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# Harmonisation in healthcare: the EU patients' rights Directive

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## Harmonisation in healthcare: the EU patients' rights Directive

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**Abstract:** In the EU harmonisation of healthcare has long been elusive. Article 168 paragraph 7 TFEU even forms a sector-specific subsidiarity clause. Meanwhile the ECJ handed down a series of judgments concerning patients' rights to reimbursement for healthcare consumed in other Member States. An initial attempt to codify this case law in the Services Directive failed in 2004. In March 2011 however, following a two-and-a-half year legislative process the EU patient's rights Directive was adopted. It codifies the old patients' rights, creates new rights to accountability and transparency, and promotes cooperation among national healthcare systems. As such it can be seen as a watershed in EU involvement in the healthcare sector.

Keywords: Healthcare; EU; harmonisation; reimbursement; legislation; codification; Patients' rights

JEL codes: I18, K23, K32

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## **1. Introduction**

This paper seeks to set out the background to and examine the content of the recent patients' rights harmonisation Directive that arguably forms a watershed in the context of EU involvement in the healthcare.

Apart from the role of harmonisation several more specific questions will be addressed:

- Does the Directive codify the patient mobility case law of the Court of Justice?
- What are the scope and the role of patients' rights in the proposal?
- Will the proposed patients' rights Directive act as a catalyst for change?

The discussion is structured in three parts:

- First the background to the Directive, its the legal basis and scope, as well as the relationship to social security regulation and the criterion of undue delay will be discussed
- Next the main two topics of the Directive are discussed: prior authorisation and the “old” patients' rights; and then common principles and “new” patients' rights
- Finally I will briefly address the provisions concerning cooperation which constitute flanking measures in the framework set by the Commission.

## **2. Background**

The EU Member States have a variety of healthcare systems that are generally classified in broad terms as either insurance based Bismarck systems (with a further distinction between benefits in kind and restitution systems) and publicly funded Beveridge systems (also known as national health services, or NHS). In all cases the Member States are deeply involved both in regulating the market structure and in setting individual entitlements.<sup>1</sup> They also share common funding problems as a result of spiralling costs due to the combination of aging populations, technological developments, and rising expectations. This in turn has triggered cost controls involving various forms of rationing, such as waiting lists. At the same time vested interests frustrate changes such as moving from centralised supply-driven systems to decentralised demand-led provision, and

promoting efficiency by means of market incentives and/or new entry. The resistance to planned reform often leads to de facto emergence of parallel systems that are outside the scope of social security and based on ability to pay. Hence rejecting change erodes solidarity.

Given this socially and politically sensitive context it should come as no surprise that the competencies of the European Union in the healthcare sector are limited. The Court of Justice has time and again recognised the right of the Member States to determine unilaterally (thus at national level) the scope of and eligibility for social security benefits.<sup>2</sup> Moreover, to bolster their control over healthcare provision, the Member States have limited the competence of the EU to take the initiative on healthcare issues further by adding an explicit Treaty provision to this effect, Article 168 TFEU.

In 2009 the Lisbon Treaty has moved “the protection and improvement of human health” to article 6 sub (a) of the TFEU which concerns activities of the Member States which the Union is competent to carry out actions to support, coordinate or supplement with regard to their European dimension. This replaces the earlier explicit connection with the objectives of the Union. The present provision fits better in the context of stressing subsidiarity, or the exercise of public powers at the lowest effective level, which also characterizes article 168 TFEU on public health. Finally in relation to 6 sub (a) TFEU, it is article 2 paragraph 5 TFEU which explicitly makes clear that the harmonisation of laws in this area is excluded.<sup>3</sup>

It is against this unpromising backdrop that, from *Kohll* to *Watts*,<sup>4</sup> the European Court of Justice has developed a remarkable line of case law over the past decade in which it

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<sup>1</sup> Cf. E. Mossialos et al. (eds), *Health systems governance in Europe: the role of European law and policy* (Cambridge University Press, Cambridge 2010).

<sup>2</sup> Cf. e.g. Case 238/82 *Duphar BV et al. v The Netherlands* [1984] ECR 523, para. 16; Joined cases C-159/91 and C-160/91 *Christian Poucet v Assurances Générales de France and Caisse Mutuelle Régionale du Languedoc-Roussillon* [1993] ECR I-637, para. 6; Case C-70/95 *Sodemare SA, Anni Azzurri Holding SpA and Anni Azzurri Rezzato Srl v Regione Lombardia (Sodemare)* [1997] ECR I-3395, para. 27 and Case C-158/96 *Raymond Kohll v Union des caisses de maladie (Kohll)* [1998] ECR I-1931, para. 17.

<sup>3</sup> “In certain areas and under the conditions laid down in the Treaties, the Union shall have competence to carry out actions to support, coordinate or supplement the actions of the Member States, without thereby superseding their competence in these areas. Legally binding acts of the Union adopted on the basis of the provisions of the Treaties relating to these areas shall not entail harmonisation of Member States’ laws or regulations” *Ibid.* This makes it all the more remarkable that the European Parliament and the Council agreed to base the Directive on patients’ rights inter alia on article 168 TFEU.

<sup>4</sup> Case C-158/96 *Kohll* supra note 2; Case C-120/95 *Nicolas Decker v Caisse de maladie des employés privés (Decker)* [1998] ECR I-1831; Case C-372/04 *The Queen, ex parte Yvonne Watts v Bedford Primary Care Trust and Secretary of State for Health* [2006] ECR I-4325. For a detailed discussion of these cases

applied the freedom to provide services to healthcare (alongside, in a number of cases, Regulation 1408/71,<sup>5</sup> the applicable social security legislation based on the free movement of workers of Article 48 TFEU). These cases were driven by patients seeking what they considered to be better (including earlier) medical treatment in other Member States (“Member State of treatment”) while claiming reimbursement of such treatment in accordance with the social security rules applicable in their home Member State (“Member State of affiliation”).<sup>6</sup> Adopting a “patient centred, needs based approach”,<sup>7</sup> the European Court of Justice has consistently supported such patient mobility. Because most Member States failed to implement this case law properly the resulting need for codification formed the Commission’s primary justification for the proposed patients’ rights Directive.

