

## Miek Peeters, Martin McKee and [Sherry Merkur](#) EU law and health professionals

### Book section

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# 14 | *EU law and health professionals*

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## 1. Introduction

In November 2005, a young French woman received the world's first ever face transplant. The operation was carried out in Amiens, France, by a team that was mainly French but contained one Belgian. This case exemplified very visibly the benefits that free movement of health professionals can bring to the delivery of the increasingly complex health care being provided in Europe. The benefits of professional mobility extend far beyond the very specialized care involved in that exceptional case. Within Europe, there are both surpluses and shortages of health professionals. The opening of borders offers a means to ensure that appropriate health professionals and potential patients are brought together, whether through movement of patients or, as is discussed in this chapter, movement of professionals. In addition, there are particular issues that arise in border areas, where patients may live closer to a hospital across the border than to one in their home state.<sup>1</sup> Especially where these areas are sparsely populated, it is simply good management of resources to ensure that health professionals can also move across borders, working in the most appropriate facilities, wherever they are situated.

Yet there are also dangers. The large economic differences between Member States, which have grown substantially with the two most recent enlargements to the European Union, pose a challenge for the poorer countries. A plentiful supply of health professionals, coupled with formidable physical barriers to migration, meant that, during the communist era, wages were very low in comparison with other occupations. The facilities in which health care was delivered reflected this situation. Cheap labour reduced the incentive to invest in labour-saving technology, which, in any case, was expensive and,

<sup>1</sup> H. Legido-Quigley *et al.*, 'Patient mobility in the European Union', *British Medical Journal* 334 (2007), 188–90.

in some cases, unobtainable because of western restrictions on the export of technology with potential security implications, such as computers. As a result, the inherited infrastructure was often highly dependent on large numbers of staff.<sup>2</sup> The removal of borders within Europe has allowed many of the next generation of health professionals needed to staff these facilities to move west, in some cases beyond the EU to the United States, thereby threatening the viability of many traditional facilities.<sup>3</sup> Although a study conducted in 2005–6 in six Member States by the High Level Group on Health Services and Medical Care suggested that health professional mobility was then still limited, they noted the potential for it to increase.<sup>4</sup> The challenges are not confined to those countries losing health professionals. Western European countries face problems too, sometimes of their own making.<sup>5</sup> The chaos associated with the implementation of a new postgraduate medical training system in the United Kingdom in 2007 was in part due to the expectations raised across Europe and beyond among doctors considering movement to the United Kingdom.<sup>6</sup>

A particular concern relates to the situation where health professionals cross borders intermittently (to provide a service rather than to become established). This could compromise continuity of care, especially where complex after-care is needed or where a patient with a chronic disorder subsequently develops complications.<sup>7</sup>

<sup>2</sup> M. McKee, 'Cochrane on Communism: the influence of ideology on the search for evidence', *International Journal of Epidemiology* 36 (2007), 269–73.

<sup>3</sup> M. M. Bala, and W. M. Lesniak, 'Poland is losing its doctors', *British Medical Journal* 331 (2005), 235; L. Starkiene *et al.*, 'The future prospects of Lithuanian family physicians: a 10-year forecasting study', *BioMed Central: Family Practice* 6 (2005), 41.

<sup>4</sup> European Commission, 'Work of the High Level Group in 2006', HLG/2006/8, 10 October 2006.

<sup>5</sup> M. A. Garcia-Perez, C. Amaya and A. Otero, 'Physicians' migration in Europe: an overview of the current situation', *BioMed Central Health Services Research* 7 (2007), p. 201.

<sup>6</sup> C. Black *et al.*, 'MTAS (UK Medical Training Application Service): which way now? Interview by Rebecca Coombes', *British Medical Journal* 334 (2007), 1300.

<sup>7</sup> K. Hendrickx, 'Buitenlandse 'eendagschirurgen' aan de slag in Belgische klinieken', *De Morgen*, 15 March 2008. As highlighted in this journal article, the Belgian association of esthetical surgeons denounced the 'blitz surgery' of French and Italian aesthetic surgeons, who just come to perform specific operations and then disappear.

This chapter examines the European legal framework within which health professionals operate. It concentrates mainly on the arrangements by which health professionals move between Member States. However, the reach of European law extends far beyond their professional mobility. Like other workers, they are subject to the panoply of legislation on issues as diverse as pension provision, discrimination, and health and safety. Clearly, it is neither possible nor especially useful to review all of these areas. There is, however, one area that will be considered in more detail. This is the Working Time Directive, which, as will be discussed, is having profound and largely unintended consequences for health professionals and the configuration of health care delivery in Europe.

## 2. Mobility of health professionals

### A. Introduction

The legal framework for patients seeking medical treatment in an EU Member State other than the one in which they are insured has been the subject of intense discussion for over a decade.<sup>8</sup> For many years, governments and others were in a state of denial, taking the view that the Treaty provisions provided adequate safeguards to prevent patients moving across borders at the expense of funders, save in very limited circumstances. This view was maintained even though academic commentators had long advised otherwise.<sup>9</sup> The *Kobll*<sup>10</sup> and *Decker*<sup>11</sup> cases shattered this complacency and, although the immediate implications of those cases applied to only a very narrow set of circumstances, unleashed a series of legal challenges that progressively expanded the circumstances in which patients could obtain treatment abroad without prior authorization. Although this issue is addressed elsewhere in this book, it illustrates several important

<sup>8</sup> M. McKee, E. Mossialos and P. Belcher, 'The influence of European Union law on national health policy', *Journal of European Social Policy* 6 (1996), 263–86.

<sup>9</sup> P. G. Svensson and P. Stephenson, 'Health care consequences of the European economic community in 1993 and beyond', *Social Science and Medicine* 35 (1992), 525–9.

<sup>10</sup> Case C-158/96, *Kobll v. Union des Caisses de Maladie* [1998] ECR I-1931.

<sup>11</sup> Case C-120/95, *Decker v. Caisse de Maladie des Employés Privés* [1998] ECR I-1831.

points that must be borne in mind when reading this chapter. First, the failure by European governments to provide a sound legislative basis for health care in Europe has created a vacuum that the Court has been forced to fill.<sup>12</sup> As it can only decide on those cases brought before it, some of which have been highly atypical, it has often left as many questions unresolved as it has answered. Second, this is an area that has been afflicted with numerous unintended consequences. Here, however, the subject under consideration is the movement of health professionals.

Professionals working in the health sector were the first professional group to be the subject of secondary European legislation facilitating free movement. This follows directly from the EC Treaty, which explicitly mentions the need for coordination of health professions (Article 47(3)). The first group to receive attention was doctors. The so-called ‘Doctors’ Directives’, Directives 75/362/EEC and 75/363/EEC (later codified in the Doctors’ Directive, Directive 93/16/EEC),<sup>13</sup> have become the model for sectoral directives for other health professions: nurses responsible for general care, dentists, veterinary surgeons, midwives and pharmacists. The remaining categories of health professionals fell under the scope of the general directives.

These Directives – subsequently consolidated into the single Directive 2005/36/EC (see below) – on the recognition of professional qualifications, contrary to what might be expected from their title, not only regulate the ‘take up’ and ‘access’ to the profession, but also coordinate professional rules concerning the ‘pursuit’ of the profession, such as the requirements related to presentation of documents and the applicability of national (disciplinary) measures. Thus, the Directive(s) on the recognition of professional qualifications provide the legal basis for all forms of mobility for health professionals, whether they are establishing themselves in another Member State or simply providing services on an occasional or temporary basis.

This section examines the European regulatory framework for the recognition of health professional qualifications, taking the old

<sup>12</sup> P. Kanavos and M. McKee, ‘Cross-border issues in the provision of health services: are we moving towards a European health care policy?’, *Journal of Health Services Research Policy* 5 (2000), 231–6.

<sup>13</sup> Council Directive 93/16/EEC to facilitate the free movement of doctors and the mutual recognition of their diplomas, certificates and other evidence of formal qualifications, OJ 1993 No. L165/1.

Directives as a starting point, before moving on to the consolidating Directive 2005/36/EC.<sup>14</sup> It asks to what extent the old and new legislation succeeds in ensuring the benefits of free movement while avoiding the pitfalls, in particular in relation to patient safety. Finally, it will highlight the issue of free movement of (para)medical students.

### *B. Before Directive 2005/36/EC: sectoral and general directives*

#### **Sectoral and general directives**

The rights enshrined in the Treaties establishing free movement of workers and services and freedom of establishment for regulated professions formed the basis of secondary legislation that sought to coordinate the rules of Member States concerning access and the pursuit of a profession. The general principle underpinning this body of legislation has been that of mutual recognition. Thus, Member States were required to accept that a qualification obtained elsewhere met a minimum level, measured almost exclusively in terms of the length of study. This approach was driven by the philosophy of the internal market, wherein mobility took priority over other considerations.

Directive 2005/36/EC on the recognition of professional qualifications, which was to be implemented by Member States by the end of October 2007, consolidated two earlier types of directives: sectoral and general ones.

*Sectoral directives* related to a named profession and provided for automatic recognition of diplomas where the training required for the award of the diploma met the minimum requirements. Many health professions were the subject of a sectoral directive (doctors, nurses, dentists, midwives, pharmacists and veterinary surgeons). The procedure of automatic recognition of basic professional qualifications obliged every Member State to act positively in response to every request for recognition. They could not decline someone with one of the diplomas listed in the relevant directive (for example, by requiring that the applicant undertake further examination). The fact

<sup>14</sup> European Parliament and Council Directive 2005/36/EC on the recognition of professional qualifications, OJ 2005 No. L255/22–142; M. Peeters, 'Free movement of medical doctors: the new Directive 2005/36/EC on recognition of professional qualifications', *European Journal of Health Law* 12 (2005), 373–96.

that a qualification is on that list implies that the training entailed in obtaining it meets the minimum requirements.

The recent enlargements of the EU into central and eastern Europe gave rise to a specific issue concerning qualifications. Prior to 1991, physicians in the three Baltic states trained under the Soviet medical system, with narrow specialization at undergraduate level. This also applied to some physicians from the central European countries who had trained in the USSR, especially those working in the public health, or sanitary-epidemiological service. This was not comparable with medical training acquired in the rest of Europe. In addition, some other qualifications obtained in countries before they acceded to the EU did not meet the criteria for mutual recognition. In response, the system of 'acquired rights' was created. This served as a mechanism that permitted the recognition of diplomas for which training was commenced before a certain date (the reference date) and therefore did not meet (all) the minimum requirements. This reference date was usually either the initial date of the entry into force of the Directive or the date of accession of the Member State, where it only became a member after the entry into force of the Directive. However, other reference dates were possible where a Member State sought a specific derogation, including those that arose following German unification. If the minimum requirements were not met, then they could have been compensated for by proof of having obtained appropriate professional experience. A so-called 'certificate of acquired rights' issued by the home state was required to accompany the diploma, and to state that the person had been engaged effectively and lawfully in the relevant activities for at least three of the five years prior to the date of issue of the certificate.

