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by
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The Author



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List of Abbreviations

Arr. Cass.	Arresten van het Hof van Cassatie
De Verz.	Tijdschrift voor Verzekeringen
ECHR	European Court of Human Rights
FDF	<i>Front Démocratique des Francophones (FDF)</i>
GP	General Practitioner
IDHL	International Digest of Health Legislation
INAMI	Institutnational d'assurance maladie invalidité
J.T.	Journal des Tribunaux
Jur. Liège	Jurisprudence de la Cour d'Appel de Liège
NVA	<i>Nieuwe Vlaamse Alliantie</i>
OJ	Official Journal of the European Communities
Pas.	Pasicrisie
PC	Communist Party
R.D.P.	Revue de Droit Pénal et de Criminologie
R.G.A.R.	Revue Général des Assurances et des Responsabilités
R.W.	Rechtskundig Weekblad
RIZIV	Rijksinstituut voor ziekte- en invaliditeitsverzekering
SLP	<i>Sociaal-Liberale Partij</i>
VI.T.Gez.	Vlaams Tijdschrift voor Gezondheidsrecht



List of Abbreviations





General Introduction

Chapter 1. The General Background of the Country

§1. GEOGRAPHY AND CLIMATE

1. Belgium is a small country lying along the northwestern coast of Europe. It covers an area of 11,779 square miles – slightly larger than the State of Maryland in the United States – and has about 40 miles of coastline on the North Sea and 860 miles of land frontiers (bordering the Netherlands, Germany, Luxembourg, and France). The country has a population of about 10.4 million and some 865 inhabitants per square mile.

Belgium generally enjoys a moderate, maritime climate; however, the Ardennes plateau tends to have certain continental climate characteristics.

§2. POPULATION

2. Belgium is composed of two main cultural-linguistic communities, speaking Flemish (Dutch) and French, and a small German-speaking community. The Flemish, who outnumber the French-speaking Walloons, live mostly in the north and west, whereas the Walloons live in the south and east. Both Flemish and French are official languages, and the capital, Brussels, is administratively bilingual. Some 9% are foreigners.

On 1 January 2005, the population of Belgium was as follows:

	Total	Men	Women
Belgium	10,396,221	5,086,976	5,309,245
Brussels Region	999,899	480,334	519,565
Flanders	6,016,024	2,966,640	3,049,384
Walloon Region	3,380,498	1,640,202	1,740,296

§3. POLITICAL AND JUDICIAL SYSTEM

3. In the course of the last three decades, Belgium has undergone a slow but unquestionable metamorphosis from a nation organized along the principles of centralism to a federal State. The Belgian Constitution was fundamentally revised on four occasions: 1970, 1980, 1988, and 1993 and to lesser degree in 2001. On



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each occasion, the federalist trend was accentuated. Belgium is no longer a unitarian country. It has become a federal State.

4. The Constitution sets out the principle of equality between the three powers of the State. The legislative power is wielded collectively by the King and Parliament; the executive power is vested in the King and his ministers, and the judicial power is in the hands of the courts and tribunals. The King reigns but does not rule. This means that although he appoints and dismisses his ministers, his person is inviolable and his ministers are responsible. No act of the King is effective unless it is countersigned by a minister. The Parliament is composed of two houses: the House of Representatives and the Senate. The members of the House of Representatives numbers 150. The Senate is composed of seventy-one members. Both are renewed every four years. Citizens who are fully 18 years old are entitled to vote. The House has full powers and is the main political parliamentary forum. The Senate has specific powers like those relating to the revision of the Constitution and treaties, the relations between the linguistic communities, and others. The Senate has also the power of evocation.

5. The state reform of 1970-1971 included three new territorial divisions in the constitution: the linguistic regions (the Dutch-speaking region, the French-speaking region, the German-speaking region, and the bilingual Brussels-Capital region), the cultural communities, and the regions. The cultural communities became responsible for cultural, educational and linguistic matters; the regions were responsible for matters of socioeconomic importance. Since the 1970 reform, the cultural communities have been able to issue decrees. These decrees have the power of law and are not subordinate to national legislation. The regions, however, were not given the power to issue decrees. With the state reform of 1980, a further step on the road to federalization was taken. The cultural communities were re-modelled into communities. This change of name was necessary, because the communities henceforth were also in charge of health and social services. Since 1980 the Flemish and the Walloon regions can also issue decrees with the power of law that are not subordinate to national legislation.

6. The two different types of territories, communities and regions, have consultative bodies (the Council or Parliament) and executive bodies (the Executive). There exist on an organic level a Flemish Parliament and a Flemish Executive for Flemish communal and regional affairs; a Walloon Regional Council and a Walloon Regional Executive for Walloon regional affairs; a French Community Council and a French Community Executive for matters concerning the French community; a Council and an Executive of the German-speaking community for matters concerning the German-speaking community; and a regional Council and a regional Executive for Brussels-Capital dealing with Brussels. All these councils are directly elected.

7. Since the state reform of 1970, the communities have had jurisdiction over cultural affairs, language, international cultural cooperation, and the school system. The state reform of 1980 enlarged the scope of the communities' responsibilities

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to include such personal-related matters as the social services and health care. The 1988 reform gave the communities responsibility for fundamental scientific research; advertising on radio and TV and support of the press; protection of children and young people; and social assistance for prisoners. The regions are responsible for environmental and urban planning; the environment; reallocation of land and nature conservation; housing; water supply and water distribution; economic policy; energy policy; subordinate authorities; employment policy; and public works and traffic.

8. Prior to 1980 the communities and the regions were financed entirely out of endowments (appropriations from the national budget) allocated to them on a horizontal budgetary scale, the formula of which could be decided by the communities and the regions autonomously. This system was clearly not an adequate template for proper financial accountability. The desire for greater financial autonomy was an increasingly pressing demand, particularly from the Flemings who felt disadvantaged by the fixed-scale allocation of financing resources. This system was replaced by an entirely new system of financing public expenditure, introduced in 1988. The greater part of the revenue of communities and regions derives from 'transfers from national taxation revenue', no longer allocated by fixed-scale criteria as endowments had been, but on locational criteria or the 'fair return' principle.

9. The final major innovation, introduced in the 1980 constitutional revision, was the setting up of a Court of Arbitration, which is a constitutional court of limited jurisdiction. This has been an important innovation because the view taken by case law since the founding of the Belgian State is that it is for the legislature itself, not the courts, to ensure that legislation is not unconstitutional. The Court is in charge of settling all conflicts of competence between laws and decrees. The competence of the Court has been enlarged in 1989 so that it can arbitrate by a law or a decree whenever a law or a decree violates the constitutional principle of equality or the constitutional guarantee of freedom of education. The competent legislature can also commission the court to investigate laws and decrees for their constitutionality. Accordingly, in 2007 the name of the Court has been changed to Constitutional Court.

10. The judiciary is responsible for ruling on disputes arising from the application of the rules of law. The following types of court exist. The police tribunals have jurisdiction over the least serious infringements of criminal law. There is one justice of the peace tribunal for each judicial district. These tribunals deal with lawsuits for minor sums and with disputes reserved by law regardless of the sum at stake. There is one tribunal of first instance for each judicial division. Each such tribunal includes one or several chambers in three sections known as civil tribunal, correctional tribunal (penal), and juvenile tribunal. Each judicial district also has a labour tribunal, which has wide authority extending over all disputes relating to labour relations. In addition, each judicial district has a commercial tribunal. There are five courts of appeal that rule on appeals against decisions rendered by tribunals of first instance and by commercial tribunals. Each territorial area covered by a

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court of appeal also has a labour court. It hears appeals against the decision of labour tribunals.

