EUROPEAN UNION GLOBAL HEALTH LAW.

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INDEX

CHAPTER 1. INTRODUCTION

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European Union Global Health Law

The concept 'EU global health law' has strong links with existing branches of law, such as 'health law', EU law, and the recent debate on international or global health law. Each with its own set of rules unique for that particular area. For instance, medical law is centered on the horizontal physician-patient relationship,[1] whereas gradually, the term 'health law' or even called 'health care law' became more common in western countries. Health law, as called hereafter, has however a broader scope: the scope of research is the triangular relationship of doctor-patient-financier.[2] Contemporary dilemmas in health care cannot ignore the role of the financier or purchaser of health care. For instance, the ongoing debate on health care rationing, i.e. denial of health care services due to financial constraints cannot be solved without understanding the role of the health insurance fund or National Health Service financing health care. Here, the leading principle is considered the right to health care, understood as a fundamental human right defining and explaining mutual relationships (patient-physician, patient-financier, and physician-financier). At the same time, it is recognised that this triangular relationship has been influenced by other actors, such as local, regional, national and even supranational entities as the EU, Council of Europe, and United Nations. Though that is not different from other branches of law, such as civil law, business law, and environmental law, and therefore excluded from the subject of health law.[3]

The notion of EU health law reflects a range of sub-areas in health care influenced by EU law (treaties, legislation and the jurisprudence of the Court of Justice of the EU), whether it concerns public health (Article 168 Treaty on the Functioning of the European Union, TFEU), the mobility of patients,[4] professionals[5] and products (pharmaceuticals[6]), competition law capable of interfering with the organisation of health care systems (Articles 101-108 TFEU), health data protection,[7] and patients' rights (human integrity, private life, non-discrimination, and equal access to health care),[8] and simultaneously, respecting national competences for national health systems. EU health law emphasizes the EU's role at

[1] I. Kennedy and A. Grubb, *Medical law: Text and Materials* (London Butterworths 1994), p. 3.
[2] See, e.g., M. Buijsen, Human Dignity and the Concept of Health Law, in A. den Exter (ed.) European Health Law (Maklu Press Antwerp, 2017), p. 17-18, J Montgomery Health Care Law, OUP 1997, p. 1-4.
[3] Buijsen (note 5) 18.
[4] Under the Cross-border Care Directive (Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare OJ L 88/45, 4.4.2011).
[5] Directive 2005/36 /EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications [2005] OJ L 255/22.
[6] E.g., D. Matthews and C. Wilson, Pharmaceutical regulation in the Single European Market, Med and Law (1997) 401-428; A. den Exter, the Pharmaceutical Sector Inquiry: Hamlet in a Nutshell, EJHL 2 (2010) 125-138.
[7] General Data Protection Regulation, Regulation (GDPR), 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), OJ L 119 4 May 2016 p. 1.
[8] Under the EU Charter of Fundamental Rights.

improving health and is characterised by its fragmented and thus incomplete approach.[9] Still, its gradually increased competences in the field of health care, directly and indirectly, justify the term 'EU health law'.[10]

As EU health law addresses the *internal* dimension, i.e. the influence of the internal market on national health systems, EU global health law approaches the *external* dimension of EU law on health issues.[11] The EU as a global actor negotiates bilateral trade agreements with so-called third countries, including health exceptions to improve health. In addition, the EU collaborates with UN based and regional organisations, such as World Intellectual Property Organization (WIPO) to facilitate access to key medicines patents, the WHO in the field of the International Health Regulations (IHL 2005), and the Council of Europe on human rights in health care issues (privacy, non-discrimination, quality of care, etc.). Also at non-state level, the EU collaborates with multinational corporations (e.g., pharmaceutical sector) and NGOs on facilitating research and funding global health initiatives, etc. EU global health law therefore examines the legal role of the EU in global health issues, covering several areas: international trade, public health security and health threats, international migration and development aid (support developing health systems, universal coverage, HIV/AIDS, preventing a "brain drain"), and the role of transnational corporations in improving health. Essentially, EU global health law is then a response to trade, health (security) threats, mobility, and new understanding of the role of transnational corporations and human rights.

The following contributions focus on a variety of global health law topics, aimed to increase further understanding of this (sub)branch of health law. The following papers are clustered around several themes: introducing the concept of EU global health law; global health and human rights; Access to Medicines; Access to Reproductive Technologies; Public Health; Social Health Insurance, and Professional Mobility

The research outcomes were presented and discussed at numerous international conferences and seminars, as well as shared with students in various European countries. The European Commission's grant facilitated visiting these meetings and acting as a guest lecturer in various European countries (Austria, Italy, Portugal, Spain, and Ukraine). A number of these presentations are included as annexes.

[9] Extensively being discussed in T Hervey and J. McHale, European Union Health Law. Themes and Implications, CUP 2015, ch. 3; p. 70.

[10] As illustrated by A. den Exter and T Hervey, *EU Health Law: treaties and legislation* (Maklu Press Antwerp 2012)

[11] At the same time, it is recognised that both the external and internal dimensions interact, therefore, EU global health law may influence EU internal health law and reverse. For instance, IHR rules have been transformed into EU law. Reserve, internal market rules have been 'exported' to reduce the spread of communicable diseases (hereafter). Hervey and McHale (note 12): "extraterritorial impact of the EU's internal market rules" (p. 531-2).

PART ONE Understanding EU Global Health Law

CHAPTER 1. EU Global Health Law

Summary
The European Union is an important player in global health issues. This paper firstly explains the concept of EU global health law and then examines a number of areas where the EU acts and may influence, directly or indirectly, global health issues. It is argued that further understanding of the effects of this emerging branch of EU law may contribute to the underlying aim: contributing to the improvement of global health.
Keywords: EU global health law; international trade; public health security and health threats; health workers' migration

1. Introduction

Inherent to major health threats such as HIV/AIDS, SARS and Ebola is that they do not respect national and regional borders, and may spread globally. International co-operation among national states and supranational organisations is therefore crucial to resolving public health problems. Traditionally, the World Health Organization (WHO) is the leading actor involved in global health operations, aiming at isolating risk factors and preventing the border-crossing spread of infectious diseases. Its main instrument is the new set of International Health Regulations (2005), which aims to offer protection against a wide range of public health threats.
But the WHO is not the only player in global health issues. In 2010, the European Union (EU) acknowledged its role as a global health actor by publishing its communication on 'The EU role in Global Health'.[12] This Communication presented an EU vision on global health, defined the guiding principles that should apply to all relevant policy sectors and presented a number of areas where the EU could act more effectively. In line with the WHO approach, the Commission documents confirm that 'public health policies need to go beyond the national level and require strong global institutions and co-ordinated efforts'.[13]
The EU as a global partner in health raises several questions, such as: what exactly is the role of the EU in global health, what are the global health activities or mechanisms, and what is the legal basis for such interventions? But also, how successful is it in improving global health? These questions trigger a more fundamental debate on an emerging field or branch of law: the concept of European Union global health law. What does it mean, and what are the legal implications of such a relatively new branch of law at Union level? Instead of analysing the 'success rate' in improving global health, which involves disciplines other than law, this paper will provide clarity on such a novel concept of law and will examine the

[12] European Commission. Communication from the Commission to the Council , the European Parliament, the European Economic and Social Committee and the Committee of the Regions 'the EU Role in Global Health', Brussels, 31.3.2010, COM(2010)128 final. The Communication is accompanied by Commission staff working documents dealing with respectively: 'Global health – responding tot he challenges of globalisation SEC(2010) 380 final; 'European research and knowledge for global health 'SEC(210) 381 final; and 'Contributing to universal coverage of health services through development policy' SEC(2010) 382 final.
[13] Communication, p.2.

role of the EU in global health, to increase understanding of the underlying principles and body of rules relating to global health.

2. What is EU global health law?

The concept 'EU global health law' has strong links with existing branches of law, such as 'health law', EU law, and the recent debate on international or global health law, each with its own set of rules unique to that particular area. For instance, medical law is centred on the horizontal physician/patient relationship,[14] whereas the term 'health law' or even 'health care law' has gradually become more common in western countries. However, health law, as referred to hereafter, has a broader scope: the scope of research is the triangular relationship of doctor/patient/financier.[15] Contemporary dilemmas in health care cannot ignore the role of the financier or purchaser of health care. For instance, the ongoing debate on health care rationing, i.e. denial of health care services due to financial constraints, cannot be solved without understanding the role of the health insurance fund or National Health Service financing health care. Here, the leading principle is considered the right to health care, understood as a fundamental human right defining and explaining mutual relationships (patient/physician, patient/financier and physician/financier). At the same time, it is recognised that this triangular relationship has been influenced by other actors, such as local, regional, national and even supranational entities such as the EU, Council of Europe and the United Nations, although that is not different from other branches of law, such as civil law, business law and environmental law, and is therefore excluded from the subject of health law.[16]

The notion of EU health law reflects a range of sub-areas in health care influenced by EU law (treaties, legislation and the jurisprudence of the Court of Justice of the EU), whether it concerns public health (Article 168 Treaty on the Functioning of the European Union, TFEU), the mobility of patients,[17] professionals[18] and products (pharmaceuticals[19]), competition law capable of interfering with the organisation of health care systems (Articles 101-108 TFEU), health data protection[20] or patients' rights (human integrity, private life, non-discrimination and equal access to health care),[21] and simultaneously respecting national competencies for national health systems. EU health law emphasises the EU's role in improving health and is characterised by its fragmented and thus incomplete approach.[22] Still, its gradually

[14] I. Kennedy and A. Grubb, *Medical law: Text and Materials* (London Butterworths 1994), p. 3.
[15] See, e.g., M. Buijsen, Human Dignity and the Concept of Health Law, in A. den Exter (ed.) *European Health Law* (Maklu Press Antwerp, 2017), p. 17-18, J Montgomery Health Care Law, OUP 1997, p. 1-4.
[16] Buijsen (note 5) 18.
[17] Under the Cross-border Care Directive (Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare OJ L 88/45, 4.4.2011).
[18] Directive 2005/36 /EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications [2005] OJ L 255/22.
[19] E.g., D. Matthews and C. Wilson, Pharmaceutical regulation in the Single European Market, *Med and Law* (1997) 401-428; A. den Exter, the Pharmaceutical Sector Inquiry: Hamlet in a Nutshell, *EJHL* 2 (2010) 125-138.
[20] General Data Protection Regulation, Regulation (GDPR), 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), OJ L 119 4 May 2016 p. 1.
[21] Under the EU Charter of Fundamental Rights.
[22] Extensively being discussed in T Hervey and J. McHale, *European Union Health Law*. *Themes and Implications*, CUP 2015, ch. 3; p. 70.

increased competencies in the field of health care, directly and indirectly, justify the term 'EU health law'.[23]

Global health law focuses not upon individual patients, but on the health of different populations in the world; more specifically, protecting the health of populations and addressing global health challenges. A key element of global or international health law is therefore the border-crossing dimension, as health problems transcend national boundaries, and the need for an international approach. Global health law is historically understood to be part of international law: i.e. the set of rules explaining the relationship between nation states and international organisations such as the WHO.[24] A more modern approach to global health law, however, also recognises the role of non-state actors, such as transnational corporations (e.g., pharmaceutical companies) and non-governmental organisations influencing public health (e.g., Médicins sans Frontières and the Bill and Melinda Gates Foundation).

Global health law is aimed at the protection and promotion of a population's health and prevention of global health concerns (obesity, cardiac diseases, malnutrition, etc). In line with the broad 'health concept' – defined as 'not only the absence of infirmity and disease but also a state of physical, mental and social well-being' – one may even argue that global health provides support for the determinants of physical and mental health (e.g. nutrition, shelter, education) and even so-called 'third generation' or group rights (solidarity rights such as peace and development, etc). Such an all-inclusive approach to global health law aims to both protect global health and to improve health inequalities worldwide. In the legal doctrine, Lawrence Gostin is one of the proponents of such a broad approach, by defining global health law as: '… the study and practice of international law – both hard law (e.g. treaties that bind states) and soft instruments (e.g. codes of practice negotiated by states) – that shapes norms, processes, and institutions to attain the highest attainable standard of physical and mental health for the world's population'.[25] Ultimately, such an established international legal framework will help 'to empower the world community to advance global health, consistent with the values of social justice'.[26] By referring to the social justice dimension, Gostin is viewing global health from an all-inclusive perspective encompassing 'multiple legal regimes outside the health sector that intersect with the health sector' (e.g. food, labour, housing).[27]

Nowadays it is generally accepted that human rights are interrelated and interdependent, but Gostin's approach goes even further, i.e. *incorporating* other human rights into the health concept to strengthen and improve (community) health. Though attractive, there is the risk that such a holistic approach makes global health a hollow phrase that covers a wide range of rights. Therefore, a more pragmatic approach is limited to the subject of global health law: the protection of a population's health, irrespective of other human rights interdependencies. Excluding the social justice component, what remains is the variety of a

[23] As illustrated by A. den Exter and T Hervey, *EU Health Law: treaties and legislation* (Maklu Press Antwerp 2012).

[24] E.g., A.L. Taylor, International Law, and Public Health Policy, (2008) *Int Encyclopedia of Public Health*, pp. 667-678; B. Toebes, International health law: an emerging field of public international law, (2015) 3 *Ind J Intern Law*, 299-328.

[25] J. Gostin, *Global Health Law* (HUP, 2014) 59.

[26] Ibid, 60.

[27] ibidem.

distinct and coherent system of international legal norms, including soft law, improving the health of populations.[28]
As EU health law addresses the *internal* dimension, i.e. the influence of the internal market on national health systems, EU global health law approaches the *external* dimension of EU law on health issues.[29] The EU as a global actor negotiates bilateral trade agreements with so-called third countries, including health exceptions to improve health. In addition, the EU collaborates with UN-based and regional organisations, such as the World Intellectual Property Organization (WIPO), to facilitate access to key medicine patents, the WHO in the field of the International Health Regulations (IHL 2005) and the Council of Europe on human rights in health care issues (privacy, non-discrimination, quality of care, etc). Also at non-state level, the EU collaborates with multinational corporations (e.g. the pharmaceutical sector) and NGOs in facilitating research and funding global health initiatives, etc. EU global health law therefore examines the legal role of the EU in global health issues, covering several areas: international trade, public health security and health threats, international migration and development aid (supporting developing health systems, universal coverage, HIV/AIDS, preventing a 'brain drain') and the role of transnational corporations in improving health. Essentially, EU global health law is a response to trade, health (security) threats, mobility, and a new understanding of the role of transnational corporations and human rights.

3. EU global health law: the quest for a legal framework

With growing acknowledgement that the role of the EU in global health law is expanding, explaining the main legal instruments will help to clarify the scope and strengths of this new branch of law. In line with EU Council Conclusions 2010, the focus is on four dominant areas of EU law, explained in more detail.[30] The variety of measures and activities embodies:

3.1 External trade and global health

The EU is known as an international actor in several policy areas. The oldest form of external policy is on trade, known as the common commercial policy (CCP) under Article 207 TFEU, which allows the EU to conclude international trade agreements with the WTO and third countries worldwide. These agreements are aimed at '… harmonious development of world trade, the progressive abolition of restrictions on international trade, … and the lowering of other barriers' (Article 206). In terms of substance, such agreements primarily deal with the trade in goods and services, intellectual property rights, foreign direct investments, etc. These trade agreements were concluded in the 1970s, and some of them need to be renewed. The most controversial examples are the Transatlantic Trade and Investment Partnership (TTIP) and the EU/Canada Comprehensive Economic and Trade Agreement

[28] D.P. Fidler, Global Health Jurisprudence: A Time of Reckoning, (2008) 96 *The Georgetown Law Journal*, p. 392-412, at. 399-400.
[29] At the same time, it is recognised that both the external and internal dimensions interact, therefore, EU global health law may influence EU internal health law and reverse. For instance, IHR rules have been transformed into EU law. Reserve, internal market rules have been 'exported' to reduce the spread of communicable diseases (hereafter). Hervey and McHale (note 12): "extraterritorial impact of the EU's internal market rules" (p. 531-2).
[30] In a follow-up study other 'leftovers' such as EU development aid, the EU-WHO relationship and human rights law, will be covered, examining the effects of such policies on global health.

(CETA).[31] Whereas other international agreements can be concluded by qualified majority in the Council, an exception was included in the case of trade of services and IPRs. In these cases, due to the political sensitivity of the areas covered, unanimity voting is the norm (Art 207(4)).[32]

Governing free trade and tariffs, these agreements apply to medicines, medical devices, food products, sanitary measures, services, IPRs and dispute settlement. For instance, the EU/Singapore trade agreement (SSFTA) aims – amongst other points – to eliminate non-tariffs barriers in the fields of pharmaceuticals and medical devices, and, simultaneously, 'promote … timely access to safe and effective pharmaceutical products and medical devices'.[33] Therefore, it will open up the pharmaceutical market while allowing general exceptions as under the GATT regime (public health). In addition, the agreement follows the safety measures set out under the Sanitary and Phytosanitary (SPS) agreement, allowing restrictive measures necessary to protect health.[34] Trade liberalisation of (health) services and electronic commerce is another key area regulated under the agreement (Chapter 8), allowing the transnational supply of (electronic) health services in line with national requirements.[35] For instance, hospital providers in EU Member States may therefore outsource diagnostic test services to laboratories located in Singapore.[36] Alternatively, an EU-based medical specialist can be invited for a tele-consultation by his/her colleague in Singapore. In this way, the options are endless, taking into account national standards concerning safety requirements, professional requirements, data protection rules, etc.[37]

Apart from the exchange of health professional services, this cross-border modality also addresses patients, i.e. patients in search of health care (online) services, in both the EU and Singapore. In this respect, the EU Directive on patients' rights and cross-border care (Dir 2011/24/EU) provides a useful format regulating trans-border health care, including the responsibilities of both the Member States of treatment and affiliation, recognition of patients' rights, establishing a national contact point, reimbursement of costs, recognition of prescriptions, etc.[38]

Finally, the chapter on 'Intellectual property' under the Singapore free trade agreement is of direct relevance to health care, as it follows the pharmaceutical patent rules under the

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[31] More recent "TTIP-light" agreements were concluded with Singapore: the EU-Singapore Free Trade Agreement (SSFTA), and with Japan: the EU-Japan Economic Partnership Agreement. The 'new generation' trade agreements exclude the 'foreign direct investment' and 'investor-state dispute settlement' clauses from exclusive EU competence (i.e. shared competence with Member States), Opinion CJEU 2/15, 16 May 2017 (ECLI:EU:C:2017:376).

[32] P. Koutrakos, 'Common External Policies' in A. Arnull, and D. Chalmers (eds.) *The Oxford Handbook of European Union Law* (2015) 280.

[33] Annex 2-C, art. 1(a)(c).

[34] Ch. 5, Art. 5.13 (1) "emergency measures".

[35] Art 8.5 on market access, except when market access commitments were stipulated; and Art. 8.6 (National treatment clause).

[36] International offshoring and outsourcing – subcontracting foreign providers for providing health services – is raising controversial questions on legal issues such as securing information privacy, contractual requirements and informed consent, since it happens 'behind the scenes', with patients unaware that certain services will be delivered by foreign providers. In more detail, see SN Singh and RM Wachter, 'Perspectives on Medical Outsourcing and Telemedicine – Rough Edges in a Flat World?' (2008) 358(15) *The New England J Medicine* 1625, quoted by: A. den Exter, e-Health law: the final frontier? In TK Hervey and others, *EU Health Law and Policy*, Elgar Publishing 2017, p. 245.

[37] E.g., as set in Art. 8.16 (mutual recognition of professional qualifications).

[38] See, for instance, A. den Exter (ed.), *EU cross-border health care and EU law* (EUR Press 2017) https://docs.wixstatic.com/ugd/78ec39_8716237843cf412c84599c748385fcb8.pdf?index=true.

TRIPS Agreement (Chapter 11). Of particular relevance is the confirmation of the so-called 'patent flexibility' incorporated by the Doha Declaration, i.e. restricting patent rights based on the public health exception ('compulsory licensing', Art. 11.30 ff).[39] Otherwise, the Singapore agreement allows for a patent extension for a maximum of five years to compensate the patent holder for the reduction in the effective patent life as a result of the administrative marketing approval process (Art. 11.31). The Singapore free trade agreement represents a new generation of EU bilateral trade agreements (e.g. Japan, Mexico, Vietnam, South Korea, etc).[40]

In the past, trade agreements gave rise to several disputes involving health, directly or indirectly. Well-known examples address food products (bananas, GMOs, etc) and health.[41] According to Hervey, 'food safety might have dominated trade disputes in the past, but the new generation trade agreements currently under negotiation have the potential to constrain policy space for health in many more areas',[42] such as the protection of pharmaceutical patent rights. In the past, several high-profile cases forced party states to amend national rules on patent protection,[43] or the seizure of generic medicines in transit under TRIPS and GATT 1994.[44] As a direct consequence of the wrongful seizure, the EU has modified its legislation to clarify the procedures relating to medicines in transit, although the new Regulation still allows for the seizure of generic medicines in transit.[45]

In addition, despite the so-called 'public health-related flexibilities' under TRIPS, low-income countries are facing serious difficulties in effectively implementing the TRIPS access to medicines exceptions.[46] The latest TRIPS amendment, introducing a permanent waiver on compulsory licensing expressly for export (Art. 31 bis), does not seem to change this situation.[47] As a consequence, barriers to essential medicines in low-income countries remain, despite public health waivers agreed by multi/bilateral trade agreements. There is no reason to believe that this is going to change under the new-generation EU free trade agreements, although some have criticised the risks of unilateral trade pressure in the latest

[39] Doha Declaration on the TRIPS Agreement and Public Health, adopted on 14 November 2001 by the Ministerial Conference of the WTO.

[40] EU-Japan Free Trade Agreement (released text, 8 December 2017); EU-Mexico negotiations textual proposal, October 2017; EU-Vietnam Free Trade Agreement, released text January 2016); Free Trade Agreement with the Republic of South Korea OJ L 127, 14 May 2011.

[41] The EU-Hormones dispute US (WT/DS321) under GATT, Bananas; approval of biotech products WT/DS291/1 under GATT 1994 and SPS Agreement; plain packaging of tobacco products (WS/DS434, 17 June 2015).

[42] Hervey (note 26) 432.

[43] WTO WT/DS114/13, 18 August 2000 Canada _Patent protection of pharmaceutical products; WT/DS196, 31 May 2002.

[44] (WT/DS408, 11 February 2011.

[45] Regulation 608/2013 on the enforcement of IP rights by customs authorities replaces the 'border measures Regulation 1383/2003 (Regulation 608/2013 of 12 June 2013, OJ L 181/15 repealing Council Regulation 1383/2003), also: W Baker, Settlement of India/EU WTO Dispute re Seizure of In-transit Medicines: Why the Proposed EU Border Regulation Isn't Good Enough, research paper 1-1-2012 Am University College.

[46] One of these options includes the so-called 'compulsory licensing' option for public health purposes, art 31 h TRIPS. It is up to each Member State to determine what constitutes a national emergency, including public health crises (those related to HIV/AIDS, tuberculosis, malaria and other epidemics). So far, the 'only' change was the interim waiver was recognised on a permanent basis (Art. 31bis TRIPS, January 2017).

[47] Under EU law, Council Regulation 816/2006 implements the TRIPS compulsory licensing waiver for public health purposes.

EU/Mercosur free trade agreement (draft text), as it imposes stricter conditions on data exclusivity and supplementary protection certificates.[48]
A special type of bilateral agreement includes the Association Agreements with non-EU countries, providing for an association including 'reciprocal rights and obligations'.[49] Originally designed as the preparatory stage for accession, its focus has changed towards a free trade area and/or political co-operation on, for example, the rule of law and fundamental rights, environmental protection, migration, public health, etc. In return for (partial) access to the internal market, the association country is required to comply progressively with EU legislation, rules and standards. How this affects health can be illustrated by the EU/Ukraine Association Agreement.[50] The agreement foresees in, for example, the protection of (health) data (Art. 15), the conditional mobility of (health) workers (Art 18), progressive market access of goods, including pharmaceuticals and medical devices (Art. 25), technical co-operation and full approximation of technical regulations (standardisation, market surveillance, accreditation, etc, Art. 55, 56), compliance with EU sanitary and phytosanitary measures (Art. 59(1)(b), progressive liberalisation of (health) services (Art. 85), mutual recognition of qualifications (Art. 106), transparency and disclosure of confidential information (Art. 107), pharmaceutical patent protection rights (Art. 219), compliance with EU competition rules in healthcare (Art. 256), consumer protection (Art. 415), public health (e.g. gradual integration of EU public health networks, approximation of public health legislation on blood, tissues and cells, and tobacco, etc., Arts. 426-428).[51]

3.2 EU Health Law and external relations

Nowadays, the European Union and health are inextricably related.[52] Under the current treaty, the 'Treaty on the Functioning of the European Union' (TFEU), the EU and its member states have shared competencies in the area of common safety concerns in public health matters, and the EU is required to take health protection into account in all of its policies.[53] But the most explicit health commitment has been made by the public health provision, Article 168(1): 'A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities', followed by more specific EU competencies in this area.
The history of the European Union's health policy can be characterised as a 'creeping competence'.[54] Since its establishment (1952), the role of what is now the EU in the field of health has gradually grown in terms of competencies, and has become more explicit. Prior to the Treaty of Maastricht (1992), health regulations were based on agricultural policy, medicine and food safety and the internal market (public health exemptions on free

[48] Unverified as the official text is not available yet, see the Joint letter on the Final Phases of EU-Mercosur Trade Talks, 1 December 2017 <www.haiweb.org/publications/joint-letter-final-phases-eu-mercosur-trade-talks>.
[49] The EU has concluded more than 20 of such association agreements (AAs) under Article 217 TFEU, mainly with its neighbours in Eastern Europe (Armenia, Georgia, Moldova and Ukraine).
[50] OJ L 161/3, 29.5.2014.
[51] Confirmed by Annex XLI to Chapter 22.
[52] Derived from Den Exter and Hervey (note 13).
[53] Consolidated version, Official Journal of the European Union C 83/47, articles 4(2)(k), 6 (a) and 9.
[54] Derived from MA Pollack, 'Creeping competence: The Expanding Agenda of the European Community' (1994) 2 *J Pub Pol.* 95-145.

movement and co-ordinating social security entitlements). Confronted with border-crossing health threats (HIV/AIDS, SARS, BSE, bioterrorism, etc), the Maastricht Treaty introduced a specific treaty-based competence aimed at public health protection (Article 129). During subsequent treaty revision, EU public health competencies have gradually increased, including standardising quality and safety of organs and substances of human origin, blood products and blood derivatives, adopting measures to combat major cross-border health threats and fostering co-operation with international organisations such as the World Health Organization and third countries in the sphere of public health.
As formal EU competence in the field of public health developed, whether or not combined with the general harmonisation provision (Art. 114 TFEU), newly-established entities such as the European Medicines Agency, the European Centre for Disease Prevention and Control and the European Monitoring Centre for Drugs and Drug Addiction became responsible for, respectively, the protection of human health through the evaluation and supervision of medicinal products, fighting infectious diseases, and providing information for drawing up informed drug laws and strategies. These, and other agencies, have an impact on the way the EU protects the health of its citizens, and supports its large health industry.
Conceptualising EU health competencies, the main focus is on Article 168 TFEU. Though understandable, this is, however, not the entire story. Other legal bases have also been lawfully applied to ensure a high level of health protection (e.g. free movement provisions, consumer and environmental protection, social policy, competition policy, etc). For instance, under the consumer protection policy, the general product safety directive (2001/95/EC) established general safety requirements for all consumer products, including medical devices. Combined with the 'horizontal' liability directive for defective products (89/374/EEC), these directives are aimed at protecting consumers' (patients') health against defective products. Additionally, EU social and employment law – aimed at protecting workers and fighting discrimination – had some unintended consequences in health care settings. A clear example is the Working Time Directive's applicability to medical professionals, which, it is claimed, has hampered the planning and organisation of medical care.[55] Furthermore, the co-ordination of social security law and the mutual recognition of diplomas of regulated health professions, combined with the harmonisation of pharmaceutical law, as well as the impact of European competition law, have a clear health dimension. At the same time, we will be confronted with new challenges, since the EU is becoming increasingly involved in human rights and health care. The EU Charter of Fundamental Rights and Human Rights Agency may influence EU law on health and health care in the member states.[56] For instance, courts may consider the Charter as the basis of judicial review of the activities of EU institutions.[57] Relevant rights may include the right to

[55] Directive 2003/88/EC, ECJ rulings Case C-303/98, *SIMAP* [2000] ECR I-7963 and Case C-151/02 *Jaeger* [2003] ECR I-8389. See AJ Maxwell, et al, 'Implementation of the European Working Time Directive in neurosurgery reduces continuity of care and training opportunities' (2010) 7 *Acta Neurochirurgica* 1207-1210.
[56] See as reference, the FRA Handbook on European data protection law (medical data paragraph) 2014, 2018 edition, and the Handbook on European law relating to the rights of the child (right to health paragraph) 2015, source: <www.fra.europe.eu/publications>.
[57] See e.g., the labelling of food stuffs and the protection of health under Art. 35 FCHR in *Deutsches Weintor* C-544/10; a licensing system for establishing private pharmacies based on public health under Art. 35 FCHR, *Susisalo* C-84/11; idem *Sokoll Seebacher* Case C-637/12 (Art. 16 FCHR); *Léger* C-528/13 on the prohibition of discrimination based on sexual orientation (Art. 21(1); Case C-220/17 questioning the validity of certain Tobacco restrictive measures under the Charter's rights 17 and 34.

conduct a business, non-discrimination, life, equal access to health care, human integrity and informed consent.
Given the increased role of EU measures protecting health, and in line with the rationale of the internal market, extending such an approach towards a European health care market may seem quite logical. However, under the current Treaty provision article 168(7), that idea has been explicitly rejected. 'Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care …'. Even the directive on patients' rights in cross-border health care does not change this, although this directive does define common principles and standards on quality and patients' rights (e.g. values of universality, access to good quality care, equity, solidarity, eligibility criteria, informed choice, personal data protection, measures for seeking remedies, etc).[58] However, the most essential elements (material scope, benefit package ('basket of care') and reimbursement decisions) remain the exclusive competence of the member states. Although constrained, health law is firmly on the map as an area of EU competence.
At the same time, although focused on the internal market, the influence of EU law on health care may also affect the EU's relationships with third countries and health institutions. For instance, in the field of public health, the European Centre for Disease Prevention and Control (ECDC) network collaborates with neighbouring countries and the WHO, focusing upon epidemiologic surveillance (developing standards, improving data quality, sharing best practice in surveillance, strengthening capacity in surveillance).[59] This 'early warning and response system' has been a model of neighbouring epidemiological surveillance systems.[60] Apart from the ECDC, the European Medicines Agency (EMA) also operates in close co-operation with Member States and partners at international level to promote the convergence of regulatory requirements, sharing of information and addressing common challenges.[61] On the globalised pharmaceutical market, EMA has concluded several agreements with different countries (Australia, Canada, Japan, United States, the WHO) to exchange confidential information and ensure regulatory co-operation,[62] including marketing authorisation and good clinical practice (GMP) inspection findings.[63] In addition, the EU has signed a number of mutual recognition agreements (MRAs) with third-country authorities concerning the conformity assessment of medicinal products. These agreements facilitate market access while protecting consumer safety, and encourage the international harmonisation of compliance standards.[64] As such, the overall

[58] Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare [20011] OJ L88/45.
[59] ECDC Long-term Surveillance Strategy 2014-2020, ECDC Corporate.
[60] Alternatively, ECDC incorporated international surveillance standards, see in case of the Zika virus transmission: 'ECDC adaptation of WHO's Zika virus country classification scheme', news 21 December 2017, ECDC (publications).
[61] www.ema.europe.eu <search for partners & networks, international agreements>.
[62] ibid, see e.g., Confidentiality arrangement Letter from EMEA TGA of the Australian Government Department of Health (1/1/2012), reference EMEA/490079/2009; Letter on the working arrangement to exchange non-public information on medical products between the European Commission's DG Sante, EMA and WHO, ref. EMA 512920/2015.
[63] ibid.
[64] These MRAs are trade agreements and allow EU authorities and their counterparts to: rely on each other GMP inspection system; share information on inspection and quality defects. Eg, Council Decision (2012/837/EU) of 18 July 2011. Agreement between the EU and Australia amending the Agreement on mutual recognition in relation to conformity assessment, certificates and marketing between the European

objective of such bilateral agreements is to 'foster international collaboration and information-sharing and to reduce unnecessary duplication'.[65]
Another example, illustrating how EU law may have an 'external effect', concerns the process of clinical trials conducted in third countries. Due to growing concern with respect to ethical and scientific standards required of clinical trials, as well as the available framework for the supervision of these trials conducted outside the EU (e.g. 'clinical trial dumping' in African countries), a system of regulatory inspections in third countries has been introduced for GCP compliance in the context of marketing approval (Union controls).[66] EMA inspections in third countries concern various aspects of CTs (infrastructure of CTs, measures implemented to protect volunteers' interest and safety, adequacy of the sponsor system and the verification of compliance with the principles of GCP, as well as local regulations). These inspections, therefore, ensure the 'ethical equivalence of CTs in third countries'. A similar approach concerns the manufacturing of medicinal products in third countries, supervised by Union inspections.[67] In the end, these Union inspections directly or indirectly influence the domestic regulatory framework on research and development and manufacturing of medicinal products in developing countries incorporating European 'ethical equivalence' standards.

3.3 Health migration

According to recent ILO estimates, there are more than 150 million migrant workers on a global level.[68] In the area of health, WHO found that 6 percent of physicians and 5 percent of nurses were living outside their country of birth (mid 1970s),[69] and most of them are working in sub-regions such as North America, Western Europe and Australia.[70] These and other studies show a significant outflow of highly-skilled professionals ('brain drain') to – among others – EU member states. Equally, data shows that the workforce mobility of health professionals is unequally distributed among Member States.[71] It is expected that shortages of health professionals in the EU will further increase due to the ageing of the EU

Community and Australia, OJ L 359/2 29 Dec 2012; Decision 1/2017 of the joint committee established under Article 14 of the Agreement on mutual recognition between the European Community and the United States of America, 1 March 2017 amending the sectoral annex for pharmaceutical GMPs (C(2017)1323 final Annex.

[65] Programme to rationalise international GMP inspections of active pharmaceutical ingredients/active substances manufacturers, 20 February 2012 EMA/INS/GMP/129953/2012, p. 2.

[66] Arts. 78, 79 CT Regulation 536/2014 OJ L 158, 27.5.2014 verifying the equivalence of rules underlying the Regulation as regards the rights and safety of the subject and the reliability and robustness of the data generated in the CT, art 25(5).

[67] Art. 16. In case a holder of a marketing authorisation fails to comply with good manufacturing practice as set out in Union law, the competent authority can suspend the authorisation from a third country, Art. 25 Commission Delegated Regulation 2017/1569/EU supplementing Regulation 538/2014 OJ L 238, 16.9.2017.

[68] ILO global estimates on migrant workers. Results and methodology, Special focus on migrant domestic workers, International Labour Geneva Office 2015.

[69] A Meija, H Pizurki, E Royston. Physician and nurse migration: analysis and policy implications. Geneva: World Health Organization; 1979.

[70] International Organization for Migration (IOM), Mobility of Health Professionals to, from and within the European Union, IOM Migration Research Series, no 48, 2014, p. 36.

[71] Most of the 'external' and 'internal' migrants (physicians and nurses) migrate to the United Kingdom. Sending countries are both former colonies and former Eastern European and Mediterranean countries: J Buchan, and others (eds.), Health professional mobility in a changing Europe. New dynamics, mobile individuals and diverse responses, European Observatory on Health Systems (2014), p. 71.

health workforce,[72] thus increasing the loss of human capital from developing countries, most likely the 'best and brightest'.

