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The recovery of the EU and strengthening the ability to respond to new challenges – legal and economic aspects

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FOREWORD

The extraordinary pandemic which has gripped the entire globe for the past three years has been overshadowed by yet another tragic event, the unfolding tragic and brutal aggression in Ukraine. In the immediate aftermath, as ever, the events only served to strengthen the resolve of the European Member States and our friends and partners across the world on the need to remain united and join forces in carving out the future we want for our continent.

Out of the extraordinary examples of solidarity, the European Commission released the roadmap for the future, that is REPowerEU, a plan that should help us quickly increase our energy saving, diversification of supply towards trustworthy and reliable suppliers and strong investments into renewable energy. In addition to the European Green Deal and the NextGenerationEU, Europe has vividly demonstrated that we are not taking our future for granted.

In a number of ways, the horrible events in Ukraine have acted to speed up the adjustment process, since we now know that our landscape has irrevocably changed. What is more, climate challenge remains. This is why the incredible transformation which will take place in Europe over the next few years is so incredibly important and consequential.

It also continues to prove the notion that investments into science and our own potential will be a key characteristic of our future successes, in which we all firmly believe. To quote the President of the European Commission, Mrs von der Leyen, “imperfect as it might be, our Union is both beautifully unique and uniquely beautiful. It is a Union where we strengthen our individual liberty through the strength of our community. A Union shaped as much by our shared history and values as by our different cultures and perspectives.”

Therein is why we are happy to continue our cooperation with ECLIC, as the different perspectives brought out in these conference proceedings only add to the wealth and the breath of our discussions. Everyone stands to gain, especially the contributing bright minds.

Ognian Zlatev
Head of Representation of
European Commission in the Republic of Croatia

THE LEGAL ASPECTS OF TELEHEALTH*

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ABSTRACT

Telehealth seems to be the new normal in this fast-changing environment. According to the European Commission eHealth was among the highest priorities before the COVID -19 pandemic. Transformation of health and care in the digital single market is among the EU's six political priorities of the Commission 2019-2024 (2018 Communication on Digital Health and Care). The pandemic caused by COVID-19 just accelerates the necessity of the inclusion of digital health into the traditional healthcare systems. Telehealth services are among the biggest eHealth trends in EU. Therefore, one of the challenges is the national, regional and regulatory priorities regarding telehealth. There is lack of telehealth special legislative and governmental policies that needs to stimulate the developing and innovative solutions in medicine through technology and to envisage the upcoming innovation technology. Therefore, the government support and adequate policy making is important to support the development of the telehealth services. One of the main challenges is the electronic transactions of patient data among the telehealth providers and services and the cross-border patient data share. Another issue is the exchange of information among the national health institutions and providers and their interoperability.

The Macedonian legislation does not have special legislation (policies, or laws) about telehealth. Telehealth is regulated as a term in the Law on health protection. Additionally, there is a lack of national acts, literature, and research in this subject matter. Thus, this paper will

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explore the telehealth from two main perspectives: scientific theories and legal practice and the users' practice.

Hence, this paper will analyze the legislation about the telehealth on the EU level and the EU Member States and the Macedonian legislation and the impact on the e-health that was made during COVID-19 pandemic. Furthermore, it will make comparative analyses among different countries into the EU zone compared with the EU aspirant country- the Republic of North Macedonia. A survey conducted among doctors in private and public healthcare institutions in the primary, secondary, and tertiary healthcare levels in the city of Stip and in the city of Skopje will provide data about the challenges, risks, and trends in telehealth before and during COVID -19.

Keywords: *Data Protection, e-Health, EU Digital Strategy, Macedonian healthcare legislation, Telehealth*

1. INTRODUCTION

The telehealth became the main cornerstone during COVID-19 among the healthcare providers, the beneficiaries, the healthcare system, and the doctors and patients. This complex system of involved stakeholders and procedures requires high level of caution and knowledge that goes beyond the traditional accessibility and use of the healthcare services in the traditional healthcare system.

