Clinical Risk in Cross-Border eHealth

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Abstract

Telemedicine and eHealth services raise a wide range of complex substantive legal issues. These complexities are further exacerbated by the ever-changing shape of the digital environment, last but not least in the light of the rapid spread of AI-based systems and related technologies. The challenging regulatory choices needed to adequately cope with the digital transformation of the healthcare sector become tremendously more pronounced when the provision of healthcare services based on ICTs bridges national borders. The contribution aims to identify solutions to possible conflicts of jurisdictions and laws within the European judicial area.

Keywords

eHealth, Telemedicine, Product Liability, Health Professional's Liability, Conflict of Jurisdiction, Conflict of Laws

1. eHealth and mHealth

The 2020-2025 Global Strategy delivered by the World Health Organization (WHO) acknowledges that 'digital transformation of health care can be disruptive; however, technologies such as the Internet of things, virtual care, remote monitoring, artificial intelligence, big data analytics, blockchain, smart wearables, platforms, tools enabling data exchange and storage and tools enabling remote data capture and the exchange of data and sharing of relevant information across the health ecosystem creating a continuum of care have proven potential to enhance health outcomes by improving medical diagnosis, data-based treatment decisions, digital therapeutics, clinical trials, self-management of care

and person-centred care as well as creating more evidence-based knowledge, skills and competence for professionals to support health care'.[1]

Already the Digital Agenda for Europe presented in 2010 by the European Commission indeed has alluded to the potential of the Internet – that is 'borderless' – and of the 'innovative and advanced online services – such as (…) eHealth', hoping 'to achieve by 2020 widespread deployment of telemedicine services'.[2] The Digital Agenda for Europe envisages specific actions relating to eHealth with the view of achieving widespread deployment of patients' access to their health data and of enhancing interoperability between Information and Communication Technologies (ICTs) products and services. Taking the view that 'the deployment of eHealth technologies in Europe can improve the quality of care, reduce medical costs and foster independent living, including in remote places',[3] the Commission indeed deplores that European citizens do not fully benefit from cross-border healthcare and eHealth technology.[4]

A year later the European Union (EU) legislator adopted the European Parliament and Council Directive 2011/24/EU of 9 March 2011 on the application of patients' rights in the field of cross-border healthcare[5] (hereinafter the 'Directive on cross-border healthcare'). On one hand, the Directive implements the case law of the European Court of Justice (ECJ) on the EU citizens' right to reimbursement of costs of healthcare incurred in Member States other than that of the citizens' habitual residence,[6] by extending the scope of that case

1 World Health Organization, 'Global strategy on digital health 2020-2025' [2021], CC BY-NC-SA 3.0. The Global Strategy also notes that 'there is a growing consensus in the global health community that the strategic and innovative use of digital and cutting-edge information and communications technologies will be an essential enabling factor towards ensuring that 1 billion more people benefit from universal health coverage, that 1 billion more people are better protected from health emergencies, and that 1 billion more people enjoy better health and well-being'. Always in 2021 the WHO published a set of guidelines on the ethical and regulatory implications of artificial intelligence applied to the healthcare sector; World Health Organization, 'Ethics and governance of artificial intelligence for health: WHO guidance' [2021], CC BY-NC-SA 3.0. Digital health is fully part of the Third Sustainable Development Goal of the United Nations Agenda 2030, which aims to ensure health and well-being to everyone, at all stages of life; UNGA Res 70/1 (21 October 2015) Un Doc A/RES/70/1.

2 Commission, 'A Digital Agenda for Europe' (Communication) COM (2010) 245 final.

3 ibid 29.

4 Commission, 'EU Citizenship Report 2010 – Dismantling the obstacles to EU citizens' rights' (Communication) COM (2010) 603 final, 8–9.

5 [2011] OJ L 88/45.

6 eg Case C–255/09 *Commission v Portugal* [2011] ECR I–10547. The ECJ case law is aptly summarized in the Directive's preamble. In particular, recital n 11 reads that: 'This Directive should apply to individual patients who decide to seek healthcare in a Member State other than the Member State of affiliation. As confirmed by the Court of Justice, neither its special nature nor the way in which it is organised or financed removes healthcare from the ambit of the fundamental principle of the freedom to provide services. However, the Member State of affiliation may choose to limit the reimbursement of cross-border healthcare for reasons

law as to encompass healthcare provided through eHealth and telemedicine[7]. On the other hand, it provides for the creation of 'a voluntary network linking national authorities responsible for eHealth designated by the Member States'. The objectives of this network are to: '(a) work towards delivering sustainable economic and social benefits of European eHealth systems and services and interoperable applications, with a view to achieving a high level of trust and security, enhancing continuity of care and ensuring access to safe and high-quality healthcare; (b) develop guidelines on: (i) a non-exhaustive list of data that are to be included in patients' summaries and that can be shared between healthcare professionals to enable continuity of care and patient safety across borders; and (ii) effective methods for enabling the use of medical information for public health and research; (c) support Member States in developing common identification and authentication measures to facilitate the transferability of data in cross-border healthcare' (art 14).[8]

In 2018 the European Commission published a Communication on the digital transformation of health and care.[9] The Communication identifies three areas of priority for future EU's actions: a) citizens' secure access to their health data, including across borders; 2) personalised medicine through shared European data infrastructure; 3) citizen empowerment with digital tools for user feedback and person-centred care.[10] Overall, the European Commission has stressed the wide-ranging beneficial impact that digital technologies, such as 5G mobile communication, Artificial Intelligence (AI) and supercomputing, may exert in increasing the well-being of EU citizens, in fostering innovation of the health sector and scientific research.[11]

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relating to the quality and safety of the healthcare provided, where this can be justified by overriding reasons of general interest relating to public health. The Member State of affiliation may also take further measures on other grounds where this can be justified by such overriding reasons of general interest. Indeed, the Court of Justice has laid down that public health protection is among the overriding reasons of general interest that can justify restrictions to the freedom of movement envisaged in the Treaties'.

7 Recital n 26 reads that: 'The Court of Justice has held that the Treaty provisions on the freedom to provide services include the freedom for the recipients of healthcare, including persons in need of medical treatment, to go to another Member State in order to receive it there. The same should apply to recipients of healthcare seeking to receive healthcare provided in another Member State through other means, for example through eHealth services.'

8 Art 14(2) last sentence '(…) The objectives referred to in points (b) and (c) shall be pursued in due observance of the principles of data protection as set out, in particular, in Directives 95/46/EC and 2002/58/EC. (…) The Commission shall, in accordance with the regulatory procedure referred to in art 16(2), adopt the necessary measures for the establishment, management and transparent functioning of this network.'

9 Commission, 'Communication on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society' (Communication) COM (2018) 233 final.

10 ibid 3–13.

11 ibid 1–3.

Nowadays the concept of 'eHealth' is used to broadly denote tools and services that rely on Information and Communication Technologies (ICTs) to improve prevention, diagnosis, treatment, monitoring and management of health-related issues and to monitor and manage lifestyle-habits that impact health. More specifically, the notion encompasses a wide range of services and information technology such as information systems and Electronic Health Records (EHR), Electronic Health Platforms (EHP), electronic transmission of prescriptions or referrals (e-prescription, e-referrals), evidence-based medicine, consumer health informatics, online pharmacy and telemedicine. A particular form of medical and public health practice supported by mobile devices such as phones, patient monitoring devices, personal digital assistants (PDAs) and other wireless devices, is also rapidly spreading.[12] This practice of 'mobile healthcare' ('mHealth') includes applications that may connect to medical devices or sensors (bracelets or watches), health information/medication reminders provided by text (sms) and telemedicine provided wirelessly. AI-driven applications that encompass genuine medical services, requiring a health professional for diagnosis and/or treatment, fall within the concept of 'e-Health': not so mere self-control/wellbeing applications.

2. Cross-border telemedicine

'Telemedicine' refers to 'the provision of healthcare services, through the use of ICTs, in situations where the health professional[13] and the patient (or two health professionals) are not in the same location. It involves secure

12 See Commission, 'Staff Working Document on the existing EU legal framework applicable to lifestyle and wellbeing apps. Accompanying the document Green Paper on mobile Health ("mHealth")' (Staff Working Document) SWD (2014) 135 final; Commission, 'Green Paper on mobile Health ("mHealth")' (Communication) COM (2014) 219 final, para 3.8, 16 ('The issue of identifying potential liability arising from the use of an mHealth solution may be complex, because of the numerous actors involved: the manufacturer of the mHealth solution, a healthcare professional, any other care professional involved in the treatment or the electronic communications provider providing the internet. The damage to patient health can come from various sources: a defective device; a wrong diagnosis by the healthcare professional based on inaccurate data; an error by an IT specialist; the patient did not use the device correctly or sent the wrong data to his doctor. This list is not exhaustive and cannot envisage all the possibilities of risks. App developers, mHealth manufacturers and healthcare professionals may request greater legal clarity on the liability risks they may face for having developed or prescribed an app that harmed the user's health and on the ways to mitigate those risks').

