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Indice-Sommario
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Editoriale

Saggi, Articoli, Commenti e Note

FOCUS

Democracy and the Rule of Law: A New Push for European Values

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EU IMPACT ON ALBANIAN MEDICAL CIVIL LIABILITY: A CASE LAW APPROACH

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1. Introduction

Albania is a small Western European country with 2.402.113 inhabitants[1] that has aimed to be part of the EU family for decades[2]. In June 2003, Albania was identified as a potential candidate country, and in June 2014, the EU awarded Albania candidate status; in July 2022, the Commission started the screening process, which is a fundamental step for EU integration[3]. Recently, in February 2025, in order to speed up the EU integration and intending to close accession negotiations by 2027, the EU officially launched the EU Integration Support Project, a €7.2 million initiative designed to assist the Albanian government in advancing its EU accession negotiations[4].

While the EU does not have general competence in private law, Articles 114 and 115 of the Treaty on the Functioning of the European Union (TFEU) allow the EU to regulate those elements of private law that create obstacles to trade in the internal market. Examples of this can be in consumer law (Directive 93/13/EEC on Unfair Terms in

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[1] INSTAT, *Population and Housing Census 2023 – Preliminary Results*, Tirana, 2024, available online at: https://www.instat.gov.al/media/13787/cens-2023.pdf.
[2] D. VESHI, *The long process of transformation in Albania in the context of the EU integration process*, in *European Union and legal reform*, 2012 (2013), p. 51 ff.; R. PANAGIOTOU, *Albania and the EU: from isolation to integration*, in *Journal of Balkan and Near Eastern Studies*, 2011, p. 357 ff.; A. ILIRJANI, *Albania and the European Union*, in *Mediterranean Politics*, 2004, p. 258 ff.
[3] European Commission, *Albania – EU Enlargement Policy*, available online at: https://enlargement.ec.europa.eu/enlargement-policy/albania_en.
[4] European External Action Service, *EU launches €72 million support programme to accelerate Albania's EU integration*, available online at: https://www.eeas.europa.eu/delegations/albania/eu-launches-€72-million-support-programme-accelerate-albania's-eu-integration_en?s=214.

Consumer Contracts and Directive 2011/83/EU on Consumer Rights), company law (Directive (EU) 2017/1132 on Company Law and Regulation (EU) 2157/2001 on the European Company), data protection (Regulation (EU) 2016/679), e-commerce (Directive 2000/31/EC on Electronic Commerce), intellectual property law (Regulation (EU) 2017/1001 on the EU Trade Mark and Directive (EU) 2019/790 on Copyright in the Digital Single Market) or succession law (Regulation (EU) No 650/2012 and 1994 EU Recommendation on the Transfer of Small and Medium-Sized Enterprises (94/1069/EC)).

Although Albania is not part of the EU, the EU law is also crucial for Albanian legislation for several reasons. First, the proposed constitutional reform of 2016 also included EU law as constitutional guidelines[5], in several norms, such as Articles 2(4), 64(4), 80a, 122(3), and Article 161. The doctrine has demonstrated that although the national Parliament did not approve these articles, still – through the interpretation of different Albanian constitutional norms or by considering TEU, TFEU, and the EUCJ's jurisprudence – the same result can still be achieved[6]. Second, Article 70(1) of the Stabilization and Association Agreement (SAA) between Albania and the EU imposes a binding obligation on Albania to harmonize both existing and future legislation with the EU *acquis communautaire*. Within the Albanian legal framework, domestic legislation must adhere to the Const. and ratified international treaties, including the SAA, as stipulated in Article 116(1) of the Albanian Const. Indeed, "based on Article 116 of the Const., the SAA, as an international agreement ratified by law, has precedence over the laws of the country that are not aligned with it" [translated by the author][7].

This paper focuses on the EU's impact on Albanian medical civil liability by reviewing the application of the rules of Directive 2011/24/EU, which establishes patients' rights in cross-border healthcare, by Albanian judges in national disputes. This contribution uses a case-law study since, in the Albanian legal system, the doctrine has shown the importance of case law in civil law[8] or medical law[9], especially after the Vetting reform[10]. In addition, Directive 2011/24/EU refers to the EU Court of Justice (EUCJ)'s jurisprudence in its premises.

This contribution has the following structure: Section 2 analyses some of the main EUCJ case law related to EU medical law. It focuses on patients' or medical doctors' mobility within the EU as well as the right to be compensated for medical treatments

[5] CDL-REF (2016)008-e, *Consolidated Version of the Constitution of Albania Integrating the Draft Constitutional Amendments*, 2016, available online.
[6] D. VESHI, *Albania's Judicial Approach to Consumer Protection and the Influence of EU Law*, in *Studi sull'integrazione europea*, forthcoming.
[7] Albanian High Court, Decision No. 636 of 25 November 2015, para 13.
[8] D. VESHI, E. KOKA, L. SHEME, *The Application of Human Rights by Judges in Civil Cases: The Case of Albania*, in *Ordine Internazionale e Diritti Umani*, 2025, no. 1, p. 87 ff.; E. KOKA, L. SHEME, *The Enforcement of Human Rights by Albanian Constitutional Judges: A Focus on Individual Constitutional Complaints in Civil Matters*, in *federalismi.it*, 2025, no. 2, p. 186 ff.
[9] D. VESHI, E. BOZHEKU, A. CASTALDO, *Reckless Medication (or Medical Negligence) in Albania: A Criminal Case Law Study*, in *federalismi.it*, 2024, no. 24, p. 279 ff.
[10] A. ANASTASI, *The Albanian justice reform in the framework of the European integration process*, in *Euro-Balkan Law and Economics Review*, 2021, no. 2, p. 1 ff.

offered by other EU Member States since the home country was not able to provide the requested medical treatment. In addition, Section 3 reviews the rules of Directive 2011/24/EU with some of the Albanian civil disputes on medical liability. In conclusion, the contribution underlines the importance of the EU rules on Albanian medical jurisprudence.

