# THE RIGHT TO HEALTHCARE UNDER EUROPEAN LAW

- André den Exter -

Abstract. Too often, the right to healthcare has been considered an illusory right that is not even a legal right, but merely an aspirational norm that cannot be adjudicated before the court. In modern human rights law, considering individual and social rights as interdependent and indivisible, such an approach is untenable. Both legal doctrine and recent case law from domestic and international courts have elaborated and confirmed the specific obligations under the right to healthcare, countering the general complaint of "shrouded vagueness". Landmark cases have even provided a functional remedy to enforce individual healthcare claims successfully. This paper will examine the revised legal status and content of such a right to healthcare from a European perspective.

Keywords: right to healthcare, human rights law, justiciability.

#### 1. Introduction

In modern human rights law, individual and social rights are considered interdependent and indivisible.<sup>1</sup> This approach affects the understanding of human rights, and the right to healthcare in particular. In order to understand the consequences of such a revised approach, this article will explore the conceptual foundations of the right to healthcare and spell out its theoretical and practical meaning in Europe. Such an explanation will challenge its generally contested 'vague or amorphous' character by arguing that the right to healthcare can be and has been operationalised, and even has been subject to adjudication and, to some extent, held justiciable by domestic and regional courts in Europe. Although effective in individual cases, this does not necessarily mean that adjudication of individual healthcare rights reduces health inequalities.<sup>2</sup> Hereafter, the focus is primarily on explaining the concept of healthcare access, the meaning of such a right in international law and various legal systems, and analysing various courts' strat-

<sup>&</sup>lt;sup>1</sup> For example, confirmed by CESCR in CESCR General Comment 3: The nature of States parties obligations (art. 2, para. 1) on 14 December 1990, Geneva.

<sup>&</sup>lt;sup>2</sup> Although relevant, that question has been addressed by other scholars such as: Yamin, Gloppen [2011].

egies in upholding such a right.<sup>3</sup> This approach starts with clarifying the doctrinal debate on the right to healthcare.

# 2. Understanding the right to healthcare: A doctrinal debate

At the international level, "the enjoyment of the highest attainable standard of physical and mental health" is recognised as a fundamental right of every human being without distinction of race, religion, political belief, economic or social condition,<sup>4</sup> whereas health is defined as "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity." This concept of the right to health has been criticised on the ground that such a right is non-existing and too broad. A *right* to be healthy (or the opposite, a right not to be healthy) cannot be claimed, similarly to happiness or love. Instead, when interpreted as a right to healthcare – claiming access to healthcare – the right to health becomes a meaningful and operational right. More problematic is the fact that under the WHO's Constitution, health is only partially dependent on preventive health measures and medical care services. There is sufficient evidence that health determinants, such as housing and working conditions, a healthy environment, lifestyle, gender, education, genetics, culture, etc., are equally, if not more, important factors influencing individual and collective health.<sup>7</sup> Under the umbrella definition of the concept of health, the right to health would be a multi-layered, illusory right which would be hard to realise.8 Interpreting the right to health as the right to health protection and healthcare is therefore more practical. This reflects both population-based services (immunisation and screening programmes) and individual medical care (therapy for illness). By narrowing the concept of the right to health to healthcare, we differentiate between the right to healthcare and to other separate rights, such as the right to food, a healthy environment, housing, education, etc. Thus, from a pragmatic point of view, these rights have been dif-

<sup>&</sup>lt;sup>3</sup> Parts of this analysis will be published in a forthcoming book: Exter den [2017].

<sup>&</sup>lt;sup>4</sup> Art. 12(1) International Covenant on Economic, Social and Cultural Rights.

<sup>&</sup>lt;sup>5</sup> Constitution of the World Health Organization, Basic Documents, 45th edition, Supplement, October 2006, Preamble.

<sup>&</sup>lt;sup>6</sup> Confirmed by, e.g., Hessler, Buchanan [2002] p. 85–86; Buijsen [2003] p. 7–8; versus Toebes [1999] and Molinari [1998] p. 46–48.

<sup>&</sup>lt;sup>7</sup> See e.g., Commission on Social Determinants of Health (CSDH), "Closing the gap in a generation: health equity through action on the social determinants of health," Final Report of the Commission on Social Determinants of Health, WHO, Geneva 2008.

<sup>&</sup>lt;sup>8</sup> Also argued by Gostin and Lazzarini, referring to the dangers of a broad notion of "a right to health", in: Gostin, Lazzarini [1997] p. 29.

ferentiated, although they remain highly interrelated, and therefore of relevance to realise the highest attainable level of health.

The doctrinal debate on the right to healthcare is part of another controversy: healthcare as a 'right', and thus creating various (state) obligations. The scholarly dispute on competing theories of rights focuses on the 'natural law theory' *versus* libertarian theories.<sup>9</sup> Although the discussion is rather abstract, its relevance for healthcare lies in the interpretation of such a right, including the obligations that result from these competing theories. For instance, Finnis identifies life, interpreted as good health, as one of the basic conditions of human good: "self--evidently necessary for human flourishing". 10 Human flourishing is the reason why persons come together as a community. 11 Applying Finnis' natural law theory to healthcare, Hayes argues that: (i) the aim of healthcare is to foster human flourishing within a community; and (ii) redistributing healthcare can be justified for community reasons: fostering life and good health of others. 12 Transferred into the modern language of rights, the human right to healthcare incorporates access to healthcare facilities and services as well as the "common good" element: equality of healthcare access that may require redistribution of resources. Finnis' theory of natural law and natural rights therefore conceptualises the right to healthcare.

Contesting the natural law doctrine, in *Anarchy, State and Utopia*, Robert Nozick defended a libertarian position, legitimising the night-watchman state, or minimal state, which protects only against violence, theft, fraud, and breach of contract.<sup>13</sup> Promoting social welfare, including good health, by facilitating health services and ensuring healthcare access does not fit the approach of maximising individual liberties and property rights. In fact, any notion of distributive justice may be seen intolerable by those seeking to minimise the tax burden and maximise their liberty. Apart from basic individual rights, the libertarian approach does not recognise a *right* to healthcare. The minimal state only protects libertarian freedom rights (property, life, bodily integrity, privacy, etc.).<sup>14</sup> Any state involvement in healthcare (e.g., fighting public health threats) is essentially aimed at protecting libertarian rights only.