Comparatively, on EU level, since early 2020, the EU countries have rushed to introduce remote health consultations and other telemedicine services at an unprecedented deployment rate. Thus, the global telehealth is expected to grow to US\$218.5 billion by 2025 (European Parliamentary Research Service, April 2021). It seems that all countries were challenged to create appropriate regulatory frameworks that will safeguard the rights of the individuals and the society, on one hand, and to stimulate the use of technology and innovations in healthcare, on the other hand. The pandemic has rapidly accelerated the use of ICT in the health care system in the EU countries. Since the pandemic began, 58 % of countries have been using telemedicine to replace face-to-face consultations, as family doctors' surgeries and hospitals restrict face-to-face contact to essential visits.¹ In December 2021, the Macedonian government enacted the Health Strategy 2021–2030, in which one of the key questions to be considered is to: enhance the health systems and the role of eHealth; assess health technology; and improve the healthcare information system.²

¹ Negrero, M., *The rise of digital health technologies during the pandemic*, European Parliamentary Research Service, 2021, p. 2

² For more, see: The Announcement of the Government in its 125th session: [<https://vlada.mk/node/27191>], Accessed 5 May 2022

Therefore, this paper aims to explore the relevance and importance of telehealth as part of the eHealth developments in the country; the adequacy of the policy making in the process of the development of the telehealth services, the need to empower eHealth literacy among professionals; the access to quality eHealthcare service delivery, and overview the legal basis for interoperability in the national healthcare system.

For the purpose of this research paper we have use comparative legal methods, mainly based on the national healthcare Strategies and positive law, the WHO reports and resolutions, the EU policies, Directives, and Regulations and other potential sources such as releases from a state's executive offices (national and international) and online research articles from which the findings in this introduction are taken. In addition to this research paper, at the beginning of 2022, an online survey with close-ended questions was conducted among doctors in private and public healthcare institutions in the primary, secondary, and tertiary healthcare levels in the city of Stip and in the city of Skopje. There were some restraints that referred to the low interest of the doctors in contributing to the online survey through Google Forms, 69 responses were collected. In terms of the complexity of the work these respondents were doctors in medicine (27,5%), specialists (59,5%) and subspecialist (13%) employed in the public and private healthcare organizations in the city of Shtip and the city of Skopje. Given the focus of this research on secondary healthcare level, specialists are the dominant respondents. In order to clarify and deepen this research, we have made direct contact with 11 doctors and conduct an open interviews and conversations. Also, considering the lack of clarity around the terms like mHealth, eHealth, telehealth, and telemedicine in the country among the health professionals, efforts were made to adjust terminology where was needed.

2. SOME GLOBAL AND EU LEVEL ASPECTS OF TELEHEALTH

eHealth trends have been on the rise in recent years. There are many examples of successful eHealth developments including health information networks, electronic health records, telemedicine services, wearable and portable monitoring systems, and health portals.³

Most of the research papers in this area emphasise the advantages of the use of telehealth “Four systematic review papers suggest that telehealth is “promising”,

³ e-Health - making healthcare better for European citizens: An action plan for a European e-Health Area, COM (2004) 356 final, Brussels, p. 4, [<https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2004:0356:FIN:EN:PDF>], Accessed 4 April 2022

tion technology in order to improve the health treatment of the patient in the field of diagnosis, treatment and monitoring of the patient, as well as in the field of professional exchange of opinions.

The use of ICTs in medicine (the Health care services) and the use of Health is inseparably connected with the internet availability of the users. Therefore, we should emphase that the eHealth is unenforceable in practice without internet access. In 2004, at least four out of five European doctors have an internet connection, and a quarter of Europeans use the Internet for health information.²⁵ Using internet has become an integral part of daily life for many European. Yet, 150 million Europeans – some 30% - have never used the internet. Often they say they have no need or that it is too expensive.²⁶

