

Pravni okvir umetne inteligence

Umetna inteligenca postaja realnost v današnjem svetu in se vključuje v vse več vidikov našega življenja. Razvoj novih tehnologij, ki delujejo na podlagi umetne inteligence predstavlja nesluten napredek, prinaša številne koristi in odpira mnoga vprašanja. Uporabi le te se ni več mogoče izogniti; potrebno se je z njo seznaniti, uporabiti njene prednosti in se hkrati zavedati izzivov, ki jih ta prinaša z rabo. Vpliv umetne inteligence gre zaznati na vseh področjih delovanja, tj. od proizvodnje, javne uprave, prometa do znanosti in izobraževanja, ter tudi v zdravstvu je na določenih področjih že močno prisotna. Za pravilno in varno uporabo je potrebno definirati ustrezen pravni okvir, ki bo postavil temelje za ustreznost delovanja in reševanje določenih pravnih vprašanj, ki se odpirajo na tem področju. Kot izhodiščni pravni okvir umetne inteligence bi lahko izpostavili s strani Generalne skupščine Unesca, tj. novembra 2021 izdan prvi globalni standard o etiki umetne inteligence „Priporočilo o etiki umetne inteligence“, ki ga je v letu izdaje sprejelo 193 držav članic Unesco. To je prvi mednarodno pravni instrument na področju etike v umetni inteligenci, ki je globalni okvir za vključujočo in odgovorno uporabo umetne inteligence v naših družbah. Zaščita človekovih pravic in dostojanstva je temelj Priporočila, ki temelji na napredku temeljnih načel, kot sta preglednost in pravičnost, pri čemer se vedno opominja na pomen človeškega nadzora nad sistemi umetne inteligence. Priporočilo je pripravljeno na način, da je dovolj obsežno, da oblikovalcem politik omogoča, da temeljne vrednote in načela prevedejo v dejanja v zvezi z upravljanjem podatkov, okoljem in ekosistemi, spolum, izobraževanjem in raziskavami, ter tudi zdravjem in socialno blaginjo ter številnimi drugimi področji. V 2023 je Svet Evropske komisije sprejel Evropsko deklaracijo o digitalnih pravicah in načelih za digitalno desetletje 2023/C 23/01, ki izpostavlja pojem digitalna preobrazba z vplivom na vse vidike življenja, pri čemer prinaša izzive za

Legal framework for artificial intelligence

Artificial intelligence is becoming a reality in today's world, and is becoming increasingly integrated into our lives. The development of new technologies based on artificial intelligence is unprecedented, bringing numerous benefits and raising many legal questions. Its use can no longer be avoided; we must familiarize ourselves with it, take advantage of its benefits, and at the same time, be aware of the challenges it brings. The impact of artificial intelligence can be felt in all areas of the economy from manufacturing, public administration, transport, science, and education. It is also strongly present in some areas of healthcare. For its proper and safe use, it is necessary to define an appropriate legal framework that will lay the foundation for its proper functioning and resolve legal issues that arise in the field of artificial intelligence. As a starting point for the legal framework for artificial intelligence, we could highlight the first global standard on artificial intelligence ethics, the "Recommendation on the Ethics of Artificial Intelligence," issued by the UNESCO General Conference in November 2021 and adopted by 193 UNESCO member states in the year of its publication. This is the first international legal instrument in the field of ethics in artificial intelligence, providing a global framework for the inclusive and responsible use of artificial intelligence in society. The protection of human rights and dignity is the foundation of the Recommendation, which is based on the advancement of fundamental principles, such as transparency and fairness, while always remembering the importance of human control over artificial intelligence systems. The recommendation is designed to be comprehensive enough to enable policymakers to translate fundamental values and principles into action, including in relation to data governance, the environment and ecosystems, gender, education and research, and health and social well-being, among others. In 2023, the Council of the European Commission adopted the European Declaration on Digital Rights and Principles for the