In addition to these 'general' acquired rights, there were 'specific' rights created on the occasion of the 2004 enlargement in relation to the Soviet Union, Czechoslovakia and Yugoslavia. These applied to diplomas for which training began in one of these states before they broke into independent successor states, with the date of break-up acting as the reference date. In these cases, a certificate of acquired rights issued by authorities in the successor states must also confirm that the professional qualifications in question have the same legal effect as ones issued currently in that Member State.

Finally, there were 'special' acquired rights, where particular professions in individual countries had been subject to specific requirements,

such as Polish nurses and midwives. If the training begun before the 'reference date' was in full conformity with the minimum training requirements of the Directive in question, then the home Member State could have issued a so-called 'certificate of conformity', stating that the relevant diploma was covered by the Directive and that it complied with the minimum training requirements.<sup>15</sup>

At each enlargement of the European Union, therefore, the sectoral directives have been modified so as to remove any barriers to the adoption of the *acquis communautaire*. The official titles of the relevant diplomas from new Member States were listed in the 'recognition lists' of the relevant sectoral directives.

As far as coordination of the *pursuit* of a profession is concerned, measures within the sectoral directives generally differed depending on whether they applied to the right of free establishment or to the free movement of services, although a few applied to *both*. The latter obliged host Member States to inform the incoming professionals about health and social security legislation, provide information on ethical issues and to guarantee that they have acquired the necessary language skills. They also allowed the host Member State to ask, in case of legitimate doubt, to confirm that the diploma, certificate or title was compliant with the minimum requirements listed in the relevant directive.

Measures to facilitate the pursuit of a profession by a migrant doctor wishing to *establish* him/herself in another Member State involved rules about documents and oaths. When a host Member State required that its citizens produce a certificate of good standing, of physical or mental health, and/or an oath or solemn declaration before practising the profession, it could ask the same from another EU citizen. However, it had to accept equivalent documents if the home Member State did not require such certificates, and had to permit an appropriate form of oath or declaration for foreign doctors.

Other measures related to cases where there was evidence that a migrant doctor may have been guilty of professional misconduct or was unfit to practice. If the host Member State obtained knowledge of a serious matter involving the migrant doctor that occurred

<sup>15</sup> R. Pochmarski, 'Working in Europe without frontiers, mutual recognition of diplomas in the enlarged EU', Report of the International Seminar, 'From Mutual Recognition to Mutual Communication', Warsaw, September 2004, p. 48.



outside its territory before the individual moved, it could – but did not have to – inform the Member State of origin. If disciplinary, legal or administrative measures were initiated in the host Member State, the Member State of origin had an obligation to forward all necessary information regarding disciplinary action or criminal penalties previously imposed.

There were circumstances in which a health professional could seek to provide *services* on a temporary or occasional basis in one Member State without becoming established there. Examples included short-term visits to undertake a particular procedure, as might be the case where a world-renowned specialist joined a surgical team conducting an unusually complex operation, or where the health professional remained in his or her Member State of establishment but examined images from a patient in another Member State.

The decision to grant permission to a foreign health professional to provide ‘services’ involved legislation that was, overall, rather more flexible than that dealing with establishment. Here, registration bodies faced certain constraints. Host Member States were explicitly obliged to exempt doctors providing services, on this basis, from any requirement to obtain authorization from or to join or register with a professional body. They could – but did not have to – take measures to implement procedures on professional conduct in their territory, by requiring either automatic temporary registration, *pro forma* membership of a professional organization or registration in a central register, provided that this did not delay or in any way complicate the provision of services or impose additional costs on the person providing the services. The sectoral directives also forbade any measure that compelled registration with a public social security body involved in settlement of accounts for services rendered, such as a sickness fund. The doctor only had to inform this body in advance or, in urgent cases, subsequently about the services provided.

Furthermore, the host Member State could request certain documents from the service provider: a prior declaration that informed the host Member State that he/she had provided services previously, a certificate of legal establishment and a certificate that the person held the necessary diploma, certificate or title. Telemedicine provides an interesting case, as the health professional does not physically move to the territory of another Member State so only the ‘service’ itself moves. This seemed to be excluded from the scope of the directives, which

applied only when the service involved a ‘temporary stay’ in its territory. Telemedicine includes a wide range of cross-border services whereby the health professional remains in his or her Member State of establishment but, for example, examines images from a patient in another Member State, or even operates on this patient by means of telesurgery. This is clearly an area where case-law is likely to fill the gap.

*General directives* arose when it became clear that, beyond those professions that were common to all Member States and where there was some very general consensus about what the terms meant (however, see below), there was a myriad of others where there was much less agreement. Often, a particular set of tasks was the responsibility of professionals with different titles in different Member States, or a package of care was the responsibility of a single profession in one Member State but divided among several elsewhere. As a consequence, a more general provision was needed that allowed for mutual – but not automatic – recognition of diplomas and other qualifications, without prior harmonization or coordination of the training requirements. The basic assumption was that every person who had obtained a professional qualification in a Member State possessed the necessary skills to practise that profession in another Member State, even if the duration and nature of training were different. Nevertheless, the host Member State was not *ipso iure* obliged to recognize their diplomas. The Member State where the individual sought employment could decide each case separately and could impose, as appropriate, compensating measures such as an aptitude test or an adaptation period. The general system included three directives: Directive 89/48/EEC concerned diplomas awarded by higher education establishments on completion of professional education of at least three years; Directive 92/51/EEC concerned programmes at a level corresponding to secondary education, possibly complemented by professional training or experience; and Directive 99/42/EC concerned qualifications in respect of professional activities not covered by the first two Directives.

For the *pursuit* of a profession, the general directives, unlike the sectoral ones, did not distinguish between establishment and provision of services. They simply coordinated the rules on required documents and oaths, as in the sectoral directives (see above). The relationship between the sectoral and general systems could be qualified as *lex specialis derogat legi generali*. Hence, the general system did not

apply to general practitioners and most specialist doctors, general nurses, dentists, veterinary surgeons, midwives and pharmacists. It applied to all the other regulated health professions that had not been dealt with in the sectoral directives. Examples included specialist nurses, specialist pharmacists, specialist dentists, psychologists, physicians, chiropractors, osteopaths and opticians. The range of possible professions created certain problems. For example, Portugal and Spain, when implementing the Directive, included in their domestic legislation an exhaustive list of professions included within its scope. They excluded those of pharmacist-biologist and hospital pharmacist, respectively, however, thus creating a barrier to the free movement of these individuals. As a consequence, the Commission referred both countries to the European Court of Justice.<sup>16</sup>

### Shortcomings

The minimum training requirements of the sectoral directives were established to guarantee the *quality* of training. In the famous cases *Kohll* and *Decker*, the Court concluded for the first time that, since the conditions of taking up and practising the medical profession were regulated by the Doctors' Directive, the quality of doctors within the EU was sufficiently guaranteed. Therefore, arguments based on public health concerns could not be used to justify limiting the free movement of patients. Theoretically, the Court simply applied the logic of the sectoral approach. The Directive was designed to facilitate free movement by precluding questions about the equivalence of the diplomas once minimum training standards were met. In the more recent case of *Stamatelaki*,<sup>17</sup> the Court followed the same reasoning. The argument that cross-border care could be restricted because the Greek social security institutions could not check the quality of treatment provided in private hospitals abroad was rejected because the Doctors' Directive rendered this unnecessary.

Actual practice was, however, slightly different. In many countries, there was evidence of distrust of foreign health professionals. The official minimum standards were seen as inadequate, as they ignored the content of training and the level of competence reached.

<sup>16</sup> See European Commission, 'Professional qualifications: infringement proceedings against Portugal and Spain', Press Release No. IP/06/1789, 13 December 2006.

<sup>17</sup> Case C-444/05, *Stamatelaki* [2007] ECR I-1385.

Furthermore, the acquired rights' system meant that even these minimum requirements did not always have to be met. While the general directives were based on the concept of mutual trust, even a brief review of the reality reveals that this had often been absent, with compensating measures often leading to cumbersome administrative processes that impeded free movement. The general system, however, offered more possibilities for quality assurance, as it permitted the host Member State to require these measures. It also overcame a problem with the sectoral system,<sup>18</sup> which was seen as slow to respond to changes in clinical practice – in particular, the emergence of new specialities – as it involved the co-decision procedure where the European Parliament and Council decided together, advised by advisory committees and groups of national officials.

One obvious issue to be considered in relation to mobility within Europe was the ability to communicate. According to the sectoral directives, host Member States had to ensure that professionals acquired the language skills necessary to communicate with their patients. The rule allowed – although not explicitly – host Member States to require that candidates have certain language skills in order to be allowed to practise. This was confirmed in the *Haim II* case,<sup>19</sup> which considered the situation of a dentist. The Court concluded that the reliability of the communication between the dentist and his patient; the administrative authorities; and the professional organizations was an imperative reason of general interest justifying that the admission as dentist is subject to linguistic requirements. How these were assessed was left to the discretion of the Member State, although the linguistic standard required could not be more than was required to do the job, establishing the principle of proportionality, whereby Member States could not demand systematic language exams. However, for medical doctors, this could be challenging, as the duty of the doctor to inform the patient in clear and comprehensible language and the reciprocal right of the patient to give informed consent demanded a high level of linguistic ability. However, the necessary language skills would differ among specialities and it seemed reasonable to require less profound knowledge from a pathologist than from a psychiatrist. On the other hand, the general

<sup>18</sup> F. Van Overmeiren, 'Kohll en Decker anders bekeken: de mobiliteit van gezondheidsmedewerkers in de Europese Unie', *Tijdschrift voor Sociaal Recht* 2 (2004), 354.

<sup>19</sup> Case C-424/97, *Haim II* [2000] ECR I-5123.

directives – unlike the sectoral ones – contained no stipulations about linguistic knowledge. A strict interpretation of the directives therefore created a paradox. The host Member State must ensure that a nurse providing general care had sufficient linguistic knowledge but needs not to do so for a specialist practitioner covered by the general system.

There were also some problems with the provisions on the pursuit of the profession. The exchange of information between Member States was far from optimal. Since the exchange of information was largely voluntary, doctors who were temporarily unable to practise their profession in one Member State may have been able to operate freely in a different one.<sup>20</sup> It was also necessary to consider sanctions against doctors whose standards were found to be inadequate. What should the host<sup>21</sup> Member State decide on the basis of information received? Could it simply forbid the doctor to practise on the basis of a decision made elsewhere? Should the Member State look at the underlying facts and then decide using its own legal instruments? In the absence of any explicit rules, the only guidelines seemed to be the non-discrimination rule and the principle of prohibition of obstacles to free movement, both based on Articles 39, 43 and 49 of the EC Treaty.

According to the non-discrimination<sup>22</sup> rule, Member States could not refuse a foreign doctor for reasons other than those they could invoke to stop their own nationals from pursuing the profession. The non-discrimination rule was, however, extremely difficult to apply in practice. Standards of practise differed enormously among the Member States. There were also certain activities that were forbidden in some states but not in others, such as performing an abortion. The situation was complicated further as Member States use different legal instruments, procedures and norms underlying disciplinary proceedings.<sup>23</sup> This raised the question of whether an individual

<sup>20</sup> H. Nys, *Medisch recht* (Leuven: Acco, 2001), p. 73.