<sup>&</sup>lt;sup>9</sup> E.g., Hayes [1992] p. 405, 414. See also Giesen [1994] p. 285, quoted by Molinari [1998] p. 47; v. libertarians such as Nozick [1974].

<sup>&</sup>lt;sup>10</sup> Other human goods are: knowledge, play, aesthetic experience, friendship, practical reasonableness and religion, Finnis, chs. III-IV, p. 59–99, as quoted by Hayes [1992] p. 406.

<sup>&</sup>lt;sup>11</sup> Ibidem.

<sup>&</sup>lt;sup>12</sup> Ibidem.

<sup>&</sup>lt;sup>13</sup> Nozick [1974] p. 26.

<sup>&</sup>lt;sup>14</sup> Ibidem, ch. 7.

Nowadays, one may criticise this one-dimensional concept of rights since it is generally accepted that negative rights may include positive obligations, or vice versa.<sup>15</sup> Moreover, any violation of the right to healthcare (e.g., the denial of a life-saving treatment) may also violate a person's private life (hereafter), which emphasises that individual and social rights are interdependent and indivisible.

### 3. The meaning of the right to healthcare under international and European law

Since World War II, international human rights law has affirmed the right to health (interpreted as healthcare) as a basic right. Article 25.1 of the Universal Declaration of Human Rights affirms:

Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including [...] medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control.

Adopted by the UN General Assembly in 1948, today the Declaration has assumed the status of international customary law. The Declaration's provisions have been elaborated in the International Covenant on Economic, Social and Cultural Rights (ICESCR). The ICESCR provides the most comprehensive article on the right to health by specifying the steps to be taken by the states, including:

- (i) the reduction of the stillbirth-rate and of infant mortality;
- (ii) the improvement of environmental and industrial hygiene;
- (iii) the prevention, treatment and control of epidemic, endemic, occupational and other diseases;
- (iv) ensuring access to healthcare services for all (Article 12).

Also at regional level, the Council of Europe's European Social Charter (Article 11), as well as the Biomedicine Convention (Article 3), and recently the European Union's Human Rights Charter (Article 35), have recognised equal access to healthcare as a basic human right. Furthermore, several 'sectoral' treaty documents have helped further develop the content of the right to healthcare, either from a human rights or a social security law perspective.<sup>16</sup>

-

<sup>&</sup>lt;sup>15</sup> Office of the High Commissioner for Human Rights. The nature of States parties obligations (Art. 2, para. 1): CESCR General Comment 3, 14 December 1990, para. 8.

<sup>&</sup>lt;sup>16</sup> E.g., Convention on the Elimination of all Forms of Discrimination against Women (CEDAW) 1981, Article 12; Convention on the Rights of the Child (1989), Article 24; International Convention on the Protection of the Rights of All Migrant Workers and Members of their Families (1990), Article 28; Convention on the Rights of Persons with Disabilities (2006), Article 25. Social security trea-

Despite the general confirmation and further attempts to define the content of the right to healthcare by international law, the general complaint regarding 'shrouded vagueness' still remained, awaiting further explanation. An important step in this direction was the publication of what is referred to as the General Comment on Health.

General Comment on Health: progressive realisation

In 2000, the Committee on Economic and Social Rights (CESCR), monitoring the ICESCR, published General Comment no. 14 (hereafter GC14).<sup>17</sup> This document is generally considered an authoritative interpretation of Article 12 of the Covenant that specifies the content of the right to healthcare in terms of general and specific obligations. One general obligation is the concept of 'progressive realisation', which requires member states to gradually realise the Covenant's rights while acknowledging the difficulties states have in complying with these obligations. Accordingly, although the concept itself has immediate effect, the full realisation of the right to healthcare 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 realisation of Article 12 ICESCR (para. 30). This flexibility device means that State parties have a "specific and continuing obligation" to move towards full realisation, which creates a strong presumption that deliberate retrogressive measures are not allowed (para. 31). 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.<sup>18</sup>

The concept of progressive realisation raises interesting questions when introducing retrogressive measures restricting healthcare access due to economic constraints. For instance, in cases of limiting healthcare access for irregular (illegal) migrants there is a strong presumption that such a measure is not permissive since

ties formulate categories of health care facilities (medical or preventive care) as entitlements and categories of entitled persons (employed, children, pensioners); see for instance Article 13 of ILO Convention C130 on Medical Care and Sickness Benefits 1969. Medical care includes: a) general practitioner care; (b) specialist care at hospitals for in-patients and out-patients, (c) necessary pharmaceutical care on prescription; (d) hospitalisation where necessary; (e) dental care, as prescribed; and (f) medical rehabilitation, including the supply, maintenance and renewal of prosthetic and orthopaedic appliances, as prescribed. Similar phrases have been used in regional social security documents, such as the (revised) European Social Security Code (1990), as well as in the (revised) European Social Charter (1996), although less explicitly.

 $<sup>^{17}</sup>$  The right to the highest attainable standard of health: General Comment no. 14 (2000) on Health, E/C.12/2000/4.

<sup>&</sup>lt;sup>18</sup> By virtue of Article 2.2 and 3 of the CESCR, the Covenant prohibits any discrimination in access to healthcare.

it breaches the progressive realisation concept and results in health-related discrimination.<sup>19</sup> Without adequate justification, however, such a deliberately taken retrogressive measure is impermissible. According to CESCR, "states have the burden of proving that they are duly justified by reference of the totality of the rights provided by the Covenant in the context of the full use of the State party's maximum available resources" (para. 32). What this means is explained as follows. First of all, retrogressive measures are presumed impermissible; therefore, they require proper justification. The key issue is: what reason can be considered a proper justification? Economic recession as such cannot be considered sufficient for justifying a retrogressive measure. What is required is a careful study of the measure's impact, while taking into account the State's obligation to protect the totality of rights under the Covenant.<sup>20</sup> In other words, it means balancing of public interests since a State may not fully comply with its Covenant obligations. Such a study should investigate whether: (i) there was a reasonable justification for the action; (ii) alternatives were comprehensively examined; (iii) there was genuine participation of affected groups in examining the proposed measure and alternatives; (iv) the measure was directly or indirectly discriminatory; (v) the measure will have a sustained impact on the realisation of the right to healthcare, an unreasonable impact on acquired rights or whether an individual or group is deprived of access to the minimum essential level of healthcare; and (vi) whether there was an independent review of the measure at the nation level.<sup>21</sup> This would mean that in cases of serious resource constraints, public spending cuts on healthcare services - such as restricting free access to medicines - can be justified, taking into account a State's obligations towards the totality of social, economic and cultural rights, the measure's non-discriminatory effect, and provided that a minimum level of healthcare access is guaranteed.<sup>22</sup>

#### *General and specific obligations*

Of further relevance are the *General Comment's* specific legal obligations to respect, to protect and to fulfil (paras. 33–37). The obligation to respect prevents

<sup>21</sup> Derived from CESCR General Comment no. 19 on Social Security. E/C.12/GC/19, 4 February 2008, para. 42.

