There is an increasing interest in the impacts of European Union (EU) law on the health care sector. Focusing on institutional matters in this respect, this article will consider three questions: What is special about EU law? What challenges and opportunities for those in the health care sector therefore arise? What kinds of questions should those involved in managing the health care sector therefore be asking themselves?

To understand the answers to these questions, we need to understand the limited competence of the EU in the field of health care; EU law making processes (both legislative and judicial); the structure of EU law, and in particular the centrality of ‘internal market’ law; and the concepts of supremacy and ‘direct effect’ or individual enforceability of EU law. We also need to consider the policy responses that the EU has adopted, and may adopt, to ‘add value’ to health care systems using EU institutions and processes.

**EU law making and the competence of the EU**

The EU is not a state. Its institutions may not make any law or adopt any policy they wish. They may only act within the powers given to the EU by its Member States.¹ This is the idea of limited competences. It is an important feature of EU law and policy-making, for it both constrains the EU and also means that the EU sometimes uses its powers for unexpected purposes.

For instance, who would have thought that the power to create a single market within the EU (an area where goods and services move freely) would give the power to adopt a Directive (an EU law) that forbids the advertising of tobacco on television;² or EU law that covers the social security entitlements of people who work in another EU country;³ or a Directive that forbids direct to consumer advertising of prescription-only pharmaceuticals?⁴

If the EU has a law-making power, the way that it can exercise that power is through a law-making process that involves three key institutions. The European Commission makes the original proposal. The European Parliament and the Council must then agree to it. But the European Commission does not have a specific ‘health care ministry’, and often the national ministers in Council that are present or involved in adopting a piece of EU law with effects for the health care sector are not ministers of health. The EU law-making process can therefore inadvertently fail to consider important ramifications for health care systems.

**The structure of EU law**

The way that EU law has developed is a product of the history of the EU. Historically, the *raison d’être* of the EU was to bring together the economies of the Member States (the countries that are part of the EU) – especially their coal and steel industries, which were the engines of warfare – in such a way as to prevent future wars in Europe. Integrated economies would mean that war was a practical impossibility. Also, the idea was to capitalise on the economies of scale that are associated with having large markets for goods and services.

Because of its history, EU law is structured around the key ideas of free movement and fair competition within a single European market. The law plays a crucial role in the process of integrating Europe’s economies. EU free movement law and EU competition law form the bedrock of EU law. EU free movement law applies essentially to the acts of ‘states’ or public authorities. It prohibits ‘restrictions’ on the free movement of goods and services within the EU’s internal market. It also includes public procurement law, to make sure that public contracts can be won by providers from anywhere in the EU, not simply given to local firms. Most EU public procurement law does not apply to the health care sector, but some of it does. EU free movement law does not simply contain...
unfettered rights to free movement – some restrictions are justified, for ‘objective public interests’, such as protecting consumers; or ensuring sufficient and permanent access to a balanced range of high quality hospital services in the Member State; or maintaining the financial viability of a health care system.6,7

So those within the health care sector need to ask questions about whether their policies or practices restrict free movement in the internal market, and if so, whether they comply with EU law.

EU competition law applies essentially to private actors – to ‘undertakings’ or firms operating within the EU. Most EU competition law therefore does not apply to the public health care sector. But there are exceptional cases where it does – if a part of the health care sector is acting as an ‘undertaking’, i.e., if it is engaged in an economic activity.7 Again, exceptions to EU competition law apply to public bodies, if they need to have a special monopolist position in the market, in order to provide a public service of special interest, such as health care.

So those within the health care sector need to ask questions about whether they are acting as an undertaking, and if so, if they are complying with EU law.

In addition to free movement and fair competition, even from the beginning, the EU had the power to adopt law and policy to soften or make fairer the impacts of creating a single market. For instance, to make sure that workers did not lose out in the process, EU law covers health and safety in the workplace. To make sure that consumers are not harmed by products or services circulating in the internal market, EU law sets safety and consumer protection standards. To make the internal market run smoothly, EU law governs commercial contracts. For instance, the system of medicines authorisation in Europe is a product of EU law. To make sure that the single market does not adversely affect the environment, a large body of EU environmental law covers matters such as air and water quality and the disposal of waste. To protect patients, EU law covers blood safety and regulates the use of human tissue and organs.8

Those within the health care sector therefore need to be aware of a wide range of substantive rules of EU law that apply to them as employers, as contractors, as producers of waste, as providers of services and so on. Specific details vary, so of course specific advice should always be sought.