2. EU Court of Justice and Medical Law

The EUCJ has been an essential institution in defining medical law within the EU and its Member States, promoting healthcare systems and policies that are fair, equitable, and lawful[11]. The court has interpreted EU law in its case law on cross-border healthcare, the State's liability to provide medical services, and public health legislation[12]. This section reviews some of the most important legal decisions related to medical law by examining some of the main guidelines established by the EUCJ.

Article 2 TEU enshrines human dignity, equality, and respect for human rights as EU founding values. In addition, Article 168 TFEU requires a high level of health protection to be integrated into all EU policies, which requires Member States to adopt healthcare measures that will be effective and in compliance with EU law, while remaining sensitive to Member States' autonomy in deciding on organizational aspects of healthcare services.

As introduced above, although the European Union does not have a general competence in the area of private law, also taking into account Articles 56 and 114 TFEU, which regulate the freedom of movement of services, Directive 2011/24/EU has established patients' rights to cross-border healthcare. One of the most defining areas where the EUCJ has influenced the shaping of medical law is precisely the patient's right to receive treatment in another Member State and to request reimbursement of expenses, even if there has been no prior approval from the country of origin. In its jurisprudence, the Court has emphasized that the national restrictions that hinder this movement constitute a violation of the freedom of services and contradict the principle of non-discrimination. These principles are later reinforced by the Directive itself, which prohibits Member States from imposing arbitrary barriers on patients' access to health services abroad. In this way, EU citizens enjoy the right to be treated in any Member State, and not to be financially or administratively punished for their choice, as long as the treatment is lawful and reasonable[13].

In the same approach, the EUCJ has also been active in improving the effectiveness and coherence of access by those who have been victims of medical malpractice by highlighting the importance of medical negligence and professional liability. Regarding

[11] E. BROOKS, *Crossing borders: A critical review of the role of the European Court of Justice in EU health policy*, in *Health Policy*, 2012, p. 33 ff.
[12] A. KACZOROWSKA, *A Review of the Creation by the European Court of Justice of the Right to Effective and Speedy Medical Treatment and its Outcomes*, in *European Law Journal*, 2006, p. 345 ff.
[13] P. QUINN, P. DE HERT, *The Patients' Rights Directive (2011/24/EU) – Providing (some) rights to EU residents seeking healthcare in other Member States*, in *Computer Law & Security Review*, 2011, p. 497 ff.

Article 169 TFEU on consumer protection and Article 47 of the EU Charter of Fundamental Rights, the EUCJ established that national healthcare systems must ensure the existence of adequate mechanisms for compensating any medical harm. Furthermore, the Court has defined the right to judicial protection by invalidating disproportionate national restrictions on medical liability claims and ensuring that cases of medical negligence are dealt with fairly, accountably, and in accordance with EU legal standards[14].

In addition, through the application of Article 53 TFEU and Directive 2005/36/EC (Professional Qualifications Directive), the EUCJ has shaped medical law through the concept of mutual recognition of professional qualifications; in particular, medical doctors[15]. In other words, the right to practice across borders has also been accompanied by measures to maintain patient safety and high standards of medical practice across the EU. The influence of the EUCJ in this regard also extends to the field of public health regulation, especially in relation to the approval of medicines, the safety of medical devices, and access to new treatments. Through the interpretation of Articles 34-36 TFEU, it has ensured that national health authorities do not impose unjustified restrictions on access to medical technology and innovation.

A key issue in medical law pertains to the creation of obstacles by the national healthcare authorities to limit patients from accessing cross-border healthcare services. These barriers are mainly administrative or economic, reducing patient mobility and restricting access to healthcare outside the country of origin. The EUCJ has continuously held that medical services, including those provided under public health insurance systems, are covered by the EU internal market. Thus, any limitation preventing patients from receiving treatment in another Member State presents a restriction on the free movement of services[16].

For this reason, the Court has emphasized that any restriction by Member States shall be justified not only by general interests, but also proportionate and necessary. In cases where patients decide to receive medical treatment in another Member State, the health system of the country of origin is obliged to guarantee their right to reimbursement, unless there are overriding reasons justifying the refusal.