<sup>&</sup>lt;sup>19</sup> A clear example is the controversial measure of the Spanish government limiting access for irregular migrants to emergency care facilities, Royal Decree 16/2012.

<sup>&</sup>lt;sup>20</sup> Also Gomez Isa [2011].

<sup>&</sup>lt;sup>22</sup> Under the Optional Protocol, CESCR formulated additional criteria for considering "resource constraints" as an explanation for any retrogressive steps taken. E/C.12.2007/1: An evaluation of the Obligation to take steps to the "maximum of available resources" under the Optional Protocol to the Covenant, 10 May 2007, para. 10.

States from denying or limiting equal access to special groups (e.g., women, prisoners, and children). The obligation to protect requires States to take necessary measures preventing third parties (e.g., health providers and insurers) from interfering with the right to healthcare. For example, social health insurance funds are obliged to accept new applicants and they are not allowed to differentiate their premiums according to the risk profile of the applicants. This obligation of protection means that regulatory steps must be taken to ensure availability, accessibility, acceptability and quality of healthcare, particularly in case governments seek to introduce market competition in the financing and delivery of care (para. 35). The obligation to fulfil requires states to develop a national health policy with a detailed plan to realise the right to healthcare, including regulatory and financial measures to facilitate the necessary infrastructure (public health facilities, professional training and education programmes, information campaigns with respect to sexual and reproductive health services, etc.).

### Obligations of immediate effect: core obligations

Although the Covenant acknowledges the constraints due to limited available resources, it also imposes obligations having immediate effect. Thus, although the right to healthcare may be achieved progressively, certain steps had to be taken immediately shortly after the Covenant entered into force for the states concerned. These steps should ensure an essential minimum level of the right to healthcare. More precisely, these core obligations include at least: adopting a comprehensive national plan to develop a health system; progressive realisation and non-discrimination in healthcare access; and ensuring equitable access to essential healthcare services and medicines (para. 43).<sup>23</sup> It means that states have to take immediate steps, i.e., adopting legislative, administrative and financial measures aimed at the realisation of these core obligations. "Any suggestion that the provisions indicated are inherently non-self-executing would be difficult to sustain."24 As a consequence, the core obligations can be directly invoked by judicial organs in national legal systems. In cases involving the violation of the core obligations, states "cannot, under any circumstances whatsoever, justify its non-compliance with the core obligations set out [...], which are non-derogable" (para. 47). Without doubt, CESCR's authoritative interpretation of specifying state obligations contributes to the understanding of the meaning of the right to healthcare.<sup>25</sup>

<sup>25</sup> GC14 gives a certain degree of clarity about the scope of the right to healthcare. In addition, measuring and monitoring progress of the realization of specific right to healthcare norms is an-

<sup>&</sup>lt;sup>23</sup> On a more practical attempt to formulate the minimum core concept of the right to healthcare, see: Tobin [2012] p. 243–252.

<sup>&</sup>lt;sup>24</sup> GC3, para. 5.

Non-discrimination and equal access

At regional level, both the Council of Europe's European Social Charter and Biomedicine Convention confirm the core elements of non-discrimination and equal access to healthcare among those in need. According to Article 3 of the Biomedicine Convention, access to healthcare should be equitable, which is not synonymous with absolute equality. Apart from unjustified discrimination, the Convention allows preferential treatment but only for objective reasons, i.e. interpreted as based on medical need and taking into account available resources. What counts are *medical* needs as concluded by medical professionals, instead of a patient's individual needs, which can be unlimited. But how should we understand medical need? The Biomedicine Convention itself and the Convention's Explanatory Report do not address this point. Instead, the Explanatory Report of the Convention's Additional Protocol on Transplantation of Organs and Tissues (2002) explains the concept of medical need as follows:

Organs and tissues should be allocated according to *medical criteria*. This notion should be understood in its broadest sense [...] extending to any circumstance capable of influencing the state of the patient's health, the quality of the transplanted material or the outcome of the transplant.<sup>28</sup>

Circumstances include, for instance, organ/tissue compatibility with the recipient, medical urgency, organ transport time, time on the waiting list, etc. It seems, therefore, the case that allocation is only permitted on the basis of arguments that can be traced back to medical criteria. Any allocation based on grounds that go beyond this scope (i.e. allocation based on arguments that are not rooted in medical grounds) should be considered unjustified discrimination.<sup>29</sup> This is affirmed in

other useful instrument articulating claims on duty-bearers and for formulating health policies. The former UN Special Rapporteur on Health, Paul Hunt, formulated a set of health indicators measuring the progressive realization as applied to reproductive health policy, UN Commission on Human Rights, "Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health", E/CN.4/2006/48, 3 March 2006; see also Hunt, MacNaughton [2007], p. 303–330.

<sup>&</sup>lt;sup>26</sup> See, for instance, the conclusions and decisions made by the European Committee of Social Rights reviewing State obligations in case of vulnerable groups under Article 11 and Article E (non-discrimination) ESC: ECSR Decision on the merits, 11 September 2012, *Médecins du Monde v France*, Complaint no. 67/2011 para. 139 (discrimination of disadvantaged groups in healthcare access); *European Roma Rights Centre (ERRC) v Bulgaria*, Complaint no. 46/2007, Decision on the merits, 3 December 2008 paras. 45–51.

<sup>&</sup>lt;sup>27</sup> Article 3, Biomedicine Convention and the Explanatory Report, paras. 24–25.

<sup>&</sup>lt;sup>28</sup> Explanatory Report, para. 37.