Our country follows the EU recommendations and stays in line with the core objectives of the Europe 2020 Strategy,²⁷ the Digital Agenda for Europe²⁸ and the eHealth Action Plan²⁹ and eHealth Action Plan 2012-2020 - Innovative healthcare for the 21st century³⁰. In 2019 the Ministry for Information Society and administration has prepared National operative broadband plan³¹. By this Plan (2020-2029) starting from 2023 until 2029 it is expected that all public institutions (e.g. public health institutions) will have symmetrical internet access at a speed of at least 1Gbps³² this will easier access to e-health services³³ and will provide more effective use of telecommunication technology in health and improve the public health care of the citizens. In the first quarter of 2020, 79.9% of households had access to the Internet at home. The participation of households with broadband connections in the total number of households as 87.8% in 2020. In the first quarter of 2020, 81.4% of the total population aged 15–74 used the Internet, and

²⁵ e-Health - making healthcare better for European citizens, *op. cit.*, note 3, p. 4

²⁶ A Digital Agenda for Europe, COM (2010)245 final, European Commission, Brussels, 19.05.2010, p. 25

²⁷ Europe 2020: A strategy for smart, sustainable and inclusive growth, COM (2010)2020, European Commission, Brussels, 03 March 2010

²⁸ Digital Agenda for Europe, COM(2010)245 final, European Commission, Brussels, 19.05.2010

²⁹ eHealth Action Plan, COM (2004) 356 final, European Commission, Brussels, 30.04.2004

³⁰ eHealth Action Plan 2012-2020 - Innovative healthcare for the 21st century, COM(2012) 736 final, European Commission, Brussels, 06 December 2012

³¹ National Operative Broadband Plan, MIOA, North Macedonia, 2019, [https://mioa.gov.mk/sites/default/files/pbl_files/documents/reports/nacionalen_operativen_brodbend_plan_finalna_verzija_02.04.2019.pdf], Accessed 5 May 2022

³² National operative Broadband Plan, Ministry of Informatic Society and Administration (MIOA), North Macedonia, 2019, p. 4

³³ *Ibid.*, p. 40

70.9% used the internet every day or almost every day.³⁴ According to the state statistical office, 40.7% of the population sought health-related information (e.g., injuries, diseases, nutrition, improving health, etc.) during this time period, while only 4.7% made an online (via web or application) appointment with a doctor (e.g., of a hospital or health care center).³⁵

The pandemic caused by COVID-19 has accelerate the use of communication technology in the healthcare, this was the only sustainable “distance measure” in the health crises. And this remained as a post-pandemic solution that became a standard that must be followed. But at the same time the research didn’t show that legal or ethical principles were established or maintained when using new forms of communication and technology in healthcare.

2.2. Survey results

In February 2022, an online survey was conducted among the doctors from the primary, secondary, and tertiary health care levels (private and public health care sector) among doctors, doctors-specialists, and doctors-subspecialists in the city of Shtip and the city of Skopje. In the survey, we collected 69 responses, 26 from men (37.7%) and 43 from women (62.3%). In terms of the complexity of the work these respondents were doctors in medicine (27.5%), specialists (59,5%) and sub-specialist (13%) employed in the public (53,6%) and private (46,4) healthcare organizations in the city of Shtip and the city of Skopje. Some additional issues were discussed face-to-face or on the phone with eleven doctors by random choice. For the purpose of this research, we will present only the results that are relevant to this topic.

Most of the respondents (63 or 81.3%) were totally or partially familiar with the essence of term digital health (eHealth).

“In effect, telemedicine allows remote group collaboration between various health-care professionals from different locations, sometimes even from different countries. Practitioners can communicate with distant colleagues, thus improving the quality of the services provided. The continuous flow of communication between healthcare professionals is motivated by the growing complexity of medicine,

³⁴ MAKSTAT database, State Statistical Office of Republic of North Macedonia [https://www.stat.gov.mk/pdf/2020/8.1.20.31_mk.pdf], Accessed 1 December 2021

³⁵ Misheva, K. *Authorized lectures EU eHealth Law, ICT and Bioethics (2020-2022)* within the Jean Monnet Project EUEHL, Official data used from MAKSTAT, State Statistical Office of the Republic of North Macedonia, year LVIII, No. 8.1.20.31 from 16 November 2020