The Court has ruled that Member States shall justify restrictions on patient mobility within the health system and that restrictions cannot be justified solely on financial grounds or national regulatory preferences. These barriers are primarily administrative or economic, reducing patient mobility and limiting access to healthcare outside the country

[14] Court of Justice, judgment of 12 July 2001, *Vanbraekel v. Alliance Nationale des Mutualités Chrétiennes (ANMC)*, case C-368/98.
[15] M. PEETERS, *Free movement of medical doctors: the new Directive 2005/36/EC on the recognition of professional qualifications*, in *European Journal of Health Law*, 2005, no. 12, p. 373 ff.; M. VAN RIEMSDIJK, *Recognition of Professional Qualifications of Foreign-Born Nurses: Gender, Migration, and Geographic Valuations of Skill*, in *Global Migration, Gender, and Health Professional Credentials: Transnational Value Transfers and Losses*, 2022, p. 211 ff.
[16] Court of Justice, judgment of 28 April 1998, *Decker v. Caisse des Maladie des Employés Privés*, case C-120/95, in *Reports of Cases*, 1998, I-1831.

of origin. These barriers make it difficult for patients to get treatments in another country, even when they are faster or of better quality. Often, patients are not adequately informed about their right to seek treatment abroad. Moreover, complicated bureaucratic procedures, lack of clear information, and additional economic costs make these opportunities unattainable for many citizens. This situation violates the principle of equity in access to healthcare and can have a negative impact on the health of patients who require immediate treatment.

Suppose a patient decides to receive medical treatment in another EU country where it is available. In that case, the healthcare system of his or her home country shall guarantee his or her rights to reimbursement, unless there are compelling reasons to deny it[17]. This principle ensures that EU patients do not face unjustified refusals for medical treatment in another Member State and that common legal standards protect their rights to reimbursement. Some examples that national States might use to deny this right are concerns regarding protecting the financial stability of their healthcare system, guaranteeing access to hospital services for everyone, or promoting the quality and safety of the healthcare system.

For instance, in *Kohl* case, the Court emphasized that restrictions on patient mobility within the health system cannot be based solely on financial reasons or national regulations but may be justified by compelling justification of general interest[18]. Furthermore, in *Geraets-Smits and Peerboms*, the Court also highlighted that the need to ensure the quality and safety of the healthcare system could also justify these restrictions[19]. The *Watts* case further emphasized that requiring prior authorization on patient mobility is allowed if it is used fairly and when necessary, in order to protect patient safety[20]. These examples highlight that while EU citizens have the right to receive healthcare in other Member States, national regulations can limit this right if there are serious and objective reasons to protect the healthcare system and the public.

In these decisions, the EUCJ has clarified that any restriction on the movement of patients must be justified not only in the name of the general interest, but also be proportionate, impartial, and based on reliable data. This means that States cannot impose blanket or unfair barriers that prohibit patients from seeking treatment in another EU member. This principle ensures that no EU citizen is prevented, without strong and proven reasons, from receiving medical care in another Member State. In this way, the right to treatment is respected and equality in access to health services is promoted throughout the EU area.

Another major issue in medical law relates to excessive waiting times, which leads to delayed treatment within national healthcare systems. The EUCJ has made it clear that

[17] Court of Justice, judgment of 28 April 1998, *Kohll v. Union des Caisses de Maladie*, case C-158/96, in *Reports of Cases*, 1998, I-1931.
[18] *Kohll*, cit.
[19] Court of Justice, judgment of 12 July 2001, *Peerbooms v. Stichting CZ Groep Zorgverzekeringen*, case C-157/99.
[20] Court of Justice, judgment of 16 May 2006, *Watts v. Bedford Primary Care Trust and Secretary of State for Health*, case C-372/04.

excessive delays without providing patients with access to medical aid entitle them to have their treatment in another Member State and to have their home country's healthcare system compensate them. This protection not only ensures that medical services are provided on time, but also that patients are offered alternative options when delays occur within the country's health system. In its judgment, the Court also held that long waiting times for medical treatment cannot be used as an excuse for denying patients reimbursement for treatment abroad, especially when a delay could seriously impair their health condition[21]. The Court emphasizes that health authorities cannot use long waits as an excuse to limit or deny a patient's right to treatment in another Member State. Simply put, this policy encourages Member States to ensure the provision of timely and effective medical services.

Thus, EU Member States have a duty to ensure that their health systems provide timely and effective medical care to all citizens. They should not impose administrative or economic barriers that limit patients' ability to receive treatment in another EU country, especially in cases where treatment cannot be provided in their home country due to delays or lack of capacity. In these situations, patients have the right to request and receive treatment in another Member State and to be reimbursed by the health system of their home country. This right applies not only to treatments that are listed in the official guidelines of the respective State, but also to those treatments that are internationally recognized as effective and widely used in medical practice.

The EUCJ has made it clear that national authorities cannot deny reimbursement solely because a treatment is not listed on the national list of covered services. Suppose the treatment is accepted in international practice and has proven positive effects. In that case, the patient cannot be penalized only due to internal administrative restrictions or formal non-inclusion in domestic protocols.

This principle guarantees that decisions on health treatment are based on scientific standards and the latest advances in the field of medicine, not on rigid local rules that may be unfair or outdated. Therefore, health authorities must be open to global developments and practices, ensuring that patients have equal access to modern, safe, and evidence-based treatments, regardless of their location or the time of medical need[22]. EU lawmakers seem to aim to give a harmonized definition of medical treatments allowed within the EU.

