be the »brain drain« of medical doctors, nurses, and other health care professionals to the EU, and the inflow of other health care personnel. Labour migration is a particularly significant issue in the EU, as it can result in double-natured effects. On the one hand, it is a solution to the problem of human resource shortage in health. On the other hand, however, an excessive import of labour can push out local labour from the labour market or can cause a shortage of labour in the country of emigration. Moreover, cross-border mobility of health workers, besides affecting the volume of labour in both the recipient country and in the country of emigration, it also affects the quality and skills of labour, as well as their distribution[17].

When Croatia joins the EU, its health care system will meet new guidelines on patient safety. The main recommendations refer to: informing patients and involving them in the process of development of their safety; stimulating safety by training health professionals; monitoring the occurrence of various harmful events to discover the way of preventing them; developing communication and technological tools and systems to enhance patient safety and facilitate collection of information; developing comparable and significant indicators for identifying problems that can endanger patients' health etc. Patient safety is one of top priorities of the EU. It covers a concept of patient safety that is broader than the mere occurrence of undesirable or harmful events related to health protection. Although EU member states are at different levels in terms of implementation and development of patient safety, there are several initiatives and recommendations of the main EU bodies that refer to the coordination of activities related to this area. According to the results of research by Eurobarometer[27], it was seen that almost half of participants of the research conducted in the EU area believed that there was a danger for their safety in health care in the country of domicile. Furthermore, statistical data show that more than 20% of EU citizens claim that they experienced medical error, 18% claim that the error occurred during hospital treatment, and 11% say that they were prescribed a wrong medicine[28]. Creating a clear and systematic access to patient safety would result in less medical errors by 50 to 70%[28]. Regional cooperation in Europe is necessary to ensure a higher level of patient safety, irrespective of whether they are looking for health care within their country or in another member state. Aiming at further promotion of health and patient safety, in 2008 the European Network for Patient Safety was established (EUNetPaS). It seeks to promote the culture of patient safety, exchange of experience, training of health professionals on patient safety, and the implementation of informing and information-sharing system[29]. The network is made of the representatives of EU health professionals (medical doctors, nurses, pharmacists, and others) and institutional partners who are active in the area of patient safety (members of national patient safety organisations and members of the ministries of health). Cooperation between the mentioned members of the organisation stimulates the exchange of experience, knowledge, and best practice to develop common principles of action, stimulate programme development, and ensure assistance to less well developed countries in the area of patient safety.

New rules on patient mobility must not be set aside. Patient mobility within the EU is one of important elements of integration's acquis. Its final objective is to ensure safe and quality health services for all citizens and enhanced cooperation and coordination between health institutions in the member states. The citizens of Croatia will be granted the option of enjoying the benefits of the European Insurance Card. As already said, patient mobility within the EU is one of important elements of inte-

gration's *acquis*. However, there is a problem of the expectation that citizens from one country enjoy solidarity and at the same time provide a share of their income to the citizens of other countries. EU cross-border health care is regulated by Directive 2011/24/EU of the European Parliament and the Council of 9 March 2011 on the application of patients' rights in cross-border health care, which came into force on 24 April 2011. The member states of the European Union must harmonise their national legislations with this Directive by 25 October 2013. The coverage of costs of health services that Croatian citizens receive abroad is mostly regulated by bilateral agreements on the coordination of social insurance concluded with individual EU member states. It is important to mention that these agreements differ considerably depending on the country partner in terms of volume of services and personal application and are often more restrictive than the rules within the EU Directive on patient mobility.

Furthermore, when joining the EU, there is a need to harmonise policies on medicines and implantable medical materials with common EU rules. EU policy on medicines and implantable medical devices is determined at each member state's national level but there are some elements that are determined at the level of the Union. For example, in all countries there are rules that prescribe that manufacturers must provide a proof of quality and safety of new medicines and/or devices. All countries regulate offer and demand on the market for medicines and implantable medical materials to control total expenditure for medicines[30]. Regulatory measures for the offer are mostly directly or indirectly related to pricing, and they most often include price and profit control, and reference pricing. Other key issues in the area of policy on medicines and implantable medical materials include assessing and preventing diseases, setting prices, compensation for expenses, and distribution. The role of the European Commission in this area continues to grow, as it encourages member states to respect and abide by EU laws and principles. It can affect the issues related to national prices, profit, compensation for expenses, free movement and competition, and market access through a harmonised and centralised authorisation procedure by the European Medicines Agency. The Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulates the prices of medicinal products for human use and their inclusion in the national health insurance systems. It must be underscored that the Commission is not entitled to set prices and profit levels in member states; it can only ensure the efficiency and transparency of the process. The establishing Treaty includes provisions that prohibit introducing unnecessary and excessive requirements for licensing, which might restrict and hamper the competition of generics[31]. The European Medicines Agency is a decentralised EU body with head office in London. The main task of this Agency is to scientifically evaluate drugs manufactured by pharmaceutical companies that will later be used in the area of the EU. The Agency cooperates with all 27 member states, the European Parliament, the European Commission, and other decentralised EU bodies with the aim of creating a quality regulatory system that will protect citizens' health. The approval for new products can be applied for either through the centralised system of the Agency or through decentralised system of mutual recognition. The main problems of the policy on medicines in EU countries are: the lack of innovation in therapy, different and high prices of medicinal products and implantable medical materials across EU countries, price as the only measure for quality and the lack of quality differentiation, increased consumption of drugs, and uneven availability of drugs and implantable devices across EU member states[17].