13 Art 3(f) of the Directive on cross-border healthcare (n 5) defines 'health professional' as 'a doctor of medicine, a nurse responsible for general care, a dental practitioner, a midwife or a pharmacist within the meaning of Directive 2005/36/EC, or another professional exercising activities in the healthcare sector which are restricted to a regulated profession as defined in art 3(1)(a) of Directive 2005/36/EC, or a person considered to be a health professional according to the legislation of the Member State of treatment'.

transmission of medical data and information, through text, sound, images or other forms needed for the prevention, diagnosis, treatment and follow-up of patients'.[14] As such, the concept of telemedicine encompasses both healthcare 'professional-to-patient' relationships (ie, situations where health-related services based on ICTs are provided at distance by healthcare professionals to patients) as well as healthcare 'provider-to-provider' relationships (ie, situations where health-related services based on ICTs are provided at distance by one or more healthcare professionals to one or more healthcare professionals). There are several forms or ways by which telemedicine services may be delivered: telemonitoring,[15] teleintervention,[16] telesurgery,[17] teleconsultation[18] and tele-education.[19] Depending on the relevant medical specialty in which telemedicine services are implemented, telemedicine takes the form of teleradiology, telepsychiatry, teledermatology, telephysiopatology, teleophtalmology, etc.

Thanks to telemedicine it is possible to provide healthcare services beyond traditional physical spaces, including national borders. The independence by physical spaces brings forward a series of advantages: better access to care, especially in case of patients living in remote areas or unable to move (elderly, disabled, inmates), greater timeliness of assistance, greater continuity of assistance for patients with chronic or rare diseases, better management of public health emergencies (such as, for example, the COVID-19 pandemic).[20] In other words, healthcare services are provided without the actual movement of the parties (health professionals and/or patients), thanks to communication tools (videoconferencing, email, smartphones or app-enabled technology), and

14 Commission, 'Communication on telemedicine for the benefit of patients, healthcare systems and society' (Communication) COM (2008) 689, 3.

15 Telemonitoring is used to enable follow-up or integrated care: health professionals remotely check and monitor the patient's data. These data are collected outside a hospital and may be set either by the patient or by another health professional or automatically by mean of monitoring devices. Telemonitoring can improve the quality of life of chronically ill patients.

16 Teleintervention relates to audiovisual telecommunications between the doctor and the patient.

17 Telesurgery technologies relate to surgical interventions carried out remotely by relying on robotised and computerised machines (such as the da Vinci model). The first long-distance telesurgical operation took place in 2001, when a physician removed the gallbladder of a patient located in France (Strasbourg) from a surgical console located in the United States (New York): on this operation (so-called 'Operation Lindbergh') see Jacques Marescaux and others, 'Transatlantic Robot-Assisted Telesurgery' (2001) 413 Nature 379.

18 Teleconsultation is similar to conventional medical consultation with the difference that doctor and patient communicate remotely, through videoconference, phone or chat. Even two or more healthcare professionals can communicate remotely (so-called 'tele-expertise').

19 Tele-education is used to make general and technical information accessible to the general population or other health-care professionals (in this case the so-called 'virtual hospitals' are used).

20 These advantages are accompanied by some critical issues, including the need to reorganise work processes in healthcare institutions and acquire the necessary technological equipment.

store-and-forward or asynchronous technologies that can transmit sensitive clinical data (video or images) collected from patient's wearable devices in order to be clinically evaluated.

By entailing a hyper-personalised and data-driven evaluation of the patient's conditions, telemedicine services raise complex regulatory choices that only partially overlap with those raised by conventional healthcare services. Telemedicine services – that fall, as traditional healthcare services, within the scope of arts 56 and 57 TFEU[21] – may indeed be characterised simultaneously as 'healthcare' service pursuant to the Directive on cross-border healthcare,[22] as well as an 'information society service' (ISS) within the meaning of the Directive 2000/31/EC on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market (hereinafter 'eCommerce Directive'[23]).[24]

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21 Already at the end of the '90s the ECJ made clear that medical services fall within the concept of 'service' within the meaning of art 57 TFEU, regardless of how the service is delivered; see eg Case C–158/96 *Raymond Kohll v Union des caisses de maladie* [1998] ECR I-01931.

22 Art 3(a) of the Directive on cross-border services (n 5) defines 'healthcare' as 'health services provided by health professionals to patients to assess, maintain or restore their state of health (…).' Art 1(2) thereof further provides that the Directive applies 'to the provision of *healthcare to patients*, *regardless of how* it is organised, *delivered* and financed (emphasis added).' It is to be noted that already in 2003 the Ministers of Health of the Member States of the European Community (EC) and other interested parties invited the European Commission to study how to enhance legal certainty in the area of cross-border healthcare, in accordance with the ECJ's case law. To that effect, healthcare services were originally included in the proposal for the Directive on services in the Internal Market. However, they were ultimately excluded from the scope of the finalized Service Directive (Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on services in the internal market [2006] OJ L376/36), as it was deemed preferable to submit a separate proposal to take into account the specificities of the matter; see European Parliament, 'Report on the impact and consequences of the exclusion of health services from the Directive on services in the Internal Market' (Report) 2006/2275(INI).

23 Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market ('Directive on electronic commerce') [2000] OJ L 178/1. The application of the eCommerce Directive to telemedicine services is not prejudiced by the Directive on cross-border healthcare (n 5, art 2(e)). The concept of 'information society service' is defined as 'any service normally provided for remuneration, at a distance, by electronic means and at the individual request of a recipient of services'; ibid (eCommerce Directive) art 2(a) and recital n 18; see further art 1(2) of the Directive 98/34/EC of the European Parliament and the Council laying down a procedure for the provision of information in the field of technical standards and regulations [1998] OJ L 204/37 (Regulatory Transparency Directive), repealed by art 1(b) of the Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (codification) [2015] OJ L 241.

24 On the characterization of telemedicine as an ISS see Stefaan Callens, 'Telemedicine and the E-Commerce Directive' (2002) 9 Eur J Health L 93; Grzegorz Glanowski, 'Legal Status of

In the case of cross-border telemedicine services, ie situations where the health professional and the patient, or more health professionals, are located in different States, several key legal issues arise: licensing/registration of healthcare professionals performing telemedicine services;[25] conditions for legitimate processing and protection of personal health data;[26] respect for the patient's

Telemedicine in the Internal Market' (2016) Eur J Health L 231. As noted by the European Commission, in order to qualify as an ISS, 'the service (…) has to be sent initially and received at its destination by means of electronic equipment for the processing (including digital compression) and storage of data, and entirely transmitted, conveyed and received by means of wire, radio, optical means or other electromagnetic means. This means that the following health services are not information society services: services provided in the physical presence of the provider and the recipient, such as medical examinations at a doctor's premises, even if using electronic equipment; services which are not using online telecommunication services, such as a telephone or telefax medical consultation or medical call-centers providing services through traditional voice telephony'; Commission, 'Staff Working Document on the applicability of the existing EU legal framework to telemedicine services' (Staff Working Document) SWD (2012) 414 final, 9. Accordingly, to the extent the telemedicine services qualify as ISS and insofar as they are provided in cross-border context, the regulatory framework of the eCommerce applies to telemedicine services. This legal framework most notably encompasses the 'country of origin' principle (art 3), the principle of responsibility of the Member State where the healthcare provider is established (art 4(1)), the duty of information of ISS providers (art 5), the duty of ISS providers to comply with specific requirements when using commercial communications for the promotion of ISS (arts 6 and 7) and the Member States' obligation to assess whether if healthcare professionals are respecting their professional rules when offering ISS (art 8).

25 In this respect, the main problem is whether or not telemedicine service providers have to be licensed/registered in the Member States where the patients are located. Besides the eCommerce Directive and the Directive on cross-border healthcare, the Directive of the European Parliament and the Council 2005/36/EC of 7 September 2005 on the recognition of professional qualifications ([2005] OJ L 255/22) also applies to telemedicine services insofar as health professionals practice a regulated profession under the laws of a Member State.

