Essays

The Intersection of Law, Medicine, and Language: Medical Devices in the Context of Covid-19 Pandemic

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ABSTRACT: The article analyses the intersection of law, medicine and language in the regulation of medical devices, particularly during the COVID-19 pandemic. It examines how the global health crisis has highlighted the complexities of translating medical and legal terminology, adapting regulatory frameworks and ensuring the safe use of these devices. Through the lens of medico-legal translation, the paper discusses the challenges of adapting medical concepts to legal contexts.

KEYWORDS: Medical device; Covid-19 pandemic; translation; semantic shift; European Union

SUMMARY: 1. Introduction – 2. A Short Legislative History of Medical Devices in the EU – 3. Legal and Medical Translation: similarities and differences – 4. Semantic Shift and the role of Comparative Law: the example of Covid 19 – 5. Conclusion.

1. Introduction

The development of medical devices (hereinafter also referred to as 'MDs'), from the medical practice to their regulation in legal systems, underscores the intricate interplay between disciplines such as medicine, technology, economics, and law. Today, MDs play a pivotal societal role, saving lives and supporting care at every stage—from prevention and diagnosis to treatment and disease management. As public health systems face increasing pressures from budgetary constraints and ageing populations, the importance of MDs has grown. As emphasized in EU policy discussions healthcare systems must adapt to meet new and future needs by fostering a shared vision of healthcare goals to address inequalities.[1] The Covid-19 pandemic has increased the centrality,

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[1] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, *EU Global Health Strategy. Better Health For All in a Changing World*, 30 November 2022, available online: https://health.ec.europa.eu/publications/eu-global-health-strategy-better-health-all-changing-world_en ; Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, *The European Health Union: acting together for people's health*, COM(2024) 206 final, 22.5.2024, available online: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52024DC0206; N. SCHOLZ, *Addressing health inequalities in the European Union Concepts, action, state of play*, European Parliament, 2020, available online: https://www.europarl.europa.eu/RegData/etudes/IDAN/2020/646182/EPRS_IDA(2020)646182_EN.pdf

highlighting the pressing need for adaptable and uniform regulatory responses to ensure timely access to essential devices while safeguarding safety and efficacy. Therefore, it is a lens through which analysing the further development of the notion of medical device.

Beyond their healthcare contributions, MDs also constitute a significant economic sector for European countries. The EU MD market is competitive and innovative and comprises a heterogeneous category of products, varying in therapeutic or diagnostic function, complexity and risk profile. It consists of more than 500,000 types of devices, ranging from simple adhesive bandages to complex heart valves and breast implants.[2] A clear example of their crucial role in Europe, but also globally, is the 23rd International Forum of Medical Device Regulators held in Brussels on March 2023. During her keynote speech, European Health Commissioner Stella Kyriakides emphasized that this sector plays an essential role in healthcare delivery worldwide, as well as the fact that it is one of the most dynamic, innovative, and economically significant sectors in the EU and the world and will play an even more important role in the future.[3]

After a short overview of the historical evolution of MDs and their regulatory framework, the present contribution examines their semantic and disciplinary transitions. Through this analysis, the aim of the paper is to clarify the historical, linguistic, and regulatory shifts shaping this field, providing insights into the challenges and opportunities of regulating an essential and rapidly evolving sector.

2. A Short Legislative History of Medical Devices in the EU

As mentioned in the previous paragraph, medical devices are crucial to European healthcare, aiding in diagnosis, prevention, treatment, and rehabilitation. It is worthy to briefly analyse the regulatory history, as it reflects the challenges of ensuring safety, innovation, and market harmonization.[4]

Historically, EU Member States regulated them independently. In Italy, for instance, the term medical devices ('dispositivi medici') was only introduced relatively recently, beforehand it was referring to 'medical and surgical supplies' ('presidi medici e chirurgici'). Dating back to the 1920s[5], these first legislative documents lacked clear definitions and a cohesive framework, addressing products on a case-by-case basis. The Presidential Decree of 1986 aimed to rationalize these regulations, dividing supplies

[2] Medical devices range from everyday items like syringes, eyeglasses, and latex gloves to advanced technologies such as implantable heart valves, pacemakers, AI-enabled systems, genetic tests, and nanostructures for prosthetics, showcasing their vast impact and innovation in medical care. A. PISANI TEDESCO, *Dispositivi medici e nuove regole: grandi riforme e qualche occasione persa*, in *Diritto e Salute-Rivista di sanità e responsabilità medica*, 2022, 19-20.

[3] Keynote Speech by Commissioner Stella Kyriakides at the 23rd International Medical Device Regulators Forum (March 27-31 2023), available online: https://ec.europa.eu/commission/presscorner/detail/en/speech_23_1941.

[4] P. FELDSCHREIBER (ed.), *The law and regulation of medicines and medical devices*, 2nd ed, Oxford, 2021.

[5] A first reference can be found in a law from the 1920s (Law of June 23, 1927, No. 1070), later incorporated into the Consolidated Law on Health of 1934 (Royal Decree of July 27, 1934, No. 1265), completed by the 1928 regulation (Royal Decree of December 6, 1928, No. 3112). Unlike the terms "drug/medicine" (in Italian *farmaco*) and "medicinal product," which have deep historical roots, the expression "medical device" has a relatively recent diffusion, even among healthcare professionals. On the notion of medicine see among others: A. CAUDURO, *L'accesso al farmaco*, Milano, 2017.

into categories: chemical supplies, medical devices, and in vitro diagnostic devices.[6] Even in France, with respect to medicines, the law on MDs came relatively late. At the national level, the legislator introduced a ministerial authorisation system for medicines as early as 1941, but it was not until 1987 that a system of authorisation by the Minister of Health was introduced for medical devices - and only for some of them.[7]

In addition to their role in diagnosis and treatment, these devices are also important because of the potential risks they pose to patients and others.[8] This is also the reason why medical devices have been regulated within the EU since the 1980s, initially through EU directives and, more recently, European regulations. The aim is to regulate all phases of their life cycle, from design to post-market surveillance. Given the rapid pace of innovations and the increasing overlap between medical devices and medicines, regulatory requirements have become increasingly stringent especially to ensure consumer safety and product performance.[9]

[6] The decree tasked the Minister of Health, in collaboration with the Ministry of Industry, with identifying product categories requiring authorization. It also set technical standards, documentation, compliance assessments, prototype testing, labelling, and manufacturing facility requirements. The decree aimed to preserve the 1920s authorization regime while enhancing transparency in the approval process. Regolamento di esecuzione delle norme di cui all'art. 189 del testo unico delle leggi sanitarie, approvato con regio decreto 27 luglio 1934, n. 1265, e successive modificazioni, in materia di produzione e commercio dei presidi medico-chirurgici. See: Ministero della Salute. Direzione generale dei farmaci e dispositivi medici (ed.), *Dispositivi medici. Aspetti regolatori e operativi*, 2010, available at: https://www.salute.gov.it/portale/documentazione/p6_2_2_1.jsp?lingua=italiano&id=1238.