Being confronted with shortages of health professionals and the high outflow of health professionals from low-income countries, the EU plays a role in the process of global migration. But what exactly is the EU's role in health migration?

In 2005, a European Commission Communication recognised that the global health workforce crisis required a comprehensive and coherent EU approach.[73] As a result, the 'programme for action to tackle the critical shortage of health workers in developing countries' defines actions at country, regional and global levels, supported by the EU.[74] At **national level**, the EU agreed with a number of countries to strengthen national health workforce capacity (e.g. providing technical assistance on planning and recruitment to overcome critical shortages, expanding 'north-south' training capacity for individual health professionals, improving their qualifications, stimulating institutional collaboration by linking health professional associations and health agencies addressing the quality of health care services, etc).[75] The EU also (financially) supports WHO training programmes responding to the fight against communicable diseases (TB, AIDS, etc) and to building an effective health care system to respond to national health priorities.[76]

EU actions at **regional level** emphasise technical and political dialogue on human resources in health at regional platforms (Africa, Asia, etc).[77] More concretely, regional observatories were also launched, collecting and analysing data on human resource capacity, training skills, best practice, etc, whereas in the African region such actions are combined with economic partnership agreements, addressing migration issues, such as limiting the 'brain drain' from south to north and 'skill-sharing'.[78]

At **global level**, the EU has recognised the need for *internal* EU action, reducing health migration to EU Member States. Here, the underlying idea is that concerted action on planning, training and recruitment of the health workforce and promoting EU 'brain circulation' will reduce internal shortages of health personnel, thus reducing the outflow from third countries. At the same time, the EU has accepted the principles of the ethical recruitment of the health workforce from third countries in the labour migration Directive: the so-called "Blue Card Directive".[79] Without doubt, the Blue Card Directive shows some overlap with the EU health migration policy (e.g. preventing a brain drain and promoting

[72] In 2012, the European Commission estimated a potential shortfall of around 1 mln. Healthcare workers by 2020, in Commission staff working document on an Action Plan for the EU Health Workforce, Strasbourg 18.4.2012 SWD (2012)93 final, p.5.

[73] 'EU Strategy for Action on the Crisis in Human Resources for Health in Developing Countries' COM (2005) 642 final, p.8.

[74] Communication from the European Commission to the European Parliament and the Council, European Programme for Action to tackle the critical shortage of health workers in developing countries (2007–2013), COM(2006) 870 final, Brussels, 21.12.2006.

[75] Ibid, p 3-4.

[76] Ibid, p 5.

[77] Ibid p 6.

[78] Ibid, p 7.

[79] WHO code of conduct minimising the negative effects on health workforce capacity in third countries, partially incorporated in the "Blue Card Directive", Directive 2009/50/EC of 25 May 2009 on the conditions of entry and residence of third-country nationals for the purpose of highly qualified employment OJ L 155/17 Directive 2009/50/EC of 25 May 2009 on the conditions of entry and residence of third-country nationals for the purpose of highly qualified employment OJ L 155/17.

'circular and temporal migration').[80] However, the Directive is first of all aimed at boosting economic growth *in Europe* by attracting highly-qualified workers from all around the world, whereas the health migration policy focuses on preventing detrimental effects of the health workforce migration on third countries. In 2014, a Commission report confirmed the risk of brain drain, reviewing the initial effects of the Directive: it was relatively successful in admitting highly-qualified (health) professionals and no ethical recruitment clauses were activated or reported by the Member States.[81] More recent evidence on the application and effects of the ethical recruitment principles is limited, and therefore the effectiveness of EU global immigration policy actions on limiting the outflow of highly qualified health professionals from third countries remains largely unknown.[82]

3.4 Global health security: the emerging health/security nexus

Since the International Health Regulations (2005) came into force, several public health crises have occurred, testing its relevance and effectiveness in responding to health threats around the globe (the influenza pandemic, SARS, Ebola and Zika).[83] Despite its shortcomings,[84] the IHR is generally considered to be a unique tool for controlling border-crossing health threats.[85] Protecting the world from the spread of diseases causing a public health risk is the primary aim of this internationally-binding treaty (Art. 2). But since the 2001 anthrax attacks, biotoxins causing biohazards, chemical and environmental threats and, more recently, the proliferation of antimicrobial resistance (AMR) and vaccine shortages may also constitute a public health emergency of international concern. These

[80] Arts.3(3) and 8(4) of the Directive provide a clause specifically requiring ethical recruitment in sectors experiencing a lack of personnel.

[81] Commission Communication on the implementation of Directive 2009/50/EC on the conditions of entry and residence of third-country nations for the purpose of highly qualified employment, Brussel 22.5.2014 COM(2014) 287 final, p. 5. Although it concerns preliminary results since the Directive was not timely implemented in more than 20 MS (mid June 2011).

[82] The 2015 stakeholder report shows that several countries have implemented the principles of ethical recruitment but the risk of brain drain of health professionals remains present: 'HealthWorkers4All. Practices of WHO Code of Conduct imlementation in Europe: the role of non-governmental actors', 2015; see also, Report of the second meeting of the expert advisory group on reviewing the Relevance and Effectiveness of the WHO Global Code of Practice on the International Recruitment of Health Personnel, 27-28 April 2015, Geneva, Switzerland, p. 4 <who.int/hrh/migration/eag2015/en; Disappointing results were presented by A Siyam, and others, Monitoring the implementation of of the WHO Global Code of Practice on the International Recruitment of Health Personnel, Bull World Health Organ., 2013 (91), p 816-23.

[83] Some authors argue that substandard and falsified medicines can also be considerd as a threat to global health security, justifying 'mechanisms of action that span national boundaries', see L. Gostin e.o. 'Substandard and falsified drugs: a threat to human and global security', (2015) 385 www.thelancet.com, 9 May 2015, p. 1893.

[84] Notably implementation gaps at national level as it remain difficult to implement in federated countries, see K Wilson, C McDougall, R Upshur, 'The new International Health Regulations and the federalism dilemma' (2006) PLoS Medicine 3: e1. But shortcomings cover more than only implementation issues. It provides opportunities for the politicization of epidemic responses (JE Suk, 'Sound science and the new International Health Regulations'(2007) Global Health Governance 1: 1–4; moreover, the failure to specify how national governments are actually supposed to collaborate with one another (D Bhattacharya, ' An exploration of conceptual and temporal fallacies in international health law and promotion of global public health preparedness' (2007) *Journal of Law, Medicine and Ethics* 35: 588–98), derived from SJ Hoffman, 'The evolution, etiology and eventualities of the global health security regime' (2010) 25 *Health Policy and Planning* 510–522, p 514.

[85] Confirmed by the GHS Conference Lyon 2016.

developments seem to widen the scope of IHR, focusing on transnational communicable diseases only. Initiated by the United States, and driven by the threat of bioterrorism, a newly conceived 'global health security' emerged. At European level, the EU responded with a framework of health security to threats to health across borders and across Europe. But what is this global health security about? And is that the role of the EU?

The concept of global health security remains a highly contested concept, as it combines different approaches to health and security with different perceptions, priorities and agendas.[86] The narrow approach emphasises the population health dimension of infectious diseases (WHO). [87] Others have questioned the collective health focus of global health security since the Ebola outbreak highlighted the *individual* health security aspect: '… substandard infection control and inadequate access to effective health products and services has demonstrated a wider notion of health security – the intertwining of collective and individual health security'.[88] As security comes from access to safe and effective health care services, this would call for a re-adjustment of priorities in global health security activities.

But even before the Ebola pandemic, policymakers argued about the importance of the direct connection between health issues and security concerns and preparing for and responding to bioterrorist threats (Global Health Security Initiative GHSI, 2002).[89] This initiative is an international collaboration between various countries 'to strengthen health preparedness and respond globally to threats of biological, chemical, radio-nuclear terrorism and pandemic influenza'. The EU is one of the partners, whereas the WHO is the expert advisor to the GHSI. Subsequently, global health security 'incorporates a diverse range of policy concerns under that heading – ranging from bioterrorism through to infectious diseases with pandemic potential'.[90]

At EU level, the Health Security Committee (HSC) follows the same approach as the GHI at global level, functioning as an informal advisory group on health security issues at European level.[91] The HSC plays a crucial role in the co-ordination of recent health crises and was given formal status by Decision 1082/2013/EU, avoiding duplications with other Union entities responsible for risk management.[92] Decision 1082/2013/EU also extended the network of surveillance and control of communicable diseases with other related threats

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[86] W Aldis, 'Health security as a Public Health Concept: A critical analysis, (2008) 23 *Health Policy and Planning* p. 369-75, p. 370.

[87] WHO narrow concept: global health security is defined narrowly as the collection of preventative and response activities that minimize the vulnerability of populations to communicable disease transmission across geographical, national or regional boundaries. WHO, World Health Report 2007: A Safer Future: Global Public Health Security in the 21st Century. Geneva: World Health Organization, p. lx.

[88] E.g., DL Heymann, 'The true scope of health security, global security', (2015) 385 www.thelancet.com, 9 May 2015.

[89] GHSI Ministerial Statement Mexico City, December 2002. Since then, various statements have extended emerging health security 'events'. Source: Ghsi.ca

[90] S Elbe, *Security and Global Health*. *Towards the Medicalization of Insecurity* (Polity Press 2010) p.5.

[91] Established on the basis of Presidency Conclusions of 15 November 2001 on bioterrorism. The HSC is one of the mechanisms within the EU health security framework. Essentially, the key objectives of EU global health security are: managing and controlling health threats on a global level (preventing avoidable outbreaks irrespective the nature of that threat); to detect threats early (preparedness), and to respond rapidly and effectively, Commission Staff working document. Health security in the European Union and Internationally, Brussels 23.11.2009, SEC(2009) 1622 final, p.3.

[92] Decision 1082/2013/EU of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC, OJ L 293/1, 5.11.2013, preamble 4 and Art.17.

(biological or chemical agents or environmental events (volcanic ash clouds), endangering the health of citizens in the entire Union). With the 'all-hazards approach', the EU has incorporated a broad notion of global health security.[93] The international dimension of Decision 1082/2013 has been reflected in the co-operation and exchange of information option with third countries and international organisations such as the WHO (preamble 26).[94] More specifically, co-operation and exchange of information may include participation in relevant epidemiological surveillance networks and alert systems on serious cross-border health threats ('Early Warning and Response System', EWRS), and the exchange of good practice in the areas of preparedness and response planning, as well as the exchange of information on measures taken pursuant to this Decision. Facilitating such international co-operation initiatives, the Decision shows the EU's preparedness to contribute to global health security.

This supportive role of the EU in global health security issues has been confirmed by the mandate of the European Centre of Disease Control (ECDC) under Regulation 851/2004. Article 9(2) includes: '… *to provide scientific and technical assistance in any field within its mission'* upon request of '… third countries and international organisations (WHO)'.[95] The most concrete examples of such assistance were the mobilisation and co-ordination of EU experts fighting the Ebola outbreak in Guinea (2015),[96] as well as monitoring the course of Zika outbreaks in the Pacific region, providing updates on cases of Zika outbreaks, including an assessment of the risk of importation of the disease into EU territory, etc.[97]

The Regulation finally calls upon the European Centre for Disease Control (ECDC) to develop 'close co-operation with the competent bodies of third countries, the WHO and other international organisations' (Art. 11(2)), to collect data and to 'be open to the participation of countries which have concluded agreements with the Community by virtue of which *they have adopted and apply legislation of equivalent effect* to Community legislation' in the field of public communicable diseases (Article 30(1)). So, apart from promoting good practice on early warning systems (i.e. technical assistance), ECDC will share data with other countries when complying with the EU communicable diseases acquis! This is a clear example of exporting EU public health standards in order to fight infectious diseases and global health threats.

4. Concluding remarks

So far, examining the legal role of the EU in global health issues has revealed a 'hodge-podge' of legal issues, rather than a distinct body of rules reflecting a coherent framework of EU law. And even that mix was incomplete, excluding leftovers such as development aid, the EU/WHO relationship and the rule of law and human rights. What is more, it is likely that each of these domains interact and thus have an effect on global health. Developing a coherent and co-ordinated framework of EU global health law, these missing links need to

[93] Article 2(1) Decision 1082/2013.

[94] Article 168 (3) of the TFEU confirms cooperation in the sphere of public health.

[95] Regulation 851/2004 of 21 April 2004 establishing a European centre for disease prevention and control, OJ L 142/1, 30.4.2004.

[96] ECDC 'reinforcing the fight against Ebola in Guinea, ECDC in the field, 15 January 2015, calling for epidemiologists willing to work in Guinea; ECDC international relations policy 2020, Stockholm 2018, www.ecdc.europa.eu.

[97] ECDC, communicable disease threats report, weekly bulletin on active public health threats, www.ecdc.europa.eu, search for publications, CDTR.

be incorporated and assessed. Only then can a well-argued conclusion on the effect of EU global health law in improving global health be drawn.
That being said, it became clear that without doubt the EU plays a major role in global health issues, although, as with the health care domain, its competencies are fragmented, incomplete, and sometimes even reflect inconsistent objectives (i.e. realising free movement and at the same time preserving solidarity and equality). These observations are also applicable when addressing international trade agreements and guaranteeing equal access to essential medicines, or the detrimental effects of health workers' migration on third countries.
Given the abovementioned limitations, further understanding of the EU's legal role in global health is crucial for improving global health.

PART TWO GLOBAL HEALTH AND HUMAN RIGHTS ISSUES

Chapter 2. Access to Medicines

Fighting excessive pharmaceutical prices: Evaluating the options

Abstract
New treatment options for various cancer therapies have appeared extremely expensive and prices may increase further. The affordability and availability of life-saving medicines is therefore a key issue in national health policy of all countries. International and European law grants several price-reducing options, including compulsory licensing. Still, states are hesitant, if not reluctant to apply for compulsory licensing and or other regulatory options to curtail pharmaceutical prices. Why is that? Evaluating the options will support health policy decision-making on safeguarding access to affordable innovative medicines.

Keywords: high-priced medicines, compulsory licesing, mandatory disclosure, competition law, joint procurement

1. Introduction: the race? to "CARs"

One of the latest medicinal innovations introduces new treatment options for life-threatening diseases such as leukaemia and other kinds of cancers.[98] These immune therapies use the patient's own gene-edited stem cells (CAR-T cells) to attack cancerous cells and adding years of their life. Some of these therapies are developed by hospitals whereas other gene and cell-based therapies have been commercialised by pharmaceutical companies, such as Novartis (Yescarta), Gilead (Kyriah). Between 2020 and 2025, the Federal Drug Agency (FDA) expects an increase of more than 200 gene-edited applications per year waiting for approval.[99] Weaponising individual's immune system is challenging but also extremely expensive (Yescarta: 373,000 USD, Kyriah: 475,000 USD). So far, the therapies do not cure, but postpone death with several month up until years. Apart from the excessive price of treatment, cancer cells may mutate which limits the effectiveness of the personalised T-cell therapy. Altering the gene-based therapy is a time-consuming process, whereas delay in treatment may decreases the patient's chance of survival. Another complication is that - for unknown reasons - patients may respond differently to the gene-based therapies, and can be differentiated in high and low treatment

[98] E.g., C. Puig-Sausa, A Ribas, 'Gene editing: Towards the third generation of adoptive T-cell transfer therapies', *Immuno-Oncology Technology* 1 (2019) 19–26; A Ghobadi, 'Chimeric antigen receptor T cell therapy for non-Hodgkin lymphoma', *Current Research in Translational Medicine* 66 (2018) 43–49; L Rein, H Yang, N Chao, 'Applications of Gene Editing Technologies to Cellular Therapies', *Biol Blood Marrow Transplant* 24 (2018) 1537–1545; Y Zhang, W Mu, H Wang, 'Gene editing in T cell therapy', *Journal of Genetics and Genomics* 44 (2017) 415-422.

[99] Food and Drug Administration. 'Statement from FDA Commissioner Scott Gottlieb, M.D. and Peter Marks, M.D., Ph.D., Director of the Center for Biologics Evaluation and Research on new policies to advance development of safe and effective cell and gene therapies', 15 January 2019. https://www.fda.gov/news-events/press-announcements/statement-fda- commissioner-scott-gottlieb-md-and-peter-marks-md-phd-director-center-biologics.

responders.[100] These medical innovations raise therefore fundamental and controversial issues such as who should be treated and based on what criteria? Ultimately such decisions would restrict and even deny certain patients access to gene-based medicines. Alternatively, governments may consider other (regulatory) mechanisms to reduce prices of these expensive medicines, increasing the accessibility of gene-based medicines to larger groups of patients. But what are these price restricting options, and are they effective: i.e. reducing excessive prices and strengthening access to innovative medicines? Unfortunately, apart from anecdotal evidence, reliable studies reviewing the impact of price reducing measures are largely absent.[101] Therefore, this paper aims at examining potentially meaningful legal options supporting policy makers decision-making on safeguarding access to affordable innovative medicines.

2. Price reducing initiatives

What options do governments have being confronted with excessive prices for gene-based medicines? Almost every European country use price regulation to curb the growth in pharmaceutical expenditures.[102] One of the most controversial measures is the compulsory licensing option aimed at both price control and, more important, safeguarding the affordability of medicines. Alternative regulatory strategies might be targeted negotiations, challenging unfair pricing by competition authorities, mandatory disclosure of economic data, and facilitating voluntary cross-border purchasing arrangements. Hereafter, these options will be further examined.

2.1 Compulsory patent licensing

The idea of compulsory patent licensing, or compulsory licensing (CL) was introduced by the Doha Declaration on Public Health, a declaration under the Agreement on Trade-related aspects of Intellectual Property Rights (TRIPS Agreement Annex 1 c), allowing patent infringements by States for reasons of 'national emergency'.[103]
The TRIPS Agreement (1995) was generally understood as an instrument to protect the exclusive rights of the right holders against any unlawful breaches by third parties. This exclusivity right to manufacture and sell patented products such as pharmaceuticals grands the pharmaceutical company a monopoly position. Without competition, this has resulted in Pharma's excessive pricing practice, particularly when it concerns rare and cancer diseases.[104] For developing countries, excessive pricing threatens access to essential

[100] By using so-called immune biomarkers predicting response to a treatment: A van Belzen, Kesmir, 'Immune biomarkers for predicting response to adoptive cell transfer as cancer treatment', *Immunogenetics* (2019) 71:71–86.
[101] A rare exception is the study of Beall and others, concluding that compulsory licensing (hereafter) did not result in lower prices for Antiretrovirals compared to international procurement, although the focus was on low income countries. RF Beall, R Kuhn and A Attaran, 'Compulsory Licensing often did not produce lower prices for Antiretrovirals compared to international procurement', *Health Affairs* 3 (2015) 493-501.
[102] E.g., tiered pricing, price cuts, and parallel trade but these strategies require a more economic analysis than a legal approach.
[103] WTO member governments adopted the Declaration on the TRIPS Agreement and Public Health by consensus at the WTO's Fourth Ministerial Conference in Doha, Qatar, on 14 November 2001.
[104] European Commission, Antitrust: Commission opens Pharma's pricing practices 2017.

medicines (HIV/AIDS, malaria, tuberculosis), and thus raises serious public health concerns. The Doha Declaration recognised the dilemma of respecting property right versus the State obligation to protect public health, by introducing so-called exceptions or 'patent flexibilities', including Compulsory licensing (CL).[105] Originally aimed for developing countries, CL can be invoked by developed countries too. This has been confirmed by the Doha Declaration: 'Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted'.[106] Therefore, all States may trigger CL, as applied by the United States (anthrax crisis in 2001),[107] and Germany (HIV/AIDS)[108] when being confronted with a national public health emergency. The national emergency situation also justifies the voluntary licence waiver (Art. 31b TRIPS).[109] Then the question remains, what constitutes a situation of national public health emergency? According to the Doha Declaration: 'Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency', and 'it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency'.[110] Reading the text closely, one may conclude that protecting public health is not limited to infectious diseases.[111] This has been confirmed by the previous section (section 4), stipulating that 'the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all'. This reaffirms the flexible use of TRIPS for this purpose.

Taking the example of excessive pricing of gene-edited cancer medicines, this could also trigger a public health emergency invoking States to invoke CL. In case access to affordable (CAR-T) gene therapy is under threat, then States may consider to apply for CL. This is more likely when it concerns life-threatening diseases where no other treatment option than gene therapy is open. Given the increased number of available gene therapies, and thus rising health care costs, the absence of affordable medicines can then be considered as a public health emergency or other circumstances of extreme urgency that justifies the CL exception, promoting affordable medicines to the patients in need. One example is Thailand (middle

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[105] Next to other flexibilities, such as parallel trade and the research exemption. The concept of CL is not mentioned in the TRIPS agreement itself, here it is referred as 'other use without authorization of the right holder' (Art. 31), and only when efforts to obtain a voluntary license have not been successful.

[106] Declaration on the TRIPS agreement and public health, Adopted on 14 November 2001, WT/MIN(01)/DEC/2, para. 5 b.

[107] http://tripsflexibilities.medicineslawandpolicy.org.

[108] Federal Court of Justice (Bundesgerichtshof), 11 July 2017, ECLI:DE:BGH:2017:110717UXZB2.17.0. Reverse, the Federal Court of Justice denied that it was in the public interest to grant a compulsory license (Praluent medicine), case X ZB 2/19 (4 June 2019).

[109] According to TRIPS Art. 31 b: 'such use (i.e. CL) may only be permitted if, prior to such use, the *proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms* and conditions and that such efforts have not been successful within a reasonable period of time'. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use.

[110] Para. 5 (c) of the Declaration on the TRIPS agreement and public health, DOHA WTO MINISTERIAL 2001: TRIPS WT/MIN(01)/DEC/2, 20 November 2001, Adopted on 14 November 2001.

[111] Also confirmed by Musungu, 'the list of diseases mentioned are only illustrative of some of the obvious cases that can constitute an emergency but in no way denotes an exhaustive list. It is not even an indicative list', SF Musungu, 'The TRIPS Agreement and Public Health', in: A Yusuf and C Correa (eds), *Intellectual Property and International Trade, The TRIPS Agreement* (3rd edition, Alphen a/d Rijn: Kluwer Law International, 2016) 515.

income country) that successfully invoked a CL for Erlotinib (lung cancer medicine) produced by Roche in 2008.[112] In 2007, the Italian Anti-Competition Authority (AGCM) granted a CL for producing a cheaper version of Finasteride (prostate cancer).[113] Currently, a so-called 'Crown licence', allowing a generic version of Pertuzumap (breast cancer medicine) under CL, is currently pending in Scottish parliament.[114] Reverse, CL of Spinraza (muscle disease) was denied in Norway due to the lack of production facilities and absence of a public health emergency.[115] This limited number of examples confirms the flexible interpretation of the public health emergency-concept, including affordable access to (gene-based) cancer treatment, reviewed on a case-by-case basis.

Apart from CL for domestic use (Art. 31 sub f), Art. 31 *bis* TRIPS introduces a CL waiver for exporting generic medicines to other countries in need, most likely low-income countries. The export waiver was already decided in the Doha Declaration but required a separate treaty amendment to prevent political uncertainties.[116]

At EU level, Regulation (EC) No 816/2006 provides the legal basis for EU Member States to grant compulsory licences for export of patented medicines to address a public health problem in the importing country, not necessarily a public health emergency situation.[117] Apart from low-income countries Art. 4 (b) of Reg. 816/2006 shows that other countries, including EU member states may act as eligible importing country too.[118] This means that, in case of a public health problem in member State A (inadequate pharmaceutical capacities or excessively-priced innovative cancer medicines), any person may apply for a CL at the competent authority in Member State B to export a patented medicine (e.g. Spinraza). During the verification process (Art. 8 Reg.), the applicant will provide evidence that efforts to obtain authorisation from the patent-holder has remained unsuccessful (Art. 9). Then, the competent authority may grant a licence to export the medicine to Member State A. However, the licensee is responsible for adequate remuneration to the patent holder. In case of a public health emergency this is maximum 4% of the total price to be paid by member State A (Art.9(9)(a). Although integrated into national law, so far the export flexibility has never been used.[119]

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[112] http://tripsflexibilities.medicineslawandpolicy.org, based on Art.31 TRIPS.

[113] AGCM A364 - MERCK-PRINCIPI ATTIVI, no. 16597, www.agcm.it, quoted by KEI Research Note: Recent European Union Compulsory Licenses, 1 March 2014, p. 13.

[114] http://tripsflexibilities.medicineslawandpolicy.org, based on Art.31 TRIPS, UK Patents Act 1977 (as amended)

[115] Innstilling til Stortinget, fra helse- og omsorgskomiteen, Dokument 8:138 S (2017–2018), Innst. 285 S (2017–2018).

[116] General Council, Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health, Decision of the General Council of 30 August 2003, 1 September 2003, WT/L/540. The amendment came into force 23 January 2017.

[117] Regulation (EC) No 816/2006 of the European Parliament and of the Council on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems of 17 May 2006, OJ EU L 157, 9 June 2006.

[118] Art. 4 reads: 'The following are eligible importing countries: … (b) 'any member of the WTO, other than the least-developed country members referred to in point (a), that has made a notification to the Council for TRIPS of its intention to use the system as an importer, including whether it will use the system in whole or in a limited way'.

[119] European Patent Office (EPO), Compulsory licensing in Europe. A country-by-country overview, Munich 2018. The only example known so far is Canada exporting a HIV medicine to Rwanda (2007) under the Doha Public Health flexibility (IP/N/10/CAN/1) source: www.wto.org, notifications by exporting countries.

A major advantage of Reg. 816/2006 is the data exclusivity waiver, meaning that when a compulsory license is granted, the applicant will automatically have access to the originator's clinical test data in order to manufacture a generic medicine (Art. 18(2)). In all other cases, the non-disclosure clause has to be respected (Directive 2004/27/EC).[120] As a result, EU data exclusivity legislation creates a significant hurdle to effectuate CL, preventing generic competitors from accessing test data to manufacture cheaper medicines.[121] Extending the data exclusivity flexibility to all cases of public health interest where CL has been issued could stimulate patients' access to affordable medicines.[122] Access to test data is therefore part of the right to health care.

2.2 Pharmacist's exemption

When CL remains controversial, an alternative option is the 'pharmacists exemption' (also known as 'compounding'), allowing (hospital) pharmacists to prepare a patented medicine for individual patients on small scale.[123] Article 27(e) of the Council Agreement on a Unified Patent Court allows EU Member States to limit pharmaceutical patent rights with: 'the extemporaneous preparation by a pharmacy, for individual cases, of a medicine in accordance with a medical prescription or acts concerning the medicine so prepared'.[124] Various Member States have incorporated the pharmacist compounding exception in national patent law.[125] Essential is the preparation for the therapeutic needs of a specific patient, or small groups of patients whose medical requirements cannot be met by industrially manufactured medicines.[126] Originally referring to products under the magistral formula rules (marketing authorisation exception),[127] national patent law may also extend the patent limitation to hospital pharmacy's preparations for the purpose of curbing excessively priced patented medicines (public health reasons). As long an such a 'limited exception do[es] not unreasonably conflict with a normal exploitation of the patent, and do[es] not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties' (Art. 30 TRIPS agreement). Since the wording is rather vague and in absence of further indications, compliance with the

[120] Directive 2004/27/EC of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use (para. 8, Art. 10). L 136/34, 30 April 2004. There is of course the 'voluntary license' option granting the generic producer access to relevant clinical data, but that option is not applicable here.

[121] E 't Hoen, P Boulet, B Baker, 'Data exclusivity exceptions and compulsory licensing to promote generic medicines in the European Union: A proposal for greater coherence in European pharmaceutical legislation', *J Pharmaceutical Policy and Practice* 10 (2017) 3.

[122] ibid, 6.

[123] Compounding is the individual preparation of medicines in pharmacies when an equivalent licensed product is unavailable or is unsuitable for use and if the use can be clearly justified clinically and pharmaceutically according to prescriptions. In other words, it is the basis of personalised medicine, source: https://www.eahp.eu/practice-and-policy/compounding.

[124] Art. 27(e) Council Agreement on a Unified Patent Court (2013/C 175/01) OJ EU C175/9, 20 June 2013.

[125] E.g., Belgium IP Act (2014) Art. XI.34. § 1; French IP Code Art. L613-5(c); German Patent Act §11(3), UK Patent Act (1977) section 60 (5)(c) and most recently (1.1.2019) the amended Dutch Patent Act (1995) Art. 53(3).

[126] idem.

[127] See Art.3(1)(2) Directive 2001/83/EC as amended referring to pharmacy preparation under the rules governing medicinal products for human use at European level.

conditions remains highly uncertain.[128] Consequently, the liability risk for patent infringement is therefore considerable.

2.3 Excessive pricing challenged by competition authorities: acting as substitute price regulators?

Since – the threat of using - CL is generally considered as the 'nuclear option' to convince pharmaceutical companies to lower its excessive prices, the search for alternative less drastic measures continues. One of these options includes the use of competition rules. More specific, reviewing intellectual property rights (patents) under the abuse of dominant position. The use of economic legal tools to challenge unfair prices of medicines is not new. It has been confirmed by Article 8.2 TRIPS:

> 'Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology'.

whereas European Union competition rules prohibit the abuse of dominant position under Article 102 TFEU as:

> 'Any abuse by one or more undertakings of a dominant position within the internal market or in a substantial part of it shall be prohibited as incompatible with the internal market in so far as it may affect trade between Member States.
> Such abuse may, in particular, consist in:
> (a) directly or indirectly imposing unfair purchase or selling prices or other unfair trading conditions; […]'

This provision in generally understood as holding a dominant position (monopoly) by developing an innovative medicine or vaccine is not necessarily problematic, but the misuse of the pharmaceutical company's market position by setting unreasonable prices or price conditions could be considered as a *abuse* of dominant position and thus breaching competition law. In the *AstraZeneca* case, the European Union Court of Justice (EUCJ) for the first time ruled that misleading patent authorities aimed to exclude generic competitors from the ulcer treatment market, is considered an abuse of dominant position.[129] Thus, exercising rights of the patent holder may attract both national and European competition law. An approach also relevant in case of fighting unfair or excessive prices of innovative gene-based therapies.
Nevertheless, the European Commission has been reluctant to assess allegedly high prices practiced by dominant enterprises under Article 102 TFEU.[130] That position might be correct in a free and competitive market: 'with no barriers to entry, high prices should normally attract new entrants. The market would self-correct.'[131] Still, with the public health interest

[128] Although the WTO Panel gave some clarity in the EC-Canada case, interpreting the phrases "limited", "normal exploitation", and "legitimated interests", WT/DS114/R, 17 March 2000, paras. 7.30-7.71.
[129] Case C-457/10 P, ECLI:EU:C:2012:770, 6 December 2012.
[130] Opinion A-G Wahl, 6 April 2017, Case C-177/16, ECLI:EU:C:2017:286 request for a preliminary ruling from the Supreme Court Latvia, para. 3.
[131] idem.

involved the Commission cannot stay inactive, particularly since life-saving medicines remain largely inaccessible.

Recalling the Court's caselaw on unfair prices, a price is excessive when it has no reasonable relation to the economic value of the product supplied.[132] Accordingly, only 'disproportionate' or 'exorbitant' prices could be in breach of Article 102 TFEU.[133] This could be measured by comparing the selling price with the cost of production (cost plus approach), as this would disclose the amount of profit margin. Here, the Court allowes Competition authorties a certain margin of discretion with the economic method to define excessive prices, but each method has its own weaknesses.[134] A-G Wahl correctly concluded that the proper approach is to combine several methods where possible to avoid the risk of errors.[135] Still, defining the line between reasonable high and unreasonable high price remains difficult.[136]

Once the excessiveness has been confirmed, it must be determined whether the price is unfair, or can be justified for objective reasons. The 'fairness-test' requires an analysis of the economic reasons of its pricing policy.[137] The economic rationale of excessive pricing generally provided is the high costs of research and development (R&D) of new medicines. Research is becoming more expensive and more complex. Also, it can take many years before a new medicine will be approved for entering the market, or not. High prices are thus necessary to cover the investment costs and stimulate future innovation. But it is difficult – and often impossible – to get reliable information on actual medicine prices as well as costs of inputs to those prices. Transparency in R&D expenditures and the methodologies underlying the calculations would help to assess whether a medicine price is fair, but remain confidential. Only in case there is no rational economic explanation for the high price than that may be qualified as abusive under 102 TFEU.[138]

In practice, national competition authorities are struggling with pharmaceutical excessive pricing investigations and so far the results are diverse. Leading cases are *Aspen* (Itay),[139] *CD Pharma* (Denmark)[140] and recently *Pfizer/Flynn* (United Kingdom),[141] followed by the

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[132] E.g., Case 27/76 *United Brands*, European Commission, 14 February 1978, ECLI:EU:C:1978:22, para. 250-2. 17 July 1997 GT-Link v DSB, ECLI:EU:C:1997:376, para. 39.

[133] Case C-323/93 *Centre d'Insémination de la Crespelle*, 5 October 1994, ECLI:EU:C:1994:368, paras. 19 and 21, as quoted by A-G Wahl, *supra* note 33.

[134] Wahl, para. 251.

[135] Para. 43. Recently, the UK Competiton Appeal Tribunal (CAT) decided in appeal that a cost plus approach, in isolation, is rather obsolete and an insufficient method to determine the excessiveness of pharmaceutical prices, para 310, and thus confirming A-G Wahl's mixed approach: *Pfizer and Flynn Pharma* [2018] CAT 11, 7 June 2018.

[136] D Chalmers, G Davies and G Monti, *European Union Law* (2nd ed. Cambridge: CUP 2010) 1002.

[137] Wahl para. 118.

[138] Wahl, para. 131.

[139] AGCM Decision 29 September 2016 (Aspen), case A-480, upholded in appeal by the Lazio Regional Administrative Tribunal, judgment no. 8948/2017, 26 July 2017, applying a theoretical and single cost plus method (difference between the selling price and costs) to determine the excessiveness, and ruled that Aspen abused its dominant position by charging unfair prices.

[140] the Danish competition authority (DCC) CD Pharma, press release, 31 January 2018. Using the cost plus-method, there was no objective justification for a 2,000% price increase of an off-patent medicine Syntocinon.

[141] In appeal, the CAT overturned the Tribunal's (CMA) assessment, as it identified 'important errors in its legal test' (para. 310). CAT highlighted that a finding of abuse through excessive pricing should rely on proper evidence and analysis, 'taking into account the real world' (para. 318) and 'using a range of methods for setting a benchmark price and establishing the excess' (para. 443(1)), Judgment [2018] CAT 11, 7 June 2018

European Commission's own pan-European investigation into excessive pricing by pharmaceutical company Aspen launched in 2018.[142]
What these excessive pricing situations have in common are the difficulties in terms of data availability and analysis, and identifying appropriate assessment standards.[143] This has led to the conclusion that the identification of excessive prices is a 'daunting, if not, impossible task'.[144] Therefore, one may question whether competition authorities are equiped for that function that is closer to the competences of a price regulator.[145]

2.4 Price transparency and mandatory disclosure

Greater transparency on pharmaceutical prices and costs imposed by law may help competition authorities and price regulators to improve the understanding of price setting, combined with constant monitoring of prices and detailed market knowlegde. Recently, the WHO Assembly approved a resolution 'urging member states to take appropriate measures for public disclosure of economic data on medicine prices', such as reports on sales revenues, prices, units sold, marketing costs, and subsidies and incentives.[146] As well as supporting research on and monitor the impact of price transparency on affordability and availability of medicines.[147] Unlike the orginal text proposal, the final resolution emphasises the voluntary nature of disclosure of R&D data (para. 1.2), which seems not very realistic.[148] Coping with the lack of transparency and information asymmetry, mandatory disclosure to public authorities in price negotiations is required.