The Court of Cassation is the Supreme Court. There is only one such court. It has general authority and it is the court of last instance for decisions arising from the infringement of a law or substantial procedural or regulatory violation under penalty of nullity. It does not judge the merits of the case.

The Council of State was set up by the Law of 23 December 1946. It is the most important administrative tribunal of the Belgian system.

11. All matters of provincial and borough interest fall under the exclusive sphere of competence of the provincial and borough councils. This notion of interest is not clearly defined legally but is taken to mean everything that the provincial and borough authorities consider as being attributed to them, excluding matters reserved by the Constitution or by legislation to another authority. The central government exercises general control through the power to suspend or annul council decisions.

12. Until the middle of the 1960s, politics were dominated almost entirely by three 'national' parties, which constituted the political expression of the Christian, socialist and liberal ideologies, respectively. Since then, the position has altered substantially: Disagreement between Walloons and Flemings has put an end to the unitary party structure. This has meant the birth of a number of autonomous parties, which, although they still largely support the same ideology, adopt a different approach, notably on relations between the Flemish and French-speaking communities.

At the same time, regional parties have emerged, with activities mostly concentrated in a specific region. In Flanders there are the *Nieuwe Vlaamse Alliantie* (NVA) and *Sociaal-Liberale Partij* (SLP) and the *Vlaams Belang* (Flemish right wing); and the *Front Démocratique des Francophones* (FDF), a party that is active in Brussels and in the surrounding area. The Communist Party (PC) is no longer represented in Parliament. More recently other parties have emerged, such as the Ecologists.

§4. POPULATION AND VITAL STATISTICS

13. The demography of Belgium evolved from both a high birth rate and a high death rate at the end of the eighteenth century to the current situation of low birth and death rates, with almost zero growth and an aging population.

Individuals aged 65 years and over made up 17.2% of the population in 2005 compared to 12.0% in 1960 (National Bank of Belgium 2006). The fertility rate had been declining from 2.56 children per woman in 1960 to 1.64 in 2005. In recent years, the birth rate has increased slightly to 11.3 per population of 1,000, after declining continuously until 2002. In 2004, life expectancy at birth was 82.4 years for females and 76.5 years for males. Since 1960, life expectancy has increased on average by two months per year. Belgian life expectancy is in line with the European average.

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14. Since the beginning of the twentieth century, mortality has continued to fall, and Belgium has experienced only one death rate peak – at the end of World War I due to the Spanish influenza epidemic.

The main causes of death in Belgium are heart and vascular disorders, neoplasms, disorders of the respiratory system, and unnatural causes of death (accidents, suicide). The prime causes of death vary according to different age groups. At a younger age (with females up to age 24 and males up age 44) non-natural causes together with cancer are mainly to blame. After this age, cancer, heart, and vascular disorders become the principal causes of death.

In the senior age groups, heart and vascular diseases are the most prevalent causes of death.

§5. SOCIAL AND CULTURAL VALUES REGARDING HEALTH

15. The results of the latest health interview survey were published in 2006 and were related to the situation in 2004. Similar surveys were also organized in 1997 and 2001. In Belgium, 23% of the population regard their health as not satisfactory. This percentage increases up to 47% at the age of 75 years and older. People with low levels of education are relatively more dissatisfied with their health. The survey results on subjective health status for 1997, 2001, and 2004 are very similar, which means that this indicator is very stable in Belgium. Approximately one quarter (24%) of the population reports having at least one long-term illness, disorder, or disabling condition. Although the population between 1997 and 2004 grew older, no important increases in the prevalence of chronic diseases were reported. This may indicate that the demographic ageing of the population goes together with an increase of healthy ageing. However, the greatest increase for chronic diseases was diabetes.

On the topic of mental health, the results of the health survey indicate that for the population of 15 years and older: One out of four (24%) has to contend with mental discomfort, a little more than half of these individuals (13% of the total) could have a rather serious mental disorder, 8% have depressive feelings, 8% have somatic complaints, 6% have feelings of fear, and 20% have sleeping problems. Furthermore, it appears that 12% of the population have thought about suicide and 4% have tried to commit suicide. Since the mid-1980s, the number of daily smokers has decreased substantially from 40.5% in 1980 to 20.0% in 2004. In 2005, 20% of the population were daily smokers and 4% were occasional smokers. Daily smokers have an average of 17 cigarettes per day. The percentage of heavy smokers (>20 cigarettes per day) is 10%. The age when people start to smoke regularly is 17 years, but 10% of the current smokers started smoking at the earlier age of 14. In 2004, 26% of the population aged 15-24 smoked, which is an improvement in comparison to 31% in 2001. The reduction in tobacco use has been achieved thanks to the adoption of non-smoking campaigns and tax increases on tobacco products. However, 34% of current smokers are moderately dependent to very dependent on tobacco, whereas 68% have already tried in vain to quit the habit. Nevertheless, smoking-related mortality has also decreased (from 321.2 per 100,000 inhabitants in 1980 to 248.5 in 1997). Both alcohol consumption and alcohol-related mortality have been decreasing since the mid-1980s.



15-15 General Introduction, Ch. 1, The General Background of the Country

The average body mass index (BMI) of Belgians aged 18 years and older is 25.1; 44% of the adult population has a BMI above 25, with 31.4% classified as overweight (BMI between 25 and 30), and 12.7% are obese (BMI above 30). Since the mid-1980s, the dental health status of Belgian children and adolescents has improved significantly. In 2001, the number of decayed, missing, or filled teeth (DMFT) was 1.1 among 12-year-olds, in comparison with 3.1 in 1985. Epidemiological study data show that Belgian schoolchildren are among those in European countries with moderate-to-low caries prevalence. However, attention should be paid to socioeconomically underprivileged children whose dental health status is significantly worse than that of privileged ones.



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Part I. The Medical Profession

Chapter 1. Access to the Medical Profession

§1. MEDICAL EDUCATION

I. Historical Note¹

50. The history of medical education in Belgium is comparable to that of other Western European countries. In the seventeenth century and after, medical practice was mainly exercised by two professional groups: the physicians, trained at a university and competent in internal medicine, and the surgeons, less respected and trained by practice. During the French Revolution all universities, including the medical schools, were abolished. By decrees of 2 and 17 March 1781 the freedom for anyone to practice medicine was proclaimed. Supervision of medical practice was abolished, and a new type of practitioner, the officer of health, replaced the prerevolutionary physician. However, the resulting chaotic situation did not last for long and the medical schools soon reopened their doors. In 1816 three State universities with medical schools were established in Ghent, Leuven, and Liège. A Decree of 1818 abolished the officers of health and created a number of paramedics, apart from the medical profession. It also restricted the simultaneous practice of medicine, surgery, obstetrics, and pharmacy. The 1835 Law on Higher Education required a university diploma for the practice of medicine, surgery, and obstetrics. However, these branches remained separate. It was not until 1849 that a law created the unified diploma of 'doctor of medicine, surgery, and obstetrics' that remained unchanged until 1991 when, as a result of the amendment of the Constitution on 15 July 1988 that gave the communities the competence to regulate by decree education, a Decree of the Flemish Community of 12 June 1991 (*Moniteur belge*, 4 July 1991) replaced this diploma by the academic title of physician (*arts*).

