# MEDICAL LAW IN BELGIUM

**HERMAN NYS** 



#### KLUWER LAW INTERNATIONAL

# Medical Law in Belgium

#### Herman Nys

This book was originally published as a monograph in the International Encyclopaedia of Laws/Medical Law.

General Editor: Roger Blanpain Associate General Editor: Michele Colucci Volume Editor: Herman Nys



AUSTIN BOSTON CHICAGO NEW YORK THE NETHERLANDS

Published by: Kluwer Law International PO Box 316 2400 AH Alphen aan den Rijn The Netherlands Website: www.kluwerlaw.com

Sold and distributed in North, Central and South America by: Aspen Publishers, Inc. 7201 McKinney Circle Frederick, MD 21704 United States of America

Sold and distributed in all other countries by: Turpin Distribution Services Ltd. Stratton Business Park Pegasus Drive, Biggleswade Bedfordshire SG18 8TQ United Kingdom Email: kluwerlaw@turpin-distribution.com

Email: customer.service@aspenpublishers.com

DISCLAIMER: The material in this volume is in the nature of general comment only. It is not offered as advice on any particular matter and should not be taken as such. The editor and the contributing authors expressly disclaim all liability to any person with regard to anything done or omitted to be done, and with respect to the consequences of anything done or omitted to be done wholly or partly in reliance upon the whole or any part of the contents of this volume. No reader should act or refrain from acting on the basis of any matter contained in this volume without first obtaining professional advice regarding the particular facts and circumstances at issue. Any and all opinions expressed herein are those of the particular author and are not necessarily those of the editor or publisher of this volume.

Printed on acid-free paper.

ISBN 978-90-411-3319-9

© 2010 Kluwer Law International BV, The Netherlands

All rights reserved. No part of this publication may be reproduced, stored in a retrieval system, or transmitted in any form or by any means, electronic, mechanical, photocopying, recording, or otherwise, without written permission from the publisher.

Permission to use this content must be obtained from the copyright owner. Please apply to: Permissions Department, Wolters Kluwer Legal, 76 Ninth Avenue, 7th Floor, New York, NY 10011-5201, USA. Email: permissions@kluwerlaw.com

Printed and bound in Great Britain by CPI Antony Rowe, Chippenham and Eastbourne

# Medical Law in Belgium

The Author	5
List of Abbreviations	15
General Introduction	17
Chapter 1. The General Background of the Country	17
§1. Geography and Climate	17
§2. Population	17
§3. POLITICAL AND JUDICIAL SYSTEM	17
§4. Population and Vital Statistics	20
§5. Social and Cultural Values Regarding Health	21
Chapter 2. General Description of the Health Care System	23
§1. General Overview of the Belgian Health Care System	23
§2. REGULATION OF THE HEALTH CARE SYSTEM	33
§3. Financing of Health Care	35
§4. Health Insurance	39
Chapter 3. Medical Law	41
§1. Definition and Functions of Medical Law	41
§2. Sources of Medical Law I. International Sources II. National Sources	42 42 44
Selected Bibliography	45

Part I. The Medical Profession	47
Chapter 1. Access to the Medical Profession	47
§1. Medical Education	47
I. Historical Note	47
II. Constitutional Competence	47
III. Undergraduate Medical Education	48
IV. Graduate Medical Education	48
§2. Licensing of General Practitioners and Medical Specialists Postgraduate Medical Education	48
§3. Manpower Planning. Freedom of Establishment	51
Chapter 2. Practice of Medicine	52
§1. Legal Conditions for the Practice of Medicine	52
I. Historical Note	52
II. Healing Arts and Medicine	52
III. Legal Monopoly of Physicians	52
IV. Legal Conditions for the Practice of Medicine	53
A. Legal Diploma	53
1. Exemption from the Legal Diploma	53
2. Assimilation Based on Mutual Recognition	53
B. Visa	54
1. Exemption from the Visa	54
2. Withdrawal of the Visa	54
3. Restricted Visa	55
C. Inscription on the List of the Order of Physicians	55
C. Inscription on the List of the Order of Physicians	55
§2. Illegal Practice of Medicine	56
I. Legal Definition of the Offence	56
II. Medical Activities	56
A. General Remarks	56
B. Specific Medical Activities	57
Preventive Medicine	57
2. Self-care	58
3. Taking of Blood: Venapunctures	58
4. Radiographies	58
5. Blood Pressure Measuring and the Use of Other Simple	
Measuring Appliances	59
6. Eye Examination and the Measuring of Eye Deviations	59
7. Psychoanalysis and Psychotherapy	60
8. Group Therapy	60
9. Acupuncture	61
10. Written and Oral Advice and Recommendations	61