<sup>21</sup> Or the home Member State when confronted with a sanction taken by the host country.

<sup>22</sup> It forbids also indirect discrimination. This is the case when a different treatment, not on the basis of nationality, but on the basis of another, legal criterion has the same disadvantageous effect.

<sup>23</sup> H. D. C. Roscam Abbing, 'Medical practice and disciplinary measures in the European Union', in P. Lens and G. Van der Wal (eds.), *Problem doctors, a conspiracy of silence* (Amsterdam: IOS Press, 1997), pp. 247–61; and H. D. C. Roscam Abbing, 'The right of the patient to quality of medical practice and the position of migrant doctors within the EU', *European Journal of Health Law* 4 (1997), 347–60.

banned from practising in his/her home country because of actions such as abortion or euthanasia could be penalized in another where they are legal. Other questions related to how to deal with cases that were not yet resolved. The general principle of innocence until proven guilty was enshrined in the European Convention for the Protection of Human Rights and Fundamental Freedoms. Yet some Member States also had mechanisms whereby someone accused of misconduct was suspended without loss of pay pending resolution of the facts. This was clearly not possible where the health professional sought to move to another Member State. Another issue related to events that took place long ago, especially where the length of disqualification imposed varied between the Member States.

In addition to the requirement that it should be non-discriminatory, the decision could not, according to the settled case-law of the Court,<sup>24</sup> hamper or otherwise make freedom of establishment, services and workers less attractive. Nevertheless, there were two ways that a national measure that was discriminatory and/or hampered movement may be justified. First, there was a limited list of grounds (among others, public health) set out in Articles 39, 46 and 55 of the Treaty. However, the Court ruled that such measures must be proportionate to the goal being pursued.<sup>25</sup> Second, there was the Court's so-called 'rule of reason'.<sup>26</sup> Measures that indirectly discriminated or hampered free movement could be justified if they fulfilled four conditions: they must be applied in a non-discriminatory manner; they must be justified by imperative requirements in the general interest; they must be able to achieve the objective being pursued; and they must not go beyond what is necessary in order to achieve the objective being pursued (the proportionality requirement). It could be argued that the Doctors' Directive, by offering no guidelines in this matter whatsoever, hampered true free movement. This could only be achieved by legal certainty, in the form of rules for coordination.

<sup>24</sup> See, for example, Case C-19/92, *Kraus* [1993] ECR I-1663; Case C-113/89, *Rush Portuguesa* [1990] ECR I-01417; P. Schoukens, *De sociale zekerheid van de zelfstandige en het Europees gemeenschapsrecht: de impact van het vrije verkeer van zelfstandigen* (Leuven: Acco, 2000), p. 313.

<sup>25</sup> Case C-101/94, *Commission v. Italy* [1996] ECR I-02691. See also Schoukens, *De sociale zekerheid*, above n.24, p. 326.

<sup>26</sup> Case C-55/94, *Gebhard* [1995] ECR I- 4165. See also K. Lenaerts and P. Vanuffel, *Europees recht in hoofdlijnen* (Antwerp, Apeldoorn: Maklu, 2008), p. 219.

The lack of any concrete criterion to distinguish between the provision of a 'service' and an 'establishment' also caused much legal uncertainty. This difference was important because more flexible rules applied to the provision of services. Often, it was a factual matter to distinguish between a service and an establishment. The key issue was how long an economic activity should continue before it changed from a 'service' to 'establishment'. European case-law did not provide any concrete guidelines. In the *Gebhard* case, the Court ruled that the temporary nature of the activities in question had to be determined in light of their duration, regularity, periodicity and continuity.<sup>27</sup> This did not preclude the provider of services, within the meaning of the Treaty, from creating some infrastructure in the host Member State (including an office, chambers or consulting rooms) in so far as this was necessary for performing the services in question.

Another problematic issue was the lack of clarity about payment or reimbursement of the costs incurred by the patient. As described above, it was forbidden for the host Member States to oblige foreign doctors who provided services on a temporary basis in their territory to register with a social security body. However, in some countries, such as Belgium, the patient could only be reimbursed if his or her doctor was registered with the social security body. Service providers had, however, a duty to 'inform' these bodies. The purpose of doing so was far from clear. Was it to register the professional with the social security body to ensure that the care provided was covered by insurance? The Court confirmed that this provision did not seek to remove all remaining obstacles to the refund of medical services by an insurance institution with whom the health care professional was not registered.<sup>28</sup> According to the Directive, Member States seemed free to decide whether or not to refund payment for such services. Yet, according to the rulings in the cases of *Kohll* and *Decker*, they were not at all free to decline to do so. Refusing reimbursement to an insured patient treated by a doctor established in another country could be seen as an infringement of the principle of free movement. This was clearly an area that required resolution.

<sup>27</sup> Case C-55/94, *Gebhard*, above n.26.

<sup>28</sup> Case C-232/99, *Commission v. Spain* [2002] ECR I-4235.

Telemedicine, where providers do not move, also raises many as yet unresolved issues. At present, the only provisions that exist are vague, deriving from Treaty provisions on free movement of services and some Court cases<sup>29</sup> stating that any restriction on the free provision of services is unlawful, unless justified by objective public interests, such as public health.

### C. Directive 2005/36/EC

#### Background

The proposal for a new Directive on the recognition of professional qualifications, which was launched in 2002, had the broad objective of creating a more uniform, transparent and flexible regime. The European Parliament, the Council and the Commission agreed that it was important to prepare an accessible, consolidated version of the legal provisions on mutual recognition of professional qualifications. The underlying philosophy of the new Directive is explicitly deregulatory, reflecting a view that professional regulation, rather than being seen as a protection for the public, is instead an obstacle to the operation of the market. Thus, the Commission's proposal<sup>30</sup> was based on the continuing liberalization of services, a reduction in barriers to recognition of qualifications, and more flexibility to update the provisions of the Directive in the light of changing circumstances. All of these goals need to be viewed in light of the Lisbon Agenda, which seeks to transform Europe into the world's most dynamic and competitive economy by 2010.

The new Directive,<sup>31</sup> which covers all professional qualifications in any sector (not just health), combines the two systems (sectoral and general), allowing the same mechanisms to apply: the '[g]eneral system (for the recognition of evidence of training)' (Chapter I) and the sectoral system (renamed as '[r]ecognition on the basis of the coordination of minimum training conditions' (Chapter III)). There is, however, a third, completely new system. This is '[r]ecognition

<sup>29</sup> See for example Joined Cases C-34/95 to C-36/95, *De Agostini* [1997] ECR I-03843.

<sup>30</sup> European Commission, 'Amended proposal for a European Parliament and Council Directive on the recognition of professional qualifications', COM (2004) 317 final, 20 April 2004.

<sup>31</sup> Directive 2005/36/EC, above n.14



on the basis of professional experience' (Chapter II). This applies primarily to areas such as industrial production, craftsmanship and trade, where individuals who are clearly qualified to undertake a role may not possess any official qualifications.

### **Automatic recognition on the basis of the coordination of minimum training conditions**

For all health professions falling under the scope of the former sectoral system – i.e., doctors, general practitioners and specialist doctors, nurses responsible for general care, dentists, dental practitioner and specialist dentists, veterinary surgeons, midwives and pharmacists – exactly the same mechanism continues to apply: automatic recognition on the basis of a completion of minimum training requirements (Article 21). However, the system now is called simply '[r]ecognition on the basis of the coordination of minimum training conditions'. As explained above, the procedure of automatic recognition of basic professional qualifications obliges every Member State to respond positively to every request for recognition. They cannot challenge the registration of someone with one of the diplomas listed in Annex V of the Directive by, for example, requiring that the applicant take another examination.

The situation with specialist qualifications in medicine and dentistry is more complicated. Again, there is a system based on mutual recognition, also involving specification of the duration of study. However, although some specialities, such as general surgery or neurosurgery are essentially the same in all Member States, others are not. Thus, in many Member States, dermatovenerology exists as a distinct speciality, whereas in others dermatology and specialization in sexually transmitted diseases are distinct categories. Moreover, the activities undertaken by doctors working in public health, and the corresponding skills required, vary greatly, so that this is only recognized as a speciality in a few Member States. There is also the difficulty of overlapping terminology, which is seen in the case of family medicine and general practice.<sup>32</sup>

Automatic mutual recognition only applies when the speciality exists in either all or in at least two Member States. In the latter case,

<sup>32</sup> I. Caixeiro, 'UEMO: lobbying letter from the Working Group on Specialist Training', *PrimaryCare* 8 (2008), 15–6.

the recognition is limited to the Member States where the speciality exists. A problem arising from the diversity of specializations is the potential to create an almost endless list of those recognized in only a few Member States. To overcome this problem, while retaining those already recognized, new applications will be permitted only if the specialities exist in two fifths of Member States (Article 26).<sup>33</sup> However, future medical specialties that do not meet this criterion will fall under the scope of the general system. This implies that host Member States can take compensatory measures in such cases. It is important to stress that individual Member States nevertheless remain free to agree among themselves the automatic recognition of medical and dental specialities common to them but not falling within the terms of this Directive.<sup>34</sup>

The minimum requirements for the training of doctors, general practitioners and specialist doctors, nurses responsible for general care, dentists, dental practitioners and specialist dentists, veterinary surgeons, midwives and pharmacists are listed in Articles 24–5, 31, 34–6, 44 and 46 of the Directive.<sup>35</sup> By creating a single committee to monitor and propose periodic revisions to the Directive, the Commission seeks to ensure easier updating of the criteria being used. This is designed to address criticisms that those criteria have, in the past, failed to adapt to the rapidly changing health system context. A comitology committee (Article 58) replaces the various advisory committees existing in the former system, which some in the Commission viewed as cumbersome, although others saw them as providing necessary safeguards, based on their detailed knowledge of the professions concerned. This quest for simplicity also reflected the challenges posed by the many more languages in use following recent enlargements. Another change

<sup>33</sup> ‘The new provision ensures that Community procedures (notification, comitology) are required only if a certain “critical mass” of Member States are actually involved. This is justified in relation to the existing rules on the grounds of reducing the procedural burden. Otherwise, all 27 Member States would be called upon to vote by qualified majority, using the comitology procedure, on requests from (in some cases) only two Member States, who would anyway remain completely free to achieve mutual recognition on a bilateral basis’. European Parliament, ‘Draft recommendation for second reading. Common position adopted by the Council with a view to the adoption of a Directive of the European Parliament and of the Council on the recognition of professional qualifications. Council common position’, 13781/2/2004 – C6–0008/2005 – 2002/0061(COD).

<sup>34</sup> Directive 2005/36/EC, above n.14. <sup>35</sup> *Ibid.*

brought in by the new Directive is the incorporation of professional organizations in the comitology committee. The system of acquired rights (see above) has been maintained (Article 23).