1. H. Nys & P. Quaethoven, 'Health Services in Belgium', in *Comparative Health Systems*, ed. M.W. Raffle (University Park and London: The Pennsylvania State University Press, 1984), 64-65.

II. Constitutional Competence

51. According to Article 127, §1 of the Constitution as amended on 15 July 1988, the Community Councils are, each in its own sphere, competent to regulate by

decree education, with the exception of the fixing of the beginning and the end of compulsory education and the minimum conditions for the granting of diplomas.

III. Undergraduate Medical Education

52. The normal course of medical studies lasts seven years. These studies are divided into two cycles: the first, lasting three years, comprises basic scientific education (bachelor); the second, spanning four years, includes three years of clinical studies and one of practical training in a hospital or a medical practice (master). There are presently seven medical schools: Antwerpen, Brussel, Bruxelles, Gent, Leuven, Liège, and Louvain en- Woluwe, whereas four university institutions offer only the basic training cycle or bachelor: Hasselt, Kortrijk, Namur, and Mons.

53. Up to 1996, the only condition to admission to a medical school was the possession of the diploma of completion of secondary school. This is usually obtained at the age of eighteen. The pursuit of medical studies from the first year onwards was only limited by failures in subsequent years.

The federal minister of health is not competent to install a *numerus clausus* for medical students, medical education being the competence of the communities (above, paragraph 51). However, the federal minister of health is competent to regulate the practice of medicine. In order to force the communities to limit the number of medical students, an amendment to the Law on the Practice of Health Care Professions has been approved in 1996. Article 35 *novies* of this law empowers the federal minister of health to limit the number of physicians who may practice under the obligatory health insurance system, unless the communities have taken satisfactory measures to limit the number of students.

IV. Graduate Medical Education

54. The exam for the academic title of physician covers fifteen different subjects, spread over at least four years of study. During the last year (the seventh year of study) practical hospital work must be done. This is the so-called internship, normally served in regional hospitals. The medical schools have a certain autonomy in programming the different subjects; for instance, the internship at the Leuven medical school is not in the seventh but in the sixth year. In the seventh year the possibility exists to specialize. There are four options of specialized training: family medicine, medical specialties, research, and social medicine.

§2. LICENSING OF GENERAL PRACTITIONERS AND MEDICAL SPECIALISTS POSTGRADUATE MEDICAL EDUCATION

55. There exists no legal obligation for specialization or continuing education. A physician is entitled to practice medicine during his or her total professional career. However, the health insurance system, through the payment of higher fees,

promotes specialization. There exist, moreover, other mechanisms that make specialization if not obligatory, at least unavoidable. For instance, hospitals will only select candidates for vacancies in the medical staff who have obtained a certificate of specialization. The Code of Professional Ethics of the National Council of the Order of Physicians forbids physicians to claim competences that they have not acquired through specialization. In addition, in judging the medical responsibility of a physician, the courts take account of the speciality practiced by that physician.

56. The postgraduate medical education of physicians has been profoundly influenced by Council Directives of the European Communities in this respect. Council Directive No. 86/457/EEC of 15 September 1986 (coordinated by Council Directive No. 93/16/EEC of 5 April 1993) on specific training in general medical practice (OJ L 267, 19 September 1986, 26-30) obliges each Member State that dispenses a complete training referred to in Article 1 of Directive 75/363/EEC (see below paragraph 58) to institute a specific training in general medical practice meeting requirements at least as stringent as those laid down in Articles 2 and 3. Article 2 requires the specific training in general medical practice to meet the following minimum requirements:

- (a) entry shall be conditional upon the successful completion of at least six years' study of undergraduate and graduate medical training;
- (b) it has to be a full-time course lasting at least two years and it has to be supervised by competent authorities or bodies. However, without prejudice to this principle of full-time training, Member States may authorize specific part-time training in general practice when the conditions mentioned in Article 5 are fulfilled;
- (c) it shall be practically rather than theoretically based. This practical instruction shall be given in licensed hospitals and licensed general medical practices or health care centres. Article 3 contains an important exception to this rule and has especially been laid down in view of the special situation in Belgium. If a Member State provided training in general medical practice at the date of notification of this directive by means of experience in general medical practice acquired by the medical practitioner in his own practice under the supervision of an authorized training supervisor, that Member State may retain this type of training on an experimental basis if certain conditions are fulfilled. On the basis of experience acquired, and in the light of developments in training in general medical practice, the Commission shall submit to the Council, by 1 January 1996 at the latest, a report on the implementation of Articles 2 and 3;
- (d) it shall entail the personal participation of the trainee in the professional activities and responsibilities of the persons with whom the candidate works. The requirement of personal participation means that according to the Belgian law the candidate must have obtained the diploma of doctor in medicine or physician before starting the specific training in general medical practice.

57. Council Directive No. 86/457 on specific training in general medical practice has been implemented by Ministerial Order of 21 February 2006, laying down licensing criteria for general medical practice (*Moniteur belge*, 27 February 2006).

58. Council Directive No. 75/363/EEC of 16 June 1975 concerning the co-ordination of provisions laid down by law, regulation, or administrative action in respect of activities of doctors (OJ L 167, 30 June 1975, 14-16) has influenced fundamentally the medical specialization in Belgium. According to Article 2 of this directive (coordinated in Council Directive No. 93/16/EEC of 5 April 1993), the Member States shall ensure that the training leading to a certificate or other evidence of formal qualifications in specialized medicine, meets the following requirements at least:

- (a) it shall entail the successful completion of six years' study within the framework of undergraduate and graduate training;
- (b) it shall comprise theoretical and practical training;
- (c) it shall be a full-time course supervised by the competent authorities or bodies;
- (d) it shall be in a university centre, in a teaching hospital or, where appropriate, in a health establishment approved for this purpose by the competent authorities or bodies;
- (e) it shall involve the personal participation of the doctor training to be a specialist in the activity and in the responsibilities of the establishments concerned.

59. The Crown Order of 29 June 1978 prescribing conditions for the licensing of medical specialists and general medical practitioners contained provisions to implement Council Directive No. 75/363. It has been replaced by Crown Order of 21 April 1983 with the same title. This Crown Order determines the agencies responsible for the licensing of medical specialists and their membership and functions, notably the Higher Council of medical specialists and general medical practitioners, licensing Commissions for the different medical specialities and a licensing Commission for general medical practitioners. It further determines the general conditions for in-service training and licensing of medical specialists and general medical practitioners and the general conditions for the licensing of in-service training supervisors and in-service training departments. Since 1978 specialization has been restricted to a limited number of candidates. To be eligible for specialization, an individual has to submit a training plan indicating the name of the supervisor with whom he or she wants to specialize and the in-service department where he or she wants to work, together with the agreement of the supervisor and the in-service department. The training plan has to be approved by the licensing Commission for the speciality concerned. Each Commission has two chambers: a Dutch-speaking and a French-speaking one. The chambers consist of eight members: four representatives of the medical schools and four representatives of the professional societies. A law of 10 December 2008 provides for rules governing the contradictory debate within the chambers and the Higher Council (*Moniteur belge*, 9 January 2009).