[7] Loi du 11 septembre 1941 relative à l'exercice de la médecine, JORF du 20/09/1941, modifiée par l'ordonnance n° 59-250 du 4 février 1959 relative à la réforme du régime de la fabrication des produits pharmaceutiques et à diverses modifications du code de la santé publique, JORF du 08/02/1959. Loi n° 87-575 du 24 juillet 1987 relative aux établissements d'hospitalisation et à l'équipement sanitaire, JORF du 25/07/1987 et arrêté du 4 février 1991 fixant la liste des produits et appareils soumis à homologation, JORF du 08/02/1991. See: D. ESKENAZ, *Le dispositif médical à la recherche d'un nouveau cadre juridique*, Université du Droit et de la Santé- Lille II, 2016.

[8] With reference to medical devices, active implantable and in vitro diagnostic medical devices, these by their very nature cannot but be considered a 'critical' type of product as they are potentially injurious to the health of the patient, the user or third parties to the point of causing death. See: I. M. MARTINS PORTUGAL DE ABREU, *The importance of medical devices in preventing and combating SARS-CoV-2 and cooperation between national regulators, academy and industry - Perspectives from the Portuguese reality*, in *Biomed Biopharm Res.*, 17, 2, 197-208, 2020.

[9] I. M. MARTINS PORTUGAL DE ABREU, *op. cit.*

In the light of the EU's 'New Approach',[10] introduced in 1985 and aiming to balance the free movement of goods with the need to manage the risks associated with certain products,[11] these devices were regulated by two primary directives: Directive 93/42/EEC on medical devices and Directive 90/385/EEC on active implantable devices.[12] These directives were incorporated into national laws across Member States, ensuring consistency in the regulatory framework. For example, in Italy, they were implemented through Legislative Decree 46/97 and Legislative Decree 507/92,[13] while in France, the provisions were incorporated into the Public Health Code under articles L. 5211-1 and subsequent sections, article R. 5211-1 of the same code sets out the purposes of products that can be described as medical devices.[14] In Germany, the directives were adopted thanks to the notification dated May 24, 1994, published in the Federal Gazette (No. 104, June 8, 1994, page 5961), and through the Medical Devices Act (Medizinproduktegesetz - MPG) of August 2, 1994, published in the Federal Law Gazette (Part I, August 9, 1994, page 1963). In Belgium, the directives were implemented by the Royal Decree of March

[10] The basic principles of this 'new approach' are that - the harmonisation ensured by Community legislation is limited to the basic safety requirements that products must meet in order to be placed on the market in the Community; - the drawing up of technical manufacturing specifications is entrusted to the bodies responsible for industrial 'standardisation' (in particular, at European level, the European Committee for Standardisation - CEN and the European Committee for Electrotechnical Standardisation - CENELEC); - the technical specifications drawn up by these bodies do not take on compulsory status, retaining the character of voluntary standards; - the administrations of the Member States are obliged to recognise that products manufactured in accordance with 'harmonised standards' are presumed to comply with the fundamental requirements laid down by the directive, and the manufacturer is free not to comply with these standards, but to assume the burden - in that case - of proving that his products comply with the fundamental requirements. On this point, see EU Council Resolution of 7 May 1985. See also: M. GRANILLO, *Sulla nozione di dispositivo medico: il caso della piattaforma telematica per la gestione dei servizi di telemedicina*, in *Rivista IUS et SALUS*, 2022; A. SOROIU, A., M. FRAZAO CORREIA MAGALHAES DE CARVALHO, *Lawtify Premium: Public.Resource.Org (T-185/19), a Judicial Take on Standardisation and Public Access to Law*, in *Review of European Administrative Law*, 15, 2, 57-76, 2022.

[11] M. TESTA, S. STORELLI (eds.), *Norme e mercato - evoluzione del medicale*, Padova, 2013.

[12] The "New Approach" is explicitly referenced twice in Directive 93/42/EEC, specifically in Recitals 8 and 9. For example, Recital 8 states: "Whereas, in accordance with the principles set out in the Council resolution of 7 May 1985 concerning a new approach to technical harmonization and standardization (6), rules regarding the design and manufacture of medical devices must be confined to the provisions required to meet the essential requirements". Similarly, it is implicitly referenced in Directive 90/385/EEC, as seen in Recital 3: "Whereas national provisions ensuring that safety level should be harmonized in order to guarantee the free movement of active implantable medical devices without lowering existing and justified levels of safety in the Member States".

[13] On 28 September 2022, Legislative Decree 137 of 5 August 2022, published in the Official Gazette on 13 September 2022, came into force, replacing both of the previous national acts. Legislative Decree 137/2022 also regulated active implantable medical devices. https://www.salute.gov.it/portale/dispositiviMedici/dettaglioContenutiDispositiviMedici.jsp?lingua=italiano&id=5919&area=dispositivi-medici&menu=settoredm&tab=1 -

[14] Code de la santé publique, available at : https://www.legifrance.gouv.fr/codes/article_lc/LEGIARTI000046126069 . Direction générale de la santé, *Les dispositifs médicaux (implants, prothèses…). Mise sur le marché, surveillance, législation*, https://sante.gouv.fr/soins-et-maladies/autres-produits-de-sante/article/les-dispositifs-medicaux-implants-protheses. Ordonnance n° 2022-582 du 20 avril 2022 portant adaptation du droit français au règlement (UE) 2017/745 du Parlement européen et du Conseil du 5 avril 2017 relatif aux dispositifs médicaux, available at : https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000045614779.

18, 1999.[15] The national implementations aimed at aligning domestic legal frameworks with EU standards, ensuring consistency across Member States.