There are some specific provisions for specialized doctors (Article 27), general practitioners (Article 30), general nurses (Article 33), dental practitioners (Article 37), veterinary surgeons (Article 39) and midwives (Article 43). Third country diplomas fall outside the scope of automatic recognition enshrined in the Directive and national authorities must make other provisions for deciding on the registration of health professionals holding them. However, the provisions adopted are subject to European law, in that Directive 2001/19/EC<sup>36</sup> requires Member States to examine not only the qualification held by the migrant but also whether he or she has acquired experience and/or training in another Member State. This followed the Court's decision in the *Vlassopoulou* case.<sup>37</sup> The Court ruled that a Member State, when deciding whether to permit an individual to practise a profession that is, according to national law, only open on the basis of a diploma or professional qualification, must take into consideration any diplomas, certificates and other evidence of formal qualification that the person concerned has obtained in another Member State in order to practise that same profession. In doing so, it must compare the knowledge and abilities certified by those diplomas with the knowledge and qualifications required in its national rules. This view was reinforced in the *Haim I* case,<sup>38</sup> where it was ruled that when competent national authorities have to check whether the nationally-prescribed practical training has been met, they must take into consideration the professional experience of the person concerned, including any professional experience obtained in

<sup>36</sup> This Directive modified both the former sectoral directives and the general ones and is also called the SLIM-Directive. Directive 2001/19/EC of the European Parliament and of the Council of 14 May 2001 amending Council Directives 89/48/EEC and 92/51/EEC on the general system for the recognition of professional qualifications and Council Directives 77/452/EEC, 77/453/EEC, 78/686/EEC, 78/687/EEC, 78/1026/EEC, 78/1027/EEC, 80/154/EEC, 80/155/EEC, 85/384/EEC, 85/432/EEC, 85/433/EEC and 93/16/EEC concerning the professions of nurse responsible for general care, dental practitioner, veterinary surgeon, midwife, architect, pharmacist and doctor, OJ 2001 No. L206/1.

<sup>37</sup> Case C-340/89, *Vlassopoulou* [1991] ECR I-2357.

<sup>38</sup> Case C-319/92, *Haim* [1994] ECR I-425.

another Member State. In the *Hocsman* case,<sup>39</sup> the Court extended this approach to include diplomas and experience obtained in third countries. Dr Hocsman obtained his basic medical training as doctor in Argentina. In Spain, where this training was recognized, he obtained a specialist diploma as a urologist, going on to practise as such for some time. He then became an EU citizen. In France, he was denied the right of establishment because his basic diploma was not recognized. The Court ruled that:

[W]here, in a situation not regulated by a directive on mutual recognition of diplomas, a Community national applies for authorisation to practise a profession access to which depends, under national law, on the possession of a diploma or professional qualification, or on periods of practical experience, the competent authorities of the Member State concerned must take into consideration all the diplomas, certificates and other evidence of formal qualifications of the person concerned and his relevant experience, by comparing the specialised knowledge and abilities certified by those diplomas and that experience with the knowledge and qualifications required by the national rules.

In this way, established jurisprudence goes beyond the Directive, which only mentions the obligation to consider diplomas and experience obtained in another Member State. Thus, it is not possible simply to refuse to recognize a third country diploma without giving it due consideration. There are a few other issues that arise in relation to diplomas obtained outside the EU. One is the question of what happens when someone who obtained such a qualification and has it recognized in one Member State seeks to work in another one. In such cases, the Member State that the individual wishes to move to is not obliged to accept the decision of the first state.

Another issue relates to training obtained partly outside the EU. This was addressed in the *Tennah-Durez* case.<sup>40</sup> The Court interpreted 'third country diploma' narrowly as only those diplomas that are actually awarded by a third country. In order to qualify as an EU diploma, it is not necessary that the training is undertaken entirely in a Member State. An Algerian woman, who had obtained Belgian nationality, had undertaken most of her undergraduate medical

<sup>39</sup> Case C-238/98, *Hocsman* [2000] ECR I-066231-6623.

<sup>40</sup> Case C-110/01, *Tennah-Durez* [2003] ECR I-6239.

education in Algeria but then completed the last year of her course in Belgium. Having obtained her medical diploma, she moved to France, where she was denied the right of establishment. The Court ruled that it is not relevant where the training was undertaken; at stake was whether the training meets the minimum requirements of the Doctors' Directive. The competent authority to make that judgement is the Belgian state. The Member State that awards the diploma approves the training undertaken in order to obtain it. In this way, a diploma awarded by a Member State provides a 'doctor's passport', enabling the holder to move within the EU without having his/her professional qualification opened to challenge, except in some very special circumstances, discussed below, which apply equally to nationals of the host country.

### The general system

As explained earlier, under the general system the host Member State can decide each case on its own merits and can, as appropriate, impose compensating measures such as an aptitude test or an adaptation period. Compensation measures are allowed when the training undertaken by the applicant is up to one year less than that required by the host Member State, when the professional role includes professional activities that do not exist in the home Member State, or where there are differences in specific aspects of the training (Article 14). Following the *Vlassopoulou*<sup>41</sup> and *Haim I*<sup>42</sup> cases, host Member States must always take into consideration the diplomas, certificates and other evidence of formal qualification, as well as the experience that the applicant has obtained in another Member State in order to practise that profession, by comparing the knowledge and abilities certified by those diplomas with the knowledge and qualifications required by national rules (Article 14(5)). Although the new Directive addresses all professional qualifications, there is one important way in which health professions are treated differently. Reflecting one of the underlying goals of the new approach, which is to facilitate greater cross-border provision of services, the new Directive bans compensation measures

<sup>41</sup> Case C-340/89, *Vlassopoulou*, above n.37.

<sup>42</sup> Case C-319/92, *Haim*, above n.38.

when they concern services. In this case, compensating measures are seen as a potential infringement of the free movement of services. Specifically, host Member States can no longer restrict the free provision of services for any reason relating to professional qualifications as long as the service provider is legally established in another Member State (Article 5(1)). However, quite explicitly, this does not apply to health professions (and public safety professions) (Article 7(4)). For them, the old rules remain applicable, thus permitting compensation measures.

Directive 2005/36/EC introduced so-called ‘common platforms’ (Article 15). Common platforms are sets of criteria for professional qualifications that can compensate for the considerable differences that have been identified between the training requirements for certain professions in different Member States. These differences are identified by comparing the duration and content of the training in at least two thirds of the Member States, but including all the Member States where the profession has been regulated. The criteria adopted are agreed as attesting to a sufficient level of competence. Common platforms may be notified to the Commission by the Member States or by professional organizations. When an applicant has a qualification that satisfies the criteria set out in the common platform, as adopted through a comitology procedure, the host Member State will have to waive the compensating measures. The system recalls the scheme of automatic recognition on the basis of minimum training requirements contained in the sectoral system. Article 15(4) does, however, stress that Member States remain competent to determine the professional qualifications required for the pursuit of professions in their territory and for the organization of education and professional training. Moreover, if a Member State considers that a common platform no longer offers adequate guarantees of professional qualifications, it shall inform the Commission accordingly (Article 15(5)).

Concerning third country diplomas, where a profession does not fall under the scope of the automatic recognition system, each Member State is free to recognize it or not. Such diplomas fall within the scope of the general scheme, on condition that the holder has three years’ professional experience in the Member State that recognized that diploma (Article 3(3)).

### *Pursuit of the profession*

#### **Establishment versus provision of services**

The new Directive merges all coordinating rules concerning the pursuit of the profession (automatic recognition, general system and recognition on the basis of professional experience).

*a. Establishment* The provisions of Directive 2005/36/EC facilitating the pursuit of a profession by a migrant health professional primarily involve the coordination of rules concerning documents and oaths (Articles 50–1), as in the old directives. When deciding whether to grant permission for *establishment* by a foreign health professional, host Member States can apply their national rules fully, as long as these do not infringe the right of establishment. An example of a national rule doing this was the requirement for the applicant to cancel his or her registration in their home Member State. The Court found that this was too absolute and general in nature to be justified.<sup>43</sup> In a recent case,<sup>44</sup> the European Court had to rule on a German regional quota for psychotherapists joining the social security system. At stake was not the existence of the quota as such, but rather the acquired rights of psychotherapists already recognized as ‘German sickness fund physiotherapists’. The Court stated that by failing to grant the same acquired right to psychotherapists working in the health insurance system of another Member State, Germany breached the right of free establishment. In a case concerning the advertisement of services and the right to establishment the Court<sup>45</sup> has stated that an Italian provision forbidding the advertisement of aesthetic medical and surgical treatments on national television is an infringement of the right of establishment, given that such advertisements are allowed under certain circumstances on local television.

<sup>43</sup> Case 96/85, *Commission v. France* [1986] ECR 1475.

<sup>44</sup> Case C-456/05, *Commission v. Germany* [2007] ECR I-10517.

<sup>45</sup> Case C-500/06, *Corporacion Dermoestetica SA* [2008] ECR I-5758. It is interesting to note that the issue of advertising by health professionals also has been brought before the Court in relation to competition law, arguing that liberal professions must be seen as ‘undertakings’ and that advertising is indispensable for free competition. However, the Court found that the Belgian law prohibiting dental care providers from engaging in advertising did not infringe Articles 81 and 10 of the EC Treaty, nor could it be seen as a (forbidden) agreement between undertakings. See the recent Case C-446/05, *Doulamis* [2008] ECR I-1377.

There are also cases pending on the establishment of pharmacists. These two joined cases<sup>46</sup> concern a decree by the Spanish region of Asturias regulating pharmacies. The Commission initiated infringement proceedings against Italy, Austria, Spain<sup>47</sup> and, later, Germany concerning national legislation restricting the right to operate chains of pharmacies.

*b. Provision of services* As was already the case with the old sectoral directives, the decision on whether to grant permission to a foreign health professional to provide 'services' on an occasional or temporary basis involves legislation that is, overall, rather more flexible than with establishment. As already noted, a key objective of Directive 2005/36/EC was to facilitate greater freedom in providing services. Previously, only the sectoral directives took a more flexible approach to services compared with establishment. The new Directive includes a separate Title (II) covering the provision of services that are common to all systems of recognition.

It is recognized that there is potential to use the procedures related to provision of services to circumvent the more stringent requirements of establishment. Thus, to avoid such 'masked establishment',<sup>48</sup> Article 5(2) clarifies that Title II (dedicated to the provision of services) shall 'only' apply where the service provider moves to the territory of the host Member State to pursue, on a temporary and occasional basis, his/her profession. In defining a 'service' in this way, the Directive implements the case-law from the *Gebhard* case,<sup>49</sup> which implies that the temporary character of the service should be assessed on a case-by-case basis, taking into account the duration, frequency and continuity of

<sup>46</sup> Joined Cases C-570/07 and C-571/07, *Pérez and Gómez* (judgment pending).

<sup>47</sup> European Commission, 'Internal market: infringement proceedings concerning Italy, Austria and Spain with regard to pharmacies', Press Release No. IP/06/858, 28 June 2006. See also Chapter 11.

<sup>48</sup> A European provision cannot in any way benefit some citizens to the detriment of others. It is therefore necessary to avoid 'masked establishment' – that is to say, where provisions relating to the free provision of services allow a migrant to avoid the provisions relating to the right of establishment in the country where he/she pursues his/her activities, in fact by enabling him/her to benefit, without any reason, from more advantageous regulations than those laid down for national citizens. See European Parliament, 'Draft recommendation', above n.33.