60. The ministerial orders of different dates prescribe special criteria for the licensing of medical specialists, in-service training supervisors, and in-service training departments for the different specialities.

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§3. MANPOWER PLANNING. FREEDOM OF ESTABLISHMENT

61. Access to undergraduate medical education has been limited since 1997 (see paragraph 53). Access to postgraduate education is limited in this sense that only a limited number of graduates with the highest degrees are admitted to one or another speciality.

62. There exist no legal restrictions regarding the freedom of establishment. A Crown Order of 15 September 2006 provides for financial measures, stimulating the establishment of GP's practices in certain areas (*Moniteur belge*, 28 September 2006).

Chapter 2. Practice of Medicine¹

§1. LEGAL CONDITIONS FOR THE PRACTICE OF MEDICINE

I. Historical Note

63. The practice of medicine is regulated by Crown Order No. 78 of 10 November 1967 concerning the practice of the healing arts, nursing, allied health professions, and the medical boards, *Moniteur belge*, 14 November 1967, *IDHL* 1969, further cited as Law on the Health Care Professions. Article 50, §1, 1 of this law has repealed the Law of 12 March 1818 governing all matters concerning the different branches of the healing arts, as interpreted by Law of 27 March 1853 and amended by the Laws of 24 February 1921, 18 July 1946, and 25 July 1952.

1. This chapter is based on H. Nys, *Geneeskunde. Recht en medisch handelen* (Brussels: Kluwer, 2005), 1-90 (Medicine. Law and medical activity) and its French translation, H. Nys, *La médecine et le droit* (Brussels: Kluwer Editions Juridiques).

II. Healing Arts and Medicine

64. Article 1 of the Law on the Health Care Professions makes a remarkable distinction between the so-called healing arts and medicine. According to this disposition, the healing arts comprise medicine, in which dentistry is included, when practiced on human beings, and pharmacy in their preventive or experimental, curative, continuous, and palliative aspects.

III. Legal Monopoly of Physicians

65. No person may practice medicine unless he holds a legal diploma of doctor of medicine, surgery, and obstetrics (the law has not been changed yet and does not mention up to now the academic title of physician, see paragraphs 50-51) and unless he satisfies, in addition, the requirements laid down in Article 7, §1 or §2. (Article 2, §1, 1 of the Law on the Health Care Professions). This means that doctors of medicine, surgery, and obstetrics, further denominated as physicians, have a so-called legal monopoly for the practice of medicine. This monopoly has two characteristics: It is exclusive, which means that with the exclusion of all others, physicians are competent to practice medicine; and it is all embracing, which means that it covers every activity that has to be considered as belonging to medicine.

66. With respect to the exclusive character of the monopoly, there exist two exceptions. Notwithstanding Article 2, §1, 1 of the Law on the Health Care Professions, any person holding the professional title of midwife, awarded in accordance with Article 21 *noviesdecies* of this law, is authorized to practice so-called normal deliveries, provided that she or he satisfies the additional requirements laid down in Article 7, §1 or §2. (Article 2, §2 of this law; see for more details paragraph 473.) The second exception is more important. According to Article 3, the practice of

dentistry, which is in legal terms a part of medicine (see paragraph 64), is a legal monopoly of the holder of the legal diploma of master in dental science. Generally speaking, physicians are not allowed to practice dentistry (see for more details, below, paragraph 443).

67. The all-embracing character of the monopoly of physicians implies that every physician is legally competent to practice all activities that belong to medicine. From the most simple to the most sophisticated procedure. Practically speaking, however, the all-embracing character of the monopoly is a fiction. Through the payment of higher fees and other mechanisms, the health insurance system promotes differentiation and specialization (see paragraph 55).

IV. Legal Conditions for the Practice of Medicine

A. Legal Diploma

68. The Law on the Health Care Professions requires the possession of the legal diploma of doctor of medicine, surgery, and obstetrics, obtained in accordance with the legislation on the award of academic degrees and the syllabi for university examinations, unless one has been exempted therefrom (Article 2, §1) or unless one has been assimilated with the holder of such a legal diploma (Article 44*bis*, §1).

69. This requirement of a legal diploma is relatively recent. Before the Law on the Health Care Professions, this requirement was not explicitly laid down in the then existing legislation. According to an advice of the Council of State, no legal provision prohibited at that time the practice of medicine without a legal diploma of doctor of medicine.¹ This prohibition was only reached in an indirect way in that Article 4 of the Law of 12 March 1818 provided that the provincial medical boards had to verify the titles and diplomas of those who wanted to practice medicine in their territory.

1. Parliamentary Documents, Senate, 1962-1963, No. 172/1, 42.

1. Exemption from the Legal Diploma

70. Article 2, §1 of the Law on the Health Care Professions leaves open the possibility of an exemption from the requirement to possess a legal diploma. Such an exemption may be obtained on different legal grounds.

2. Assimilation Based on Mutual Recognition

71. Chapter IV*bis*, of the Law on Health Care Professions, as amended by the Crown Order of 27 March 2008, has implemented Directive 2005/36/EC of 7 September 2005 on professional qualifications.¹

1. See for more details, M. Peeters, 'Free Movement of Medical Doctors: The New Directive 2005/36/EC on the Recognition of Professional Qualifications', *European Journal of Health Law* (2005): 373-396.

B. Visa

72. According to Article 7, §1 of the Law on Health Care Professions, no physician may practice his profession unless he has received a visa from the provincial medical board competent for the place in which he intends to practice. According to Article 37, §2, a, the medical board has to verify and approve the qualifications of the physician. In practice the visa is attributed by the Federal Ministry of Health.

1. Exemption from the Visa

73. According to Article 44^{terdecies} of the Law on the Health Care Professions, a national of a Member State of the European Union may temporarily practice medical activities in Belgium without having to fulfil the obligation of a visa. In that case he has to inform the Ministry of Public Health in advance.

2. Withdrawal of the Visa

74. A provincial medical board may withdraw the visa of a physician if it is found, in the opinion of medical experts designated by the National Council of the Order of Physicians, that this physician no longer possesses the physical or mental fitness required to enable him to continue to practice his profession without danger to the health of his patients. For the purpose of carrying out this duty, the medical board consists solely of the chairman, the vice-chairman, and the secretary, who are all physicians, and two more physicians. The other members of the medical board (pharmacists, dentists, midwives, nurses, and paramedical personnel) do not take part in this decision. The physician concerned may lodge an appeal with the medical board on appeal, the composition, organization, and operation of which have been determined by Crown Order of 7 October 1976, *Moniteur belge*, 4 February 1977. Such an appeal shall not stay the implementation of the decision (Article 25 of the Law of 8 June 2008, *Moniteur belge*, 16 June 2008 has amended Article 37, §4 of the Law on Health Care Professions in this regard). The person concerned may be assisted, both in the initial proceedings and on appeal, by any person he chooses. All decisions taken, whether in the initial proceedings or on appeal, have to be communicated immediately by the medical board to the Order of Physicians (Article 37 of the Law on the Health Care Professions).

75. The attribution of the visa is a purely administrative measure. Hence, it cannot be refused to a physician who is at that moment unfit, mentally or physically, to practice. The procedure before the medical boards is also hindered

because of the uncertainty on the competence to bring a case before a medical board. According to Article 11 of Crown Order of 7 October 1976 concerning the organization and operation of the medical boards, *Moniteur belge*, 4 February 1977, a member of a medical board has to inform the president of the board of any case of unfitness to practice he knows of. The president then may start the procedure to withdraw the visa. It is unclear, however, whether this procedure may start at the request of a colleague or other third person. Medical secrecy impedes a treating physician to inform the medical board of the unfitness to practice discovered with a colleague.