26 See in particular Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector Directive on privacy and electronic communications) [2002] OJ L 201/37 (emended by Directive 2009/136/EC of the European Parliament and of the Council of 25 November 2009 [2009] OJ L 337/11); Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation) [2016] OJ L 119/1. See also European Commission, 'Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space' (Communication) COM (2022) 197 final.

self-determination;[27] reimbursement of the services[28]. The most problematic

27 Pursuant to art 5 of the 1997 Oviedo Convention on Human Rights and Biomedicine: 'an intervention in the health field may only be carried out after the person concerned has given free and informed consent to it'. Moreover, the patient 'shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks [and] (…) may freely withdraw consent at any time.'; Council of Europe, Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (opened to signature 4 April 1997, entered into force 1 December 1999), ETS 164 (Oviedo Convention). In telemedicine, patient's consent is normally given remotely by mean of electronic signature. In some legal orders, the patient has the right to refuse telemedicine services in favor of conventional healthcare services, unless the latter is unavailable due to local conditions and the organization of healthcare services. Worth mentioning is art R6316-2 of the French Public Health Code (*Code de la santé publique*), according to which 'Les actes de télémédecine sont réalisés avec le consentement libre et éclairé de la personne, en application notamment des dispositions des articles L 1111-2 e L 1111-4. Les professionnels participant à un acte de télémédecine peuvent, sauf opposition de la personne dûment informée, échanger des informations relatives à cette personne, notamment par le biais des technologies de l'information et de la communication.' In Italy, the 2012 Italian Ministry of Health's national guidelines on Telemedicine (*Linee di indirizzo nazionali sulla Telemedicina*) read that: 'It is necessary to clearly bring to the attention of the patient the information necessary to allow a weighted choice. In the particular case of remote services, it is necessary to evaluate the need or not to repeat the consent for each service, and the opportunity to specifically explain the risks that are run (such as, the risks associated with the lack of physical contact and the clinical gaze of the doctor, the impossibility of a complete visit and immediate intervention in an emergency)'. The Italian Ministry of Health' Decree of 21 September 2022 (*Decreto del Ministero della salute del 21 settembre 2022* Approvazione delle linee guida per i servizi di telemedicina - Requisiti funzionali e livelli di servizio, 22A06184, GU Serie Generale n 256 del 2 novembre 2022) refers to the 'informed consent that the patient expresses following appropriate information received which will be prepared by the Ministry of Health in collaboration with the Authority for the protection of personal data and with the regions/PAs, authorizing all the professional figures involved for said treatment'. For an analysis of the issues related to the applicable data protection law see, among others, Jan D Lüttringhaus, 'Doctors Without Borders? The Law Applicable to Cross-Border eHealth Services and AI-Based Medicine' in Marcelo Corrales Compagnucci and others (eds), *AI in eHealth: Human Autonomy, Data Governance and Privacy in Healthcare* (CUP 2022) 311, 317.

28 Art 7(7) of the Directive on cross-border healthcare (n 5) provides that: 'The Member State of affiliation may impose on an insured person seeking reimbursement of the costs of cross-border healthcare, including healthcare received through means of telemedicine, the same conditions, criteria of eligibility and regulatory and administrative formalities, whether set at a local, regional or national level, as it would impose if this healthcare were provided in its territory. This may include an assessment by a health professional or healthcare administrator providing services for the statutory social security system or national health system of the Member State of affiliation, such as the general practitioner or primary care practitioner with whom the patient is registered, if this is necessary for determining the individual patient's entitlement to healthcare. However, no conditions, criteria of eligibility and regulatory and administrative formalities imposed according to this paragraph may be discriminatory or constitute an obstacle to the free movement of patients, services or goods, unless it is objectively justified by planning requirements relating to the object of ensuring sufficient and permanent access to a balanced range of high-quality treatment in the Member State

profiles, though, are the patients' clinical risk and the liability of healthcare professionals or facilities when patients suffer personal harm in connection with the use of telemedicine services and products. These issues will precisely be the main focus of the following sections.

3. Clinical risk

Clinical risk is the measure of likelihood that patients may incur in adverse events and suffer personal harm in connection with the provided medical treatment. Patients' personal harm may consist *inter alia* in a prolongation of the hospitalisation period, the worsening of health conditions or even death.[29] The occurrence of personal harm for patients may be linked to very different kinds of events, actions or omissions. On one hand, personal harm for patients may derive from defects or malfunctioning of the equipment used by professionals to provide medical treatments (eg defects in the manufacturing or a malfunctioning in the use of the relevant equipment, inadequate instructions given by manufacturer, inadequate maintenance through the equipment's lifecycle etc). On the other hand, personal harm for patients may derive either from actions or omissions of healthcare professionals (eg errors in the identification of the relevant patient, delay in diagnosis or medical interventions, operative errors in practicing the relevant treatment, surgical errors etc) or from structural or organizational deficiencies of healthcare facilities (eg shortages of the available medical personnel or medical equipment).[30]

The occurrence of personal harm for patients may of course trigger civil liability claims. To this effect, civil liability may be divided in 'product' liability and 'professional' liability depending on subject matter of the relevant dispute. Indeed, depending on the factual circumstances of the specific case, the harmed patient could bring civil claim in courts by focusing either on the harm caused by a defective medical equipment or on the harm caused by actions or omissions of healthcare professionals or stemming from healthcare facilities' deficiencies (or a combination thereof).

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concerned or to the wish to control costs and avoid, as far as possible, any waste of financial, technical and human resources'.

29 Linda T Kohn, Janet M Corrigan and Molla S Donaldson (eds), *To err is human: building a safer health system* (National Academy Press Washington 1999) X.

30 ibid: '(…) errors are responsible for an immense burden of patient injury, suffering and death. Second, errors in the provision of health services, whether they result in injury or expose the patient to the risk of injury, are events that everyone agrees just shouldn't happen. Third, errors are readily understandable to the American public. Fourth, there is a sizable body of knowledge and very successful experiences in other industries to draw upon in tackling the safety problems of the health care industry. Fifth, the health care delivery system is rapidly evolving and undergoing substantial redesign, which may introduce improvements, but also new hazards'.

Both types of civil liability claims may in turn involve several national legal systems. Consider for instance the case in which a professional located in State A performs robotic surgery on a patient citizen of State B (domiciled and resident in State C) using equipment designed in State D and manufactured in State E. If personal harm occurs, the patient's claim potentially involves both types of liability and five legal systems.[31] To the extent that a dispute concerning product liability and/or health professionals' liability in the context of telemedicine and eHealth touches upon different legal orders, private international law issues come into play. Based on the distinction between product liability and health professionals' liability, the following sections (4.–5.) assess the extent of substantive harmonisation achieved at EU-wide level and the role played by the general instruments of EU private international law to address potential conflicts of jurisdiction and of laws. The paper ends with some concluding remarks (6.).

4. Product liability

4.1. Harmonised substantive rules

As far as liability for defective products is concerned, ever since the '80s the European Community (EC) has established harmonised rules through the Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products[32] (hereinafter the 'Product Liability Directive'). This Directive has established the principle of objective liability – strict or faultless liability – of the producer/importer as well as of the supplier insofar as the producer/importer cannot be identified. The EU legislator considers the imposition of a strict liability regime upon producers to be 'the sole means of adequately solving the problem, peculiar to our age of increasing technicality, of a fair apportionment of the risks inherent in modern technological production'.[33] When more than one person is liable for the same damage, joint and several liability applies and the injured person (usually the patient) is entitled to claim full compensation for the damage suffered by any one of the liable persons (art 5). To establish liability for defective products, the injured person has to prove the damage, the defect and the causal relationship between defect and damage (art 4), without being required to further demonstrate the existence

31 See Bernard M Dickens and Rebecca J Cook, 'Legal and ethical issues in telemedicine and robotics' (2006) 94 Intl J Gynecology and Obstetrics 73.

32 [1985] OJ L 210/29, subsequently amended by Directive 1999/34/EC of the European Parliament and of the Council of 10 May 1999 [1999] OJ L 141/20.

33 ibid, recital n 2.

of fault or negligence on behalf of the liable person. Producer's liability may only be excluded or reduced under rather strict circumstances (arts 7 and 8). Member States shall provide in their legislation that a limitation period of three years applies to proceedings for the recovery of damages (the limitation period shall begin to run from the day on which the plaintiff became aware, or should reasonably have become aware, of the damage, the defect and the identity of the producer) as well as that the rights conferred upon the injured person shall be extinguished upon the expiry of a period of ten years from the date on which the producer put into circulation the actual product which caused the damage (arts 10 and 11). Moreover, the strict liability regime established under the Directive does not affect the rights granted to the injured person under the Member States' rules of the law of contractual or non-contractual liability (art 13).

The Product Liability Directive only applies to tangible products (art 2). By contrast, it does not cover software and other intangible digital assets, which – as already mentioned – are of fundamental importance for the provision of telemedicine and eHealth services.