Moreover, patient mobility is also applied in outpatient medical services. Thus, unnecessary restrictions that delay access to outpatient care in another Member State are contrary to EU law, unless there is a valid public interest[23]. The Court has emphasized that prior authorization for outpatient services should not be sought, unless there is a clear and objective reason. In this context, administrative barriers that cause unjustified delays in access to healthcare across borders may constitute violations of EU law. National rules

[21] *Watts*, cit.
[22] Court of Justice, judgment of 12 July 2001, *Geraets-Smits v. Stichting Ziekenfonds VGZ and Peerbooms v. Stichting CZ Groep Zorgverzekeringen*, joined cases C-157/99 and C-385/99.
[23] Court of Justice, judgment of 13 May 2003, *Mueller-Faure v. Onderlinge Waarborgmaatschappij OZ Zorgverzekeringen UA and Van Riet v. Onderlinge Waarborgmaatschappij ZAO Zorgverzekeringen*, joined cases C-385/99 and C-386/99.

restricting access to outpatient services without sufficient justification are incompatible with the principle of free movement. Thus, in simple words, the EUCJ has ruled that Member States should ensure the possibility of receiving outpatient services across borders, without prior authorization, except in cases where there is a legitimate public interest requiring it. This principle provides the free provision of health services in the EU and prevents the use of administrative mechanisms to restrict patient mobility. Therefore, national health systems that impose unjustified barriers to cross-border outpatient care may conflict with EU law. Member States are obliged to facilitate, not hinder, access to necessary medical services. This jurisprudence reminds health authorities of the obligation to support, not to restrict, the exercise of patients' rights under EU law[24].

Furthermore, the EUCJ has taken a stand against financial discrimination in healthcare as well, suggesting that patients who have been wrongly rejected approval for medical treatment in another country must receive full reimbursement. If a national healthcare system defies the right to treatment and unfairly denies a patient's right to treatment abroad, that healthcare system is clearly obliged to reimburse the patient not just the cost of the procedure in the country in which it was performed, but also any additional damage that was caused due to the wrongful denial by the healthcare system[25]. This principle is essential for ensuring that health systems do not prevent patients from exercising their right to be treated in another Member State. In addition, it ensures that financial considerations are not used as a mechanism to deny access to health care. Furthermore, if a patient has been unfairly refused treatment abroad, he or she is entitled to receive not only reimbursement for the costs of the procedure in the country where the treatment was performed, but also compensation for any additional harm caused by this refusal. This standard is essential to ensure that national health systems do not use economic factors to limit patients' rights.

The EUCJ has contributed to the development of EU medical law by verifying that national health policies are compatible with the primary law of the EU; in particular, the principle of proportionality. For instance, the EUCJ has also examined the policy on blood donation regarding the permanent disqualification of groups of people, including homosexuals (in particular, men who have sex with men, MSM). EU law prohibits restrictions if they are not based on scientific evidence. Directive 2004/33/EC (Directive on Blood Transfusion) prohibits restrictions if they are not based on scientific evidence of carrying serious infectious diseases that can be transmitted through blood[26].

In this context, the principle of proportionality set out by the EUCJ requires that any restriction be justified and not go beyond what is necessary to protect public health. This means that, if the same level of safety can be achieved through lighter measures, such as

[24] *Ibid.*
[25] Court of Justice, judgment of 12 July 2001, *Vanbraekel v. Alliance Nationale des Mutualités Chrétiennes (ANMC)*, case C-368/98.
[26] Court of Justice, judgment of 29 April 2015, *Geoffrey Léger v. Ministre des Affaires sociales*, case C-528/13.

postponing blood donations, individual risk assessment, or using more advanced tests, then a complete ban is not justified and can be considered illegal under EU law[27]. The EUCJ has also emphasized that exclusionary policies should be regularly reviewed in light of scientific and technological advancements to prevent any form of unjustified discrimination. Any measure in the field of public health must be in accordance with the fundamental rights enshrined in the EU Charter, including the prohibition of discrimination under Article 21. The EUCJ rulings show that this principle applies not only in specific cases, but in a general way across the entire area of EU medical law, helping to avoid unjustified obstacles and ensuring that Member States' health policies are aligned with the highest standards of safety, equity, and fairness[28].

To sum up, the EUCJ has guaranteed that national healthcare policies align with EU principles and that patient rights are protected. In contrast, national authorities and medical professionals have their obligations enforced. The EUCJ rulings are a consistent legal framework that prevents unjustified restrictions on access to healthcare, clarifies professional liability, and enforces public health regulations to comply with EU law. As medical law keeps on changing, the EUCJ continues to be a central institution for defining the legal standards for medical practice, patient rights, and healthcare policies in the EU.

3. Albanian medical jurisprudence and Directive 2011/24/EU

This Section studies medical civil liability through Albanian case law, underlining its importance under the rules established by Directive 2011/24/EU, since it connects the obligations deriving from European standards with the concrete practices of Albanian jurisprudence, making domestic courts more sensitive to the concept of legal harmonization within the EU.

First, "the Member State of treatment shall ensure that healthcare providers provide relevant information to help individual patients to make an informed choice" (Art. 4(2)(b) Directive 2011/24/EU). At the EU level, informed consent is not only established as one of the responsibilities of the Member State of treatment in the secondary source (Art. 4 Directive 2011/24/EU), but also as a cornerstone of the EU primary source (Art. 3(2) EU Charter of Fundamental Human Rights).