III. An Unauthorized Person	61
IV. In an Habitual Way	61
A. The Meaning of Habitual	61
B. Exceptions	61
1. Repetition	61
2. Publicity	62
3. Abuse of Titles	62
V. Sanctions	62
§3. Use of Automatic 'External' Defibrillators	62
§4. Non-conventional Practices in Medicine	62
Chapter 3. Control over the Practice of Medicine	64
§1. The Order of Physicians	64
I. Historical Note	64
II. Registration on the List of the Order	64
A. Obligation to Register on the List	64
B. Exceptions	64
<ol> <li>Nationals of EU Member States</li> </ol>	64
2. Military Doctors	65
C. The Obligation to Register and the Freedom of Association	65
D. Competent Provincial Council	65
E. Refusal or Delay of Registration	66
F. Registration after Being Struck Off the Register	66
G. Removal from the List	66
H. Maintenance of the Registration Subject to Restrictions	66
III. Disciplinary Competence of the Order of Physicians	67
A. Control over the Observance of the Rules of Professional	
Conduct	67
<ol> <li>General Description of the Disciplinary Competence</li> </ol>	67
2. Rules of Professional Conduct and Standards of Discretion,	
Probity, and Dignity	68
a. The code of professional ethics	68
b. Legally determined rules of professional conduct	69
c. Normative authority of the provincial councils	70
d. The precedent authority of disciplinary decisions	70
e. Advice of the provincial councils	71
f. Advice of the national council	71
3. Limitations to the Disciplinary Power of the Provincial	
Councils	71
<ul> <li>a. Non-interference in fundamental freedoms</li> </ul>	71
b. Duty to motivate decisions	72
4. Disciplinary Sanctions	72
a. Possible disciplinary sanctions	72
b. Consequences of a disciplinary sanction	72

	1. Regarding the right to vote and to be elected	12
	ii. Regarding the right to practice medicine	73
	5. The Disciplinary Procedure and Article 6 of the European	
	Convention	73
	a. The applicability of Article 6 of the European	
	convention in disciplinary proceedings	73
	b. Public character of disciplinary proceedings	74
	c. Hearing within a reasonable time	74
		75
	d. Right to challenge members of councils	13
	6. Disciplinary Procedure before the Provincial Councils and	7.5
	the Appeals Councils	75
	B. Preventive Control	76
	IV. Organs of the Order of Physicians and Their Function	76
	A. Provincial Councils	76
	1. Composition	76
	2. Functions	77
	B. Appeals Councils	77
	1. Composition	77
	2. Functions	77
	C. The National Council	78
	1. Composition	78
	2. Functions	78
	Province of the province	78
32.	PROFESSIONAL LIABILITY	100
	I. Introduction	78
	II. Civil Liability	80
	A. Classification of Physician's Liability	80
	B. Contents of the Physician's Duty	81
	C. The Basis of Liability and Burden of Proof	83
	1. Fault	83
	2. Damages	84
	3. Causation	85
	D. Aspects of Vicarious Liability	85
	<ol> <li>Liability of Hospitals for the Acts of Their Medical Staff</li> </ol>	85
	2. Physician's Liability for Medical Activity of Other Persons	87
	III. Criminal Liability	88
22	Other ray According to	88
3.	QUALITY ASSURANCE	00
§4.	MEDICAL ETHICS COMMITTEES	91
	I. General Remarks	91
	II. Ethics Committees in Hospitals	91
	III. The Federal Council on Bioethics	92
	A. Composition of the Council	93
	B. The Competences of the Council	93
	C. Dissemination of the Work of the Council	94
	The state of the s	-

