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Current eHealth trends in CEE and Turkey

The healthcare industry is currently undergoing a major digital transformation, with eHealth – including telemedicine – at the forefront of this change. In recent years, governments and healthcare providers across Central and Eastern Europe and Turkey have been implementing new solutions in order to enhance the delivery of medical services and to further support the digitisation of healthcare systems.

Private healthcare providers and eHealth start-ups are driving current healthcare industry growth, offering innovative solutions such as online consultations and health exams, remote patient health monitoring, and electronic prescriptions. These advancements are not only making healthcare more accessible but also improving efficiency and security.

Since our previous February 2022 report, many countries in the region have made significant progress in the field of eHealth. This updated report provides a comprehensive overview of the latest trends and advancements. Among other things, it offers detailed country-by-country insights into eHealth-related developments.



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Bulgaria

In Bulgaria, despite the COVID-19 pandemic, no explicit regulation or regulatory regime is in place for telemedicine services. The provision of healthcare services remotely via telecommunication means is not prohibited or restricted, but must be provided in compliance with the regulations and standards generally applicable to the medical profession and its services. In this respect, the existing reimbursement regime has also not been adapted to specifically accommodate and facilitate medical assistance via telemedicine.

In practice, the telemedicine sector in Bulgaria has improved over the past three years, mainly as a result of a necessitated pandemic response. Much of the efforts, however, have come from the private sector, as public officials have shown resistance to offers of outside assistance. Such private efforts came via a number of newly created mobile apps and platforms, such as Healee, Consento, Synevo HomeDoc and EasyDoc, that allow practitioners to offer remote consultations to patients. Such private healthcare services filled a pandemic-induced sector gap between supply and demand with respect to technological advancements.

In recent years, Bulgaria has taken a number of steps to move to paperless and contactless healthcare. Indeed, the Covid-19 pandemic has only exemplified the challenges associated with such a shift. Presently, the Ministry of Health maintains a National Health Information System (NHIS), which provides centralized management and storage of information on electronic referrals and electronic prescriptions. A separate medical assessment processing system is used by various Bulgarian public authorities. The purpose of the NHIS is to maintain electronic profiles and health records for all persons undergoing, or who have undergone, a medical examination. The NHIS is available to doctors, the social security authorities, medical commissions and other local medical bodies, who can all add and locate information concerning the previous healthcare status of the respective patients. At the end of 2022, the Ministry of Health facilitated public access to patient health records in the NHIS through the e-Health mobile application. The health records of each patient are accessible via a qualified electronic signature. The system contains information on medical examinations, test results and prescriptions, but only to the extent that these have been submitted by the respective healthcare professionals, which is not yet always the case. The mobile application is still in the process of development and new functionalities are expected to be added.

So far, the greatest government-backed telemedicine-related advance in Bulgaria has been the introduction of e-prescriptions in 2020. Medical professionals can now prescribe medicinal products electronically; records can then be accessed by pharmacists through an electronic system. Another positive development is the introduction of e-referrals for medical diagnostic tests (for example PCR tests), which have become widely used by general practitioners, and e-referrals for hospitalizations, which are widely considered to be a significant time-saver. The aim is for this process to become completely paperless – but no official timeframe for this has yet been unveiled.

Simultaneously, several hospitals with Covid-19 departments have established web-based telemedicine models, which transcribe a selected number of patient health indicators, such as temperature and heart rate, and present this in real time via an app which all caregivers can access remotely. The aim is to increase doctor safety, reducing in-person time with patients, while at the same time increasing overall efficiency.

In 2021, the Ministry of Health introduced a procedure for providing financial aid to state-owned and municipal medical institutions with a proposed budget of nearly BGN 129 million. The aim of the project is to move past the pandemic and strengthen the overall healthcare system. Medical institutions were able to apply and obtain state aid based on set criteria and methodologies, including the implementation and development of telemedicine.

In July 2022, a proposal for an amendment to the Bulgarian Health Act was submitted to the Bulgarian parliament, which aimed at, among other things, regulating the use of telecommunication technologies in the healthcare sector. However, due to ongoing political instability the proposal has yet to be approved.