Precisely to fill the regulatory gap concerning the liability for emerging digital technologies and AI-based systems, in 2018 the European Commission delivered an interesting Working Document[34] which was subsequently followed by the presentation in 2022 of a package of proposals for directives aiming to adapt the liability rules to the digital age. To that effect, the European Commission proposed the adoption of two distinct yet complementary acts, one dealing with liability for defective products[35] and the other one with the liability for damages caused by AI systems. Both the instruments should have had the effect of integrating the EU legislation on the safety and performance of medical

34 Commission, 'Liability for emerging digital technologies' (Staff Working Document) SWD (2018) 137 final.

35 European Commission, 'Proposal for a Directive on liability for defective products' (Communication) COM (2022) 495 final. The Explanatory Memorandum attached to the proposal addresses *inter alia* the relationship between the proposal itself, the Product Liability Directive (PDL) and national liability regimes. In this regard, it emphasizes that: 'national liability regimes exist in each Member State that allow compensation claims in more situations than under the PLD: claims can be made against a broader range of liable persons for a broader range of damages. These claims cover services as well as products, and often allow more time to make a claim. However, injured persons have to prove the wrongdoer's fault, which is not required under the PLD. The PLD, as a no-fault (strict) liability regime, does not affect these rights, so the PLD is consistent with the broader national regimes…The draft Directive on adapting non-contractual fault-based civil liability rules to artificial intelligence, adopted as a package with this proposal, seeks to facilitate access to information and alleviate the burden of proof in compensation claims pursued under national fault-based liability regimes in cases where certain AI systems are involved in causing damage. There is no overlap with claims brought under the PLD'.

devices (including AI-based medical devices) envisaged by the Regulation (EU) 2017/745 of 5 April 2017 on medical devices.[36]

In 2024 the Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence (Artificial Intelligence Act, hereinafter the 'AI Act') and the Directive (EU) 2024/2853 of the European Parliament and of the Council of 23 October 2024 on liability for defective products were actually adopted.

As for this Directive[37], the most relevant novelty for the purpose of the liability of providers of telemedicine services lies in the expansion of the concept of 'product'. This notion is no longer limited to tangible products and is extended as to encompass 'digital manufacturing files … and software'.[38] The

36 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 [2017] OJ L 117/1.

For an analysis see Sofia Palmieri, Paulien Walraet and Tom Goffin, 'Inevitable Influences: AI-Based Medical Devices at the Intersection of Medical Devices Regulation and the Proposal for AI Regulation' (2021) 28 Eur J Health L 341. The Medical Devices Regulation makes clear that softwares are included among the medical devices covered by the Regulation's scope of application when the software manifests itself as a stand-alone medical device or when is integrated in a medical device based on AI systems. Under Directive 93/42/EEC (now repealed by the Medical Devices Regulation), the ECJ clarified that 'software, of which at least one of the functions makes it possible to use patient-specific data for the purposes, inter alia, of detecting contraindications, drug interactions and excessive doses, is, in respect of that function, a medical device (…) even if that software does not act directly in or on the human body'; Case C–329/16 *Syndicat national de l'industrie des technologies médicales (Snitem) and Philips France v Premier ministre and Ministre des Affaires sociales et de la Santé* [2017] ECLI:EU:C:2017:947. The preamble of the Medical Devices Regulation makes clear that: 'where, in the course of a clinical investigation, harm caused to a subject leads to the civil or criminal liability of the investigator or the sponsor being invoked, the conditions for liability in such cases, including issues of causality and the level of damages and sanctions, should remain governed by national law' (recital n 66). Art 69 provides that: 'Member States shall ensure that systems for compensation for any damage suffered by a subject resulting from participation in a clinical investigation conducted on their territory are in place in the form of insurance, a guarantee, or a similar arrangement that is equivalent as regards its purpose and which is appropriate to the nature and the extent of the risk'.

37 [2024] OJ L 2853/1.

38 ibid art 4(1). Recital 13 reads that: 'Products in the digital age can be tangible or intangible. Software, such as operating systems, firmware, computer programs, applications or AI systems, is increasingly common on the market and plays an increasingly important role for product safety. Software is capable of being placed on the market as a standalone product or can subsequently be integrated into other products as a component, and it is capable of causing damage through its execution. In the interest of legal certainty, it should be clarified in this Directive that software is a product for the purposes of applying no-fault liability, irrespective of the mode of its supply or usage, and therefore irrespective of whether the software is stored on a device, accessed through a communication network or cloud technologies, or supplied through a software-as-a-service model. Information is not, however, to be considered a product, and product liability rules should therefore not apply to the content of

overarching aim of the Directive is to establish EU-wide uniform rules enabling persons who suffered personal or financial injury as a result of defective AI systems to more easily claim compensation from the supplier of the AI system or from the manufacturer who integrated an AI system into another product. To that effect, art 10 sets out particularly relevant provisions on the burden of proof. On one hand, it lays down the conditions under which the defectiveness of the product shall be presumed (art 10(2)) and, on the other hand, it establishes the presumption about the existence of the causal link between the defectiveness of the product and the damage 'where it has been established that the product is defective and the damage caused is of a kind typically consistent with the defect in question' (art 10(3)).

The AI Act[39] involves a very complex and technical discipline. As far as we are concerned, it is enough to remember here that it categorizes AI systems according to the level of risk associated with them (by "risk" is meant "the combination of the probability of an occurrence of harm and the severity of that harm") and pays particular attention to prohibited AI practices (art 5) and high-risk AI systems (art 6) [40] including those used in healthcare services

digital files, such as media files or e-books or the mere source code of software. A developer or producer of software, including AI system providers within the meaning of Regulation (EU) 2024/1689 of the European Parliament and of the Council, should be treated as a manufacturer'.

39 [2024] OJ L 1689/1.

40 "High-risk AI systems should only be placed on the Union market, put into service or used if they comply with certain mandatory requirements. Those requirements should ensure that high-risk AI systems available in the Union or whose output is otherwise used in the Union do not pose unacceptable risks to important Union public interests as recognised and protected by Union law. On the basis of the New Legislative Framework, as clarified in the Commission notice 'The "Blue Guide" on the implementation of EU product rules 2022', the general rule is that more than one legal act of Union harmonisation legislation, such as Regulations (EU) 2017/745 (on medical devices) and (EU) 2017/746 (on *in vitro* diagnostic medical devices) … may be applicable to one product, since the making available or putting into service can take place only when the product complies with all applicable Union harmonisation legislation. To ensure consistency and avoid unnecessary administrative burdens or costs, providers of a product that contains one or more high-risk AI systems, to which the requirements of this Regulation and of the Union harmonisation legislation listed in an annex to this Regulation apply, should have flexibility with regard to operational decisions on how to ensure compliance of a product that contains one or more AI systems with all applicable requirements of the Union harmonisation legislation in an optimal manner. AI systems identified as high-risk should be limited to those that have a significant harmful impact on the health, safety and fundamental rights of persons in the Union and such limitation should minimise any potential restriction to international trade" (recital 46). "AI systems could have an adverse impact on the health and safety of persons, in particular when such systems operate as safety components of products. Consistent with the objectives of Union harmonisation legislation to facilitate the free movement of products in the internal market and to ensure that only safe and otherwise compliant products find their way into the market, it is important that the safety risks that may be generated by a product as a whole due to its

(Annex III, point 5 (a) and (d)). The inclusion of AI systems for use in the medical field among those classified as high risk is not without significant implications for operators in the sector, ie for manufacturers, distributors, retailers and deployers[41].

4.2. Conflicts of jurisdiction

In the absence of more specific EU legislation, the allocation of adjudicative jurisdiction between Member States' courts over civil claims arising out of the alleged infringement of product liability rules in the context of telemedicine or eHealth products and devices is governed by the Council Regulation (EU) 1215/2012 of 12 December 2012 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters (recast) (hereinafter 'Brussels I-bis Regulation').[42]

As far as product liability disputes arising out of telemedicine products are concerned, the Brussels I-bis Regulation is likely to simultaneously attribute jurisdiction to the courts of different Member States. Although the rules on exclusive jurisdiction lay down in art 24 thereof may hardly be of any relevance in this context, exclusive jurisdiction could in principle derive from a choice-of-court agreement eventually concluded between the parties (art 25). If the relevant choice-of-court agreement does not confer exclusive jurisdiction or such an agreement had not been concluded at all, jurisdiction of the court seized could also be based on the defendant's appearance in the forum (art 26) or on the application of the special rules aimed at protecting the claimant as a weaker party in his relationship with the defendant, most notably those applicable to consumer contracts (arts 17–19). More realistically, the injured party will have to resort, at his or her choice, either to the general forum of the defendant's domicile (art 4) or, since product liability disputes very often arise in the absence of a contract linking the interested parties, to the special *forum delicti* (art 7(2)). Art 7(2) applies to claims generally relating to 'tort, delict or quasi-delict' and vests jurisdiction upon the courts of the place where the 'harmful event' occurred or may occur, a notion that for distance torts encompasses both the place where

digital components, including AI systems, are duly prevented and mitigated. For instance, increasingly autonomous robots, whether in the context of manufacturing or personal assistance and care should be able to safely operate and performs their functions in complex environments. Similarly, in the health sector where the stakes for life and health are particularly high, increasingly sophisticated diagnostics systems and systems supporting human decisions should be reliable and accurate" (recital 47).

41 Regarding aspects relating to civil liability see Søren Holm, Catherine Stanton and Benjamin Bartlett, 'A New Argument for No-Fault Compensation in Health Care: The Introduction of Artificial Intelligence Systems' (2021) 29 Health Care Analysis 171; and, more generally, Benedetta Cappiello, *AI-systems and non-contractual liability. A European private international law analysis* (Giappichelli 2022).