2.5 Cross-border collaboration initiatives: solving imbalances in market power

Although important, mandatory disclosure alone will not solve the actual imbalances in market power between national/local procurers and payers vs globally acting pharmaceutical companies. Therefore, collaboration may be considered a more successful avenue. Collaboration between different public payers and purchasers at different levels: regional, national and cross-border level addressing a range of topics, from the exchange of information on medicines and pharmaceutical policies, to joint price negotiations of

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[142] European Commission, 'Antitrust: Commission opens formal investigation into Aspen Pharma's pricing practices for cancer medicines', IP/17/1323.
[143] OECD DAF/Com 2018, p 6.
[144] D Evans and J Jorge Padilla, 'Excessive Prices: Using Economics to Define Administrative Legal Rules', *J Competition Law and Economics* (2005) 97-122, at 118.
[145] E.g., B Kianzad, T Minssen, 'How much is too much? Defining the metes and bounds of excessive pricing in the pharmaceutical sector', *EPLR* 3 (2018) 15-30, at 16; C Calcagno, A Chapsal, and J White, 'Economist's Note. Economics of Excessive Pricing: An Application to the Pharmaceutical Industry', *J European Competition Law & Practice*, 3 (2019) 166-171, at 171, quoting the CAT in its Flynn/Pfizer judgment, 'competition authorities should be wary of casting themselves in the role of price regulators. Generally, price control is better left to sectoral regulators, where they exist, and operated prospectively; ex post price regulation through the medium
of competition law presents many problems', para. 462.
[146] World Health Organization. Resolution WHA 72.8: Improving the transparency of markets for medicines, vaccines, and other health products. 2019, A72/A/CONF./2 Rev.1, 28 May 2019.
[147] Idem para. 2.3.
[148] As painfully illustrated by the Dutch Pharmaceutical code of conduct (2020) emphasizing transparency as core value for all stakeholders but is silent on *price* transparency, https://www.verenigginnovatievegeneesmiddelen.nl/.

(selective) medicines.[149] The underlying idea is that joint collaboration initiatives will help to overcome information asymmetry and enhance the buyers' bargaining power.[150] A good example of multilateral collaboration is the Beneluxa initiative, concluding positive joint reimbursement negotiations on Spinraza, a medicine for Spinal Muscular Atrophy (SMA),[151] as well as the Velatta Alliance, a number of south European countries, bargaining collectively with the giant pharmaceutical companies.[152]

At EU level, Decision 1082/2013/EU facilitaties the joint acquisition of medicines by introducing a joint procurement mechanism, the Joint Procurement Agreement (JPA), for purchasing vaccines and medicines to combat major cross-border health threats.[153] Based on the Treaty's public health provision (Article 168(5) TFEU), the JPA option is limited to cross-border health threats, transmitted from person to person, and thus excluding non-contagious diseases.[154] Extending the common purchase procedure to individual health care-related medicines with no direct border crossing health risk, would exceed the Union's public health mandate. Therefore, in case of high-priced cancer medicines, the JPA instrument is not feasible.

Instead, EU Member States may – also on a voluntary basis - consider the cross-border public procurement option for high priced medicines provided by Directive 2014/24/EU.[155] According to Article 39 of the Directive, 'contracting authorities from different Member States may act jointly in the award of public contracts by using one of the means provided for in this Article'. For this purpose, participating contracting authorities may establish a joint entity entrusted with the procedure to strengthen buyers bargaining power (Art.39(5) Directive). The large volume of medicines purchased, and thus lower prices, makes this type of acquisition an attractive option for all parties involved. Still, there are several hurdles to cross-border procurement of medicines, particularly since regulations on prices and procurement may differ by country. Or, for more opportunistic reasons, individual countries believe they may reach a better result, i.e. a lower price, by confidential price

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[149] Horizon Scanning aims to highlight important pharmaceutical and medical technology innovations before they reach the market by continuously gathering data and analyzing research and literature. This improves insight in expected costs and enables timely decision making and (joint) price negotiations.

[150] S Vogler, V Paris, D Panteli, 'Ensuring access to medicines: How to redesign pricing, reimbursement and procurement?' Policy brief 30, European Observatory on Health Systems and Policies (2018) 20-21.

[151] https://beneluxa.org, an initiative of the Health Ministers of Austria, Belgium, Ireland, Luxembourg, the Netherlands. The Spinraza agreement was on joint pricing, and successfully concluded between Beneluxa partners Belgium and the Netherlands (12 July 2018).

[152] The Valetta Declaration, signed by the Ministers for Health of Cyprus, Greece, Ireland, Italy, Malta, Portugal, Romania, Spain, Slovenia and Croatia (8-9 May 2017). The cooperation allows for sharing of information about medicinal products, policies, legislative proposals and procedures being adopted by the different participating countries,
https://www.gov.mt/en/Government/DOI/Press%20Releases/Pages/2019/August/28/pr191795en.aspx .
Other joint negotiations initiatives include: the Nordic Pharmaceuticals Forum (2016), Declaration of Sofia (2015), and the Romanian and Bulgarian Initiative (2015).

[153] Article 5 of the Decision sets the conditions for the joint procurement of medicines, Decision 1082/2013/EU on serious cross-border threats to health and repealing Decision No 2119/98/EC, OJ L 293/1, 5 November 2013.

[154] According Art. 3 (g) of the Decision, a serious cross-border threat to health means 'a life-threatening or otherwise serious hazard to health of biological, chemical, environmental or unknown origin which spreads or entails a significant risk of spreading across the national borders of Member States, and which may necessitate coordination at Union level in order to ensure a high level of human health protection'.

[155] Directive 2014/24/EU on public procurement, which repeals Directive 2004/18/EC on public works. OJ L 94, 28.3.2014, p. 65, 26 February 2014.

agreements.[156] Despite these and other political obstacles, voluntary cross-border purchasing arrangements are potentially promising, particularly for small countries.

3. Conclusion

Almost every European country has been confronted with emerging innovative medicines and the increased costs of pharmaceuticals. Fighting excessive pharmaceutical prices, this paper examined a 'toolbox' of price reducing measures. Each of these alternatives has its limitations, but cross-border collaboration on (price and cost) negotiation of selective medicines seems the most feasible remedy to create advantages of economies of scale, and thus providing access to affordable new medicines. Triggering CL, transparency and mandatory disclosure of economic costs and criteria, as well as the pharmacy's exemption and Competition authorities' price assessments remain highly complex, riskful and/or doubtful in terms of a meaningful impact on affordability. Curtainling their property rights, one must even fear the risk of opening Pandora's box when pharmaceutical companies withdraw their product from the market.

[156] J Aspin and others, 'How can voluntary cross-border collaboration in public procurement improve access to health technologies in Europe?', Policy brief 21, European Observatory on Health Systems and Policies (2016) 18.

CHAPTER 3. Access to new Health Technologies and Age-based Rationing

1. Introduction

The elderly in many countries are living longer than before. Healthy food, safer working and environmental conditions, a healthier lifestyle, and advanced medical care contribute to an ageing population, are causing various challenges in society.
The longer life expectancy, combined with new technologies and increasing costs of health care raises questions on: what are the limits of health care, should we invest in life-threatening rare diseases, or facilitate life-extending treatment options for the elderly, irrespective the costs, and whether there is a willingness to reallocate scarce resources in favour of the younger generation. These are all highly controversial as it wrongly suggests that the elderly have a lower value in society than others. Elderly do not contribute less to society and deserve the same – perhaps more - respect and have the same human rights as anybody else.
Still, the increased demand on health care in the end-of-life stage, combined with and the rise of high-cost health technologies, will ultimately trigger the question whether society is willing to consider rationing health care; more specific, based on age and limited to life-extending technologies. That question is less theoretical as we may think since it is already practiced at the bed-side, but in secrecy. Age-based rationing has been even defended by some health ethicists. But human rights and health lawyers have been largely absent in that discussion. Therefore, this chapter aims to contribute to the rationing debate finding legal arguments that may justify age-based rationing of specific health technologies.
To understand the relevance of human rights in the age-based rationing debate, firstly, this chapter will start with explaining key human rights dominant in the health care access debate for elderly. Since international human rights law leaves States considerable room to manoeuvre for allocating scarce resources in health care, then the focus will be on a particular type of rationing: age-based rationing. Is it 'ageist'[157] and thus discriminatory, or not necessarily?

2. Access to new health technologies: A human rights issue

For several years we have witnessed a wave of innovations and breakthroughs in health care, from the human genome sequencing, the idea of precision medicine in fighting 'the war on cancer', and the use of big health data, to name a few examples. But how can individuals, the elderly in particular, benefit from these new health technologies (new medicines, medical devices, or treatment methods).[158] What are the key human rights

[157] Just like racism or sexism are based on ethnicity and gender, ageism is a form of systematic stereotyping and discrimination against people simply because they are old. As a group, older people are categorised as rigid in thought and manner, old fashioned in morality and skills. They are boring, stingy, cranky, demanding, avaricious, bossy, ugly, dirty and useless. An ageist younger generation sees older people as different from itself; it subtly ceases to identify with its elders as human beings (RN BUTLER, ET AL, 'AGE-ISM: ANOTHER FORM OF BIGOTRY', 4 THE GERONTOLOGIST, 243-246 (1969).
[158] A Health technology as defined by the International network of agencies for health technology assessment (INAHTA) "any intervention that may be used to promote health, prevent, diagnose or treat disease, or for the

relevant in access of these health technologies, and what does that mean in terms of State obligations to realise these rights?

Access to health care goods and services

Access to health technologies is included in the right to health, as accepted under the International Covenant on Economic, Social and Cultural Rights (Article 12 ICESCR). Generally accepted as a 'social' right, such a 'right of everyone to the enjoyment of the highest attainable standard of physical and mental health' requires individual States to gradually realise such a right while acknowledging the difficulties states have in complying with these obligations (so-called 'progressive realisation').[159] Accordingly, although the concept itself has immediate effect, the full realization of the right to health enables countries to take necessary measures to give effect to that right over a longer period of time. Such measures should be concrete, deliberate and targeted towards the full realization of Article 12 ICESCR.[160] This flexibility device means that State parties have a 'specific and continuing obligation' to move towards full realization, which creates a strong presumption that deliberate retrogressive measures are not allowed.[161] Combined with the (health-related) non-discrimination principle, the progressive realisation concept introduces individual elements in a social right that were traditionally reserved to classical freedom rights.[162]

In order to realise the Convention's right to health, States will set the conditions 'which would assure to all medical service and medical attention in the event of sickness' (Article 12.2 d ICESCR). This includes 'the provision of equal and timely access to basic preventive, curative, rehabilitative health services …, and the provision of essential medicines'.[163] Even more, access to essential medicines is considered as a core obligation that must be ensured under Article 12 of the Convention.[164]

A key element to exercise the right to health, and socio-economic rights in general, is the prohibition of discrimination (Article 2.2 and 3). This proscribes any differential treatment in access to health care for a variety of reasons, which 'has the intention or effect of nullifying or impairing the enjoyment or exercise of the right to health'.[165] Assuming that age can be included under "other status", this would mean that age is an internationally prohibited ground for any discrimination in health care access. In principle, since the Committee interpreting the Covenant leaves States some room to manoeuvre, as explained hereafter.

At Council of Europe level, the International Covenant's right to health provision has been confirmed in the Oviedo Convention, reiterating that 'Parties, taking into account health

rehabilitation or long-term care. This includes pharmaceuticals, devices, procedures and organisational systems used in health care", INAHTA glossery <htaglossery.net>.

[159] The Right to the Highest Attainable Standard of Health: General Comment (GC) no. 14 (2000) on Health, 11/08/2000, E/C.12/2000/4

[160] Idem para 30

[161] Para 31

[162] By virtue of Article 2.2 and 3 of the CESCR, the Covenant prohibits any discrimination in access to healthcare

[163] GC 14, para 17

[164] Para 43, referring to the WHO list of essential medicines.

[165] Para 18

needs and available resources, shall take appropriate measures with a view to providing, within their jurisdiction, equitable access to healthcare of appropriate quality (Article 3).[166] In the preparatory stage it already became clear that no individual will obtain *all* the demands of health care, but the Convention focusses on the *health* needs and available resources.[167] The next question, then, is: what are these health needs? A general interpretation is given by the Working Party by interpreting health needs to comprise the medical needs for preventive, diagnostic and therapeutic interventions, but, still, this covers practically all medical services prescribed.[168] Similar contingencies of care can be found in the European Social Security Code (Article 10), defining the need for general practitioner and specialist care inside and outside hospitals, pharmaceutical care, dental care, medical rehabilitation and emergency transport. The wide range of health needs is, however, restricted by the reference to 'available resources', emphasising that human and financial resources are limited and may differ by country.

The health care services and goods provided should be of 'appropriate quality', meaning 'designed to ... improve a person's state of health or alleviate suffering', and the care must fit the 'standard in the light of scientific progress and subject to continuous quality assessment'.[169] Apart from complying with scientific standards, health care should also comply with medical *professional* standards, a broader concept as explained in Article 4 of the Convention.

Still, the precise standards of medical care are to be defined by individual States, as long as the level is in accordance with international medical standards. This would imply that newly developed treatment methods which are not generally considered as good medical practice do not have to be covered by national social security law or, in the case of 'necessary pharmaceutical care', States cannot be forced to reimburse the most expensive medicine when an equally effective generic for a certain treatment is available.[170]

Finally, what can be concluded from the drafting discussions is that the wording 'shall take appropriate measures to provide equitable access' and 'taking into account the available resources' does not create an individual right which would entail an obligation to produce a certain result, i.e. equitable access. Instead, the Convention's Committee on Bioethics formulated an obligation with regard to the *means* employed by requiring parties to 'take appropriate steps with a view to ...', aimed at securing equitable access.[171] So, in the end, it can be concluded that Article 3 includes a binding obligation to take appropriate steps to achieve equitable access, as far as the available resources permit, meaning that it is not aimed at creating an individual or personal right to be used as a basis for legal action against the State, but rather to urge States to take adequate measures to ensure access for all.[172]

Right to life and newly developed medicines

Protected under the European Convention on Human Rights (Article 2 ECHR) and other international treaty documents, it is nowadays accepted that the right to life is not limited

[166] Officially, the 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, Oviedo 4.April 1997, ETS 164

[167] CORED 1-3/06/93, p. 16

[168] Ibid CDBI, CORED 1-3/06/93, p. 16

[169] Explanatory Report (EXP) ETS 164, para 24

[170] EXP European Code of Social Security (Revised) 1998, paras 124-6

[171] CDBI 29/11-3/12/93, p. 17

[172] CORED 24-27/01/94, p. 18; EXP para 26

to refraining from taking life intentionally and unlawfully but also implies the States' duty to take appropriate steps to safeguard the lives of its citizens.[173] In the context of health care, this provision has been used to claim access to promising newly developed medicines, not covered by national health plans. It was argued that the refusal to make life-saving medicines available under the national social health insurance scheme is considered an act of omission under Article 2. On rare occasions, the European Court of Human Rights (ECtHR) has accepted such an obligation based on Article 2. For instance, in *Panaitescu* v *Romania*, the Court confirmed the domestic courts' ruling that the State had failed to provide adequate treatment, putting an elderly's life at risk.[174] In this particular case, the life-saving cancer drug Avastin was not yet registered on the list of medicines covered by the health insurance scheme but already approved by the National Medicines Agency at the time the domestic procedure started. Still, the Health Insurance Fund refused to enforce the domestic court order for providing the necessary anticancer treatment for free. According to the ECtHR, the patient's right to free medical care was more than once hindered, mainly on bureaucratic grounds, which ultimately resulted in the patient's death. The Court concluded that since there was no justification for the State's conduct and given the gravity of the illness, the authorities failed to take timely measures (i.e. listing and providing Avastin for free), therefore – unanimously – holding a breach of Article 2.[175] In this exceptional case of unreasonable obstruction of enforcing a court order, the State has not adequately protected the patient's right to life.
But the State obligation to provide lifesaving medicines under Article 2 is restricted to *medically accepted* treatment options. This became clear in *Hristozov v Bulgaria*, where the applicants complained that the Bulgarian authorities refused authorisation for using a non-registered and untested medicine involving a life-threatening disease.[176] According to the Court, it is true that the positive obligations under Article 2 include a duty to regulate the conditions market entry of medicines. Clinical trials testing a product's safety and efficacy are an essential part of the market authorization procedure, and therefore of market access. By exception, non-registered medicines could be granted market access but only if they are studied in clinical trials in other countries. In this particular case that was not being undertaken. In the Court's view, Article 2 does not impose an obligation to regulate access to unauthorised medicines for terminally ill persons 'in a particular way'.[177] Member states have a wide margin of appreciation setting the conditions for such medicines.

Without doubt, both *Panaitescu* and *Hristozov* are tragic cases though with different outcomes. This can be explained by the fact that Avastin was already approved by the Romanian Medicine Agency but not yet covered by the list of reimbursed medicines. Therefore, Avastin can be classified as a regular and authorised medicine, which was not the case in *Hristozov*. Secondly, in *Panaitescu*, the breach of Article 2 was based on 'bureaucratic unwillingness' to put Avastin on the positive list for reimbursement, as concluded by the national courts. 'Listing', therefore, could be considered as a positive obligation, whereas refusal to act was a breach of the State's procedural obligations under Article 2.

[173] E.g., *LCB v the United Kingdom*, (ECtHR 9 June 1998), para 36 (14/1997/798/1001)
[174] *Panaitescu v Romania*, appl no. 30909/06 (ECtHR, 10 July 2012).
[175] Ibid para 37
[176] *Hristozov and others v Bulgaria,* appl nos. 47039/11 and 358/12 (ECtHR, 29 April 2013)
[177] Ibid para 108.

Private life and medical devices

The concept of private life under Article 8 of the European Convention is a wide concept encompassing a person's physical and psychological integrity, personal development and personal autonomy,[178] and has been frequently applied in the health care context. What is relevant in the rationing setting, are the complaints about (the lack of) public funding to facilitate the mobility and quality of life of disabled applicants. Primarily understood as an obligation of the State not to intervene unlawfully the private sphere of the individual, the Court has frequently used the concept of 'positive obligations', i.e. the assumption that States are under the obligation to actively respect the individual's private life by means of safeguarding socio-economic rights.[179] Such a positive obligation to publicly fund medical care services in order to guarantee the effective enjoyment of private life can be deduced from the wording of Article 8.[180] Whether or not there will be such a positive State obligation exists 'regard must be taken to the fair balance that has to be struck between the competing interest of the individual and the community as a whole, and in any case the State enjoys a certain margin of appreciation'.[181]

For instance, in *Sentges v. the Netherlands*, a teenage boy with multiple handicaps, Nicki *Sentges*, complained when his request for a robotic arm was denied.[182] He claimed that under Article 8, the authorities were under a positive obligation to provide him with this medical device, arguing that the concept of private life encompassed notions pertaining to the quality of life, including personal autonomy, and the right to establish and develop relationships with other human beings. *Sentges* argued that the constraints on him were unacceptable as he was never able to be alone and his total dependency on others 'forced him to establish and develop friendships that he might not have chosen had he not been disabled'. While the essential object of Article 8 is to protect the individual against arbitrary interference, the Court has held that this provision may also include positive obligations inherent in effective respect for private or family life.[183] These obligations may involve the adoption of measures designed to secure respect of private life.[184] But in order to find a positive obligation on the part of the state there needs to be a 'direct and immediate link' between the measures sought by the applicant and his private life. But the Court declined to decide whether such a link had been established. Instead, the Court concluded that with regard to issues involving the assessment of priorities of limited health care resources, national authorities enjoy a particularly wide margin of appreciation since they 'are in a better position to carry out this assessment than an international court' (the "fair balance" test). Here, the Court considered that the provision of a robotic arm fell within the margin doctrine since the applicant had access to the standard package of health care provided by the health insurance scheme, i.e. an electric wheelchair with an adapted joystick.

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[178] *McDonald v the United Kingdom*, Appl no. 4241/12 (ECtHR, 20 August 2014) para 46.

[179] see in more detail, I LEIJTEN, *CORE SOCIO-ECONOMIC RIGHTS AND THE EUROPEAN COURT OF HUMAN RIGHTS*, (CUP 2018).

[180] P. van Dijk at al, THEORY AND PRACTICE OF THE EUROPEAN CONVENTION ON HUMAN RIGHTS, (KLUWER INTERNATIONAL 1998) 535, although rarely accepted.

[181] Case *López Ostra v. Spain*, Appl no. 16798/90 (ECtHR, 9 December 1994), para 51.

[182] *Sentges v the Netherlands*, (dec.) Appl no. 27677/02 (ECtHR, 8 July 2003)

[183] See also *Guerra and Others v. Italy*, Appl no. 14967/89, 1998; *Botta v. Italy*, App. No. 21439/93, Eur. Ct. H.R. 12 (1998).

[184] See for instance, *Stubbings and Others v. the United Kingdom*, Appl no. 22083/93, 22095/93, Eur. Ct. H.R. 44, § 62 (1996).

Following *Sentges*, the Court's is hesitant to link the health care right with private life, and its "fair balance" test, means it is extremely difficult, if not impossible, to enforce health care claims on this basis.[185] The court's reluctancy to intervene is further illustrated in *McDonald v. the United Kingdom*, where local authorities replaced night-time care with a cheaper alternative.[186] Initially, Elaine McDonald – a elderly disabled person – was assessed for and provided with a sleep-in care worker for seven nights a week. But the Court reaffirmed that States have a wide margin of appreciation in issues of healthcare policies and that this margin is particularly wide when the issues involve an assessment of priorities in the context of the allocation of limited State resources (par 54-55). It also found that the proportionality of the decision to reduce the applicant's care package was fully considered by the national courts, taking into account the local authority's efforts to consult the applicant and its concerns for her safety, independence and other care users (par 57). Consequently, the Court concluded that the requirements under Article 8 paragraph 2 ECHR were met and the State did not exceed the margin of appreciation afforded to it. The complaint was therefore found to be manifestly ill-founded and rejected. Earlier, the Court of Human Rights made it very clear that 'the allocation of public funds in the area of health care… is not a matter on which the Court should take a stand. It is for the competent authorities Member States to consider and decide how their limited resources should be allocated'.[187]

In other jurisdictions, outside the Council of Europe, a similar tendency can be observed: holding individual States accountable for non-compliance to health-related rights and health care access obligations. Groundbreaking is the South African *Treatment Action Campaign* (TAC) case, in which the Constitutional Court ruled that the restricted provision of a life-saving medicine that was safe and had no cost implications, was unreasonable and unconstitutional.[188] Even when a Constitutional right to health is absent, that did not withheld the Supreme Court of India to conclude the right to health as an integral part of the right to life, as protected by the national Constitution, and thus obliging the State to take the necessary measures ensuring good health.[189]
Inspired by the European Court of Human Rights' jurisprudence, the Inter-American Court of Human Rights held the right to health justiciable by applying the right to (private) life, and the progressive realisation principle recognised by the American Convention on Human Rights (Article 26).[190]

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[185] Confirmed in *Pentiacova and Others v Moldova,* Appl no 14462/03 (ECtHR, 4 January 2005) insufficient public funding of haemodialysis and out of pocket payments). *McDonald v UK*, note 22, para 57. No failure to strike a fair balance of competing interests, i.e. protecting the person's physical and psychological integrity v. public funding as a whole.
[186] See note 22
[187] *Wiater v Poland*, Appl no. 42290/08 (ECtHR, 15 May 2012) para 39.
[188] *Minister of Health v. Treatment Action Campaign* (2002) Case CCT 8/02, 5 SA 721 (CC), paras 80-81, applying the so-called 'reasonableness-test' on State's compliance with socio-economic rights obligations.
[189] Consumer Education and Research Centre v. Union of India (1995) 3 SCC (globalhealthrights database)
[190] E.g., *Artavia Murillo and others v. Costa Rica* (IVF treatment) 28 November 2012 (private life); Vinicio Vilches v. Chile, 8 March 2018 (emergency medical services and the right to life, right to health and progressive development of socio-economic rights); *Cuscul Pivaral and others v. Guatemala*, 23 August 2018 (HIV treatment under Article 26 IACHR). Similar examples enforcing health care rights are described in: COLLEEN FLOOD and AEYAL GROSS, *THE RIGHT TO HEALTH AT THE PUBLIC/PRIVATE DIVIDE. A GLOBAL COMPARATIVE STUDY* (CUP, 2014).

3. Access to medical technologies and (age-based) rationing

Understanding health care rationing

Confronted with a rapidly ageing population in need of medical care, and the drive for technological innovations in healthcare (e.g. diagnostic devices, therapy options and medicines), the need for rationing healthcare is unavoidable.[191] Here, healthcare rationing is understood as more than the allocation of scarce resources. Rationing is defined as setting limits to the basket of care that will result in the denial of, or delay in specific medical interventions. Exclusion of necessary health care for other than medical - read financial - reasons. When alternatives to contain costs of health care have failed, or appeared inadequate (efficiency measures, co-payments, etc.), more drastic cost saving measures as rationing health care become reality.

Nowadays, most health care systems are familiar with some kind of rationing, either explicitly or implicitly.[192] Ideally, choices in health care are made explicit, based on transparent, democratic and participatory decision-making procedures, valuing verifiable reasons or criteria known in advance. Except for the National Institute for Health and Care Excellence (NICE) – responsible for the appraisal of new technologies based on clinical and economic evaluations - such a deliberate and explicit process is unknown in most countries.[193]

More common is implicit rationing decided by clinicians at the bedside. Neither the decision, nor the basis for that decisions is clear. It happens in secrecy, 'behind the scenes', and lacks public scrutiny.[194] As a result, implicit rationing has been criticized since physicians fail to inform the patients about the real reason for the denial of a necessary treatment, primarily to prevent distress or an uncomfortable position. Nowadays, implicit rationing has been generally rejected.[195]

Who decides?

As rationing comes in a variety of forms, there are several actors involved in rationing decision-making. The most common and least problematic form of rationing occurs at hospital level in case of organ transplantation. Given the scarcity of human organs, the allocation of scarce organs is based on medical criteria (medical need, urgency, waiting time,

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[191] See for the notion of rationing in more detail: CHRIS NEWDICK, *WHO SHOULD WE TREEAT? RIGHTS, RATIONING, AND RESOURCES IN THE NHS* (OUP 2005); KEITH SYRETT, *LAW, LEGITIMACY AND THE RATIONING OF HEALTHCARE: A CONTEXTUAL AND COMPARATIVE PERSPECTIVE* (CUP 2007); JOCHEM TAUPITZ, 'GESUNDHEITSVERSORGUNG BEI RESSOURCENKNAPPHEIT – RECHTLICHE ASPEKTE, IN RATIONALISIERUNG UND RATIONIERUNG IM DEUTSCHEN GESUNDHEITSWESEN', AKEDEMIE DER WISSENSCHAFTEN UND DER LITERATUR, SYMPOSIUM AM 6.5.1998 IN MAINZ, 86-108; BETTINA SCHOENE-SEIFERT, ALENA M BUYX, JS Ach, *GERECHT BEHANDELT? RATIONIERUNG AND PRIORISIERUNG IM GESUNDHEITSWESEN* (MENTIS, 2006)

[192] Rationing comes in a variety of forms. An alternative classification differentiates rationing by denial, by selection, by deterrence, by deflection, or by delution, in: RUDOLF KLEIN, JO MAYBIN, *THINKING ABOUT RATIONING*, (THE KING'S FUND, 2012) vi.

[193] https://nice.org.uk/guidance; other attempts to ration health care include the 'Oregon Health Plan', M HALL, 'THE PROBEMS WITH RULE-BASED RATIONING', (1994) 19 *J MED PHILOS* 4; Commissie Keuzen in de zorg. Kiezen en delen (in DUTCH 'CHOICES IN HEALTHCARE') MINISTRY OF HEALTH, (RIJSWIJK, 1991).

[194] E.g., STEFAN HUSTER AND OTHERS, 'IMPLIZITE RATIONIERUNG ALS RECHTSPROBLEM', 25 *MedR,* 703-706 (2007).

[195] E.g. GRACE OEI, 'EXPLICIT VERSUS IMPLICIT RATIONING; LET'S BE HONEST', 7 *AMERICAN J BIOETHICS*, 68-70 (2016); FRIEDRICH BREYER, 'IMPLIZITE VERSUS EXPLIZITE RATIONIERUNG VON GESUNDHEITSLEISTUNGEN', Bundesgesetzblatt 55, 652-659 (2012).

benefit, risks), and standardised procedures as agreed among medical professionals and/or confirmed by government regulations.
Little consensus is about bedside rationing by individual clinicians. In this case, the physician has to decide which patient will receive the last available bed at the Intensive Care unit, because of the high co-payment associated with the patient's insurance. Illustrative is the situation in Russia as described by Vlassov where leading physicians, acting as head of departments deny costly interventions not covered by insurance, although argued for reasons of "controlling proper use", instead of rationing.[196]
At macro level, the NHS England and the Clinical Commissioning Groups (CCGs) – succeeding the commissioners role from the Primary Care Trusts (PCTs) - have a mandate to decide which treatments are available and which are restricted due to restricted resources.[197] As mentioned these decisions of both NHS England and CCGs are guided by NICE appraisal guidelines. In exceptional cases, by submitting an individual funding request (IFR), patients will be granted a treatment or procedure not generally available in the NHS.[198]
In social health insurance (SHI) systems, the 'package of care' decision-making has been institutionalised by federal or national bodies (e.g., the Federal Joint Committee (Ge), High Authority for Health (Fr), or the Health Care Institute (NL)), with a wide range of regulatory powers. These decisions, 'listing or delisting' services from the benefit catalogue are based on evaluation of evidence-based reports by the Institute for Quality and Efficiency in Health Care (IQWiG, Ge), and similar authoritative bodies (Health Care Institute, NL, etc). So far, these evaluation studies have focused primarily on cost-effectiveness of new medicines. Initiatives at European level, such as establishing an EU-wide network on Health Technology Assessment (HTA) and the Commission's proposal of a Regulation on HTA might help to improve the evaluation process, while increasing transparency in the appraisal decision-making process.[199] But overall, an explicit rationing mechanism or cost-effectiveness threshold is absent in most SHI systems.[200]

Based on what criteria?
Probably the most difficult question to be addressed is based on which criteria should we ration? Well known criteria used, are clinical effectiveness, medical necessity, and cost-effectiveness (CE) to define what should be covered or not, although these criteria are not always specified in detail. For instance, what is considered medically necessary may change over time, depending on developments and innovations in medical science.[201] Scientific research and medical practice may question the clinical effectiveness of particular interventions or technologies, whereas cost effectiveness studies may urge the exclusion or inclusion of existing and new therapies. CE analysis is an analytical technique that allows comparing the costs of two health interventions (surgery or medication) with the expected

[196] V VLASSOV at al, 'THE IDEA ALIEN TO BOTH WORLDS: WHY HEALTH CARE RATIONING IS NOT ACCEPTABLE IN THE USA AND RUSSIA', 3 J Medical Law & Ethics 231-239 (2019)
[197] M SHEPPARD, 'RATIONING IN THE ENGLISH NHS AND THE TENSION BETWEEN PATIENT CHOICE AND SOLIDARITY', 3 J Medical Law & Ethics 269-285 (2019)
[198] SHEPPARD, 275-276.
[199] See the HTA Core Model of EUnetHTA (www.EUnetHTA.eu) and the Proposal for a Regulation on health technology assessment and amending Directive 2011/24/EU, 31 January 2018, COM(2018)51 final.
[200] It was suggested to apply a bandwidth with a median value of €40,000/per added life-year (QALY), CPB Document no. 152, 10 (in Dutch), see: www.zorginstituutnederland.nl.
[201] B. GIBIS et al, 'SHIFTING CRITERIA FOR BENEFIT DECISIONS IN SOCIAL HEALTH INSURANCE SYSTEMS; IN: SALTMAN ET AL (eds.) (n.7), 189-190.

health gains, or effectiveness (adverse reactions avoided, prevented death).[202] Although opponents may criticize the idea of valuing live time in money, this is what economists do by calculating the cost-effectiveness ratio based on a number of days saved by treatment in 'quality-adjusted life-years' (QALYs). The goal of the decision-maker is to adopt a low QALY threshold for the costs of treatment.[203] Above this threshold, treatment will be considered unaffordable and be excluded from coverage. The decisive criterion for coverage is therefore the maximization of QALYs gained. For instance, NICE in the United Kingdom has formulated a relative threshold of £20,000-£30,000.[204] In the Netherlands, such a (flexible) ceiling value was recommended but has never accepted by the Dutch government.[205] Setting a limit at policy level appears extremely difficult. Still, the idea of economic evaluation studies may increase the need for transparency in coverage decision-making. It urges policy-makers to argue why a certain intervention is excluded from coverage, and thus, provides the transparency needed to legitimize coverage decisions.[206] What should be emphasized is the *additional* role of CE, next to clinical effectiveness studies in coverage decision-making.

Age-based rationing

Is there a fair degree of consensus about the need for rationing, denial of beneficial medical services based on (chronological) age as an independent criterion, is highly controversial. Critics consider it per se 'ageist' and thus discriminatory to exclude the elderly from necessary health care for costs reasons.[207] Knowing that it has been applied in practice already,[208] it is the question of whether certain forms of age-based rationing can be justified by international human rights law.[209] Finding an answer, understanding the non-discrimination concept is vital. Here, it is argued that interpreting that notion based on

[202] The leading economist NEUMANN has made a plea to incorporate cost-effectiveness analysis, next to existing criteria, in coverage decision-making. PETER J NEUMANN, *USING COST-EFFECTIVENESS ANALYSIS TO IMPROVE HEALTH CARE. OPPORTUNITIES AND BARRIERS* (OXFORD UNIVERSITY PRESS 2005)

[203] ALAN M GARBER ET AL., THEORETICAL FOUNDATIONS OF COST-EFFECTIVENESS ANALYSIS (reference made in NEUMANN, note 46)

[204] NICE has always avoided the term 'threshold'.

[205] It was suggested to apply a bandwidth with a median value of €40,000/per added life-year (QALY), CPB DOCUMENT NO. 152, 10 (in Dutch), see: www.zorginstituutnederland.nl.

[206] ANDRE DEN EXTER, 'COST-EFFECTVENESS ANALYSIS: WHAT'S LAW GOT TO DO WITH IT?' *INT J LAW AND MEDICINE* 285-297, at 290 (2014)

[207] Ageism: just like racism or sexism are based on ethnicity and gender, ageism is a form of systematic stereotyping and discrimination against people simply because they are old. As a group, older people are categorized as rigid in thought and manner, old fashioned in morality and skills. They are boring, stingy, cranky, demanding, avaricious, bossy, ugly, dirty and useless. An ageist younger generation sees older people as different from itself; it subtly ceases to identify with its elders as human beings (RN BUTLER ET AL, 'AGE-ISM: ANOTHER FORM OF BIGOTRY', 4 THE GERONTOLOGIST, 243-6 (1969), reference made by I DORON AND N GEORGANTZI (eds.), *AGEING, AGEISM AND THE LAW: EUROPEAN PERSPECTIVES ON THE RIGHTS OF OLDER PERSONS* (ELGAR PRESS 2018), 4

[208] Country evidence shows that age, independent of comorbidity, directly influenced cardiac decision-making: C HARRIES ET AL, 'WHICH DOCTORS ARE INFLUENCED BY A PATIENT'S AGE?', 16 QUAL SAF HEALTH CARE 23-27 (2007); D JENNI ET AL, 'EVIDENCE FOR AGE-BASED RATIONING IN A SWISS UNIVERSITY HOSPITAL', 131 SWISS MED WKLY 630-634 (2001).