76. From the moment that a decision to withdraw a visa has become definitive, the physician concerned is no longer legally competent to practice medicine. According to Article 38, §1, 1 of the Law on the Health Care Professions, it is an offence to practice medicine without possessing a visa. According to Article 37, §4 of the same law and Article 23, §1 of the Crown Order of 7 October 1976, a decision to withdraw a visa has to be reported immediately to the competent provincial council of the Order of Physicians. This council will then erase the name of the physician concerned from the list of the Order of Physicians (Article 6, 1, 2 of the Law on the Order of Physicians; see for more details, paragraph 113).

76bis. Initially, the withdrawal of a visa was intended as an administrative measure to protect the health of the patients of a physician unfit to practice for health reasons. Hence, it was not a sanction. However, Article 69; 7 of the Law of 19 December 2008 containing diverse dispositions related to health care (*Moniteur belge*, 31 December 2008, 3rd edn) has amended Article 37, §1, 2 of the Law on the Health Care Professions by adding a new littera h to it). This amendment empowers the professional medical boards to withdraw the visa of a physician when he has made himself guilty of criminal behaviour that does not correspond with the requirements to practice medicine. The Crown has still to determine the date of entering into force of this competence. Moreover, the procedure also has still to be determined by a Crown Order.

3. Restricted Visa

77. According to Article 37, §1, 2, b and h of the Law on the Health Care Professions, a provincial medical board may subject the maintenance of the visa to the acceptance of restrictions that it imposes if it is found that a physician is unfit to practice for health reasons or has made himself guilty of criminal behaviour that does not correspond with the requirements to practice medicine. Such a restricted visa does not as such question the competence to practice but limits this competence. Therefore, it is discussed in detail below (see paragraph 117).

C. Inscription on the List of the Order of Physicians

78. According to Article 38, §1, 1 of the Law on the Health Care Professions, it is an offence for anyone to practice medicine habitually without being inscribed

on the list of the Order of Physicians. According to Article 31 of the Law on the Order of Physicians, it is an offence for a physician to practice medicine without being inscribed on the list of the order. In the latter case a habit is not required. (The inscription on the list of the Order of Physicians is discussed in detail under paragraphs 102 et seq.).

§2. ILLEGAL PRACTICE OF MEDICINE

I. Legal Definition of the Offence

79. According to Article 38, §1, 1 of the Law on the Health Care Professions, it is an offence to carry out in an habitual way an act or acts that belong to the field of medicine either without holding the required diploma or without being legally exempted from it, or either without obtaining a visa from the medical board or without being inscribed on the list of the Order of Physicians.

80. In this definition three elements can be distinguished: the carrying out of the same or different activities belonging to medicine (see Section II) by an unauthorized person (see Section III) in a habitual way (see Section IV).

II. Medical Activities

A. General Remarks

81. Article 38, §1, 1 of the Law on the Health Care Professions uses the terms 'act or acts belonging to medicine' without giving a definition of the terms. Nowhere else does the law give a definition of this notion.

82. Article 2, §1, 2 and §2, 3 of the same law determine the meaning of the illegal practice of medicine. From this disposition it may be concluded that an act belongs to the field of medicine and thus may be considered as an act of medicine whenever it has the purpose or the purported purpose, in respect of a human being:

- either the examination of the state of health;
- or the detection of diseases and disabilities;
- or the establishment of a diagnosis;
- or the introduction or administration of any treatment of a pathological condition, whether physical or mental, real or supposed;
- or a vaccination;
- or the supervision of pregnancy, childbirth and puerperium, as well as any related procedure.

83. Article 2, §1, *in fine* empowers the Crown to specify the activities to which the preceding paragraph applies. Up to now, the Crown has not made use of this competence.

84. There exist several legal dispositions preserving the carrying out of certain activities to physicians. One may regard also these activities as medical activities. The treatment of a sexually transmittable disease is according to Article 2 of the Health Law of 24 January 1945, *Moniteur belge*, 26 January 1945, a competence of physicians. Another example is the removal or transplantation of an organ that, according to Article 3 of the Organ Transplantation Law of 13 June 1986, *Moniteur belge*, 14 February 1987, can only be practiced by a physician. Also the termination of a pregnancy has to be carried out by a physician in order to be legal (Article 350 Criminal Code, as amended by the Law of 3 April 1990, *Moniteur belge*, 5 April 1991). According to a Law of 19 January 1961, *Moniteur belge*, 31 July 1961, certain medical acts may be carried out in exceptional circumstances by persons who are not legally authorized to practice medicine. The Crown Order of 1 August 1961, *Moniteur belge*, 25 August 1961, has determined these acts. They are intravenous injections and venapunctures. The removal of any therapeutic substance of human origin such as blood, red blood cells, sera, plasma, and the like has to be carried out by a physician or under his direction according to Article 3 of the Law of 7 February 1961 relating to therapeutic substances of human origin, *Moniteur belge*, 22 May 1964. This law has been replaced by the Law of 5 July 1994 concerning Blood and Blood Derivates from Human Origin, *Moniteur belge*, 8 October 1994. Euthanasia may only be practiced by a physician in order not to be a crime (Articles 3 and 4 of the Act of 28 May 2002 on euthanasia, *Moniteur belge*, 22 June 2002). The removal of human bodily material may only be practiced under the responsibility of a physician (Article 4, §1 of the Law of 19 December 2008 regulating the procurement and use of human bodily material for medical application in humans or scientific research, *Moniteur belge*, 30 December 2008; see also in this regard Article 20bis of the Law on the Health Care Professions, added by the Law of 19 December 2008 regulating the procurement and use of human bodily material for medical application in humans or scientific research).

B. Specific Medical Activities

1. Preventive Medicine

85. Article 2, §1 of the Law on the Health Care Professions does not mention among the medical activities (see paragraph 81) activities to prevent diseases except for vaccination. Does it mean that preventive medical activities do not fall under the legal monopoly of physicians to practice medicine? The answer is negative. According to Article 1 of the law, the healing arts comprise medicine in both its curative and preventive aspects (see paragraph 64). Moreover, the enumeration of activities given in Article 2, §1 is not limited to curative medicine although in a few cases this limitation is implied. This is obviously the case for the administration of a treatment. But in other cases, such as the examination of the state of health, the detection of diseases or the establishment of a diagnosis, it concerns activities that can be practiced either in a curative or preventive context. Hence, preventive medicine belongs to the legal monopoly of physicians insofar that activities mentioned in Article 2, §1, 2 and §2, 3 are practiced.

2. Self-care

86. Self-help or self-care is not considered as illegal practice of medicine because the law on the Health Care Professions only envisages the situation that medical activities are practiced *vis-à-vis* another person.

87. According to the Court of Appeal of Brussels,¹ it would be ridiculous to condemn relatives and neighbours to care when this care is of a calming and banal nature and does not require any special knowledge. Although one can accept this opinion without hesitation, the legal foundation of it is rather unclear. The Law on the Health Care Professions does not make any distinction according to the complexity of the activities nor does it require that the acts of medicine be practiced on a professional basis.