<sup>49</sup> Case C-55/94, *Gebhard*, above n.26.



the activity. This does not prevent the provider of services from equipping him/herself with infrastructure in the host Member State, in so far as such infrastructure is necessary for the purpose of performing the services in question. As a consequence, EU citizens may find it almost impossible, in practice, to differentiate ‘services’ and ‘establishment’. Unfortunately, the Directive missed the opportunity to set a concrete time limit (sixteen weeks per year was initially suggested) to distinguish between these concepts. It is, however, crucial to differentiate them because of the different legal bases under which they operate.

The provision of services across borders where the health professional does not physically move, as with telemedicine, remains excluded from the scope of this application under Articles 1 and 2. This is another area where legal clarification is needed. Despite some explicit exceptions (see below), the Directive establishes the principle that host Member States can fully apply their own professional rules to the incoming service provider (Article 1(3)). Rules of this kind relate, for example, to the organization of the profession and professional standards, including those concerning ethics, supervision and liability. The case-law of the Court of Justice, such as the *Van Binsbergen* case,<sup>50</sup> however, shows that the application of professional rules is not unconditional. Although the Court in general agrees upon the principle that rules governing the activities of professionals in host Member States apply to service providers, the application of these requirements does not seem to be unconditional. They must be justified objectively by the need to ensure that professional rules of conduct are observed. The rules are thus to be judged on a case-by-case basis. If called upon to do so in litigation, Member States will have to justify their actions when applying their national rules and it is up to the Court to judge them, balancing free movement – and, more generally, the internal market – and public health.

The host Member State can ask for a prior declaration the first time a service provider moves into its territory (Article 7(1–2)). The declaration should be written and the service provider may supply it by any appropriate means. Such a declaration must be renewed once for each year that the professional intends to provide services. In a currently pending procedure,<sup>51</sup> France has to justify its requirement that

<sup>50</sup> Case 33–74, *Van Binsbergen* [1974] ECR 1299.

<sup>51</sup> European Commission, ‘Professional qualifications: infringement procedures against France, Greece and Spain’, Press Release No. IP/06/888, 29 June 2006.

incoming services employing doctors, dentists and midwives produce such a declaration for each service and for each patient seen. As well as declarations, host Member States may require proof of nationality, evidence of professional qualifications and an attestation of legal establishment. The latter must certify that the person is 'not prohibited from practising even temporarily'. Explicit exceptions in the Directive relating to the applicability of host Member State rules to service providers include two important exemptions (Article 6), as was the case with the old sectoral directives. Host Member States cannot require that incoming service providers register with a professional organization or with a social security body. However, a temporary registration or membership pro forma with the host professional organization is possible. To lighten the administrative burden for the incoming service provider, this occurs automatically. The competent authority will therefore send the written declaration and required documents to the professional organization. The second prohibition, involving registration with a social security body, implies that the unclear situation regarding the payment or reimbursement of the costs for the patient (see above) remains.

At the time of writing, Estonia<sup>52</sup> has been confronted with a reasoned opinion from the Commission in view of its rules prohibiting the recognition of medical prescriptions made out by medical practitioners who are qualified to act in their Member State of establishment but not registered in Estonia. The Commission takes the view that these provisions restrict both the freedom of health professionals to provide services as well as patients' rights, and that they are contrary to Article 40 of the EC Treaty.

### **Quality: continuing to practise**

As noted above, professional mobility is based on the mutual recognition of professional qualifications, which assumes that someone registered to practise in one Member State is competent to do so in all others. As noted above, however, the actual practice is slightly different. There seems to be distrust towards foreign health professionals in some countries. Yet existing systems of regulation are seen by many as failing in

<sup>52</sup> European Commission, 'Free movement of services: infringement proceedings against Estonia and Portugal', Press Release No. IP/08/1033, 26 June 2008.

their pursuit of their primary goals: provision of a system of professional accountability; ensuring that basic standards of care do not fall below those that are acceptable; and promoting continuing improvements in quality of care.<sup>53</sup> Specifically, the acquisition of a qualification, perhaps many years previously, is no longer seen as sufficient evidence of fitness to practise. There is also increasing recognition that some skills decline over time, an effect found to be present in a number of aspects of care in a recent systematic review of sixty-two studies.<sup>54</sup> In a number of countries, one response has been the introduction of periodic revalidation and requirements to undertake lifelong learning. These developments are not, however, recognized by the existing European legal framework. Progress has been limited. At a 2006 meeting of the High Level Group on Health Services and Medical Care, the group concluded that ‘there is no clear consensus reached on which concrete actions to develop in order to take forward issues such as CPD [continuing professional development]’.<sup>55</sup> The introduction of revalidation mechanisms, which aim to ‘demonstrate that the competence of doctors is acceptable’, draws on the experiences of the United States, Canada, Australia and New Zealand.<sup>56</sup> In Europe, practice varies.<sup>57</sup> In its most basic form, it involves participation in continuing medical education (CME), which is designed to keep physicians up to date on clinical developments and medical knowledge. The broader concept of continuing professional development (CPD) includes CME, along with the development of personal, social and managerial skills. More demanding methods incorporate peer review, external evaluation and practice inspection.

<sup>53</sup> T. A. Brennan *et al.*, ‘The role of physician specialty board certification status in the quality movement’, *Journal of the American Medical Association* 292 (2004), 1038–43; K. Sutherland and S. Leatherman, ‘Does certification improve medical standards?’, *British Medical Journal* 333 (2006), 439–41.

<sup>54</sup> N. K. Choudhry, R. H. Fletcher and S. B. Soumerai, ‘Systematic review: the relationship between clinical experience and quality of health care’, *Annals of Internal Medicine* 142 (2005), 260–73.

<sup>55</sup> European Commission, ‘Report on the work of the High Level Group’, above n.4.

<sup>56</sup> L. Southgate and M. Pringle, ‘Revalidation in the United Kingdom: general principles based on experience in general practice’, *British Medical Journal* 319 (1999), 1180–3; D. H. Irvine, ‘Everyone is entitled to a good doctor’, *The Medical Journal of Australia* 186 (2007), 256–61.

<sup>57</sup> S. Merkur *et al.*, ‘Physician Revalidation in Europe’, *Clinical Medicine* 8 (2008), 371–6.

However, it is important to recognize that, within Europe, there are very differing traditions of how the professions and the state should interact, which will shape the nature of systems in assessing continuing fitness to practise. Even within countries, there are differences in the approaches advocated, a situation that is not helped by the very weak evidence base that such systems are effective. Thus, in the United Kingdom, the majority of public as well as family doctors believe that physicians should be assessed regularly to ensure their knowledge and skills are up to date.<sup>58</sup> Yet some commentators – most notably, Onora O’Neill in her 2002 Reith Lectures – have argued cogently that overzealous regulation could be harmful.<sup>59</sup>

Currently, the Netherlands and Germany have explicit revalidation systems in place. Since 2005, Dutch physicians have had to undertake CME and undergo a visit by peers every five years. Revalidation is a requirement to remain on the medical register. The visits (*visitation*), by a team of three other doctors, including one recently visited and one about to be, involve a comprehensive assessment of practice, with ongoing discussions on monitoring adherence to clinical guidelines and patient input. While physicians in Germany receive their licence to practise from regional ministries and are regulated through their regional chambers (professional associations), the 2004 Social Health Insurance (SHI) Modernization Act introduced revalidation requirements for physicians at the federal level. Germany’s revalidation scheme requires physicians to fulfil CME requirements every five years (250 credit points of approximately 45 minutes each). Physicians contracted with the SHI funds and working in ambulatory care are not subject to detailed regulations on the topics that must be covered by CME. In contrast, specialists working in hospitals have to show that 70% of their vocational training has been on topics concerning their speciality. Radiologists are subject to an additional recertification procedure if they read mammograms. These programmes are voluntary for purely private physicians. In the event of non-compliance, the Regional Associations of SHI Physicians can reduce reimbursement rates after one year by 10% and after two years

<sup>58</sup> Ipsos MORI, ‘Attitudes to medical regulation and revalidation of doctors’ research among doctors and the general public’, Research Study Conducted for Department of Health, MORI (2005).

<sup>59</sup> O. O’Neill, *A question of trust* (Cambridge: Cambridge University Press, 2002).

by 25%. If the CME certificate is not achieved within two years after the due date, accreditation may be withdrawn. All regions, except for one (Baden Wurttemberg), have implemented a computer-based registration system for CME. At the end of June 2009, the CME system will be reviewed for the first time. It is expected that participation in CME should be combined with quality assurance systems, thus promoting a broader system of CPD.

In the United Kingdom, the General Medical Council has proposed that physicians would have to prove their fitness to practise. Current proposals are that revalidation should include two requirements: relicensure to permit practise as a medical practitioner, and additional recertification to practise as a general practitioner or specialist.<sup>60</sup> Relicensure, every five years, would be based on a revised model of appraisal used in the National Health Service, but applied to all doctors wherever they work. Recertification procedures would be speciality specific, led by the Royal Colleges. Physicians who failed in either process would spend a period of time in supervised practise. In some other countries, including Austria, Belgium, France and Spain, programmes are heavily dependent upon participation in CME as the mechanism to maintain physician competence.

Austria, Belgium and France also take their systems a step further by including peer review. There is a mandatory CME programme for licensed medical doctors in Austria, the *Diplom-Fortbildungs-Programm*. Although legal responsibility resides with the Austrian Medical Chamber, the actual implementation of the programme rests with the Academy of Physicians. Physicians must acquire CME credits, 80% of which have to be acquired through speciality-related certified CME programmes, with 27% of the total within the physician's particular speciality. Undergoing peer review is another means of accumulating such credits, and certificates are awarded over a three-year cycle.

Also, in Belgium there is a legal obligation for general practitioners and specialists to comply with set standards and the pursuit of accreditation is supported by financial incentives. Accreditation is granted by the Institut national d'assurance maladie-invalidité/Rijksinstituut

<sup>60</sup> L. Donaldson, 'Good doctors, safer patients: proposals to strengthen the system to assure and improve the performance of doctors and to protect the safety of patients', Report for the UK Department of Health, 14 July 2006.

voor ziekte- en invaliditeitsverzekering (INAMI/RIZIV) for a period of three years if the physician meets additional requirements, including participation in CME and peer review. While accreditation is not required, it enables physicians to charge higher reimbursable fees to patients, boosting a physician's annual salary by about 4%.<sup>61</sup> In order to keep their professional title, general practitioners are required to regularly maintain and develop their knowledge, skills and medical performance by undertaking at least twenty hours (200 credits) of continuing professional development annually, including four hours in group peer review.<sup>62</sup> Hospital physicians are required to participate in the peer review process, regardless of whether they seek accreditation.

In France, CME and medical audit (known as the Evaluation of Professional Practices (EPP)) have been introduced. Both are intended to be compulsory, with participation assessed every five years. However, they have come under criticism by the Inspector General of Social Affairs as neither system is monitored. Furthermore, because the legal status of the institutions responsible for the regulation of CME and EPP requirements are not the same, EPP has been difficult to implement and enforcement has been delayed.