Aligned with it, Article 55 of the Albanian Constitution underlines the right to health care, which, combined with other norms – such as Articles 21 (right to life) or 25 (Prohibition of Torture) – give constitutional protection to informed consent. Moreover, Art. 6(2)(ç) Law No. 10.107 of 30.3.2009 *On Health Care* recognizes the right to give

[27] U. BELAVUSAU, *Towards EU sexual risk regulation: Restrictions on blood donation as infringement of active citizenship*, in *European Journal of Risk Regulation*, 2016, no. 4, p. 801 ff.
[28] *Ibid.*

consent to health care. Furthermore, Albanian judges should also consider Art. 25 of the Code of Medical Ethics as well as the Albanian Patient Card[29].

According to contemporary legal literature, informed consent has moved from a traditional clinical concept to a legal right based on human rights. Transparency and complete information have been considered essential to ensure not only patient protection, but also the proper functioning of the health system in accordance with the principle of the rule of law. This approach emphasizes the importance of respecting patients' autonomy and actively involving them in the medical decision-making process[30].

Based on this legal framework, Albanian case law has also recognized informed consent. According to Albanian judges, informed consent refers to healthcare providers' legal and ethical obligation to ensure that patients are adequately informed about the nature, risks, benefits, and potential outcomes of medical treatments *ante* they are administered[31]. Thus, healthcare professionals shall provide patients with accurate and comprehensive information, allowing them to make decisions that align with their personal values and medical preferences[32].

From a legal perspective, the application of informed consent in Albanian jurisprudence expands the scope of medical negligence beyond physical errors to include failures in communication. Traditionally, negligence has been understood as a failure to meet a standard of care, but in this instance, the failure to inform the patients constituted a breach of that standard, as – for instance – in the case that the hospital deprived the parents of critical information needed to make an informed decision about their pregnancy[33]. This ruling is transformative in that it recognizes communication failures as actionable negligence under medical law, highlighting the importance of patient autonomy in decision-making processes.

This approach is a crucial step towards aligning Albanian court decisions with the fundamental principles of EU law. As Albania moves closer to EU membership, the impact of European legislation, especially Directive 2011/24/EU on patients' rights in cross-border healthcare, is increasingly felt in the way Albanian courts review cases related to medical liability. As a result, the Supreme Court has begun to treat informed consent not only as an ethical obligation for doctors and health personnel, but also as a legal standard that guarantees the patient's right to make informed decisions, based on accurate and complete data on the treatment offered.

Recent court decisions have shown a clear trend towards the direct application of EU rules, increasing transparency in medical processes, and holding institutions more accountable when patient information is lacking. This indicates that the Albanian judicial

[29] E. PUPE, *Case-Law on Informed Consent in Germany: A Model for Albania?* in *Liverpool Law Review*, 2023/44(1), p. 63 ff.
[30] M.L. FLEAR, *Governing Public Health: EU Law, Regulation and Biopolitics*, Oxford, 2012; T.K. HERVEY, J.V. MCHALE, *European Union Health Law: Themes and Implications*, Cambridge, 2015.
[31] Supreme Court of Albania, judgment No. 00-2022-2376 of 25 October 2022.
[32] *Ibid.*, para. 14, p. 9.
[33] Supreme Court of Albania, judgment No. 00-2022-1671 of 18 July 2022.

system is gradually evolving, moving toward European standards. Today, the protection of patients' rights, the responsibility of the State, and respect for human dignity are becoming the main pillars of modern health law in Albania.

In concrete, recital 20 and Art. 4(2)(b) Directive 2011/24/EU state that healthcare providers should provide patients with information on specific aspects of their healthcare services and treatment options upon request. This might include that future parents shall be informed of fetal anomalies during prenatal screening[34]. Thus, information about prenatal irregularities is not only a medical act, but a legal obligation that guarantees the right to informed choice and management of pregnancy according to the personal convictions of the parents. At the supranational level, the interpretation of recital 20 and Art. 4(2)(b) Directive 2011/24/EU seems to include the right to an informed medical decision is the right of individuals to receive clear, comprehensive, and understandable information that enables them to make informed choices about their care. In this case, the Supreme Court of Albania established that the hospital's non-performance in diagnosing and informing the parents about the fetal anomaly contravened the patient's right to comprehensive informed medical services and, thus, her right to make decisions on pregnancy management.

As it is well-known, errors in diagnostic accuracy can lead to profound medical and legal implications, so it is imperative that patients can trust the accuracy of diagnostic tests. Moreover, Directive 2011/24/EU once again lays down the necessary framework, particularly highlighting that the medical profession and institutions providing diagnostic services in general must act with a high degree of care.

However, the initial rulings found that healthcare providers had caused harm and that they had to pay compensation for moral and existential damages[35]. The Supreme Court also confirmed these decisions and reinforced the legal and ethical obligation of medical facilities to provide complete and accurate information[36]. This ruling enhances healthcare providers' accountability and offers legal certainty in medical negligence cases. It also underscores the need for establishing clear standards on transparency in medical communication, making full disclosure an essential element of legal responsibility in the healthcare field.