<sup>&</sup>lt;sup>29</sup> As discussed by Buijsen, Exter den [2010] p. 69–85.

the Declaration on the Promotion of Patients' Rights in Europe.<sup>30</sup> As regards the equal treatment of patients, it is stated there that

[...] in circumstances where a choice must be made by providers between potential patients for a particular treatment which is in limited supply, all such patients are entitled to a fair selection procedure for that treatment. That choice must be based on medical criteria and made without discrimination.

### Defining healthcare benefits

Although inspired by the basic health provision of ICESCR, there is no substantive effort to classify or define healthcare services in Article 3 of the Biomedicine Convention. Therefore, one should read the Explanatory Report, which interprets healthcare as including diagnostic, preventative, therapeutic and rehabilitative interventions aimed at improving a person's health or alleviating suffering.<sup>31</sup> Still, the content and the methods of ensuring access to healthcare vary by country and may take different forms. In this respect, European social security law, listing medical benefits under the right to healthcare as an essential element of social security, can be of further assistance. For instance, the (revised) European Code of Social Security (hereafter, the Code) further classifies medical care as including general practitioners and specialist care; pharmaceutical and dental care, hospital care; medical rehabilitation and medical transportation.<sup>32</sup> Still, the precise standards of medical care are to be defined by individual member 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 good medical practice do not have to be covered by national social security law. Or, in case of "necessary pharmaceutical care", member states cannot be forced to reimburse the most expensive medicine when an equally effective generic for a certain treatment is available.<sup>33</sup>

#### *Cost-sharing measures*

At the same time, the Code allows cost-sharing measures, which implies that States may set rules to limit the provision of medical care. For instance, by introducing patients' co-payments, delisting medical services, etc., "as long as these restrictions do not impose hardship or render medical and social protection

<sup>32</sup> European Code of Social Security (revised) 1990, ETS no. 139, Art. 10, s. 1.

<sup>&</sup>lt;sup>30</sup> A Declaration on the Promotion of Patients' Rights in Europe (1994). WHO document ICP/HLE 121, 28 June 1994.

<sup>&</sup>lt;sup>31</sup> Explanatory Report, para. 24.

<sup>&</sup>lt;sup>33</sup> Explanatory Report on the European Code of Social Security (Revised) 1998, paras. 124–126.

less effective."<sup>34</sup> This so-called standstill clause corresponds to the obligation of non-retrogression (or non-regression) under the ICESCR. In line with the Covenant, the Code's standstill effect is subject to exceptions, as long as the restriction does not nullify social rights. Under the Code this means that the upper limit of co-payments may not exceed the level of 25% for general practitioner care, hospital care and for pharmaceutical supplies; and 33.3% for conservative dental care.<sup>35</sup> Since the (revised) Code is silent about these fixed figures, the assessment of the standstill effect remains difficult, depending on general phrases like: "the financial burden must not detract from the effectiveness of medical protection."<sup>36</sup> The Explanatory Report, however, is more concrete: the risk of hardship can be averted by excluding vulnerable groups (e.g. the unemployed, chronic patients, etc.) from cost-sharing.<sup>37</sup>

### 4. Shaping the right to healthcare in national law

Although numerous human rights treaties confirm and describe the right to healthcare, national law – the Constitution and statutory law – remains crucial in operationalising and guaranteeing the right to healthcare. In Europe, constitutional approaches to protect health differ in focus and the degree to which they protect health and health-related rights. For instance, some Constitutions focus on specific categories, such as public health, medical care, and overall health.<sup>38</sup> Alternatively, the right to healthcare or health-related right has been accepted indirectly, i.e. either as part and parcel of a social security right, or by interpreting other fundamental human rights, such as the right to life, bodily integrity, and combined with

<sup>&</sup>lt;sup>34</sup> Article 10(2) ECSS (revised), as derived from ILO Convention no. 121 (Art. 11[2]), and no. 130 (Art. 17). Reviewing the Swiss law's conformity with the Code, the Committee of Ministers confirmed that "since the Code makes no provision for sharing by insured persons in the cost of medical care in cases of occupational injury, it should be made clear whether the above mentioned provision (on cost sharing) applies in practice only to the victims of non-occupational accidents." Committee of Ministers Resolution CSS (86)10.

<sup>&</sup>lt;sup>35</sup> Protocol to the European Code of Social Security, (1964), addendum 2, Art. 10 (2), being referred in the (revised) Code's explanatory report, paras. 128–129.

<sup>&</sup>lt;sup>36</sup> Though, occasionally the Council of Ministers requested member states to respect the cost sharing thresholds: CM(2000)22 Addendum III 18 April 2000, Belgium Appendix I; Resolution CM/ResCSS(2007)18 Turkey; Resolution CM/ResCSS(2009)6 France.

<sup>&</sup>lt;sup>37</sup> Explanatory Report, para. 132.

<sup>&</sup>lt;sup>38</sup> E.g., in Spain, public health protection is expressed as a state obligation: "It is incumbent upon the public authorities to organize and watch over public health by means of preventive measures and the necessary benefits and services" (Art. 43 Constitution); the Latvian Constitution (1992) declares that "the State shall [...] guarantee a basic level of medical assistance for everyone" (Art. 111); in Hungary "everyone shall have the right to the highest possible level of physical and mental health" (Art. 70 D).

the social state principle.<sup>39</sup> Also the nature of such a healthcare right differs by country: generally considered as an object of state policy, to be realised progressively,<sup>40</sup> therefore providing aspirational protection; or declared an explicit duty of the state to protect citizens' health more as a guaranteed right, as in Italy.<sup>41</sup>

What these provisions have in common is setting a continuum of state obligations that require a range of statutory laws and other mechanisms to realise access to high-quality healthcare services. For instance, according to the Czech Charter on Fundamental Rights, "citizens are entitled under public insurance to free medical care and to medical aids under conditions set by law." This entitlement imposed an obligation to establish a universal social health insurance system covering the main health risks.<sup>42</sup> This health insurance model follows the so-called 'Bismarckian' approach in which the Constitutional right to healthcare has been interpreted in terms of entitlements as defined by national law,<sup>43</sup> as illustrated by the German Social Security Code (Sozialgesetzbuch V), defining a wide range of statutory entitlements under the social health insurance scheme complying with quality, medical effectiveness, economic efficiency standards and medical necessity.44 Under the German social health insurance scheme, an independent institution called the Federal Joint Committee sets quality and efficiency directives for existing and new technologies that should comply with national and international standards of medicine (evidence based). These directives are binding for social health insurance funds and create individual entitlements for the insured. Conversely, healthcare services that do not comply with the directives are excluded

<sup>&</sup>lt;sup>39</sup> For instance, the German Constitutional Court interprets Art. 2 of the Constitution (private life, right to life and integrity) in combination with Art. 20 (the 'Social state' principle) as imposing a state obligation to guarantee equal access by means of statutory health insurance, e.g. 1 BvR 347/98 (6 December 2005 'Nikolaus-Beschluss'); alternatively, "everyone has the right to lead a life of human dignity. These rights include in particular the right to social security, the protection of health and [...] medical assistance" (Art. 23 Belgian Constitution).