There is currently a procedure underway at the Council of the European Union for enacting a new Directive on transparency of measures regulating the prices of medicinal products and their inclusion in the national health insurance systems, whose aim is to reduce deadlines for rendering decisions on the requirements for setting prices, which will also entail sanctions for failure to abide by deadlines, and the development of new ordinances.

Up to this moment, Croatia has succeeded in harmonising national regulations with EU regulations in the area of health, in particular as regards: cross-border health care, regulated professions, prices of medicinal products and their inclusion in the Essential and Co-Pay medicines lists of the Croatian Health Insurance Institute, medical devices, blood, tissues and cells, and environmental protection (noise, chemicals and biocide preparations, food, and radiations) and from this point of view, health sector is considered to be ready to join the EU.

The impact of European integration on health care systems is limited irrespective of certain rules that affect health care indirectly or directly. Health is considered to be one of integral parts of the new EU development strategy and a significant element of competitiveness. The area of health is directly and indirectly regulated through different laws and directives in the area of drug policy, protection of patients' rights, public procurement, patient safety, prevention etc. Health care policy must ensure and encourage health and health sustainability for all citizens. With this aim in mind, cooperation between member states is recommended, as well as the development and application of new health technologies, improvement of the system of monitoring and responding to health threats, introduction of regulations related to tobacco, alcohol, mental health and other social and economic issues that may potentially affect human health. When defining which direction Croatia will take in its development, it is necessary to consider EU guidelines and decisions that are mentioned in the main strategic documents on health, such as »Together for Health: A Strategic Approach for the EU 2008–2013«, Europe health programme for 2008–2013, the new programme for 2014–2020 »Health for growth« that includes the budget of 446 million euros, health policy »Health 2020« proposed by the World Health Organisation, and a broader EU development strategy »Europe 2020«. Conclusively,

concerning the implications of the accession of the Republic of Croatia to the European Union, this research indicates that the accession will bring about better information flow, growth of competitiveness of Croatian health care, increased quality, inflow of EU funds, development of health tourism, enhanced labour migration, and potential increase in the costs of health care services. Longer functioning within the EU might lead to harmonisation with European standards, further development of health tourism, but also to the concentration of staff and institutions in larger cities. When re-thinking and developing strategies for future development of Croatian health care, it is necessary to consider all identified effects and create priorities and measures that will minimise potential negative effects and enhance potential positive ones.

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IMPLIKACIJE UČLANJENJA REPUBLIKE HRVATSKE U EUROPSKU UNIJU NA HRVATSKI ZDRAVSTVENI SUSTAV

S A Ž E T A K

Ulazak Republike Hrvatske u Europsku uniju (EU) odrazit će se na sve segmente ekonomije i društva, pa tako i na zdravstveni sustav te je važno utvrditi potencijalne efekte učlanjenja u EU na hrvatski zdravstveni sustav, ali i spremnost ovog sustava na ulazak u navedenu regionalnu ekonomsku integraciju, a što sve predstavlja glavni doprinos ovog rada. U radu se identificiraju sva potencijalna područja utjecaja učlanjenja u EU na hrvatski zdravstveni sustav i analiziraju rezultati provedenog empirijskog istraživanja metodom dubinskih intervjua na uzorku od 49 ispitanika, predstavnika zdravstvenih profesionalaca iz javnog i privatnog sektora, zdravstvenih osiguravajućih tvrtki, farmaceutskih tvrtki i veledrogerija te nevladinih udruga, odnosno udruga pacijenata. Pridruživanjem EU-u Republika Hrvatska će se susresti s: novim pravilima i prioritetima u skladu s aktualnom europskom strategijom zdravstva, mogućnostima povlačenja sredstava iz europskih kohezijskih fondova, migracijama radne snage, novim smjernicama o sigurnosti i mobilnosti pacijenata. S aspekta usklađivanja nacionalne regulative s regulativom Europske unije iz područja zdravstvenog sektora, hrvatski zdravstveni sustav može se ocijeniti spremnim za ulazak u EU. Učlanjenje Republike Hrvatske u EU može rezultirati boljim protokom informacija, rastom konkurentnosti hrvatskog zdravstvenog sustava, povećanjem kvalitete, priljevom sredstava od EU, razvojem zdravstvenog turizma, ali i povećanjem migracija zdravstvenog osoblja te potencijalno poskupljenjem zdravstvenih usluga. Funkcioniranje u okviru EU, moglo bi dovesti do usklađenosti s europskim standardima i normama, ali i koncentracije kadrova i ustanova u većim gradovima.