Second, quality and safety in healthcare services are fundamental. Indeed, "Member States retain responsibility for providing safe, high quality, efficient and quantitatively adequate healthcare to citizens on their territory" (recital 4 Directive 2011/24/EU). In addition, "healthcare shall be provided in accordance with standards and guidelines on quality and safety laid down by the Member State of treatment" (Art. 4(1)(b) Directive 2011/24/EU). Moreover, one of the objectives of the European reference networks established in Art. 12 Directive 2011/24/EU is "to encourage the development of quality

[34] Supreme Court of Albania, judgment No. 00-2022-2376 of 25 October 2022.
[35] Administrative Court of Tribunal of First Instance of Tirana, judgment No. 794 of 2 March 2017, upheld by the Administrative Court of Appeal, judgment No. 38 of 26 January 2021.
[36] Supreme Court of Albania, judgment No. 00-2022-2376 of 25 October 2022.

and safety benchmarks and to help develop and spread best practice within and outside the network".

In concrete, (public) hospitals are liable for medical negligence. A critical aspect of this case is the obligation of public hospitals to uphold fundamental patient rights and maintain consistent standards of medical care. The principles of legal certainty and accountability in healthcare services demand that public institutions be held to a high standard of professional responsibility. The initial ruling held that the hospital was liable, and the minor, the victim of the medical negligence, and his family were to be compensated for material and non-material damages[37]. It is further supported by the notion that public healthcare institutions should be made to account for negligence[38]. It seems that Albanian judges are sensitive to the quality and safety of medical care services, as also established in Art. 4(1)(b) Directive 2011/24/EU. Moreover, this approach of the Albanian courts shows that the quality and safety of medical services are not only administrative objectives, but mandatory standards for public institutions, which must protect the fundamental rights of patients.

This rule is also applied in cases of a patient's death[39], even if this relates to pre-operative assessments, and to monitor the patient's condition post-surgery points properly[40]. In these cases, the hospitals are liable to compensate for the loss of life, funeral expenses, and lost income of the victim's minor children[41]. This approach complies with the standards set by EU law, according to which public health institutions have a positive obligation to guarantee the safety and quality of medical services, as provided for in Article 4(1)(b) of Directive 2011/24/EU.

The premise of the Albanian judicial approach, as well as Article 4(1)(b) of Directive 2011/24/EU, seems to be the application of Article 2 of the TEU, which aims at the respect for human dignity and the right to life. These principles are fundamental values of the EU. In this context, the lack of proper care leading to the loss of life constitutes a serious violation of these values, requiring not only financial compensation but also systematic improvements in standards of medical care and legal accountability. Thus, the relevant Supreme Court decisions ordering compensation for loss of life reinforce the concept that health treatment is not just a service, but a fundamental right that is protected at the national and European level.

Moreover, quality and safety in healthcare services also apply to private entities offering medical services[42]. In concrete, the initial ruling rejected the claim, stating that no causal link was found between the laboratory test and the claimant's health condition,

[37] First Instance Court of Tirana, judgment No. 247 of 22 January 2015; Administrative Court of First Instance of Tirana, judgment No. 00-2015-473 of 26 February 2015, upheld by the Administrative Court of Appeal of Tirana, judgment No. 2590 of 2 October 2019.
[38] Supreme Court of Albania, judgment No. 00-2022-1671 of 18 July 2022.
[39] Administrative Court of First Instance of Vlorë, judgment No. 1740 of 17 December 2015; Administrative Court of Appeal of Tirana, judgment No. 495 of 9 February 2017.
[40] First Instance Court of Tirana, judgment No. 6301 of 5 June 2013.
[41] First Instance Court of Tirana, judgment No. 8684 of 9 November 2015.
[42] Supreme Court of Albania, judgment No. 00-2022-1339 of 20 June 2022.

based on the conclusions of a forensic medical expert[43]. However, it was later defined that the expert lacked specialization in the relevant medical field and that the assessment by the lower court was insufficient[44]. Instead of issuing a final ruling, the appeal referred the case back for retrial at the initial court level. Upon review, the Supreme Court did not confirm this procedural approach, stating that the appeal should have made a substantive decision rather than sending the case back. As a result, the Supreme Court ordered a retrial, emphasizing the importance of expert credibility and thorough evidence evaluation[45].

Third, the importance of medical records has been underlined since they contain "information such as diagnosis, examination results, assessments by treating physicians and any treatment or interventions provided" (recital 25 Directive 2011/24/EU). Albanian judges dealt with the omission of medical professionals to include a complete patient's history and important risk assessments in the surgery planning, which led to death. The lower courts rejected the claim for violations of the medical protocols, citing inconclusive forensic evidence that failed to establish medical negligence[46]. Still, the Supreme Court did not confirm this decision, allowing a judicial review and ordering a new trial to examine the doctors' actions and responsibilities[47]. Consequently, the doctors were found guilty but received probationary sentences, while the civil case for damages went back to the lower court to determine the appropriate compensation for the victim's family.