[209] Variants proposed by leading ethicists such as CALLAHAN with a "natural lifespan" view D CALLAHAN, *SETTING LIMITS: MEDICAL GOALS IN AN AGEING SOCIETY,* (1987 NY Simon & Shuster); N DANIELS AND JE SABIN, *SETTING LIMITS FAIRLY: CAN WE LEARN TO SHARE MEDICAL RESOURCES?* (OXFORD ONLINE 2009); and L FLECK, *JUST CARING : HEALTH CARE RATIONING AND DEMOCRATIC DELIBERATION* (OUP, NEW YORK 2009).

international human rights law may support the idea that limited forms of age-based rationing are not necessarily considered to be discriminatory, or can be reasonably justified for reasons derived from other disciplines and, conditionally, considered as permissible.[210] Consider two patients equally in need of an expensive life-saving treatment. Then preference will be given to the younger patient (age 30) instead of the elderly patient (age 85), because of his age, and because of different prospects for long-term survival (average 50 vs 5 years health gain). A certain age level then functions as a threshold for deprioritising the elderly. This differential treatment has been justified with the "fair-innings" argument.[211] The general idea of the fair-innings view is that, in the event of competing equal needs, the healthcare interests of the elderly should not be ignored, but should be deprioritised in favour of the younger patient. During his life, the older patient has received the *chance* to access all necessary healthcare services, and as a consequence has lived a relatively comfortable and satisfied life and received his "fair innings", including education, building a career, marriage, and starting a family.[212] As such, the age of 85 functions as a threshold. The younger patient, however, has not received that chance, and consequently will die prematurely if the particular treatment is denied due to scarce resources. The fair-innings theory assumes that the death of the elderly at the age of 85 is a loss, but unavoidable as everybody will die anyway, whereas the death of a young patient is considered a tragedy that could have been prevented by prioritising his treatment. It is emphasised that the health needs of the elderly will not be ignored, meaning that all kinds of necessary care will be provided aimed at maintaining or improving quality of life, rather than prolonging life.[213] Age-based rationing proposals therefore do not generally advocate the withholding of all medical treatment from the elderly, but only limited to high-cost life-extending care, taking into account relevant circumstances such as survival prospect, and degree of effectiveness or benefits (subtle age rationing).[214]

Is such an age-based threshold discriminatory? Not necessarily, taking into account the conditions set by CESCR in General Comment 20, which clarifies the Committee's understanding of non-discrimination in socioeconomic rights.[215] In the Committee's view, "discrimination constitutes any distinction, exclusion, restriction or preference or other differential treatment that is directly or indirectly based on the prohibited grounds of discrimination and which has the intention or effect of nullifying or impairing the recognition, enjoyment or exercise, on an equal footing, of Covenant rights".[216] States must therefore "immediately adopt measures to prevent, diminish and eliminate the conditions and attitudes which cause or perpetuate substantive or de facto discrimination".[217]

Still, the Committee recognises that some forms of differential treatment can be permissible, provided that "the justification for differentiation is reasonable and

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[210] As argued by FLECK, ibid, p 294-299.

[211] As applied by JOHN HARRIS, *THE VALUE OF LIFE. A INTRODUCTION TO MEDICAL ETHICS* (ROUTLEDGE 1991) 91-94

[212] ibid

[213] G BOGNAR, 'FAIR INNINGS', 4 *BIOETHICS* 251-261, at 252 (2015)

[214] L FLECK, 'JUST CARING: IN DEFENSE OF LIMITING AGE-BASED HEALTHCARE RATIONING', 19 *Cam. Q. Healthcare Ethics* 27-37, at 35 (2010).

[215] CESCR, General Comment (GC) no. 20 Non-discrimination in economic, social and cultural rights, E/C12/GC/20, 2 July 2009, para 7.

[216] GC no. 20, para 7. A similar definition has been used in art. 1 ICERD; art. 1 CEDAW; and art. 2 CRPD

[217] Ibid, para 8.

objective".[218] Moreover, there must be a clear and reasonable relationship of proportionality between the aim sought to be realised and the measures or omissions and their effects. Also important is that "a failure to remove differential treatment on the basis of the lack of available resources is not an objective and reasonable justification unless every effort has been made to use all resources that are at the State party's disposal in an effort to address and eliminate the discrimination, as a matter of priority".[219]
Assuming that age can be considered as discrimination based on 'other status', it means that age-based rationing, to be justified, needs to comply with the Committee's conditions as mentioned above. Here it is argued that the rapidly increasing costs of long-term healthcare may provide such a reasonable justification. Latest trends on healthcare spending in OECD countries show an average increase of 3.4% on average in 2016.[220] Prior to the financial crisis (2009), that rate was even at around 4-6% per year.[221] Largely funded by public sources, various cost control measures (e.g. spending cuts on pharmaceuticals, salary control, de-listing services, high out-of-pocket payments) have reduced health spending sharply – in the early crisis years – but strong growth resumed quickly after this period, in particular long-term care expenditure.[222] While healthcare spending will continue to rise over the next 50 years, the pressure on long-term care costs in OECD countries is particularly worrying, explained by both demographic drivers (ageing population and disproportionate healthcare expenditure close to death, so-called 'death-related costs'), and non-demographic drivers (medical technology).[223] Without drastic measures, increased healthcare spending may threaten the financial sustainability of publicly funded healthcare systems. Confronted with these dramatic spending scenarios, the denial of life-prolonging medical care to the elderly (last chance therapies) contributes to ensuring the financial sustainability of the healthcare system, and is therefore considered a reasonable justification taking into account the specific circumstances as mentioned.
Such a controversial measure will be compatible with the Convention rights, assuming that the aim and effects of age-based rationing 'promote general welfare' (sustainability), while respecting the elderly's health needs, except for life-sustaining treatment. Secondly, defining a maximum age for age-based rationing is considered an objective standard, to be defined by State parties, allowing (groups of) individuals the right to participate actively in the decision-making process over the selection of such a criterion ('democratic deliberation').[224] This approach requires then access to and disclosure of all relevant information, a transparent and participatory decision-making process, regulated by law, and mechanisms for legal redress when rights have been violated. In a way, such a fair and accountable procedure combines both substantive and procedural principles, echoing the accountability for reasonableness standards advocated by Daniels and Sabin.[225]

[218] Ibidem, para 13.
[219] Ibidem
[220] OECD, SPENDING ON HEALTH: LATEST TRENDS, OECD June 2018, p.1.
[221] OECD 2013, WHAT FUTURE FOR HEALTH SPENDING?, OECD ECONOMIC DEP. POLICY NOTE, NO 19, 1.
[222] Ibid, p. 4; see also OECD HEALTH STATISTICS 2018 (long-term care spending) providing health data by country
[223] From 1.6% to 2.7% of GDP, i.e., an increase of almost 70%, OECD 2013, AT 9-11. One of the main drivers of death-related costs is dementia, read: OECD, ADDRESSING DEMENTIA, THE OECD RESPONSE, OECD HEALTH POLICY STUDY (PARIS 2015).
[224] Also argued by FLECK, note 53, ch.5.
[225] AfR: is the idea that the reasons or rationales for important limit-setting decisions should be publicly available. In addition, these reasons must be ones that "fair-minded" people can agree are relevant to

4. Criticism age-based rationing

Although the fair-innings view in age-based rationing has certain weaknesses, it is the least worst of selection criteria. Alternative criteria (gender, socio-economic status, religion, disability, cost-effectiveness thresholds, random lottery) appear arbitrary and are therefore rejected. When other cost-curbing measures have failed, then limited age-based rationing remains the least onerous, but most necessary, option to cope with an imminent public health threat.

What remains problematic are the relevant conditions or individual circumstances. Here, it is argued that age-based rationing is limited to high-cost life-extending interventions with relative marginal benefit or effect to an elderly compared with a non-elderly. It remains to be seen whether other conditions can also be justified (e.g., "last chance therapy").

Another difficulty is the question about what age should functioning as a threshold for rationing. Both the conditions as well as the maximum age limit require a public debate and democratic decision-making process as proposed.[226]

Furthermore, there is the assumption of equality of chances. What if an elderly has never had no fair innings at all: no opportunity for wellbeing over his lifetime? Or has this unfortunate person received something else of value in life that the younger did not receive yet? Finally, another difficulty is how to deal with "too close to call" cases, both in their seventies. Would then the fair innings argument deny both the necessary but costly therapy? And, even more problematic when both critically ill are nonelderly?

Perhaps, we should accept that the fair innings view has its limitations, leaving certain rationing scenarios unsolved.

5. Conclusion

Access to new health technologies is generally considered as part of the social right to health, creating state obligations to realise such a right progressively, by taking concrete and publicly deliberated measures, towards the full realisation. Nowadays, individual rights as the right to life and private life are also interpreted as creating positive State obligations in the field of health care to protect life and private life of the elderly. However, such positive obligations are restricted by the available resources which may differ by country. Since health care needs are unlimited but resources restricted, international human rights law has recognised the need for health care rationing.

Being confronted with hard choices, it has been argued that apart from a transparent and participatory procedure, there is a need for substantive criteria to ration health care, and open for judicial review. Age is here considered the least-worst option, and not necessarily ageist. Based on the fair innings argument and applying the non-discrimination principle, justifies limited forms of rationing beyond some age. Elderly people at the end-stage of life can therefore lawfully be excluded from extraordinary expensive treatment options with limited benefit or effectiveness.

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pursuing appropriate patient care under necessary resource restrictions (N DANIELS AND J SABIN, note 53, ch. 4, ebook).

[226] LM FLECK, 'JUST CARING: HEALTH CARE RATIONING, TERMINAL ILLNESS, AND THE MEDICALLY LEAST WELL OFF', 1 J LAW, MED & ETHICS 1 156-171 at 164 (2011).

Defending a fair allocation of scarce resources in health care using the age-criterion, is paradoxally also in the interest of future elderly, as it ensures the long-term need of necessary care. It is therefore recommended that any health policy considers such a rationing scenario based on both procedural and substantive principles, making it fair and accountable.

CHAPTER 4. Access to Reproductive Care Technologies

Towards a European cross-border fertility market?

1. Introduction

For centuries, mankind has been confronted with (the consequences of) infertility and searched for alternative ways of starting a family. A well known example of overcoming infertility was described in the Old Testament when Sarah, already in her nineties, encouraged Abraham to 'visit' her maid Hagar, who became pregnant with Ismael.[227] Such a 'ménage à trois' or surrogacy option has been observed in many cultures.[228] Nowadays, contemporary medicine and medical technology have developed more sophisticated methods for overcoming infertility. The first 'test tube' baby born by in vitro fertilisation (IVF) in the 1970s was generally considered a breakthrough in reproductive health: overcoming female infertility using medical or assisted reproductive technologies (ARTs). New methods at the interface of assisted reproduction and genetics have since been developed. These have enabled the selection of genetically 'healthy' embryos and modification of the genetic makeup, causing controversies on genetic selection and 'designer babies'.

Each country has its own way of dealing with ARTs and is very much influenced by social, ethical, legal and religious norms and values. As a direct result of the diversity in regulatory frameworks on ART treatment, a new phenomenon has arisen: cross-border reproductive care (CBRC) or reproductive tourism. Apart from human rights concerns, such reproductive health services may also trigger free trade principles. 'Repro' health services fall within the scope of European Union law, i.e. the free movement of services treaty provision, whilst the outcomes (cells and embryos) may be regarded as health goods distributed on a free market. This raises new questions about the role and dynamics of EU law when donor gametes (sperm, oocytes or fertilised embryos) cross borders. What exactly is the EU's role in cross-border access to reproductive care and is it possible to regulate this phenomenon at Union level? If not, are there any alternative options to promote universal access to ART treatment across Europe?

2. Understanding cross-border reproductive care

Contemporary medical science offers various treatment options for overcoming male and female infertility. These include IVF and related treatment methods, such as preimplantation genetic diagnosis (PGD) and screening (PGS), intracytoplasmic sperm injection (ICSI) aimed at tackling male infertility, gamete donation, frozen embryo transfer, frozen oocyte replacement (cryopreservation) in the case of cancer patients or delaying motherhood, as well as posthumous reproduction and surrogacy arrangements with or without a genetic link between the gestating woman and the child. Future developments include genome-editing technologies (CRISPR) for infertility treatment and the idea of

[227] Old Testament, Book of Genesis 16(2): .. "The Lord has kept me (Sarah) from having children. Go, sleep with my slave; perhaps I can build a family through her".

[228] E.g., in ancient Hindu society there existed a practice known as *Niyog Pratha*, wherein the wife was childless due to impotency of her husband. Here the brother in law was the surrogate father, quoted by A.M. Vyas, Surrogacy: The only hope for a few (2017) 3 *IJMSSR* (2017) p. 44.

'artificial wombs'.[229] Understanding the legal context of cross-border reproductive care, the analysis focuses on the internal market.[230]

Cross-border reproductive care: a free movement issue under EU law?

Although the human rights approach dominates the access-to-ARTs debate, European Union law and the internal market principles in particular, they also play a (limited) role in facilitating *cross-border* access to ART treatment. A well known example is the case of Diane Blood, triggering the free movement of services, when exporting sperm of her deceased husband to another member state in order to be inseminated abroad.[231] In this national case, the English Court of Appeal agreed that the free movement provision (Art. 56 TFEU) was applicable and should have been take into account in the decision to authorise the export.[232] Diane Blood is no exception, as recent studies show the growing popularity and thus emerging trend of 'fertility tourism' or infertile couples seeking cross-border reproductive care in other EU member states.[233] Reasons for crossing borders vary from avoiding legal restrictions in the resident country (e.g. fertility treatment for single or lesbian woman in France), the expected better quality of care (e.g. better success rates abroad), to avoid waiting times at home (egg donation in the United Kingdom) or for less expensive treatment.[234] The reasons given illustrate patients' willingness to cross borders and therefore their reliance on the internal market rules.

Dealing with health care services, the first question raised is whether such services and ARTs in particular can be considered a 'service' under the Treaty on the Functioning of the European Union (Arts. 56-62 TFEU). Secondly, can national measures restricting health professionals providing health services abroad or patients in search of such services abroad be justified under EU law?

Apart from the confirmative answer given by the English Court of Appeal in the Diane Blood case, in the famous cases on *Decker* and *Kohll*, the European Court of Justice, renamed the Court of Justice of the European Union (CJEU), accepted that health services fall within the scope of 'services' under the treaty.[235] Health services are no different from other economic activities, where they are normally provided for remuneration' and thus have an economic nature. Despite the specific context in which health care is normally provided, the social security setting cannot deprive its economic nature of the health service in question (para 21). That being so:

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[229] E.g., J.C. Harper (ed.) Preimplantation Genetic Diagnosis (2nd ed. CUP 2012); L. Tang and others, CRISPR/Cas9-mediated gene editing in human zygotes using Cas9 protein, Molecular Genetics and Genomics (2017) DOI: 10.1007/s00438-017-1299-z; A. Deglincerti and others, Self-organization of the in vitro attached human embryo, *Nature* 533, 251–254 (12 May 2016).

[230] For the human rights framework, see a more extensive version: A. den Exter (note 1).

[231] *R. v Human Fertilization and Embryology Authority*, ex parte Blood [1997] 2 All ER. 687.

[232] In more detail: T.K. Hervey and J.V. McHale, *European Union Health Law. Themes and Implications* (CUP 2015), p. 95.

[233] Although the exact data for cross-border reproductive care are unknown, there is some reliable evidence for an emerging trend based on a 2010 survey performed by the European Society for Human Reproduction and Embryology, F. Shenfield and others, 'Cross-border reproductive care in six European countries' (2010) 6 *Hum Reprod* p. 1361-1368. The study revealed some data on the frequency and destination countries estimating that there may be between 24,000-30,000 cycles of CBRC taking place in Europe per year, involving between 11,000-14,000 patients, at 1365.

[234] G. Pennings and others, ESHRE Task Force on Ethics and Law 15: Cross-border reproductive care, (2008)10 *Hum Reprod* 2182-2184, at 2182; F. Shenfield and others, 'Cross-border reproductive care in six European countries' (2010) 6 *Hum Reprod* p. 1361-1368, at 1363-64.

[235] *Kohll*, para 29.

> 'Article 49 EC (currently Art. 56 TFEU) applies where a patient … receives medical services in a hospital environment for consideration in a Member State other than her State of residence, regardless of the way in which the national system with which that person is registered and from which reimbursement of the cost of those services in subsequently sought operates.[236]

As a consequence, restrictions on the freedom of patients in search of cross-border (reproductive) health care services in another Member State are prohibited under EU economic law … at least, in principle. In various rulings, the Court has been confronted with the delicate balance between Member States' autonomy to regulate and organise their health care system and upholding the basic freedoms applied in health care. To cope with that dilemma, any justification for restricting these freedoms must be necessary and proportionate. In the case of ART treatment, the main question concerns possible grounds for justified impediments. On several occasions, the Court reviewed the arguments presented to justify national restrictions on free movement. Starting with the restriction as such, it is clear that the refusal of reimbursement of health care services abroad is considered an important barrier to free movement. This is even more the case when the claimed service is covered by the national health care system. The justification is then based on the general or public interest argument raised in social security issues, i.e. the risk of uncontrolled health expenditure. Although purely economic reasons cannot justify any restriction of the fundamental freedoms, in *Kohll*, the Court accepted the argument that 'the risk of seriously undermining the financial balance of the social security system may constitute an overriding reason in the general interest' justifying such a barrier (para 41). But in the case of the costs of dental treatment abroad, such a risk is unlikely. This would be different in the case of services provided in a hospital setting or using highly complex medical equipment and requiring a planning system. Here, the overriding risk of undermining the financial balance as well as wasting resources is more likely. Restricting free movement in the case of inpatient or 'high-tech' health services abroad can therefore be justified.[237] This reasoning was confirmed in the so-called Patient Mobility Directive (Directive 2011/24/EU) reading that 'the Member State of affiliation (i.e. the home state, *AdE*) may limit the application of the rules on reimbursement for cross-border health care based on overriding reasons of general interest, such as planning requirements relating to the aim of ensuring sufficient and permanent access to a balanced range of high quality treatment in the Member State concerned or to the wish to control costs and avoid, as far as possible, any waste of financial, technical and human resources.'[238] The planning argument can be considered a public health justification and thus a reason of general interest: necessary to guarantee long term access for the entire population. But only as long as such restrictions are 'necessary and proportionate, and non-discriminatory'.[239] Article 8(2)(b)(c) includes another exemption: 'in case the treatment presents a particular risk for the patient or the population', or in the case of serious quality and safety concerns of the care provided abroad. Here, one may argue that innovative reproductive technologies using gene-editing techniques (e.g. CRISPR technology) may cause such a public health concern (risk of 'designer babies').

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[236] *Watts*, para 90 ECLI:EU:C:2006:325.
[237] See *Smits-Peerbooms* (Case C-157/99) ECLI:EU:C:2001:404; *Commission v France* (Case C-512/08), ECLI:EU:C:2010:579.
[238] Art. 7[9] Directive 2011/24/EU.
[239] Art.7(11)).

What should be emphasised is that Directive 2011/24/EU is only applicable to health services covered by the national benefit scheme to which the person is entitled (Art. 7(1)). In the case of a national ban on ARTs, the Directive and therefore reimbursement is not applicable. Nevertheless, EU citizens may receive these reproductive services abroad, but then at their own costs. This raises the question whether less fortunate infertile couples, when confronted with a national ban on ART treatment, could claim reimbursement of treatment abroad based on EU Charter rights?

Cross-border reproductive care and "Charter shopping"

Since the Lisbon treaty, the EU Charter on Fundamental Rights has had the status of primary law, which rights can and must be invoked under both national courts and the Court of Justice.[240] Claiming access to ART treatment would be most likely be based on Article 35 providing that 'everyone has … the right to benefit from medical treatment under the conditions established by nation laws and practices.'[241] Challenging this right, one may argue that, according to contemporary human rights doctrine, the Charter rights create a positive obligation to provide and facilitate access to ART treatment. If accepted, this would mean an unprecedented infringement of the discretionary freedom of Member States to organise their own health care system. Most scholars, however, find it unlikely that the Charter right - or principle - to healthcare can be held justiciable.[242] This 'aspirational' norm leaves Member States a wide margin of appreciation on how to organise and to define the nature and scope of the health benefit scheme. And even when interpreted as a justiciable right, reading Article 35 more precisely, it has accepted such an ART ban by referring to 'the right benefit from medical treatment *under the conditions established by national law and practices.'*

Challenging the ART ban under the more 'individual rights' such as private and family life provisions (Art. 7) and gender-based non-discrimination (Art. 21(1))[243] also seems unlikely because neither rights are absolute, allowing restrictions set by law when necessary and proportionate. But in the absence of any case law, it is not known how the CJEU will interpret such a combined individual-social rights claim.[244] Moreover, and this is the most

[240] FRA fundamental rights report 2016 on how national courts apply Charter rights. The FRA Case-law database provides a compilation of CJEU case law with direct reference to the Union Charter, such as *Brüstle* case (C-34/10)(human dignity), *Schremps* case (C-362/14) (private life); *Legér* case (C-528/13) (non-discrimination); *Weintor* (C-544-10)(public health), paras 42-59.

[241] Either or not combined with other Charter rights, such as the right to private life (Art.7 corresponding to Art. 8 ECHR), and non-discrimination (Art. 21(1)).

[242] E.g., Hervey and McHale, Article 35, although the potential for a right to healthcare claim is there, particularly in case of vulnerable groups, in: S. Peers and others (eds), *The EU charter of fundamental rights: a commentary* (Hart 2014), p. 957; and linked with more individual rights, see Hervey and McHale p. 160, 176-7; the same line of reasoning, see N. Koffeman, *Morally Sensitive Issues and Cross-border Movement in the EU. The cases of reproductive matters and legal recognition of same-sex relationships* (Diss.) (Intersentia 2015), p. 70-80; D. Anderson and C. Murphy, 'The Charter of Fundamental Rights', in A. Biondi. P. Eeckhout, S. Ripley (eds), *EU Law after Lisbon* (OUP 2012), p. 161-2.

[243] Art. 21(1) including gender or sexual orientation-based discrimination of lesbian, bisexual and transgender women excluded from ART treatment.

[244] So far, available case law concerning Art.35 focusses on the protection of health then access to health care services, see CJEU C-544/10, *Deutsches Weintor*, 6 September 2012 (on marketing alcoholic beverages), CJEU C-570/07 and C-571/07 *Blanco Perez* (protection of public health) ECLI:EU:C:2010:300; C-267/10 and C-268/10 (selling tobacco products); CJEU C-343/09 Opinion A-G (interpreting precautionary principle). In *Stamatelaki* however, the A-G concluded that 'this right (to health care, AdE) is perceived as a personal entitlement, unconnected to a person's relationship with social security…". Althought the A-G considered the matter within

problematic hurdle when relying on the EU Charter Rights, the Charter refers to Union institutions and Member States only when they are implementing Union law (Art. 51(1)).[245] This is not the case with health care, as there is simply no EU health care system.[246] Although 'Union law and regulation on economic and fiscal governance is beginning to have an effect … on national health care systems.'[247] But does this apply to ARTs? ART treatment is based on the use of human reproductive cells (sperm, eggs and embryonic stem cells), as covered by the Human Tissues and Cells Directive (Dir. 2004/23/EC, recital 7).[248] The Directive aims at standardising the quality and safety procedures of gametes, amongst others, as applied in ARTs (Art. 1). Implementing the Directive's quality and safety standards in national measures would therefore 'trigger' the application of the Charter and thus the possibility of human rights review. At the same time, however, Article 51(2) does not extend the field of application *beyond* Union competences or establish any *new* power for the Union and therefore cannot be used as a gateway to general fundamental rights competence.[249] This is also confirmed by the Directive as it 'should not interfere with decisions made by Member States concerning the use or non-use of any specific type of human cells' (recital 12). Only when 'any particular use of such cells is authorised in a Member State, will this Directive require the application of all provisions necessary to protect public health…' (recital 12). This means that Member States remain free to exclude ARTs from the health benefit scheme, and are thus excluded from the Charter's scope implementing Union law. But when approved, it should respect Union safety and quality norms, including donor rights such as informed consent and anonymity, respecting privacy and confidentiality and the non-discrimination principle.

Slightly different, but the similar result concerns the in vitro diagnostic medical devices Directive (IVDD), to be replaced by the new IVD Regulation.[250] The IVD Directive sets technical standards for manufacturers placing IVD products as applied for IVF treatments, on the market. Harmonisation of national legislation will remove existing barriers to free movement of IVD equipment within the EU. Although Member States will not create any obstacles to placing these devices on the market (Art. 4), the harmonising effect does not affect the Member States' exclusive competence to decide on the organisation and funding of IVD equipment under the public health or social insurance scheme (rec. 4). Revision of the IVDD under the forthcoming Regulation will not change this approach.[251] The trade-

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the free movement of services context, he noted that 'citizens' right to health care are unjustifiably and disproportionately restricted (para 65), case C-444/05, 11 January 2007.

[245] See also, e.g., case C-617/10 *Akerberg Fransson* [2013] ECR ECLI:EU:2013:105.

[246] Also Hervey (note 18).

[247] ibid

[248] Directive 2004/23/EC on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage, and distribution of human tissues and cells, OJ L 102, 7 April 2004.

[249] The limited applicability of Union fundamental rights and the narrow approach taken by the Court of Justice soafar, has also been critized, see E. Spaventa, The interpretation of Article 51 of the EU Charter of Fundamental Rights: the dilemma of stricter or broader application of the Charter to national measures, a study performed on behalf of DG for Internal Policies, 2016, p. 15 available at: www.europarl.europa.eu/supporting-analyses.

[250] Directive 98/79/EC OJ L 331, 7.12.1998, as amended.

[251] Idem under the IVDR, Article 1(9): this Regulation shall not affect national legislation concerning the organisation, delivery or finance of health services and medical care, such as the requirement that certain medical devices may only be supplied on a medical prescription, the requirement that only certain health professionals or health care institutions may dispense or use certain devices or that their use is accompanied by specific professional counselling.

related approach of the IVDD/IVDR will therefore not support ART treatment claims under the EU Charter of Fundamental Rights.

3. Prospects for more coherence in regulating repro rights

Apart from harmonising safety and quality standards under the Human Tissues and Cells Directive, the availability, eligibility for treatment and requirements for reproductive health services remain the exclusive competence of Member States. This has resulted in a highly differentiated regulatory landscape of ART treatment, challenging women's reproductive rights in the EU.[252] The *Diane Blood* case made painfully clear that one can bypass more strict national regimes by invoking internal market principles. What's more, it reveals a new inequality: cross-border ART treatments for wealthy, well informed EU citizens in search of more advanced, more successful and less ethical(?) alternatives. EU law, however, seems unable to solve this inequality. Apparently, that is the price we pay for the lack of regulatory convergence in this field.[253]

The divergence in reproductive rights in Europe has been challenged by European Parliament. In a non-binding resolution on human rights, it was recognised that 'sexual and reproductive health and rights (SRHRs) are grounded in basic human rights and essential elements of human dignity, gender equality and self-determination', insisting 'on the role of the Union in awareness-raising and promoting best practices on this [women's reproductive health and rights, *AdE*] issue'.[254] Promoting best practices among Member States starts with collecting data on gender-based discrimination and reproductive health. This particularly applies for certain groups of women (lesbian, bisexual and transgender women) facing discrimination on the basis of their sexual orientation or gender identity. In the 2016 resolution, European Parliament repeated that call, but instead of incorporating gender in the EU Health Strategy, it called the Commission to include gender issues in all its policies, incorporating 'a systematic gender impact assessment as part of the fundamental rights compliance assessment'.[255] The systematic monitoring of progress in gender equality and reproductive health issues makes it possible to identify gaps at country level and to analyse progress. In a way, the Gender Equality Index 2015 already addresses women's health and gender equality but it does not differentiate in reproductive health issues.[256] Using reproductive health indicators (e.g. access and availability of reproductive health services, infertility rate, reproductive health rights legislation, accountability mechanisms, etc.)[257]

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[252] K. Berg Brigham and others, 'The Diversity of regulation and public financing of IVF in Europe and its impact on utilization' (2013) 3 *Hum Reprod* 666-675; European Society of Human Reproduction and Embryology (ESHRE), Comparative Analysis of Medically Assisted Reproduction in the EU: Regulation and Technologies, Final Report 2009 ESHRE, p 20-26.

[253] M. Frischhut, Legal and ethical issues of croos-border reproductive care from an EU perspective, in M.K. Smith and L. Puczkó (eds), *The Roudledge Handbook of Health Tourism* (Routledge, London 2017), pp. 203-218, at 213.

[254] European Parliament of 8 September 2015 on the situation of fundamental rights in the EU (2013-2014), (2014/2254(INI)), rec 69.

[255] European Parliament resolution of 13 December 2016 on the situation of fundamental rights in the EU in 2015, (2016/2009(INI)) Women's rights, para 78.

[256] Eige.europa.eu/gender-statistics/.

[257] Measuring gender-related change in the field of access to reproductive health services over time between men and women, and special groups such as LTGBI in particular. There are a number of such indicators developed by inter alia, the World Health Organization (WHO Reproductive Health Indicators. Guidelines for

with gender equality indicators[258] makes it possible to measure manifest gaps in reproductive rights and gender inequalities and to monitor a country's progress in improving access to reproductive services, including ART treatment. In this process, the European Institute for Gender Equality (EIGE) should play a key role in selecting relevant indicators, reviewing the impact of national measures and actions taken to improve reproductive rights and access to reproductive services for marginalised groups in particular. The outcomes will trigger a national and European debate about raising awareness and promoting best practices on improving reproductive rights in Europe, as emphasised by European Parliament. The subsequent debate may hold countries accountable for identified gaps, promoting the 'transferability' of national achievements across Member States. This approach to measuring the progress of reproductive health rights does not necessarily harmonise the divergent regulatory frameworks in Europe but it certainly contributes to the underlying concepts on progressive realisation of reproductive rights and holding countries accountable for gender and health inequalities and gender-based discrimination in access to reproductive health services. In fact, the use of indicators, benchmarks and exchanging best practices may produce more coherence (and convergence?) of standards on reproductive rights, as observed in other fields.[259]

This 'soft law' method used as guidance for EU and national legislatures reflects the core elements of the ICESCR and CEDAW state obligations (e.g. taking steps to fulfil women's right to health care according to the maximum available resources, measures to eliminate barriers to accessing reproductive health services, developing a reporting system to ensure equal access, etc.).[260] However, any future trend towards more coherence does not detract Member States to restrict reproductive health rights (e.g. by limiting access to ART treatment). But such limitations 'should be justified on grounds of public order or public health'[261] and be strictly necessary for the promotion of the general welfare in a democratic society (Article 4 ICESCR). And, even more interestingly, although public health motivated restrictions can be justified, ... 'they should be of limited duration and subject to review' (para 29). Focusing on ART treatment, this means that permanently excluding certain groups (LGTBI) for reasons of public order or public health would be unjustified as this could be considered an act 'aimed at the destruction of any of the rights … recognised herein, or at their limitation to a greater extent than is provided for in the Covenant' (Article 5 ICESCR). Finally, the identified gaps and inequalities *between* Member States call for improving cross-border collaboration in the field of reproductive rights. As under the ICESCR international cooperation clause, all States, including EU Member States, are obliged to collaborate to comply with the full realisation of Article 12 as 'gross inequalities in health status of the people …. are politically, socially and economically unacceptable, and therefore of common concern to all countries' (para 38). This can be interpreted as an obligation to conclude

their generation, interpretation and analysis for global monitoring, 2006), and the Guttmacher Institute, Sexual and Reproductive Health and Rights Indicators for the SDGs (2015) available at: www.guttmacher.org.

[258] Including both international and national indicators such as the sustainable development goals (SDGs), developed at UN level, regional indicators, the 'OECD Gender Index' and UNECE 'Indicators of Gender Equality' (2015), and other national criteria.

[259] Notably social security and social protection, see e.g, F. Pennings and G. Vonk, *Research Handbook on European social security law* (Edward Elgar Publishing, 2015), p 223-229; Although there is a fierce debate over the value of soft law. D. Chalmers, and others, *European Union law* (3rd ed. CUP, 2010) 102-3.

[260] As referred in GC no. 14 (Art. 12 ICESCR) and GR no. 24 (Art. 12 CEDAW

[261] CESCR interpretation of the Article 4 clause, GC no. 14, para 28.

bilateral agreements which facilitate cross-border access in the field of essential, and therefore reproductive, health services where possible and required.

4. Final remarks

Reproductive health care services remain a non-harmonised area of EU law. Excluded from EU competences, the divergence in regulatory frameworks and reproductive rights has not triggered [national courts] or the CJEU to remove the barriers hindering the free movement of reproductive health services, and access to ART treatment in particular. Even under the Fundamental Rights Charter, this is unlikely to be changed because it does not establish any new power for the Union and cannot therefore be used to hold Charter rights justiciable. Instead, filling the gaps in reproductive rights and improving access to ART treatment in particular, the use of soft law mechanisms on monitoring, measuring gender and reproductive health indicators and exchanging best practices may promote the use of a common set of principles or standards on reproductive health services and for holding Member States accountable for barriers to and new inequalities in access to reproductive treatment options.

PART THREE Social Health Insurance

CHAPTER 5. Social health insurance and health care access in Europe

1. Introduction

The way health care systems in Europe are organised stems from specific historical, political and cultural traditions. Traditionally, we differentiate between the Bismarck and the Beveridge models, social health insurance (SHI) versus the national health system (NHS), which both purchase and provide necessary health care services for those in need.[262] But this typology of health care systems is far beyond reality given the heterogeneity of SHI systems and NHS models (UK, Italy, Spain, etc.), and ignoring other (hybrid) systems like those in Scandinavia.[263]

When comparing health care systems, the focus in this chapter will be on the Bismarck SHI systems. Despite the patchwork of SHI systems, there are some common concerns, for example the struggle to define the health basket, problems of rationing services to cut costs and the need for more transparent decision-making, as well as the impact of human rights legislation on guaranteeing access to high quality care for all.

Focusing on the role of courts, one might question whether and how the judiciary has influenced health basket decision-making. The underlying assumption is that a better understanding of health care claims based on social and individual human rights may help policy decision-makers make hard choices in priority setting or rationing health care services, 'listing' and 'delisting' health services and medicines from the benefit package, etc. As argued, the human rights approach as applied by various courts does not necessarily contravene policy decision making on SHI benefit packages.

2. Understanding SHI in Europe[264]

In Europe, social health insurance (SHI) systems provide coverage for the majority or even the entire population. These - nearly – universal SHI schemes are generally part of a broader national social security system and are highly regulated by law (organisational structure, scope and nature of healthcare entitlements covered, (contractual) relationship insurer-providers, tariffs, cost-sharing measures, etc.). Depending on the legal system, the health insurance entities (sickness funds, mutualities, state funds, etc.) may have limited or extensive self-regulatory powers to compete on quality and/or prices.[265]

Since the 1990s, several Central and Eastern European countries have introduced similar social health insurance systems based on the Bismarck approach and have been

[262] In more detail on this classification see e.g. H.E. Sigerist, From Bismarck to Beveridge: developments and trends in social security legislation. Journal of Public Health Policy (4) 1999, pp. 474-496.

[263] A more systematic review of countries' health care system can be found on the European Observatory on Health Systems and Policies ('Health Systems in Transition, HiT') website: <www.euro.who.int>.

[264] Derived from Syrett and Den Exter, 'Access to health care in Europe', in: Research Handbook in Comparative Health Law (forthcoming).