In September 2022, the Ministry of Health and the Ministry of Education, in cooperation with two hospitals and four schools, announced the launch of a new project for the implementation of telemedicine in schools. The participating schools are equipped with a station through which students can contact doctors at the participating two hospitals for a medical consultation. According to the Bulgarian government this programme will improve current unsatisfactory healthcare in schools resulting from a shortage of medical staff. No results from the pilot project have yet been announced.

The regulation of other activities, such as remote diagnoses, setting up therapy programmes, offering consultations, medical care, therapy and rehabilitation – all without the physical presence of medical professionals – has not yet been implemented by the government.

Croatia

In Croatia, the legal framework for telemedicine is prescribed via the Healthcare Act and Ordinance on the conditions, organisation, and manner of performing telemedicine. Under this regime, healthcare professionals can provide remote healthcare services by using communication technologies and, more precisely, provide remote patient monitoring, consultancy healthcare services, preventive measures, diagnostic and therapeutic procedures, etc. The law differentiates telemedicine from so-called mobile healthcare (in Croatian: mZdravstvo), which includes using mobile technologies for the collection of medical and public health data.

Telemedicine services are intended to be provided equally at the primary, secondary and tertiary levels of healthcare by both public and private healthcare organisations. A majority of these within the fields of cardiology, neurology, radiology, and neurosurgery are predominantly in the private sector, and cover healthcare professional-to-healthcare professional relations. A few exceptions are found where telemedicine has been applied for patient communications and patient treatment. Various pilot projects have already been implemented in Croatia. So, far, the "Staying Alive" app is widely viewed as producing the best results, particularly during the summer tourism season. The app was developed in collaboration with the French AEDMAP foundation and can recognize the current location of users and display the nearest AVD (automatic external defibrillator) devices. It also contains a guide on how to perform a resuscitation procedure and locates the nearest properly trained volunteer to carry out a resuscitation. Meanwhile, mZdravstvo services are widely available and offered through an e-citizen platform introduced by the Croatian government in 2014. All personal medical data, prescriptions, referrals, past and future scheduled visits to primary healthcare physicians, medical results, applied therapy and other data are available online by simply entering the user's ID credentials. Medical data is at the same time available to healthcare professionals and organisations through an internal system called Healthnet, leading to an almost paperless system. One Healthnet feature, namely the so-called A5 prescription, particularly proved its usefulness during the Covid-19 pandemic (which placed a huge burden on specialized physicians). Using A5 prescriptions means no need for direct appointments with medical specialists, with primary healthcare doctors able to seek a specialist opinion through the Healthnet system.

Asides from the above-described developments, as well as the ability to schedule online vaccination appointments and PCR tests, the Covid-19 pandemic has had no significant impact on the practical implementation of telemedicine services in Croatia. The existing Croatian legal framework offers more room for the future development of telemedicine services – which has clearly not yet been fully realised.

Telemedicine is recognized in the Ministry of Health's Strategic plan for 2020-2022 as an important factor in ensuring more accessible health care, especially for those Croatians who live on the county's many islands, or in rural areas, areas of special state care, and for healthcare organisations lacking professional staff. The Strategic plan for 2023 has not yet been adopted but the same efforts will likely continue in the ensuing years, with the development of telemedicine services following the general direction of the digitalization of Croatian public services.



Czech Republic

In our last report, we informed you about important developments in eHealth legislation in the Czech Republic, namely the Electronic Healthcare Act, which is gradually coming into force. While the first set of regulations began to apply on 1 January 2022, the start of 2023 brought another set of regulations introducing a so-called "Data Integration Interface". The Data Integration Interface is intended to provide the Czech healthcare system with a unified infrastructure for the communication and exchange of medical documentation between subjects participating in the electronic healthcare system. In particular, the Data Integration Interface includes registers of information concerning healthcare institutions, healthcare professionals and patients.

The Act on Electronic Healthcare serves as a general legal framework for all healthcare services provided by electronic means. It introduces the basic infrastructure of different subjects in the electronic healthcare system and stipulates their rights and obligations, as well as the rights and obligations of patients connected through eHealth services. The law sets uniform standards for the provision of electronic healthcare in the Czech Republic.