42 [2012] OJ L 351/1.

the event giving rise to the damage (*forum actus*) and the place of the damage (*forum damni*) occurred or may occur.[43] As regard product liability torts claims, the ECJ case law has localized the *forum actus* at the place where the relevant product had been manufactured.[44] Admittedly, the *forum actus* very often does not offer any meaningful alternative for prospective plaintiffs to the general forum of the defendant's domicile. By contrast, the *forum damni* may offer interesting alternatives for prospective plaintiffs, by often enabling them to bring proceedings in their own 'home' forum and in other additional fora.[45] For product liability torts, the ECJ case law seems to localize the *forum damni* in the place where the initial damage occurred as a result of the normal use of the product, provided that the relevant product was purposefully marketed in that place.[46]

A product liability claim could eventually be assigned by the injured individual to another person acting as a claimant or could be brought by a representative entity on the individual's behalf (eg non-profit organizations, associations, bodies etc): this is the so-called 'collective redress'[47]. To this effect, the EU legislator has adopted the Directive (EU) 2020/1828 of 25 November 2020 on representative actions for the protection of the collective interests of consumers (repealing Directive 2009/22/EC).[48] The directive lays down some minimum harmonisation rules by obliging the Member States to provide at least one procedural mechanism enabling representative entities that fulfill certain qualifying requirements to bring claims for injunction and compensation on behalf of individual consumers.[49] This procedural mechanism must be available for claims arising out of alleged infringements of a long list of EU law instruments insofar as the infringement affects or may affect consumers' general interests.[50] Such a list includes *inter alia* the Medical Device Regulation.[51] Since the Directive

43 Ever since Case 21/76 *Handelskwekerij G. J. Bier BV v Mines de potasse d'Alsace SA* [1976] ECR 1735, paras 12–25.

44 Case C–45/13 *Andreas Kainz v Pantherwerke AG* [2014] ECLI:EU:C:2014:7, paras 26–29 and 33.

45 eg Jan von Hein, 'Protecting Victims of Cross-Border Torts under Article 7 No. 2 Brussels I*bis*: Towards a more Differentied and Balanced Approach' (2015) XVI Yearb priv int law 241; Etienne Farnoux, 'Delendum est Forum Delicti? Towards the Jurisdictional Protection of the Alleged Victim in Cross-Border Torts' in Burkhard Hess and Koen Lenaerts (eds), *The 50th Anniversary of the European Law of Civil Procedure* (Nomos 2020) 259.

46 Case C–189/08 *Zuid-Chemie BV v Philippo's Mineralenfabriek NV/SA* [2009] ECR 2009 I-06917, paras 25–32; Case C–343/19 *Verein für Konsumenteninformation v Volkswagen AG* [2020] ECLI:EU:C:2020:534, paras 32–40.

47 See generally Alexia Pato, *Jurisdiction and Cross-Border Collective Redress: A European Private International Law Perspective* (Hart Publishing 2019).

48 [2020] OJ L 409/1.

49 ibid arts 1–2, 4, 7–9. See further recitals n 7, 10–12, 24–31, 40–51.

50 ibid art 2(1) and Annex I.

51 Medical Devices Regulation (n 36), ibid (Annex I) point 57.

applies in principle to both domestic and transnational representative actions,[52] it may to some extent facilitate the conditions under which injured persons may bring cross-border collective proceedings against e-Health services providers for alleged infringements of provisions of EU law on medical devices. Yet, the Directive neither affects the existing private international law rules on jurisdiction, choice of law and recognition/enforcement of judgments nor establishes such rules.[53] As such, the Brussels I-bis Regulation remains fully applicable with respect to collective product liability claims in the context of eHealth products and devices. Unfortunately, the Brussels I-bis Regulation has long been acknowledged in literature as being built upon a traditional conception of two-party proceedings, a tenet that the ECJ case law has carefully and constantly safeguarded.[54] For the time being, the only rule on jurisdiction enshrined in the Brussels I-bis Regulation that may constitute a solid ground of jurisdiction for collective redress proceedings is general forum of the defendant's domicile (art 4).[55] Although the *forum damni* under art 7(2) as an alternative to the general rule based on art 4 remains in principle available,[56] its application to collective redress proceedings suffer significant drawbacks primarily because of the consolidated principle in the ECJ case law that special jurisdiction needs to be determined independently and separately for each claimant and each claim.[57]

52 ibid arts 2(1), 3(6)–(7) and 4(1)–(2).

53 ibid art 2(3), recital n 21.

54 eg Arnaud Nuyts, 'The Consolidation of Collective Claims Under Brussels I' in Arnaud Nuyts and Nikitas E Hatzimihail (eds), *Cross-Border Class Actions: The European Way* (Sellier European Law Publishers 2013) 69; Burkhard Hess, 'Collective Redress and the Jurisdictional Model of the Brussels I Regulation' in Arnaud Nuyts and Nikitas E Hatzimihail (eds), *Cross-Border Class Actions: The European Way* (Sellier European Law Publishers 2013) 59; T M C Arons, 'Cross-border dimension of collective proceedings in the Brussels Ibis regime: jurisdiction, *lis pendens* and related actions' in Peter Mankowski (ed), *Research Handbook on the Brussels Ibis Regulation* (Edward Elgar Publishing 2020) 1; Frederick Rielaender, 'Aligning the Brussels Regime with the Representative Actions Directive' (2022) 71 ICLQ 107.

55 ibid.

56 eg Case C–167/00 *Verein für Konsumenteninformation v Karl Heinz Henkel* [2000] ECLI:EU:C:2002:555; Case C–191/15 *Verein für Konsumenteninformation v Amazon EU Sàrl* [2016] ECLI:EU:C:2016:612; Case C–343/19 *Verein für Konsumenteninformation v Volkswagen AG* [2020] ECLI:EU:C:2020:534.

57 Case C–147/12 *ÖFAB, Östergötlands Fastigheter AB v Frank Koot and Evergreen Investments BV* [2013] ECLI:EU:C:2013:490, para 58; C–352/13 *Cartel Damage Claims (CDC) Hydrogen Peroxide SA v Evonik Degussa GmbH and Others* [2015] ECLI: EU:C:2015:335, paras 35–36; Case C–498/16 *Maximilian Schrems v Facebook Ireland Limited* [2018] ECLI:EU:C:2018:37, para 48. Several scholars consider the topic of jurisdiction over collective redress proceedings as one of the key aspects in respect of which the Commission should propose amendments to the Brussels I-bis Regulation; eg Burkhard Hess and others, 'The Reform of the Brussels Ibis Regulation' (2022) 6 MPILux Research Paper Series 1; Rielaender (n 54) 110.

4.3. Conflict of laws

The aforementioned instruments of EU law only address limited aspects of the several substantive legal issues relating to product liability in the context of eHealth products and devices. To the extent that uniform substantive rules had not been established at EU and international level, national courts of the EU Member States will have to solve conflicts between national product liability regimes primarily by reference to the general instruments of EU private international law, and most notably by reference to the Council Regulation (CE) 864/2007 of 11 July 2007 on the law applicable to non-contractual obligations (Rome II Regulation)[58]. Unlike the Brussels I-bis, the Rome II Regulation includes some provisions specifically applicable to matters of product liability (art 5). Based on the *lex specialis* principle, the specific conflict-of-law rules enshrined in art 5 supplants the Rome II Regulation's general conflict-of-law rule according to which the law applicable to non-contractual obligations is the law of the place where the damage occurs (art 4(1)). The conflict-of-law rules enshrined in art 5 are underlined by the 'objectives of fairly spreading the risks inherent in a modern high-technology society, protecting consumers' health, stimulating innovation, securing undistorted competition and facilitating trade.'[59] To strike a fair balance between these objectives, art 5(1) provides for a 'cascade systems connecting factors, together with a foreseeability clause.'[60] The conflict-of-law rules enshrined in art 5(1) only applies if the parties to the dispute have their habitual residence in different countries.[61] The *lex causae* identified by reference to the connecting factors under art 5(1) may exceptionally be displaced by the law of another country with which the relevant tort is manifestly more closely connected in the light of all the circumstances of the specific case (art 5(3)). The cascade of connecting factors identified in art 5(1) is largely built upon the criterion of the 'marketing' of the product.[62] First of all, the law of the allegedly injured person's habitual residence applies if the product was marketed in that country. If the injured person does not have his or her habitual residence

58 [2007] OJ L 199/40. See Paola Ivaldi, 'Civil Liability for Health Damages and Uniform Rules of Private International Law' (2017) 53 Rivista di diritto internazionale privato e processuale 857. Some EU Member States (France, Spain, Croatia, Slovenia, Finland, the Netherlands and Luxembourg) have ratified the Convention of 2 October 1973 on the Law Applicable to Products Liability of 2 October 1973 (entered into force 1 October 1977) (Hague Products Liability Convention). Under art 28(1) Rome II, this Convention takes precedence over the Rome II Regulation; Piotr Machnikowski 'Art 5 - Chapter II: Torts/Delicts' in Ulrich Magnus and Peter Mankowsky (eds), *Volume 3 Rome II Regulation – Commentary* (Verlag Dr. Otto Schmidt 2019) 212.