[265] For example, the Dutch social health insurance scheme is generally considered to be one of the most 'competitive' systems, introducing the concept of managed competition derived from Enthoven's managed care model. A.C. Enthoven, The History and Principles of Managed Competition, Health Affairs Vol. 12, no. suppl. 1, p. 24-48, whereas other health insurance schemes have less or limited self-regulatory powers and are regarded more as part of the executive branch (e.g. French mutualities), source: European Observatory on Health Systems, Health Systems in Transition: France (2015) <euro.who.int>.

experimenting with elements of regulated competition on quality (Czech Republic, Bulgaria, Poland, etc.).[266] Based on European core values like non-discrimination, collective responsibility and risk and income solidarity (i.e. low and high income groups, individuals with families, elderly and young, healthy and sick people), SHI systems are constructed to redistribute the financial risks of ill health to guarantee universal health care access. These underlying values and characteristics make SHI more than a simple insurance based on actuarial principles, but rather a 'way of life'.[267]

Like other systems, SHI systems have been confronted with rising expenditure in health care. Countries vary considerably in their methods for controlling health care costs, ranging from delisting health services from the benefit catalogues, increasing premiums, introducing co-payments and deductibles for health services paid by consumers, the use of cost-effectiveness criteria and different contract types and payment mechanisms. Several systems have even introduced market elements, triggering competition among providers and/or purchasers, aiming at improved efficiency and cost containment (Switzerland, the Netherlands, Germany).[268] The effects of what is called 'regulated competition' on equal access remains a matter of heated debate among various scholars.[269] For example, Den Exter and Guy argue that the Dutch experience reveals serious concerns about whether a system of regulated competition and emerging private health arrangements respects the basic human right of equal access to health care services. From a human rights perspective, combining competition and private initiatives on health care markets with restrictive measures inspired by social values (e.g. solidarity and equity) appears to be an extremely difficult exercise.[270]

Key characteristics of SHI models have largely been set by statutory law and derived from constitutional rights such as the right to health care, right to life, the social state principle, or a combination of these rights. SHI systems therefore reflect and realise the State obligation to guarantee access to health care facilities for the entire population in terms of health insurance entitlements, established by law and organised according to national traditions, i.e. public (administrative) law (Germany, France, Austria, etc.) or civil law (Netherlands) based systems.

Unlike the NHS, SHI systems define a statutory catalogue of health to which the insured is entitled, the benefit package. Established by law, some countries opt for a rather detailed list of entitlements (e.g. the Czech Republic, Romania),[271] whereas others identify more general categories of care (ambulatory and hospital care, as in the Netherlands), elaborated by health professionals (guidelines) and/or in insurance policies or health plans.

Traditionally, the range of services may differ in each country, depending on the criteria applied for defining the services covered and on the available (financial) resources. Most countries use 'medical necessity', 'effectiveness' and 'cost effectiveness' (CE) to define

[266] A. den Exter, Health care law-making in Central and Eastern Europe. Review of a legal-theoretical model (Intersentia 2002); R. Saltman, R Busse and J. Figueras (eds.), Social Health Insurance systems in Western Europe (Open University Press 2004).

[267] Saltman, p. 5.

[268] Based on the concept of "managed competition", see Alan Enthoven, 'the History and principles of managed competition', (1993) *Health Affairs* 12:24-48

[269] E.g. M.J. Sandel, What Money Can't Buy: The Moral Limits of Markets (Allen Lane, 2012).

[270] A. den Exter and M. Guy, Market Competition in Health Care Markets in the Netherlands: Some Lessons for England? (2014) *Medical Law Review*, Vol. 22, No. 2, pp. 255–273

[271] By using so-called "framework contracts", set by the MoH, listing the statutory entitlements and as well as the terms of contracting providers (Romania, HiT 2016:29).

health benefits, although these are not always mentioned in detail by law.[272] What is considered medically necessary may change in time, depending on developments and innovations in medical science. Scientific research and medical practice may question the effectiveness of particular interventions or technologies, while CE studies may urge the exclusion or inclusion of existing and new therapies. Periodical review of the current necessity and appropriateness of listed services is therefore crucial to guarantee access to good quality care. Apart from these criteria, SHI countries differ in applying either negative or positive lists, or a combination of both, when defining the benefit catalogue.
Within these systems, coverage decision making has been institutionalised by federal or national bodies (e.g. the Federal Joint Committee (Germany), High Authority for Health (France), or the Health Care Institute (NL), with a wide range of regulatory powers. Decisions on "listing or delisting" services from the benefit catalogue are based on an evaluation of evidence-based reports by the Institute for Quality and Efficiency in Health Care (IQWiG) and similar authoritative bodies (Health Care Institute, NL, etc.). So far, however, these evaluation studies have tended to focus on the cost effectiveness of new medicines, while more controversial interventions such as genetic reproductive technologies and nanomedicine require a multidisciplinary approach of relevant disciplines, providing input for decision making in policy and practice. Initiatives at European level, such as establishing an EU-wide network on Health Technology Assessment (HTA) and the Commission's proposal of a (draft) Regulation on HTA, might help improve the evaluation process whilst increasing transparency in the appraisal decision making.[273] Nevertheless, an explicit rationing mechanism or cost effectiveness threshold is absent in most health insurance systems.

3. The justiciability of health care rights/SHI entitlements[274]

The term 'justiciability' refers to the ability to claim a remedy before an independent and impartial body when a violation of a (human) right has occurred or is likely to occur.[275] In the case of SHI entitlements, domestic and international courts held such claims justiciable on several occasions, providing an effective remedy to enforce its implementation.[276] Nonetheless, courts recognise that the necessary means are not infinite. Human rights concepts such as progressiveness, core obligations, proportionality and the state's margin of appreciation therefore provide important tools to mitigate excessive health care claims. Hereafter, selected cases adjudicate the constitutionality of the health care claims, under the right to health care, the right to (private) life and equality, whether or not by referring to international human rights treaties. The examples are merely illustrative for the approach

[272] B. Gibis et al, Shifting criteria for benefit decisions in social health insurance systems, in: Saltman and others, p 189-190.
[273] See, the HTA Core Model of EUnetHTA (EUnetHTA.eu) and the Proposal for a Regulation on health technology assessment and amending Directive 2011/24/EU, Brussels, 31.1.2018, COM(2018)51 final.
[274] Based on A. den Exter, 'The right to health care', in: A. den Exter (ed.) *European Health Law* (Maklu Press 2017) pp. 121-130.
[275] International Commission of Jurists, Courts and the Legal Enforcement of Economic, Social and Cultural Rights. Comparative experiences of justiciability, Geneva 2008, p. 6.
[276] For an interesting overview, read C. Flood, A. Gross (eds.), *The Right to Health at the Public/Private Divide: A Global Comparative Study* (CUP 2014), describing national experiences on litigating health care access such as: *Minister of Health v. Treatment Action Campaign (*TAC) 2002 5 SA 721 (CC) South Africa; Colombian Constitutional Court ruling T-760/08, 31 July 2008, etc.

applied by the judiciary when reviewing the constitutionality of health insurance reforms, and in the case of enforcing health care access, notably regarding access to new medical treatment methods and high cost medicines.

Triggering the constitutionality of health insurance reforms

In former socialist countries, newly established Constitutional Courts held that the introduction of a public health insurance system, restricting existing benefits and introducing cost-sharing measures, might be regressive by nature but not necessarily unconstitutional. Measures adopted by the state, restricting the content of entitlements already guaranteed by legislation, have been upheld when constitutional principles are respected and essential elements are protected, not arbitrary, thus necessary and non-discriminatory. For example, the Polish Constitutional Tribunal confirmed that Article 68(2) of the Constitution (i.e., the right to health protection) grants the legislature far-reaching discretionary power within the condition of considering other constitutional principles and norms. 'This means that the legislature can modify social rights, both in favour or to the detriment of individuals as long as it does not deprive the right from its essence, that is guaranteeing a right or benefits necessary for a basic minimum of existence'.[277] A similar reasoning was applied by the Czech Constitutional Court when reviewing the constitutionality of introducing patient payments for medicines under Article 31 of the Human Rights Charter.[278]

So far, Constitutional Courts have provided 'mere' procedural protection against violations of the right to health care. The Slovenian Constitutional Court was more rigorous when it annulled a retrogressive measure by means of substantial review, since the reduction of medical care to emergency care was deemed unconstitutional and unjustified.[279] Similar cases striking down retrogressive legislation have been found in Portugal and Belgium.[280] These examples confirm that constitutional review may provide an effective remedy to enforce (components of) the right to health care.

New medical technologies and limited cost effectiveness

In the *Nikolaus* case, the German Constitutional Court interpreted the progressiveness concept by lifting the ban on the reimbursement of experimental treatment methods.[281] A young patient suffers from a Duchenne Muscle disease (DMD), a progressive and fatal illness. At present, no effective therapy for DMD is available. Reimbursement of the costs of

[277] CT Ruling K 8/96, 275 and K7/95, 414.

[278] Pl. US 1/08, 23 September 2008. The CC applied the reasonableness test: i. defining the essence (essential content) of the social right i.c. Art. 31 Charter; ii. whether the statute (health care reform) does not affect the essential content; iii) when confirmative, the court applies the proportionality test, i.e. whether the interference of the essential content is based on the absolute exceptional current situation, which could justify such an interference. Since the measure did not violate the essential content of public health insurance (limiting excessive use of health care services), furthermore pursued a legitimate aim and was considered reasonable, the court upheld the constitutionality of the statutory reforms. For a similar approach, see Decision no. 2, 22 February 2007 on CC No 12/2006 of the Bulgarian Constitutional Court, deciding that more restrictive rules on health insurance introduced by the National Health Insurance Fund were not unconstitutional.

[279] U-I-390/02-27, example derived from I. Blaz, 'Constitutional Review of the Slovenian Health Law' (2007) 14 *EJHL*, p.342.

[280] Portuguese Constitutional Tribunal, Decision no. 39/84, 11 April 1984 on abrogating the National Health Service; Belgium Constitutional Court (previously Court of Arbitration) 27 Nov. 2002, no. 169/2002 and 14 January 2004, no. 5/2004.

[281] Case BvR 347/98, 6 December 2005, also known as the 'Nikolausbeschluss'.

a new treatment method, the so-called immune biological therapy, was rejected by the social insurance fund because it was not evidence-based ("wirksamkeit" criterion). However, the Court ruled that statutory criteria for limiting health benefits (i.e. 'ausreichend, zweckmässig, wirtschaftlich') should be interpreted in line with constitutional values such as the right to life, bodily integrity and the welfare (or social) state principle.[282] More specifically, in the case of life-threatening diseases for which there is no medical treatment according to general medical standards, apart from experimental treatment with a curative or positive effect ("spürbare positive Einwirkung") on the progress of the disease, this alternative cannot be excluded in the absence of scientific evidence. The alternative's effectiveness could be based on other evidence, for example expert opinions and medical practice.[283]
With this ruling, although in exceptional cases, the Court has extended health care access to newly developed and in most cases extremely expensive, diagnostic and treatment methods that are likely to have a positive effect on the progress of the disease.[284] This means that when scientific evidence is absent, the required probability standard of effectiveness is fairly flexible: the more severe, the more hopeless the situation, the less stringent the likeliness standard.[285] And although the Court recognised the "Wirtschaftlichkeitsgebot" (Art. 12 SGB V) and the need for cost (or cost-benefit) considerations,[286] these criteria were not decisive. The *Nikolaus* ruling stirred feelings in German legal doctrine.[287] In essence, it shows that despite the legislature's (c.q. G-BA) discretionary powers to formulate binding guidelines on evidence-based medicine and applied selection criteria, standards should ultimately comply with constitutional values.

How different is the outcome in the *Myozyme I* case from the Swiss Supreme Court.[288] On appeal, a Swiss health insurance fund challenged the court order of the Insurance Tribunal to continue reimbursement of an experimental treatment for Morbus Pompe, a rare and life-threatening disease. The Supreme Court annulled the Tribunal's ruling for reasons based on lack of clinical effectiveness ("Wirksamkeit") and cost effectiveness (i.e. a limited cost-benefit ratio rated in so-called '*quality-adjusted life years'* or QALYs). The costs of treatment were calculated at CHF 700,000 per year (€565,000).
Because there were no general criteria to assess cost effectiveness, the Court applied a cost-benefit analysis, concluding that the excessive costs of treatment would be disproportionate compared to the benefit (i.e. only relieving the symptoms of the disease, not delaying or preventing its fatal outcome). Moreover, approval would violate the equality principle when a disproportionate quantity of scarce resources were allocated to a certain individual but

[282] ibid, para 55.
[283] ibid, para 66.
[284] See also Art. 12 (3) SGB V incorporating the *Nikolaus* ruling; Examples accepted under this provision concern an experimental combined therapy for ovarian cancer (€15,000 p.m.) BvR 2045/12, 26 February 2013; experimental stem cell transplantation LSG Baden Würtemberg, 13 November 2012, L11 KR 2254/10.
[285] However, the life-threatening element has been interpreted narrowly, i.e. an immediate threat and not a potential lethal outcome, in: BVerfG, 1 BvR 452/17, 11 May 2017, paras 26-27.
[286] Note 20 at 57-59.
[287] J. Huster, 'Anmerkung' (2009) 9 *JuristenZeitung* 466-468; G. Dannecker and A.F. Streng, 'Die Bedeutung des Nikolaus-Beschlusses für die Priorisierungsdebatte', in B. Schmitz-Luhn and A. Bohmeier (eds.), *Priorisierung in der Medizin. Kriterien im Dialog* (Springer 2013) 135-146.
[288] Judgment of the Federal Supreme Court of Switzerland of 23 November 2010 (BGE 136 V 395).

not to others in the same position.[289] This line of reasoning has been criticised by legal scholars.[290] Although cost-benefit/effectiveness analysis is relevant at macro level (benefit package decision making), it seems less appropriate at the individual doctor-patient level because it will ultimately force the judiciary to decide on society's willingness to pay for rare diseases, which can only be answered by the legislature.
Unlike the *Nikolaus* case, the Swiss Supreme Court declined to review the constitutionality of denial under the right to life, personal freedom and the right to assistance when in need.[291] Unfortunately, as these rights were not challenged in the Supreme Court, it could abstain from such a human rights assessment. Ultimately, this case triggered public deliberation, which resulted in a Federal by-law providing a legal basis and guiding principles of cost considerations in coverage decision making, but without setting a threshold.[292] Instead, health insurance funds must review (partial) reimbursement of expensive interventions on a case-by-case basis, applying cost-effectiveness evidence.
Several years later, in *Myozyme II*, the Swiss health insurer again refused to reimburse myozyme treatment in the case of Morbus Pompe.[293] Unlike *Myozyme I*, from 1 November 2011, Myozyme was included in the so-called 'Spezialitätenliste' (SL), followed by a 50% price reduction (around CHF 370,000 per year).[294] Listed medicines comply with the statutory conditions of clinical and cost effectiveness and efficiency (Art. 32 Swiss HIA) and are therefore not open for judicial review. Refusal of cost reimbursement can only be justified in the case of non-compliance with the SL restrictions (e.g. medical indication, provided by a qualified physician, etc.). Taking myozyme's cost effectiveness for granted, the court concluded that the insurer's duty of care required reimbursement of the claimed treatment.

Health care access and international law
When constitutional review is absent, as in the Netherlands, the judiciary has frequently applied international human rights to enforce health insurance claims. The Dutch Central Appeals Tribunal's (CRvB) case law on long-term care reveals an emerging interest in international treaty law, both human rights treaty law (ECHR)[295] and international social security law (ILO Conventions and the European Code of Social Security),[296] whether or not combined with general non-discrimination treaty provisions (e.g. International Covenant on

[289] ibid 7.7-7.8
[290] E.g. F Kesselring, 'First Fundamental Decision of the Federals Supreme Court of Switzerland on Cost-Effectiveness in the Area of Human Healthcare' (2011) 3 *EJRR*, 442-446; S Huster and A Bohmaier, 'Die Myozyme-Entscheidung des Sweizerischen Bundesgerichts aus der Perspektive des deutschen Verfassungs- und Krankenversicherungsrecht' (2012) 106 ZEFQ 443-448.
[291] Articles 10 and 12 of the Swiss Federal Constitution.
[292] Federal By-law on Health Insurance AS 2011 654 (Explanatory note), Art. 71a (3) KVV, reading: 'Die zu übernehmenden Kosten müssen in einem angemessenen Verhältnis zum therapeutischen Nutzen stehen (…)', which can be interpreted as an implicit cost-benefit assessment, idem Art 71 b (3) KVV; confirmed by the government's reply on Parliamentary question no 11.3154 (6 June 2011), in particular question no 4.
[293] BGE 142 V 478, 16 September 2016 www.bger.ch
[294] But still far more than the Myozyme I threshold of CHF 100,000 per QALY.
[295] A and others v. UWV, 18 October 2007 (ECLI:NL:CRVB:2007:BB6578); X v. CIZ, 9 May 2012 (ECLI:NL:CRVB:2012:BW5345); X. v. Agis, 6 June 2012 (ECLI:NL:CRVB:2012:BW7707)
[296] A. v. Achmea Zorgverzekeringen, 8 September 2006 (ECLI:NL:CRVB:2006:AY8221); C. v. BAZ Nijmegen, 29 May 1996 (ECLI:NL:CRVB:1996:AL0666).

Civil and Political Rights, Article 26).[297] In practice, such appeals based on international treaty norms are only successful in exceptional circumstances, but the impact can be considerable. In 2006, the Tribunal concluded that the European Code of Social Security included some self-executing treaty provisions (articles 32 and 34), which prohibit co-payments in terms of occupational health related injuries.[298] As a direct consequence of this ruling, the Dutch Parliament agreed to partially denounce the European Code (part VI) and simultaneously ratify the Revised Code, which allows more flexibility in terms of co-payments.[299] A similar response was considered in 1996, when the CRvB also held that the ILO-Convention 102/103 (Article 10) was self-executing, thereby prohibiting cost sharing in terms of in-patient maternity care.[300] The criteria used by the Tribunal to determine whether norm-setting treaties or treaty provisions are self-executing include the nature (instructive or imperative) and the specificity of the wording of the specific provision. Therefore, the reliance on the direct effect of ILO social security treaties provides Dutch citizens with a limited claim to enforce the social right to health care before domestic courts. Conversely, the judiciary repeatedly rejected such reliance in the case of the ICESCR, since its provisions are insufficiently precise and the instructive nature provides States with a broad margin of appreciation to fill in the necessary steps in order to realise these rights.[301] So far, the judiciary has continued that line of reasoning and is unwilling to incorporate the concept of "progressive realisation" of social rights.

In the case of immigrants without a residence permit (illegal migrants), however, the Dutch Tribunal seems more generous, notably where children are concerned. Although illegals are excluded from a long-term care scheme by law, on several occasions the Tribunal annulled that rule based on Article 8 of the European Convention (right to private life, ECHR), but only in a very exceptional case, where the humanitarian grounds against the removal are compelling.[302] These cases concern aliens with life-threatening diseases who are facing deportation, where it is clear that the necessary medical facilities and family support are not available in the individual's home country.[303] The Tribunal has confirmed the European Court of Human Rights' doctrine that the Convention may create a positive obligation to provide access to necessary care.[304] Furthermore, a search for a fair balance between the demands of the general interest of the community and the requirements of the protection of the individual's fundamental rights is inherent to Article 8 of the Convention. Withholding necessary care under these exceptional circumstances cannot be considered a 'fair balance'.

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[297] In case of differential treatment of cost sharing: A. v. NUTS, 13 December 2001 (ECLI:NL:CRVB:2001:AE8567).

[298] See note 35, 8 September 2006.

[299] Termination Part VI European Code of Social Security, Stb. 474, 2009. Upholding ratification would cause an estimated loss of maximum €80 million. Parliamentary Proceedings II (2007-8) 31 267, no. 6, p. 4, Ratification European Code on Social Security (revised).

[300] F. v. BAZ Nijmegen (note 35). Although in this particular case, co-payments were based on the former Health Insurance Act (ZFW). Denunciation was allowed at the end of any successive period of five years after ratification and thereafter. Since that period had expired, denunciation failed.

[301] X v. Maastricht, 14 December 2010 (ECLI:NL:CRVB:2010:BO6734).

[302] Contrary to Council of State decision (no life-threatening situation, breach of Article 3) 25 February 2015 ECLI:NL:RVS:2015:593; 7 September 2017, ECLI:NL:RVS:2017:2435

[303] X. v. Achmea, 9 September 2011, ECLI:NL:CRVB:2011:BT1738; X v. Agis, 4 August 2011 (ECLI:NL:CRVB:2011:BR5381; X v. Agis, 20 October 2010 (ECLI:NL:CRVB:2010:BO3581); contrary: X v. Achmea 6 June 2012 (ECLI:NL:CRVB:2012:BW7703).

[304] See *D v. UK* App no. 30240/96 (ECtHR, 2 May 1997) (St Kitts) though the Court used Article 3 and not Article 8 of the Convention.

Non-listed treatment methods and the ECHR

Apart from domestic courts, the European Court of Human Rights (ECtHR) has also handled the adjudication of health care access claims, although rarely successfully. In case of non-available or excluded medical services or medicines, the Human Rights Court has linked the right to health care with the Convention's right to life (Article 2), prohibition of torture (Article 3) and private life (Article 8). For example, it is now accepted that under the Court's jurisprudence, the right to life is not limited to refraining from taking life intentionally and unlawfully, but also implies the States' duty to take appropriate steps to safeguard the lives of its citizens.[305] In the health care context, this could mean that the refusal to make life saving medicines available under the social health insurance scheme is considered an act of omission under Article 2. In *Panaitescu v Romania*, the Court confirmed the domestic court's ruling that the State had failed to provide adequate treatment, putting the patient's life at risk.[306] In this particular case, the lifesaving cancer drug Avastin was not yet registered on the list of medicines covered by the health insurance scheme, although it had already been approved by the National Medicines Agency when the domestic procedure started. Nevertheless, the Health Insurance Fund refused to enforce the domestic court order to provide the necessary anticancer treatment for free. According to the Human Rights Court, the patient's right to free medical care was hindered more than once, mainly on bureaucratic grounds, which ultimately resulted in the patient's death. The Court concluded that as there was no justification for the State's conduct and given the gravity of the illness, the authorities had failed to take timely measures (i.e. listing and providing Avastin for free), therefore – unanimously – violating Article 2. In this exceptional case of unreasonably obstructing the enforcement of a court order, the State had not adequately protected the patient's right to life.

In another case, *Hristozov v. Bulgaria*, the applicants complained that the Bulgarian authorities had refused to authorise the use of a non-registered and untested medicine in the case of a life-threatening disease.[307] According to the Court, there was no breach of the Convention's right to life, prohibition of torture or private life. It is true that the positive obligations under Article 2 include a duty to regulate the conditions for market entry of medicines. Clinical trials that test the safety and efficacy of the product are an essential part of the market authorisation procedure and thus market access. By exception, non-registered medicines could be granted market access but only when it is undergoing clinical trials in other countries. That was not the case here. In the Court's view, Article 2 did not impose an obligation to regulate access to unauthorised medicines for the terminally ill 'in a particular way'.[308] Based on a survey, it appeared that the regulatory requirements allowing untested medicinal products outside the clinical trials differ in each country.[309] Member states have a wide margin of appreciation for setting the conditions for such medicines. As such, the applicants argued unsuccessfully that the Bulgarian rules were 'overly restrictive', thus rendering meaningless the exceptional nature of such permission.
The Court's majority view was criticised in two dissenting opinions by using the safety valve

[305] See for instance, *Calvelli and Ciglio v. Italy* App no. 32967/96 (ECtHR, 17 January 2002) 48-49.
[306] *Panaitescu v Romania* App no. 30909/06 (ECtHR, 10 April 2012).
[307] App no. 47039/11 and 358/12 (ECtHR, 13 November 2012).
[308] ibid, para 108.
[309] ibid, 54, 55.

of a "wide margin of appreciation" *before* analysing the scope and purposes of the positive obligations undertaken under Article 8 of the Convention, 'leaving the impression that this phrase has been interpreted not in a sense of evaluation of merit, but as an instrument to justify national authorities' complete failure to demonstrate any appreciation whatsoever of the applicant's right to personal life, or to strike the requisite balance between this right and the presumed counterbalancing public interest.'[310] Although the dissenter recognises the potential public health threat of untested medicines, extending the exception clause can be justified when the risks posed by the product are not unreasonable, do not outweigh the risks posed by the disease and is recommended by the treating physician. In addition, the physician should explain extensively the (un)known risks and that access to unauthorised medicines remains an option of last resort.[311] The counterargument that access to unauthorised medicines may hinder clinical trials seems rather unfounded since it remains a strict exception to the general rule. This is similar to the argument that access would undermine the patient's willingness to participate in future clinical trials. When conventional therapies are not effective, 'desperate' patients will remain available to volunteer in such trials. Compassionate use of unauthorised medicines remains an ultimum remedium for life-threatening situations only. Under these conditions, widening the exception clause seems justified. Unfortunately, in *Durisotto v Italy,* the Court's latest ruling on compassionate use, it abstained from such a review on the merits and confirmed the Member states' wide margin of appreciation formula under Article 8, thus denying the patient's access to unauthorised medicines.[312]

Undoubtedly, both *Panaitescu* and *Hristozov* are tragic cases, albeit with different outcomes. This can be explained by the fact that Avastin had already been approved by the Romanian Medicine Agency but was not yet covered by the list of reimbursed medicines. Avestin can therefore be classified as a regular and authorised medicine, which was not the case in *Hristozov*. Secondly, in *Panaitescu*, the breach of Article 2 was based on 'bureaucratic unwillingness' to put Avestin on the positive list for reimbursement, as concluded by the national courts. 'Listing' could therefore be considered a positive obligation, whereas refusal to act was a breach of the State's procedural obligations under Article 2.

In the case of non-listed medical devices, the Strasbourg Court leaves Member States a similar wide margin of appreciation. Illustrative is the *Sentges* case requesting a highly expensive medical device (robotic arm) that was neither approved nor listed as a health insurance entitlement.[313] Under those circumstances, the Court does not interfere in the State's margin of appreciation in determining the scope of the health insurance entitlement.

Substitution of existing 'entitlements'

The Sentges approach was confirmed in *McDonald v. the United Kingdom*, where local authorities replaced night-time care by a cheaper alternative.[314] Initially, Elaine McDonald – a disabled person - was assessed for and provided with a sleep-in care worker for seven nights a week. Later, local authorities decided that this could be replaced by providing

[310] Partly Dissenting Opinion Judges Kalaydjieva, Gaetano and Vicinic.

[311] Dissenting Opinion Judge Vicinic Para 8.

[312] *Durisotto v Italy* App no. 62804/13 (ECtHR, 6 May 2014) 36. Although the medicine was in a clinical trial stage, the Court abstain from a so-called "merits review" of the applicable conditions.

[313] *Sentges v. the Netherlands* (Dec.) App no. 27677/02 (ECtHR, 8 July 2003).

[314] McDonald v UK App no. 4241/12 (ECtHR, 20 August 2014)

incontinence pads for use at night and cutting care support. Both national courts and the ECtHR were asked whether local authorities were allowed to withdraw or amend care support when the recipient's circumstances are unchanged but where a cheaper alternative is available.
Referring to its previous case law (e.g. *Sentges v. the Netherlands*), the Court reaffirmed that States have a wide margin of appreciation in issues of health care policies and that this margin is particularly wide when the issues involve an assessment of priorities in the context of the allocation of limited State resources.[315] It also found that the proportionality of the decision to reduce the applicant's care package had been fully considered by the national courts, taking into account the local authority's efforts to consult the applicant and its concerns for her safety, independence and other care users.[316] The Court therefore concluded that the requirements under Article 8 para. 2 ECHR had been met and that the State had not exceeded the margin of appreciation afforded to it. As such the complaint was found to be manifestly ill founded and rejected.

Medical asylum cases
By exception, the Human Rights Court accepted a claim on health care access based on the prohibition of inhumane and degrading treatment, in the case of an alien facing deportation to his home country. In *D v. the United Kingdom*, the applicant was arrested at the UK airport for the possession of cocaine and given a three-year custodial sentence. Immediately before his release, immigration authorities issued instructions for the applicant's deportation. Pending his removal, he requested to remain in the UK since he was suffering from AIDS in an advanced and terminal stage, arguing that his removal to St. Kitts would entail a loss of medical treatment that he was receiving in the UK. Having been unsuccessful in the national courts, he applied to the Strasbourg Court arguing, inter alia, that his deportation to St. Kitts would be an Article 3 violation.
So far, Article 3 has been applied in the context in which the individual has been subjected to harmful treatment emanating from intentionally inflicted acts of the public authorities. In this case, the Court applies Article 3 in another context, i.e. the situation where the harm would stem from withholding life-saving treatment when the person was deported outside the territory. By interpreting Article 3 in a more flexible manner, the Court 'must subject all the circumstances surrounding the case', such as the advanced stage of a terminal and incurable disease, the absence of adequate healthcare facilities in the home country which will hasten his death, and the lack of evidence for any support from relatives or other form of moral or social support in St Kitts. Based on these exceptional circumstances, the decision to deport the applicant would amount to inhumane treatment by the Contracting state, thus constituting a violation of Article 3. According to the Court, a breach of Article 3 for medical asylum cases can only be established on the application of this so-called 'exceptional circumstances' test.[317] With this ruling, one may criticise the Court since finding a breach of Article 3 in the present case would open up the floodgates to medical immigration and make Europe vulnerable to becoming the "sick bay" of the world'. However, the "floodgates" argument seems totally misconceived given that since this

[315] Ibid, paras 54-55.
[316] Ibid, para 57.
[317] ibid, 52-53.

judgment, the Court has never concluded that the proposed deportation of an alien from a Contracting State gives rise to a violation of Article 3 on the grounds of medical asylum.[318]

Although incomplete, these examples on the enforcement of the right to health care/SHI entitlements illustrate how the judiciary carefully navigates between justified individual requests for life-saving treatments and respecting the state's duty to safeguard equal access to basic health care for all. The outcomes show that on some occasions courts have upheld the right to health care, and in individual cases have even promoted health care rights by judicialisation. But the price can be high, as seen in the Netherlands: triggering the political debate on sovereignty. On other occasions, the Constitutional court has been criticised by crossing the boundaries of what society can afford (e.g. *Nikolaus* ruling in Germany). Even more delicate is the question of the maximum costs of individual health care intervention in the court, a political issue not to be decided by the judiciary. But what if politicians are reluctant or unable to decide about the threshold? As such, the Swiss Supreme Court acted as substitute legislator by applying an economic analysis and setting the maximum. Finally, the innovative approach of the European Human Rights Courts by adopting extensive definitions of civil rights does not necessarily provide a functional remedy, since the safety valve of margin of appreciation denied the enforcement of many health care claims.

5. Conclusion

In most SHI systems, the right to health care has been embedded in social health insurance legislation and more specific policies, setting the standard and normative content of such a right. In addition, monitoring and enforcement mechanisms have helped specify the content of such benefit entitlements in more detail. Even setting limits to unlimited medical needs by taking into account the sustainability of SHI systems and respecting the margin of appreciation of States. Apart from adjudicating existing SHI entitlements in the court, such cases have triggered a social debate on (new) health technologies accessible for all.

[318] See for example, *Karara v Finland* App no. 40900/98 (HIV) (ECtHR, 29 May 1998), *SCC v Sweden* App no. 46553/99 (HIV) (ECtHR, 15 February 2000), *Bensaid v the UK* App no. 44599/98 (schizophrenia) (ECtHR, 6 February 2001); *Arcila Heneao v the Netherlands* App no. 13669/03 (HIV-positive) (ECtHR, 24 June 2003); *N v UK* 26565/05 (HIV positive) (ECtHR, 27 May 2008). *A.S. v Switzerland* App no. 39350/13 (post-traumatic stress disorder) (ECtHR, 30 September 2015). Examining the facts of each case, they were all HIV positive or had a serious psychiatric disorder, but not close to death, whereas treatment was 'in principle' available in the home country, and/or having relatives able to support the applicant.

CHAPTER 6. Dutch Health Insurance Dispute Resolution and Fake Courts

Abstract
The 2006 Dutch health insurance reforms introduced an alternative mechanism to settle disputes. This so-called “binding advice” is a binding third-party ruling to resolve disputes on the denial of coverage and the refusal to reimburse health services.
More than 12 years after it was introduced, the alternative dispute resolution (‘ADR’) regime gives reason for concern: legal criteria are interpreted differently by the ADR entity and the courts, thus causing inequalities in health care access under the Dutch Health Insurance Act. It is concluded that the privatisation of formal adjudication has largely frustrated citizens claiming access to medical technologies satisfying the ‘international medical science and practice’ test. It is therefore recommended that citizens opt out for the default option, challenging health insurance disputes in court.

Keywords: social health insurance claims, alternative dispute settlement, ‘science and practice test’, evidence-based medicine.

1. Introduction

The introduction of the new Health Insurance Act (2006) dramatically changed the system of social health insurance in the Netherlands. It moved to extend insurance to all citizens and simultaneously introduced a much greater role for the private sector in terms of relying on competing private for-profit health insurers. The concept of regulated competition appeared to be dominant not only on the health insurance market but also when purchasing and contracting health care services.
‘Privatising’ social health insurance also affected the enforcement of health insurance benefit entitlements. Instead of traditional litigation in the courts, an alternative mechanism to settle disputes was introduced. This so-called “binding advice” is a binding third-party ruling to resolve disputes on the denial of coverage and the refusal to reimburse health services (abroad).
Comparing the binding advice outcome with traditional litigation in the courts reveals some remarkable difference in interpreting reimbursement rules, in particular the ‘science and practice’ test. Diversity in outcomes has major consequences for the insured.
The author will explain the concept of binding advice, analyse the decisions made concerning the ‘science and practice’ standard, and compare this with several high-profile rulings from national courts.

2. Main characteristics of the Dutch health insurance system

Prior to 2006, the Dutch health insurance system was characterised by a dual system of social (compulsory) and private or voluntary health insurance. Those who were too wealthy to qualify for the social health insurance scheme (essentially equivalent to a public health insurance system in tax-financed system) were free to purchase private health insurance. Social insurance was based on the notion of 'solidarity' and regulated by statutory law. In health care, the solidarity principle means that there is no relationship between the premium paid and access to insurance entitlements. Solidarity was institutionalised by

means of social security legislation and therefore accomplished by (legitimised) force. Its redistributive effect demonstrates that solidarity is based on the notion of social justice.[319]
One of the main pillars of the Dutch health insurance system was the former Health Insurance Act ('*Ziekenfondswet* 1966'), establishing a statutory insurance scheme for curative care. Sickness funds were private entities, operating on a non-profit basis (associations or foundations) that entered into contracts with health care providers that delivered the insured care. 65% of the population (all those earning below € 32,000 in 2005) were covered for curative care by sickness funds. A further 5% of the population was covered by a health insurance scheme for public servants. Dutch citizens earning above the sickness fund threshold (30%) were free to purchase private insurance for curative care.
The *Ziekenfondswet* 1966 defined in general terms the entitlements for those covered by sickness funds. More specific details of benefit provisions were regulated by By-laws and specific policies of sickness funds. Sickness funds were statutorily obliged to guarantee access to medical care under the insurance scheme. This obligation of result forms the essence of the benefit-in-kind health care scheme, for which the insurer is accountable and could be held liable for non-compliance. This is in contrast to national health care systems such as those in England and New Zealand, where there is no specific list of entitlements and no resulting contractual liability on the part of the public insurer to provide the same.
In the Netherlands, the nature and scope of the packages covered by private medical insurance for the wealthier 30% of the population, who were excluded from the social health insurance scheme, were largely identical to those required to be provided by the sickness funds pursuant to the *Ziekenfondswet*. However, private medical insurance policies were more flexible, allowing for free choice of provider and permitting cash benefits instead of benefits-in-kind entitlements.
This dual approach (social and private insurance) created inequality in health care access. Due to the statutory regime, administrative courts ruled on sickness fund litigation procedures, while civil courts adjudicated private insurance disputes using civil-law principles. Civil courts proved willing to recognise patients' reimbursement claims with reference to general contractual norms such as reasonableness and fairness. Administrative courts, on the other hand, were inclined to reject patients' claims by defining health care benefits with reference to public law.[320] The divergence in judicial interpretation was one of the reasons given by the government for health care reforms and the elimination of the two-tiered health insurance scheme. What is important to note, is that the insurance status (sickness fund or privately insured) did not affect the waiting time for medical treatment. In other words, having private insurance did not allow those insured to jump queues for treatment because treatment is based on objective medical criteria (medical necessity) only. Furthermore, as hospitals charged similar tariffs for public and privately insured patients, there was no incentive to treat patients differently.
Since the introduction of the *Ziekenfondswet* in 1966, successive governments proposed various comprehensive health insurance reform plans, the 2006 reforms being the most radical. The current model is a regulated competitive health insurance market that

[319] For more details, see A. den Exter, "Health care access in the Netherlands: The true story" in: C. Flood & A. Gross (eds.), *The Right to Health at the Public/Private Divide* (Cambridge: CUP, 2014), 188-207; A. den Exter, "Health System Reforms in The Netherlands: From Public to Private and its Effects on Equal Access to Health Care", *European Journal of Health Law* 17 (2010), 223-233.
[320] H. Hermans & A. den Exter, "Priorities and Priority-setting in Health Care in the Netherlands", *Croatian Medical Journal* 39 (1998), 346, 353-354.

nonetheless aims to provide universal access to health care to the Dutch population. The new Health Insurance Act, the '*Zorgverzekeringswet*' (hereafter 'HIA 2006', or 'HIA') came into force on 1 January 2006, replacing the *Ziekenfondswet*.[321] Unlike the *Ziekenfondswet,* under the HIA 2006, beneficiaries pay a flat-rate premium (€ 1362 in 2018), and an income-dependent employer contribution is automatically deducted by the employer. In addition, a compulsory "excess" was introduced for primary and secondary care providers (€ 385 per annum in 2018), which may be combined with a flexible system of voluntary excess ranging from € 100 to € 500 per annum. To offset the high fixed premium, lower-income groups are partly compensated by means of a 'health care allowance'.