Regulation (EU) 2017/745 (Medical Device regulation or MDR)[16] and Regulation (EU) 2017/746 (In Vitro Diagnostic Regulation or IVDR)[17] updated the regulatory framework, reflecting sector developments over the past two decades. The new regulations aim to ensure safety, support innovation, and harmonize standards across the EU market.[18] Key elements include strengthening the role of Notified Bodies, creating a European database of medical devices, and enhancing cooperation between Member States.[19] These Regulations also refine the definition of MDs and expand upon terms to ensure consistency across the EU.[20]

Conformity with the requirements established initially by the Directives and now by the Regulations is demonstrated by the presence of the CE mark, which is affixed to the product at the conclusion of the conformity assessment procedure. In the EU market, specific categories of goods must undergo these assessment procedures and obtain the corresponding conformity certification to be legally marketed. This requirement stems from the necessity to ensure that such products meet essential standards concerning the safety they guarantee and the performance they deliver. The legislator's commitment to protecting the paramount value of health is reflected in the choice of including medical devices among

[15] The text is available online at: https://www.ejustice.just.fgov.be/mopdf/1999/04/14_1.pdf#page=35-. See also: Agence fédéral des médicaments et des produits de santé, https://www.afmps.be/fr/humain/produits_de_sante/dispositifs_medicaux/generalites/legislation. Belgium was late in the transposition of the directive and therefor the European Court of Justice on 20 March 1997 declared that Belgium failed to fulfil its obligations. Case C-294/96, Commission of the European Communities v Kingdom of Belgium, ECLI:EU:C:1997:182, available at: https://eur-lex.europa.eu/legal-content/FR/ALL/?uri=CELEX%3A61996CJ0294.

[16] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, https://eur-lex.europa.eu/eli/reg/2017/745/oj/eng .

[17] Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU, https://eur-lex.europa.eu/eli/reg/2017/746/oj/eng .

[18] Summaries of EU Legislation, *Garantire la sicurezza e le prestazioni dei dispositivi medici*, available at: https://eur-lex.europa.eu/legal-content/IT/TXT/?uri=LEGISSUM:4301046 ; Ministero della Salute, *Dispositivi Medici,* available online: https://www.salute.gov.it/portale/dispositiviMedici/dettaglioContenutiDispositiviMedici.jsp?lingua=italiano&id=4971&area=dispositivi-medici&menu=settoredm .

[19] Direction générale de la santé, *Les dispositifs médicaux (implants, prothèses…). Mise sur le marché, surveillance, législation*, https://sante.gouv.fr/soins-et-maladies/autres-produits-de-sante/article/les-dispositifs-medicaux-implants-protheses .

[20] E.g.: unique device identifier (definition 15), clinical data (definition 48), clinical evidence (definition 51) and serious accident (definition 65). Furthermore, the MDR enhances transparency by requiring public dissemination of information on medical devices and related studies. The new European Database for Medical Devices (EUDAMED) will play a central role in making this data accessible and in improving both its quantity and quality, as outlined in Article 33. According to Recital 44 and Article 26 of the MDR, an internationally recognised medical device nomenclature must be made available free of charge to manufacturers and other individuals or entities obligated to use it under the Regulation. The European Commission is also expected to make this nomenclature available, where reasonably practicable, free of charge to other stakeholders in order to support the effective functioning of EUDAMED. See: Comunità Europea, *Fabbricanti di dispositivi Cosa c'è da sapere*, https://health.ec.europa.eu/document/download/88eff4e3-9763-435e-a3b9-75aadfc8df65_it.

these regulated goods.[21] Consequently, it is vital to clearly define which products fall under this category, for the double purpose of safeguarding consumers and patients and at the same time avoiding unnecessary bureaucratic burdens for economic operators.[22]

This brief historical overview and the transition from Directives to Regulations highlight how European legislators recognized the need to evolve the regulatory framework. The factors that brought this shift are many, including changing socio-economic conditions, technological advancements, scientific progress, the expansion of the European Union, and the shortcomings of the previous regulatory approach.[23]

As it has been highlighted, the actual regulatory framework aims to be more comprehensive, detailed, and directly applicable, reducing the scope for interpretation by Member States and ensuring greater uniformity in the implementation of the rules. However, the European legislator has entrusted Member States with the responsibility of defining sanctions for violations and adopting all necessary measures to ensure their enforcement (in particular articles 113 MDR and 106 IVDR).[24]

In this context, the SARS-CoV-2 virus significantly impacted the sector of MDs. First of all, it should be remembered that also due the spreading of the virus the entry into force of the new regulations has been delayed.[25]

Moreover, at the start of 2020, the Covid-19 pandemic triggered an unprecedented and exponential surge in demand for MDs. For instance, in the European Union market, the rising demand for Personal Protective Equipment (PPE)—including masks, gloves, protective suits, goggles, and specific gowns—has placed significant strain on supply chains, particularly affecting the availability of disposable masks.[26] The crisis demonstrated the importance of responding quickly to public health emergencies, ensuring high safety standards, and reducing interpretative uncertainties that could prevent or delay the timely market entry of essential medical devices.

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[21] Comunità Europea, *Fabbricanti di dispositivi Cosa c'è da sapere*, https://health.ec.europa.eu/document/download/88eff4e3-9763-435e-a3b9-75aadfc8df65_it.

[22] For instance see the analysis of the CJEU Judgment C-219/2011, Brain Products GmbH v BioSemi VOF, in which a manufacturer, in order to avoid being subject to the restrictions of the medical device legislation, qualified its product, software equipped with an electro-technical device for recording human brain activity, not as intended for medical use but for the study of a physiological process. On the one hand, the judgement emphasised that the system could be used as a diagnostic tool and, on the other hand, it argued that a marketing restriction would be contrary to the principle of free movement of goods. M. GRANILLO, *Sulla nozione di dispositivo medico: il caso della piattaforma telematica per la gestione dei servizi di telemedicina*, cit.

[23] As recalled by Pisani Tedesco, among the most emblematic cases that have laid bare the limits of the directive-based system is that of breast implants produced by the French company Poly Implant Prothèse SA (PIP), one of which came before the EU Court of Justice, following a preliminary referral made by the Bundesgerichtshof (*E. Schmitt v. TÜV Rheinland LGA Products GmbH*, C-219/15). See: A. PISANI TEDESCO, *Dispositivi medici e nuove regole: grandi riforme e qualche occasione persa*, cit, 26 and 37-38.

