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Guest Editorial

EU law and national health policies: problem or opportunity?

TAMARA K. HERVEY*
Professor of European Law, University of Nottingham, UK

The European Union's (EU) legal system was set up primarily to establish and maintain the 'single market', based on the 'integration' of the separate markets of the Member States. This integration forms the bedrock of the peace and security sought by the original 'founding fathers' of the EEC. The legal tools of integration include a deregulatory entitlement of economic actors (mainly, firms operating in the EU) to challenge discriminatory barriers to trade and other impediments to access the markets of other Member States. They include enforceable legal norms to ensure free competition within the single market. They also include regulatory powers (or competences) of the institutions of the EU, to adopt harmonized legislation necessary to create and sustain the single market. Nothing here, the casual observer might remark, to touch on national health policies, and certainly nothing that might destabilize their fundamental values and principles.

Not so. There is no doubt that EU law does affect national health policies, both directly and indirectly. The deregulatory, market-based rules of EU law have been presented as at least having the potential to challenge some of the fundamental principles upon which European health care systems are built, such as territoriality, solidarity in provision or equality of access irrespective of means. However, it is my view that, rather than being merely a source of destabilization with negative consequences, EU law may be seen as presenting *opportunities* for development of national health policies in the Member States.

The EU has a very long pedigree of regulatory measures affecting national health policies. For instance, because pharmaceuticals, medical devices, and other medical 'products' need to be able to circulate freely within the single market (at least as a matter of law), there is a significant body of EU law, dating back to the 1960s, covering their marketing authorization; labelling, packaging, and advertisements; and quality and safety. Recent additions to this legislative

*Correspondence to: Professor Tamara K. Hervey, School of Law, Law and Social Sciences Building, University of Nottingham, University Park, Nottingham NG7 2RD, UK. Email: tamara.hervey@nottingham.ac.uk

canon include the Blood Safety Directive 2002/98/EC[1] and the Human Tissue Directive 2004/23/EC,[2] which respectively regulate the collection, testing, processing, storage, and distribution of human blood and blood components, and human tissue and cells. In the future, we can expect a similar Directive on human organs. In accordance with Article 152 of the EC Treaty, such regulatory measures may not prevent Member States from setting higher standards. Thus, EU-level harmonized standards represent a minimum regulatory base. Although such a base means that higher standards maintained within particular Member States are not formally contrary to EU law, the acceptance of these regulatory measures and their promulgation in EU-level legal norms may have a destabilizing effect on principles or values in particular Member States; either because they alter the range of acceptable policy positions that are in the frame of national policy debates, or because they alter the interpretative environment in which national courts approach national regulatory measures in the same field. For instance, although the Blood Safety Directive mandates unpaid blood donations 'as far as possible', it implies that payment for blood donations may be lawful within the EU, a principle that is fundamentally at odds with health care law in Member States such as France.

To give just one more example, the Working Time Directive 93/104/EC (as amended), although it contains opt-outs and derogations, has been the subject of litigation brought by health care professionals in Spain (Case C-303/98 *SIMAP*) and Germany (Case C-151/02 *Jaeger*) on its application to 'on-call' work.[3] The permitted derogation from the maximum weekly working time for doctors in training runs out in 2009, or at the very latest 2012. At this point, junior hospital doctors' hours in the United Kingdom will need to be cut by around 25 per cent, raising concerns about adequacy of professional cover, and thus access to health care services, and the traditional models of training that are part of the culture of the health service in Member States such as the United Kingdom and Ireland.

This EU regulatory legislation is adopted by the institutions of the European Union: the European Commission, the European Parliament and the Council of Ministers. The legislative procedures differ according to time and subject matter, but it is not always the case that the government of each Member State enjoys a veto. Once the legislation is adopted, it becomes binding not only on the governments of the Member States themselves, but also on all public actors ('emanations of the state') within the Member States, and is potentially enforceable through litigation. The national legal position for public providers of

1 To be implemented by the Member States by February 2005, although Eurlex (http://eurlex.europa.eu.) cites no implementing measures for several Member States.

2 To be implemented by April 2006; at the date of writing Eurlex cites implementing measures for only two Member States.

3 A clarifying legislative amendment has been proposed (COM 2004 (607) final; COM 2005 (246) final), according to which 'on call time' during which the health care professional is not actually working does not count as 'working time'. Political agreement in Council is expected in November 2006.

health care is changed. EU law may also alter both the policy-making and the jurisprudential environment within Member States. There are questions about the legitimacy of EU legislation, particularly where it has effects in fields that are not closely related to the single market. How can we be confident that the distant institutions of the EU have the capacity, experience and representative quality to adopt the appropriate legislation, or the legislation that the citizens (or patients) of Europe desire? This is the classic notion of the EU's 'democratic deficit', and it has a particular application in health care regulation.