The HIA 2006 introduced a compulsory health insurance scheme for the entire population, administered by for-profit insurance companies. Health insurance agreements are private-law contracts and are therefore based on principles such as freedom of contract. However, the legislature imposes certain restrictions to protect the principle of equal access to health care. The prohibition of risk selection by health insurers is one clear example of this. In addition, all health insurers must participate in a risk equalisation system which ensures that those insurers who cover individuals with a higher risk profile receive more funding. Such a levelling mechanism prevents direct or indirect risk selection of so-called 'high-risk' insured (i.e. the chronically ill). This and other restrictions of the HIA's free contracting principle reflect the tension between promoting market-like competition whilst still attempting to ensure solidarity in accessing health care.

The HIA provides coverage for essential curative care tested against the criteria of necessity, proven efficacy, cost-effectiveness and collective or individual responsibility.[322] Instead of a pre-established list of types of treatment for which reimbursement is guaranteed, the HIA only includes a general description of the care covered by the insurance package (i.e. medical (specialist) care, dental care, pharmaceutical care, medical devices, etc.). Although the law sets legal requirements for what entitlements are included, it is up to the health provider and insurer to further define 'necessary care' under the law. Thus, what constitutes 'necessary care' is determined by "the state of medical science and practice".[323] The state of medical science and practice criterion follows the principles of evidence-based medicine ('EBM'). EBM is an internationally accepted leading approach for clinical decision-making but is also used as a criterion to assess whether care complies with the international science and practice standard.[324] According to EBM principles, randomised clinical trials (RCTs) are considered to be "hard evidence". Other sources, such as observational studies, authoritative expert opinions, positive experiences of health professionals and patients, are also relevant but are classified as "soft evidence". Such evidence is systematically searched and selected and reviewed by the Health Care Institute ('ZiN'), resulting in either a positive or negative opinion. ZiN has the statutory task to advise the ADR body in the case of

[321] The Health Insurance Act (Zorgverzekeringswet, Zvw *Stb.* 2005, 358) came into force on 1 January 2006, replacing the Sickness Fund Act (ZFW of 15 October 1964).

[322] Based on the method for priority setting by the Dunning Committee "Choices in Health Care" (1991). This framework of criteria basically functions as a series of sieves separating care that should be funded from that which should not be funded.

[323] Besluit Zorgverzekeringswet (Decision Status Health Insurance], *Stb.* 2008, 549, Article 2.1, sub. 2.

[324] M. Offringa et al. (eds.), *Inleiding in evidence-based medicine* 4th edn. (Houten: Bohn Stafleu, 2014) (in Dutch).

coverage and reimbursement disputes (Article 114(3) HIA).[325] This authoritative opinion is leading in the dispute settlement procedure.
Although it is largely up to the health insurer to decide which types of treatment satisfy the 'medical science and practice' standard, in applying that criterion, the insurer must act on the basis of what is sufficiently tried and tested by *international* medical science. Widening the state of medical science and practice criterion to what is considered normal among *international* circles is a direct consequence of the *Smits-Peerbooms* and *Müller-Fauré* cases decided by the Court of Justice of the European Union ('CJEU').[326] This could mean that where a certain treatment has been sufficiently tested by international science, the health insurer would not be able to refuse authorisation on the grounds that it is not presently provided in the Netherlands.[327] The only justifiable reason to refuse approval is where, given the need to maintain an adequate supply of hospital care and to ensure the financial stability of the health insurance system, the "same or equally effective treatment can be obtained without undue delay".[328] "Undue delay" is defined as the period within which medical treatment is necessary with respect to the patient's medical condition, the history and probable course of their illness, the degree of pain they are in and/or the nature of their disability.[329]
Although the Court of Justice rulings have restricted national sovereignty vis-à-vis denial of coverage for medical services sought abroad, this did not automatically extend the insured's right to cross-border care in health insurance disputes. Except for the 'undue delay' cases, proving that an alternative treatment satisfies the 'international medical science' test remains extremely difficult for the complainant (hereafter).

3. Health insurance dispute settlement: the 'Dutch' approach

One of the main changes introduced by the Dutch Health Insurance Act was the introduction of an alternative dispute settlement mechanism for resolving coverage and reimbursement disputes. Unlike the previous public-law insurance system, the current health insurance regime is regulated by civil law. Consequently, legal protection follows the civil-law proceedings. But instead of formal adjudication by the court, the HIA introduces the option of "binding advice" outside the judicial system (Article 114 HIA). An out-of-court settlement entity, called SKGZ, has established an independent and impartial disputes committee ('*Geschillencommissie Zorgverzekeringen'*).[330] This committee of 'binding advisors' gives a binding decision on disputes between individual insured people and the health insurer.

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[325] Article 64 (1) HIA defines the mandate as: "to promote a uniform interpretation of the nature, content and scope of the insured entitlements".
[326] Case C-157/99, *Geraets-Smits v. Stichting Ziekenfonds VGZ* and *Peerbooms v. Stichting CZ Groep Zorgverzekeringen*, 2001 E.C.R. I-5473; Case C-385/99, *Müller-Fauré v. Onderlinge Waarborgmaatschappij OZ Zorgverzekeringen* and *Van Riet v. Onderlinge Waarborgmaatschappij ZAO Zorgverzekeringen*, 2003 E.C.R. I-4409.
[327] As shown in *Elchinov*, Case C-173/09, *Elchinov v. Natsionalna zdravnoosiguritelna kasa*, 2010 E.C.R. I-8889, a claim challenging the denial of reimbursement of proton therapy in Germany. Though not available in Bulgaria, the national health fund was forced to reimburse this treatment abroad since it fulfilled the international medicinal science test, though not explicitly classified as an entitlement under the social health insurance scheme.
[328] Case C-372/04, *The Queen, on the application of Yvonne Watts v. Bedford Primary Care Trust and Secretary of State for Health*, 2006 E.C.R. I-4325, para. 119.
[329] *Ibid.*, para. 63.
[330] In name independent and impartial, though the SKGZ is largely funded by health insurance companies (75%) subsidy (20%), source: annual report 2017, www.skgz.nl.

Although the option of formal adjudication by the court remains open, once the complainant has chosen the binding advice route, the outcome is final. The option of judicial review only remains open in exceptional cases (e.g. contrary public morals, public policy).[331] This review is not a full appeal as the Dutch Civil Code ('CC') only allows a marginal review of the decision of the binding advisors when this is manifestly unreasonable or unfair (7:904(1) CC).[332] The procedural rules for the binding advice procedure are set by the SKGZ.[333]
The binding advice procedure is part of the self-regulatory system of ADR.[334] Binding advice should be differentiated from arbitration. Both can be characterised as private dispute settlement mechanisms, based on agreement. Binding advice, however, is entirely based on what parties agree on in advance, while arbitration is ruled by the Civil Proceedings Act ('WvBRv'). Still, the binding advice agreement can be considered a so-called contract of settlement, as regulated in the Dutch Civil Code (Article 7:900 DCC), providing its legal basis.[335] Furthermore, the binding advice procedure is generally considered less formal, has a different legal basis and its outcome does not provide executorial effect ('exequatur').[336] An arbitral ruling, however, will provide for an executorial title relatively easily and can therefore be enforced by the court (Article 1062 and 1063 Rv.).
In the case of a coverage dispute arising from the Health Insurance Act, the health insurer will invite the insured to resolve the dispute by means of binding advice. The binding advice procedure can only be initiated when the complainant has first requested his/her health insurer to reconsider its position concerning the dispute (first mandatory filter). If the complaint is not resolved, the complainant may submit the complaint to the SKGZ disputes committee. First, however, mediation by the SKGZ Ombudsman is offered, although the complainant is free to decline mediation (second filter). The outcome of this Ombudsman stage has resulted in a limited number of settlements (approximately 19% in 2016).[337] If the Ombudsman mediation is not successful or declined, the complaint will be resolved by the SKGZ disputes committee. This committee will review the complaint pursuant to the Health Insurance Act, the health insurance policy, jurisprudence and codes of conduct.[338] Both parties (the insured and the health insurer) are invited to submit written documents

[331] Case law reveals it can only be assumed in exceptional circumstances:
Supreme Court 18 June 1993, *NJ* 1993/615 (Gruythuysen/SCZ), para. 4; Supreme Court 25 March 1994, *NJ* 1995/23 (Midden Gelderland/Lukkien), para. 3.3, quoted by M. Knigge & E. Verhage, "The impact of the ADR Directive on Article 7:904 par 1 DCC", explored in Breedveld-de Voogd e.a. (eds.), *Core Concepts in the Dutch Civil Code. Continuously in Motion*, (Wolters Kluwer, 2016), 62; also P.E. Ernste, *Bindend advies* (SDU, 2015), 95-102.
[332] Article 904(1) reads: "an assessment made by ... a third party is voidable if its binding force, in view of its content or the way in which it was made, would in the given circumstances be unacceptable according to standards of reasonableness and fairness".
[333] "Procedure", Reglement Geschillencommissie Zorgverzekeringen, www.skgz.nl (9 July 2015).
[334] Though there is no carte blanche, as ministerial regulations provide fundamental procedural guarantees for out of court complaint committees, *Stb* (2006), 520. Also, the European "ADR Directive" (2013/11/EC) introduced certain procedural changes in the Dutch ADR system, see Ernste (note 13), 97.
[335] Article 7:900 (1) DCC defines the settlement agreement as: "parties bind themselves toward each other, in order to end or to avoid any uncertainty or dispute about what applies to them legally, to the assessment and establishment of a new legal status between them, indented to apply as well as far as it differs from their previously existing legal status".
[336] The decision does have the force of a contractual agreement. Non-compliance is considered as a breach of contract, and a party can request enforcement before the court, Knigge and Verhage (note 13), 62.
[337] In 2017 the Ombudsman received more than 3050 requests to mediate, of which 19% resulted in a friendly settlement, SKGZ annual report (2016), 6.
[338] Complaint Commission, Rules of procedure, Article 3(3), 9 July 2015.

supporting their claim. In addition, as stipulated by law, the Health Care Institute ('ZiN') will provide written advice concerning the disputed coverage claim (Article 114(3) HIA). In the subsequent procedure, parties are invited to a plenary hearing to explain their argument to the committee and to reflect on the formal advice of ZiN.[339] Although the hearing itself is in private, parties may be represented by their (legal) representative and may invite witnesses and experts.[340] After the hearing, the SKGZ committee will deliver a motivated decision within ninety days, published anonymously on the SKGZ website.[341]
The shorter, less formal and more accessible procedure – legal representation is not required and, therefore, less costly than civil litigation – make the binding advice route an attractive option compared to civil litigation. As a result, large numbers of litigants are channelled into binding advice instead of gaining access to formal adjudication. Although the insured is informed about opting out, this information is limited and based on persuasive arguments regarding the disadvantages of traditional litigation. As a result, binding advice appears to be the default option. The 'choice' for binding advice, therefore, has a strong element of compulsion. Given the diversity in outcomes (hereafter), opting in or out of binding advice becomes a crucial decision with far-reaching consequences!

The 'international medical science and practice' test in ADR practice
As the ZiN advice is leading, the SKGZ disputes committee followed that opinion in nearly all cases on coverage disputes.[342] These disputes relate to specialised medical care whose effectiveness has been challenged, i.e. whether the planned intervention complies with the 'international medical science and practice' test. In the case of new medical technologies, the disputes committee ignored the international practice dimension in the absence of reliable randomised clinical trials. Where hard evidence is lacking, 'lower level' evidence remains, i.e. what the particular profession considers to be "safe and adequate care".[343] This open norm is supported by scientific and semi-scientific studies, positive clinical and patient experiences, and authoritative opinions of medical scientists. In practice, however, the committee has never concluded that medium or low-level evidence complies with the international science and practice test.[344] If two randomised studies show a negative

[339] *Ibid.*, Article 10(1) on the hearing.
[340] *Ibid.*, Article 10, sections 4 and 10.
[341] *Ibid.*, Article 13.
[342] Based on the analysis of published decisions challenging "medical specialised care" over the period 2007-2018, e.g.: case ANO07054, 4 April 2007 (discus prothesis); case ANO07146, 6 June 2007 (reconstructive surgery); case ANO07120, 20 June 2007 (hernia treatment); case 200900672, 36 August 2009 (Bechterew's disease); case 201000678, 27 October 2010 (cell therapy); case 200902749, 27 October 2010 (hyaluronic acid injections); case 2013.00727, 9 July 2014 (shockwave therapy, ESWT); case 201303204, 15 October 2014 (High-intensity focused ultrasound, HIFU); case 201500354, 28 October 2015 (Hirudo-therapy); case 201500558, 28 October 2015 (no tube treatment); case 201601360, 5 April 2017 (Lyme's disease); case 201602448, 31 May 2017 (Lyme's disease); case 201602395, 5 July 2017 (anti-snoring device).
[343] Article 2.1 Bzv, section 2.
[344] SKGZ website case 201300727, 9 July 2014 (electro shock treatment); case 201300980, 29 August 2014 (TMS); case 201303204, 15 October 2014 (High-intensity focused ultrasound, HIFU); case 201500751, 19 August 2015 (plastic surgery); case 201500354, 28 October 2015 (Hirudo-therapy); case 201500558, 28 October 2015 (NoTube treatment); case 201503317; 14 September 2016 (MOM-hip prosthesis); case 201600911, 26 October 2016 (YAG-laser treatment); case 201602661, 10 May 2017 (rehabilitation); case 201601360, 5 April 2017 (Lyme disease); case 201602502, 19 April 2017 (FreeStyle libre glucose monitoring system); case 201602448, 31 May 2017 (Lyme's disease); case 201602254, 5 July 2017 (chemotherapy); case 201600774, 5 July 2017 (rTMS); case 201602395, 5 July 2015 (sleep apnoea syndrome); contra G.R.J. de Groot, "De stand van de wetenschap en praktijk", *TvGR* (5) (2006), 287-303, at 290.

outcome, i.e. a negative opinion, reimbursement will be refused, irrespective of the international practice and experiences component.[345] Research (i.e., statistical) evidence and derived professional guidelines, therefore, precedes individual professional expertise and patient values, even knowing that scientifically proven medical care is not synonymous with the delivery of good care.[346] By focusing on the science instead of *integrating* the practice component, the disputes committee incorrectly applied the statutory 'international science and practice' test.

4. Civil court litigation: EBM guidelines not necessarily decisive?

In civil litigation, however, 'low quality' evidence and practice experiences have been admitted in evidence when reviewing the science and practice test. In several cases, this favoured the insured. In particular, Lyme disease disputes reveal that divergence in assessing evidence. Among Dutch health professionals, long-term antibiotic treatment for Lyme-related symptoms is generally considered ineffective and thus does not comply with the standard of international science and practice (revised guideline Lyme disease 2013 CBO).[347] Those advocating long-term antibiotic treatment, so-called "believers", refer to an international guideline of the International Lyme and Associated Disease Society ('ILADS' 2014), including various national guidelines from Belgium, Germany and the United States, as well as internal authoritative written opinions.[348]
Over the years, courts have ruled differently on whether long-term antibiotic treatment complies with the science and practice test.[349] In these cases, relevant guidelines were interpreted differently, which is explained by the absence of hard evidence (high-quality RCTs), inconsistencies in outcomes and diversity in quality and patient groups. According to the Appeal Court Arnhem, in the case of conflicting outcomes "the national CBO guideline is not leading but is still superior to the ILADS 2013 guideline in terms of reliability and quality".[350] The Court regards the fact that individual doctors use the ILADS guideline as a starting point in practice as insufficient. Low-quality evidence, such as personal experiences and positive results published by individual doctors, is outweighed by multiple new scientific studies and reports concluding the limited effectiveness of long-term antibiotic therapy.[351] Although the patient's claim for reimbursement was denied, the Court integrated the individual practice in its judgement, thereby correctly interpreting the science and practice criterion.

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[345] See, e.g., case 201602154, 24 January 2018 (hysteroscopy and IVF, in Dutch).
[346] Raad Volksgezondheid en Samenleving (Council for Health and Society), "Zonder context geen bewijs. Over de illusie van evidence-based practice in de zorg" (No evidence without context. About the illusion of evidence-based practice in healthcare, in Dutch) (The Hague: June 2017), 29.
[347] "Documents", CBO guideline Lyme disease 2013, RIVM www.rivm.nl.
[348] E.g., R.B. Stricker, "Benefit of intravenous antibiotic therapy in patients referred for treatment of neurologic Lyme disease", *Int J Gen Med*. (4) (2011), 639-46, concluding that "long term intravenous antibiotic therapy is associated with improved cognition, fatigue, and myalgias in patients referred for treatment of neurologic Lyme disease".
[349] Accepted in: Appeal Court Amsterdam 28 February 2012, ECLI:NL:GHAMS:2012:BV7524; District Court Gelderland 26 May 2016, ECLI:NL:RBGEL:2016:3300; Appeal Court Arnhem 25 July 2017, ECLI:NL:GHARL:2017:8016; District Court Gelderland 6 September 2017, ECLI:NL:RBGEL:2017:4910. Denied: District Court Gelderland 12 February 2014, ECLI:NL:RBGEL:2014;1412; Appeal Court Arnhem-Leeuwarden 19 December 2017, ECLI:NL:GHARL:2017:11105.
[350] Appeal Court Arnhem-Leeuwarden 19 December 2017, ECLI:NL:GHARL:2017:11105, para. 4.28.
[351] *Ibid.*, para. 13.

A similar, more balanced approach has been applied in so-called PTED cases, an alternative surgical technique for the treatment of lumbar disc herniation, which is less invasive than the standard surgical intervention. Prior to 2006, and according to the former Health Insurance Act, PTED interventions were considered "standard care". With the new Health Insurance Act, however, ZiN changed its position, claiming that there was insufficient evidence for PTED to be included for reimbursement from the health insurance scheme.[352] As a result, patients were forced to pay the costs of the PTED treatment out of their own pockets. In appeal, ZiN was highly criticised by the Court.[353] When reconsidering its position, with far-reaching consequences for the insured, a valid argument is essential but lacking in this particular case. It is unclear which type of spinal disc herniation is involved (recurrent or not) and when recruiting an expert opinion, to what extent has a 'dissenting opinion' been included?[354] Moreover, the ZiN advice ignored recent international development in research, treatment and health insurance reimbursement.[355] As such, the opinion does not satisfy the *Smits-Peerbooms* norm of the Court of Justice, the standard of international science and practice.[356] As a consequence, the insured did some medical research herself. Being a medical professional, she was able to interpret the research outcomes. Although high-level evidence was lacking, she was able to provide low-level evidence, such as successful experiences abroad (10,000 patients successfully treated in the Alpha clinic Munich, an additional study identifying eighty-five clinics performing PTED worldwide (2008)), as well as several patient studies and written expert opinions confirming PTED as an accepted and authorised intervention. The appeal court interpreted these low-level evidence studies and practice experiences as complying with the international science and practice test.[357] This ruling was confirmed in subsequent lower court rulings.[358, 359] Most recently, the Supreme Court annulled the Amsterdam appeal court ruling, as it incorrectly interpreted the international science and practice test.[360] The frequency of positive outcomes *itself* does not justify the conclusion that PTED complies with international science and practice. Low-level evidence (individual professional experiences and patient studies) must be *generally* accepted and based on consensus. Only then does the intervention comply with the *Smits-Peerbooms* approach of internationally sound and respected testing. Given the diversity of expert opinions and the lack of consensus among medical professionals, the appeal court incorrectly interpreted the hierarchy of evidence, concluding PTED as complying with the international science and practice test.[361] Although

[352] PTED opinion, www.zorginstituutnederland.nl (7 July 2008, in Dutch). Repealed and eligible for public reimbursement conditionally (1 January 2016), Parliamentary Proceedings *II* 2015/16, 29689, 649, 4.
[353] District Court Utrecht 30 December 2010, ECLI:NL:RBUTR:2010:BO9347 and Appeal Court Amsterdam 18 December 2012, ECLI:NL:GHAMS:2012:BY6499.
[354] *Ibid.*, ECLI:NL:GHAMS:2012:BY6499, para. 4.11.
[355] *Ibid.*, para. 4.13.
[356] *Smits-Peerbooms*, paras 94 and 98.
[357] *Ibid.*, para. 4.16.
[358] District Court Rotterdam 29 July 2014, ECLI:NL:RBROT:2014:1832; District Court Noord-Nederland 24 March 2016, ECLI:NL:RBNNE:2016:1200, contrary: District Court Arnhem 2 November 2009, ECLI:NL:RBARN:2009:BK1774, but annulled in appeal Court Arnhem-Leeuwarden 21 March 2016, ECLI:NL:GHARL:2016:2072, confirmed by the Supreme Court decision 24 February 2017, ECLI:NL:HR:2017:306.
[359] Compared to SKGZ cases, 31 out of 36 PTED cases were denied reimbursement by concluding PTED as not evidence-based (2007-2017).
[360] Supreme Court 30 March 2018, ECLI:NL:HR:2018:469.
[361] *Ibid.*, 4.4.2.

the Supreme Court confirmed the non-binding status of the (authoritative) ZiN opinion, courts must still explain any deviation explicitly and adequately, and correctly apply the conditions for replacing high-level evidence with low-level evidence. In practice, this means that courts should respect the hierarchy of evidence: "poor quality" evidence cannot overrule "high level" evidence, at least in principle.[362]

Reasonableness and fairness: grasping at straws?

When the standard of science and practice cannot provide clarity on a treatment's (clinical) effectiveness and efficiency, one may challenge the civil-law principles of "reasonableness and fairness" to claim the necessary treatment. Exceptionally, the Supreme Court has accepted those principles extending the scope of the insured entitlements and insurance policies. In *Bosentan,*[363] the Court reluctantly accepted the reasonableness and fairness argument to widen the statutory health insurance entitlements, but only conditionally:

i. it concerns a medicine that has been excluded for particular reasons from the insured entitlements, although it should have been listed;
ii. the insured cannot afford the high-priced medicine or treatment;
iii. there are no alternative treatment options;
iv. a life-threatening condition or condition causing serious suffering;
v. it is more than likely that the intervention will be listed in the near future, i.e. will be covered by the health insurance scheme as it complies with the requirements of effectiveness, necessity and efficiency.

To be successful, all those conditions should be met.[364] The *Bosentan* case is particular because it concerned a claim for a so-called "off-label" prescription medicine, i.e. using an approved prescription medicine (label A) for unapproved use of a disease or condition, as it may have a positive effect on that different disease or condition (label B).[365] The presumed positive effect should be justified based on facts and circumstances.

As the *Bosentan* case focuses on pharmaceutical care, one may question whether it is applicable to other types of medical care, such as claiming medical specialist care under the Dutch health insurance scheme. Both pharmaceutical and medical specialist care are insured entitlements under the Health Insurance Act, when in compliance with the science and practice test. That would be in favour of such an argument based on civil-law principles. Whereas pharmaceutical care entitlements are clustered as a restricted list of medicines, no such list exists for medical specialist care. The open system leaves the health insurer some discretionary power to decide whether or not to consider a particular intervention as standard care, i.e. complying with the science and practice norm. Given the Court's conditional approach, one may consider the life-threatening character of a particular disorder or serious suffering as the minimum threshold. It must be sufficiently clear, and there must be no alternatives.[366]

5. Conclusion

[362] Paras 4.4.1-4.4.4, corresponding the Advocate General's conclusion, paras 4.18-4.21.
[363] Supreme Court 19 December 2014, ECLI:NL:HR:2014:3679.
[364] *Ibid.*, para. 3.6.3.
[365] Such as when chemotherapy is licensed to treat one type of cancer, but healthcare providers use it to treat a different type of cancer.
[366] See District Court Gelderland 21 September 2015, ECLI:NL:RBGEL:2015:5933 (*neurostimulation abroad*).

Where the average citizen is invited to opt for the SKGZ binding advice procedure, those claims will rarely be successful. Referring to the evidence-based medicine formula, the challenged intervention will not comply with the science and practice standard. When high-quality randomised clinical studies are missing, the disputes committee will relapse into the same mode of Dutch practice, ignoring the international practice experiences or selectively choosing dissenting opinions. This explains why lawyers do not trust the *pseudo* court's outcome. Particularly in disputes questioning the nature and content of insured entitlements, the binding advice procedure is no real option for the insured. For obvious reasons, health insurers do not inform their insured about this practice.
What remains is judicial review. Costly and time-consuming, but the chance of success, and thus reimbursement of the contested intervention, is more likely but depends on the quality of evidence provided, the reliability of international research results, practice experiences and expert opinions. Access to justice, therefore, only remains open to the well informed and the well off.

PART FOUR. PUBLIC HEALTH

CHAPTER 7. The Dutch Critical Care Triage Guideline on Covid-19

Abstract

Recently, the Dutch Medical Doctors Association drafted the 'Covid-19 triage guideline ICU admission' that has age cut-offs that deprioritise or exclude the elderly. Such an age limit for intensive care unit (ICU) admission in case of a national emergency seems discriminatory, and thus is it inappropriate to use, or not? The question is whether age *in itself* can be considered as an acceptable selection criterion.

Keywords

Covid-19; intensive care unit (ICU) triage; age; discrimination

In times of public health emergencies such as the Covid-19 pandemic, there is an ongoing discussion on whether the elderly in need should be deprioritised for admission at intensive care units due to scarcity of ventilators. Recently, the Dutch Medical Doctors Association drafted the 'Covid-19 triage guideline ICU admission' that has age cut-offs that deprioritise or exclude the elderly.[367] Such an age limit for intensive care unit (ICU) admission in case of a national emergency seems discriminatory, and thus is it inappropriate to use, or not? The question is whether age *in itself* can be considered as an acceptable selection criterion, thus not as a medical-related criterion.

One may argue that in very exception circumstances, (chronological) age can be a permissible allocation criterion, next to medical criteria (medical need, urgency, etc.). A certain age level then functions as a threshold for deprioritising elderly from the ventilator and critical care beds. Such a differential treatment of the elderly can be justified by the 'fair innings' argument.[368] The general idea of the fair innings view is that, in the event of competing equal needs, the healthcare interests of the elderly should not be ignored, but should be deprioritised in favour of the younger patient. During their life, the older patient has received the *chance* to access all necessary healthcare services, and as a consequence has lived a relatively comfortable and satisfied life and received their 'fair innings', including education, building a career, marriage and starting a family.[369] As such, the age of – let us say – 80 years functions as a threshold. The younger patient, however, has not yet received that chance, and consequently will die prematurely if the ventilator treatment is denied due to scarce resources. The fair innings theory assumes that the death of a person at the age of 80 is a loss, but unavoidable, as everybody will die when they are older anyway, whereas the death of a young patient is considered a tragedy that could have been prevented by

[367] 'Draaiboek Triage op basis van niet-medische overwegingen voor IC-opname ten tijde van fase 3 in de COVID-19 pandemie' (Covid-19 triage guideline ICU admission), 16 June 2020, https://www.rijksoverheid.nl/documenten/publicaties/2020/06/16/draaiboek-triage-op-basis-van-niet-medische-overwegingen-voor-ic-opname-ten-tijde-van-fase-3-in-de-covid-19-pandemie, retrieved 23 August 2020,.

[368] As applied by J. Harris, *The Value of Life: An Introduction to Medical Ethics* (London: Routledge, 1991), pp. 91-94

[369] *Ibid.*

prioritising their treatment. It is emphasised that the health needs of the elderly will not be ignored, meaning that all kinds of necessary care will be provided but aimed at maintaining or improving quality of life, rather than prolonging life.[370] Age-based rationing proposals therefore do not generally advocate the withholding of *all* medical treatment from the elderly, but only limited to scarce life-extending care, taking into account relevant circumstances such as survival prospects, and degree of effectiveness or benefits (subtle age rationing).[371]

From a legal perspective, such an age-based threshold is not necessarily discriminatory, taking into account the conditions set by the United Nations Committee on Economic, Social and Cultural Rights (CESCR) in General Comment 20, which clarifies the Committee's understanding of non-discrimination in socio-economic rights.[372] In the Committee's view:

> discrimination constitutes any distinction, exclusion, restriction or preference or other differential treatment that is directly or indirectly based on the prohibited grounds of discrimination and which has the intention or effect of nullifying or impairing the recognition, enjoyment or exercise, on an equal footing, of Covenant rights.[373]

States must therefore 'immediately adopt measures to prevent, diminish and eliminate the conditions and attitudes which cause or perpetuate substantive or de facto discrimination'.[374]
Still, the Committee recognises that some forms of differential treatment can be permissible, provided that 'the justification for differentiation is reasonable and objective'.[375] Moreover, there must be a clear and reasonable relationship of proportionality between the aim sought to be realised and the measures or omissions and their effects. Also important is that 'a failure to remove differential treatment on the basis of the lack of available resources is not an objective and reasonable justification unless every effort has been made to use all resources that are at the State Party's disposal in an effort to address and eliminate the discrimination, as a matter of priority'.[376]

It means that age-based rationing, to be justified, needs to comply with the Committee's conditions as mentioned above. Here it is argued that the lack of ventilators, critical care beds and scarcity of human resources (intensive care health workers) to operate the life-saving equipment is absolute and not all patients who require intensive care can be admitted. In the most severe scenario when other medical and ethical principles will not work (e.g., 'first come, first served'), and all reasonable State efforts to increase critical care capacity remain unsuccessful, then age may become a reasonable justification for the denial of life-prolonging medical care to the older patient in favour of the younger person with equal medical needs.

So, in the most critical stage of the escalation model (stage 3 C), the Ministry of Health has to authorise the triggering of the so-called black scenario in which physicians may

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[370] G. Bognar, 'Fair Innings', *Bioethics* 4 (2015) 251-261, at p. 252.
[371] L.M. Fleck, 'Just Caring: In Defense of Limited Age-Based Healthcare Rationing', *Cambridge Quarterly of Healthcare Ethics* 19 (2010) 27-37, at p. 35.
[372] CESCR, General Comment (GC) no 20: Non-discrimination in economic, social and cultural rights, E/C12/GC/20, 2 July 2009, para. 7.
[373] *Ibid*. A similar definition has been used in Art. 1 ICERD; Art. 1 CEDAW; and Art. 2 CRPD.
[374] *Supra* note 6, para. 8.
[375] *Ibid*., para. 13.
[376] *Ibid.*

exclude a patient from the IC units based on non-medical criteria as described by the pandemic triage guideline (i.e. priority to health workers, age). Random selection may only be applied as a last resort option when other non-medical criteria are insufficient. By authorising the stage 3 C selection procedure, that approach – when applied correctly – complies with the 'standard of good care', as defined by national law.[377]

So, based on the above-mentioned considerations, age-based rationing in case of the Covid-19 pandemic can indeed be justified to promote general welfare (accessibility of critical care services), while respecting the elderly's health needs, except for life-sustaining treatment. In that case, defining a maximum age (or relative age groups) for age-based rationing is considered an objective standard, to be defined by State Parties, allowing (groups of) individuals the right to participate actively in the decision-making process over the selection of such a criterion ('democratic deliberation').[378] That approach then requires access to and disclosure of all relevant information, a transparent and participatory decision-making process regulated by law, and mechanisms for legal redress when rights have been violated. In a way, such a fair and accountable procedure combines both substantive and procedural principles, echoing the accountability for reasonableness standards advocated by Daniels and Sabin.[379]

Although the fair innings argument in age-based rationing has certain weaknesses, it is the least worst of the selection criteria. Alternative criteria (gender, socio-economic status, religion, disability, cost-effectiveness thresholds and random lottery) appear arbitrary and are therefore rejected. When other mechanism have failed (first come, first served; utility), then limited age-based rationing remains the least onerous, but most necessary, option to cope with the global public health threat.

[377] The general standard of 'good care' is the duty of health providers to provide care that is safe, effective, provided at the right time and is patient-centred, and formed by research and consensus within the professional group, preferably laid down in standards, guidelines and protocols, defined by national law under the 'Wet Kwaliteit, Klachten en Geschillen Zorg – Wkkgz'), Art. 2.

[378] As argued by L.M. Fleck, *Just Caring: Health Care Rationing and Democratic Deliberation* (New York: Oxford University Press, 2009), ch. 5; and L.M. Fleck,' Just Caring: Health Care Rationing, Terminal Illness, and the Medically Least Well Off', *Journal of Law, Medicine & Ethics* 1(2011) 156-171 at p. 164.

[379] 'Accountability for reasonableness (AfR)' is the idea that the reasons or rationales for important limit-setting decisions should be publicly available. In addition, these reasons must be ones that 'fair-minded' people can agree are relevant to pursuing appropriate patient care under necessary resource restrictions. See N. Daniels and J. Sabin, *Setting Limits Fairly: Can We Learn to Share Medical Resources?* (New York: Oxford Online, 2009), ch. 4, ebook).

PART FIVE. MIGRATION & HEALTH

CHAPTER 8. Strasbourg Medical Expulsion Rulings: Beyond the Deathbed Requirement

Abstract

For decades, the European Court of Human Rights (ECtHR) has applied a restrictive interpretation on the Article 3 threshold in extradition cases. The removal of aliens from the contracting state is lawful unless the applicant faces an imminent risk of death (*D* v. *the United Kingdom* (*St Kitts*)). However, with the *Paposhvili* ruling the Court has lowered the deathbed requirement to a more favourable standard as confirmed in the latest *Savran* case. But will those facing medical expulsion really benefit from this new standard at national level?

Keywords

medical expulsion; threshold; severity approach; intense mental suffering; Savran

1 Introduction

For decades, the European Court of Human Rights (ECtHR) has applied a restrictive interpretation on the Article 3 threshold in extradition cases. The removal of aliens from the contracting state is lawful unless the applicant faces an imminent risk of death due to the seriousness of his health condition and the absence of medical care in the returning country (known as the threshold of severity test in the *St Kitts* case). Seriously ill aliens fit to fly for removal and where there is no direct prospect of dying will not pass the 'extreme' threshold, therefore cannot claim inhuman and degrading treatment under Article 3, and can thus be removed.

Unexpectedly, in the *Paposhvili* case, the Court finally left that strict approach, lowering the threshold of severity on medical grounds (2016). Last month, that more liberal approach was confirmed in the *Savran* case where the applicant, facing extradition to Turkey, was diagnosed with a serious psychiatric illness and the risk of serious deterioration of his health due to the lack of necessary health care in the country of destination.