Moreover, the Czech Ministry of Health has prepared a draft amendment to the Health Services Act, which proposes to introduce a definition of telemedicine health services into Czech law. In particular, according to the draft amendment, telemedicine health services may be provided only in line with the law and only if the technical requirements for quality and security of communication are met. The draft amendment allows the use of telecommunication and information technologies, including their remote use, and the collection of information related to a patient's health status, which is automatically sent to a relevant healthcare provider.

Czech health insurance companies currently reimburse telemedicine health services, including those provided by general practitioners, clinical psychologists and psychiatrists, under certain conditions. However, the reimbursement of telemedicine services by public health insurance is likely to be expanded with the expected incorporation of telemedicine health services into the Czech legal framework.

Hungary

The first wave of the Covid-19 pandemic cast a new light on the importance of telemedicine in Hungary. A telemedicine regulatory regime was first introduced in April 2020 on a trial basis. As a result of the positive experiences gained during this initial phase, the Hungarian government extended the trial and subsequently enacted a permanent telemedicine regulatory regime, applicable irrespective of the current pandemic.

Under this regime, healthcare services may be provided by healthcare professionals via IT infrastructures from a remote location, provided that the nature of the treatment and healthcare considerations permit their use.

As part of telemedicine services, healthcare professionals may - among others - establish diagnoses and set up therapy programmes, offer patient consultancy services, provide medical care, carry out therapy and rehabilitation activities, and prescribe pharmaceutical products and medical devices.

Healthcare providers must provide the appropriate IT devices and medical devices necessary for carrying out telemedicine services in compliance with data protection rules governing health-related data. In addition, healthcare providers must provide patients with a policy and patient information guide related to the specific telemedicine services offered by the given healthcare provider. Healthcare providers must also guarantee appropriate internet connections, data transmission, data security and cybersecurity. Certain telemedicine services may be reimbursed under a separate regulatory regime.

The above rules serve as a general framework for the Hungarian telemedicine regulatory regime. We anticipate that detailed rules will be introduced gradually in the coming months and years.

Romania

The first telemedicine-related legislation in Romania was adopted in 2018. The creation of a legal framework for telemedicine was subsequently given added impetus by the Covid-19 pandemic. In March 2020, the Romanian government adopted temporary rules on remote consultations, valid during the existing state of emergency. The temporary legislative framework on telemedicine was kept in force by a Romanian government Emergency Ordinance valid until the end of September 2020.

From November 2020, a permanent telemedicine regulatory regime was introduced via Government Emergency Ordinance no. 196/2020. This enactment introduces a few general rules on telemedicine, defining the concept as representing all remotely provided medical services, without the physical presence of medical personnel and of the patient for the purpose of (a) establishing a diagnosis, (b) determining treatment, (c) monitoring diseases, or (d) providing methods for preventing diseases, via IT infrastructure.

The implementation norms in this respect were introduced via Government Decision no. 1133/2022, effective as of 15 September 2022. Aside from rules on the general conditions for granting medical assistance via telemedicine, this enactment provides a list of medical services that may be provided remotely (e.g., teleconsultations, telepathology, teleradiology, etc.) and the areas of practice falling under the umbrella of telemedicine (e.g., endocrinology, cardiology, gastroenterology, haematology, pneumology, sports medicine etc.).

According to the implementation norms, telemedicine services may be provided:

- by outpatient medical offices of family doctors and other specialties, diagnostic and treatment centres, medical centres, health centres, laboratories, as well as through other public and private health units, which must follow certain structural and organisational requirements,
- by (i) real-time remote consultation between the healthcare professional and the patient or (ii) sending the information to another healthcare professional for further analysis in order to interpret the transmitted data, establish a diagnosis and/or treatment.

Patient rights must be observed, including obtaining the patient's explicit consent. In any event, telemedicine is not deemed appropriate where the health professional and patient do not speak the same language at a sufficient level to ensure proper communications.

After receiving a telemedicine service, patients may be given various health-related documents, such as electronic prescriptions, referrals for specialty tests, treatments or vaccinations.