In this context, the lack of information to the patient is no longer seen as a simple administrative matter or lack of documentation, but as a serious violation of the fundamental rights of the individual, especially the right to physical integrity and autonomous decision-making. This brings legal consequences for the health institution, placing it facing civil and ethical responsibility in cases where the patient has not been fully informed about the nature, risks, and treatment alternatives. Albanian courts, in this context, are increasingly treating the lack of information as a form of professional negligence, which can result in moral and existential harm to the patient or his family members.

Fourth, the right to reimbursement of medical services is the cornerstone of Directive 2011/24/EU, which also includes "the prescription, dispensation and provision of medicinal products and medical devices where these are provided in the context of a health service" (recital 16 Directive 2011/24/EU). Focusing on the national case-law, Albanian judges have answered the possibility of cancer treatment not offered by a public hospital[48]. The lower courts did not accept the claim, reasoning that the hospital was not responsible for covering the costs of medications not included in the reimbursement

[43] First Instance Court of Tirana, judgment No. 8684 of 9 November 2015.
[44] Court of Appeal of Tirana, judgment No. 513 of 24 February 2017.
[45] Supreme Court of Albania, judgment No. 00-2022-1339 of 20 June 2022.
[46] First Instance Court of Vlorë, judgment No. 296 of 11 June 2018, upheld by the Court of Appeal of Vlorë, judgment No. 537 of 18 October 2018.
[47] Supreme Court of Albania, judgment No. 00-2021-1107 of 23 December 2021.
[48] Supreme Court of Albania, judgment No. 00-2015-1152 of 13 January 2015.

schedule[49]. However, the Supreme Court did not confirm these decisions, highlighting that the key issue was reimbursement and the hospital's legal duty to provide full and effective treatment[50]. The Court emphasized that the institution's failure to supply the necessary medication directly harmed the patient, violating the fundamental right to healthcare. As a result, the Court accepted the claim and allowed a retrial, stating that when a hospital's failure to provide essential treatment causes harm, it constitutes a violation of patient rights. This ruling set an important precedent, affirming that public hospitals cannot deny critical treatment and must deliver comprehensive care to the best of their ability. It also highlighted that institutional restrictions or strict administrative criteria cannot prevail over the patient's fundamental right to receive the necessary treatment, especially when the absence of such treatment poses a serious risk to life or health. The Court reinforced the legal obligation of public health providers to follow a patient-centered approach, even in cases where reimbursement procedures or lists of approved medicines may present limitations.

This ruling represents a significant improvement in patients' rights and, at the same time, makes the healthcare system in Albania compatible with the EU legal system, particularly in terms of addressing financial barriers to healthcare services. Through the alignment of national jurisprudence with the EU legal framework, with the principles of equality and access, the decision takes Albania one step closer to fulfilling its obligations under the *acquis communautaire*. Also, the decision reflects a broader shift in judicial reasoning, from a formal interpretation of rights to a more significant, patient-driven understanding of healthcare. Indeed, the decision limits the reimbursement to what is necessary and proportionate and may not constitute a means of arbitrary discrimination (Art. 7(11) Directive 2011/24/EU). This principle ensures that any restrictions on reimbursement are based on objective and evidence-based criteria. It excludes the implementation of general policies that disproportionately affect vulnerable patients and requires national authorities to evaluate each case individually, while maintaining the principles of fairness and non-discrimination in access to health services.

To sum up, the impact of the EU on the Albanian legal system, specifically through case law, highlights the level of the country's evolution toward EU standards. Judicial decisions have shown a gradual but notable change, particularly in the areas of healthcare rights, state liability, and patient protection. Albanian courts have started to gradually adopt principles derived from EU secondary law, such as the right to informed consent, effective access to treatment, and quality and safety standards, interpreting national norms in line with EU values. This consistency is particularly evident in decisions dealing with compensation for medical negligence, the institutional responsibility of public health structures, and the State's positive obligations to protect patients' fundamental rights. Moreover, this legal development not only strengthens individual protection within the Albanian healthcare system but also contributes to the broader process of legal

[49] First Instance Court of Tirana, judgment No. 8130 of 12 October 2009, upheld by the Court of Appeal of Tirana, judgment No. 1683 of 28 September 2010.
[50] Supreme Court of Albania, judgment No. 00-2015-1152 of 13 January 2015.

harmonization necessary for European integration, ensuring that domestic jurisprudence reflects the fundamental values of human dignity, proportionality, and equality in access to healthcare, enshrined in EU law.

4. Conclusions

This paper examines the impact of EU law on medical civil liability in Albania. Although Albania is not an EU Member State, its judicial system frequently refers to EU legislation as a guiding framework. In particular, the jurisprudence of the CJEU has played a pivotal role in shaping medical law at the EU level, preceding and complementing legislative action by the EU lawmaker. Several provisions of Directive 2011/24/EU on patients' rights in cross-border healthcare reflect principles established by the CJEU. Given that the EU does not possess general legislative competence in private law, its primary interventions in medical law have focused on cross-border healthcare and the mobility of medical professionals, relying primarily on Articles 114 and 168 TFEU.

Traditionally, informed consent has been considered within the context of the physician-patient relationship. However, in the evolving framework of EU medical law, informed consent now extends to the right to be adequately informed about the possibility of receiving medical healthcare services in other Member States under certain conditions. Furthermore, the concept of medical services within EU law encompasses not only inpatient care but also outpatient medical services, prescription and dispensation of pharmaceuticals, and the provision of medical devices within the framework of a healthcare service.