In Spain, CME is reported as fragmented, but there is growing interest in developing certification and recertification schemes in the regions, which are responsible for the provision of health care. National legislation has identified the need for these programmes and the medical colleges have established voluntary CME systems. In 1998, the Spanish Commission of Continuing Education of Health Professionals initiated a nationwide CME system based on Catalonia's experience, but by 2005 it had been implemented by only nine regional commissions (out of seventeen).

In a Europe where the right to professional mobility is enshrined in law, on the basis that all Member States have in place effective systems to ensure quality of care, diversity on this scale in the absence of any European legal framework creates obvious problems, and the reasoning that a sufficient level of quality is assured through formal

<sup>61</sup> C. Peck *et al.*, 'Continuing medical education and continuing professional development: international comparisons', *British Medical Journal* 320 (2000), 432–5.

<sup>62</sup> Arrêté ministerial du 21 Février 2006 fixant les critères d'agrément des médecins generalists, *Moniteur Belge* 1 (2006), 10277.

qualifications, as enshrined in European secondary law and followed by the Court of Justice, therefore seems unrealistic.

The European Accreditation Council for CME (EACCME) was established in January 2000 by the European Union of Medical Specialists to provide a practical instrument to improve the quality of CME in Europe. By recognizing high quality specialist education, it connects the existing and emerging accreditation systems in Europe and act as a clearing house for accreditation of CME and credits.<sup>63</sup>

### Practices allowed

Within Europe, there is considerable diversity in the roles undertaken by different professionals. For example, nurses prescribe drugs and manage clinics treating chronic diseases in some countries but have much more limited roles in others.<sup>64</sup> Directive 2005/36/EC does not envisage any coordination of these roles, despite the obvious implications for someone trained in a system where, for example, the nursing role is extremely restrictive and then moves to one where it is more expansive. In the *Bouchoucha* case,<sup>65</sup> the Court judged that, given the lack of a Community definition of ‘medical activities’, Member States are free to regulate these activities as they see fit. At stake was a complaint by a holder of a British diploma in osteopathy. According to the Court, the French rule requiring that a qualified medical doctor provide osteopathic treatments does not breach the right of free establishment.

The same reasoning was followed in the *Gräbner* case.<sup>66</sup> The Court ruled that the German requirement of being a qualified medical doctor in order to practise the profession of ‘*Heilpraktiker*’ (lay health practitioner) did not obstruct the free movement of services or the right to free establishment. So far, the Court seems to respect the Member State’s choice to reserve certain activities for persons with a specific qualification, such as medical doctors.<sup>67</sup>

<sup>63</sup> See also the EACCME web site, [www.uems.net/main.php?category=6](http://www.uems.net/main.php?category=6).

<sup>64</sup> M. McKee, C.-A. Dubois and B. Sibbald, ‘Changing professional boundaries’, in C.-A. Dubois, M. McKee and E. Nolte (eds.), *Human resources for health in Europe* (Maidenhead: Open University Press, 2006), pp. 63–78.

<sup>65</sup> Case C-61/89, *Bouchoucha* [1990] ECR I-3551.

<sup>66</sup> Case C-294/00, *Gräbner* [2002] ECR I-6515. <sup>67</sup> *Ibid.*, para. 48.

### Disciplinary matters

Member States are required to exchange information regarding 'disciplinary action or criminal sanctions taken or any other serious, specific circumstances' that are likely to be relevant for the pursuit of the profession, while respecting the EU's privacy legislation. The effective and timely exchange of information about health professionals between Member States is important to protect patient safety. The 'Health Care Professionals Crossing Borders Project' is relevant here. This project seeks to facilitate an efficient proactive method of information exchange. This informal initiative, which originated under a Dutch EU Presidency, is led by the Alliance of United Kingdom Health Regulators on Europe (AURE), a consortium of bodies regulating the various health professions in the United Kingdom, and brings together all health care regulators across the European Economic Area. In October 2005, it developed a model of information exchange known as the 'Edinburgh Agreement'. Among its other activities, it has developed a 'European Certificate of Current Professional Status'. Member States were expected to implement this certificate scheme by the time that Directive 2005/36/EC came into force in October 2007. Nevertheless, some problems remain. As was the case with the old directives, the new Directive does not stipulate anything about the possible extraterritorial effect of those measures. So, it is still not clear what the host Member State is supposed to decide on the basis of information received, or what the home Member State should do when confronted with a sanction taken by the host country. As noted above, the only guidelines seem to be the principles of non-discrimination and the prohibition on hampering free movement, both based on Articles 39, 43 and 49 of the Treaty, which can be extremely difficult to apply in practice. However, as was discussed in relation to revalidation, the extent to which medical practice is regulated by the state varies enormously among Member States, as do the legal instruments and procedures employed, and the norms underlying disciplinary proceedings.<sup>68</sup> To complicate matters further, the situation is changing. An example is the intention in the United Kingdom to apply the civil standard of proof in cases of alleged professional misconduct, where guilt will be assessed on the balance of probabilities, instead of the

<sup>68</sup> Roscam Abbing, 'Medical practice', above n.23, pp. 247–61; Roscam Abbing, 'The right of the patient', above n.23.



previous criminal standard, where it was judged on the basis of being beyond reasonable doubt. The principle of non-discrimination would suggest that the standards of the Member State to which the professional was seeking to move should be applied. However, this clearly raises issues concerning the ability to take evidence and reach conclusions about events in another legal jurisdiction.

The situation is complicated further by the way in which national data protection legislation is interpreted, which is sometimes used as a reason not to allow Member States to exchange information, a rationale that is entirely contrary to the European legislation, which was intended to facilitate its transfer where necessary. There does seem to be a need to establish a European legal duty<sup>69</sup> to exchange such data. Finally, it should be noted that, although not yet in use, the new Directive does offer the possibility to introduce professional cards that would summarize a person's training, experience and any penalties incurred (Preamble, Point 32).

As this brief review shows, there is clearly much legal uncertainty that, unless resolved, will continue to hamper true freedom of movement.

#### *D. Access to training: free movement of students*

Some Member States restrict access to (para)medical training by applying a system of so-called *numerus clausus*. Controls on the number of health professionals are used by these Member States as a tool for planning, seeking to avoid overproduction in the health sector. A 1986 European Court of Justice case<sup>70</sup> is relevant in this regard. The Court confirmed that no rule of the European Communities *obliges* Member States to restrict the access of medical students. The Italian Court had consulted the Court to clarify this issue, as Italy had imposed no restrictions but was concerned that it might have to, an issue that was controversial given the high number of medical graduates seeking jobs in Italy at that time. Differing policies among Member States have led to problems. Students in Member States that

<sup>69</sup> As proposed by the Alliance of UK Health Regulators on Europe in its 'Response to the EC Consultation regarding Community action on health services', January 2007.

<sup>70</sup> Joined Cases 98/85, 162/85 and 258/85, *Bertini and Bisignani and Others* [1986] ECR 1885.

apply the *numerus clausus* system can obtain training in a neighbouring Member State, by using their right of free movement, which precludes them being discriminated against on the basis of nationality. Austria and Belgium face a special situation in this regard. Between 30% and 50% of medical students in Austria are German. Germany and Austria both apply strict *numerus clausus* systems. Belgium (Wallonia) also has a high proportion of medical students from France.<sup>71</sup> The European Court of Justice<sup>72</sup> stated clearly that Austria's requirements for holders of a secondary education diploma from other Member States to prove that they have met conditions governing access to higher education in their home Member State (e.g., having passed an entrance exam or obtained a grade to qualify for the *numerus clausus* system in the home Member State) was in breach of the European principle of non-discrimination. This judgment was heavily criticized. As a reaction to this judgment, Austria amended its Universities Act, imposing a quota by which 75% of the places for medical and dental studies could be reserved for holders of an Austrian secondary education diploma (with 20% for other EU diplomas and 5% for third country diplomas). Having received a letter of formal notice from the Commission, Austria argued the quota was necessary because of potential shortages of health care professionals practising in Austria. The Commission, confronted by prima facie evidence, therefore decided to suspend the infringement case (1998/2308) for five years in order to give the Austrian authorities the opportunity to provide supplementary data supporting the argument that the measure is necessary and proportionate.<sup>73</sup>

A similar situation arose with a decree from the French community in Belgium (*Communauté française*) in June 2006, which sought to limit the number of non-Belgian students in certain (para)medical studies by imposing a quota of 70% reserved places for students who are resident in Belgium. The quota covers nine separate subject areas in total, including medical and veterinary studies. The French

<sup>71</sup> K. Groenendijk, 'Free movement of workers in Europe 2005', European Report, European Commission Employment, Social Affairs, and Equal Opportunities (2006).

<sup>72</sup> Case C-147/03, *Commission v. Austria* [2005] ECR I-07963.

<sup>73</sup> European Commission, 'Access to higher education: the Commission suspends its infringement cases against Austria and Belgium', Press Release No. IP/07/1788, 28 November 2007.

community provided evidence that this was necessary to maintain sufficient territorial coverage and quality in its public health system. The Commission also decided to suspend this infringement case (2006/4760) for five years in order to give the authorities the opportunity to provide supplementary data.<sup>74</sup> It is apparent that applying the *numerus clausus* system to control access to training does not seem to be an effective planning tool when only some Member States do so. Students will simply go to another Member State for training and return to their home Member States with their diplomas, where they will be recognized on the basis of Directive 2005/36/EC. Restricting the pursuit of the profession within the framework of social security is another planning tool. Instead of restricting the number of students – or access to training – it restricts the number of health professionals that can participate in the social security system (see the above discussion on the German regional restriction imposed on psychotherapists) – or access to the pursuit of the profession within the framework of the social security system. The situation continues to evolve. Belgium recently adopted a similar measure in relation to physiotherapists. As it applied to students already in training, it led to a major debate on acquired rights. Given the findings of the recent German case, any measure that only protected the acquired rights of Belgian students may be in breach of European law.

### *E. Ethical recruitment guidelines*

As already noted, free movement of health professionals poses a potential threat of ‘brain drain’. Recruitment of health professionals from other Member States and from outside the European Union (a situation that, in some cases, is facilitated by European law on third country diplomas), may exacerbate existing shortages of health personnel in the countries of origin. This has risen rapidly up the international agenda, as increasing numbers of western European countries have engaged in active recruitment of foreign health personnel, especially nurses.<sup>75</sup> This issue was addressed by the High Level Group on Health

<sup>74</sup> *Ibid.*

<sup>75</sup> See, for example, [www.nurses.be](http://www.nurses.be); a recruitment firm established in Belgium, specialized in recruiting nurses in Romania and Bulgaria.

Services and Medical Care in 2006<sup>76</sup> and, on 7 April 2008, a Code of Conduct on Ethical Cross-border Recruitment and Retention in the Hospital Sector was signed by the European Federation of Public Service Unions (EPSU) and the European Hospital and Healthcare Employers Association (HOSPEEM), representing, respectively, health care unions and employers.<sup>77</sup> It is, however, purely a voluntary agreement. The opposite situation has occurred in the United Kingdom, where there is a tradition of foreign doctors working as junior doctors, with some progressing to substantive senior posts in the United Kingdom, while others return to their countries of origin, in many cases having gained valuable experience. A new computerized system for the recruitment of medical training posts was introduced in 2007. The system was a spectacular failure but, during the course of its prolonged collapse, it became clear that it was attracting over 10 000 applicants from outside the European Union and it was likely that, even if only a fraction of them were successful, many British graduates would be unemployed. In February 2008, the Secretary of State for Health announced a ban on such applicants. This ban was challenged in the British courts by the British Association of Physicians of Indian Origin on the grounds that health ministers did not have the authority to change immigration law.<sup>78</sup> In May 2008, the United Kingdom Law Lords supported them, but on the specific grounds that the Secretary of State had acted unlawfully by simply announcing the change of policy on a web site managed by a nongovernmental organization, rather than bringing it before parliament where she would have had to defend her position publicly.