Part II. The Physician-Patient Relationship	95
Chapter 1. General Description	95
§1. RIGHTS AND DUTIES OF PATIENTS AND PHYSICIANS  I. The Law on the Rights of Patients  A. The Duty of the Patient to Cooperate  B. The Right to Quality Care  C. The Right to Free Choice  D. Rights Related to Information about the State of Health	95 95 95 96 97
<ol> <li>The Right to Information about One's State of Health</li> <li>The Right Not to Know about One's State of Health</li> <li>Relinquishing the Right to Information</li> <li>Not Informing about a Patient's State of Health at the Physician's Initiative (The Therapeutic Exception)</li> </ol>	97 97 98 98
<ul> <li>E. The Right to Give Consent</li> <li>1. The Right to Well-Informed, Free and Prior Consent</li> <li>2. The Way of Giving Consent</li> <li>3. Content of the Information</li> <li>4. Presumed Consent in Cases of Emergency</li> </ul>	98 98 98 99
<ul><li>F. The Right to Refuse or Withdraw Consent</li><li>G. Rights Related to the Patient's Medical Record</li><li>1. The Right to a Medical Record</li><li>2. The Right to Addition</li></ul>	99 100 100 100
<ul> <li>3. The Right to Access</li> <li>4. The Right to a Copy</li> <li>5. Access by Next of Kin after the Death of the Patient</li> <li>H. The Right to Protection of Privacy and Intimacy</li> <li>I. The Right to Representation in the Event of Incompetence</li> </ul>	100 101 101 101 102
J. The Right to Lodge a Complaint K. The Right to Palliative Care and Pain Relief II. The Legal Duty to Help A. Law on the Health Care Professions	103 104 104 104
<ul> <li>B. Articles 422bis and 422ter Criminal Code</li> <li>1. Article 422bis</li> <li>a. Applicability to physicians</li> <li>b. Constitutive factors of Article 422bis</li> <li>i. Great danger</li> </ul>	106 106 106 107 107
<ul><li>ii. Knowledge of the great danger</li><li>iii. Refusal to help</li><li>iv. No serious danger for oneself or others</li><li>2. Article 422ter</li></ul>	107 108 108 108
3. Law on Emergency Medical Care III. Respect for the Privacy of the Patient A. General Rule for Processing of Personal Medical Data B. Exceptions	108 108 109 109

		C. Guarantees with Respect to the Processing of Personal	
		Health-Related Data	110
		D. Rights of the Data Subject	110
		Duty of Medical Secrecy	111
		A. General Principle	111
		B. Exceptions	112
		1. Testimony in a Court or Before a Parliamentary Committee	112
		2. Statutory Obligations to Disclose Confidential Information	112
		C. Notification of Criminal Acts	113
		D. Consent of the Patient or Waiver	114
		E. Deliverance of Medical Certificates to Third Parties	115
	V.	Medical Fees	115
		A. Right to Fees or Remuneration for Services	115
		B. Amount of the Fee	116
		C. Fee-Splitting	117
		D. Unlawful Enrichment	117
Ch	apte	r 2. The Physician-Patient Relationship in Specific	
		Terms	119
§1.	Тне	MINOR PATIENT	119
§2.	Тне	MENTAL PATIENT AND INVOLUNTARY PLACEMENT	120
0		Legal Framework	120
		Involuntary Placement in a Mental Hospital	121
		A. Admission for Observation	121
		1. Simple Procedure (Non-emergency Cases)	121
		2. Emergency Procedure	122
		3. Practical Modalities of the Admission for Observation	122
		B. Prolonged Stay	123
	III.	Care within a Family	123
		The Rights of an Involuntary Placed Mental Patient	124
	-	2 2 1	
§3.		DYING PATIENT	124
	Ι.	Euthanasia	124
		A. Definition of Euthanasia	124
		B. Conditions and Procedure in Case of an Actual Request by	105
		a Terminally III Patient (Article 3, §1-§2)	125
		C. Conditions and Procedures in Case of an Actual Request by	10/
		a Patient Who Is Not Terminally III (Article 3, §3)	126
		D. The Actual Request of the Patient (Article 3, §4-§5)	126
		E. Notification and Control	129
	**	F. No Obligation to Perform Euthanasia	131
		Withholding or Withdrawing (Cessation) of Treatment	132
		Termination of Treatment (at the Request of the Patient)	134
	IV.	Pain Relief with Life-Shortening Effects	136