[24] A. PISANI TEDESCO, *Dispositivi medici e nuove regole: grandi riforme e qualche occasione persa*, cit., 37-38

[25] Regulation (EU) 2020/561 of the European Parliament and of the Council of 23 April 2020 amending Regulation (EU) 2017/745 on medical devices, as regards the dates of application of certain of its provisions, Recitals (4) and (5). https://health.ec.europa.eu/medical-devices-sector/new-regulations_en

[26] Commission Recommendation (EU) 2021/1433 of 1 September 2021 on conformity assessment and market surveillance procedures within the context of the COVID-19 threat, available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32021H1433

3. Legal and Medical Translation: similarities and differences

The sector under analysis operates at the intersection of various disciplines, such as medicine, technology, and law and thus benefits from a comparative approach. In this context, characterized by a multifaceted regulatory framework, it is equally essential to reflect on the role of language and translation in bridging these domains and ensuring effective communication and understanding.

In law, translation also holds significant historical importance, with early examples dating back to the 13th century.[27] At first seen as an instrument rather than an object of research,[28] legal language and translation gradually became integral to comparative legal studies, especially as globalisation and the increasing role of international and supranational institutions made it a core element of legal practice and scholars research.[29] Legal language is inherently complex, dealing with issues such as the translation of untranslatable terms and the shifting meaning of legal concepts across legal systems.[30] The legal language of the European Union is a cultural and social phenomenon as well as a legal one. To fully understand its nature and effects, it must be considered in its temporal and spatial context.[31] These challenges highlight the centrality of translation in the evolving nature of law.

Translation has long played a crucial role in science, facilitating the global exchange of knowledge. Its importance grew exponentially with the invention of movable type in the 1500s, revolutionizing the dissemination of scientific ideas. Fields such as physics, chemistry, and medicine owe much of their worldwide impact to translators who bridged linguistic and cultural gap, enabling the ideas of countless scientists to reach a global audience.[32]

Medical translation has a long history, beginning with Ancient Mesopotamia, and continues to be a vital part of global healthcare. It is considered one of the oldest forms of translation.[33] It ensures access

[27] Among the first examples the peace treaty between Egypt and the Hittite Empire in 1271 BC and the translation of the *Corpus Iuris Civilis,* first translated into Greek and after in several languages. See: M. GALDIA, *Comparative law and legal translation*, in *The European Legal Forum* (E), 1, 2003,1-4.

[28] E. IORIATTI, *A Twenty-First Century Approach to Law and Language in Europe*, in O. MORÉTEAU, A. PARISE (eds.), *Comparative Perspectives on Law and Language*, Maastricht, 2022, 35-62.

[29] Among others see: E. DIDIER, *Langues et langages du droit*, Montréal, 1990; R. SACCO, L. CASTELLANI (a cura di), *Les multiples langues du droit européen uniforme*, Torino, 1999; M. R. FERRARESE, *Il diritto comparato e le sfide della globalizzazione. Oltre la forbice differenze/somiglianze*, in *Rivista critica di diritto privato*, 3, 3, 2013, 369-402; B. POZZO, *Comparative Law and the New Frontiers of Legal Translation*, in S. SAŘCEVÍC (ed.), *Language and Culture in EU Law. Multidisciplinary Perspectives*, Farnham, 2016; E. IORIATTI, *A Twenty-First Century Approach to Law and Language in Europe,* cit.

[30] L. BIEL, *Linguistic Approaches*, in M. SIEMS, P. J. YAP (eds.), *The Cambridge Handbook of Comparative Law*, Cambridge, 2024, 97. See also: O. BRAND, *Language as a Barrier to Comparative Law,* in F. OLSEN, A. LORZ AND D. STEIN (eds.), *Translation Issues in Language and Law*, London, 2009. Linguistic scholars distinguish between Legal Linguistic and Legal Translation Studies (LTS). See L. BIEL, *op. cit.,* 95. LSP – Medicine and its language?

[31] E. IORIATTI, *Visualizing EU law through meta-concepts and legal formants*, in L. BIEL, H. J. KOCKAERT (eds.), *Handbook of Terminology. Vol 3 Legal Terminology*, Amsterdam, 2023, 289-309.

[32] Among others: H. FISCHBACH, *Translation, the Great Pollinator of Science: A Brief Flashback on Medical Translation*, in S. E. WRIGHT, JR. L. D. WRIGHT, *Scientific and Technical Translation*, Amsterdam/Philadelphia, 1993, 91; V. MONTALT, *Medical translation and interpreting*, in GAMBIER, Y., & DOORSLAER, L. V. (eds.), *Handbook of translation studies, 2*, Amsterdam/Philadelphia, 2011.

[33] "(T)he most universal and oldest form of scientific translation because of ubiquitousness of human anatomy and physiology (after all, the human body is much the same everywhere), the long, venerable and well-documented history of medicine, and the hitherto uniform character of the language of medicine, at least in the West"

to healthcare for linguistic minorities but also facilitates the dissemination of new medical research and regulatory developments.[34] The technical nature of medical language, which often uses specialized terms and reflects linguistic and stylistic norms, necessitates accurate translation for effective communication. Medical translation is traditionally focused on specialized texts and terminology,[35] as medical language, due to its specificity, belongs to the group of languages for specific purposes that reflect linguistic and stylistic characteristics.[36] Nevertheless, modern medical translation spans a broader range of contexts, including clinical practice, education, and popular science communication.[37] Furthermore, a number of texts are translated due to regulatory requirements covering new medical items and medical devices, as well as new applications of pharmacological products.[38]

Medical and legal translation have both similarities and differences. Although both require precision, as errors can have serious consequences, and sometimes rely on standardised language, there are significant differences in their focus. Medical translation primarily facilitates patient care, safety and education, while legal translation ensures the accuracy of legally binding documents, adhering closely to source texts to preserve legal intent. Despite their common goal of clarity,[39] legal translation can sometimes retain vagueness or ambiguity in response to the flexibility of interpretation inherent in legal systems.[40]

"For the medical translator, however, the identity in both languages of the object or concept to be translated certainly gives him or her an edge. This lowers the misunderstanding quotient appreciably in the scientific transfer process".[41]

As the quote underlines, a key factor that simplifies medical translation is the universality of human anatomy and physiology, which remains consistent across cultures. Differently, legal translation

([12]: 1–2)". H. FISCHBACH, *Some Anatomical and Physiological Aspects of Medical Translation: Lexical equivalence, ubiquitous references and universality of subject minimize misunderstanding and maximize transfer of meaning*, *Meta: Translators' Journal*, 1986, 31, 16-21.