In July 2008 the Commission proposed a draft Directive on the application of patients’ rights in cross-border healthcare (“the Proposal”) in the context of the renewed social agenda of the EU.<sup>8</sup> After considerable debate and a significant number of amendments in first and second reading the text of the Directive has recently been adopted at technical level and formal votes in the European Parliament and the Council are expected to take place in January or February 2011 in order to confirm this outcome.<sup>9</sup> This proposal was daring because as was mentioned above so far the Member States generally regard healthcare reform not just as one of the most intractable political problems but also as an issue that should remain the preserve of national politics. Moreover an attempt by the Commission in 2004 to codify the patient mobility case law in the context of the Services

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and further references see W. Sauter, TILEC Discussion Paper No. 2008-034, available at SSRN: <http://ssrn.com/abstract=1277110>.

<sup>5</sup> Regulation (EEC) No 1408/71 of the Council of 14 June 1971 on the application of social security schemes to employed persons and their families moving within the Community (OJ 1971 L149/2), last amended by Regulation (EC) No 1992/2006 of the European Parliament and of the Council of 18 December 2006, OJ 2006 L392/1 (“Regulation 1408/71”). It replaced Council Regulation No 3 on social security for migrant workers, OJ 1958, p. 597. On May 1<sup>st</sup> 2010 Regulation 1408/71 was replaced by Regulation (EC) 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems, OJ 2004 L166/1. Cf. F. Pennings, *European social security law*, 5<sup>th</sup> edition (Intersentia, Antwerpen 2010).

<sup>6</sup> This is the usage in the proposed patients’ rights Directive (“the Proposal”), which will be employed here.

<sup>7</sup> G. Davies, “The effect of Mrs Watts trip to France on the National Health Service”, (2007) *King’s Law Journal* 158.

<sup>8</sup> Commission Communication of 2 July 2008, Proposal for a Directive of the European Parliament and of the Council on the application of patients’ rights in cross-border healthcare presented by the Commission, COM(2008) 414 final.

<sup>9</sup> Directive of the European Parliament and of the Council on the application of patients’ rights in cross-border healthcare, OJ 2011, L88/45.

Directive had backfired. It ended up having to withdraw the relevant provisions and adding an explicit exception for healthcare in order to save the Services Directive itself.<sup>10</sup>

The process summarised above suggests the occurrence of a familiar pattern in EU law where disparities between national markets lead to private litigation based on directly effective rights under the Treaty that triggers Court intervention striking down national barriers – resulting in deregulation (or “negative integration”) – which is then duly followed by legislative proposals to fill the remaining and/or resulting regulatory gaps by new rules at EU level – concluding by re-regulation (or “positive integration”).<sup>11</sup> This process of interaction between case law and legislation tends to involve both harmonisation and liberalisation of the applicable rules as well as a reassessment of the scope of legitimate public interests requirements. This paper will examine whether the proposed Directive on patients’ rights fit this mould. If so this would be all the more remarkable given the sector-specific subsidiarity clause of article 168 paragraph 7 TFEU that was already mentioned above.

### **3. Summary of the case law**

In the course of its case law over the past decade the Court of Justice has developed a parallel regime for patient mobility based on the freedom to provide services of article 56 TFEU, alongside the pre-existing rules based on the free movement of workers provided by Regulation 1408/71. It successively determined that restitution based insurance systems,<sup>12</sup> benefits in kind based insurance systems,<sup>13</sup> and systems national health services<sup>14</sup> were obliged to enable the reimbursement of cross-border healthcare.

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<sup>10</sup> European Commission, Proposal for a Directive of the European Parliament and of the Council on services in the internal market 2004/0001 (COD) [SEC(2004) 21] COM(2004) 2 final/3, 5 March 2004, especially Article 23 thereof. Cf. Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on services in the internal market, OJ 2006 L376/36 (Services Directive), Article 2 para. 2 sub f, and the Preamble, recital 23.

<sup>11</sup> Cf. G. Davies, “The Community’s internal market-based competence to regulate healthcare: Scope strategies and consequences”, (2007) *Maastricht Journal of European and Comparative Law* 215; F.W. Scharpf, “Negative and positive integration in the political economy of European welfare states”, in G. Marks et al., *Governance in the European Union* (Sage, London 1996), 15; and F.W. Scharpf, “The European social model: Coping with the challenges of diversity”, (2002) *Journal of Common Market Studies* 645.

<sup>12</sup> Case C-158/96, *Kohll*, supra note 5; Case C-120/95, *Decker*, supra note 5.

<sup>13</sup> Case C-157/99, *B.S.M. Geraets-Smits v Stichting Ziekenfonds VGZ and H.T.M. Peerbooms v Stichting CZ Groep Zorgverzekeringen (Smits and Peerbooms)* [2001] ECR I-5473; Case C-385/99, *V.G. Müller-Fauré v Onderlinge Waarborgmaatschappij OZ Zorgverzekeringen UA and E.E.M. van Riet v Onderlinge Waarborgmaatschappij ZAO Zorgverzekeringen (Müller-Fauré)* [2003] ECR I-4509.

<sup>14</sup> Case C-372/04, *Watts*, supra note 5.



Greatly simplified, this case law can be summed up as follows.<sup>15</sup> The scope of social security coverage as such is determined by the Member State of affiliation alone and therefore not at issue. Nor is the right of individual patients to seek treatment abroad and pay for it themselves at stake: they are free to do so. Instead the focus of both the Article 56 TFEU regime and that of Regulation 1408/71 is on *the conditions for the reimbursement of treatment abroad*, when a patient is in principle entitled to the treatment involved in his Member State of affiliation.

- When Article 56 TFEU is relied on reimbursement is at the level of domestic treatment in the Member State of affiliation, based on Regulation 1408/71 reimbursement is at the level of the Member State of treatment.<sup>16</sup>
- More complicated is the question whether prior authorisation may be required. Based on Regulation 1408/71 prior authorization of treatment abroad is always required as a condition for reimbursement. Based on Article 56 TFEU, prior authorization (which is in principle a barrier to the freedom to provide services) may be required for hospital services. This is considered justified to safeguard the financial balance of the national social security system of the Member States and planning in the hospital sector.
- So far the Court has never required evidence before allowing this justification. Over time it has come to accept that prior authorization may be justified provided that material and procedural due process guarantees are respected concerning the objective and proportionate nature of the authorization process, notably fleshing out the concept of “undue delay” by requiring due regard to the individual circumstances of each patient. These requirements are similar if not identical for the Article 56 TFEU setting and that of Regulation 1408/71.