Future legislative developments are expected to cover certain areas of this sector in greater detail, such as prescribing the specific manner of documenting patient consent.



Serbia

The application of telemedicine and other remote healthcare services has been on the rise in Serbia for several years, particularly with respect to private healthcare providers. A number of applications and websites offering telemedicine services are available to patients, such as the DokTok application and LekarInfo website – both enabling the scheduling of video calls and consultations with medical professionals at short notice.

Despite this, the Healthcare Protection Act adopted in 2019 failed to introduce even basic high-level rules in this respect. The provision of telemedicine services is not in any way separated from rules on regular patient examinations – i.e. it falls under the same scope of general rules on medical examinations and relations between patients and medical professionals as provided by the Healthcare Act and Patient Rights Act of 2013, as amended in 2019.

However, the Serbian state does not formally prohibit or hinder the development of the local telemedicine sector. Indeed, the state is in fact facilitating the development of telemedicine by introducing solutions that enable online communication between patients and medical professionals. The most notable example is the government website eZdravlje, envisaged as a platform through

which a patient will be able to "...connect with a doctor, counsellor, trainer, friend, insurance company, exchange directly information about habits, physical activities, certain laboratory parameters, radiological recordings and therapies". Although this website is still under development, it already found use during the Covid-19 pandemic, providing valuable information and enabling medical consultations with potentially infected patients, or those subject to quarantine orders.

Recently, additional functionalities were introduced to the eZdravlje website, such as a confirmation concerning the issuing of prescribed medicines or the online monitoring of oncology patients, whereas the latter also provides for a possibility for patients to consult with oncologists from the Serbian National Cancer Research Center via a video link.

Furthermore, in accordance with the Programme of Digitalization in the Healthcare System of the Republic of Serbia for the Period Between 2022 and 2026, adopted on 11 February 2022 (the "Programme"), and the Action Plan for the Realization of the Programme in the Period 2022 to 2023, adopted on 5 May 2022, the introduction of telemedicine services was declared as one of the strategic goals of the Programme, with a projected aim of 30% of patients registered on the eZdravlje website having remote consultations with a doctor or pharmacist by the end of 2023. Accordingly, and despite the lack of a proper regulatory framework, the expansion of telemedicine services are evidently considered a key goal of the Serbian government in terms of the overall improvement of healthcare services in the country.



Slovakia

In 2019, the Slovak government adopted the Digital Transformation Strategy 2030 to serve as a policy document defining specific priorities in the context of the digital transformation of the economy and society. The document also addresses the transformation of the healthcare sector with regard to emerging digital technologies.

No specific laws currently regulate eHealth in Slovakia. However, Act No. 153/2013 Coll., on a National Health Care Information System, did create a legal framework for the introduction of eHealth services. The law created several administrative registries, including for healthcare professionals, providers, and also disease registries. Electronic health records of outpatient care providers are mandatory and allow information to be shared among providers, in most cases subject to patient consent. The Health Care Surveillance Authority and health insurance companies are permitted by law to access patient medical records when necessary for fulfilling tasks within the healthcare system. The majority of patients take advantage of e-prescriptions. Using electronic national ID cards, any patient can access their electronic medical records. The secondary usage of data collected by the National Health Care Information System for research and public health is presently restricted.

Emergency rescue service providers began to use STEMI and STROKE Android-based mobile applications in 2017 to facilitate the diagnosis of myocardial infarction and strokes. Application licences were processed centrally by the Emergency Services Operations Centre. Application usage is legally justified via expert guidance issued by the Ministry of Health. These applications have since been replaced by a MedText application meeting the ISO 9001, ISO 27001 and ISO 27701 requirements.

The government's current policy programme includes references to telemedicine and new technologies. Moreover, the government has committed itself to support the introduction of innovative modern technologies through current payment mechanisms. In 2020, the Ministry of Health created a specialised working group on telemedicine and new technologies with the participation of a number of leading external experts.

The Covid-19 pandemic has significantly reduced the number of patients visiting general practitioners and specialists. The Ministry of Health has issued various guidelines allowing consultations by email, web applications or via voice and video call technologies. Such consultations are reimbursed from public health insurance by all insurers and serve as a form of triage to assess patient medical needs leading to further referrals. In 2021, the reimbursement of email, video messaging and e-prescriptions tripled year-on-year.