[34] L. LEONARDI, *The importance of accurate medical translation in the context of the COVID-19 pandemic*, in *Granite Journal*, 7, Issue 1, 2022, 2. Differently, when referring to "medical knowledge translation" Translational research emerged in the 1990s in the biomedical field to address the slow and insufficient application of scientific discoveries in clinical practice. Its main objective is to bridge the gap between laboratory research and practical use by integrating research-based knowledge into policy and care. This approach addresses both temporal and quantitative challenges, ensuring a faster and more effective transfer of knowledge. Although initially focused on medicine, translational research has also influenced other areas, such as climate change governance, emphasising its broader societal importance. Among others see: J. ØDEMARK, E. ENGEBRETSEN, *Challenging medical knowledge translation: convergence and divergence of translation across epistemic and cultural boundaries*, in *Humanities and Social Sciences Communications*, 9, 71, 2022.

[35] V. MONTALT, *Medical translation and interpreting*, cit., 79.

[36] P. TRZASKAWKA, J. KIC-DRGAS, *Penetration of COVID-19 Related Terminology into Legal, Medical, and Journalistic Discourses*, in *International Journal for the Semiotics of Law*, 35, 2022, 937-960, 942.

[37] V. MONTALT, *op. cit.*, 79.

[38] W. KARWACKA, *Medical Translation*, in Ł. BOGUCKI, S. GOŹDŹ-ROSZKOWSKI, P. STALMASZCZYK (eds.), *Ways to Translation*, Wydawnictwo Uniwersytetu Łódzkiego, 2015, 271-298, 272.

[39] For instance, a lack of accuracy and correctness in translation can lead to significant errors, as exemplified by Leonardi, who highlights the problems and mistakes that arise when translations rely solely on machine translation. L. LEONARDI, *The importance of accurate medical translation in the context of the COVID-19 pandemic,* cit.

[40] H. FISCHBACH, *Translation the Great Pollinator of Science: A Brief Flashback on Medical Translation,* cit., 93.

[41] *Ibidem*.

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involves exploring distinct legal systems and conceptual frameworks, which vary widely across jurisdictions, dealing with often different legal concepts in the source and target cultures.[42] However, the advantage of medical translation diminishes when medical concepts need to enter and be translated into legal contexts.

During the COVID-19 pandemic, this interplay was especially apparent. Medical terminology once confined to healthcare was adapted for legal and public use, with translation ensuring accurate communication across borders. The rapid development and global sharing of research, treatments, and vaccines underscored the importance of clear translation, particularly in regulatory documents, instructions, and safety guidelines. As the demand for medical goods surged, precise translations of technical manuals and product instructions became essential to ensure their safe and effective use worldwide.[43]

The overlap between legal and medical translation becomes particularly evident when medical concepts are incorporated into legal frameworks. This 'double translation' process involves not only linguistic translation across languages but also conceptual adaptation, ensuring that medical definitions align with legal and regulatory criteria. The notion of a medical device, for example, shifts from its medical context, where it focuses on functionality, to a legal context, where it incorporates safety, compliance, and regulatory considerations. This intersection reflects a semantic shift, where the meaning of terms evolves as they transition between disciplines.

4. Semantic Shift and the role of Comparative Law: the example of Covid 19

Language is a dynamic system evolving in response to societal and cultural changes. While grammatical and phonological structures tend to remain stable and take some time to change, vocabularies adapt quickly to reflect shifts in life, culture and societal needs.[44] The COVID-19 pandemic was a prime example of this, as it reshaped not only daily life but also the language used to describe emerging concepts and circumstances. This shift underscores the critical role of language in understanding societal changes and highlights the intersection of disciplines like medicine, law, and technology.

As it has been pointed out, the outbreak of the coronavirus pandemic revealed numerous translation challenges. These ranged from the urgent need to communicate critical information to multilingual populations to the rapid translation of laboratory research into vaccines and treatments. As the boundaries between the private and collective spheres, as well as between medicine and other disciplines, became blurred, diverse cultural and linguistic responses emerged, capturing the shared yet individual experience of Covid-19.[45]

In this context, linguistic and legal comparative tools offer valuable insights for analysing both the pandemic and its aftermath. According to Traugott's linguistic studies, a *semantic shift* refers to the

[42] *Ibidem*.

[43] L. LEONARDI, *The importance of accurate medical translation in the context of the COVID-19 pandemic,* cit. See also: P. TRZASKAWKA, J. KIC-DRGAS, *Penetration of COVID-19 Related Terminology into Legal, Medical, and Journalistic Discourses*, cit.

[44] J. MWERI, *Corona Virus Disease (COVID-19) Effects on Language Use: An Analysis of Neologisms*, in *Linguistics and Literature Studies*, 9, 1, 2021, 36-47.

[45] M. ARNALDI, E. ENGEBRETSEN, C. FORSDICK, *Translating COVID-19: From Contagion to Containment*, in *Journal of Medical Humanities,* 43, 2022, 387-404.

evolution of meaning in language, driven by lexical, grammatical, social, cultural, and cognitive factors.[46] In the context of the pandemic, this shift extended beyond individual terms, reflecting how concepts transitioned between disciplines—such as from medicine to law—and how these shifts can be better understood through a comparative approach at both national and supranational levels.

A prime example of semantic shift due to the COVID-19 pandemic is the term "quarantine", which transitioned from medical to legal terminology. Initially, in medical contexts, quarantine referred to isolating individuals who might have been exposed to a contagious disease to prevent its spread. Over time, the word became associated with a 40-day isolation period (from the Italian *quaranta*, meaning forty), intended to limit the transmission of diseases like the plague. Its use spread in all the major European languages, such as French 'quarantaine' or German 'Quarantäne' or English 'quarantine', in the last two cases the link with the word meaning forty has disappeared. Therefore, by the 17th century the meaning of quarantine had solidified in medical contexts, referring primarily to the separation of individuals who may have been infected by a contagious disease[47]. During the pandemic the term was object of a linguistic confusion, as quarantine (or *quatorzaine* a neologism created in French referred to the fourteen days of isolation)[48] was sometimes used interchangeably with self-isolation, which applies to those already diagnosed with an infection.[49] Beyond healthcare, quarantine also experienced a semantic shift within legal frameworks. During the pandemic, the term expanded its scope beyond the medical domain, gaining widespread use within legal contexts. It became tied to compliance with government orders, enforcement of restrictions, and legal consequences for non-compliance.[50] The term also sparked debates over constitutional rights, with discussions of personal freedoms versus the public good. Legal scholars and practitioners were forced to consider how quarantine measures aligned with existing legal principles, such as the right to freedom of movement and personal autonomy.[51] Through comparative analysis of how different legal systems approached quarantine

[46] E. Closs Traugott, *Pragmatics and language change*, in K. Allan, K. M. Jaszczolt, *The Cambridge Handbook of Pragmatics*, Cambridge, 2012.