In this manner the Court has balanced the public interest justifications invoked by the Member States with the rights of individual patients based on free movement. Against this background, the proposed patients’ rights Directive will be discussed.

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<sup>15</sup> Cf. T.K. Hervey, “The current legal framework on the right to seek healthcare abroad in the European Union”, (2007) Cambridge Yearbook of European Legal Studies 261.

<sup>16</sup> Where the latter is lower than the former, the difference may be claimed based on Article 56 TFEU. Cf. Case C-368/98, *Abdon Vanbraekel et al. v Alliance nationale des mutualités chrétiennes (Vanbraekel)* [2001] ECR I-5363.

#### 4. The legislative context

##### *Renewing the social agenda*

The Proposal for a Directive “on the application of patients’ rights in cross-border healthcare” as presented in July 2008 formed part of a raft of some twenty documents and proposals jointly billed as a renewed social agenda for 21<sup>st</sup> century Europe.<sup>17</sup> In stark contrast to the earlier attempt to embed patient mobility in the undiluted economic logic of the Services Directive, the connecting theme behind the July 2008 package was to complement the Lisbon growth strategy of the EU from a social perspective.

Another difference between the proposed patients’ rights Directive and the failed earlier attempt to include a single article on healthcare in the Services Directive is that the Proposal is a full-fledged dedicated legal instrument purporting to provide a complete and coherent legal regime for all the issues involved.

##### *Impact assessment: quantifying the case for codification*

The Proposal was published with an Impact Assessment which the Commission used to motivate its choice between different policy options.<sup>18</sup> The Impact Assessment stated that over 12 months 4% of the EU population had received medical treatment in another Member State, that 70% of the EU population believes such treatment would be reimbursed and that just over half the EU population was open to travelling to another EU Member State to receive treatment.<sup>19</sup>

The Impact Assessment further states that cross-border healthcare accounts for 1% of public healthcare expenditure.<sup>20</sup> Hence, the overall impact of patient mobility in the EU is small, although its local impact may be much greater e.g. in border regions, smaller

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<sup>17</sup> Cf. Commission Communication of 2 July 2008 on the Renewed social agenda: Opportunities, access and solidarity in 21st century Europe, COM(2008) 412 final; Commission press release IP/08/1070, Commission proposes renewed social agenda to empower and help people in 21<sup>st</sup> century Europe, Brussels, 2 July 2008; Commission memo MEMO/08/471, Renewed Social Agenda: The elements of the package, Brussels 2 July 2008.

<sup>18</sup> Supra note 9 (with an Explanatory Memorandum); Commission staff working document of 2 July 2008, accompanying document to the proposed patients’ rights Directive: Impact Assessment, SEC(2008) 2163.

<sup>19</sup> Impact Assessment, supra note 12, pp. 6-7 citing Flash Eurobarometer series #210, Cross-border health services in the EU, Analytical report for DG Sanco, 2007.

<sup>20</sup> I.e. approximately €9.7 billion. EU GDP is €12,149 billion of which some 7.6% (€967 billion) is spent on public healthcare. Impact Assessment, supra note 4, p. 9 (Eurostat figures 2006/2007).



Member States, in tourist areas, and in systems or for treatments involving high co-payments (out of pocket expenses for patients).

Overall, the Impact Assessment identifies “a rising trend for cross-border healthcare and significant potential demand from citizens to explore cross-border healthcare where it is quicker, better, cheaper or more convenient for them”.<sup>21</sup> The Impact Assessment shows that a dedicated Directive covering both hospital and non-hospital care provides net benefits in relation to the costs involved, more specifically a positive balance of € 179,6 million, with 780,000 extra patients receiving treatment for the EU as a whole.

These gains appear rather small as a basis for making the case for EU action. There is a contradiction at play here. The Commission struggled with the need to argue on the one hand, that something meaningful is at hand requiring EU legislation and, on the other hand, that the impact of this legislation on national social security regimes will be small enough that prior authorisation requirements are unlikely to be justified.

The Commission has not been successful in doing the latter: one of the main differences between the Proposal and the Directive as adopted is that the latter leaves considerable room for appeals to overriding reasons of general interest based on an exception for planning that the Court had earlier recognised in this context. This planning exception can even be invoked by the Member State of treatment to justify safeguard measures that had not been foreseen in the Proposal. It is still an open question to what extent quantification will be required in terms of demonstrating the necessity and proportionality requirements with respect to the planning exception. So far however the Court has not required quantification.

#### *The dynamics of “old” and “new” patient’s rights*

“Patients’ rights”, the key to the title chosen by the Commission for the Proposal, refers to a concept that is much broader in scope than the reimbursement of cross-border medical treatment (the “old” patients’ rights that the Court had developed in its case law).<sup>22</sup> This broader concept is primarily linked to the common principles that are framed as obligations of the Member State of treatment. These include quality and safety standards, access to the information necessary for (or “relevant to”) informed choice (i.e.

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<sup>21</sup> Ibid., p. 11.

transparency), the means to complain and obtain remedies (i.e. accountability), compensation for harm and privacy rights. These can in effect easily be rephrased as a set of “new” and potentially highly significant rights to cover all patients, not merely mobile ones. In this way “old” patients’ rights may be generating “new” ones: both categories will be examined further below.

## **5. Legal basis and scope**

### *Legal basis*

In line with the Proposal, the Directive as it was ultimately adopted is based on the harmonization provision of article 114 TFEU. The European Parliament and the Council have added article 168 TFEU to this so the Directive also has a sector-specific basis in the Treaty. The use of article 114 TFEU shows the Directive aims to secure the establishment and functioning of the internal market.<sup>23</sup> This is justified by the fact that although the Court judgments clarified patients’ rights they have not proven sufficient in and of themselves to enable patients to avail themselves of these rights widely or in an effective manner. (Or: they have so far been frustrated by the Member States.)