59 ibid recital n 20, first sentence.

60 If the parties habitually reside in the same country, the law of the parties' common habitual residence applies (art 4(2).

61 Art 5 Rome II Regulation applies 'without prejudice to Article 4(2)' thereof; ibid art 5(1).

62 Piotr Machnikowski (n 58) 218.

within the country where the product was marketed, the law of the country of 'marketing' applies when the product was acquired in that country (art 5(1)(b)), or failing that, the damage occurred in that country (art 5(1)(c)). In any event, the law applicable on the basis of art 5(1)(a)–(c) is displaced by the law of the country where the alleged tortfeasor habitually resides if he or she could not reasonably foresee the circulation of the product in either of the countries mentioned under letters (a)–(c) (art 5(1)2). The applicable law will determine the basis and the extent of liability, the level of compensation and the nature and the assessment of the damage.

5. Health professional's liability

5.1. Harmonised substantive rules

As already anticipated, the harm suffered by patients could derive from a misconduct of health professionals or from more structural and organizational deficiencies in healthcare facilities. Accordingly, for the purpose of the present paper, the very concept 'health professional's liability' should be understood widely as to encompass the liability arising from 'medical treatment', that in turn encompasses all health measures aimed at improving the patient's health conditions. As such, health professional's liability encompasses the liability arising from both health professionals' misconducts (eg wrongful diagnosis and/or operative errors in practicing the relevant treatment) and from more structural and organizational deficiencies of the healthcare facilities (eg shortages of medical staff and/or inadequate organizational choices).

The health professional's civil liability arising from health treatments provided through telemedicine and eHealth devices raises delicate and complex substantive legal issues in a cross-border context. Typical substantive legal issues which could arise include issues about apportionment of liability between the health professionals and the producers of telematic devices/services (eg failure of the health treatment because of the device' loss of connectivity), the extent of health professionals' discretion in choosing between a conventional treatment or a treatment based on ICTs devices (eg health professional's choice of resorting to telemedicine in a situation where it would have been more appropriate to resort to conventional medicine or vice versa), issues about the type and the extent of fault required for establishing the health professional's liability and whether or not reliance on telemedicine should require different insurance regimes than those applicable to conventional medicine.

The Directive on cross-border healthcare contains some helpful provisions, albeit clearly not solving all substantive legal issues that could arise in connection with the cross-border provision of telemedicine services. The Directive

lays down certain obligations for the Member State where the health treatment is provided (the 'Member State of treatment'). As far as conventional medicine is concerned, the 'Member State of treatment' is the Member State on whose territory healthcare is provided to the patient (art 3(1)(d), first sentence). As regard telemedicine, the Directive provides that 'healthcare is considered to be provided in the Member State where the healthcare provider is established' (art 3(1)(d), second sentence). As such, with respect to telemedicine services the Directive seems to establish a legal fiction according to which the patient should be treated as if he or she has moved from the territory of the Member State where the treatment was actually provided to the Member State of establishment of the healthcare's provider. The Directive provides that, 'taking into account the principles of universality, access to good quality care, equity and solidarity, cross-border healthcare shall be provided in accordance with: (a) the legislation of the Member State of treatment; (b) standards and guidelines on quality and safety laid down by the Member State of treatment; and (c) Union legislation on safety standards' (art 4(1)).[63] The Directive then specifies that the Member State of treatment shall ensure that 'healthcare providers provide relevant information to help individual patients to make an informed choice, including on treatment options, on the availability, quality and safety of the healthcare they provide in the Member State of treatment and that they also provide clear invoices and clear information (…) on their insurance cover or other means of personal or collective protection with regard to professional liability'; that 'there are transparent complaints procedures and mechanisms in place for patients, in order for them to seek remedies in accordance with the legislation of the Member State of treatment if they suffer harm arising from the healthcare they receive' and that 'systems of professional liability insurance, or a guarantee or similar arrangement that is equivalent or essentially comparable as regards its purpose and which is appropriate to the nature and the extent of the risk, are in place for treatment provided on its territory' (art 4(2)(b)–(d)). Patients should receive from the national contact point of the Member

63 Recital n 49 further reads that: 'when a patient receives cross-border healthcare, it is essential for the patient to know in advance which rules will be applicable. The rules applicable to cross-border healthcare should be those set out in the legislation of the Member State of treatment, given that, in accordance with art 168(7) TFEU, the organisation and delivery of health services and medical care is the responsibility of the Member States. This should help the patient in making an informed choice, and should avoid misapprehension and misunderstanding. It should also establish a high level of trust between the patient and the healthcare provider.' It should be pointed out, though, that the rules on the free provision of services contained in Directive 2005/36/EC of 7 September 2005 on the recognition of professional qualifications do not apply if the patient does not move to another Member State than that of his or her habitual residence to receive the healthcare service. As made clear by art 5(2), in fact, the Directive on the recognition of professional qualifications 'shall only apply where the service provider moves to the territory of the host Member State to pursue, on a temporary and occasional basis, the profession'.

State of treatment, upon request, a) relevant information on the standards and guidelines on quality and safety laid down by the Member State of treatment, 'including provisions on supervision and assessment of healthcare providers, information on which healthcare providers are subject to these standards'; b) 'relevant information to help individual patients to make an informed choice, including on treatment options, on the availability, quality and safety of the healthcare they provide in the Member State of treatment and … clear information on prices, … insurance … or other means of personal or collective protection with regard to professional liability' (art 4(2)(a)–(b)). Failure to provide such information could also have a role in establishing the liability of actors involved in the provision of cross-border healthcare services.[64]

Intermediary healthcare service providers are subject to the provisions of the eCommerce Directive establishing a gradual liability scheme for intermediaries of information society services (arts 12–15). Patients may indeed have an interest in suing intermediary healthcare service providers, rather than persons or entities directly responsible for making available certain contents or information on a given Internet-based device (eg producers or designers). Thus, for instance, when the harm suffered by the patient is due to the loss of online connectivity of the relevant telemedicine device, liability for such harm could also lie upon the competent Internet service provider and not only upon the relevant producer or designer of the relevant Internet-based telemedicine devices.

Nevertheless, the protective provisions set forth in the Directive on Consumer Rights 2011/83/EC[65] are not applicable to patients of healthcare services. Indeed, the Directive explicitly excludes contracts for the provision of healthcare services from its scope of application (art 3(3)(b))[66] on the ground that 'healthcare requires special regulations because of its technical complexity, its importance as a service of general interest as well as its extensive public funding' (recital 30).

5.2. Conflicts of jurisdiction

Matters of international jurisdiction are not specifically dealt with by both the Directive on cross-border healthcare and the eCommerce Directive. On one hand, the Directive on cross-border healthcare applies 'without prejudice to (…) Union rules on private international law, in particular rules related to court jurisdiction' (art 2(q)). On the other hand, in the same vein, the eCommerce

64 Commission (n 24), 20–21.

65 Directive 2011/83/EU of the European Parliament and of the Council of 25 October 2011 on consumer rights, amending Council Directive 93/13/EEC and Directive 1999/44/EC of the European Parliament and of the Council and repealing Council Directive 85/577/EEC and Directive 97/7/EC of the European Parliament and of the Council [2011] OJ L 304/64.

66 A similar exclusion, though, cannot be found in the Council Directive 93/13/EEC of 5 April 1993 on unfair terms in consumer contracts [1993] OJ L 95/29.

Directive 'does not establish additional rules on private international law nor does it deal with the jurisdiction of Courts' (art 1(4) and recital 23). Accordingly, international jurisdiction over civil claims arising out of health professionals' liability in the context of telemedicine should, once again, be determined by reference to the Brussels I-bis Regulation.

With the view of providing guidance on how the Brussels I-bis Regulation should apply to those claims, the European Commission draws a distinction between three different scenarios involving the cross-border provision of telemedicine services.[67] In all three scenarios claimants may generally avail themselves of jurisdiction at the general forum of defendant's domicile (art 4 Brussels I-bis) as well as of the jurisdiction of courts identified through a choice-of-court agreements eventually concluded with the other party (art 25). Besides these fora, the applicable grounds of jurisdiction under the Brussels I-bis Regulation will depend on the nature of the legal relationship existing between the relevant parties to the dispute. The first scenario identified by the Commission relates to situations where cross-border telemedicine involves health professionals/physicians and other eHealth providers only (ie professional-to-professional relationships). In this scenario, the claimant may avail himself or herself of the *forum contractus* (art 7(1)(b)), so that he or she will be able to bring proceedings before the court of the place where, under the contract, the services were provided or should have been provided.[68] The second scenario relates to legal relationships between healthcare professionals and patients (professional-to-patient relationships). According to the Commission, the patient, to the extent the professional's activity is directed to the Member State of the patient's domicile, may avail himself or herself of jurisdiction of the courts of the Member State of his or her domicile pursuant to protective rules on jurisdiction applicable to consumer contracts (art 18(1)).[69] If the professional does not 'direct' its activities to the patient's domicile pursuant to the ECJ case law,[70] the patient may avail himself or herself of the jurisdiction of

67 Commission (n 24), 24ff.

68 ibid 25.