### 3. The Working Time Directive

As can be seen in several places in this book, European legislation not specifically directed at the health sector can have a profound and even unintended impact on it. One of the clearest examples is the

<sup>76</sup> European Commission, 'Report on the work of the High Level Group', above n.4.

<sup>77</sup> European Federation of Public Service Unions, 'EPSU-HOSPEEM code of conduct and follow up on ethical cross-border recruitment and retention in the hospital sector', European Federation of Public Service Unions (2007).

<sup>78</sup> J. Carvel, 'Doctors from outside EU barred from consultant training', *The Guardian*, 7 February 2008.

Working Time Directive. With its legal basis in Article 137 of the EC Treaty, it pursues a social objective – the protection of the health and safety of workers and the improvement of their working conditions – as fundamental goals and without reference to the internal market.

The initial Working Time Directive 93/104/EC<sup>79</sup> was amended by Directive 2000/34/EC<sup>80</sup> and later consolidated in Directive 2003/88/EC,<sup>81</sup> which function as *lex specialis* in relation to Directive 89/391/EEC.<sup>82</sup> The latter contains general principles concerning the safety and health of workers at work and remains fully applicable to the areas covered by the Working Time Directive, without prejudice to more stringent and/or specific provisions in the later Directive. The Working Time Directive lays down minimum periods of daily and weekly rest, annual leave, and maximum weekly working time, as well as regulating certain aspects of night work, shift work and working patterns. The Directive applies to most workers and to all in the health sector. Yet, for many years there was a collective denial among many governments that the Working Time Directive would ever be applied to hospital staffing, perhaps because the consequences were so great. Only a very few countries, such as the Netherlands and the United Kingdom, made any substantive provision for its effects. The *SIMAP*<sup>83</sup> ruling shattered this complacency (see below). Only in 2000 were doctors in training explicitly included in its scope of application, when it was decided to implement it over five years from 1 August 2004. Requirements on rest periods came into force at once, but the length of the working week is being reduced progressively until it reaches forty-eight hours in August 2009. A generation ago, doctors worked extremely long hours, posing a threat to their own health and the health of their patients.<sup>84</sup> For example, surgeons who missed a

<sup>79</sup> Council Directive 93/104/EC concerning certain aspects of the organization of working time, OJ 1993 No. L307/18.

<sup>80</sup> European Parliament and Council Directive 2000/34/EC amending Directive 93/104/EC concerning certain aspects of the organisation of working time to cover sectors and activities excluded from that Directive, OJ 2000 No. L195/41.

<sup>81</sup> European Parliament and Council Directive 2003/88/EC concerning certain aspects of the organisation of working time, OJ 2003 No. L299/9.

<sup>82</sup> Council Directive 89/391/EEC on the introduction of measures to encourage improvements in the safety and health of workers at work, OJ 1989 No. L183/1.

<sup>83</sup> Case C-303/98, *SIMAP* [2000] ECR I-07963.

<sup>84</sup> M. McKee and N. Black, 'Does the current use of junior doctors in the United Kingdom affect the quality of medical care?', *Social Science and Medicine* 34 (1992), 549–58.

night's sleep made 20% more errors and took 14% longer to perform a simulated operation than those at the start of a shift. For many, therefore, the Working Time Directive was a welcome initiative.<sup>85</sup>

An immediate problem was how to deal with on-call responsibilities, with many differing views.<sup>86</sup> This has since been clarified in case-law by the European Court of Justice, which defined 'working time' and 'on-call service'. However, this was only the beginning of a lengthy discussion on how to implement the rulings, given the many practical difficulties involved (see Box 14.1).

It is now apparent that implementation of the Directive, as interpreted by the Court, will pose a threat to the survival of small hospitals serving dispersed populations.<sup>87</sup> To ensure twenty-four-hour, year-round coverage in a speciality, the rota must include up to ten doctors. This is far in excess of the number actually employed in some specialities, even in quite large hospitals. Furthermore, although the overall hours worked are less, the resulting shift patterns can be very disruptive of family life. Finally, reduced hours, coupled with a transfer of much care out of hospitals, greatly reduce opportunities for training.

### A. *The contents of the Directive*

It is important to stress that Member States are free at any time to apply laws that go further than the Directive (Article 15) to protect the health and safety of workers. The minimum requirements include: a forty-eight-hour maximum working week, including overtime (Article 6); a minimum of eleven hours of continuous rest in every twenty-four-hour period (Article 3), a rest break after every six hours worked (Article 4); a minimum period of twenty four hours of continuous rest in each seven-day period (Article 5); and a minimum of four weeks' paid annual leave (Article 7). Night workers should not work longer than eight hours in any twenty-four-hour period where their work involves special hazards

<sup>85</sup> N. J. Douglas, 'Sleep, performance and the European Working Time Directive', *Clinical Medicine* 5 (2005), 95–6.

<sup>86</sup> R. Baeten and Y. Jorens, 'The impact of EU law and policy', in Dubois, McKee and Nolte (eds.), *Human resources*, above n.64, pp. 214–34.

<sup>87</sup> B. Rechel, C.-A. Dubois and M. McKee, *The health care workforce in Europe: learning from experience* (Copenhagen: WHO Regional Office for Europe on behalf of the European Observatory on Health Systems and Policies, 2006).

### Box 14.1 Experience in implementing the European Working Time Directive in the United Kingdom

The implications of the Directive have been reported on most extensively from the United Kingdom. One study was undertaken in a stroke unit that had a senior doctor in training based on the ward each weekday to provide regular input at times when other members of the rehabilitation team were working. During weekdays in the three months following the implementation of the Directive, none of the most junior doctors in the training grades were present on 52% of the days, while on 42% of the days none of the more senior doctors in training were present. On 28% of days, no doctor in training attended the ward. Although it is especially important to ensure medical involvement in the assessment of such patients during normal working hours, the implementation of the Directive substantially reduced the opportunities to do so.<sup>88</sup>

Another study examined the provision of neonatal care in three hospitals providing obstetric services.<sup>89</sup> It concluded that, although some rationalization was possible by having only one hospital providing the most complex care, by requiring senior staff to work night shifts (although they questioned how sustainable this was in the long term), and by enhancing the roles of nonmedical staff, implementation of the Working Time Directive would ultimately require a major reconfiguration of services. However, this would require careful planning and coordination of hospital services at the regional level at a time when the English Department of Health was seeking to increase competition between facilities.<sup>90</sup>

or heavy physical or mental strain (Article 8). Night workers are entitled to a free health assessment, and should be transferred to day work, whenever possible, if they develop health problems related to night

<sup>88</sup> M. O. McCarron, M. Armstrong and P. McCarron, 'Effect of the European Working Time Directive on a stroke unit', *Quality and Safety in Health Care* 15 (2006), 445–6.

<sup>89</sup> C. Campbell and S. A. Spencer, 'The implications of the Working Time Directive: how can paediatrics survive?', *Archives of Disease in Child* 92 (2007), 573–5.

<sup>90</sup> C. Ham, *When politics and markets collide: reforming the English National Health Service* (Birmingham: Health Services Management Centre, 2007).

work (Article 9). More generally, night and shift workers should have dedicated health and safety protection, including access to protection and prevention services or facilities appropriate to the nature of their work (Article 12). Article 16 lays down reference periods during which these requirements should be fulfilled. For example, for the forty-eight-hour week, this is averaged over four months.

It was not until the *SIMAP*<sup>91</sup> and *Jaeger*<sup>92</sup> judgments in the European Court of Justice that ‘working time’, in relation to on-call duties, was defined in the health sector. The Directive defines ‘working time’ as the period a worker is working, at his/her employer’s disposal and carrying out his/her activity or duties (Article 2(1)). Many employers had assumed that time spent awaiting emergency calls but not actually working was excluded from working time.

In the *SIMAP* case, the Court ruled that on-call duty by doctors counts as working time when they are present at the facility but when they are on call from home, it only counts when they are actually working. The *Jaeger* case between the German municipal authorities and Dr Jaeger was brought before the Court to clarify whether on-call duty hours in the emergency department were to be considered working time. The authorities argued that German law distinguishes between ‘readiness for work’, ‘on-call service’ and ‘stand-by’, stating that only ‘readiness for work’ constitutes actual work that is eligible for payment, while the others are considered resting time, as no professional tasks are performed. However, the Court ruled in favour of Dr Jaeger, stating that his on-call hours at Kiel municipal hospital were to be considered to be working time, regardless of whether he actually treated patients or rested. Thus, this ruling further clarified that being present in the hospital but not carrying out activities must be seen as ‘working time’, even when the doctor is resting. An example of how on-call work in Hungary relates to payment within the framework of the Working Time Directive is presented in Box 14.2.

### B. Derogations and opt-outs

Derogations from the minimum requirements do, however, remain possible under the conditions of Article 17. They should be set out in

<sup>91</sup> *Ibid.*

<sup>92</sup> Case C-151/02, *Jaeger* [2003] ECR I-8389.



### Box 14.2 Experience in implementing the European Working Time Directive in Hungary

Doctors in Hungary can undertake on-call work for eighteen consecutive hours or twenty-four hours in emergencies; however, differentiation is made between on-call work (e.g., surgeons), qualified on-call work (e.g., doctors working in drug clinics, anaesthesiology or neurotraumatics) and 'silent' on-call work, as stated in the Labour Code and Government Decree 233/2000 on the Application of the Public Employees Act to Health Care. Wages are calculated according to the amount of actual work involved, but, when this was not recorded, or there is no collective agreement, then only four to six hours of on-call duty is regarded as actual work. Therefore, it is quite common for doctors to begin their regular eight-hour shift after spending twenty-four hours on-call, and only receive payment for six hours of work during the on-call period.<sup>93</sup>

In April 2005, a Hungarian doctor decided to challenge these regulations through the Hungarian labour courts on the basis that they conflicted with the Working Time Directive. He argued that, according to the ECJ, if a doctor has to remain at his/her workplace when on call, then the total time has to be considered to be working time, regardless of whether he/she had undertaken any actual work. If the higher courts share the same opinion, then the health care system of Hungary will face a significant crisis. The Hungarian Chamber of Doctors estimated that around 25 000 Hungarian doctors were in a similar situation, and may be able to recover the wages they have lost.<sup>94</sup> The state has tried to resolve the dispute without setting a legal precedent.

laws, regulations, administrative provisions or (collective) agreements and should provide compensatory rest ensuring at least the same degree of protection. Derogations from the rest requirements (in Articles 3, 4 and 5), the eight-hour night work schedule (Article 8), and the reference periods (Article 16) are explicitly allowed where (health) services must

<sup>93</sup> É. Magyar, 'Jogharmonizáció immáron, bentról' szemlélve: a munkaidő szabályozásának lehetséges irányai I', *Munkaiügyi Szemle* 5 (2004), 19–23.

