Contents

	Acki	nowledgements	age xi	
	Table of abbreviations		xiii	
	Table of conventions and treaties			
	Tabl	Table of EU legislation		
	Tabl	le of national provisions		
	Tabl	le of cases	lv	
	Part	t One		
1	Intr	oduction	3	
	I	Health law and the European Union	3	
	II	What is health law?	6	
	9.	What is health?	7	
		The evolution of law's engagement with health	10	
		Definitions: delineating the boundaries of a discipline	13	
		The elements of "health law"	16	
	III	Conclusion	27	
2	Hist	corical, legal and institutional contexts	31	
	I	Introduction: what is the European Union?	31	
	II	What does the European Union do?	37	
	III	What methods of governance does the European Union employ	? 43	
		Deregulation	44	
		"Old style" harmonisation	48	
		"New approach" harmonisation	53	
		Regulatory coordination	59	
		"Soft" coordination	61	
		Financial incentives	62	
	IV	Courts and fundamental rights	63	
	V	Conclusions	67	

3	Community competence in the field of health		69
	I	Introduction	69
	II	Article 152 EC	72
		Historical context	72
		The elements of Article 152 EC	76
		Secondary legislation adopted on the basis of Article 152 EC	81
	III	Other legal bases	84
		Common policies as legal basis: "mainstreaming" of health	
•		protection	84
		Article 308 EC: health protection as a Community objective	87
		The internal market	90
	IV	Conclusions	105
	Dart	t Two	
1		ess to health care services	109
7			
		Introduction	109
	11	Access to health care services	112
		Free movement of patients	112
	***	Impact on access to health services and wider implications	138
		"Reproductive tourism"	144
	IV	Conclusions	156
5	Data protection and health information privacy		
	I	Introduction	159
		Why safeguard health information privacy?	160
	II	Rights to health information privacy in international and EU law	163
	TIT		166
	LLL	Introduction	166
		Processing of personal data	168
		Ordinary personal data	169
		Special data	170
		Further exceptions allowing disclosure	177
		Clinical research and public health monitoring	179
		Control rights for data subjects	182
		Implementation and compliance with the Directive	184
		Transfer of data outside the EU	185
	IV	Conclusions	185
6	Roc	gulation of health care professionals	189
0	1100		
	1	Introduction	189
	II	The impact of EU law on health care professional practice	193

		EU employment law	194
		EU law on provision of services	197
	III	EU law and entry into professional practice in Member States	199
		Freedom of establishment: Treaty provisions	199
		The sectoral (professional) directives	203
		The general directives on mutual recognition of	
		qualifications	215
		Assessment of the sectoral and general directives	218
		Non-EU citizens and qualifications from non-EU states	230
	IV	Conclusions	233
7	The	regulation of clinical research	237
	I	Introduction	237
	II	Co-ordinating and funding clinical research activities	239
	III	The Clinical Trials Directive	248
	IV	The regulation of medical research using genetic technology	259
		Cloning	271
		Stem cell research	274
	V	Conclusions	280
8	Reg	ulating pharmaceuticals: risk, choice	
	_	compensation	282
	I	Introduction	282
	II	EU-level patient (consumer) protection measures	288
		Introduction	288
		Marketing authorisations	289
		Pharmacovigilance	300
		Labelling and packaging	302
		Advertisement	304
		Product liability	307
	III	Proposed reform and wider implications	312
		Reform proposals	312
		Wider implications and assessment	317
	IV	Internal market law	319
		The Transparency of Pharmaceuticals Pricing Directive	323
	V	Conclusions	327
9	Pub	olic health law	330
	I	Introduction	330
	II	Communicable diseases	334
		Introduction	334
		HIV/AIDS	336
		BSE/nvCID	348

	III	Health promotion	366
		Cancer and tobacco	368
	IV	Conclusion	384
	Part	Three	
10	Cor	nclusions and future prospects	389
	I	Introduction: the roles of the EU in health law	389
		Four themes of "European health law"?	390
	II	The "spectrum": how does EU law affect health law and	
		policy in the member states?	394
		Areas of health law affected most strongly	395
		Areas of health law affected by general measures of EU law	396
		Marginal effect	399
		"Slow convergence" effect	400
		No prospect of convergence or consensus?	400
	III	Future directions	404
		The Draft Constitutional Treaty	404
		A "health" open method of coordination?	412
		Enlargement	414
		Regulating the use of human material	421
		"e-Health"	426
		Further future developments?	433
	IV	Conclusions: health law and the European Union	436
	Rihl:	iography	437
	Inde		467