At the same time the Directive is required to respect not just the general subsidiarity provision in article 5 TEU but also the provisions of article 6 sub (a) and 2 paragraph 5 TFEU and Article 168 paragraph 7 TFEU, which provides a special subsidiarity clause with respect to the responsibility of the Member States for the organization and delivery of healthcare. As was already clarified by the Court in *Müller-Fauré* and *Watts* however, this provision does not mean that adjustments to national systems may not be required by other Treaty obligations, such as Article 56 TFEU on the freedom to provide and receive services.<sup>24</sup>

In this context, the Directive aims to form a framework that provides clarity about the rights to reimbursement for healthcare provided in other Member States as well assures that such cross-border healthcare is of high quality, safe and efficient, which could not be done effectively by individual Member States.

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<sup>22</sup> Cf. the World Health Organisation at <http://www.who.int/genomics/public/patientrights/en/>.

<sup>23</sup> On the relevant legal basis cf. D. Wyatt, “Community competence to regulate medical services”, in M. Dougan and E. Spaventa (eds), *Social welfare and EU law* (Oxford, Hart 2005), 131.

<sup>24</sup> Case C-385/99 *Müller-Fauré*, supra note 4, para. 102 (without specific reference to Article 152 para. 5 EC); Case C-372/04 *Watts*, supra note 5, para 147.

The basic assumption however is that, in line with Article 168 EC, the Member States retain full responsibility for determining what medical services are covered by their national social security regimes and for the actual provision of healthcare.<sup>25</sup> Article 6 sub (a) TFEU itself is reflected in Article 168 paragraph 1 TFEU which states that “A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities.” This means that the effects on public health must be assessed for every legislative proposal (even when the latter deals with an entirely different subject), a process called “mainstreaming”.<sup>26</sup> The Directive is the first piece of harmonisation legislation in the area of healthcare: we may now expect any future such legislation to be based on article 168 TFEU as well.

Finally article 168 TFEU is also relevant for the cooperation efforts of the Member States with relation to healthcare and/or public health, some of which are covered by the Directive (such as E-health and the other cooperation topics that will be addressed below).

### *Scope*

The scope of the Directive appears to cover all types of curative care without distinction in relation to their funding regime, hence it is not limited to healthcare in the sense of article 168 paragraph 7 TFEU, but also healthcare that is provided privately outside the public health setting.<sup>27</sup> The Proposal had made this explicit in its definition of healthcare. Article 3(a) of the Directive now defines healthcare as follows:

““Healthcare” means health services provided by health professionals to patients to assess, maintain or restore their state of health, including the prescription, dispensation and provision of medicinal products and medical devices.”

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<sup>25</sup> Cf. Preamble of the Directive, recitals 3a and 5a, as well as article 7 paragraph 3 of the Directive which reads: “It is for the Member State of affiliation to determine, whether at a local, regional or national level, the healthcare for which an insured person is entitled to the assumption of costs and the level of assumption of those costs, regardless of where the healthcare is provided.”

<sup>26</sup> Cf T.K. Hervey en J.V. McHale, *Health Law and the European Union* (Cambridge University Press, Cambridge 2004), pp. 76-81.

<sup>27</sup> I.e.: “Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the

However the right to reimbursement – which is actually the core of the Directive – is linked to the position of the patient as an insured person covered by a social security system in line with Regulation 883/2004. Long term care and the donation or medical use of organs and blood, and public immunisation schemes are not covered.

## 6. Parallel regimes based on article 56 TFEU and article 48 TFEU continued

### *The right to treatment*

The EU will continue to have two parallel regimes for the authorisation and/or reimbursement of cross-border healthcare: one the existing regime based on Regulation 1408/71 (and thereby on article 48 TFEU on free movement of workers); and the other the new regime of the Directive, replacing that directly based on Article 56 TFEU (never implemented in most Member States).

The Court had effectively merged the two regimes as far as the right to treatment was concerned, based on the “undue delay” criterion, first effectively in the *Inizan* case,<sup>28</sup> and then explicitly in *Watts*:<sup>29</sup>

“(…) there is no reason which seriously justifies different interpretations depending on whether the context is Art. 22 of Regulation No 1408/71 or Art. 49 EC, since in both cases the question is (…) whether the hospital treatment required by the patient’s medical condition can be provided on the territory of his Member State of residence within an acceptable time which ensures its usefulness and efficacy.”

Under the terms of the Directive its relationship with the Regulation will henceforth be determined by a clear priority rule and an exception to this rule, while responsibility for both of which is clearly assigned as well. This is because article 8 paragraph 3 of the

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resources assigned to them. The measures referred to in paragraph 4(a) shall not affect national provisions on the donation or medical use of organs and blood.”

<sup>28</sup> Determining undue delay requires “to have regard to all the circumstances of each specific case and to take due account not only of the patient's medical condition at the time when authorisation is sought and, where appropriate, of the degree of pain or the nature of the patient's disability which might, for example, make it impossible or extremely difficult for him to carry out a professional activity, but also of his medical history”. Case C-56/01, Case C-56/01, *Patricia Inizan v Caisse primaire d'assurance maladie des Hauts-de-Seine* [2003] ECR I-12403, para. 46 with reference to Case C-157/99 *Smits and Peerbooms*, supra note 14, para. 104, and Case C-385/99, *Müller-Fauré*, supra note 14, para. 90.

<sup>29</sup> Case C-372/04, *Watts*, supra note 5, para. 60.

Directive provides that in case of a request for prior authorisation the Member State of affiliation will determine whether the conditions for the application of Regulation 883/2004 are met. If this is the case the prior authorisation is granted in accordance with the Regulation unless the patient himself requests otherwise – i.e. requests to obtain a prior authorisation in accordance with the Directive instead. This appears to be a relatively straightforward system that leaves little room for misunderstandings and a distinct improvement over the Proposal which left too many responsibilities on this count with the patient – especially determining whether “undue delay” might be involved. This means that the earlier risk that the meaning of “undue delay” would come to diverge between the two legal instruments has also been addressed.

*Undue delay: a time-limit which is medically justifiable*

The right to treatment without undue delay had not been properly addressed by the Proposal because it only came up in relation to the procedure for the treatment of prior authorisation requests but not as a material norm for assessing these requests themselves. On this issue therefore the Directive also provides a clear improvement over the proposal.

