Workshop 2 Aurélie Mahalatchimy

European health law and innovation: substantive aspects and embedding in national legal orders

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Presentation

Innovation in health is valued and promoted, not least because it creates new treatment opportunities for patients. But the risks attendant to innovation mean that it is also subject to control. Law plays a vital role in controlling these risks. This workshop looks at European health law understood as comprising the law of the European Union (EU), the Council of Europe (CoE) and the European Patent Organisation (EPO).

Within the EU, the European Commission (Commission) has recognised innovation as multidimensional in that it can take various forms: "Innovation can be incremental or radical, it can result from technology transfer or through the development of new business concepts, it can be technological, organisational or presentational." The Commission gives the following concise definition of innovation: "the successful production, assimilation and exploitation of novelty in the economic and social spheres". Innovation intrinsically includes the ideas of economic and social interests. Innovation in health is seen as being at the crossroads between public health and economic objectives. The links between these objectives often raise tensions between freedom to innovate and constraints. At the EU-level, there is a continuous effort to balance these objectives and to achieve complementarity. However, although it is noted "health is a value in itself" it is also made instrumental as "a precondition for economic prosperity". The CoE has a very different approach, which reflects its institutional objectives of defending human rights, democracy and the rule of law. Consequently, the word "progress" is preferred to the one of "innovation" as it is not primarily linked to economic objectives. The EPO seems to be squarely focused on "innovation" – this being a condition for the award of a patent.

The workshop will be in two parts.

1/The first will be devoted to an exploration of the substantive aspects of European health law relating to innovation in healthcare. Key questions to be addressed include: How does European health law regulate innovations in the field of health? What, if any, are the specific concepts, techniques and procedures of European health law? What is the added value of European health law in comparison with national health law?

2/On this basis, the second part will focus on the embedding of European health law within national legal orders. It particular, this part will discuss the potential for collaboration between European health lawyers in order to further the implementation of European law within national legal orders. Key questions to be addressed in this part include: What are the ways in which European health law is – or could be – embedded within national legal orders? What role could European health lawyers play together as actors who could contribute towards the shaping of European health law and its embedding in national legal orders? Should an EAHL interest group be established to take forward the questions discussed in this workshop?

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