demokracijo, gospodarstvo in posameznike. Za smernico je določeno, da naj bi bile digitalne javne storitve na spletu dostopne nemoteno in varno, zasnovane za učinkovito izpolnjevanje potreb ljudi, vključno z digitalnimi zdravstvenimi storitvami in storitvami oskrbe, predvsem z dostopom do elektronske zdravstvene dokumentacije. V okviru Evropskega parlamenta in Sveta je bila dne 13. junija 2024 sprejeta Uredba (EU) 2024/1689 o določitvi harmoniziranih pravil o umetni inteligenci in spremembi uredb (ES) št. 300/2008, (EU) št. 167/2013, (EU) št. 168/2013, (EU) 2018/858, (EU) 2018/1139 in (EU) 2019/2144 ter direktiv 2014/90/EU, (EU) 2016/797 in (EU) 2020/1828 (slednja imenovana Akt o umetni inteligenci). V Aktu o umetni inteligenci so izpostavljene tudi z umetno inteligenco omogočene manipulativne tehnike, ki se lahko uporabljajo za napeljevanje oseb k neželenemu vedenju ali za njihovo zavajanje, tako, da se jih spodbuja k odločitvam na način, ki spodkopava in ovira njihovo avtonomijo, odločanje in svobodno izbiro. Prepovedi takih praks dopolnjujejo določbe Direktive 2005/29/ES Evropskega parlamenta in Sveta, zlasti v smislu, da so nepoštenne poslovne prakse, ki potrošnikom povzročajo ali gospodarsko ali finančno škodo, prepovedane v vseh okoliščinah, ne glede na to, ali se izvajajo prek sistemov umetne inteligence ali kako drugače. Prepoved manipulativnih in izkoriščevalskih praks iz te uredbe ne bi smela vplivati na zakonite prakse v okviru zdravljenja, kot je psihološko zdravljenje duševne bolezni ali telesna rehabilitacija, kadar se te prakse izvajajo v skladu z veljavnimi pravnimi medicinskimi standardi in zakonodajo, npr. izrecna privolitev posameznikov ali njihovih zakonitih zastopnikov. Izpostavljeni so avtonomni roboti, ki bi morali biti sposobni varno delovati in opravljati svoje funkcije v kompleksnih okoljih, še posebej v zdravstvenem sektorju, v katerem je tveganje za življenje in zdravje še posebej visoko, uporabljajo vse bolj izpopolnjene diagnostične sisteme in sistemi, ki podpirajo človeške odločitve, morajo biti zanesljivi in točni. Predpisano je prav tako, da bi bilo potrebno sisteme umetne inteligence, ki se uporabljajo za ocenjevanje in razvrščanje klicev v sili fizičnih oseb

Digital Decade 2023/C 23/01, which highlighted the concept of digital transformation affecting all aspects of life, posing challenges for democracy, the economy, and individuals. The guideline stipulates that digital public services should be securely accessible online without interruption and be designed to effectively meet people's needs, including digital health and care services, in particular, access to electronic health records. Regulation (EU) 2024/1689 harmonised rules on artificial intelligence, as did amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (referred to as the Artificial Intelligence Act). The Act on Artificial Intelligence also highlights manipulative techniques enabled by artificial intelligence that can be used to induce individuals to engage in undesirable behavior or to mislead them by encouraging them to make decisions in a way that undermines and impedes their autonomy, decision-making, and free choice. Prohibitions on such practices complement the provisions of Directive 2005/29/EC of the European Parliament and of the Council, in particular, in the sense that unfair commercial practices causing economic or financial detriment to consumers are prohibited in all circumstances, regardless of whether they are carried out through artificial intelligence systems or otherwise. The prohibition of manipulative and exploitative practices in this Regulation should not affect legitimate practices in the context of medical treatment, such as the psychological treatment of mental illness or physical rehabilitation, where such practices are carried out in accordance with applicable legal medical standards and legislation, including the explicit consent of individuals or their legal representatives. The Artificial Intelligence Act sets out autonomous robots are highlighted, which should be able to operate safely and perform their functions in complex environments, especially in the healthcare sector, where the risk to life and health is particularly high.

Increasingly sophisticated diagnostic systems and systems that support human decisions must be reliable and accurate. The Artificial Intelligence Act stipulates it is also stipulated that artificial intelligence systems

ali za pošiljanje oz. določanje prednosti pri napotitvi služb za ukrepanje ob nesrečah, vključno s policijo, gasilci in medicinsko pomočjo, ter sistemih triaže pacientov v nujnem zdravstvenem varstvu, razvrstiti med sisteme visokega tveganja, saj sprejemajo odločitve v zelo kritičnih razmerah za življenje in zdravje oseb ter njihovo premoženje. Da bi zagotovili ustrezen okvir za uporabo umetne inteligence na posameznih področjih, je bila sprejeta še vrsta pravnih regulacij in smernic, ki poskušajo opredeliti meje in načela za uporabo naprednih tehnologij; če izpostavim zgolj temeljno, tj. BELA KNJIGA o umetni inteligenci – evropski pristop k odličnosti in zaupanju, ter PRIPOROČILO KOMISIJE (EU) 2019/243 z dne 6. februarja 2019 o evropski obliki izmenjave elektronskih zdravstvenih zapisov.