Several telemedicine interventions are reimbursed from public health insurance including:

- 1. consultations via email, SMS or phone;
- 2. consultations using web applications or teleconferencing;
- 3. the prescription of medicine in response to an email, phone or SMS request; and
- 4. crisis psychotherapeutic intervention, individual psychotherapy or psychodiagnostics.

With regards to the use of applications for telemedicine, no specific rules apply. However, wider personal data protections and cyber security laws apply.

In addition, Act No. 358/2021 Coll., on the creation of a National Institute for Value and Technology in Health Care, was adopted in September 2021. The Act creates a legal framework for health technology assessments. The Institute was established on 1 January 2022 and its activities are expected to drive the introduction of new telemedicine technologies.

Turkey

In 2015, the Ministry of Health introduced, on the basis of Article 3 of the Fundamental Law on Health Services (Law No. 3359), an E-Pulse System, which currently provides the widest range of online health services in the country. The E-Pulse System offers a single platform where patients can access personal health data at any time and also schedule appointments with physicians at public health institutions. Since 2018, the E-Pulse System has also offered an integrated "teleradiology and telemedicine system" service allowing patients and physicians to access radiological examination imagery and enabling teleconsultations between radiologists for the purposes of consultations.

Prior to the current Covid-19 pandemic, beyond the functions outlined above, the E-Pulse System did not enable patients to obtain online medical advice. In October 2020, the Ministry of Health issued a Tele-Health Integration Guide and introduced a Visual Examination Appointment service enabling patients in contact or diagnosed with Covid-19 (within a so-called "Risk Group") to be examined via a Central Physician Appointment System (MHRS) without the need to visit the relevant public health institution. Through this service, Risk Group citizens are able to make an appointment with those public health institutions that have the infrastructure to perform video examinations by physicians. Accordingly, patients can be examined, diagnosed and issued with the respective e-prescriptions. Although this system only covers public hospitals, most private hospitals and clinics have also modified their own e-appointment systems to enable patients to consult with physicians via video calls – irrespective of whether or not they are in the Risk Group.

The above developments and practices raised questions as to the scope of the principle under Turkish law whereby physicians must physically examine patients before prescribing any treatment. In response, the Ministry of Health published the Regulation on the Provision of Remote Healthcare Services (the "**Regulation**") in February 2022 and the Guidelines on Remote Healthcare Information Systems in May 2022 and (the "Guidelines").

The Regulation and the Guidelines provide the framework for the establishment, scope and operation of "remote healthcare information systems" (or "USBS") enabling written, audio or visual communication between patients and healthcare professionals. USBSs can be developed by the Ministry of Health, or by developers approved by the ministry. Any healthcare institutions seeking to provide remote healthcare services are required to use a USBS that has been registered with the ministry and to obtain an operation permit from the ministry. Healthcare institutions already providing remote healthcare services prior to the publication of the Regulation were required to obtain a permit by August 2022. Currently, more than 20 healthcare institutions have obtained the said permit and have their USBSs registered with the ministry.

The Regulation stipulates that only certain healthcare services may be provided remotely by healthcare institutions, chiefly including examinations and consultations (to the extent they can be provided remotely under the specific circumstances), the evaluation of clinical parameters (such as blood sugar or blood pressure), certain services relating to interventional and surgical operations (within a scope to be determined by the Ministry of Health), the issuance of e-prescriptions and the tracking of health data through wearable technologies. If any healthcare institution provides remote services other than those listed in the Regulation, the healthcare institution will first be issued with a warning and instructed to remedy the non-compliance within a one-month grace period. In the event of repeated failures to comply with the Regulation, the relevant healthcare institution may face the termination of the relevant service and the withdrawal of its operation permit along with a ban on applying for a new permit for a period of one year. In the event a healthcare institution provides remote healthcare services without an operation permit, the Regulation authorises the respective local governorship to immediately terminate its operations.