The right to treatment without undue delay surfaces twice in the Directive:

- Article 8 paragraph 5 concerning healthcare that can be subject to a prior authorisation requirement provides that such authorisation may not be refused if the healthcare in question is among the benefits to which the insured person is entitled in the Member State of affiliation and when this healthcare cannot be provided on its territory within a time-limit which is medically justifiable, based on an objective medical assessment of the patient’s medical condition, the history and probable course of his illness, the degree of pain he is in and/or the nature of his disability at the time when the request for authorisation was made or renewed. This means the central role for this important material norm developed in the case law is maintained by the Directive.
- Article 9 paragraph 3 of the Directive provides that requests for prior authorisation must be treated within a reasonable time limits (as did the Proposal, although it did no more) made public in advance, and that when considering a request for cross-border healthcare Member States shall take into account the specific medical

condition and urgency and individual circumstances. In addition to this material norm article 9 paragraph 4 sets out the procedural requirements developed in the case law such as the right to a reasoned decision on a case by case basis and subject to judicial review.

In this manner undue delay was given an appropriate role, preventing divergence on this criterion with the case law as well as in relation to Regulation 883/2004. As a result the consistency between the three systems was increased, while reducing the room to invoke the freedom to provide (or enjoy) services directly without reference to the Directive.

#### *The right to reimbursement*

The basis for reimbursement (at the level prevailing in the Member State of treatment for Regulation 1408/71 and at that of the Member State of affiliation for Article 56 TFEU, or now the proposed patients' rights Directive) will continue to differ under the two regimes. Whereas under Regulation 1408/71 the general rule is that patients do not have to meet the costs of treatment directly, under the regime of the proposed patients' rights Directive payment by the patient subject to subsequent reimbursement is the rule.

#### *Would an amendment of the social security rules have sufficed?*

These observations on the similarities and the differences between the two systems raise the question whether a separate Directive is in fact necessary and whether amending Regulation 1408/71 (read: its successor Regulation 883/04) would have sufficed instead. This could have been done, for example, by simply providing that the more favourable of the two funding regimes applies and by codification of key elements of the case law. Would this not have been logically consistent with the aim of strengthening the renewed social agenda?

It is striking that this arguably most obvious solution did not even feature as an option in the Impact Assessment. Perhaps it is partly explained by the fact that two competing Directorates General of the Commission are involved here (SANCO, for the Directive, and EMPLOY for Regulation 883/2004). In this context it is important what type of dynamics the Directive is likely to entail: in large measure this is likely to be determined by the new patients' rights and to a lesser extent by the cooperation provisions. However the increasing need to provide comparable data on prices and quality and even costs



(when required to motivate a reimbursement granted or requested) triggered by the “old” patients’ rights may yet help shake up national healthcare markets.

## **7. The framework for cross-border healthcare: the “old” patients’ rights**

We now move on to the codification of the Court’s patient mobility case law.

### *Reimbursement of actual costs*

The core of the codification of the obligations for the Member State of affiliation is formed by article 7 on general principles for reimbursement of costs; article 8 regarding prior authorisation requirements and article 9 on the procedures concerned.<sup>30</sup>

As a counterpoint to the obligations of the Member State of treatment set out in Article 4 of the proposed patients’ rights Directive, its Article 7 sets out a number of obligations on the Member States of affiliation in relation to patients (“insured persons”) travelling to other Member States for treatment that is covered by the benefits to which they are entitled in their Member State of affiliation. The most important of these obligations is that the Member States of affiliation must reimburse the actual costs for such treatment up to the level applicable to the same or similar treatment in the Member State of affiliation. However Member States are not blocked from going beyond their obligations under the Directive to provide supplementary reimbursement of treatments in other Member States.<sup>31</sup>

Member States of affiliation will also be required to have a transparent mechanism for the calculation of such costs, which must be based on objective, non-discriminatory criteria that are known in advance.<sup>32</sup> This seemingly self-evident requirement is likely to have far-reaching consequences especially for benefits in kind and NHS systems that in most cases are likely to lack useful pre-existing cost information on which reimbursement can be based. Given the difficulties associated with the introduction of sound cost accounting

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<sup>30</sup> Article 5 on the responsibilities of the Member State of affiliation provides an anchor for the various obligations, such as ensuring that the cost for cross-border healthcare is reimbursed in accordance with the Directive.

<sup>31</sup> HvJ EG, zaak C-208/07, *Petra von Chamier-Glisczinski v Deutsche Angestellten-Krankenkasse* [2009] ECR I-6095.

<sup>32</sup> Cf. Case C-358/99, *Müller-Fauré*, supra note 14, para. 107; Case C-372/04 *Watts*, supra note 5, para. 143. Cf. Davies, supra note 8, at 164-165.

principles where such practices were not already in place, a common EU understanding of the relevant costing principles may be required before long.

#### *Supplementary conditions*

Article 7 paragraph 7 of the Directive also provides for the possibility for the Member State of affiliation to impose additional conditions at national, regional or local level upon insured persons who are requesting reimbursement of costs for cross-border healthcare, such as selection criteria and conditions of an administrative or regulatory nature, as it would impose if this healthcare were provided in its territory. However these conditions cannot be discriminatory or go beyond what can be justified based on the planning exception with respect to ensuring access to healthcare and/or controlling healthcare expenditure which is repeated at this point of the Directive (and which will be more fully addressed below).

#### *Non-hospital care: full liberalisation*

What the Proposal had made explicit is regulated by omission in the Directive: patients are entitled to seek non-hospital care which is covered by their national social security regime in other Member States without prior authorization, and are entitled to reimbursement at the level as if the care had been provided in the Member State of affiliation. It is assumed therefore that this will by definition not undermine the financial equilibrium of social security systems.

Although the categories intramural and extramural care do not appear in the Directive – the distinction is now between healthcare that may or may not be subjected to a prior authorisation requirement – the distinction between these two types of care remains sensitive. Apart from the question whether an overnight stay is involved which is easily answered (although it may be answered differently between different jurisdictions or different healthcare providers within them) healthcare that can be subject to prior authorisation requirements also concerns healthcare involving the use of highly specialised and cost-intensive infrastructure or medical equipment.<sup>33</sup> The Proposal intended to regulate this based on a list to be set up and regularly updated by the Commission. In the Directive the Member States themselves determine which types of care are involved and notify these to the Commission.

