Health Law and the European Union

How does the law of the European Union affect health law and policy? At first sight, the impact of EU law in this area seems limited. However, despite its restricted formal competence, over recent years, the EU has become increasingly involved in the health field. Litigation based on EU law has resulted in a 'right to receive health care services' across national boundaries within the EU, which may have huge practical implications for national health systems. The EU has promulgated legislation regulating clinical research, and the marketing of pharmaceuticals; patients' rights are affected by EU legislation on data protection and product liability; the qualifications of health care professionals are legally recognised across the EU; and the EU has acted to promote public health. The authors of this book (expert in EU law and health law respectively) seek to explain and explore the various impacts of measures of EU law on national health law and policy. Through elaboration of selected examples, the authors show that, within the EU, health law cannot be regarded as a purely national affair.

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> For Rosalind, Geneviève and James, without whom this book would probably have been written years ago . . .

Health Law and the European Union

Tamara K. Hervey ^{and} Jean V. McHale



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The law contained in this book is, to the best of our knowledge, accurate as at 1 December 2003. Some minor amendments up to 1 May 2004 have been included in the footnotes. In particular, at the time of writing, the EU had 15 Member States: it now has 25.

TKH and JVM, Nottingham and Leicester, May 2004.

Table of abbreviations

| AC | Appeal Cases |
|--------|--|
| AG | Advocate General |
| AIDS | Acquired Immune Deficiency Syndrome |
| All ER | All England Reports |
| BMJ | British Medical Journal |
| BMLR | British Medical Law Reports |
| BSE | Bovine Spongiform Encephalopathy |
| CA | Court of Appeal |
| CAP | Common Agricultural Policy |
| CFLQ | Child and Family Law Quarterly |
| CLJ | Cambridge Law Journal |
| CMLR | Common Market Law Reports |
| CMLRev | Common Market Law Review |
| COM | Commission document |
| Court | European Court of Justice |
| CPMP | Committee for Proprietory Medicinal Products |
| DCT | Draft Treaty establishing a Constitution for Europe |
| DG | Directorate General |
| EC | Treaty establishing the European Community |
| ECOSOC | Economic and Social Committee |
| ECHR | European Convention on Human Rights and Fundamental Freedoms |
| ECR | European Court Reports |
| EEC | Treaty establishing the European Economic Community |
| EFSA | European Food Safety Authority |
| EHRLR | European Human Rights Law Review |
| EHRR | European Human Rights Reports |
| ELJ | European Law Journal |
| ELRev | European Law Review |
| EMEA | European Medicines Evaluation Agency |
| EPC | European Patent Convention |
| EST | expressed sequence tag |
| EU | European Union |
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Table of abbreviations

| EUCFR | Charter of Fundamental Rights of the European Union |
|-------|---|
| EUI | European University Institute |
| EWHC | England and Wales High Court |
| FLR | Family Law Reports |
| HIV | Human Immunodeficiency Virus |
| HRLR | Human Rights Law Review |
| ICH | International Conference on Harmonisation |
| ICLQ | International and Comparative Law Quarterly |
| IGC | intergovernmental conference |
| ILJ | Industrial Law Journal |
| ILRM | Irish Law Reports Monthly |
| IVF | in vitro fertilisation |
| JCMS | Journal of Common Market Studies |
| JSWFL | Journal of Social Welfare and Family Law |
| LQR | Law Quarterly Review |
| MEP | Member of the European Parliament |
| MJ | Maastricht Journal of European and Comparative Law |
| MLR | Modern Law Review |
| NGO | non-governmental organisation |
| nvCJD | new variant Creutzfeldt Jacob Disease |
| OJ | Official Journal |
| OJLS | Oxford Journal of Legal Studies |
| OMC | open method of coordination |
| QB | Queen's Bench |
| QMV | qualified majority voting |
| SARS | severe acute respiratory syndrome |
| SI | statutory instrument |
| SME | small and medium-sized enterprise |
| SUSAR | suspected unexpected serious adverse reaction |
| TEU | Treaty on European Union |
| TRIPS | Agreement on Trade Related Aspects of Intellectual Property Right |
| UK | United Kingdom |
| US | United States of America |
| WHO | World Health Organisation |
| WLR | Weekly Law Reports |
| WTO | World Trade Organisation |
| YEL | Yearbook of European Law |

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