<sup>&</sup>lt;sup>40</sup> As understood under the Dutch Constitution: "The authorities shall take steps to promote the health of the population", Art. 22(1).

<sup>&</sup>lt;sup>41</sup> Art. 32: "The Republic shall safeguard health as a fundamental right of the individual and as a collective interest and shall guarantee free medical care to the indigent" (1947 Constitution of Italy).

<sup>&</sup>lt;sup>42</sup> Apart from establishing a social insurance system, the constitutional right to healthcare imposes a system of quality standards, facilitating or safeguarding the provision of healthcare, patients' rights legislation, etc.

<sup>&</sup>lt;sup>43</sup> In the early 1990s, most Central and Eastern European countries transformed their healthcare system towards a Bismarckian-type health insurance system, see: Exter den [2002].

<sup>&</sup>lt;sup>44</sup> Art. 27 SGB V in conjunction with Art. 2(1) and 12 SGB V.

from reimbursement.<sup>45</sup> Other countries follow more or less similar standards for coverage.<sup>46</sup> Still, the nature and scope of the benefits may differ by country, meaning that the interpretation of these standards leaves competent authorities a considerable margin of discretion. On many occasions, this discretionary power has been challenged by individuals claiming that excluding a certain medical treatment of medicine from reimbursement is considered unconstitutional (e.g., *Nikolaus* ruling, hereafter).

The Bismarckian insurance-based model differs from the Beveridge National Health Service (NHS) model as applied in the United Kingdom and some Mediterranean countries, or from the Nordic mixed model.<sup>47</sup> In the (Portuguese) NHS-model, the right to health is to be met by a universal and general national health service that will be free of charge.<sup>48</sup> Within such a model, benefits are based on citizenship instead of insurance contributions and entitlements, which complicates adjudication of healthcare access.

So far, several observations can be made. First, international and constitutional law have recognised the right to healthcare by setting normative standards, imposing state authorities to realise this social right progressively. Second, irrespective of the differences between the healthcare models, it is statutory law that specifies the meaning of the right to healthcare by defining the nature and scope of healthcare benefits. Lastly, international and domestic law alone cannot guarantee the realisation of the right to healthcare. This requires another essential element: the need for judicial review to protect citizens' right to healthcare if the state fails to act according to its obligations. Needless to say that litigation is not the only means to ensure state compliance. Although the overall concept of state accountability is broader than that of judicial review, the focus is on independent judicial

<sup>&</sup>lt;sup>45</sup> Nonetheless, the Constitutional Court forced the legislature to extend the list of benefits with non-proven treatment methods for life-threatening diseases that may contribute to treatment of the disease (art. 12(3) SGB V (Decision BvR 347/98). Further details, see: Jabornegg et al. [2007] p. 37.

<sup>&</sup>lt;sup>46</sup> E.g., the Netherlands: necessity, proven efficacy, cost effectiveness, and collective or individual responsibility (Parliamentary Proceedings Health Insurance Act 2006, 29763, no 3, p. 38); Switzerland: effectiveness; appropriateness and efficiency, art. 32 Health Insurance Act (KVG), followed by a list of benefits included or excluded from reimbursement (so-called 'positive or negative lists').

<sup>&</sup>lt;sup>47</sup> Although the classification Bismarck v Beveridge model oversimplifies the variety in healthcare systems, and ignores the latest developments which even suggest a convergence of both models, see e.g. Leiter, Theurl [2012] p. 7–18.

<sup>&</sup>lt;sup>48</sup> See e.g., Article 64 Portuguese Constitution.

review, excluding quasi-judicial bodies' decisions which may also have contributed to the right to healthcare jurisprudence.<sup>49</sup>

# 5. Justiciability of the Right to Healthcare

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.<sup>50</sup> In case of the right to healthcare, on several occasions, domestic and international courts held claims on healthcare access justiciable, providing an effective remedy to enforce its realisation.<sup>51</sup> Nonetheless, courts recognise that the necessary means are not infinite. Therefore, concepts such as progressiveness, core obligations, proportionality, and the state's margin of appreciation provide important tools to mitigate excessive healthcare claims. Hereafter, selected cases adjudicate the constitutionality of the right to healthcare or related rights-claims, such as the right to (private) life and equality; either by referring or not referring to international human rights treaties. The examples are merely illustrative of the innovative approach applied by the judiciary when reviewing the constitutionality of health insurance reforms, and in cases of enforcing healthcare access, notably regarding access to new medical treatment methods and high-cost medicines.

# 5.1. Issues of Justiciability at domestic courts

*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, may 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 have been respected and essential elements are protected. Moreover, such restrictive measures may not be arbitrary, thus necessary and non-discriminatory. For instance, the Polish Constitutional Tribunal confirmed that

<sup>&</sup>lt;sup>49</sup> For instance, the Council of Europe's European Committee of Social Rights conclusions and decision on the right to health and vulnerable people, such as: *FIDH v France* Complaint no. 14/2003 (3 November 2013), paras. 33–34; *MFHR v Greece* Complaint no. 30/2005 (1 Dec. 2006), para. 202; *Medicines du Monde v France* Coll. Complaint no. 67/2011.

<sup>&</sup>lt;sup>50</sup> International Commission of Jurists, Courts and the Legal Enforcement of Economic, Social and Cultural Rights. Comparative experiences of justiciability, Geneva 2008, p. 6.

<sup>&</sup>lt;sup>51</sup> For an interesting overview see: Flood, Gross [2014], describing national experiences on litigating healthcare access.