Here it is argued that the Court's latest medical refoulement cases impose a shift away from an overly restrictive exception towards a more humanitarian approach. But at national level, the *Paposhvili* argument appears hardly successful, at least in the Netherlands.

2 ECtHR and Medical-related Expulsion

2.1 *The Harsh* St Kitts *Approach*

In *D* v. *the United Kingdom* (also known as the *St Kitts* case),[380] the Court accepted that in very exceptional cases, the expulsion of a seriously ill alien could trigger the protection of Article 3 of the Convention on humanitarian grounds. Although states have the right to

[380] *D* v. *the United Kingdom*, App. no. 30240/96 (ECtHR, 2 May 1997).

control the entry, residence and expulsion of aliens (para. 46), expulsion could nevertheless give rise to an issue under Article 3, when the person faces a real risk of being subjected to torture or inhuman and degrading treatment in the receiving country. The very exceptional circumstances of *D* v. *the United Kingdom*, and the life-threatening situation due to his illness, justified granting an exception to expulsion based on medical grounds. The risk of being exposed to ill treatment in the receiving country (St Kitts), caused a severe level of suffering, far below Article 3's threshold of severity. The assessment of the minimum threshold, as confirmed in the Court's jurisprudence, includes the following circumstances:

- The severity of the illness (real and direct risk of dying). But the life-threatening prospect itself, or decreasing life expectancy is not considered as an imminent risk (critical but stable condition, not expected to deteriorate, *N* v. *the United Kingdom*).[381]
- The absence of medical treatment options or medicines in the receiving country, interpreted as the availability and not financial accessibility (para. 52). Not relevant is the *level* of medical treatment infrastructure or pharmaceutical care.
- The lack of moral and social support and care by the family provided in *St Kitts* (para. 52).

Given these circumstances, the threshold of severity required by Article 3 requires an extreme vulnerability of the applicant, causing intense suffering contrary to human dignity. That line of reasoning has been applied on several occasions, depriving other tragic cases of medical expulsion from the benefit of the Article 3 exception.[382]

2.2 *The* Paposhvili *Test: A More Favourable Standard*

In *Paposhvili* v. *Belgium*, the applicant was facing extradition to Georgia, claiming that during imprisonment he was diagnosed with leukaemia and his health was deteriorating.[383] Although considered life threatening, his vital organs were still functioning. The Chamber thus concluded that his health condition was stable and under control as a result of the treatment provided in Belgium.[384] As a result he was not in imminent danger, and fit to travel. And since medication for treatment of his disease is available in Georgia, there were no exceptional circumstances precluding the applicant's removal.[385] So far, the Chamber's ruling acknowledged the severity threshold as mentioned in *N* v*. the United Kingdom* and there was no 'close-to-death' case. But in *N* v*. the United Kingdom* the Court argued that in other very exceptional cases then 'close to death' might fall below the Article 3 minimum threshold, but it never explained what these other occasions might be.[386] That was the main reason for referral to the Grand Chamber (GC), clarifying 'other very exceptional cases', as it raised 'a serious issue of general importance' that goes beyond this particular situation.[387]

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[381] *N.* v. *the United Kingdom*, App. no. 26565/05 (ECtHR [GC], 27 May 2008), para. 47.

[382] E.g., *supra* note 2: no exceptional circumstances since the individual (HIV infected but stable condition and under control as a result of treatment received), and his life was not in imminent danger; *Bensaid* v. *the United Kingdom* App. no. 44599/98 (ECtHR, 6 February 2001), psychiatric treatment in hospital at 75 km distance passing 'terrorist area'; *Yoh-Ekale Mwanje* v. *Belgium*, App. no. 10486/10 (ECtHR, 20 March 2012), advanced but not critical stage HIV patient and appropriate medication available; *Tatar* v*. Switzerland* App. no. 65692/12 (ECtHR, 14 July 2015), removal of psychiatric patient to a country with inferior treatment facilities. All of them were seriously ill persons whose condition was under control as a result of medication provided in the sending state, and who were fit to travel.

[383] *Paposhvili* v. *Belgium,* App. no. 41738/10 (ECtHR [GC], 13 December 2016).

[384] Ibid., 136.

[385] Ibid., 137.

[386] *Supra* note 2, para. 43.

[387] *Paposhvili,* paras. 181–182; Article 43 of the Convention.

The GC therefore continued the examination clarifying the meaning of other very exceptional cases complying with the severity threshold. According to the GC, that is the case when:

> a seriously ill person [….] would *face a real risk*, on account of the *absence* of *appropriate treatment* in the receiving country or the *lack of access* to such treatment, of being exposed *to a serious, rapid and irreversible decline in his or her state* of health resulting in intense suffering or to a significant reduction in life expectancy', when being removed. (para. 183)

That means it is up to the applicant to provide evidence showing that there are substantial grounds, but not clear proof, that expulsion would cause such a risk contrary to Article 3.[388] It is up to the state to refute any doubts about whether such a risk will appear, and 'the returning state must consider the foreseeable [*health-related, AdE*] consequences of removal for the individual concerned in the receiving state'.[389] That means, that the risk assessment made by the returning state should include information from the receiving state on the availability and accessibility of health care services and medicines required in this particular case. Also, information provided by authoritative organisations such as WHO, non-governmental organisations, and the patient's medical file should be sought (para. 187).

When the applicant has provided the requested evidence, then it is for the returning state to prove that 'the medical care generally available in the receiving state is sufficient and appropriate in practice for the treatment of the applicant's illness'. It should be emphasised that the level of care provided should not be equivalent or inferior to that provided in the returning state (para. 189), but sufficient and appropriate. What is also relevant is that substantial out-of-pocket payments for medicines is considered to be a major barrier to the financial accessibility of health care, and long distances to visit health care facilities may hinder the geographical accessibility.

Finally, in case the risk assessment reveals serious doubts about the impact of removal on the person, the returning state must assure that appropriate treatment will be available and accessible to the applicant (para. 191). Otherwise, that would trigger the risk of treatment prohibited by Article 3.

Applying the above-mentioned criteria, the GC concluded that the conditions were not satisfied.[390] The information provided by the Belgian authorities appeared manifestly inadequate. Apart from the 'close to death but stable situation, and thus fit to travel' as concluded by the Belgian medical officer, none of the arguments provided by the applicant were examined by the authorities. Since the doubts on the risk of ill treatment were not refuted, removal of the applicant to Georgia would violate Article 3.

2.3 Savran: *Confirmation and Application*

In *Savran* v. *Denmark*,[391] the applicant claimed that his deportation to Turkey would be in violation of Articles 3 and 8 of the Convention. *Savran* entered Denmark with his family at the age of 6 (1991). In 2007, he was convicted of assault under highly aggravating circumstances. After imprisonment, in line with Danish immigration legislation he was facing

[388] *Ibid*., 186.
[389] *Ibid*., 187.
[390] *Ibid*., 200–206.
[391] *Savran* v. *Denmark*, App. no. 57467/15 (ECtHR, 1 October 2019).

deportation from Denmark. During the criminal proceedings, *Savran* was diagnosed with paranoid schizophrenia and a cannabis dependence syndrome. In preparation of deportation, the Immigration Service requested information on the treatment options and the availability of necessary medication in Turkey.

Fighting deportation in several instances, *Savran* claimed that he would not have a real possibility of receiving appropriate and necessary psychiatric treatment in Turkey, in the region of Konya. Accordingly, he would suffer a relapse and the risk and suffering would be a breach of Article 3. He referred to the medical report of his treating psychiatrist during imprisonment that in order to prevent a relapse, supervision by a regular contact person would be essential (para. 37). The government, however, concluded that the applicant could continue the same medical treatment in the Konya area, and supervised by medical staff able to communicate in the required language (Kurdish). They also observed that the 100 km distance to the nearest hospital would not be considered a real risk towards the availability of necessary psychiatric care.[392]

In its assessment, the Court repeated the *Paposhvili* 'very exceptional circumstances' argument in which the person would face a real risk, to be exposed to a serious, rapid and irreversible decline of health due to the absence or lack of access to the appropriate treatment (para. 45) and that such a situation, although not close to death, would cause inhuman and degrading treatment. So, prior to expulsion, the authorities of the returning state must on a case-by-case basis verify:

i. whether in practice, there is sufficient and appropriate care available to treat the applicant's disease;
ii. the extent to which these health services are accessible (i.e., geographical and financial accessibility), as well as the existence of a family network for support;
iii. in case of serious doubts, whether there are adequate assurances from the receiving state about the availability and accessibility of appropriate treatment;
iv. pending expulsion, that the potential consequences of removal have been considered given the applicant's illness (paras. 46–49).

Despite the availability of psychiatric care in Turkey, the Court had some serious doubts about whether the applicant would de facto have access to appropriate medical treatment, and consequently face the deterioration in his health condition due to the risk of a psychotic relapse (para. 53). Although psychiatric treatment in general is available in Turkey, and even covered by the national health system, a follow-up and control scheme by means of a daily contact person for supervision to prevent a relapse is essential but not available; nor did the Danish authorities receive any assurances from Turkey that such outpatient therapy assistance would be available (para. 64). Since absence of appropriate psychiatric treatment would worsen his psychotic symptoms and increase the risk of aggressive behaviour, the applicant would then be exposed to a serious, rapid and irreversible decline in health, resulting in intense suffering, as concluded in *Paposhvili*. Such a removal would then be considered as a violation of Article 3.

3 Comments

[392] *Bensaid* v. *the United Kingdom* 44599/98 (ECtHR, 6 June 2001), para. 42. Summarized in *European Journal of Health Law*, 2019, no. 5, ECHR 2019/19.

Paposhvili has been welcomed for extending the Article 3 threshold, from an 'imminent risk of dying' to 'facing a real risk […] of being exposed to a serious, rapid and irreversible decline in his or her state of health resulting in intense suffering or to a significant reduction in life expectancy'. Although mentioned in *N* v. *the United Kingdom*, only in *Paposhvili* did the Court clarify the meaning of 'other very exceptional cases' different from 'close to death'. Although the threshold remains high, without doubt *Paposhvili* means a shift the Court's medical expulsion case law. As it was ruled unanimously by the Grand Chamber, it is potentially promising for similar cases. In that respect, *Savran* has confirmed the very exceptional cases approach.

3.1 *Fake or Genuine Psychosis*

Still, *Savran* is important on its own since the Court recognises that severe mental suffering (paranoid schizophrenia) can also be interpreted as a 'very exceptional case' under the threshold; but then, only on a case-by-case review and taking into account the additional requirements. What is interesting is the dissenting opinion of Judge Mourou-Vikström, arguing that a mental illness is more 'volatile' and open to question, referring to the risk of a person faking psychotic symptoms, and thus lying about his mental disorder. Removal of a person with a mental disorder should therefore not be perceived in the same way as for a person with a physical disease such as leukaemia. Indeed, mental disorders may require a different approach (differentiating between genuine or malingered psychosis), but it is doubtful whether this approach should result in a *higher* threshold for finding a violation of Article 3, as suggested by the dissenter. That would not be consistent with the *Paposhvili* approach. It is up to the court to assess the consequences of withholding antipsychotic medication, whether it would expose the applicant to 'a serious, rapid and irreversible decline of his state of health resulting in intense suffering'.

3.2 *A Less Strict* Paposhvili *Test?*

According to three dissenters (Kjølbro, Motoc and Mourou-Vikström) the Court failed in this assessment by taking the medical experts' report for granted (the risk of pharmaceutical failure and consequently the worsening of the applicant's psychotic symptoms, and a greater risk of aggressive behaviour, para. 11) and in a way that seems correct, and thus criticises the Court's seemingly more permissive approach. But reading paragraphs 65–66 carefully, it does appear that the Court did apply the serious, rapid and irreversible decline in health test, at least implicitly. The Court recognised the seriousness of the mental disorder, qualifying the need for follow-up medical services as 'essential', in combination with the serious doubts as to the impact of removal on the applicant's health and the absent assurances of the availability of the required health services in Turkey. Under these circumstances, removal would trigger the inhuman and degrading treatment under Article 3, by imposing the applicant to 'a serious, rapid, and irreversible decline of his health resulting in intense suffering or to a significant reduction in life expectancy'. It is therefore unlikely that the Court applied the *Paposhvili* rule less strictly.

3.3 *Timely, Available Medical Services?*

What's important is that the applicant has to provide evidence that appropriate treatment in this particular case is absent or de facto not available, due to the lack of essential health services, equipment or medicines, and also not financially accessible given the high costs of

treatment. But 'available' could also be interpreted as *available on a timely basis*. If so, then what is considered as timely? It can be argued that timely means the time normally necessary for obtaining the treatment in question in the returning state, considering the applicant's current health status and the probable course of his health. More specifically, this means that an excessively long waiting time which is medically not justifiable, and deteriorates the patient's health condition, results in an undue delay in treatment and therefore could be interpreted as not available in practice.[393] It is therefore for the applicant to provide evidence of the undue delay scenario in the returning state.

3.4 *Assurances of Appropriate Treatment*

Prior to *Paposhvili*, the embassy report and returning state report on the general availability of health care services provided sufficient evidence to conclude that there was no obstacle to medical deportation. But since *Paposhvili* and confirmed in *Savran*, that practice has appeared to be insufficient. Serious doubts about the impact of removal on the applicant's health status require 'individual and sufficient guarantees from the receiving state', that the appropriate treatment will be available and accessible.[394] Apart from official observations, these assurances should be based on factual information on both the availability and accessibility of the required medical services (national reports on waiting times/lists, WHO country studies, NGO reports, etc.). Substantial financial hardship, travel distances to medical services and/or language skills may create an obstacle to the accessibility of such services, and thus need to be verified in the country report on 'appropriate treatment'. This will definitely increase the burden of proof by the sending state.

4 Some Post-*Paposhvili* Experiences: The Case of The Netherlands

What has been the effect of *Paposhvili* and *Savran* so far at national level? Here, the focus is on one case study: the Netherlands, although not necessarily representative for other countries.

Prior to *Paposhvili*, the 'medical deportation' exception followed the close-to-death rule. But on 11 April 2017, the minister responsible for aliens' affairs informed the Dutch Parliament about the shift towards *Paposhvili*.[395] Since then, other very exceptional cases might justify delaying deportation.[396]

In practice this means that seriously ill aliens will be granted leave to stay in case of other very exceptional circumstances, operationalised as a 'short term medical emergency'. Here, an emergency is understood as a situation in which the applicant, without treatment, most likely will die or suffer from invalidity or other serious mental or physical disorder within a period of a maximum of three months.[397] The likeliness of death or suffering is based on

[393] In line with CJEU ruling Case C-372/04 *Watts* v. *the United Kingdom*, para. 57.
[394] *Savran*, para. 48.
[395] Parliamentary Letter 11 April 2017, no. 19637, no. 2312.
[396] Dutch Aliens Act, (Vreemdelingenwet 2000) elaborated by secondary law (Vreemdelingencirculaire 2000)
[397] The three months period is based on providing a reliable estimation when medical treatment will be cancelled. A longer period would result in speculation, hindering the 'serious, rapid and irreversible decline in health' test.

contemporary medical-scientific understanding. In short, the Aliens Act exception has been extended with 'other mental and physical suffering'.

4.1 *Medical Emergency and the Judiciary*

The next question is, how has the judiciary applied the *Paposhvili* rule so far? As expected, no *Savran* references were found in the national case law database (database: rechtspraak.nl, 1 November 2019) but *Paposhvili* revealed 106 hits in total (including 22 appeal cases). Thus, since the *Paposhvili* ruling, courts in first instance (regional courts) and the appeal court (the Council of State) referred and applied the *Paposhvili* very exceptional standard test.

Still, the outcomes are quite disappointing as in all cases, the appeal court dismissed the applicant's claim of a medical emergency due to the lack of evidence. The appeal court repeatedly echoed the ECtHR's wording that 'it is for the applicant to adduce evidence capable of demonstrating that there are substantial grounds for […] a real risk of being subjected to treatment contrary to Article 3'.[398]

Such evidence should be found in the availability and accessibility of necessary health care in the destination state. According to the appeal court the mere claim that medicines are not available, or financially not accessible, remains insufficient to conclude that there are 'substantial grounds'.[399] For instance, a letter provided by the applicant's treating physician about the lack of medical care in San Paulo (Brazil), or the non-confirmed statement that a certain medicine in Guinea is only available in private pharmacies and is therefore actually inaccessible, is simply inadequate.[400]

Although no 'clear proof' is required, the threshold of evidence remains extremely high as shown by the Guinea example. According to the appeal court, the limited number of psychiatrists (five!) for the entire population does not mean that necessary psychiatric care is actually not available in Guinea.[401] And since there is no reason to question the sending state's medical advisory opinion concerning the absence of medical emergency (no *rapid* decline in health status), the appeal failed.[402]

Based on the Dutch judiciary practice one may conclude that the *Paposhvili* very exceptional standard has been generally accepted and applied in medical expulsion cases. But poor evidence of the factual availability and accessibility of medical services and goods provided, makes it practically impossible to comply with the rule that 'it is for the applicant to adduce evidence capable of demonstrating that there are substantial grounds for […] a real risk of being subjected to treatment contrary to Article 3'.

Questioning the poor quality of evidence, the most likely argument is the lack of effort/time to search for more reliable information than Internet sources, medical opinions in the destination country and unfounded statements. Fact-finding by contacting

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[398] *Paposhvili*, para. 186.

[399] ECLI:NL:RVS:2019:983, para. 3.2 (actual accessibility medicines private clinic); ECLI:NL:RVS:2919:2392, para. 3.1; ECLI:NL:RVS:2019:988, para. 1.3; ECLI:NL:RVS:2019:987, para. 3.2; ECLI:NL:RVS:2019:986, para. 3.3; ECLI:NL:RVS:2017:2629, para. 9.1; ECLI:NL:RVS:2019:983, para. 5; ECLI:NL:RVS:2019:984, para. 3.2; ECLI:NL:RVS:2019:2739, para. 8.1; ECLI:NL:RVS:2019:571, para. 2.1; ECLI:NL:RVS:2017:1733, para. 1.7; ECLI:NL:RVS:2019:1288, para. 4.

[400] ECLI:NL:RVS:2019:988, para. 1.4; also online Wikipedia information on the availability and accessibility of psychiatric care in Guinea, ECLI:NL:RVS:2017:2627, para. 8.2; ECLI:NL:RVS:2018:2362 evidence costs of immunodeficiency treatment, para. 5.2.

[401] Evidence provided by a national NGO, ECLI:NL:RVS:2019:2392, para. 5.1.

[402] ECLI:NL:RVS:2019:132 para. 3.1; idem ECLI:NL:RVS:2017:2628 (risk of suicide), para. 6.3–6.4.

(inter)national NGOs, hospitals, other health providers and WHO reports may provide a certain level of evidence required, though not 'clear proof'. In the majority of appeal cases, such information was simply absent. But even then, the Article 3 threshold remains sky-high as shown by the Guinea mental health case. Since the applicant has not been successful in providing evidence of substantial grounds of a real risk, there is no reason for the sending state to ask the destination state for assurances about the availability and accessibility of medical care.

5 Conclusion

In *Paposhvili*, the Court has 'closed the gap in the protection against inhuman treatment', as concluded by Judge Lemmens (concurring opinion). That might be true from the Convention's perspective, but at national level a high threshold of harm remains. The Guinea case painfully shows that the very exception standard functions more as a fig leaf which seems unrealistic to comply with, at least in the Netherlands.

CHAPTER 9. Health services: migrant professionals

Legal framework

According to the 2018 EU Labour Mobility report, there were 352 000 mobile health professionals, 20 per cent of which were doctors and 40 per cent of which were nurses working in another Member State.[403] Health professionals (doctors, nurses, dentists, pharmacists) have been working abroad for many years, either temporarily or permanently. Driving forces for health professionals to move to another MS to work include, for example, financial reasons, better training and career opportunities, working environment and conditions.

With the focus on 'Mode 3' mobility of services delivery, i.e. commercial presence abroad, the emphasis will be on the regulatory framework concerning health professionals who permanently stay in another MS after graduation with the purpose and effect of delivering health services.

The right to pursue a profession, either in a self-employed or employed capacity, in another Member State has been generally recognised as a key right under the Treaty on the Functioning of the European Union (TFEU), either under Article 49 (freedom of establishment) or Article 56 (services). In addition, 'the European Parliament and the Council shall issue directives for the mutual recognition of diplomas, certificates and other evidence of formal qualifications', allowing health professionals to pursue their professional activities in another MS, either as self-employed or a worker. The applicable directive is the Professional Qualifications Directive 2005/36/EU, replacing the so-called 'sectoral' directives[404] and setting out more detailed rules to regulate the mutual recognition of professional qualifications.[405] The Professional Qualifications (PQ) Directive modernises the sectoral directives (doctors, nurses, dentists, midwifes and pharmacists), in a way that it consolidates different several recognition regimes (professional qualifications and professional experiences), for providing cross-border services or pursuing activities as a self-employed person or an employee. The Directive confirms several key principles regulated by the sectoral directives: equal treatment of qualifications; automatic recognition of regulated professions and minimum level training conditions, while incorporating new issues such as language requirements; mutual assistance; regulating so-called third-country diplomas by introducing compensatory measures; the exchange of information on 'problem doctors'; and excluding cross-border telemedicine, as it is based on the 'country of origin principle'. The Directive sets the rules for providing services on a temporary and occasional basis, and also for professionals who want to establish on a permanent basis. For health professionals, the

[403] European Commission, 2017 annual report on intra-EU labour mobility, Final Report January 2018, p.114 <https://op.europa.eu/en/publication-detail/-/publication/cd298a3c-c06d-11e8-9893-01aa75ed71a1/language-en > accessed 20 July 2020.

[404] Including the following professions: doctors (Council Directive 75/362/EEC of 16 June 1975 OJ L 167/1); dentists (Council Directive 78/686/EEC of 25 July 1978 OJ L 233/1); veterinary surgeons (Council Directive 78/1026/EEC of 18 December 1978, OJ L 362/6); midwives (Council Directive 80/154/EEC of 21 January 1980 OJ L 33/1); pharmacists (Council Directive 85/432/EEC of 16 September 1985, OJ L 253/34); architects (Council Directive 85/384/EEC of 10 June 1985 OJ L 223/15)

[405] Directive 2005/36/EC of 7 September 2005 on the recognition of professional qualifications, OJ L 255/22.

automatic recognition (AR) system (Article 21) is applicable for regulated professions (doctors, nurses, dentists, midwifes, pharmacists, veterinarians, and architects), meaning that access to that profession is based on the possession of a given formal qualification ensuring that the person concerned has undergone training which meets the minimum conditions laid down (Article 3(1)(a)). This AR system also applies to (new) medical specialities recognised by at least two MSs. The professional recognition allows the health professional to pursue the profession in the territory of another MS – on a temporary or occasional basis – under the same conditions as its nationals (Article 4). This could mean registration at the Medical Professional Chamber as an administrative condition prior to pursuing the profession, as well as confirming the professional Code of Conduct applicable, and the rules of professional liability, as these rules are directly linked to the practice of medicine and thus the professional rules of the Directive (Article 5(3)). That would be different when the rules concerned are not directly related to the actual professional practice (Konstantinidis, Case C-475/11). In that case, national rules on calculation of fees and advertising fall outside the scope of the Directive's professional rules, but must be examined under the principle of free movement of services (Article 56 TFEU), taking into account the public health and consumer protection exemption (Konstantinidis, Case C-475/11, para 58).

Each MS shall recognise the evidence provided of such regulation of professions, which satisfy the minimum training conditions. For instance, in the case of medicine basic medical training shall comprise a total of at least six years of study or 5500 training hours of both theory and practice at university level (Article 24(2)). Similar conditions apply to other regulated medical professions. Still, the Directive does not harmonise or coordinate the conditions for continuous professional development *after* completing the education programme. As a consequence, these permanent development and education standards differ by country and health professions (both in content and duration), with mandatory and voluntary systems. To some extent that omission has been recognised by the revised Directive (Directive 2013/55/EU), amending Directive 2005/36/EC as it encourages continuous professional development, so that health professionals are able to update their knowledge 'to maintain a safe and effective practice' (Article 22). But apart from encouraging the exchange of best practices of permanent education, the revised Directive does not solve that issue.
For other health professions that do not qualify for automatic recognition (e.g. physiotherapists, health assistants) the general regime of diplomas is applicable.
Although the system has recognition as its starting point, MSs are allowed to impose compensatory measures (adaptation period, or an aptitude test) under certain conditions (Article 14).
The PQ Directive is applicable to MS diplomas and qualifications. In the case of third-country diplomas, MSs may employ these qualified health professionals – nurses and physicians – but must ensure compliance of professional qualifications with the minimum training requirements at EU level (and if necessary, apply compensation measures). This practice is based on the CJEU jurisprudence on third-country diplomas (Tawil-Albertini C-154/93, Haim C-319/92, Hocsman C-238/98).

The revised Directive also confirms the Court's case law on partial access to a profession where the activities covered by a regulated profession differ from one country to another

(Colegio de Ingenieros de Caminos, Canales y Puertos, C-330/03; Nasiopoulos, C-575/11). It can benefit professionals who engage in a genuine economic activity in their home Member State which does not exist, in its own right, in the Member State where they wish to work. The competent authority (CA) may grant partial access when: (i) the professional is fully qualified in the home MS; (ii) the application of compensation measures would amount to requiring the applicant to complete the full programme of education in the host MS; (iii) the professional activities can be split in separable parts falling under the regulated profession in the host Member State (Article 4f). Still, the refusal of partial access can be objectively justified for reasons of general interest (e.g. consumer and health protection). But in *Nasiopoulos*, the total exclusion from even partial access to the profession of physiotherapist goes beyond what is necessary since a less restrictive measure was more likely. Consequently, the host MS has to accept and organise partial access to pursue the paramedic profession. But that does not mean that MSs have to lower the relevant qualification standards (Malta Dental Technologists Association and Reynaud, C-125/16, paras 47-49).

In order to pursue the profession in the host MS, knowledge of the language is essential. The PQ Directive does not specify the level of knowledge, just declaring that the level must be 'necessary for practising the profession', which means that the professional can communicate effectively in the host MS (Article 53). In addition, the revised Directive allows standard language controls applied for professionals with patient safety implications (Article 53(3)). But the language requirement should be separated from the professional requirements and will be tested by the MS CAs, and limited to the knowledge of one official language of the host MS. In general, the assessment of the language skills should be proportionate to the activity to be pursued, which gives State authorities some flexibility. Still, the Court's case law on mandatory language tests has proved rather problematic to solve (Commission/Belgium, C-317/14, paras 27-31).

In order to simplify the recognition procedure, the revised Directive makes the electronic exchange of administrative information, the Internal Market Information (IMI) system, mandatory. In addition, new features such as the European Professional Card (EPC) and an alert system were introduced to facilitate the mobility of health professionals within the EU. The EPC is an online tool that supports the holder of a professional qualification in applying for the CA of the host MS, within the IMI system (Article 4a). The home MS will verify whether the applicant's professional diploma is valid and authentic, and provide the relevant data to the host MS, who will decide within a certain time limit to decide on issuing the EPC. In the case of justified doubts, the host MD may request additional information. Where the host country authority fails to take a decision within prescribed deadlines, the EPC is issued automatically. The corresponding IMI file has become an important platform to notify changes in the professional qualifications. For instance, the file will be updated with information regarding criminal and disciplinary sanctions related to the prohibition or restriction of practising the profession. In line with the Data Protection Regulation (Reg. 2016/679) such updates shall include the deletion of information which is no longer required. Both the holder and CAs have access to the IMI file and will be informed immediately after any updates (Article 4e).

The EPC was introduced in 2016 and currently available for a limited number of professions (nurses, physiotherapists, pharmacists – Regulation 2015/983). It is expected that it will be extended to other health professions in the near future.

The second new element, the alert mechanism, was created to ensure patient safety by preventing 'rogue' health professionals, who have been prohibited or restricted from practice in one EU country, or who have used falsified diplomas, from continuing to practice across national borders. The alert mechanism is applicable to all health professions whose actions could affect patient safety (Article 56a). When a professional has been banned, even temporarily, from carrying out their professional activity, an IMI alert will be sent by a CA to all other relevant CAs in other Member States. These alerts will include key information relating to the professional such as: the identity; the profession concerned; the scope of the restriction or prohibition; and the period during which the restriction or prohibition applies (Article 56a (2)).
A Commission evaluation in 2018 concluded that both policy tools, the EPC and alert mechanism, functioned well and had added value.[406] Apart from the steadily increasing number of EPC applications by profession, it showed a significant rise in alerts sent by all MSs. The vast majority of the alerts were for cases where a professional was restricted or prohibited from practice (p. 18). It is emphasised that it is the national sanction that triggers the alert and not the alert mechanism itself, as national sanctions and disciplinary systems differ by country. For instance, what is included as 'professional misconduct' differs by country. This diversity may cause some difficulty in case the action is lawful under the home MS legislation. For instance, the practice of euthanasia has been prohibited in many MSs, and physicians will be sanctioned when being involved in such practices in the host country. An IMI notification of such a criminal or disciplinary ruling will be send to all MSs, including the home MS which has legalised euthanasia. Still, that decision (e.g. removal of the right to practice) has to be respected on the basis of the mutual recognition principle (of court decisions). Common understanding of the contextual differences is therefore important.

The revised Directive also introduced access to online information on all regulated health professions in each MS.[407] The information, including the contact details of the CA and other administrative formalities by country, is aimed to facilitate professional mobility and will be publicly accessible. In addition, 'assistance centres' will be established in each MS to support citizens with the recognition procedures of professional qualification, and inform them about the applicable national legislation and the rules of ethics (Article 57b).

In the context of the fight against the coronavirus pandemic, the Commission issued a communication to help MSs in addressing the shortages of certain health professions in emergency situations.[408] The communication clarifies how to speed up mutual recognition procedures of temporary migrating health professionals in line with the flexibilities allowed by the PQ Directive 2005/36/EC. It also clarifies how EU countries can ensure that the

[406] European Commission, Assessment of stakeholders' experience with the European Professional Card and the Alert Mechanism procedures, Brussels, 9.4.2018 SWD(2018) 90 final.
[407] European database on regulated professions: https://ec.europa.eu/growth/tools-databases/regprof/
[408] European Commission, Communication from the Commission, Guidance on free movement of health professionals and minimum harmonisation of training in relation to COVID-19 emergency measures – recommendations regarding Directive 2005/36/EC Brussels, 7.5.2020 C(2020) 3072 final

Directive's rules on minimum requirements on doctors and nurses training can be respected in cases where students are not able to complete their training because of disruptions due to the coronavirus crisis, including by requesting a derogation from these rules.

Not covered by the PQ Directive are the licensing conditions for opening a private practice in the host MS. As a general rule, the freedom of establishment can be duly restricted for reasons of general interest (public health protection) but national measures must apply an objective and consistent standard when assessing the 'need' for newly established private clinics as part of the proportionality test (Hartlauer mbH v. Wiener Landesregierung and Oberösterreichischer Landesregierung, C-169/07, paras 63-64).
Since Hartlauer, the Court has confirmed the marginal testing of the restrictive measure in Blanco Pérez, where a licensing system for new pharmacies was aimed to ensure pharmaceutical care of good quality and the measure appropriate to realise the public health objective, taking into account the geographical circumstances (Blanco Pérez and Chao Gómez, joined cases C-570/07 and C-571/07, paras 75-80).
Another justified restriction of both the freedom of establishment and freedom of workers, is a repay clause of the awarded bursary for training purposes abroad, in case the candidate fails to meet the bursary condition to practise the medical profession in the home MS after finalising their medical speciality in the host MS. Since the repay clause was intended to guarantee access to medical specialist care in the MS's region, and given the necessity and appropriateness to recruit a sufficient number of medical specialists, such a restriction was justified to protect public health (Simma Federspiel, C-419/16, paras 45-49).

Final comment. Without doubt, the PQ Directive and the freedom of movement and establishment have facilitated the mobility of health professionals in the EU. The consequent loss of high skills and/or competencies in one MS, means the gain of 'brains' for the receiving MS. In the long term, the imbalance of the health workforce among MSs and scarcity of – categories of – health professionals may undermine the continuity and sustainability of national health care systems. To fight this problem, the repay and licensing option as mentioned may contribute to solving that problem. But other 'retention' initiatives and European recruitment strategies to circulate and 'regain the brains' will be necessary to manage health workforce imbalances.[409]

Scholarly work
Tamara K Hervey, Jean V McHale, *European Union Health Law*: *Themes and Implications*, (CUP 2015) 127-155.
Ellen Kuhlmann and others, 'EU law, policy and health professional mobility' in: Tamara K Hervey, Calum A Young and Louise E Bishop (eds), *Research Handbook on EU Health Law and Policy* (Elgar 2017) 111-133.

[409] Kuhlmann, 131.

CHAPTER 10. Telemedicine

Defining telemedicine

Telemedicine, the online provision of health care services without physical contact between the patient and health provider, has extended the patient's access to medical services locally and elsewhere. This is particularly relevant for those patients located in remote areas, where medical specialist care is absent. Telemedicine, as defined by the European Commission, is "the provision of healthcare services, through use of information and communication technologies, in situations where the health professional and the patient (or two health professionals) are not in the same location. It involves secure transmission of medical data and information, through text, sound, images or other forms needed for the prevention, diagnosis, treatment and follow-up of patients."[410]

Essential for telemedicine is use of IT by which the patient consults his health professional from a distance (teleconsultation, tele-assistance). But online medical consultations are not restricted to doctor-patient contacts. Other telemedicine applications may include interactions between health professionals where they are not on the same location (e.g. online general practitioner - medical specialist contacts, long distance surgery supervision (tele-expertise), and even international outsourcing of tele-radiology services). Telemedicine is part of the overall concept of e-Health, which is not restricted to individual health care only. E-health is 'the use of ICT in health products, services and processes combined with organisational change in healthcare systems and new skills',[411] covering innovations such as the use of electronic prescriptions, cross border access to electronic patient records, and deployment of so-called medical and public health tracing and warning 'apps' (Covid-19). In fact, telemedicine functions within an e-health ecosystem. As telemedicine applications will become more user-friendly and reliable, they will play a key role in the provision of health care, and not only in remote areas.

Legal basis

Telemedicine takes place in a complex legal environment. For instance, legal concerns address human rights aspects such as privacy, confidentiality, access to high quality healthcare services, while the border crossing dimension of telemedicine applications further complicate the realisation of IT in health care. Buying telemedicine services (international outsourcing tele-radiology, tele-consultations, and remote monitoring) are no longer hypothetical occurrences, although the scale is unknown. Particularly international offshoring and outsourcing - subcontracting foreign providers for providing health services - are raising controversial questions on legal and policy issues such as securing information

[410] COMMISSION OF THE EUROPEAN COMMUNITIES, COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS, on telemedicine for the benefit of patients, healthcare systems and society, Brussels, 4.11.2008 COM(2008)689 final, p.3.

[411] European Commission, eHealth Action Plan 2012-2020 - Innovative healthcare for the 21st century, Brussels, 6.12.2012 COM(2012) 736 final, p. 3.

privacy, contractual requirements, and informed consent, since it happens 'behind the scenes', with patients unaware that certain services will be delivered by foreign providers.[412]

Telemedicine is both a health service and information society services that falls under the scope of Article 57 TFEU and existing EU secondary legislation, in particular Directive 2011/24/EU (the Cross-border Care Directive), and Directive 2000/31/EC (the e-Commerce Directive). The e-Commerce Directive aims to ensure that electronic commerce (including telemedicine services) could fully benefit from the internal market by setting basic rules and removing legal obstacles. It means, for instance, that Member States are not allowed to restrict the freedom to provide information society services from another Member State (Art.3(2)), although that prohibition is not absolute (derogations). Health services providers under this Directive shall be entitled to operate on the health services market in another Member State, by providing relevant information (i.e. the details of the service provider, including his electronic mail address for contacting, place of registration, and in case of regulated professions, professional body with which the service provider is registered, the professional title and the Member State where it has been granted, and a reference to the applicable professional rules in the Member State of establishment and the means to access them (Art. 5(1)(f)).
A key rule of the e-Commerce Directive is the internal market clause. i.e. in case of business-to-business activities such as telesurgery and radiology, the country of origin principle applies, meaning that the rules where the physician is established are applicable. But for business-to-consumer telemedicine services, such as patient consultations and monitoring of diabetes or chronic heart failure, the rules of the recipient's country are applicable (where the services are accessible).
Finally, since there are no European norms on medical malpractice, national medical liability rules are applicable in case something went wrong in providing telemedicine services.