There is, however, a more profound sense of deficit in EU law. This deficit arises through the EU's peculiar legal or 'constitutional' structure. While regulatory measures necessary to secure the single market *may* be adopted by the EU institutions, these measures are not *mandated* by EU law, and are adopted only where there is sufficient political will and consensus to reach an agreed legal text. In some circumstances, the EU may lack the legal power to adopt regulatory measures with a social aim (see, for example, Case C-376/98 *Tobacco Advertising*). Yet the other central tools for legal integration, enforceable legal rules aimed at ensuring the free movement of goods and services, and free competition, within the internal market, have no such restrictions. These legal rules (found in the Treaty establishing the European Community itself, the EU's – *existing* – 'constitution', not to be confused with the ill-fated 'Constitutional Treaty') can be relied upon by private litigants, before their national courts. The free movement and competition rules take precedence over conflicting national rules, *of any type*, even over conflicting subsequent legislation adopted by national parliaments (there is a debate about whether they even take precedence over national constitutional rules). The result is that the national regulation is to be removed, leaving free access to national markets, or free competition. This applies even if the aim of the national rules at issue is something other than trade or competition, for instance the protection of social welfare or public health. This means that there is an imbalance – a deficit – between the EU's regulatory powers and its deregulatory powers. While it may be difficult to secure regulatory integration, particularly in areas of social policy, deregulatory integration is secured by unpredictable acts of private litigation. National regulatory norms, including those aimed at achieving social policy goals, may be removed by the power of EU market law.

What does this mean for health care? For example, it means that, in certain circumstances, patients in the EU, relying on the EU's Treaty rules on free movement of services, may seek health care in another Member State, and have that care reimbursed by their national health (insurance) system (Case C-158/96 *Kohll*; most recently Case C-372/04 *Watts* (16 May 2006)). This implies some loss of national control over elements of national health (insurance) systems. National systems must operate so as to eliminate any effect of discrimination against service providers in other Member States, or any unjustified deterrence of patients from seeking health care from such providers. Member

States may, as a consequence, be unable to use certain policy tools, for instance the requirement of authorization for non-hospital care only in another Member State (Case C-158/96 *Kohll*); differential rates of reimbursement for treatment in another Member State (Case C-368/86 *Vanbraekal*); the use of closed lists of national contractors (Case C-157/99 *Geraets-Smits/Peerbooms*; Case C-385/99 *Müller-Fauré/Van Riet*); some uses of hospital waiting lists[4] (Case C-157/99 *Geraets-Smits/Peerbooms*; Case C-385/99 *Müller-Fauré/Van Riet*; Case C-56/01 *Inizan*; Case C-372/04 *Watts*); or the requirement that the patient wait for authorization before receiving the care (Case C-8/01 *Leichtle*). National policies requiring prior authorization for *hospital* care abroad may however be justified by reference to the financial impact removing such a policy would have on a carefully planned, rationalized, stable and accessible national health care system (Case C-158/96 *Kohll*; Case C-157/99 *Geraets-Smits/Peerbooms*; Case C-368/86 *Vanbraekel*; Case C-385/99 *Müller-Fauré/Van Riet*; Case C-8/01 *Leichtle*).

The impact of deregulatory EU law may also mean that, in some circumstances, EU competition law applies to bodies within national health systems. Pension funds forming part of the national social security system can fall within the scope of EU competition law (Case C-67/96 *Albany*). There seems no reason to treat health care insurance funds differently, at least where, like the pension funds at issue in *Albany*, they compete with private insurance companies in the relevant market.[5] The Court decided on whether EU competition law applies to a purchasing body which then uses the goods and services purchased for a non-economic activity (providing health care) in Case C-205/03P, *FENIN* (11 July 2006). The Court agreed with the Court of First Instance and the Advocate General that the organizations which run the Spanish national health system do not act as 'undertakings' when purchasing medical goods and equipment for use in Spanish hospitals. However, this conclusion may depend upon a lack of competition in fact between public and private actors in the provision of public health care in Spain.[6] The implication of this would be that EU competition law does apply wherever private actors take part in the provision of public health care. Moreover, the Court of Justice confirmed the reasoning of the Court of First Instance, which implies that the act of purchasing may not be severed from the act of providing health care, both of which are carried

4 The question of what is 'undue delay' in this context has not been specified by the European Court of Justice, save that it is for national courts to determine, in each particular case, whether the waiting time exceeds a medically acceptable period, Case C-372/04 *Watts*.

5 In *Albany*, the funds operated according to capitalization rather than cross-generational solidarity and set their own contribution and benefit levels (subject, of course, to regulation applicable also to private insurers).

