

Preface

Nowadays, the European Union and health are inextricably related. Under the current treaty, the ‘Treaty on the Functioning of the European Union’ (TFEU), the EU and its member states have shared competences in the area of common safety concerns in public health matters, and the EU is required to take health protection into account in all its policies.¹ But the most explicit health commitment has been made by the public health provision, article 168(1) ‘A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities’, followed by more specific EU competences in this area.

The history of the European Union’s health policy can be characterized as a “creeping competence”.² Since its establishment (1952) the role of what is now the EU in the field of health has gradually grown in terms of competences, and has become more explicit. Prior to the Treaty of Maastricht (1992) health regulations were based on agricultural policy, medicines and food safety and the internal market (public health exemptions on free movement and co-ordinating social security entitlements). Confronted with border-crossing health threats (HIV/AIDS, SARS, BSE, bioterrorism, etc.), the Maastricht Treaty, introduced a specific treaty-based competence aimed at public health protection (article 129). During subsequent treaty revision, EU public health competences have gradually increased including standard setting of quality and safety of organs and substances of human origin, blood products and blood derivatives, adopting measures to combat major cross-border health threats, and fostering cooperation with international organizations like the World Health Organization and third countries in the sphere of public health.

As formal EU competence in the field of public health developed, whether or not combined with the general harmonization provision (art. 114 TFEU), newly established entities such as the European Medicines Agency, the European Centre for Disease Prevention and Control, and the European Monitoring Centre for Drugs and Drug Addiction, became responsible for respectively, the protection of human health through the evaluation and supervision of medicinal products, fighting infectious diseases, and providing information for drawing up informed drug laws and strategies. These, and other agencies, have an impact on the way the EU protects the health of its citizens, and supports its large health industry.

Conceptualising EU health competences, the main focus is on article 168 TFEU. Though understandable, this is however not the entire story. Other legal bases have also been lawfully applied to ensure a high level of health protection (eg. free movement provisions, consumer and environmental protection, social policy, competition policy, etc). For instance, under the consumer protection policy, the general product safety directive (2001/95/EC) established general safety requirements for all consumer products, including medical devices. Combined

1 Consolidated version, Official Journal of the European Union C 83/47, articles 4(2)(k), 6 (a) and 9.

2 Derived from MA Pollack, ‘Creeping competence: The Expanding Agenda of the European Community’ (1994) 2 *J Pub Pol.* 95-145.

with the ‘horizontal’ liability directive for defective products (89/374/EEC), both directives are aimed to protect consumers’ (patients’) health against defective products. Additionally, EU social and employment law - aimed at protecting workers and fighting discrimination - had some unintended consequences in health care settings. A clear example is the Working Time Directive’s applicability to medical professionals, which it is claimed has hampered the planning and organization of medical care.³ Furthermore, the coordination of social security law, the mutual recognition of diplomas of regulated health professions, combined with the harmonization of pharmaceutical law, as well as the impact of European competition law, have a clear health dimension. At the same time we will be confronted with new challenges since the EU is becoming increasingly involved in human rights and health care. The recently endorsed EU Charter of Fundamental Rights and newly established Human Rights Agency may influence EU law on health and health care in the member states. For instance, courts may consider the Charter as the basis of judicial review of the activities of EU institutions. Relevant rights may include the right to life, equal access to health care, human integrity, and informed consent.

Given the increased role of EU measures protecting health, and in line with the rationale of the internal market, extending such an approach towards a European health care market may seem quite logical. However, under the current Treaty provision article 168(7) that idea has been explicitly rejected “Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care...” Even the recently adopted directive on patients’ rights in cross-border health care does not change this, although this directive does define common principles and standards on quality and patients’ rights (eg, values of universality, access to good quality care, equity, and solidarity, eligibility criteria, informed choice, personal data protection, measures for seeking remedies, etc).⁴ However, the most essential elements (material scope, benefit package (‘basket of care’) and reimbursement decisions), remain the exclusive competence of the member states. As a consequence ‘health will continue to be a highly constrained area of EU competence.’⁵ Nevertheless, health law is firmly on the map as an area of EU competence.

Since awareness of the influence of EU law on health care continues to increase under the new Treaties, *‘European Union Health Law. Treaties and Legislation’* aims to contribute to that process by providing a volume of EU health related legislation relevant to further discussion. Despite the availability of numerous handbooks, a collection of EU legislation on health issues was missing. *‘European Union Health Law. Treaties and Legislation’* fills that need. This volume includes an up-to-date overview of relevant treaty law provisions, and secondary legislation

3 Directive 2003/88/EC, ECJ rulings Case C-303/98, *SIMAP* [2000] ECR I-7963 and Case C-151/02 *Jaeger* [2003] ECR I-8389. See AJ Maxwell et al, ‘Implementation of the European Working Time Directive in neurosurgery reduces continuity of care and training opportunities’ (2010) 7 *Acta Neurochirurgica* 1207-1210.

4 Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients’ rights in cross-border healthcare [20011] OJ L88/45.

5 E Mossialos et al, ‘Health systems governance in Europe: the role of EU law and policy in: E Mossialos, G Permanand, R. Baeten and TK Hervey, *Health Systems Governance in Europe. The Role of European Union law and Policy* (CUP 2010) 45.

(abridged) on health or health related norms. Unless explicitly indicated, all legislation should have been implemented by the Member States as at May 2012. The book's structure is based on EU policy themes and subjects that currently influence the health sector. All together, these chapters reflect the EU health legal framework. Each chapter covers a major issue, subdivided in sections and clustered as: EU treaties, human rights and health; public health; patient safety, consumer protection; patient mobility; mobility of health professionals and regulation of the workplace; pharmaceuticals; medical devices; data protection; insurance; and competition law. 'Soft law' documents like Council conclusions, recommendations, strategy papers, green and white papers, reports, etc., although of key importance in interpreting binding legal texts, are excluded for reasons of space. A list of key decisions of the Court of Justice of the European Union is included for reference.

Finally, this volume is a joined initiative of the Erasmus Observatory on Health law (Erasmus University) and the LLM European Health Law and Policy at the University of Sheffield Law School and will be applied to Health law training programmes, though it could be a helpful document providing rapid access to sources of EU health law for all trainers, health professionals and students interested in the European Union and its emergent health law.

Rotterdam & Sheffield 2012