The practice of teleconsultations and telemonitoring has also been recognised by the Cross-border Care (CBC) Directive 2011/24/EU.[413] Patients in search of necessary care do not need to move physically to visit the medical expert for a consultation abroad, nor will the physician required to transfer to check his patient's health condition. Similar as in case of face-to-face doctor-patient contacts, online telemedicine services must be provided according the standards on quality and safety in the member State of treatment, which refers to the Member State on where the service is actually provided to the patient (Art. 3(d)), i.e. where the health provider is established.
Moreover, patients' rights recognised by the Directive (informed consent, access to medical data, data protection and the right to erasure, etc.) are also applicable in the border crossing telemedicine doctor-patient setting (Art.4(2)(b)(e)(f)), as well as Member States' obligation to ensure a system of professional liability insurance, or equivalent arrangement, is in place for treatment provided on its territory (Art.4(2)(d)). But the reimbursement of cross-border telemedicine services follow the national reimbursement rules of the state of affiliation (Art. 7(4)), and only in as much that service is covered by the patient's national health system/social insurance scheme.

[412] SN Singh and RM Wachter, 'Perspectives on Medical Outsourcing and Telemedicine —Rough Edges in a Flat World?' (2008) 358:15 NEJM 1625.
[413] Directive 2011/24/EU, on the application of patients' rights in cross-border healthcare, article 14; OJ L88/45, art 14

A key condition for such cross-border teleconsultations is a safe and secure network and data exchange system. Such a voluntary eHealth network - designated by the Member States - is supported and facilitated by the Union (Art.14(1)),[414] ultimately aimed at 'enhancing continuity of care and ensuring access to safe and high-quality healthcare' (Art.14(2)(a)). For that reason, there is a need for guidelines on: (i) standardizing the exchange of patient data online; (ii) the use of medical information for public health and research (Art.14(2)(b), as well as developing technical standards or methods for the secured transfer of medical data in cross-border healthcare' (Art.14(2)(c)). These 'guidelines' must ensure the interoperability, and thus the widespread use of telemedicine technologies. In 2013, the Commission published a first release of the guidelines on the basic elements for the electronic exchange of patient's summary records across borders.[415] Taking into account the primary responsibility of the Member States in the field of healthcare provision (Art.168(7) TFEU), the term 'guidelines' should therefore be interpreted as a set of recommendations, suitable for both cross-border and national use.

Correlation ePs and EHRs

Telemedicine services will trigger a digital revolution in health care services in general. First of all, online doctor-patient consultations may go hand in hand with the electronic transfer of electronic prescriptions to the local pharmacy in another MS, the ePrescription (ePs) system. The use of intelligent electronic prescriptions can increase the safety (reduce improperly prescribed medications) and efficiency of the prescribing process.

Art. 11 of the CBC Directive allows the mutual recognition of electronic prescription dispensed in another MS. To facilitate that process, the implementing Directive introduces a minimum data set of information that will enable a health professional to verify the authenticity of foreign prescriptions.[416] But restrictions on the recognition of individual prescriptions can be justified 'to safeguard human health, or based on legitimate and justified doubts about the authenticity or content of the prescription' (Art.11(1)(b)). Moreover, such 'EU-prescriptions' should respect domestic legislation, i.e. the prescribed medicine is marketed in the national territory. At the same time, prescribing by brand name remains a common practice in most countries, whereas generic substitution of non-available prescribed medicines (brand names) is prohibited in some countries, but encouraged by others.[417]

Ultimately, ePrescriptions will be integrated into the patient's electronic health record (EHR), available for physicians at local, national and European level. Reading the patient's history in his EHR or patient's summary record (country of origin) allows the physician in the MS of treatment to continue medical treatment without duplicating all kinds of diagnostic tests, treatment methods and thus to ensure continuity of care and save costs.

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[414] E.g., Commission Implementing Decision 2019/1765/EU repealing Decision EU [2011/890] providing the rules for the establishment, the management and the functioning of the network of national responsible authorities on eHealth, OJ L 270/83.

[415] E.g., guidelines for the electronic exchange of so-called Patient Summaries relevant for telemedicine consultations abroad, 19 November 2013; (https://ec.europa.eu/health/sites/health/files/ehealth/docs/guidelines_patient_summary_en.pdf)

[416] Commission Implementing Directive 2012/52/EU laying down measures to facilitate the recognition of medical prescriptions issues in another member State [2012] OJ L356/68

[417] L San Miguel and others, 'Recognition of Pharmaceutical Prescriptions across the EU: A Comparison of five MS' Policies and Practices' (2014) 116 Health Policy 206

Numerous obstacles, some of which are legal, to the exchange of medical information hamper the deployment of cross-border EHRs. Therefore, the 'Article 14' network formulated guidelines on the standardization of patient summary records to be exchanged across borders. At the same time, the voluntary network will support MSs in developing common identification and authentication measures to facilitate transferability of data in cross-border health care (Art 14(2)(c)) to enhance the security on health information exchange. According to the European Commission, these measures should contribute 'to reap all the benefits from a fully mature and interoperable eHealth system in Europe'. [418]

Scholarly work
S Callens, 'Telemedicine and European Law', Medicine and Law (2003) 733-741
A den Exter, 'eHealth law: The final frontier?' in: TK Hervey, CA Young and LE Bishop (eds.) Research Handbook on EU Health Law and Policy (Elgar 2017) 242-263
Shashi Gogia (ed.) *Fundamentals of Telemedicine and Telehealth*, (Academic Press 2019)

[418] Commission, note 2: 3

FINAL REMARKS

The outcomes of this book are the result of a 3-years research and training project 'EU Global Health Law', granted by the European Commission. The topic covers a wide range of issues and is not restricted to the limited number of issues addressed above.

the research started with exploring the main features of EU global health law, legal basis, outcomes so far, and the interaction between various modes of EU global health law. The variety of topics reveals the link between international trade, health, and human rights, either directly or implicitly. One of the book's objective is to clarify these relationships and to examine (potential) conflicts between the different dimensions (trade law, human rights law and health law). The separate chapters have addressed these issues in more detail, confirming the relevance of health law principles and human rights in economic trade and other EU policies.

The research outcomes have been published separately in peer-reviewed journals, and disseminated among academics, societal organizations, and other interested persons in global health issues. As well as presented on various occasions during guest lectures at various universities, international conferences and seminars. These discussions enabled the Jean Monnet chair to exchange ideas on global health law and strengthening cooperation with other parties and institutions dealing with global health issues. The outcomes of these discussion are included in the Annexes of this book, as well as disseminated on various online platforms and social media.

Finally, the author expresses his gratitude to the European Commission, who has facilitated to finalize this work by a generous Jean Monnet grant (587253-EPP-1-2017-1-NL-EPPJMO-CHAIR).

Fighting Excessive Pricing Medicines

Gene-based medicines (CAR-Ts) promising but highly expensive

Effectiveness price-reducing options life-saving medicines: anecdotal evidence

Toolbox price-reducing measures:
(i) Compulsory licensing:'patent flexibility'
'nuclear option', hardly used for gene-based therapies: too controversial;
despite 'data-exclusivity waiver': disclosure clinical test data (Art. 18(2) EU Reg. 816/2006
(ii) Pharmacist's exemption: justified exception national patent law
liability risk patent infringement considerable
(iii) Abuse dominant position excessive pricing (EU competition rules)?
Competition authorities unfit as price regulators
(iv) **cross-border purchasing medicines** (e.g. Beneluxa - Spinraza case):
joint procurement CAR-T medicines (EU Dir 2014/24/EU, art.39): attractive option EU MS

Conclusion: Despite obstacles *voluntary* CB purchasing innovative medicines is potentially promising price-reduction option

Source: *EJHL* 27(2020) 1-13

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The risk of re-identifying genomic data under the GDPR

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Round table XV International School Young Scientists & Lawyers, 1 June 2020, Moscow

GDPR objective and rules

Overall objective: harmonize data protection rules across the EU

- Lawful processing, General rules:
- Consent is King!
- **Consent**: Cornerstone for the processing of personal data
- "freely given, informed, specific and unambigious" (Art. 6 GDPR & Art. 8 EU Charter)
- The right to withdraw consent at any time

Health Data: Specific regime (art. 9(1))

Research exemption: some flexibility

- Prohibited, *unless* it is authorised under Art. 9(2):
  - (a) explicit consent
  - (j) research and statistical purposes & Art. 89:

Implications research exemption:

- secondary use, art. 5(1)(b)
- 'disproportionate effort', art. 14(5)(b)
- 'the right to be forgotten', art. 17(3)(d)

Defining Genetic Data

- 'Genetic data' under Article 4(13) GDPR/ Recital 34:
  - means personal data relating to the inherited or acquired genetic characteristics of a natural person which give unique information about the physiology or the health of that natural person and which result, in particular, from an analysis of a biological sample from the natural person in question;
- Principles of data protection apply to personal data which have undergone pseudonymisation, whereas
- Duty to anonymize as soon as is practicable (Article 5(1)(e))
- Anonymous data are not subject to the GDPR (Recital 26)

Key challenge genetic research

- Re-identifiability of genomic data (HIV status or mental health condition) and its implications
- Identity disclosure and thus breaching privacy
- Implications open-access platforms: individuals and relatives
- Likelyhood of the risk of re-identification
- Identifiability: context matters (cross-references databases)
- How to respond?

Response: Managing data protection risks

- Discharging data controllers' accountability obligations (art. 89) [2])
- Controlled access (user agreements): hindering scientific research?
- Risk-based approach:
  - accountability (Art. 5(2) & 24 GDPR)
  - data protection by design and default (Art. 25)
- Soft law approach: International guidelines/professional codes of conduct

Conclusion

- Importance of access to research data & exchange
- Anonymization protects genomic privacy (public trust)
- Awareness risks of re-identification
- Need for good practices on data sharing
- Responsible genomic data sharing initiatives (Beacon Project) with different levels access

Outline

- Introduction Online Pharmacies
- Legal Challenges Online Pharmacies: National level
- Legal Framework Online Pharmacies: EU Law
- Latest Developments: Fighting counterfeits
- International Approaches
- Discussion
- Conclusions

Introduction

- What are online pharmacies?
- Types of online pharmacies:
  - Traditional online pharmacy
  - Prescribing-based site pharmacy
  - Rogue pharmacy
- Benefits of Online Pharmacies:
  - Convenience
  - Availability
  - Privacy
  - Price competition

Dangers of some types of Online Pharmacies

- Illegal pharmaceutical industry is growing
- Consumer's difficulty distinguish legal/rogue pharmacy
- Consumers have easy access to low-quality, expired, counterfeit, unapproved medicines
- No limits on quantity bought; possibility of increased antibiotic resistance arising from their misuse;
- Risks consumers' privacy violations when dealing with online pharmacies
- Medicines purchased from foreign sites may have incorrect and dangerous labelling and packaging
- There may not be a patient-physician relationship

- Examples:
  - Obtaining weight loss medication from online pharmacy by inputting the information of a seven-years-old child into the website;
  - Obtaining Viagra for a cat from online pharmacy (castrated)

Legal Challenges Online Pharmacies

- National level: Diversity regulatory systems
- Deficiency in effective regulation: websites and suppliers can be located in different countries from customers (jurisdictional limits)
- Need for international action

Jurisprudence Online Pharmacies EUCJ: *DocMorris* case (C-322/1, 2003)

- The case concerned the provision of prescription and non-prescription pharmaceuticals in Germany by the DocMorris company, which was established in the Netherlands but did much of its trade in Germany. DocMorris was taken to the EU Court of Justice following an accusation of illegal practice by the German Association of Pharmacists. Pharmaceuticals could be ordered from the company in several ways, including telephone, fax and online. Some products offered by the company were 'prescription-only' in either Germany or the Netherlands.

- EUCJ: "Member States may not prohibit the sale of *non-prescription* medicines (OTC medicines) on the Internet "

- Thus, the court notes that a Member State may prohibit the distance selling of *prescription* medicines: diverse picture in 28 MS

Legal Framework Online Pharmacies: EU Law

- Art. 168(7) TFEU
- EU free movement principles (EU Treaty)
- Directive 2011/24/EU on CBC
  - Art. 11: ePrescriptions
    * Mutual recognition CB prescriptions
    * Exceptions
    * Reimbursement
- Advantages: accessible to health providers, patient and HIF; Information & comparing prescription behaviour; fully operational in Scandinavian countries
- Interoperability ePs (Directive 2012/52/EU)
- Cross-border sale of medicines; towards an open EU online market?

Latest Developments: Fighting Counterfeits

- Track and trace system (Tackle counterfeiting life-saving medicines: Directive 2011/62/EU)
- Buying medicines online: common EU logo (Art 85c, Reg. 699/2014)

- Online retailers registered with national authorities EU MS (Dir 2011/62/EU)
- eCommerce Directive (online contracting, eg medicines)

International Approaches: WHO and Counterfeits

- WHO's "soft-law" tools:

  - WHO Guidebook *Medical Products and the Internet*

  - International Medical Products Anti-Counterfeit Taskforce ('IMPACT') presenting 'guiding principles for model legislation'

International Approaches (2): INTERPOL

- Other Stakeholders: Law enforcement agencies
- INTERPOL & the fight of counterfeit medicines
- Pharmaceutical crime as a global problem
- Primary trend: increased use of illicit online pharmacies operated by transnational criminal groups
- INTERPOL's Response: Operation Pangea IX (2016)

Council of Europe: "Medicrime Convention" No. 211 (2011)

- 1-1-2016
- First international criminal law instrument to oblige States Parties to criminalise:
  - the manufacturing of counterfeit medical products;
  - supplying, offering to supply and trafficking in counterfeit medical products;
  - the falsification of documents;
  - the unauthorised manufacturing or supplying of medicinal products and the placing on the market of medical devices which do not comply with conformity requirements.

- Framework for national and international co-operation

- Foresees the establishment of a monitoring body to oversee the implementation of the Convention by the States Parties

- Limited ratifications so far (8)

Discussion

- Diversity regulatory and policy mechanisms online pharmacy

- Need for cohesive international legal framework enforcing this domain

- Towards a UN Framework Convention on Internet Pharmacy

- Content of the Framework Convention:
  - Global instrument ("Medicrime Convention")
  - Differentiate types of online pharmacies, targeting 'rogue pharmacies'
  - Setting standards for prescription medicines online (COMPACT)
  - Registration
  - Central Database
  - Disclosure essential information website
  - Reporting 'dangerous substances' dispensed
  - In-person doctor-patient examination required
  - International enforcement mechanisms

Conclusions

- Online pharmacy: Important phenomenon going that is continuing to spread, despite partial regulation
- Deficiencies in (inter)national regulations
- Accordingly, patients not adequately protected
- Need for cohesive international action: EU, WHO, CoE & Interpol
- Implementing a comprehensive international regulatory regime (Framework Convention)

Pharma's global pressures & EU's response

- Outsourcing CTs in developing countries
- Lack of innovation and patent expiration 'block busters': IPR vs competition law
- New medicines pricing policies (e.g., Spinraza) and cost control mechanisms
- Accessibility medicines in low-income countries & Corporate Social Responsibilities: disclosure non-financial information (Dir 2014/95): improving corporate transparency *and accountability*
- Tackle counterfeiting life-saving medicines (2011/62/EU) and online sales

EU Response to global pharmaceutical sector pressures

- Corporate Social Responsibilities (CSR)
- Strategies and mechanisms for Pharma's CSR
- Monitoring Pharma's CSR efforts
- EU response:
  - Legitimacy to act
  - Promoting business ethics (Pharma sector inquiry 2009)
  - Trade/development policies promoting CSRs
  - Improving Pharma's social *accountability*
  - …..

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The Oviedo Convention and Health Care Access: Key challenges

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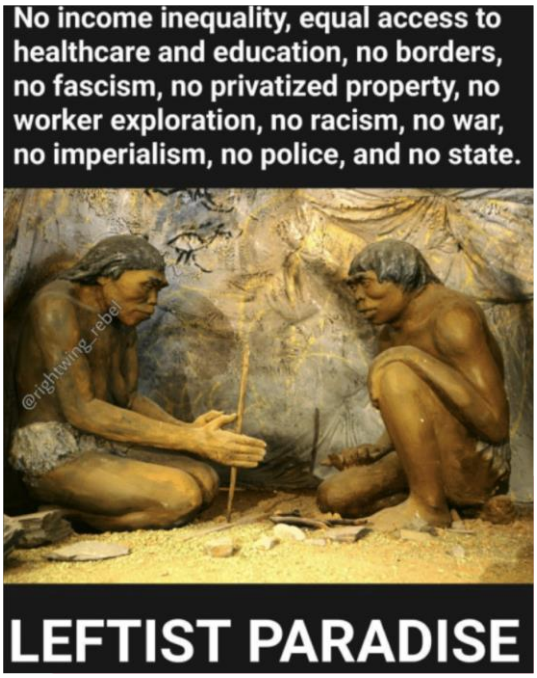
Access to New Medical Technologies

Article 3

Equitable access to health care

‘ Parties, taking into account health needs and *available resources*, shall take appropriate measures with a view to providing, within their jurisdiction, *equitable access to health care* of *appropriate quality.’*



Meaning of Article 3

- Social Right
- Equitable access: avoiding unjustified discrimination
- What are the health needs?: Reference ESSC classification & professional standards
- Available resources restriction
- Reference to Article 12(2) ICESCR; General Comment No. 14 on Health (14.7.2000)
  - Minimum core obligations
  - AAAQ
  - Non-retrogression
  - Monitoring effectiveness measures

Content of Equal Access: National law

- Constitutional/Statutory Right

  including:

  - Equitable distribution & non-discriminatory access;

  - treaty obligations/core content outlined in international law, including OC

- Monitoring/review system (accountability)

Article 3 Challenges: Precision Medicine

- Super Responder patients: a patient diagnosed with Stage IV gastric cancer [HER-2+] and given six months to a year to live. He was put on trastuzumab every 3 weeks; he is alive seven years later. Cost has been $17,000 every three weeks; roughly $1.5 million so far.
- Others with that “same cancer” [HER-2+] gained only 1-2 extra years of life
- **Did all have an equal just claim to the medicine?**
- Still others might only gain 3 extra months of life with 6 months to a year of treatment (and related costs). Do they too have an equal just claim to trastuzumab, especially if we knew before the fact that this would be the outcome?
- **How should we think about this from the perspective of either solidarity or health care justice?**

Derived from L.Fleck, 18 Nov PM Conference Salerno

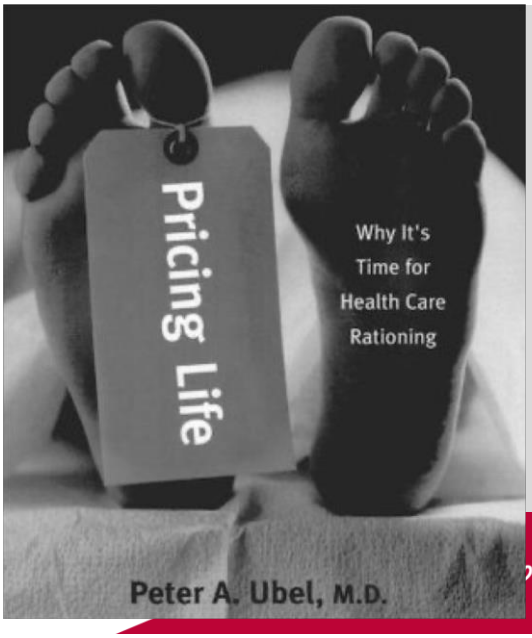
Problem #2

- Trastuzumab has essentially the same price per month, whether an individual gains six extra months of life or six extra years of life.
- But then we have CAR T-cell immunotherapy for B-cell lymphoma (cost of $475,000).
- 30% of these patients will only gain an extra year of life, primarily because of resistance.
- **If we have biomarkers that can identify such patients before the fact, may they justly be denied access to this therapy at social cost because it would do too little good at too high a cost?**
- **Or does a commitment to solidarity, "equal concern and respect" for all, require that all patients with B-cell lymphoma who have ANY degree of likely benefit have a just claim to this therapy as a matter of solidarity?**

Derived from L.Fleck, 18 Nov PM Conference Salerno

Health Care Rationing Challenges

- Understanding Health Care Rationing
- Defining Health Care Rationing
- Who decides?
- What criteria?
- Methods



Rationing and Human Rights

- Human Rights
- Legitimacy
- Liability

Bedside rationing example. The use of scarce MRI slots

A neurologist works at a county hospital that does not have a magnetic resonance image (MRI) scanner. The hospital puts money aside each year so that six patients can receive an MRI at a nearby hospital. A physician evaluates a patient who has a ‘soft indication' for an MRI. The physician could order an MRI for the patient. However, he knows that if he requests an MRI for this patient, he denies an MRI to another patient, who may need it more. Thus, he tells the patient that an MRI is unnecessary.

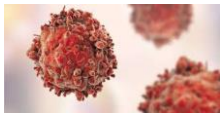
Derived from P Ubel, *Recognizing Bedside rationing*, AIM 1(1997), 74

Age-based Rationing: Immoral or unavoidable?

- Excluding elderly patients from *specific* life-extending treatment options for cost constraints
- Age level as a threshold: “fair-innings” argument
- Discriminatory by nature or justified for specific reasons?
- *CESCR General Comment no. 20* Non-discrimination (E/C12/GC/20)

illustratie merlijn draisma

Ibrutinib: Wicked Rationing Challenge



- Some CCL patients fail ibrutinib after 1-2 years; others fail after 5-6 years or more; this is the problem of cancer drug resistance. Some of these patients might be in their 50s; others in their 70s; what then?
- CD 19 CAR T-cell therapy is an alternative (€425,000). In one trial 55% survived less than 9 months; 10% survived seven years.
- Challenge: Assume future research gives us a biomarker that can tell us with 90% confidence which CLL patients will not survive one year with CAR T-cell therapy. **Would age-based rationing allow us to deny such patients this therapy at social cost? Would it matter that some of these patients were in their 50s, others in their late 70s?**

Derived from L.Fleck, 18 Nov PM Conference Salerno

Health Care Rationing & the Judiciary: Some experiences

Rationing Litigation in the UK

- NICE and cost-effectiveness threshold
- Postcode lottery
- General rule: courts will not interfere with the decision about how money is allocated unless that decision is 'frankly irrational'
- Meaning of rationality ?
- *Swindon NHS Primary Care Trust* (Herceptin litigation)

Challenging Rationing Decisions: Germany and Switzerland

- New technologies and limited cost-effectiveness:

  - *Nikolausbeschluss* (BVG 6 Dec 2005) German CC:
    - lifesaving (experimental) medicine and Constitutional rights
    - "*spürbare positive Einwerkung*"
    - Elaborated by Fed. Social Crt (BSG) 2006

  - Narrowed in IVIG therapy: life-threatening, critical situation
    Off-label use BVG 11 April 2017

  - *Myozyme cases I & II,* Sw. Supreme Crt. 23 Nov 2010; 2015
    - Cost-effectiveness threshold 100.000 CHF QALY
    - "limited cost-effectiveness"

Rationing (Litigation) in the Russian Federation

- Explicit rationing and Constitutional law: no legal basis?
- Implicit rationing by health professionals
- Variety in daily practice (control commissions, guidelines, lists of treatment options, etc.)
- Rationing challenged in courts?

Source: V. Vlassov et al, '*Why HCR is not acceptable in Russia*', (in press)

Rationing and the ECtHR: Reduction in night-time care for an elderly lady

- *McDonald v United Kingdom*, No 4241/12, 28 August 2014
- The applicant complained that a reduction in night-time care disproportionately interfered with her right to respect for her private life under Article 8 ECHR.
- ECtHR: State did not exceed the margin of appreciation

EUCJ: Is Eurostar/Thalys the solution?

- *Decker/Kohll case* C-120/95
- *Smits/Peerbooms & Müller-Fauré/van Riet* cases C-157/99 and C-385/99
- *Elchinov*, case C-173/09
- *Cie. v Frankrijk*, case C-512/08
- *Petru*, case C-268/13

Discussion: recent Developments

- Use of Health Technology Assessment (HTA) - But do not forget human rights
  - Draft regulation on HTA COM(2018) 51 final
- Statutory HTA requirement (and cost-effectiveness threshold) in SHI Act?

Conclusions

- Rationing unavoidable and necessary
- Rationing litigation: Need for public debate on fair rationing: democratic deliberation (L. Fleck) (plea for explicit rationing)
- Incorporating HTA in rationing debate
- Role of the courts: triggering that debate and holding health rights justiciable

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The Dutch Critical Care Triage Guideline on Covid-19. Ageist or not, that's the Question

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The Dutch Approach to the Corona Virus

Range of (legal) measures fighting the Covid-19 pandemic

Legal basis incomplete: Public Health Act, local and regional emergency regulations

(Potential) clashes with Constitutional rights: private life and human integrity vs health (care)

Ad hoc measures: 'Corona-app Act'; mandatory testing

Self-regulation: Covid-19 Guidelines Health Professionals

- Covid-19 triage guideline ICU admission phase 3 C, 16 June 2020 (‘Code Black’)
- Developed by Medical Doctors Assoc. icw other health groups (HC Inspectorate, Hospitals, Patients Groups, etc.)
- Absolute scarcity, medical selection criteria insufficient; highest level escalation model
- Aim: to organise and allocate health care: guarantee continuity of care

‘Code Black’

- Only applicable ICU care
- Both COVID-19 and other ICU patients
- ‘first come, first serve’ not appropriate and justified
- Priority to patients with short term admission (expected) (Clinical Frailty Scale)
- Priority to health professionals (exposure COVID-19)
- Selection based on age categories (0-20; 20-40; 40-60; 60-80; 80+): ‘fair innings’ argument
- Irrelevant: social status, disability, etnicity, nationality, sexe; own fault
- Lottery as last resort option

‘Code Black’ II

- Authorised by the MoH, on request
- Triage as part of the standard of ‘good care’, as defined by national law

Justification

- Ethics: ‘ Fair innings’ argument
- Law: understanding of the non-discrimination concept (GC no 20, CESCR)
  - ‘Any distinction excluding patients is prohibited…. but differentiation can be permissable’
  - Reasonable, objective & proportionality aim – and effect of measure
  - Last resort measure
  - Decision-making process: ‘democratic deliberation’
  - Mechanisms for legal redress
- Least onerous, but necessary option

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Health and Fundamental Rights in the EU

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Outline

- Fundamental Rights and EU Law
- EU HR Charter
- Conclusions

Fundamental Rights in EU Treaties and EU Human Rights Charter

- Art. 2 TEU: respect for fundamental rights
- Art. 6 amendments Treaty of Lisbon:
  - Recognition Charter rights, Charter on Fundamental HRs
  - towards accession ECHR
  - ECHR's rights recognised as principles of law
- EU Charter rights:
  - Content: Innovative approach
  - General limitations clause: Art 51(1)
  - Discriminatory approach: Art. 52(5) 'principles' incapable creating directly enforceable rights
  - Art 52(3): 'materially incorporates the ECHR' into EU law

Fundamental Health Rights and EU law

- General Data Protection Regulation
- 'Fertility tourism' and free movement
- Patient Mobility Directive
- Clinical Trials Regulation and informed consent
- Protecting Biotechnological innovations and Human Dignity
  - *Brüstle v Greenpeace* (C-34/10)
  - *International Stem Cell Corporation v Comptroller General of Patents* (C-364/13)

References EU Charter Fundamental Rights and Health

- Art. 35 Health Care

  - CJEU C-544/10 *Deutsches Weintor* par 48-53
  - ECJ C-84/11, *Susisalo*, para 37
  - ECJ C-444/05 / Opinion AG - *Stamatelaki v NPDD , para 65.70*
  - ECJ C-570/07, C-571/07 / Opinion AG - *Blanco Pérez*
  - ECJ C-528/13 *Léger v Ministre des Affaires sociales*

- Art. 17: Freedom of establishment. Case C-367/12 *SokollSeebacher*
- Art. 34 Social Security

Conclusions

- EU's compliance with human rights: Myth or Reality?
- Charter contributes to constitutional legitimacy EU
- CJEU: integrated HR in EU legal order
- Future Challenges

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EU Public Health Law

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EU Public Health: Historical Background

- Rome Treaty 1958: restrictions on import/export
- Euratom Treaty 1956: protection for the effect of radiation
- Single European Act 1986: Art 100A(3)
- 1992 Maastricht Treaty: Art. 129 Public health protection
- 1996 - BSE emerges
- 1997 Treaty of Amsterdam
- EUCFR 2009: Article 35

1. EU's Compentence in Public Health

- Treaty on the Functioning of the European Union (TFEU):
  - Protection of public health, Article 168
    - * Division of powers
    - * Commission coordinates and initiates (s. 2)
    - * Cooperation 3rd parties
    - * Limited powers blood, tissues, cells, organs, tobacco, crossborder health threats
    - * Subsidiarity principle (s.7)
  - Article 114 (approximation of laws)
  - Article 169 (consumer protection)
  - Restrictions on Free movement of goods and persons

EU PH: Ensuring the safety and quality of donated blood, tissue, cells and organs

- The 'Blood Directive' 2002/98/EC (and implementing directives)
  - voluntary and unpaid donations, Art. 20
- The 'Organ Directive' 2010/53/EU on standards of quality and safety of human organs; Action Plans
  - case study Organ Action Plan (**working group**)
- The 'Tissues and Cells' Directive 2004/23/EC
  - ensuring traceability cells, tissues

Recent development

Art 168(6):
Council Recommendation of 7 December 2018, on strengthening cooperation against vaccine-preventable diseases (2018/C 466/01)

Report ‘the Organisation and delivery of vaccines in the EU’, on the vaccine uptake in EU MS (2018)

Joint Procurement mechanism CB health threats (Art. 5 Dec 1082/2013/EU)

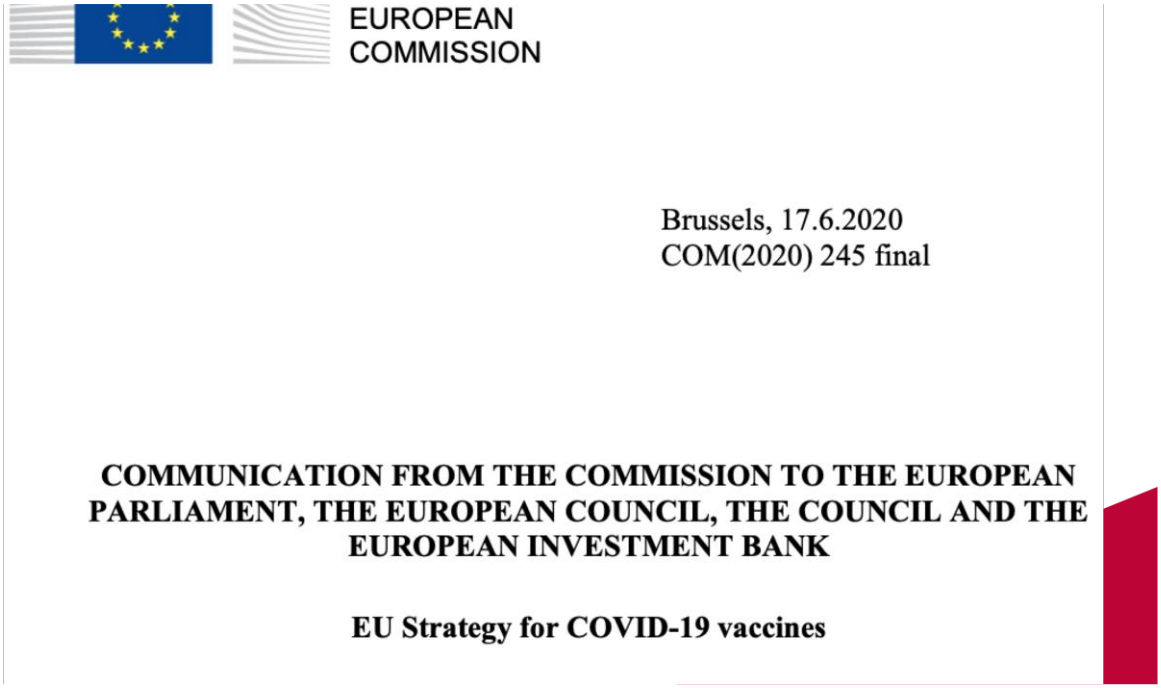
EU citizens want more competences for the EU to deal with crises like COVID-19

Press Releases - 26-05-2020 - 15:14

EU in action: medical equipment from RescEU reserve being delivered to Spain in May 2020. ©EU/A.P.E.

Further information

PDF Public opinion in the EU in time of Coronavirus crisis


EUROPEAN
COMMISSION

Brussels, 17.6.2020
COM(2020) 245 final

COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE EUROPEAN COUNCIL, THE COUNCIL AND THE EUROPEAN INVESTMENT BANK

EU Strategy for COVID-19 vaccines

2. EU Health Protection and Health Threats

- Reg. 851/2004/EC: Protecting citizens from health threats
  - – Establishing a European centre for disease prevention and control (ECDC)
  - – Mission: surveillance, identifying and responding (emerging) health threats
  - – Integrating Early Warning and Response System (EWRS Decision 2000/57/EC)

ECDC Developments

- Decision 1082/2013: public health emergency under International Health Regulations (2007)
- New Outbreaks: Ebola, Zika, Corona; What's the response of the EU?:

  http://europa.eu/!dU66vD
- ECDC Rapid Risk Assessment (Corona virus, ECDC Risk Assessment update 20-2-2020 [What is the risk for healthcare systems in the EU/EEA?])
- Health Security Committee activities: Refugees; H1N1 pandemic; shortage radio isotopes medical use; laboratory shortages related to Covid-19 testing supplies and ventilators
- EC: rescEU stockpile works & Covid Joint procurement ICU equipment

3. EU Public Health Policy (1): Health Action on Health Determinants

- Tobacco
- Nutrition and physical activity
- Alcohol and drugs
- Mental health
- Environment and health
- Social determinants and health inequalities

EU Public Health Policy (2): EU Disease Prevention

- Cancer
- Mental disorders, Alzheimers
- Cardiovascular disease
- Rare diseases

Recent developments (2): What if we could fight coronavirus with artificial intelligence (AI)?

- Analytics have changed the way disease outbreaks are tracked and managed, thereby saving lives.
- global response is fractured and uncoordinated,

Q. How can AI technologies be used to manage this type of global health emergency, without undermining protection of fundamental values and human rights?

- Potential impacts and developments

- Anticipatory policy-making

European Union, 2020.

Recent developments:

Portugal brings down obesity by taxing sugary drinks

04-03-2020

On World Obesity Day, 4 March, we highlight the success Portugal has had in tackling childhood obesity – one of the main health challenges in the WHO European Region – with their sugary drinks tax.

WHO /Christopher Black

Childhood obesity is a complex public health issue – caused by many factors, it intersects significantly with socioeconomic status. As obesity can establish behaviours at a young and vulnerable age, countries have a duty to protect children from a phenomenon that can become a health burden for the rest of their lives.

In Portugal, the combination of unhealthy diets and a rise in sedentary lifestyles has precipitated a public health struggle with childhood obesity. The consequences of this have implications for Portugal to achieve the wider targets for noncommunicable diseases (NCDs) by 2030.

4. Conclusions

- Europeanization of public health
- Subsidiarity principle blocking further integration