[47] On the etymology and uses of the word "quarantine" see: Treccani online, "quarantena" , https://www.treccani.it/vocabolario/quarantena/ ; J. Schwarcz, *The Word "Quarantine" Comes from the Italian Word "Forty Days"*, available online: https://www.mcgill.ca/oss/article/did-you-know-health/word-quarantine-comes-italian-word-forty-days .

[48] E. Garrigou-Kempton, *Covid-19 as a Foreign Language. How France learned the Language of the Pandemic*, in P. Blumczynski, S. Wilson (eds.), *The Language of Covid-19. Translational and Multilingual Perspectives on Global Healthcare*, Oxford, 2023. Differently, in Italy *Accademia della Crusca* underlined that it is needless to create a neologism, as the word "quarantine" in Italian treatise usage has also been used for several centuries for periods other than forty days. See: https://accademiadellacrusca.it/it/consulenza/una-quarantena-pu%C3%B2-durare-anche-solo-quattordici-giorni/1745 .

[49] E. Garrigou-Kempton, *Covid-19 as a Foreign Language. How France learned the Language of the Pandemic*, op. cit. On the distinction between quarantine and isolation see also, for instance: J. N. Shah, et. al., *Quarantine, isolation and lockdown: in context of COVID-19*, in *Journal of Patan Academy of Health Sciences*, 2020, 7, 1, 48-57.

[50] See: I. G. Cohen, A. R. Glucky, K. L. Kraschel, C. Shachar (eds.), *Covid-19 and the Law. Disruption, Impact and Legacy*, Cambridge, 2024.

[51] Among others see: I. G. Cohen, A. R. Glucky, K. L. Kraschel, C. Shachar (eds.), *Covid-19 and the Law. Disruption, Impact and Legacy*, cit.; A. Stojanovic, L. Scarcella, C. R. Mosalagae (eds.), *The First 100 Days of Covid-19. Law and Political Economy of the Global Policy Response*, Singapore, 2023; S. Calzolaio, *Sistema di allerta Covid-19. Osservazioni sull'art. 6, d.l. 28/2020*, in E. Calzolaio, M. Meccarelli, S. Pollastrelli (eds.), *Il diritto nella pandemia Temi,*

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regulations, it became evident that the pandemic exposed the interdisciplinary nature of law, medicine, and public health. For example, different countries used various terms related to physical distancing and reducing COVID-19 transmission, but these terms lacked standardized definitions, highlighting differences in national regulatory frameworks.[52]

The term "ventilator" provides another example. Before the pandemic, ventilators were primarily understood as medical devices used in hospitals to assist patients who could not breathe independently due to severe respiratory conditions like chronic obstructive pulmonary disease (COPD) or critical injuries. In this context, ventilators had a narrowly defined function: to provide mechanical ventilation, ensuring oxygen could reach the patient's lungs when they were unable to breathe on their own.

From a technical standpoint, ventilators are not particularly complex machines. Essentially, they are sophisticated pumps that control the flow of oxygen and air into patients' lungs, supporting them when their natural breathing function is compromised. Ventilators can be categorized into invasive mechanical ventilation (IMV) and non-invasive ventilation (NIV). IMV is the primary treatment for acute respiratory distress syndrome (ARDS)[53], while NIV offers advantages, such as reducing complications associated with sedation, muscle paralysis, and long-term ventilator use.[54]

During the pandemic, the demand for ventilators surged as many patients infected with SARS-CoV-2 developed severe respiratory conditions. This led to the term ventilator entering everyday language, necessitating clarification of its meaning. In Italy, for instance, a podcast titled *"DizionaVirus - Glossario minimo per un'epidemia"* was created to explain new terms.[55] Moreover, translation difficulties but also the lack of specialized language knowledge among journalists were outlined. For instance, in Italian, there are two words — 'respiratore' and 'ventilatore'—which seem to be synonyms, but the term 'respiratore' is almost exclusively used by the general public, as it is immediately understandable even

problemi, domande, Macerata, 2020, 75-89; A. COSSIRI, *Le norme di contrasto al contagio tra funzione sociale ed efficacia giuridica*, in E. CALZOLAIO, M. MECCARELLI, S. POLLASTRELLI (eds.), *Il diritto nella pandemia Temi, problemi, domande*, Macerata, 2020, 43-35.

[52] An interesting neologism is the term Lockdown (Confinement in French "Covid 19 language"). https://resources.hygienehub.info/en/articles/4455046-what-is-the-difference-between-physical-distancing-and-other-terms-like-lockdown-self-isolation-quarantine-or-shielding. The WHO Regional Office for Europe, the European Commission (EU), and the European Observatory on Health Systems and Policies jointly undertook a Health System Response Monitor collecting and organizing information on how countries were responding to the crisis between 2020 and early 2022. In May 2020 a report was published on the various measures for isolation, quarantine, and contact tracing differ among countries. https://eurohealthobservatory.who.int/monitors/hsrm/analyses/hsrm/how-do-measures-for-isolation-quarantine-and-contact-tracing-differ-among-countries .

[53] ARDS Definition Task Force, Ranieri VM, Rubenfeld GD, Thompson BT. Acute respiratory distress syndrome: the Berlin Definition, in *JAMA*; 307, 2012, 2526-2533, available at: https://jamanetwork.com/journals/jama/article-abstract/1160659.

[54] M. CARPANO; G. CORSI; L. NERI; F. TAGARIELLO; L. PISANI, *La ventilazione meccanica non invasiva nel paziente con ARDS da COVID-19*, in *Rassegna Di Patologia dell'Apparato Respiratorio*, *37*, 2, 2022, 137-140. https://doi.org/10.36166/2531-4920-A098. See also: https://www.ncbi.nlm.nih.gov/books/NBK482178/ . Interestingly, a helmet has been invented and manufactured in Italy, and almost only Italian resuscitators use it. This strange device (it looks like a diving helmet) allows patients with severe respiratory failure, such as those with Covid-19 pneumonia, to breathe. See: https://www.quotidianosanita.it/scienza-e-farmaci/articolo.php?articolo_id=94218 .