1. Court of Appeal Brussels, 24 Jan. 1974, *J.T.*, 1974, 249.

3. Taking of Blood: Venapunctures

88. The analysis of blood is clearly an examination in the sense of Article 2 of the Law on the Health Care Professions. Whether the taking of blood also falls under the legal monopoly of physicians has been disputed. A Crown Order of 1 August 1961 considers venapunctures as an act of medicine (see paragraph 81). A Crown Order of 11 March 1985 prescribing the list of technical services in nursing care and the procedures that a physician may delegate to nurses, the manner in which they are to be carried out and conditions regarding the qualifications required, *Moniteur belge*, 22 March 1985, mentioned venapunctures. This Crown Order has been nullified by the Council of State¹ and has been replaced by the Crown Order of 18 June 1990, *Moniteur belge*, 26 July 1990. Also this Crown Order considers venapunctures as technical services in nursing care that may be practiced by nurses on the prescription of a physician. From these legal dispositions it follows that the taking of blood samples is an act of medicine that may only be performed by physicians or nurses on the prescription of a physician.

Also the courts have taken this point of view. A special case is the taking of blood samples for determining the alcohol level, which always has to be performed by a physician.

1. Council of State, *Kinart*, No. 27.781, 3 Apr. 1987.

4. Radiographies

89. The courts consider a radiography as a purely technical procedure that as such does not belong to the practice of medicine. As long as the maker of the radiography does not use this for establishing a diagnosis, he cannot be condemned for illegal practice of medicine.¹

1. Court of Cassation, 28 Apr. 1987, *VI.T.Gez.*, 1987-1988, 30; Court of Appeal, Antwerp, 20 Jan. 1984, *Pas.*, 1984, II, 99.

5. Blood Pressure Measuring and the Use of Other Simple Measuring Appliances

90. Up to now there is no jurisprudence on the use of a blood pressure measuring appliance and other simple appliances to measure, for instance, heartbeat and pulsation. As long as this appliance is used in the context of self-examination and self-care, this cannot be considered as (illegal) practice of medicine (see paragraph 82). Whenever this appliance is used to examine the state of health of another person it can be considered as an act of medicine reserved to physicians.

6. Eye Examination and the Measuring of Eye Deviations

91. It is generally accepted that an optician may measure deviations of the eye through the so-called subjective method. Whether he may use the so-called objective method that implies the intervention of an appliance such as an ophthalmometer, a sciascope, and so on has been differently answered by the courts. A judgment of the Cour de Cassation¹ has considered the decision of an optician that a deviation of the eye has not a pathological origin as the establishment of a diagnosis and thus as an act of medicine. The Cour de Cassation ruled in that judgment that, although opticians who are not medical doctors are authorized to perform acts designed to correct defects of a purely optical nature, whether or not they use equipment or instruments for that purpose, they are nonetheless prohibited from examining the state of vision of their clients otherwise than by using a method under which the patient alone determines the sight defects from which he suffers, inter alia on the basis of printed scales, which may be incorporated in a control instrument and which the patient himself corrects by choosing, as the optician proposes, the lenses that satisfy him. The optician is obliged to advise his client to consult an ophthalmologist if the indications thus obtained leave any doubt as to the nature of the defect that has been established. In answer to the questions referred to it by the Tribunal de Première Instance de Bruxelles by judgment of 27 March 1996, the European Court of Justice ruled that as community law stands at present, Article 52 of the EC Treaty (now, after amendment, Article 43 EC) does not preclude the competent authorities of a Member State from interpreting the national law governing the practice of medicine in such a way that, within the context of the correction of purely optical defects, the objective examination of a client's eyesight, that is to say, an examination that does not use a method under which the client alone determines the optical defects from which he is suffering, is reserved, for reasons relating to the protection of public health, to a category of professionals holding specific qualifications, such as ophthalmologists, to the exclusion, in particular, of opticians who are not qualified medical doctors. It is for the national court to assess, in the light of the treaty requirements relating to freedom of establishment and the demands of legal certainty and the protection of public health, whether the interpretation of domestic law adopted by the competent national authorities in that regard remains a valid basis for the prosecutions brought in the case in the main proceedings.² The Court also remarked that an assessment of this kind is liable to change with the passage of time, particularly as a result of technical and

scientific progress. It is significant in this regard that the Bundesverfassungsgericht (Federal Constitutional Court) (Germany) concluded, in its decision of 7 August 2000 (1 BvR 254/99), that the risks that might follow from authorizing opticians to carry out certain examinations of their clients' eyesight, such as tonometry and computerized perimetry, are not such as to preclude them from conducting those examinations.

1. Court of Cassation, 28 Jun. 1989, *Arr. Cass.*, 1989, 1293.
2. European Court of Justice, 1 Feb. 2001, in case C-108/96.

7. Psychoanalysis and Psychotherapy

92. On the question whether psychoanalysis and psychotherapy are acts of medicine, the opinions widely diverge. The discussions are concentrated on the two following matters. Can psychoanalysis and psychotherapy be considered as a treatment in the sense of Article 2 of the Law on the Health Care Professions? Is the use of verbal and non-verbal forms of communication a treatment? Are psychoanalysis and psychotherapy directed towards a pathological state? It is impossible for lawyers to answer these questions. The only existing judgment¹ in this respect has decided that a psychoanalyst did not perform acts of medicine and behaved only as a friend or a spiritual advisor. This judgment has been criticized by Meert-Van De Put.² The Court of appeal of Ghent³ judged that relaxation and hypnosis sessions are to be considered as acts of medicine when they aim at influencing the mental state of the persons concerned so that their self-confidence grows stronger.

1. Criminal Tribunal Charleroi, 9 Jun. 1965, *J.T.*, 1965, 603.
2. R. Meert-Van de Put, 'Psychothérapie et art de guérir', *R.D.P.*, 1968-1969, 655.
3. Court of Appeal Ghent, 30 Nov. 1988, *Pas.*, 1989, II, 132.

8. Group Therapy

93. Group therapy has in the literature long been considered as not belonging to the field of medicine because only acts directed towards one individual person could be regarded as such.¹ This opinion is out of date. It does not take into consideration the evolution of medical techniques. In certain cases, especially in the field of genetic diagnosis, a group-oriented approach is often required. In other cases the dynamics within a group of patients may be of therapeutical value for an individual patient. Therefore, there is no decisive reason to exclude group-oriented diagnostic or therapeutical procedures from the field of medicine.²

1. See, for instance, R. Grosemans, 'Considérations sur l'exercice illégal de l'art de guérir', *R.D.P.* (1955-1956): 163.
2. See on group-therapy also J.H. Hubben, 'Legal Complications Arising from Group-Therapy', in *Trends in Law and Mental Health*, Proceedings of the 13th International Congress on Law and Mental Health, eds F. Koenraadt & M. Zeegers (Arnhem: Gouda Quint, 1988), 151-155.

9. Acupuncture

94. The jurisprudence¹ has decided unanimously that acupuncture has to be considered as an act of medicine in the sense of the Law on the Practice of Medicine. See also paragraph 101*ter*.

1. Cour de Cassation, 20 Jun. 1990, *Pas.*, 1990, I, 1189.

10. Written and Oral Advice and Recommendations

95. According to a unanimous doctrine, written and oral advices and recommendations concerning diseases and their treatment cannot be considered as acts of medicine. However, if the recommendations only concern one specific disease and are directed towards a defined group of patients and contain very detailed prescriptions it is not excluded that all these elements together constitute (illegal) practice of medicine.

