

# Dutch Health Insurance Dispute Resolution and Fake Courts

André den Exter\*

*Associate professor in health law and Jean Monnet chair EU health law, Erasmus School of Health Policy and Management/Erasmus School of Law, Erasmus University Rotterdam, the Netherlands*

## 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.*

## I. 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,

---

\* DOI 10.7590/221354019X15538518338599 2213-5405 2019 Journal of Medical Law and Ethics

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.<sup>1</sup>

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

---

<sup>1</sup> 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.

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.<sup>2</sup> 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 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*.<sup>3</sup> 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

<sup>2</sup> H. Hermans & A. den Exter, "Priorities and Priority-setting in Health Care in the Netherlands", *Croatian Medical Journal* 39 (1998), 346, 353-354.

<sup>3</sup> 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).

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.<sup>4</sup> 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".<sup>5</sup> 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.<sup>6</sup> 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

---

<sup>4</sup> 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.

<sup>5</sup> *Besluit Zorgverzekeringswet* (Decision Status Health Insurance), *Stb.* 2008, 549, Article 2.1, sub. 2.

<sup>6</sup> M. Offringa et al. (eds.), *Inleiding in evidence-based medicine* 4th edn. (Houten: Bohn Stafleu, 2014) (in Dutch).

ADR body in the case of coverage and reimbursement disputes (Article 114(3) HIA).<sup>7</sup> 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’).<sup>8</sup> 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.<sup>9</sup> 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”.<sup>10</sup> “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.<sup>11</sup>

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).

---

<sup>7</sup> Article 64(1) HIA defines the mandate as: “to promote a uniform interpretation of the nature, content and scope of the insured entitlements”.

<sup>8</sup> 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.

<sup>9</sup> 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.

<sup>10</sup> 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.

<sup>11</sup> *Ibid.*, para. 63.

### 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’*).<sup>12</sup> This committee of ‘binding advisors’ gives a binding decision on disputes between individual insured people and the health insurer. 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).<sup>13</sup> 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).<sup>14</sup> The procedural rules for the binding advice procedure are set by the SKGZ.<sup>15</sup>

The binding advice procedure is part of the self-regulatory system of ADR.<sup>16</sup> 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 regu-

<sup>12</sup> 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](http://www.skgz.nl).

<sup>13</sup> 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.

<sup>14</sup> 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”.

<sup>15</sup> “Procedure”, Reglement Geschillencommissie Zorgverzekeringen, [www.skgz.nl](http://www.skgz.nl) (9 July 2015).

<sup>16</sup> 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.

lated in the Dutch Civil Code (Article 7:900 DCC), providing its legal basis.<sup>17</sup> Furthermore, the binding advice procedure is generally considered less formal, has a different legal basis and its outcome does not provide executorial effect ('*exequatur*').<sup>18</sup> 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).<sup>19</sup> 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.<sup>20</sup> Both parties (the insured and the health insurer) are invited to submit written documents 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.<sup>21</sup> Although the hearing itself is in private, parties may be represented by their (legal) representative and may invite witnesses and experts.<sup>22</sup> After the hearing, the SKGZ committee will deliver a motivated decision within ninety days, published anonymously on the SKGZ website.<sup>23</sup>

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

<sup>17</sup> 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".

<sup>18</sup> 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 & Verhage (note 13), 62.

<sup>19</sup> In 2017 the Ombudsman received more than 3050 requests to mediate, of which 19% resulted in a friendly settlement, SKGZ annual report (2016), 6.

<sup>20</sup> Complaint Commission, Rules of procedure, Article 3(3), 9 July 2015.

<sup>21</sup> *Ibid.*, Article 10(1) on the hearing.

<sup>22</sup> *Ibid.*, Article 10, sections 4 and 10.

<sup>23</sup> *Ibid.*, Article 13.

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.<sup>24</sup> 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”.<sup>25</sup> 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.<sup>26</sup> If two randomised studies show a negative outcome, i.e. a negative opinion, reimbursement will be refused, irrespective of the international

<sup>24</sup> 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).