[55] https://www.raiplaysound.it/audio/2020/03/DizionaVirus--Glossario-minimo-per-unepidemia-6-Respiratore--cc98c64a-1085-4060-9854-4cc5d5cf8d18.html .

without medical expertise. In contrast, medical experts, technicians, and device manufacturers tend to use the term 'ventilatore' in their communications, which reflects the more technical lexicon. These aspects are relevant for journalists and other communicators but become even more important in translation from and into English – nowadays the *lingua franca.*[56] There is a risk of making inappropriate choices or of running into potential false friends.[57] For instance, in American English, it is incorrect to use 'ventilator' and 'respirator' interchangeably, as they refer to different types of devices. The first is a mechanical ventilation device used to assist or replace respiratory function, often to keep a patient alive in a medical context. On the other hand, a 'respirator' is a protective device that covers the mouth, nose, or entire face to prevent inhalation of smoke, dust, or toxic substances. In medical settings, it is used as a precautionary measure for healthcare workers, not patients.[58]

The pandemic also created a "race" for ventilators.[59] For example, in Italy, one of the hardest hit regions, an engineer had the innovative idea of converting scuba diving masks into makeshift ventilators. Working with colleagues and medical staff, a valve was designed and fitted to these masks, transforming them into working ventilators and helping to meet the urgent need.[60] This confirm that technically they are not particularly complex.

While the basic function of these devices may not be overly complicated, the challenges lie in their operation, which must be extremely reliable. This underscores the intersection of medicine, technology, and law. The pandemic is a clear example that to fully understand medical devices, we must consider not only their medical function but also their regulatory, ethical, and legal implications, as the real-life example just presented raises several regulatory, safety and ethical issues. Abstracting from the specific case and speaking generally about ventilators, it is clear that the COVID-19 pandemic has significantly broadened the scope of the term.

The regulatory aspects became particularly prominent. Governments and healthcare regulators had to quickly determine whether existing ventilators could meet the increased demand and whether emergency approval pathways could ensure the safety and efficacy of new devices. For example, due to the urgency, the Medical Device Coordination Group (MDCG)[61] endorsed a guidance document[62] for

[56] At the beginning Latin and Greek played a pivotal role in medicine. Nevertheless, nowadays, English in becoming the language of international communication, as for instance, in the scientific world is predominantly English-speaking and major scientific journals publish papers in English. See: H. FISCHBACH, *Translation, the Great Pollinator of Science: A Brief Flashback on Medical Translation*, cit., 93; W. KARWACKA, "*Medical Translation"*, cit., 273.

[57] For instance, see: Rassegna di Patologia dell'Apparato Respiratorio - fascicolo 5/2011; https://www.terminologiaetc.it/2020/03/31/differenza-respiratori-ventilatori-mascherine-covid19/.

[58] J. Kelly, *Respirator vs. Ventilator: What Is The Difference?*, 2020, available at: https://www.dictionary.com/e/respirator-vs-ventilator/

[59] J. L. Penarredonda, *Covid-19: The race to build coronavirus ventilators*, available at: https://www.bbc.com/future/article/20200401-covid-19-the-race-to-build-coronavirus-ventilators. See also: S. MANTENA, K. ROGO, T. F. BURKE, *Re-Examining the Race to Send Ventilators to Low-Resource Settings*, in *Respiratory care*, 2020 available at: https://home.liebertpub.com/publications/respiratory-care/682 .

[60] A. FERRIGOLO, *Maschere da sub di Decathlon trasformate in ventilatori ospedalieri*, available at: https://www.agi.it/cronaca/news/2020-03-21/coronavirus-mascherine-maschera-sub-decathlon-7744124/ .

[61] Established by Article 103 of Regulation (EU) 2017/745, the MDCG is composed of representatives of all Member States and chaired by a representative of the European Commission.

[62] The text starts with a clear disclaimer "this is not a document of the European Commission and cannot be regarded as reflecting the official position of the European Commission. The views expressed in this document

ventilators and related accessories, which were previously regulated under the Council Directive 93/42/EEC (MDD). The document stated that devices placed on the market under MDD must comply with its requirements until May 27, 2024, after which they must meet the standards set by MDR. It also emphasized that medical devices can only be marketed if they meet the MDD's essential requirements, including undergoing conformity assessments as specified in Article 11 of the MDD.[63]

The rush to produce ventilators raised legal concerns about liability and compliance with safety standards. At the same time, manufacturers faced an economic downturn caused by the lockdown and intense pressure to meet demand, raising questions about the quality and availability of equipment, as international supply chains were stretched to the limit as countries with the highest caseloads competed for these life-saving devices.[64]

The scarcity of ventilators also sparked significant ethical dilemmas. Legal frameworks had to address who would receive access to these devices, particularly in resource-limited environments.[65] In some countries, triage protocols were developed, requiring legal input to ensure decisions were made fairly and in accordance with public health guidelines.[66] Issues also arose regarding patient consent—if a patient could not provide informed consent due to their condition, legal and ethical questions regarding patient autonomy and medical decision-making became critical.[67] The evolution of "ventilator" from a term denoting a purely medical device to one that encapsulates regulatory compliance, ethical decision-making, and legal accountability illustrates the interdisciplinary nature of the pandemic's impact.

5. Conclusion

The pandemic acted as a pivotal moment, accelerating profound changes in communication, with language playing a central role in these transformations. The rapid rise of new realities—such as remote

are not legally binding and only the Court of Justice of the European Union can provide binding interpretations of Union law".

[63] MDCG 2020-9 *Regulatory Requirements for Ventilators and Related Accessories*, April 2020, available at: https://health.ec.europa.eu/system/files/2020-09/md_mdcg_2020-9_regulatory_requirements_ventilators_en_0.pdf ; K. LIDDELL, JM. SKOPEK, S. PALMER, et al., *Who gets the ventilator? Important legal rights in a pandemic*, in *Journal of Medical Ethics,* 46**,** 2020, 421-426.

[64] F. FOX, J. HAYES, B. WHELAN, D. CASEY, M. CONNOLLY, *Key Factors Impacting a Medical Ventilator Supply Chain During the COVID- 19 Pandemic: Lessons for Pandemic Preparedness*, in *Disaster Medicine and Public Health Preparedness*, 2024; 18 e 65; M. G. ATTINASI, M. BALATTI, M. MANCINI, L. METELLI, *Supply chain disruptions and the effects on the global economy*, in *ECB Economic Bulletin*, Issue 8/2021, available at: https://www.ecb.europa.eu/press/economic-bulletin/focus/2022/html/ecb.ebbox202108_01~e8ceebe51f.en.html .