Article 68(2) of the Constitution (i.e., the right to health protection) provides the legislature with far-reaching discretionary powers 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 them of the right from its essence, that is guaranteeing a right or benefits necessary for a basic minimum of existence." A similar reasoning has been applied by the Czech Constitutional Court when reviewing the constitutionality of introducing a patient's own payment for medicines under Article 31 of the Human Rights Charter.

So far, Constitutional Courts provided 'mere' procedural protection against violations of the right to healthcare. More rigorous was the Slovenian Constitutional Court when it annulled a retrogressive measure by means of substantial review, since the reduction of medical care to emergency care was held unconstitutional and unjustified.<sup>54</sup> Similar cases striking down retrogressive legislation have been found in Portugal and Belgium.<sup>55</sup> These examples confirm that constitutional review may provide an effective remedy to enforce (components of) the right to healthcare.

New medical technologies and limited cost-effectiveness

In the *Nikolaus* case, the German Constitutional Court interpreted the concept of progressiveness by lifting the ban on reimbursement of experimental treatment methods.<sup>56</sup> This case involves a young patient suffering from Duchenne muscular dystrophy, a progressive and lethal illness. At present, there is no effective therapy for this disease. Reimbursement of the costs of a new treatment method, referred to as immune biological therapy, was rejected by the social insurance

<sup>&</sup>lt;sup>52</sup> CT Ruling K 8/96, 275 and K7/95, 414.

<sup>&</sup>lt;sup>53</sup> Pl. US 1/08, 23 September 2008. The CC applied the reasonableness test, i.e., i) defining the essence (essential content) of the social right: 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.

<sup>&</sup>lt;sup>54</sup> U-I-390/02-27, example derived from Ivanc [2007] p. 342.

<sup>&</sup>lt;sup>55</sup> Portuguese Constitutional Tribunal, Decision no. 39/84, 11 April 1984 on abrogating the National Health Service; Belgian Constitutional Court (previously Court of Arbitration) 27 Nov. 2002, no. 169/2002 and 14 January 2004, no. 5/2004.

<sup>&</sup>lt;sup>56</sup> Case BvR 347/98, 6 December 2005, also known as the 'Nikolausbeschluss'.

fund on the ground that it was not evidence-based (the *Wirksamkeit* criterion). The Court ruled, however, 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 (para. 55). More specifically, in cases of life-threatening diseases for which medical treatment is lacking according to general medical standards, an experimental treatment with curative or positive effect ("spürbare positive Einwirkung") cannot be denied in the absence of scientific evidence. The alternative's effectiveness could be based on other evidence, for instance expert opinions and medical practice (para. 66).

With this ruling the Court has, although in exceptional cases, extended healthcare access to newly developed, and in most cases extremely expensive diagnostic and treatment methods that are likely to have a positive effect on the course of the disease.<sup>57</sup> It means that when scientific evidence is absent, the required probability standard of effectiveness is rather flexible: the more severe, the more hopeless the situation, the less stringent the likeliness standard. And although the Court recognised the "Wirtschaftlichkeitsgebot" (Art. 12 SGB V) and the need for cost or cost-benefit considerations (paras. 57–59), these criteria were not decisive.

The *Nikolaus* ruling stirred feelings in German legal doctrine.<sup>58</sup> In essence, it shows that despite the legislature's (here the Federal Joint Committee, 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* case from the Swiss Supreme Court.<sup>59</sup> On appeal, a Swiss health insurance fund challenged the court order of the Insurance Tribunal to continue reimbursement of an experimental treatment for Pompe's disease, a rare and life-threatening disease. The Supreme Court annulled the Tribunal's ruling by reasons based on both lacking 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).

<sup>&</sup>lt;sup>57</sup> 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.

<sup>&</sup>lt;sup>58</sup> Huster [2006]; Dannecker, Streng [2015].

<sup>&</sup>lt;sup>59</sup> Judgment of the Federal Supreme Court of Switzerland of 23 November 2010 (BGE 136 V 395).

Because general criteria to assess cost-effectiveness were absent, the Court applied a (controversial) 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 postponing or preventing its fatal outcome). Moreover, approval would violate the equality principle when a disproportionate amount of scarce resources would be allocated to a certain individual but not to others who are in the same position (paras. 7.7–7.8). This line of reasoning has been criticised by legal scholars.<sup>60</sup> Although cost-benefit/effectiveness analysis is relevant at macro level (benefit package decision-making), it seems less appropriate at the individual doctor-patient level since it will ultimately force the judiciary to decide about society's willingness to pay for rare diseases, which can only be answered by the legislature.<sup>61</sup>

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.<sup>62</sup> Unfortunately, as these rights were not challenged at 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.<sup>63</sup> Instead, health insurance funds are supposed to review (partial) reimbursement of expensive interventions on a case-by-case basis, applying cost-effectiveness evidence.

#### Reliance on international law

When constitutional review is absent, as in the Netherlands, the judiciary has frequently applied international human rights to enforce the right to healthcare. 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)64 and international social security law (ILO Conventions and

<sup>&</sup>lt;sup>60</sup> E.g., Kesselring [2011]; Huster, Bohmaier [2012].

<sup>61</sup> Exter den [2014].

<sup>&</sup>lt;sup>62</sup> Articles 10 and 12 of the Swiss Federal Constitution.

<sup>63</sup> 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.

<sup>64</sup> A 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) (in Dutch).

the European Code of Social Security),65 whether or not combined with general non-discrimination treaty provisions (e.g., International Covenant on Civil and Political Rights, Article 26).66 In practice, such appeals based on international treaty norms are successful only in exceptional circumstances, but the impact can be considerable. In 2006, the CRvB concluded that the European Code of Social Security included some self-executing treaty provisions (articles 32 and 34) which prohibit co-payments in case of occupational health-related injuries.<sup>67</sup> As a direct consequence of this ruling, the Dutch Parliament agreed to partially denounce the European Code (part VI) and to simultaneously ratify the Revised Code, which allows more flexibility in terms of co-payments.<sup>68</sup> 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. 69 The criteria used by the CRvB 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 healthcare before domestic courts. Conversely, the judiciary rejected such reliance repeatedly in ICESCR cases, 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.<sup>70</sup> So far, the judiciary has continued that line of reasoning and is not willing to incorporate the concept of 'progressive realisation' of social rights.