	V. Palliative and Terminal Sedation VI. Physician Assisted Suicide	138 138
Ch	apter 3. Specific Activities	141
§1.	TERMINATION OF PREGNANCY (ABORTION)  I. Short Overview of the Existing Legal Rules on Termination	141
	of Pregnancy II. Short Historic Overview of the Legislation on Termination of	141
	Pregnancy	142
	III. Termination of Pregnancy by a Physician  IV. Evaluation of the Application of the Law of 3 April 1990	143 144
§2.	Sterilization	146
	I. Surgical Contraconception	146
	II. Sterilization of Mentally Handicapped	147
§3.	MEDICALLY ASSISTED PROCREATION	148
	I. Legal Framework	148
	II. Medically Assisted Procreation	148
	A. Definition	148
	B. Monopoly of Fertility Centres for IVF and Cryopreservation	148
	C. Access to Medically Assisted Procreation	149
	III. Medically Assisted Procreation with Embryos or Gametes	149
	A. General Conditions	149
	<ol> <li>Evaluation of Causes of Sterility, Infertility or Sub-fertility</li> <li>Information and Counselling</li> </ol>	149 149
	3. Agreement between the Infertility Centre and the	
	Candidate(s)	150
	B. Medically Assisted Procreation through Implantation of	
	Embryos In Vitro	150
	C. Medically Assisted Procreation through Artificial Insemination IV. Surrogacy	152 153
84.	Human Genetics	154
3	I. Higher Council on Human Genetics	154
	II. Centres for Human Genetics	154
	III. Genetic Testing and Insurances	155
	IV. Pre-implantation Genetic Diagnosis	156
§5.	Removal and Transplantation of Organs	156
	I. Scope of the Organ Transplantation Law	156
	II. Removal of Human Bodily Materials from Living Donors	157
	A. Under the Organ Transplantation Law	157
	1. General Conditions	157
	2. Minor Donors	157
	3. Special Cases	158

			4. Informed Consent	158
			5. Duties of Physician Removing Organs	159
		В.	Under the Law on the Procurement and Use of Human	
			Bodily Material	159
	III.	Rei	moval of Human Bodily Material after Death	160
			Under the Organ Transplantation Law	160
			Under the Law on the Procurement and Use of Human	
			Bodily Material	163
		C.	Autopsies	163
	IV.		cipients	163
				172
\$6.	RES			163
	1.		search with Human Persons	163
			Field of Application	164
		В.	General Provisions Concerning the Protection of Subjects of	165
			Experiments  1. Property for Ethical and Scientific Quality Propriements	165
			Respect for Ethical and Scientific Quality Requirements     Scientific Assemblisher	165
			Scientific Acceptability     Proportionality (Palance between Panefits and Picks)	165
			3. Proportionality (Balance between Benefits and Risks)	165
			4. Informed Consent of the Subject	
			5. Primacy of the Human Being	166 166
			6. Favourable Opinion of an Ethics Committee	167
			a. Definition of 'ethics committee'	
			b. Composition	167 167
			c. Independence	167
			d. Competent ethics committee	168
			e. Task of the competent ethics committee(s)	169
			f. Time limits to issue an opinion	
			g. Legal value of an opinion	170 170
			7. Intervention of a Qualified Health Care Practitioner	170
			8. No-Fault Liability	171
			9. Obligation to Enter into an Insurance Contract	17
		C.	Specific Provisions for the Protection of Minors Participating	171
			in Experiments	171
			1. Informed Consent of the Parents or the Guardian	
			2. Respecting the Explicit Will of the Minor	171
			3. Directly Linked to the Clinical Condition of the Participant	172
			or Directly Beneficial for Minors	172
			4. Validation of Previous Research	172
			5. Proportionality  6. Minimal Pain Discomfort Foot and Risk	172
			6. Minimal Pain, Discomfort, Fear and Risk 7. Compatones of Ethics Compating Pagerding Pagerding	
			7. Competence of Ethics Committee Regarding Paediatrics	173 173
		D	8. No Incentives or Financial Inducements  Specific Provisions for the Protection of Adults Incapable	1/.
		D.	Specific Provisions for the Protection of Adults Incapable	173
			to Consent to an Experiment  1. Informed Consent of the Legal Representative	173
			2. Directly Related to the Clinical Condition of the Participant	172