<sup>94</sup> L. Dux, 'Working time of Hungarian doctors one year after 2004', *Transition Studies Review* 13 (2006), 23–5.

ensure continuity of care (Article 17(3)(c)(i)). As mentioned previously, for doctors in training there is a specific transitional period before full implementation of the 'forty-eight-hour week' requirement (Article 17(5)) in Directive 2000/34/EC, which takes 'the specific nature of activities of doctors in training into account' (Preamble, Point 7). Although intended to be implemented by 2009, a Member State can request the Commission to grant a further delay of three years, but must justify its case. In no case has a doctor in training been allowed to work more than fifty-eight hours per week since August 2007, fifty-six hours since September 2007, and will be prevented from working more than fifty-two hours from September 2009.

There is, however, a potential escape clause for governments, as Member States can decide to allow individual workers to opt out of the forty-eight-hour limit (Article 22). However, as confirmed in the case of *Pfeiffer*,<sup>95</sup> consent should be given expressly and freely by the individual and referral to a collective agreement is not sufficient. Some have done so, specifically to alleviate some of the problems created by the *SIMAP* case. Cyprus, France, Germany, Malta, the Netherlands, Slovenia and Spain have done so, but only for health workers, while the United Kingdom has enabled all workers to do so.

### C. Moving forward

There are some measures that can ameliorate the problems outlined above. There is substantial scope to transfer responsibility for many conventionally medical roles to other health care professionals. Of course, this must be accompanied by corresponding improvements in the status and pay of those taking on these extended roles.<sup>96</sup> There is also much scope for cross-cover of activities, for example, by different sub-specialities within surgery. However, in many cases, the only feasible solution is the merger of small hospitals, potentially creating problems with access to services.<sup>97</sup> There is also considerable scope

<sup>95</sup> *Ibid.*

<sup>96</sup> McKee, Dubois and Sibbald, 'Changing professional boundaries', above n.64, pp. 63–78.

<sup>97</sup> M. McKee, *Reducing hospital beds. What are the lessons to be learned?* (Copenhagen: WHO Regional Office for Europe on behalf of the European Observatory on Health Systems and Policies, 2004).

for greater efficiency in training, in particular making much greater use of actors performing the roles of patients and using simulators, but this has enormous financial consequences for medical schools.

Notwithstanding the scope for such changes, there remains a broad consensus that the existing legislation poses serious problems, largely because the Court has interpreted 'working time' in a way that is different to that envisaged by some of those who enacted the original Directive. Consequently, the European Commission launched a public consultation on the Directive in early 2004. In September 2004, it proposed updating key aspects of the Directive, suggesting that the inactive time spent on call would not be considered to be working time, while compensatory rest should be provided after seventy-two hours. An individual opt-out would remain possible but subject to stricter conditions. However, the European Parliament fundamentally amended this Commission proposal in May 2005 on its first reading, stating that waiting time should be considered entirely as working time.<sup>98</sup> The European Commission then presented a new proposal in an attempt to reach a compromise.<sup>99</sup> It has, however, proven extremely difficult to achieve an agreement within the Council, with a meeting of employment ministers during the 2006 Finnish Presidency concluding that, at that time, there was no prospect of reaching a consensus.<sup>100</sup> A sticking point has been the insistence, by Cyprus, France, Greece, Italy and Spain, that the opt-out should be phased out over time, while others, such as the United Kingdom, want it to remain indefinitely. It is also clear that there is no enthusiasm for treating health care as a special case.

In the second half of 2007, the Portuguese Presidency proposed that: (a) the opt-out would be seen as an *exception to the general rule* of a forty-eight-hour working week in the EU; (b) implementation of the opt-out must be laid down by collective agreement, agreement between the social partners or by national law; and (c) a

<sup>98</sup> European Parliament Legislative Resolution on the proposal for a Directive of the European Parliament and Council amending Directive 2003/88/EC concerning certain aspects of working time (COM (2004) 0607 – C6–0122/2004 – 2004/0209 (COD)), P6\_TA-PROV(2005)0175, 11 May 2005.

<sup>99</sup> European Commission, 'Amended proposal for a European Parliament and Council Directive amending Directive 2003/88/EC concerning certain aspects of the organisation of working time', COM (2005) 246 final, 31 May 2005.

<sup>100</sup> R. Watson, 'European Working Time Directive: battles in time', *British Medical Journal* 334 (2007), 770–1.

weekly limit of working hours would be set for workers who agree to the opt-out, among other stipulations.<sup>101</sup> Agreement on the Working Time Directive and similar measures applying to temporary agency work<sup>102</sup> was postponed in December 2007, after the British prime minister threatened to boycott the Treaty signing ceremony in Lisbon. He argued that giving enhanced rights to temporary workers would damage the flexible employment market in the United Kingdom<sup>103</sup> and linked the issue to the EU Treaty. Nevertheless, a majority of Member States are in favour of action to help agency workers.<sup>104</sup> In the meantime, there have been complaints, upheld by the European Ombudsman, that the Commission is not dealing with infringement complaints on the Working Time Directive in a timely manner.<sup>105</sup> In June 2008, the Council finally reached a political agreement on the Commission proposal. This agreement considered active on-call time at the workplace to be working time, in contrast with inactive on-call time, which does not have to be regarded as working time unless national law so provides.<sup>106</sup> This position was endorsed by the European Commission<sup>107</sup> but rejected again by the European

<sup>101</sup> 2837th Council Meeting on Employment, Social Policy, Health and Consumer Affairs, Doc. No. 16139/07 (Press 284), Luxembourg, 5–6 December 2007.

<sup>102</sup> The Council sought to reach political agreement on two draft directives: amending Directive 2003/88/EC and establishing working conditions for temporary agency workers. Due to difficulties in finding separate solutions for these drafts, the Portuguese Presidency decided that there would be added value in working on a simultaneous and integrated solution.

<sup>103</sup> The United Kingdom Government was concerned that if agency workers were treated equally to permanent workers, flexible employment would become less useful.

<sup>104</sup> European Citizen Action Service, 'EU ministers bow to Brown over working time, temp work', *EurActiv*, 7 December 2007, [www.euractiv.com](http://www.euractiv.com).

<sup>105</sup> European Citizen Action Service, 'Ombudsman urges Commission: "get going on working time"', *EurActiv*, 19 September 2007, [www.euractiv.com](http://www.euractiv.com).

<sup>106</sup> Common Position (EC) No. 23/2008 of 15 September 2008 adopted by the Council, acting in accordance with the procedure referred to in Article 251 of the Treaty establishing the European Community, with a view to the adoption of a Directive of the European Parliament and of the Council amending Directive 2003/88/EC concerning certain aspects of the organisation of working time, OJ 2008 No. C254/26.

<sup>107</sup> Communication from the Commission to the European Parliament pursuant to the second subparagraph of Article 251(2) of the EC Treaty concerning

Parliament at its second reading.<sup>108</sup> The Parliament reconfirmed its view that non-active on-call time should also be considered as waiting time. By April 2009, the Parliament and Council had failed to find a compromise during the conciliation process, including the issue of on-call time, concluding a five-year effort to agree a revision of the Directive. This is the first time that no agreement could be found through the conciliation process since the Amsterdam Treaty, which significantly extended the scope of the co-decision procedure. The Commission is left with three options: do nothing; start infringement procedures against the Member States that are facing problems complying with the European Court of Justice judgements on on-call time calculations; or come up with a new proposal to revise the Directive.

#### **4. Conclusion**

Mutual recognition of diplomas and the coordination of rules regarding the pursuit of a profession enabled the large-scale cross-border movement of health professionals within the European Union. Yet, as was realized as long ago as the fourteenth century when the Venetian Republic introduced quarantine to counteract the hazards of free trade, free movement can conflict with public health. Here, the concern relates to patient safety. Once again, the search for a coherent legal framework involves the quest for balance between the internal market and public health.

The legal framework provided by Directive 2005/36/EC contains shortcomings and fails to resolve legal uncertainty. Examples reviewed in this chapter include the lack of coordination of disciplinary measures, of continuing professional development systems and of potential problems concerning cross-border payment or reimbursement of costs

the Common Position of the Council on the adoption of a proposed Directive of the European Parliament and of the Council amending Directive 2003/88/EC concerning certain aspects of the organisation of working time, COM/2008/0568 final – COD 2004/0209.

<sup>108</sup> European Parliament Legislative Resolution of 17 December 2008 on the Council Common Position for adopting a Directive of the European Parliament and of the Council amending Directive 2003/88/EC concerning certain aspects of the organisation of working time (10597/2/2008 – C6–0324/2008 – 2004/0209(COD)).

by social security bodies. The lack of a clear definition of ‘services’ in relation to ‘establishment’, the exclusion of telemedicine from its scope of application, and the system of acquired rights exemplify the missed opportunities. A more active harmonization of training requirements and the conditions under which individuals pursue health professions seems to be needed. The principle of free movement will only be accepted by European citizens when they can overcome mistrust of the quality of training provided in some other Member States and when the remaining legal issues discussed above are resolved. Yet the challenges involved are profound. Within the EU, there are very different views about the acceptable relationship between the state and the health professional. Those countries with strong traditions of liberal professions would find it quite unacceptable to have the very high level of state control seen in, for example, the United Kingdom, where the activities undertaken by family doctors are set out in an extremely detailed payment schedule. Similarly, there are great differences in how countries view misdemeanours by health professionals that are unrelated to their professional work. Thus, a British doctor recently appeared before the General Medical Council (the professional regulator) accused (but subsequently acquitted) of disorderly behaviour at a football match when off duty. In particular, an especially intrusive role for the state may raise concerns in those new Member States where, within living memory, there were many examples of victimization of health professionals on political grounds. It seems especially unlikely that Member States with such diverse cultures would be able to achieve any meaningful agreement at a European level, much less give the European institutions the power to enforce some pan-European model.

Turning to the Working Time Directive, this is clearly a law that was enacted for the best possible reasons, seeking to abolish into history the horrendous working schedules that existed a generation ago. However, the specific characteristics of the health care sector have made it extremely difficult, in practice, to create provisions that would be appropriate in that sector. The health care sector stands out as being extremely labour intensive, yet demands continuity of care. To achieve this, it traditionally made maximum use of its personnel – especially doctors in training – who were, albeit often reluctantly, willing to work such long hours to optimize exposure to experience and in the knowledge that it would only last a few years. The

challenges faced by governments, professionals and other health care providers are formidable. The process of adaptation will be long and difficult but, in the long run, these changes are needed. The Working Time Directive provides a much needed incentive to make the best possible use of scarce human resources.

As is apparent from many chapters in this book, European Community law does not always take account of the specific characteristics of health care. Health systems in Europe differ greatly and are continually changing. This makes it difficult to ensure that relevant EU legislation takes account of the implications for health care. The challenge is to find compromises between the need to promote effective, equitable and efficient health care, while adhering to the underlying principles of EU law.