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<sup>33</sup> Case C-512/08, *Commission v France* (extramural treatment), judgment of 5 October 2010 (nyr).

*Hospital care and specialised care: the end of prior authorisation regimes?*

For the most contested type of cross-border care, that which requires at least one overnight stay as well as specialised and cost-intensive care the Directive allows the Member State of affiliation to introduce a prior authorisation system.<sup>34</sup> Article 8 paragraph 2 reads as follows:

“Healthcare that may be subject to prior authorisation shall be limited to healthcare which:

- (a) is made subject to planning requirements relating to the object of ensuring sufficient and permanent access to a balanced range of high-quality treatment in the Member State concerned or to the wish to control costs and avoid, so far as possible, any waste of financial, technical and human resources and:
  - (i) involves overnight hospital accommodation of the patient in question for at least one night; or
  - (ii) requires use of highly specialised and cost-intensive medical infrastructure or medical equipment;
- (b) involves treatments presenting a particular risk for the patient or the population, or
- (c) is provided by a healthcare provider which, on a case-by-case basis, could raise serious and specific concerns relating to the quality or safety of the care with the exception of healthcare which is subject to Union legislation ensuring a minimum level of safety and quality throughout the Union.

Member States shall notify the categories of healthcare referred to in point (a) to the Commission.”

Moreover, a prior authorization system must be limited to what is necessary and proportionate, and may not constitute a means of arbitrary discrimination.

The Proposal had set up something very different: the Member States would have had to provide actual evidence that the outflow of patients due to cross-border hospital care

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<sup>34</sup> Hospital services and specialized care concern healthcare that requires an overnight stay (for one or more nights) or that is included on a limited list that is established according to comitology procedures and

*seriously* undermines their social security system or planning in the hospital sector. However, the Commission clearly believed these data did not exist and even proposed that the Directive should state so explicitly.<sup>35</sup>

The Directive itself requires only that prior authorisation systems are not just based on planning requirements related to access and/or costs (the financial balance of the social security system is no longer cited as a separate overriding reason of general interest but is also subsumed by the planning exception) but also meet the requirement of necessity and proportionality. It seems that this is a much lighter burden of proof which also approximates the approach that the Court itself has followed so far more closely. A secondary but not unimportant aspect is that in this manner evidence of the underlying cost structure is also less likely to be required. The chance that Member States will prefer to forfeit the opportunity of introducing a prior authorisation system in order to avoid having to justify their costs is likewise reduced: hence there is more room to introduce or maintain prior authorisation systems under the Directive than there was under the proposal.

Apart from article 8 paragraph 2 sub (a) about prior authorisation requirements for “intramural care” article 7 paragraph 7 on conditions, criteria of eligibility and regulatory and administrative formalities (such as the requirement to consult a general practitioner in order to obtain a referral for specialised care) article 7 paragraph 9 opens the possibility to subject the rules on reimbursement themselves to limitations based on the planning exception. In all three cases the planning exception is invoked, i.e. planning requirements relating to the object of ensuring sufficient and permanent access to a balanced range of high-quality treatment in the Member State concerned or to the wish to control costs and avoid, so far as possible, any waste of financial, technical and human resources.

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involves the use of highly specialized and costly medical infrastructure or equipment, or involves treatments that present a particular risk to the patient or the population at large.

<sup>35</sup> Thus recital 31 of the Preamble to the Proposal read: “The evidence available indicates that the application of free movement principles regarding use of healthcare in another Member State within the limits of the cover guaranteed by the statutory sickness insurance scheme of the Member State of affiliation will not undermine the health systems of the Member States or financial sustainability of their social security systems.” Likewise in its Explanatory Memorandum (supra note 18, p. 16) the Commission clearly states that based on its Impact Assessment, “there is no evidence to suggest that such care [hospital care] will undermine the financial sustainability of health and social security systems overall or the organization, planning and delivery of health services.” Ibid., at p 14: “The evidence available as set out in the impact assessment indicates that the application of free movement principles regarding use of healthcare in another Member State within the limits of the cover or the sickness insurance scheme of the Member State of affiliation will not undermine the health systems of the Member States or financial sustainability of their social security systems”. I.e. not undermine at all, let alone seriously.

More remarkable is the fact that based on article 4 paragraph 3 of the Directive the same planning exception applies for the Member States of treatment. In this respect the Directive is both more detailed and more coherent than the original Proposal, although it also means significantly increasing the scope of the overriding reason of general interest as formulated in the case law. A final important difference is that whereas the Proposal required cross-border healthcare to “seriously undermine” the financial balance and/or planning of healthcare in the Member State of affiliation before the exception could be invoked the Directive itself only mentions the existence of an “objective justification”. This means the requirements for a successful reference to the overriding reason of general interest have been relaxed considerably. In relation to the proposal and in some respects the case law (in relation to safeguard measures as well as eligibility criteria and the reimbursement rules themselves). These are changes with respect to the Proposal which provide the Member States additional possibilities to fence off their national healthcare markets. Hence, apart from the fact that the norm for the exception was relaxed it can now also be applied more widely.

#### *Reasons to refuse prior authorisation*

Before discussing the new patients’ rights as well as cooperation I will briefly cover another innovation in the Directive: the reasons for refusal.

Paragraph 6 of Article 8 of the Directive now encapsulates the possible grounds for a refusal of a request for prior authorisation. The availability or otherwise without “undue delay” of alternative treatment options within the Member State of affiliation is the ground that has so far played a prominent role in the case law. In addition the new provision lists an unacceptable patient (health) risk; a risk that the general public will be exposed with reasonable certainty to a substantial safety hazard; and healthcare to be provided by a healthcare provider that raises serious and specific concerns relating to the respect of standards and guidelines on quality of care and patient safety. This limitation of the grounds for refusal is appropriate given the broadened scope for requiring prior authorisation respectively throwing up barriers to cross-border healthcare based on planning exceptions.