69 ibid.

70 ibid, the European Commission (ibid) makes reference to the 'targeting' test relied upon by the ECJ in *Pammer and Alpenhof* for establishing whether the trader has 'directed' its activity to the consumer's domicile pursuant to art 17(1)(c) Brussels I-bis, as a precondition for triggering the application of the rules on jurisdiction for the protection of consumers under art 18–19 Brussels I-bis; Joined Cases C–585/08 and C–144/09 *Peter Pammer v Reederei Karl Schlüter GmbH & Co. KG and Hotel Alpenhof GesmbH v Oliver Heller* [2010] ECR 2010 I-12527, paras 80-94. According to the ECJ, attention should be given to a non-exhaustive list of factors, such as 'the international nature of the activity, mention of itineraries from other Member States for going to the place where the trader is established, use of a language or a currency other than the language or currency generally used in the Member State in which the trader is established with the possibility of making and confirming the reservation in that other language, mention of telephone numbers with an international code, outlay of expenditure

the competent court pursuant to the *forum contractus* (art 7(1)(b)).[71] The third and last scenario considered by the Commission is the legal relationship between a patient and a specialist consulted by the reference professional (who, for example, for a more accurate interpretation, sends him the images on the basis of a teleradiology services contractual relationship between the hospitals to which they belong). In this situation the patient may avail himself or herself of the *forum delicti* (art 7(2)). According to the Commission, the place where the event giving rise to the damage occurred (*forum actus*) should be localized in the Member State where the professional is located when delivering the service, whereas the place where the damage occurred (*forum damni*) shall be located in the Member State where the patient was located when he received the medical advice or treatment.[72]

In some parts the reconstruction made by the Commission might not be entirely convincing and its solidity could be questioned. First of all, such a reconstruction is based on the undemonstrated assumption that the relationship between the patient and the healthcare professional is to be generally characterized as 'contractual' in nature. Yet, comparative legal analysis would not so decisively point towards a 'contractual' characterization of such a relationship. For instance, the German legal system, whose main focus had traditionally been centered over the patient's absolute right to physical integrity and life, tends

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on an internet referencing service in order to facilitate access to the trader's site or that of its intermediary by consumers domiciled in other Member States, use of a top-level domain name other than that of the Member State in which the trader is established, and mention of an international clientele composed of customers domiciled in various Member States'. On the other, the ECJ stressed that the 'mere accessibility of the trader's or the intermediary's website in the Member State in which the consumer is domiciled is insufficient.' In literature, 'targeting' tests, such as the one established by the ECJ in *Pammer*, are very often regarded as rather viable solutions for geographically localizing (ubiquitous and borderless) digital and Internet-based activities; eg Tobias Lutzi, *Private International Law Online. Internet Regulation and Civil Liability in the EU* (OUP 2020) 145–147. For the time being, the ECJ has limited the scope of such a 'targeting' test only to the Brussels I-bis' jurisdictional provisions for consumers' protection and has largely refused to rely on it under other grounds of jurisdiction that often comes into play in respect to Internet-based activities, most notably the *forum delicti* under art 7(2); eg Case C–170/12 *Peter Pinckney v KDG Mediatech AG* [2013] ECLI:EU:C:2013:635, para 42; Case C–251/20 *Gtflix Tv v DR* [2021] ECLI:EU:C:2021:1036, paras 41–42. The ECJ justifies the rejection of 'targeting' under art 7(2) on the basis of the textual argument that this latter provision, differently than art 17(1)(c), does not require the defendant's activity to be 'directed' towards the competent forum. However, the reason of such a rejection is probably to be found in the difficult conciliation between the flexibility characterizing 'targeting' tests and the consolidated principle in the ECJ case law that the grounds of jurisdiction under the Brussels I regime should be highly predictable for the parties to the dispute and promptly applicable by Member States' courts; Edina Márton, *Violations of Personality Rights through the Internet: Jurisdictional Issues under European Law* (Nomos 2016) 251; cf Dan Jerker B. Svantesson, *Solving the Internet Jurisdiction Puzzle* (OUP 2017) 81–82.

71 Commission (n 24), 25.

72 ibid.

to position professional-to-patient relationships within the boundaries of the *Deliktmaterie*. In any event, it should also be emphasized that professional-to-patient relationships are increasingly mediated by healthcare institutions and infrastructures (either public or private), so that a contractual relationship could eventually be deemed to exist, if at all, between the patient and the healthcare institution, rather than between patient and professional practicing within such an institution. Similarly to the German legal system, also the Italian legal system, albeit slightly less markedly, points in the direction of characterizing professional-to-patient relationships as 'non-contractual' in nature. In more recent times, that system has to some extent moved towards a 'contractualization' of medical liability. This is especially the case for relationships involving patients and self-employed physicians, on one hand, and relationships involving patients and healthcare institutions acting as employers of the relevant physicians, on the other hand. Yet, also under the Italian legal system, the 'non-contractual' characterization of medical liability persists as regard relationships between patients and physicians acting as employees of healthcare institutions. Regardless of the foregoing, admittedly, it seems hardly feasible to identify a common ground among different EU Member States about the contours of medical liability and its characterization as 'contractual' or 'non-contractual'. For drawing the line between 'contractual' and 'non-contractual' matters within the general instruments of EU private international law, the ECJ qualifies as 'contractual' any 'legal obligation freely consented to by one person towards another' and defines 'non-contractual' matters negatively and residually as encompassing 'all actions which seek to establish the liability of a defendant and are not related to a contract'.[73] On this basis, the ECJ case law generally suggests a preference for the 'contractual' characterization.[74] However, the ECJ has not yet been specifically faced with issues relating to the characterization of medical liability, nor any clear guidance on this issue may be inferred from its general case law. Even if it is to be assumed that medical liability should be characterized as 'contractual' in nature from the perspective of EU private international law - a solution

73 Under the Brussels I regime see, seminally, Case C–26/91 *Jakob Handte & Co. GmbH v Traitements Mécano-chimiques des Surfaces SA* [1992] ECR 1992 I-3967, para 15; Case C–189/87 *Athanasios Kalfelis v Bankhaus Schröder, Münchmeyer, Hengst and Co. and others* [1988] ECR 1988 05565, para 18. Under the Rome I and II regulations see, eg Joined Cases C–359/14 and C–475/14 *'ERGO Insurance' SE v 'If P&C Insurance' AS and 'Gjensidige Baltic' AS v 'ZU Lietuva' UAB DK* [2016] ECLI:EU:C:2016:40, paras 42–46. In literature: Alfonso-Luis Calvo Caracava and Javier Carrascosa González, 'Art 1 - Chapter I: Scope' in Ulrich Magnus and Peter Mankowsky (eds), *Volume 2 Rome I Regulation – Commentary* (Verlag Dr. Otto Schmidt 2016) 62–72; Peter Mankowsky, 'Art 1 - Chapter I: Scope' in Ulrich Magnus and Peter Mankowsky (eds), *Volume 3 Rome II Regulation – Commentary* (Verlag Dr. Otto Schmidt 2019) 69–90; Marta Requejo Isidro, Edith Wagner and Matteo Gargantini, 'Art 7' in Marta Requejo Isidro (ed), *Brussels I Bis: A Commentary on Regulation (EU) No 1215/2012* (Edward Elgar Publishing 2022) 94–103 and 112–115.

74 ibid, see also Burkhard Hess, *Europäisches Zivilprozessrecht* (De Gruyter 2021) 6.55.

that may be questioned from a comparative assessment of the EU Member States' legal systems - further doubts may arise as regard to the characterization of the contract for the provision of healthcare services as a 'consumer' contract. The outright solution of characterizing patients as a 'consumers' pursuant to Brussels I-bis Regulation, as pointed out to by the Commission, might be deemed hardly reconcilable with the contextual approach followed by the ECJ in this respect[75]. Moreover, the solution of characterizing contracts for the provision of healthcare services as 'consumer' contracts could also be questioned in the light of the EU's legislator choice under Directive on Consumer Rights 2011/83/EC to exclude contracts for the provision of healthcare services from its scope of application because of the specificities of the healthcare sector.

As for the figure of the doctor consulted, it is not excluded that it could be equated to the auxiliary, so that the structure/consultant doctor would be liable for any damage. Finally, we cannot ignore the need – felt in many States – to curb the excess of responsibility to which the medical profession is exposed, while at the same time contrasting the excess of defensive medicine practices.[76] In fact, an increasing number of systems (including France[77] and Belgium[78]) envisage alternative social security systems which – as already the defective products Directive – disregard the ascertainment of non-fulfillment or fault (so-called no-fault systems), favor the compensatory function of the damage (to the detriment of the deterrent one) and are characterised by quantitatively lower refreshments.