		3. Minimal Pain, Discomfort, Fear and Risks	174
		4. Proportionality	174
		5. Competence of Ethics Committee Regarding Patient	
		Population	174
		6. No Incentives or Financial Inducements	174
		7. As Soon as Possible, Informed Consent of Participant	175
	Ē	Specific Provisions for the Protection of Persons Whose	
	L.	Consent Cannot Be Obtained Due to Emergency	175
			1/3
		Direct Relation with the Life-Threatening Clinical     Condition of the Subject	175
		Condition of the Subject	175
		2. Validation of Previously Obtained Data	175
		3. Minimal Pain, Discomfort, Fear and Risk	175
		4. Proportionality	175
		5. Competence of Ethics Committee Regarding Disease	
		and Patient Population	175
		6. No Incentives or Financial Inducements	176
		7. As Soon as Possible, Informed Consent of the Subject	176
	II. Re	search with Embryos In Vitro	176
		Prohibited Procedures with Embryos In Vitro	177
		Prohibition to Create Embryos In Vitro Solely for Research	
		Purposes	177
	C	Research with Embryos In Vitro	177
	С.	Research with Supernumerary Embryos	178
		2. Conditions Related to the Research	178
		3. Conditions Related to Place and Expertise	178
		4. Informed Consent of the Persons Concerned	178
			179
		5. Favourable Opinion of the Local Ethics Committee	175
		6. No Objection of the Federal Committee for Research on	170
		Embryos	179
		7. Yearly Report on the Research	180
		8. Follow-Up by the Federal Committee	180
	III. Se	condary Use of Human Bodily Material for Research Purposes	180
	IV. Bi	o-banks	180
§7.	PROFES	SSIONAL FREEDOM. PRESCRIBING DRUGS. TREATMENT WITH	
	DRUGS	-Substitutes	181
	I. Le	gal Framework of Professional Freedom	181
	II. Co	ontrol over the Professional Freedom	181
		escription of Drugs	181
		eatment with Drugs-Substitutes	182
		cumbin with Diago Bucontains	
Par	t III.	The Physician and the Health Care System	183
Ch	anter	. Relations with Other Health Care Providers	183
	r		
§1.	PHARM	IACISTS	183
		Practice of Pharmacy	183

§2. Dentists		185
<ol> <li>The Practice of Der</li> </ol>	ntistry	185
II. Professional Relation	ons between Physicians and Dentists	186
§3. Physiotherapists		187
I. The Practice of Phy	vsiotherapy	187
	ons between Physicians and Physiotherapists	187
§4. Nursing Profession		188
I. The Practice of Nur	rsing	188
	ons between Physicians and Nurses	191
§5. Paramedical Profess	IONS	191
§6. Midwives		192
Chapter 2. Relations w	vith Health Care Provisions	194
§1. Hospitals		194
§2. Relations between F	HYSICIANS AND HOSPITALS	195
§3. Health Insurance		196
Index		197

#### KLUWER LAW INTERNATIONAL

## Medical Law in Belgium

#### Herman Nys

This book was originally published as a monograph in the International Encyclopaedia of Laws/Medical Law.

General Editor: Roger Blanpain Associate General Editor: Michele Colucci Volume Editor: Herman Nys



AUSTIN BOSTON CHICAGO NEW YORK THE NETHERLANDS

#### The Author



Professor Dr Herman Nys (born 20 January 1951) studied law at the K.U. Leuven (1969-1974) and the K.U. Nijmegen (1974-1975). From 1975 to 1980 he worked as assistant, specializing in health care law, at the Center for Hospital Sciences in Leuven, where in 1980 he received his doctor's degree with a thesis on legal aspects of health care planning. In the years 1981 through 1989 he was affiliated with the law school in Leuven, first as lecturer in medical law and since 1985 as associate professor. He is the director of the Center of Biomedical Ethics and Law in Leuven and has held this position since 1989. In 1992 he was appointed professor. Between 1986 and 1999 he was an adviser to different ministers of health with respect to medical law.

Between 2000 and 2006 he also has been a professor

in international health law at the University of Maastricht, the Netherlands. Prof. Nys is the author of numerous books and articles on medical law and health care policy. He is a member of the editorial boards of several learned journals.

He is co-founder and director of the European Association of Health Law (2008) and governor of the World Association of Medical Law (2008).