It seems that the new approach of EU law links informed consent to human dignity and patient autonomy, enshrined in Article 3 of the EU Charter of Fundamental Rights. This conceptual development strengthens the legal position of the patient not only as a passive recipient of treatment, but also as an active participant with clear rights to make informed decisions regarding their healthcare. This is particularly important in cases affecting reproductive health, as evidenced by the practices of Albanian courts that have faced the lack of information to mothers about fetal abnormalities.

The CJEU has played a crucial role in defining and interpreting EU medical law, particularly beyond the scope of cross-border healthcare services. Although the EU does not hold direct legislative competence in substantive medical law, CJEU case law has effectively influenced its interpretation and application. *E.g.*, the CJEU has ruled that where those medical treatments are internationally recognized, a Member State is obliged to reimburse treatment received in another Member State, even if that treatment is not officially listed within the home country's medical guidelines. This might reflect the broader objective of the CJEU to establish a common EU definition of medical healthcare treatment, ensuring greater harmonization across national healthcare systems. Additionally, the Court has reinforced the principle of non-discrimination in access to

healthcare. Any blanket exclusion of specific groups – such as the prohibition of MSM from donating blood – must be justified on a case-by-case basis rather than through a categorical restriction, in accordance with the principle of proportionality.

This comprehensive approach of the EUCJ also influences the development of a sustainable balance between the health care system and the protection of fundamental rights. Jurisprudence has emphasized that any restriction, such as prohibitions on blood donation by certain groups, must be based on scientific evidence and pass the proportionality test. This principle is widely applicable to other cases affecting public health and individual rights, an approach that Albanian courts are increasingly reflecting in the analysis of medical liability and standards of care.

Although Albania is not an EU Member State, this paper demonstrates that Albanian judges have incorporated Directive 2011/24/EU elements into their medical civil liability reasoning. This is evident in legal disputes concerning informed consent, healthcare quality and safety, medical records, and the right to reimbursement for medical services. In particular, the analysis highlights similarities between the wording of specific provisions in Directive 2011/24/EU and Albanian judicial decisions on medical civil liability. Two potential explanations for this convergence that are not mutually exclusive emerge: first, EU medical law exerts a noteworthy influence on Albanian judicial reasoning; and second, the principles enshrined in Directive 2011/24/EU reflect widely accepted legal norms that have already been integrated into Albanian legal practice. It is important to note, however, that according to the Albanian Progress Report (2024)[51], Albania has made no significant developments in cross-border health threats, and alignment with the EU acquis in this domain remains partial. Nevertheless, according to Annex 1, of the nine decisions analyzed here, three referred to the EU legislation, while eight of them referred to the EU values established in Article 2 TEU, such as human rights, freedom, human dignity, the rule of law, and equity.

However, the impact of EU law on Albanian jurisprudence should not be seen simply as a consequence of proximity to European integration. It also reflects a transformation of the legal mindset towards a more standardized and patient rights-oriented model, where transparency, institutional accountability, and equality constitute strong pillars of judicial action. This indicates an improvement in the reliability of Albanian courts in addressing sensitive issues, including health, dignity, and social protection.

This paper underscores the critical role of the CJEU in advancing patient rights protection within the EU legal framework. Furthermore, it highlights the parallels between Directive 2011/24/EU on cross-border healthcare services and Albanian case law on medical civil liability, demonstrating the extent to which EU legal principles have influenced judicial practice in Albania.

In conclusion, the case of Albania demonstrates that the impact of EU law on non-member countries extends beyond the normative to the practical. This analysis aimed to

[51] European Commission, *Albania 2024 Report*, available online at: https://enlargement.ec.europa.eu/document/download/a8eec3f9-b2ec-4cb1-8748-9058854dbc68_en?filename=Albania%20Report%202024.pdf.

show that the fundamental concepts of EU health law are becoming an integral part of domestic law through judicial interpretation. As Albania progresses towards EU membership, the progressive integration of European standards into the legal and medical system will be essential to ensure an effective protection of patients' rights and strengthen the rule of law in the field of health.

ABSTRACT: Albania, a small Western European nation, has long pursued EU accession as a strategic objective. The constitutional reform of 2016 was intended to align national legal frameworks with EU standards; however, it failed to secure parliamentary approval. Despite this setback, comparable outcomes may be achieved through an interpretative approach to EU primary law, the Albanian Constitution, and the jurisprudence of the Court of Justice of the EU. This paper underscores the significance of *jurisprudence constante* and conducts a comparative analysis of EU and Albanian case law in the field of medical law, with a particular focus on patients' rights and medical civil liability. While the first part examines the legal framework governing access to healthcare services in cross-border contexts, highlighting the role of EU law in shaping national healthcare policies, the second part explores the extent to which EU norms, whether explicitly or implicitly, inform national adjudication of medical civil liability disputes in Albania. By engaging in this analysis, the paper seeks to elucidate the evolving interaction between supranational legal principles and domestic legal orders in the realm of medical civil liability.

KEYWORDS: Albania – Case-law – Cross-border medical services – EU medical law – Patient's rights.