65 A v Achmea Zorgverzekeringen, 8 September 2006 (ECLI:NL:CRVB:2006:AY8221); C v BAZ Nijmegen, 29 May 1996 (ECLI:NL:CRVB:1996:AL0666) (in Dutch).

<sup>&</sup>lt;sup>66</sup> In case of differential treatment of cost sharing: *A v NUTS*, 13 December 2001 (ECLI:NL:CRVB:2001:AE8567) (in Dutch).

<sup>&</sup>lt;sup>67</sup> See note 65, 8 September 2006.

<sup>&</sup>lt;sup>68</sup> 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).

<sup>&</sup>lt;sup>69</sup> F v BAZ Nijmegen (note 65). 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 was expired, denunciation failed.

<sup>&</sup>lt;sup>70</sup> X v Maastricht, 14 December 2010 (ECLI:NL:CRVB:2010:BO6734) (in Dutch).

### 5.2. Issues of justiciability at European level

Non-listed treatment methods and the ECHR

Apart from domestic courts, the European Court of Human Rights (ECtHR) has also dealt with the adjudication of healthcare access claims, although rarely successful.<sup>71</sup> In cases of non-available or excluded medical services or medicines, the Human Rights Court has linked the right to healthcare with the Convention's right to life (Article 2), prohibition of torture (Article 3), and private life (Article 8). For instance, it is nowadays 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.<sup>72</sup> In the healthcare 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 domestic courts' ruling that the State had failed to provide adequate treatment, putting the patient's life at risk.<sup>73</sup> 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 Human Rights Court, 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 (para. 34). 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 (para. 36). In this exceptional case of unreasonable obstruction of enforcing a court order, the State has not adequately protected the patient's right to life.

In another case, *Hristozov v Bulgaria*, the applicants complained that the Bulgarian authorities refused authorisation for using a non-registered and untested medicine involving a life-threatening disease.<sup>74</sup> According to the Court there was no breach of the Convention's right to life, prohibition of torture, nor private life. It is true that the positive obligations under Article 2 include a duty to regu-

<sup>&</sup>lt;sup>71</sup> However, in the case of vulnerable groups and healthcare needs, such as prisoners, the ECtHR appears more generous.

<sup>&</sup>lt;sup>72</sup> See for instance, Calvelli and Ciglio v Italy App no. 32967/96 (ECtHR, 17 January 2002), paras. 48–49.

<sup>73</sup> Panaitescu v Romania App no. 30909/06 (ECtHR, 10 April 2012).

 $<sup>^{74}</sup>$  App no. 47039/11 and 358/12 (ECtHR, 13 November 2012).

late the conditions for market entry of medicines. Clinical trials testing a product's safety and efficacy are an essential part of the market authorisation 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 Court's view, Article 2 does not impose an obligation to regulate access to unauthorised medicines for terminally ill persons "in a particular way" (para. 108). From a survey it appeared that the regulatory requirements allowing untested medicinal products outside the clinical trials differ by country (paras. 54–55). Member states have a wide margin of appreciation setting the conditions for such medicines. That being so, 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 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.<sup>75</sup>

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 the product is recommended by the treating physician. In addition, the physician should explain at length the known risks and the possibility of unknown risks, and access to unauthorised medicines remains an option of last resort. The counterargument that access to unauthorised medicines may hinder clinical trials seems rather unfounded since it remains a strict exception to the general rule. And so is the argument that access would undermine patient's willingness to participate in future clinical trials. When conventional therapies are not effective, 'desperate' patients will continue volunteering 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

<sup>&</sup>lt;sup>75</sup> Partly Dissenting Opinion Judges Kalaydjieva, Gaetano and Vicinic.

<sup>&</sup>lt;sup>76</sup> Dissenting Opinion Judge Vicinic, para. 8.

on compassionate use, the Court 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.<sup>77</sup>

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 a positive obligation, whereas refusal to act was a breach of the State's procedural obligations under Article 2.<sup>78</sup>

In cases involving 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.<sup>79</sup> Under those circumstances, the Court does not interfere in the State's margin of appreciation in determining the scope of the health insurance entitlement.

# Medical asylum cases

By exception, the Human Rights Court has accepted a claim on healthcare access based on the prohibition of inhuman and degrading treatment, in 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 sentenced to a three-year term of imprisonment.<sup>80</sup> Immediately prior to his release immigration authorities issued orders 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 he was receiving in the UK. Unsuccessful in his requests to the national courts, he applied to the Strasbourg Court arguing, *inter alia*, that his removal to St. Kitts would be an Article 3 violation.

<sup>&</sup>lt;sup>77</sup> *Durisotto v Italy* App no. 62804/13 (ECtHR, 6 May 2014) 36. Although the medicine was in a clinical trial stage, the Court abstained from a so-called "merits review" of the applicable conditions.

<sup>&</sup>lt;sup>78</sup> In a pending case, *Dumitrescu v Romania* App no. 55498/13 (ECtHR, 1 April 2014), the circumstances of the case are more or less similar, questioning whether Romania had violated the applicant's right to life by not making available an unlisted but temporarily approved medical product.

<sup>&</sup>lt;sup>79</sup> Sentges v the Netherlands (Dec) App no. 27677/02 (ECtHR, 8 July 2003).

<sup>&</sup>lt;sup>80</sup> *D v the United Kingdom* App no. 30240/96 (ECtHR, 2 May 1997).

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 applied Article 3 in another context, i.e. the situation where the harm would stem from withholding life-saving treatment when expelling the person 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 of any support from relatives or any other form of moral or social support in St Kitts. Based on these exceptional circumstances, the decision to expel the applicant would amount to inhumane treatment by the Contracting state, therefore considered a violation of Article 3. According to the Court, a breach of Article 3 for medical asylum cases can be established only on the application of this so-called "exceptional circumstances" test (paras. 52–53). With this ruling, one may criticise the Court as finding a breach of Article 3 in the present case would open the floodgates to medical immigration and make Europe vulnerable to becoming the 'sickbay' of the world. However, the 'floodgates' argument seems totally misconceived given that since this judgment, the Court has never concluded a proposed removal of an alien from a Contracting State to give rise to a violation of Article 3 on grounds of medical asylum.<sup>81</sup>

Although incomplete, this survey on the enforcement of the right to healthcare components illustrates how the judiciary carefully manoeuvres between justified individual requests for life-saving treatments and respecting state's duty to guarantee equal access to basic health care for all. The outcomes show that on some occasions courts have upheld the right to healthcare, and in individual cases have even promoted healthcare rights by adjudication. 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 for crossing the boundaries of what society can afford (e.g. the *Nikolaus* ruling in Germany). Even more delicate is triggering the question of the maximum costs of individual healthcare 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?