### **8. Common principles for healthcare: the “new” patients’ rights**

### *Rights to accountability and transparency*

Consistent with Article 168 paragraph 7 TFEU, the Directive starts by setting out the key principle that the Member State of treatment bears responsibility for the organization and delivery of healthcare. The main innovation in this respect is that its Article 4 sets out common principles for healthcare that can be seen as a new set of patients' rights. These correspond with the responsibilities of the Member States of treatment and are not based on the free movement case law of the Court. Instead, the principles are based on Council Conclusions of 2006 to the same effect,<sup>36</sup> which drew on the existing systems (or at least ambitions) of the Member States.<sup>37</sup> Universality, access to high-quality care, equity and solidarity are asserted as the guiding principles for Member States of treatment.

In substance the Directive mainly requires the Member States of treatment to provide quality and safety standards for healthcare based on dynamic international best practice standards (the application of which is monitored and enforced), and to ensure the right to the information necessary for an informed choice, the right to make complaints and guarantees of redress and remedies, to privacy, equal treatment and non-discrimination. The right to an informed choice involves in particular information about availability, prices and outcomes of healthcare. The Member State of treatment is obliged to provide for adequate systems of liability insurance. Finally, the Member States of treatment must also create national contact points where patients can access the information concerned.

Especially the duty to provide information appears to be of greater significance. It is worth noting that the relevant information to enable patient choice is hardly available at national level, never mind information relevant to patient choice that is comparable to information derived from other Member States.<sup>38</sup> Article 4 does include the proviso that Member States of treatment who already provide "relevant information" to their inhabitants do not need to provide more extensive information for the benefit of patients from other Member States. In this context the meaning of the term "relevant information"

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<sup>36</sup> Council Conclusions on common values and principles in European Union health systems, OJ 2006 C146/1 (Statement in Annex).

<sup>37</sup> This corresponds with the overarching values identified, *ibid.*, para. 6. The Council had resisted earlier proposals to define patients rights at EU level. Cf. T.K. Hervey, "The legal basis of European Community public health policy", in M. McKee, E. Mossialos and R. Baeten (eds), *The impact of EU law on health care systems* (PIE.-Peter Lang, Brussels 2002), pp. 46-47.

<sup>38</sup> Cf. O. Damman, Public reporting about healthcare users' experiences: the Consumer Quality Index (PhD thesis Tilburg University, April 2010).



is significant: the Proposal had required “all relevant information”. Should the information concerned facilitate making choices between treatments in different Member States or just between treatment options? At least the latter appears probable. The references to information concerning “outcomes of the healthcare provided” have been purged from the Directive. The toughest category however – that of quality – has been retained. This limited obligation to provide information may yet provide the thin end of the wedge towards transparency-based reform.

#### *Universal applicability for the new patients’ rights?*

In the proposal the scope of this important provision was not clearly defined:

- The Council Conclusions on which the text is based are clearly of general application.
- The heading (“Member State of treatment”) suggested norms that apply for patients from other Member States.
- The wording (referring to healthcare in general, and not to cross-border healthcare) of the provision itself implied a general application.

This has now been changed: the responsibilities concerned are clearly marked as regarding cross-border healthcare. This does not change the general applicability of the underlying Council Conclusions. Moreover it is difficult to see how such fundamental norms of accountability and transparency could possibly be implemented solely for the benefit of patients from other Member States. Hence it is assumed here that they are universal rights that will come to apply to all patients, not just those moving across borders. This would involve a major step in terms of accountability to patients, and by healthcare providers.

#### *Safeguards measures for Member States of treatment*

Although the Proposal enabled a derogation from free movement to the Member State of affiliation in the shape of prior authorisation requirements it foresaw none for the Member State of treatment. In this regard the Directive has introduced an important change: according to article 4 third paragraph of the Directive the same planning exception (concerning access to healthcare and/or cost control) that can be invoked by the Member State of affiliation will become available to the Member State of treatment as well. The

measures introduced in this respect must be made public in advance. This is an exception to the principle of non-discrimination with regard to nationality that applies to patients from other Member States more generally, including with respect to the prices charged for the healthcare provided.

This is significant as in the absence of tariff rebalancing it may clearly happen that charges for treatment of patients from other Member States are out of line with actual costs but attractive to the healthcare provider in question (e.g. to “fill empty beds”). In such cases payment is likely to cover only marginal costs rather than a share of fixed costs – putting pressure on public funding. Meanwhile competition between healthcare providers to attract mobile patients is likely to trigger new dynamics feeding through into the national market. On the one hand such developments could well contribute to undermining the financial sustainability and coherence of the existing national social security systems – while on the other hand contributing to pressure toward much needed rationalization and rebalancing. Hence the impetus toward change as a result of the rights Directive is likely to involve Member States in their role as Member States of treatment, not just as Member States of affiliation.

## **9. Cooperation**

The Directive envelopes five types of cooperation that were so far the subject of the intergovernmental Open Method of Coordination (OMC).<sup>39</sup> This concerns:

- Mutual assistance and cooperation: this regards all kinds of (including bilateral) cooperation including the information exchange between the national contact points that are to be established according to article 4 of the Directive.
- Recognition of prescriptions issued in another Member State: if a medicinal product is authorised to be marketed on their territory prescriptions issued for such a product in another Member State must be recognised and dispensed (this provision enables delegated rule making by the Commission).

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<sup>39</sup> Cf. S.L. Greer en B. Vanhercke, “The hard politics of soft law: the case of health”, in E. Mossialos et al. (red), *Health systems governance in Europe: the role of European law and policy* (Cambridge University Press, Cambridge 2010), 186.

- European reference networks: these are voluntary networks that aim to combat in particular rare diseases requiring highly specialised healthcare, and promote e.g. the development of new diagnoses and treatments (this provision enables delegated rule making by the Commission as well).
- E-Health: this concerns electronic developments in healthcare and the work that is being done on developing the interoperability between systems, the necessary minimum data set, with a view toward building a high level of trust and security.
- Cooperation on health technology assessment: this aims to avoid needless duplication of procedures and thereby to contribute to a faster and more effective assessment of the relevant technological developments.

Although not key in the harmonisation setting of the Directive these elements are nevertheless important to the continued collaboration between the Member States in this field and by creating cross-border policy communities they may contribute of support for further integration of healthcare markets – possibly by spill-over, and including further harmonisation.