[65] See among others: S. MANTENA, K. ROGO, T. F. BURKE, *Re-Examining the Race to Send Ventilators to Low-Resource Settings*, in *Respir Care*, 65, 9, 2020, 1378-1381.

[66] RD. TRUOG, C. MITCHELL, GQ. DALEY, *The Toughest Triage — Allocating Ventilators in a Pandemic*, https://www.nejm.org/doi/full/10.1056/NEJMp2005689 ; J.J. FINS, *COVID-19 and Clinical Ethics Reflections on New York's 2020 Spring Surge*, in I. G. COHEN, A. R. GLUCKY, K. L. KRASCHEL, C. SHACHAR (eds.), *Covid-19 and the Law. Disruption, Impact and Legacy*, Cambridge, 2024, 18.

[67] H. BHATT, S. SINGH, *The ethical dilemma of ventilator sharing during the COVID-19 pandemic*, in *J Glob Health*, 10, 2, 2020 Dec :020392; I.G. COHEN, A.M. CRESPO, D.B. WHITE, *Potential Legal Liability for Withdrawing or Withholding Ventilators During COVID-19: Assessing the Risks and Identifying Needed Reforms*, in *JAMA*; 323, 19, 2020, 1901–1902.

work, videoconferencing, e-learning, and telemedicine—forced governments to implement urgent legislative actions, sometimes in conflict with national constitutions and established legal frameworks. This evolving landscape generated new terminology and expressions, influencing contemporary communication while also triggering significant shifts in the meanings and uses of language.[68]

As noted by Oxford Languages "in a short period of time, specialist epidemiological and medical vocabulary entered everyday discourse, such as the R number and community transmission. Public health initiatives rapidly introduced new or unfamiliar terms—lockdown, social distancing, self-isolation—into our language and our lives, fundamentally altering our behaviours in ways that would have seemed inconceivable under normal circumstances".[69]

Thinking about the pandemic some essential questions arise: when does a crisis justify changes to safety and liability regulations? Could a more coordinated, unified regulatory framework and language have facilitated a more effective response to the pandemic? In her 2020 State of the Union address, Ursula von der Leyen, then President of the European Commission, emphasized the need for a European Health Union. The subsequent adoption of the "European Health Union: Acting Together for People's Health" Communication in May 2024[70] further reinforced the importance of cross-border cooperation to protect public health— both in times of crisis and in more stable times. Issues such as underlying health conditions, strong health systems and workforce training require attention.[71]

These considerations emphasise the critical role of language in times of crisis but also call for the development of adaptable legal, ethical, and regulatory frameworks[72] capable of responding to

[68] P. TRZASKAWKA, J. KIC-DRGAS, *Penetration of COVID-19 Related Terminology into Legal, Medical, and Journalistic Discourses*, cit.

[69] *Oxford Languages 2020 - Words of an unprecedented year*, 5, available at: https://languages.oup.com/wp-content/uploads/oxford-languages-words-of-an-unprecedented-year-2020.pdf.

[70] Communication from the Commission to the European Parliament, the Council, the European Economi and Social Committee and the Committee of the Regions, *The European Health Union: acting together for people's health*, COM(2024) 206 final, 22.5.2024, available online: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52024DC0206.

[71] EC *European Health Union Protecting our health together*, https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/promoting-our-european-way-life/european-health-union_en ; M. PEDRAZZOLI, *2EU Commission pushes for European health union*, available online at: https://www.eunews.it/en/2024/05/22/european-commission-pushes-for-european-health-union/.

The idea of a European Health Union in much more discussed also in scholarly debate after the pandemic. See among others: M. MCKEE, A. DE RUIJTER, *The path to a European Health Union*, in *The Lancet Regional Health - Europe* 36, 2024: 100794; I. KICKBUSCH, A. DE RUIJTER**,** *How a European health union can strengthen global health*, in *Lancet Reg Health Eur.*, 1, 2021:100025; F. MUNARI, L. CALZOLARI, *Le regole del mercato interno alla prova del COVID-19: modeste proposte per provare a guarire dall'ennesimo travaglio di un'Unione incompiuta*, in *Eurjus special Issue "L'emergenza sanitaria Covid-19 e il diritto dell'Unione europea. La crisi, la cura, le prospettive*" available online at: https://rivista.eurojus.it/lemergenza-sanitaria-covid-19-e-il-diritto-dellunione-europea-la-crisi-la-cura-le-prospettive/; Ó. FERNÁNDEZ, R. KISSACK, *The European Union's Role in Global Health: Embracing Governance Complexity?*, in O. COSTA, E. SOLERI LECHA, M.C. VLASKAMP (eds.), *EU Foreign Policy in a Fragmenting International Order. The European Union in International Affairs*, Cham, 2025.

[72] Regulation (EU) 2025/327 establishes the European Health Data Space (EHDS) and exemplifies the call for adaptable legal and regulatory frameworks. The Regulation reflects the growing convergence of legal and healthcare domains—both conceptually and linguistically—and introduces a harmonised framework for the access, use, and reuse of electronic health data. *Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space and amending Directive 2011/24/EU and*

unprecedented challenges. In the field of medical devices—defined not only by innovation but by evolving semantics—such frameworks are essential for ensuring sustainable health solutions and guiding societies through future crises more effectively.

From a methodological perspective, the analysis underscores the importance of interdisciplinary approaches that integrate legal and linguist analysis, and health policy. The interplay between language and law—especially during emergencies—demands tools that are both conceptually flexible and operationally robust. The notions of 'double translation' and semantic shift provide a framework for visualising and understanding how medical concepts must be translated not only across languages but also across disciplinary boundaries. This process involves adapting medical terminology to enter legal and regulatory frameworks—such as in the case of 'medical device', which gains new layers of meaning when evaluated through compliance, safety, and liability criteria. Understanding these shifts is essential for coherent regulatory responses and effective crisis governance. Future research should consider developing comparative frameworks for examining crisis communication and regulatory adaptation across jurisdictions. In addition, greater attention to terminology, framing, and discursive shifts can offer insight into how legal language shapes, and is shaped by, societal responses to various scenarios, including health emergencies.

Regulation (EU) 2024/2847 (Text with EEA relevance), available online: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32025R0327; https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space-regulation-ehds_en. See also: S. STEFANELLI, N. CONDITI, *Health Data Space: cosa cambia per il mondo medical device*, 2025, available online: https://www.aboutpharma.com/legal-regulatory/health-data-space-cosa-cambia-per-il-mondo-medical-device/.