III. An Unauthorized Person

96. See §1 of this chapter (paragraphs 63 et seq.) for a description of the conditions to practice medicine. From this description follows, *mutatis mutandis*, who is an unauthorized person.

IV. In an Habitual Way

A. *The Meaning of Habitual*

97. Article 38 of the Law on the Health Care Professions requires that medical acts be performed in an habitual way in order to be an offence (see paragraph 79). The meaning of ‘habitual’ has been disputed. According to the correctional tribunal of Namur, the existence of a *habitude* has not to be evaluated quantitatively but has to be judged in the light of the concrete circumstances of the case. But, in general, the existence of an *habitude* is expressed in quantitative terms. According to some, two acts suffice if there is a link between both acts to have a *habitude*. Others require at least three acts. These acts do not necessarily have to concern different persons. Nor is it required that different acts have been performed.

Habitual may not be interpreted as professional. The law does not require that one has performed medical acts in a professional way.

B. *Exceptions*

1. Repetition

98. A *habitude* is not required when someone has previously been condemned because of illegal practice of medicine (Article 38, §2, 1).

2. Publicity

99. When the illegal practitioner has made use of whatever means of publicity for his practice, a habitude is not required (Article 38, §2, 2).

3. Abuse of Titles

100. Neither is a habitude required when an act of medicine has been practiced while using a title or whatever denomination with the purpose to make people believe that one is a competent practitioner. The law does not specify the title. It may be that the title of doctor in medicine but also other titles, legally protected or not, are intended. The use or abuse of such a title is in itself not a constitutive element of the offence of illegal practice.

V. Sanctions

101. Article 38, §1, 1 of the Law on the Health Care Professions provides for a penalty of eight days to six months confinement and/or a fine of EUR 500 to EUR 5,000 for illegal practice of medicine. In the case of repetition within three years, these sanctions can be doubled, without exceeding six months confinement or a fine of EUR 50,000 (Article 42).

§3. USE OF AUTOMATIC 'EXTERNAL' DEFIBRILLATORS

101bis. Article 2 of the law of 12 June 2006 on the use of so-called automatic 'external' defibrillators (*Moniteur belge*, 21 September 2006) allows the use of such an apparatus for purposes of reanimation if all the conditions determined in the Royal Decree of 21 April 2007 (*Moniteur belge*, 18 May 2007) are respected.

§4. NON-CONVENTIONAL PRACTICES IN MEDICINE

101ter. Non-conventional medicine is regulated by the law of 29 April 1999 on the non-conventional practices in medicine (*Moniteur belge*, 24 June 1999). Article 2 of this law introduces provisions for homeopathy, chiropractic, osteopathy, and acupuncture and provides for the recognition of other complementary/alternative techniques. Article 3 establishes a Commission to advise the government on the practice of complementary/alternative medicine, particularly registration of practitioners, membership in recognized professional organizations, insurance for professionals, regulation of advertising, and restrictions on medical acts. In order to register, practitioners must demonstrate that they provide high-quality and accessible care that has a positive influence on their patients' health. Article 6, §1 requires the Commission to be composed of five allopathic practitioners (with at least one being a GP), nominated by faculties of medicine, and five complementary/alternative

practitioners, nominated by recognized professional organizations. The Commission, in Article 6, §2, is also designated to advise the government on organizing a peer review system and a code of professional ethics. Until today this Commission is, however, not yet in operation. By Article 8, the practice of a registered complementary/alternative form of medicine is allowed only when the practitioner is licensed for that practice by the Ministry of Social Affairs, Public Health, and Environment. In Article 9, complementary/alternative practitioners are required to maintain medical records for each patient. Complementary/alternative practitioners who are not also allopathic physicians must obtain a recent allopathic physician's diagnosis from their patient prior to commencing treatment. If patients choose not to consult an allopathic physician before seeing a complementary/alternative practitioner, they must put their wishes in writing. Registered complementary/alternative practitioners must take precautions to ensure that patients are not deprived of allopathic treatment. As a result, complementary/alternative practitioners who are not also allopathic physicians must keep allopathic physicians informed of the health of their patients. With patient consent, complementary/alternative practitioners are permitted to seek the advice of other complementary/alternative practitioners who are not allopathic physicians.

Infringement of the law – in particular, practicing complementary/alternative medicine without a license or treating a patient without having obtained an allopathic physician's diagnosis or without having the patient's desire to avoid such diagnosis in writing – risks a fine (under Article 11) or the suspension or withdrawal of the provider's license to practice (under Article 8).¹

1. *Legal Status of Traditional Medicine and Complementary/Alternative Medicine: A Worldwide Review* (Geneva: World Health Organization, 2001), 88.

Part II. The Physician-Patient Relationship

Chapter 1. General Description

§1. RIGHTS AND DUTIES OF PATIENTS AND PHYSICIANS

I. The Law on the Rights of Patients

197. The rights and duties of physicians and patients are regulated in the law on the rights of patients of 22 August 2002. *Patient* means 'the natural person to whom health care services are provided, *whether at his request or not*' (Article 2, 1°). This means that a patient is also someone who undergoes an examination of his state of health at the request of a third party, for example, an employer or insurer. *Health care* means 'the services that a health professional provides in order to promote, determine, preserve, restore or improve a patient's state of health or in order to support a dying patient' (Article 2, 2°). This is a customary definition of health care. Removing an organ from a donor, terminating a pregnancy, and performing euthanasia are, therefore, activities that do not constitute health care in the sense intended by the law on patient rights. They are regulated by other acts. Moreover, medical experiments involving persons are not covered by the law's domain of application. For the purposes of the patient rights law, *health professional* means the practitioner provided for in Royal Decree No. 78 of 10 November 1967 on the practice of the health professions (Article 2, 3°). As far as the current state of the legislation is concerned, this means the following professional groups: physicians, dentists, midwives, pharmacists, physiotherapists, nurses, paramedics, and nurse's assistants. Practitioners of non-conventional medicine, as defined in the Act of 29 April 1999 concerning such practices, are also health professionals.

A. *The Duty of the Patient to Cooperate*

198. Health professionals shall comply with the provisions of this act within the limits of the competence conferred on them by or under the law and to the extent that the patient cooperates (Article 4, 1°). In what does the patient's duty to cooperate consist? The only practical legal meaning would seem to be that a health professional who is sued by a patient may seek a defense in the invocation of patient negligence. This amounts to invoking an error committed by the victim.

B. The Right to Quality Care

199. According to Article 5, the patient has the right to receive high-quality health care that meets his needs, with respect for his human dignity and his self-determination, and without any discrimination on any grounds whatsoever. The precise implication of the expression 'high-quality health care' is further explained in the explanatory memorandum, requiring a physician to act according to 'the applicable standards and the current state of scientific knowledge'. In other words, Article 5 makes it mandatory for a physician to act as a '*bonus medicus*'. However, what does 'acting in accordance with the applicable standards and the current scientific knowledge ("*bonus medicus*")' mean? The applicable standards refer, among others, to guidelines and protocols set up by the medical profession. They contain rules concerning the medical profession as well as technical rules that can be used either as a standard or as guidance in malpractice cases. When deciding whether a physician acted as a '*bonus medicus*', a judge needs to establish what the physician should have done in the particular case and not what is commonly done.