<sup>&</sup>lt;sup>81</sup> See for instance, *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* App no. 26565/05 (HIV positive) (ECtHR, 27 May 2008). Examining the facts of each case, they all were 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.

As such, the Swiss Supreme Court acted as substitute legislator by applying an economic analysis and setting the maximum. Lastly, the innovative approach of the European Human Rights Court by adopting expansive definitions of civil rights does not necessarily provide a functional remedy since the safety valve of margin of appreciation denied the enforcement of many healthcare claims.

#### 6. Conclusion

Enshrining the right to healthcare in international and national law can be considered a first step towards strengthening such a right. Still, it needs to be embedded into specific policies, legal and other measures focusing on public health and medical care of good quality accessible for all. To a certain extent, the documents as described have contributed to formulating more precise standards on the normative content of the right to healthcare. What is needed next is monitoring and measuring progress in State compliance to these normative standards, for instance with the use of health indicators. This is, however, a rather new area for health lawyers to explore.

Besides monitoring, more common are the functional remedies to ensure the right to healthcare. Incidentally, adjudicating healthcare access in the court appears to be successful by applying modern human rights concepts. But whether these landmark cases have galvanised more equitable access for all remains unclear. Nonetheless, these cases have triggered a social debate on existing and new health technologies accessible for all.

#### References

- Buijsen [2003] M. Buijsen, *The Concept of Health Law*, [in:] *Frontiers of European Health Law*, A. den Exter and J. Sandor (eds), Erasmus University Press, Rotterdam 2003.
- Buijsen, Exter den [2010] M. Buijsen and A. den Exter, Equality and The Right to Health Care, [in:] Human Rights and Biomedicine, A. den Exter (ed.), Maklu Press, Antwerp 2010, p. 69–85.
- Dannecker, Streng [2015] G. Dannecker and A.F. Streng, Die Bedeutung des Nikolaus-Beschlusses für die Priorisierungsdebatte, [in:] Priorisierung in der Medizin. Kriterien im Dialog, B. Schmitz-Luhn and A. Bohmeier (eds), Springer Verlag, Berlin Heidelberg 2015, p. 135–146.
- Exter den [2002] A. den Exter, Health Care Law-making in Central and Eastern Europe. Review of a Legal-theoretical Model, Intersentia, Antwerp 2002.
- Exter den [2014] A. den Exter, "Cost-effectiveness analysis. What's law got to do with it?" *Journal of the International Institute for Law and Medicine* 2014, p. 285–297.
- Exter den [2017] A. den Exter (ed.), European Health Law, Maklu Press, Antwerp 2017.

- Flood, Gross [2014] C. Flood, A. Gross (eds.), *The Right to Health at the Public/Private Divide: A Global Comparative Study*, Cambridge University Press, New York 2014.
- Giesen [1994] D. Giesen, "Health Care as a Right: Some Practical Implications", *Medicine & Law* (13) 1994, p. 285–296.
- Gomez Isa [2011] F. Gomez Isa, "The Reversibility of Economic, Social and Cultural Rights in Crisis Contexts," *Globalization, Privatisation and Human Rights* 2011, URL = http://www.globaleducationmagazine.com [28.2.2017].
- Gostin, Lazzarini L.O. Gostin and Z. Lazzarini, Human Rights and Public Health in the AIDS Pandemic, Oxford University Press, New York 1997.
- Hayes [1992] J.A. Hayes, "Health Care as a Natural Right," *Medicine & Law* (11) 1992, p. 405-416.
- Hessler, Buchanan [2002] K. Hessler and A. Buchanan, Specifying the Content of the Human Right to Health Care, [in:] R. Rhodes et al., Medicine and Social Justice: Essays on the Distribution of Health Care, Oxford University Press, New York 2002.
- Hunt, MacNaughton [2007] P. Hunt, G. MacNaughton, *Human Rights-Based Approach to Health Indicators*, [in:] *Economic, Social, and Cultural Rights in Action*, M. Baderin and R. McCorquodale (eds.), Oxford University Press, Oxford 2007, p. 303–330.
- Huster [2006] S. Huster, "Anmerkung," Juristenzeitung (9) 2006, p. 466-468.
- Huster, Bohmaier [2012] S. Huster and A. Bohmaier, "Die Myozyme-Entscheidung des Sweizerischen Bundesgerichts aus der Perspektive des deutschen Verfassungsund Krankenversicherungsrecht," Zeitschrift für Evidenz, Fortbildung und Qualität im Gesundheitswesen (106/6) 2012, p. 443–448.
- Ivanc [2007] B. Ivanc, "Constitutional Review of the Slovenian Health Law," *European Journal of Health Law* (14/4) 2007, p. 335–347.
- Jabornegg et al. [2007] P. Jabornegg et al., Grenzen der Leistungspflicht für Krankenbehandlung, Manz Verlag, Wien 2007.
- Kesselring [2011] F. Kesselring, "First Fundamental Decision of the Federal Supreme Court of Switzerland on Cost-Effectiveness in the Area of Human Healthcare," European Journal of Risk Regulation (3) 2011, p. 442–446.
- Leiter, Theurl [2012] A.M. Leiter and E. Theurl, "The convergence of health care financing structures: empirical evidence from OECD-countries," *The European Journal of Health Economics* (13/1) 2012, p. 7–18.
- Molinari [1998] P.A. Molinari, "The Right to Health: From the Solemnity of Declarations to the Challenges of Practice," *International Digest of Health Legislation* (49/1) 1998, p. 41-60.
- Nozick [1974] R. Nozick, Anarchy, State and Utopia, Basic Books, New York 1974.
- Tobin [2012] J. Tobin, *The Right to Health in International Law*, Oxford University Press, Oxford 2012.
- Toebes [1999] B.C.A. Toebes, *The Right to Health as a Human Right in International Law*, Intersentia, Amsterdam 1999.
- Yamin, Gloppen [2011] A.E. Yamin and S. Gloppen (eds), *Litigating health rights: can courts bring more justice to health*, Harvard University Press, Cambridge, MA 2011.