<sup>25</sup> Article 2.1 Bzv, section 2.

<sup>26</sup> 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.



practice and experiences component.<sup>27</sup> 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.<sup>28</sup> 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).<sup>29</sup> 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.<sup>30</sup>

Over the years, courts have ruled differently on whether long-term antibiotic treatment complies with the science and practice test.<sup>31</sup> 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

<sup>27</sup> See, e.g., case 201602154, 24 January 2018 (hysteroscopy and IVF, in Dutch).

<sup>28</sup> 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.

<sup>29</sup> “Documents”, CBO guideline Lyme disease 2013, RIVM [www.rivm.nl](http://www.rivm.nl).

<sup>30</sup> 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”.

<sup>31</sup> 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:2014:11412; Appeal Court Arnhem-Leeuwarden 19 December 2017, ECLI:NL:GHARL:2017:11105.

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”.<sup>32</sup> 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.<sup>33</sup> 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.

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.<sup>34</sup> 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.<sup>35</sup> 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?<sup>36</sup> Moreover, the ZiN advice ignored recent international development in research, treatment and health insurance reimbursement.<sup>37</sup> As such, the opinion does not satisfy the *Smits-Peerbooms* norm of the Court of Justice, the standard of international science and practice.<sup>38</sup> 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 ac-

<sup>32</sup> Appeal Court Arnhem-Leeuwarden 19 December 2017, ECLI:NL:GHARL:2017:11105, para. 4.28.

<sup>33</sup> *Ibid.*, para. 13.

<sup>34</sup> PTED opinion, [www.zorginstituutnederland.nl](http://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.

<sup>35</sup> District Court Utrecht 30 December 2010, ECLI:NL:RBUTR:2010:BO9347 and Appeal Court Amsterdam 18 December 2012, ECLI:NL:GHAMS:2012:BY6499.

<sup>36</sup> *Ibid.*, ECLI:NL:GHAMS:2012:BY6499, para. 4.11.

<sup>37</sup> *Ibid.*, para. 4.13.

<sup>38</sup> *Smits-Peerbooms*, paras 94 and 98.

cepted and authorised intervention. The appeal court interpreted these low-level evidence studies and practice experiences as complying with the international science and practice test.<sup>39</sup> This ruling was confirmed in subsequent lower court rulings.<sup>40, 41</sup> Most recently, the Supreme Court annulled the Amsterdam appeal court ruling, as it incorrectly interpreted the international science and practice test.<sup>42</sup> 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.<sup>43</sup> Although 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.<sup>44</sup>

### 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*,<sup>45</sup> the Court reluctantly accepted the reasonableness and fairness argument to widen the statutory health insurance entitlements, but only conditionally:

<sup>39</sup> *Ibid.*, para. 4.16.

<sup>40</sup> 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.

<sup>41</sup> Compared to SKGZ cases, 31 out of 36 PTED cases were denied reimbursement by concluding PTED as not evidence-based (2007-2017).

<sup>42</sup> Supreme Court 30 March 2018, ECLI:NL:HR:2018:469.

<sup>43</sup> *Ibid.*, 4.4.2.

<sup>44</sup> Paras 4.4.1-4.4.4, corresponding the Advocate General’s conclusion, paras 4.18-4.21.

<sup>45</sup> Supreme Court 19 December 2014, ECLI:NL:HR:2014:3679.

- 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.<sup>46</sup> 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).<sup>47</sup> 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.<sup>48</sup>

## 5. Conclusion

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 se-

---

<sup>46</sup> *Ibid.*, para. 3.6.3.

<sup>47</sup> Such as when chemotherapy is licensed to treat one type of cancer, but healthcare providers use it to treat a different type of cancer.

<sup>48</sup> See District Court Gelderland 21 September 2015, ECLI:NL:RBGEL:2015:5933 (*neurostimulation abroad*).

lectively 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.