## **10. Further analysis**

The development of the law on patient mobility appears to fit the mould of the standard interaction between positive and negative integration: first national measures obstructing the freedom to provide services (in this case) are struck down by the Court, and then the need arises for re-regulation to fill the gap left, providing sufficient consensus for a more liberal Community regime to emerge. This can be illustrated by a more detailed discussion of the following two topics: justifying prior authorisation requirements; and the scope for change based on the “new” patient’s rights.

### *Prior authorisation requirements: liberalisation*

As we have seen the scope for invoking the planning exception has been increased in the Directive. However the necessity and proportionality of the measures involved – notably prior authorisation requirements – remain to be shown by the Member State of affiliation. The practical difficulties of demonstrating the need for a prior authorization system are considerable. The Proposal with its exception based on the financial balance of the social

security system raiser questions such as how in a sector where the cost of an individual treatment is not known could it be plausibly argued that transferring such treatments abroad would jeopardise the financial balance of the system?; and how to demonstrate the financial balance of a social security system is threatened if basic measures of sound administration and business practice such as proper cost accounting and tariff rebalancing are lacking.

This problem may have been reduced but did not disappear where the planning exception speaks of the wish to control costs and ways to avoid wasting resources. It may therefore be that in spite of the Member States' (in Council) best efforts to increase the scope of the planning exception its application may raise difficulties for them.

#### *New patients' rights: harmonisation*

Apart from harmonisation of the standards for the prior authorisation scheme, harmonisation is to be found in the main innovation of the proposal in relation to the case law, which are the obligations of Member States of treatment, or “new” patients' rights. These are likely to ensure the enduring impact of patient mobility on Member States both when sending patients abroad, and when receiving them. The obligations involved have their origins in Council Conclusions of 2006,<sup>40</sup> but under the Directive will be made legally binding and justiciable. Moreover, the ensuing rights – especially to accountability, and transparency on availability, prices and outcomes of healthcare – will accrue not just to mobile patients, but to all patients in each Member State. Arguably, this is the key element of positive integration to be introduced by the Directive. In sum, the addition of the broader “new” patients' rights (to accountability and transparency) to the codification of the “old” patients' rights to reimbursement could create momentum for broader change.

Potentially we are therefore looking at a chain of events leading toward fundamental change. The links of this chain are the following:

1. the creation of rights to reimbursement for treatment abroad in the patient mobility case law of the Court
2. the creation of rights to a certain standard of treatment abroad by the Directive

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<sup>40</sup> Supra note 36.

3. the extension of these rights to patients treated at home by the Directive
4. the leveraging of these rights (especially in terms of transparency and accountability) to begin transforming national healthcare systems.

So far thus hypothetical dynamic is at step 2.

By choosing the legislative route on patient mobility the Commission is taking the calculated risk that in the course of the legislative process the relatively clear-cut and far-reaching case law of the Court based on Article 56 TFEU itself would be diluted. This may now have paid off because the Directive incorporates a number of elements designed to set in motion further changes in healthcare systems at national level – to a significant degree precisely based on “patients’ rights”, which will in the longer term promote both greater efficiency and accountability.

At the same time the fact that the focus both of the recent case law and of the proposed Directive has been centred on the patient fits well within a consumer (and/or citizen) oriented approach to European integration and is consistent with the social policy agenda that is being developed as a response to public scepticism about the benefits of the EU – just as it would be in line with a demand based economic view. It is also consistent with most perspectives that accept the potential of a positive role for the EU.

## **11. Conclusion**

The Directive sets out a framework for cross-border healthcare in the EU. In doing so it follows the logic of positive integration following negative integration, and being combined with a formalisation of OMC based cooperation. Old rights to reimbursement of costs are supplemented by new rights to transparency and accountability. Benefits are not harmonised but the conditions for access to cross-border healthcare to a significant extent are.

The main technical content of the Directive can be divided into three parts:

- In the first place, the Directive is based on the planning exception. For the Member State of affiliation this concerns (i) the system of prior authorisation in article 8 paragraph 2, as well as (ii) the other requirements that can be imposed in

article 7 paragraph 7, (iii) the possibility to limit the application of the rules on reimbursement in article 7 paragraph 9. For the Member States of treatment the planning exception can be invoked for (iv) safeguard measures. (It is worth noting that options (ii) through (iv) did not appear in the original Proposal.) The norm applied is whether recourse to this exception is objectively justified, necessary and proportional. In line with the case law – but in contrast to the Proposal – it does not appear necessary for the Member States to provide quantitative evidence (a burden of proof that would have been difficult to meet given the likely scale of cost imbalances prevalent in the various healthcare systems).

- Second (and again in contrast to the Proposal) the Directive is clearly based on the concept of “undue delay”, which appears in the limited set of grounds on the basis of which prior authorisation may be refused in article 8 paragraph 5a, and in the administrative requirements for this procedure (concerning time limits) in article 9 paragraph 2a. In this manner the Directive is also more in line with Regulation 883/2004 as well as with the relevant case law than was the proposal.
- Third, and finally, other due process guarantees are imposed as well, such as the right to a decision on a case by case basis that is subject to judicial review in Article 9(3), and the (entirely new) limited list of grounds for refusal in article 8(5a) that was already mentioned. This completes the material and procedural norms that had already been developed in the case law.

Based on these three elements the Directive forms a coherent system that for this reason alone already forms an improvement on the Proposal concerning the aspects just discussed. However apart from leaving less room for uncertainty it also leaves less room for secondary effects such as exposing the way in which the costs of treatment are accounted for. In sum, the EU’s approach followed the familiar sequence whereby striking down barriers to the market freedoms breeds the need for elaborating rights and obligations in legislation that strikes a new balance between private freedoms and legitimate public interests. For healthcare this is a watershed given the constitutional barriers that had been erected in the Treaty against harmonisation in this field.



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The Dutch Healthcare Authority (NZa) is the regulator of health care markets in the Netherlands. The NZa promotes, monitors and safeguards the working of health care markets. The protection of consumer interests is an important mission for the NZa. The NZa aims at short term and long term efficiency, market transparency, freedom of choice for consumers, access and the quality of care. Ultimately, the NZa aims to secure the best value for money for consumers.



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even if they do not necessarily fall within 'Law & Economics' in the sense of the specific school of thinking which has arisen out of the work of US academics and is now well-established everywhere.

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