6 Advocate General Poiares Maduro proposed remission to the Court of First Instance to determine whether the Spanish national health system meets its obligations to provide free universal health care entirely through public bodies, or whether private actors also play a part.

out by the purchasing body. However, one might equally argue that it is Spanish hospitals, not the purchasing body, that carry out the health care (outside of competition in any market), but that purchasing is a separate activity, which may take place within a market, if private actors are also present. If this approach is accepted as implied by the *FENIN* ruling, then most health care purchasing bodies will fall within the scope of EU competition law. If EU competition law applies, then the body concerned may not 'abuse' its 'dominant position', for instance by keeping other actors out of the market through its contracting practices, or by keeping prices below 'competitive' levels.[7] Again, the application of EU deregulatory law may preclude the use of certain policy tools, such as closed contracts or fixed pricing, by Member States.

The logic of the application of EU free movement and competition law in health care settings suggests the possibility of destabilization of some of the principles and values of national health care systems. If health care systems cannot be 'closed' at national borders, how can equality of access through solidarity of the citizens of that state be ensured? How can capacity maintenance and planning be carried out? If the rules of free competition apply, what happens to solidarity mechanisms whereby some actors are kept out of the market, so that the needs of all may be met through cross-subsidization? More fundamentally, what happens to 'patients' if the power of the language of EU law, and its underpinning ideas, sees only 'service recipients'?

However, this assessment of the relationship between EU law and national health care systems is unduly pessimistic. This is for two inter-related reasons. First and foremost, the legal construct of the internal market has never been that of a simple deregulatory space, along the lines suggested by neo-liberal economics. The Treaty itself, and the jurisprudence of European Court of Justice, contain strong indications that the most destabilizing effects of free movement and competition law are not mandated by the single market's rules. Member States can lawfully justify impediments to market access and to competition by reference to social values, including protection of public health, financial stability of public welfare institutions, and social solidarity (this is seen in the jurisprudence concerning free movement of patients, above). Secondly, the implied tension between the market and social policy in EU law (social regulation must be removed through deregulatory market-based litigation, yet the EU has power to 're-regulate' only where this is necessary for the single market) has been put into question. The EU's 'Lisbon Agenda' recognizes that social welfare – including a European model of health care – is a valuable part of the EU's economy. The message that 'health is wealth' is permeating the EU's institutions, and this may, in time, permeate its legal rules also.

7 The EC Treaty, Article 86 (2), does provide an exemption for 'services of general interest' which may preclude the application of EC competition law where a monopoly position is necessary to achieve the tasks assigned to the body concerned.

Through various innovative institutional mechanisms (including- a 'high level reflection process',[8] a new 'High Level Group on Health Services and Medical Care'[9] and an 'open method of coordination'), the EU has become a focus for discussions, especially based on sharing 'best practice', on common concerns of national health care systems, including equality of access, patient safety, patients' rights, life-style related health concerns, and so on. Where health concerns have cross-border effects, EU action is being supported, not only in legislation such as the Tobacco Advertising directives, but also in exchange of information and research into all sorts of health issues. It is hard to resist the conclusion that at least some of the energy behind this political activity may be explained by the (perceived) threats from destabilizing litigation. Rather than jeopardizing national health care systems, the potentially destabilizing effects of EU law have been seen as an *opportunity* to develop EU-level structures, such as the new institutions and governance mechanisms mentioned above. Over time, we may also see development of EU-level norms (probably in the first instance, soft law norms, such as an agreed EU Charter of Patients' Rights) in this field. Internal market legislation may include explicit regulatory responses to the problems raised by its application in public health care contexts, such as we have seen in the robust debates over the proposed new Services Directive (COM (2004) 2). The courts, including the European Court of Justice, may develop the legal concept of justified derogations from free movement law in health care contexts, in particular to protect financial robustness and stability of Europe's solidarity-based, equal access national health care systems. The courts may clarify the scope of application of EU competition law, as excluding solidarity-based public health care structures, and, even where competition law does apply, may find exemptions for health care as a 'service of general interest', offered on a universal and equitable basis within Member States. The articulation of these legal principles in the context of EU law may help to secure those values implicit therein, which underpin national health care systems in the Member States, against deregulatory tendencies, irrespective of whence these emerge. The EU lacks the competence and the legitimacy to take the place of national health care systems. Its deregulatory deficit is therefore here to stay in the context of health care. However, EU law may provide opportunities, in particular in articulating the limits of its application in free movement of services and competition law contexts, to shore up the 'European social model' of health care, and to protect its fundamental values and principles.

8 Final report: High Level Reflection Group, *High Level Reflection Process on Patient Mobility and Healthcare Developments in the European Union* HLPR/2003/16, 9 December 2003. Former Commissioner Byrne also launched an electronic reflection process, see D Byrne, 'Enabling Good Health for all: a reflection process for a new EU Health Strategy' 15 July 2004, http://europa.eu.int/comm/health/ph_overview/strategy/health_strategy_en.htm.

9 Made up of senior officials from Member States and chaired by the Director General of the European Commission's DG SANCO.