With the Ministry of Health's enactment of the Regulation and the Guidelines, the terms applicable to healthcare institutions for providing telemedicine services have been clearly defined in respect of (i) the eligible platforms (i.e. USBS), (ii) the necessary permits, and (iii) the scope of healthcare services that can be provided remotely. As such, the Regulation and the Guidelines have delineated the terms and scope of telemedicine services that are essentially exempt from the legally enshrined principle that physicians must examine patients physically before prescribing any treatment.

Ukraine

The initial debates on the introduction of a telemedicine regulatory environment in Ukraine began at a national level in 1994.

In 2007, the Ministry of Health established the State Telemedicine Clinical Research Center to coordinate the establishment of telemedicine systems throughout the country. Furthermore, industry-specific regulation was also introduced, establishing a legal framework for the functioning of telemedicine. In some regions of Ukraine, pilot telemedicine projects have taken place. Additionally, private clinics have used telemedical consultations to facilitate doctor-patient consultations. Since 2016, a number of digital health platforms and apps, such as Doctor Online, Medikit, and Medinet, have been developed and launched by the private sector. Some have provided free-of-charge access to certain services during the Covid-19 pandemic.

The adoption of the Increased Availability and Quality of Medical Services in Rural Areas Act in 2017, introducing a nationwide telemedicine system, meant that this matter now became a priority for the Ukrainian government. In February 2018, the Ministry of Regional Development, Construction and HCS, the Ministry of Health, the World Bank and the Canadian Ministry of Foreign Affairs signed a joint Memorandum on the Introduction of Telemedicine Services. The Ministry of Health then developed a roadmap on the introduction of a nationwide telemedicine system, and, in 2019, also approved a document titled Methodological Recommendations for the Diagnosis and Treatment of Certain Diseases using Telemedicine. Crucially, in Ukraine, telemedicine may be applied at all levels of medical care and is not subject to additional licensing requirements. Telemedicine has been included in the Healthcare Guarantee Programme. Hence, applicable services will be reimbursed by the National Health Service of Ukraine. This factor is contributing to a wider use of telemedicine for primary health care.

Presently, no specific law regulates the use of telemedicine or patient access to modern diagnostic and treatment methods by means of digital technologies. However, considering the increased relevance of telemedicine in recent years, the Head of the Parliamentary Committee on National Health announced the development of a draft law on telemedicine to be unveiled by the end of 2023.

Special War Regime. Since the beginning of Russia's full-scale war against Ukraine in 2022, telemedicine has gained additional critical importance. Active hostilities have resulted in significant difficulties in providing medical care in some regions of Ukraine. In order to respond to dramatically increased healthcare demands during this war a number of pilot telemedicine projects have been launched and successfully integrated into healthcare institutions. Moreover, several crucial laws were adopted in 2022 enabling the use telemedicine services during the current period of martial law (and within 6 (six) months after its cancellation/termination). Presently, martial law applies until 20 May 2023 (with further extensions all but certain).

The Ministry of Health of Ukraine (the "MOH") has drafted a list of injuries, wounds, and other medical conditions, for which telemedicine can be used, approved by the Order of MOH No. 1062, dated 20 June 2022.

The MOH has also adopted a procedure for providing medical care via the use of telemedicine, and for rehabilitation assistance via the use of telerehabilitation, during the period of martial law in Ukraine or its certain localities, approved by MOH Order No. 1695 dated 21 October 2022 (the "Procedure"). The Procedure specifies the mechanism for organizing and ensuring medical care and rehabilitation assistance by means of telemedicine and telerehabilitation and is designed to guarantee equal access to quality services across Ukraine. The Procedure is applicable to healthcare institutions (regardless of ownership and subordination) and to individual entrepreneurs who have obtained a license to conduct business activities in the field of medicine.

Additionally, on 29 July 2022, the Ukrainian Parliament adopted a law offering "amendments to certain legislative acts on increasing access to medical and rehabilitation care during the period of martial law in Ukraine" (the "Healthcare Access Act"). This law allows foreign specialists (save for citizens of the Russian Federation and the Republic of Belarus) to provide medical care and rehabilitation assistance using telemedicine and telerehabilitation, subject to their registration in the respective information and communication system.

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