The supremacy of EU law
Unlike ordinary international law, EU law has a special legal status in the legal systems of its Member States. This legal status was not explicitly agreed by the Member States, but has been ‘created’ by the European Court of Justice (ECJ). However, it has been accepted by national courts. This is the idea of supremacy of EU law – it means that EU law applies over any contradictory national law, and national law that contradicts EU law must be ‘disapplied’.9 The consequence of supremacy of EU law is that national parliaments cannot legislate their way out of EU law that they do not support. Nor can, for instance, self-regulating professional associations do so. They must comply with EU law.

The consequence of non-compliance for a state is first political censure and (eventually) being brought before the ECJ. But for public bodies within states, a much more important dynamic is at work. This is known as the ‘direct effect’, or enforceability of EU law.

The enforceability of EU law
Not only is EU law supreme, but it also has another very important feature – it is enforceable by individuals before their national courts. Not all of EU law is enforceable in this way, and not all of it is enforceable in this way against private individuals. But it is enforceable against state bodies, which would include a wide range of public health care institutions within the Member States.10

The consequence of the ‘direct effect’ of EU law is that a private individual may enforce a right in EU law against their own state, or any part of it, or public body within it, such as national health care bodies. This enforcement happens within national courts.

This is the basis on which the by now infamous patient mobility cases were brought to court.5,6,11 Various patients, unhappy with the level of provision in their national health care systems for various reasons – too long a wait; not the treatment that they hoped to get; cheaper treatment available abroad – brought cases in their own national courts, challenging their health authorities’ refusal to authorise them to receive treatment abroad. In some of these cases, the ECJ (which is asked by national courts for its interpretation of EU law in such cases) found that there was an unjustified restriction on free movement, and so a breach of EU law. The best-known of these cases in the UK is the Watts case.12 The UK has now changed its practice, to comply with EU law on this point, and guidelines for local health commissioners are available. Other cases include a recent decision involving restricted access to university medical training, which was challenged on the basis that it breached EU law allowing citizens of EU states to move freely, including for the purposes of education.13

What may turn out to be more significant than individual human beings (patients) relying on EU law in the health care sector is the use of EU law by firms, particularly larger firms, operating in the health care sector, that seek to challenge national policies that impede their marketing or operational strategies. So, for instance, Spanish law on the licensing of pharmacies, which limited the number of pharmacies by population density, has recently been challenged (with partial success) as breaching EU law on freedom of establishment.14

All of this means that people working in a sector such as the health care sector, which is not structured according to market logic, have to be vigilant in terms of where EU law – which nevertheless has binding force within the Member States of the EU – might interface with their activities.

Policy responses
The EU not only adopts laws to achieve its aims. It also makes use of a wide range of policy instruments. These include EU funding for research. EU research funding is organised into ‘Framework Programmes’ and gives opportunities to conduct collaborative research across borders. Many research projects – for instance, on rare diseases – have been supported by the EU. ‘European Reference Networks’ – groups of health care experts in a particular field – work together, supported by the EU, to share knowledge and expertise in state of the art medical practice. The idea is that the EU can ‘add value’ to activities that would not be so effective if carried out at national level alone. The EU’s public health programmes also provide opportunities for funding for collaborative work in the health field.

There is also the opportunity to feed into the development of ‘best practice’ at EU level. The EU gathers and compares a wide range of health data that can be used to inform decision-making processes at all levels. From this, we can begin to discern
best practice. So, for example, the Council has adopted a recommendation on patient safety, including health care associated infections. For example, the EU has been instrumental in developing the ‘European Code Against Cancer’, a collection of recommended protocols on cancer screening, as well as best practices for the prevention and treatment of all cancers.15,16

Conclusions

In one sense, there is no EU health care law or policy – there is a patchwork of different laws and policies that apply in the health care sector. It is very difficult to make sense of the patchwork through the lens of health care.17

European public health care systems are based on the sharing of resources with those in need through taxation and redistribution organised by the state for those within that state – a model of solidarity. Health systems are organised on a national basis, and the benefits for those within each system are achieved, in part, by exclusion of those outside the nation state concerned. By contrast, the EU’s internal market law is concerned with abolishing national barriers to the movement of the factors of production. The benefits of internal market law include access to a wider market, with consequent efficiencies and economies of scale, that are implied in removing national laws, administrative practices and other barriers to cross-border trade. In other words, the logic of public health systems is based on protection through exclusion and closure; the logic of internal market law is based on the benefits of inclusion and openness.

This ‘clash of logic’ explains why the application of EU law within the health care sector is so problematic and challenging. However, harnessing the benefits of collaborating and cooperating at EU level also presents an opportunity for those involved in the health care sector.

References

1. Article 5 Treaty on European Union.
13. Case C-73/08 Bressol judgment of 13 April 2010, nyr in ECR.
14. Cases C-570 & 571/07 Pérez and Gomez judgment of 1 June 2010, nyr in ECR.