Okvir nacionalne zakonodaje, ki bo postavil temelje za uporabo umetne inteligence v Republiki Sloveniji je Zakon o izvajanju Uredbe (EU) o določitvi harmoniziranih pravil o umetni inteligenci. Ministrstvo za digitalno preobrazbo je med cilje zakona zapisalo: spodbujanje inovacij in razvoj naprednih rešitev, ki služijo ljudem, ter hkrati varovanje zdravja, varnosti in temeljnih pravic posameznika. Izpostavila bi, da je to šele začetek, saj se dnevno pojavljajo vprašanja, kje in kako lahko umetna inteligenca pomaga, kaj sploh to pomeni, kje je njena učinkovitost največja in s kakšnimi odprtimi vprašanji se srečujemo pri njeni uporabi. Kot največjo uporabnost te sodobne tehnologije, se izpostavlja določena rutinska opravila, ki zahtevajo natančno analizo večjih količin podatkov, saj sodi v uporabno računalniško znanost, ki prek računalniških algoritmov izvede določena opravila. Umetna inteligenca se danes potemtakem lahko uporablja v različnih fazah postopkov zdravljenja, pri čemer vsaka faza vključuje različne specifične primere uporabe. Ta uporaba mora biti odgovorna in preverljiva, kot recimo analiza podatkov pacienta in pomoč pri odločanju o možnosti zdravljenja, ki pa mora temeljiti na odločitvi usposobljenih zdravniških timov in ne sme biti izključno odločitev algoritma. Problem lahko nastane, če se zdravniške odločitve sprejemajo izključno z uporabo algoritmov umetne inteligence. V zdravstvenem okviru uporaba

used to assess and classify emergency calls from individuals, or to dispatch or prioritize emergency services, including the police, firefighters, and medical assistance, as well as systems for triaging patients in emergency medical care, should be classified as high-risk systems, as they make decisions in situations that are critical to the life and health of individuals and property. To ensure an appropriate framework for the use of artificial intelligence in specific areas, a number of legal regulations and guidelines have been adopted that attempt to define the limits and principles for the use of advanced technologies, of which I would like to highlight the »White paper on artificial intelligence - the European approach to excellence and trust, and Commission recommendation« (EU) 2019/243 of 6 February 2019 on a European model for the exchange of electronic health records.

The framework of national legislation that will lay the foundations for the use of artificial intelligence in the Republic of Slovenia is the Act Implementing Regulation (EU) on the establishment of harmonized rules on artificial intelligence. The Ministry of Digital Transformation has set out the following objectives for the Act: to promote innovation and the development of advanced solutions that serve people, while protecting the health, safety, and fundamental rights of individuals. I would like to point out that this law is only the beginning, as questions arise daily about which areas the economy artificial intelligence could help, where its effectiveness is greatest, and what open questions remain for its use. The greatest utility of this modern technology is highlighted in routine tasks that require precise analyses of large amounts of data, as it belongs to the field of applied computer science, which performs tasks using computer algorithms. Artificial intelligence can therefore be used in various stages of treatments, with each stage involving different specific use cases. Every use must be responsible and verifiable, such as analyzing patient data and assisting in determining treatment options, which must be based on the decisions of qualified medical teams, and not solely on the decisions of an algorithm.

A problem may arise when medical decisions are made solely through the use of artificial intelligence algorithms. In a healthcare setting, the use of artificial

tehnologije umetne inteligence prinaša dodatne pomisleke, saj medicinske odločitve ne bi smele temeljiti na avtonomnih sredstvih, ki jih zdravniki ne morejo razumeti. Izpostavlja se, da bi moral zdravnik, da bi zadostil standardu skrbnega ravnanja, vsako odločitev algoritma kritično presoditi, kar pomeni, da naj bi bil namen uporabe umetne inteligence razširitev in izboljšanje zdravnikovega sedanjega znanja, ne pa njegovo nadomeščanje.

Avtonomna orodja umetne inteligence bo torej potrebno vpeljevati premišljeno in predvsem z ustreznimi pravnimi rešitvami za odgovorno rabo ter v zaščito tako pacientov kot zdravstvenega osebja. Pri teh izzivih sta torej medicinska in pravna stroka izjemno povezani.

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intelligence raises additional concerns because medical decisions should not be based on autonomous means that doctors cannot understand. I should emphasize that to meet the standard of care, a doctor should critically evaluate every decision made by an algorithm, which means that the purpose of using artificial intelligence should be to expand and improve the doctor's current knowledge, not to replace it. Autonomous artificial intelligence tools will therefore need to be introduced in a considered manner, and above all, with appropriate legal solutions for responsible use and the protection of both patients and healthcare personnel. The medical and legal professions are therefore closely linked when it comes to such challenges.

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