5.3. Conflict of laws

In the absence of a uniform substantive regulation of health professionals' liability at EU and international level, conflict of laws matters will to a large extent have to be solved again by reference to the general instruments of EU private international law. On one hand, the Directive on cross-border healthcare applies 'without prejudice to (…) Union rules on private international law (…)' (art 2(q)). On the other, the eCommerce Directive does not establish additional private international law rules but simply requires the Member States to ensure that, within eCommerce Directive's 'coordinated field', providers of

75 eg Stephanie Law, 'Art 17' in Marta Requejo Isidro (ed), *Brussels I Bis: A Commentary on Regulation (EU) No 1215/2012* (Edward Elgar Publishing 2022) 253–267.

76 The concept of defensive medicine refers to all health services provided by doctors to prevent the risk of legal complaints by patients (or their relatives) for malpractice. Hypothetically including all the clinical activities (superfluous visits and/or tests) that doctors carry out for fear of legal disputes beyond the standard treatments suggested by their professional skills, the additional services induced by defensive medicine tend to generate an artificial increase of health care costs.

77 *Loi* relative aux droits des malades et à la qualité du système de santé, n° 2002-303 4 mars 2002.

78 *Loi* relative à l'indemnisation des dommages résultant de soins de santé, 31 mars 2010.

ISS are not 'made subject to stricter requirements than those provided for by the substantive law in force in the Member State in which the service provider is established.'[79]

According to the Commission,[80] in contractual relationships between healthcare professionals (professional-to-professional relationships) the applicable law may be identified through a choice-of-law agreement entered by the parties (art 3 Rome I Regulation). Failing that, the law of the Member State where the service provider has his or her habitual residence will apply (art 4 (1)(b)), intended as his or her principal place of business (art 19 (1)).

The Commission does not mention it, but it could also be thought of using the exception clause by invoking the ubiquity of the e-Health service and the closest connection with the patient's country of residence:[81] this solution would make it possible to avoid possible conflicts of the law of the place of business of the service provider with the law of the patient's habitual residence, and to have to verify the presence of mandatory rules in this last law, pursuant to art 9 (such as, for example, rules that prohibit the provision of certain services exclusively by telemedicine, in the diagnosis and/or treatment phase, with the consequence that the provision of those services would be unlawful pursuant to art 9(3)).

On the other hand, in the case of a relationship between doctor and patient, the Commission considers the protective rules for consumers applicable under art 6 Rome I Regulation which recalls the law of the country where the consumer has his habitual residence (art 6(1) Rome I Regulation), however leaving the parties the possibility to choose the applicable law, provided that such a choice hasn't the result of depriving the consumer of the protection afforded

79 Joined Cases C–509/09 and C–161/10 *eDate Advertising GmbH and Others v X and Société MGN LIMITED* [2011] ECR 2011 I-10269, para 67. Ever since *eDate and Martinez* (ibid paras 53–68), the ECJ made clear that the so-called 'country of origin' or 'internal market' principle enshrined in art 3 eCommerce Directive, although not laying down a conflict-of-law rule, limits the reach of the applicable law determined by the pertinent conflict-of-law rules of the EU Member States. In other words, the 'country of origin' principle operates as a substantive corrective requiring the Member States not impose upon ISS providers, by virtue of the law deemed applicable pursuant to the relevant conflict-of-law rules, more stringent regulatory standards than those provided for by the law of the Member State of establishment of the ISS. This substantive corrective applies within the eCommerce Directive's 'coordinated field' (art 2(h)), that clearly encompasses the rules on civil liability; in literature eg Tobias Lutzi, 'Internet Cases in EU Private International Law – Developing a Coherent Approach' (2017) 66 ICLQ 689; Tobias Lutzi (n 70) 21; Pedro De Miguel Asensio, *Conflict of Laws and the Internet* (Edward Elgar Publishing 2021) 74–78.

80 Commission (n 24), 26ff.

81 Thus Jan D. Lüttringhaus (n 27) 323, which recalls the US practice based on the method of the 'most significant relationship'; see Megan Cloud, 'Robots Are Coming: A Discussion of Choice-of-Law Issues and Outcomes in Telesurgical Malpractice' (2019) 6 Texas A&M L R 707.

to him by provisions that cannot be derogated from by agreement by virtue of the law of the country where the consumer has his habitual residence (art 6(2) Rome I Regulation). However, if the healthcare professional does not direct his activities to the Member State where the patient has his habitual residence, the general rules that recall the law chosen by the parties are applicable (on the basis of art 6(3)) or, failing that, the law of the country where the trader has his principal place of business (arts 3 and 4(1)(b)).

Finally, in a non-contractual relationship, unless the parties have chosen the applicable law (according to art 14 Rome II Regulation), the law of the country in which the damage occurs – irrespective of the country in which the event rise giving to the damage occurred, and of the country in which the indirect consequences of that event occur – is applicable (art 4(1)): '(h)owever, where the person claimed to be liable and the person sustaining damage both have their habitual residence in the same country at the time when the damage occurs, the law of that country shall apply' (art 4 (2)). It should be noted that art 17 ('Rules of safety and conduct') paves the way for the application of the good professional standards[82] of the place where the eHealth provider operates (*lex loci damni*). Finally, the scope of the applicable insurance contract or of the insurance regime with regard to cross-border situations will come into play.

The Commission does not mention the possible intervention of overriding mandatory rules of the forum (arts 9 Rome I and 16 Rome II Regulations),[83] of rules of safety and conduct in force at the place of the event giving rise to the liability (art 17 Rome II) and of public policy exception (arts 21 Rome I and 26 Rome II Regulations). But above all the Commission solves the question scholastically, neglecting the problems of qualification already pointed out with regard to jurisdiction. Regulations Rome I and II also do not solve the problem of the combination of both contractual and non-contractual liability. In this regard, in my opinion, the secondary connection envisaged by art 4(3) Rome II, which – after providing for the exceptional application of the law of the country with which, from all the circumstances of the case, the tort/delict is manifestly more closely connected – specifies that '(a) manifestly closer connection with another country might be based in particular on a pre-existing relationship between the parties, such as a contract, that is closely connected with the tort/delict in question'. This solution is particularly interesting for Member States whose legal system allows both contractual and non-contractual obligations

82 Art 4 Oviedo Convention (n 27): 'Any intervention in the health field (…) must be carried out in accordance with relevant professional obligations and standards.'

83 On the possible relevance of the prohibition of remote processing provided for by the rules of the Medical Order, as overriding mandatory provisions under art 9 Rome I Regulation and/or rules of safety and conduct under art 17 Rome II Regulation, see – with reference to Germany – Andreas Spickhoff, 'Rechtsfragen der grenzüberschreitenden Fernbehandlung' (2018) 36 Medizinrecht 535.

between the same parties. 'By having the same law apply to all their relationships, this solution respects the parties' legitimate expectations and meets the need for sound administration of justice. On a more technical level, it means that the consequences of the fact that one and the same relationship may be covered by the law of contract in one Member State and the law of tort/delict in another can be mitigated'.[84] Thus, the non-contractual liability of healthcare professionals could be absorbed by the *lex contractus*, which would thus govern both contractual and non-contractual liability.

6. Concluding remarks

Telemedicine and eHealth services raise a wide range of complex substantive legal issues. These complexities are further exacerbated by the ever-changing shape of the digital environment, last but not least in the light of the rapid spread of AI-based systems and related technologies. The challenging regulatory choices needed to adequately cope with the digital transformation of the healthcare sector become tremendously more pronounced when the provision of healthcare services based on ICTs bridges national borders. Private international law is generally understood as a discipline aimed at enabling the interoperability of diverse (unharmonised) legal orders. In recent years the EU legislator has undoubtedly presented itself as a particularly active player in harmonising the Member States' substantive regimes on civil liability, last but not least in the light of 2024 package of rules aimed at adapting liability rules to the AI-based digital ecosystems. Yet, the path of deepening substantive harmonisation is deeply unlikely to result in complete EU-wide standardisation of national civil law regimes, primarily because of structural limitations of the EU legal order. Against this background and despite their technologically neutral approach, the general instruments of EU private international law have, for the time being, proved to be rather resilient and relatively fit for accommodating diverse legal orders in the digital age. Yet, their interaction with cross-border telemedicine and eHealth services remains to some extent complex and uncertain, last but not least in the light of the uncertain characterization of medical liability. If the widespread deployment of eHealth is truly meant to be achieved within the EU, consistently with the position seminally expressed by the European Commission back in the 2010 Digital Agenda for Europe, private international law issues of eHealth should not be neglected. Quite on the contrary, delivering sound guidance on how the general instruments of EU private international are meant to govern cross-border eHealth services should remain a critical priority

84 Commission, 'Proposal for a Regulation of the European Parliament and the Council on the law applicable to non-contractual obligations ("Rome II")' (Communication) COM (2003) 427 final, sub art 3 'General exception and secondary connection'.

to achieve interoperability of eHealth in Europe to the benefit of EU citizens, the EU Member States' healthcare sectors and medical research.