Thus, when making a decision on the case, the judge can rely on protocols and guidelines issued by medical organizations, but he is not bound to do so. The significance of clinical practice guidelines in judging the quality of care was already apparent in case law before the development of patients' rights laws. The Brussels Court of Appeal, for example, assigned a decisive role to recommendations formulated in medical literature. The court judged that an experts' report cannot be followed if this report deviates from the recommendations in the literature. In *casu*, it concerned recommendations, about which a broad consensus existed in medical science. Moreover, it became clear from the recommendations that the intervention carried out by the physician was not without risk. The importance of observing safety regulations issued by a professional organization became clear from the decision of the Court of Liège on 20 October 1998. The case concerned the liability of an anaesthetist, who had neglected to personally carry out essential controls, entirely in contrast to what is prescribed by the Belgian safety rules concerning anaesthesia (*Safety-First* norms). It concerned, in particular, the inspection of the respirator and monitoring alarm. Moreover, he performed different anaesthesias simultaneously and, as a result, he neglected to constantly watch his patient. The court blamed the anaesthetist because he had not observed the *Belgian Safety-First* norms, which were enacted for the safety of a patient during anaesthesia. These standards had been approved by the Belgian Professional Association of Specialists in Anaesthesia and Reanimation (BSAR) and had been in effect since 1 January 1995. The court also stated that these safety rules merely confirm the usual practice as well as some elementary requirements that each careful and devoted physician would have observed in the same circumstances. These cases clearly show that courts do refer to standards/norms issued by a medical professional organization when verifying whether the physician has acted carefully.

Article 5 deals with the patient's *needs* rather than *desires*. The patient may not invoke this right in order to claim a treatment for which there is no medical indication.

C. The Right to Free Choice

200. According to Article 6, the patient has the right to freely choose his health professional and to change that choice, except for some restrictions in cases determined under the law.

D. Rights Related to Information about the State of Health

1. The Right to Information about One's State of Health

201. The patient has the right to receive from the health professional all relevant information necessary to assess his state of health and his prognosis (Article 7, 1°). It is question of *all* the relevant information that is *necessary* for gaining some idea of the patient's state of health and its likely progression. This may be not only information already available but also information not yet available, which can be brought to light by appropriate diagnostic methods. Communication with the patient must take place in clear language (Article 7, 2°, first paragraph), which means that the method of providing information is adapted to each individual patient. The patient may request that the information be confirmed in writing (Article 7, 2°, second paragraph).

Because informing the patient is a fundamental element of medical practice, this obligation cannot be delegated by a physician to nursing or paramedical personnel. This is not to say that nurses and paramedics have no duty to inform the patient concerning the activities that they may legally perform. Therefore, physicians and other health care providers should make clear arrangements to guarantee that the right to information of the patient is fully respected.

2. The Right Not to Know about One's State of Health

202. Information is not provided to the patient if the latter explicitly requests not to know (Article 7, 3°, first paragraph, first sentence). If the patient exercises this right, the health professional may not inform the patient: The duty to inform becomes a duty not to inform.

The explicit request not to know can be given in writing, in which case it is annexed to the patient's medical record, or orally, in which case it is noted in the medical record (Article 7, 3°, second paragraph).

Notwithstanding the patient's explicit request not to know information, the health professional will communicate this information to the patient when not communicating it would clearly do grave harm to the health of the patient or to a third party. This is on condition that the health professional has previously sought the opinion of another health professional in this matter and a confidant designated by the patient, if any (Article 7, 3°, first paragraph).

3. Relinquishing the Right to Information

203. Long before the right not to know was recognized, it was already accepted that the patient has a right to relinquish his right to information. In order to be legally valid, this relinquishing must take place voluntarily and it must be certain. If the patient relinquishes his right to information, then the physician is no longer required to inform (he does not need to inform the patient). If the patient exercises his right not to know, then the physician is prohibited from informing.

4. Not Informing about a Patient's State of Health at the Physician's Initiative (The Therapeutic Exception)

204. In exceptional cases, the health professional may withhold information about the patient's state of health if disclosure would cause grave harm to the patient and on condition that the health professional has sought the opinion of another health professional (Article 7, 4°, first paragraph). Not informing the patient under these circumstances is referred to as the therapeutic exception. It is generally accepted.

E. The Right to Give Consent

1. The Right to Well-Informed, Free and Prior Consent

205. The patient has the right to consent well informed, freely, and in advance to any service provided by a health professional (Article 8, 1°, first paragraph). The consent of the patient is only valid for the medical intervention consented to. Sometimes during an operation a new ailment may be discovered that requires an immediate intervention. Such a so-called extended operation creates no problem when this discovery was foreseeable and the extension has been discussed previously with the patient. However, not all events are foreseeable. Van Quickenborne makes a distinction as to whether the 'extended operation' of the unforeseeable ailment has important disadvantageous consequences for the patient or not. In the latter case, consent to the 'extended operation' may be presumed. In the former case, however, consent has to be asked for except for an emergency, in which case the duty to help prevails.

2. The Way of Giving Consent

206. Consent must be given expressly except when the health professional, after having informed the patient adequately, can reasonably infer consent from the patient's behaviour (Article 8, 1°, second paragraph). Consent not given expressly is also referred to as implicit, tacit, or non-verbal consent. The consent shall be recorded and added to the patient's medical record at the patient's or health professional's request and with the health professional's or patient's approval (Article 8, 1°, third paragraph).

3. Content of the Information

207. The information supplied to patients for the purpose of giving the consent referred to in Article 8, paragraph 1, relates to the objective and nature of the medical service; to the degree of urgency, the duration, the frequency, the patient-specific contraindications, side effects, and risks involved in the service; and to the post-care, the possible alternatives, and the financial consequences. In addition, this information relates to any other clarifications that the patient or health professional deems fit to make, including, if necessary, the legal provisions to be complied with in relation to a medical service (Article 8, 2°).

4. Presumed Consent in Cases of Emergency

208. When, in an emergency case, there is uncertainty as to the will of the patient or his representative, health professionals shall immediately deliver all necessary services in the interest of the patient's health. The health professional shall record this in the patient's medical record and shall act as soon as possible in accordance with the provisions of the preceding paragraphs (Article 8, 5°).

F. The Right to Refuse or Withdraw Consent

209. Patients have the right to refuse or withdraw their consent for any intervention (Article 8, 4°, first paragraph). Article 8, 4°, third paragraph provides explicitly that neither refusal nor withdrawal of consent shall end the right to high-quality care referred to in Article 5. In other words, refusal by itself does not terminate the legal relations between the patient and physician.

210. If the patient has made a written statement refusing a given medical intervention at the time when he or she was still capable of asserting the rights covered in the law on the rights of patients, this refusal shall be respected as long as the patient does not revoke it in a period when he is competent to exercise his rights himself (Article 8, 4°, fourth paragraph). This provision, which establishes the binding character of a so-called advance refusal, is perhaps the most controversial part of the patient rights law. According to the explanatory report, an advance refusal has in principle the same legal effect as a currently expressed refusal: The health professional is not authorized to act and must respect the refusal. In order for an advance refusal to be binding, two conditions must be met. Firstly, it must apply to a 'well-defined medical intervention'. A refusal that uses vague terms is not binding. Secondly, there may be no lingering doubt that the refusal comes from the person involved. In an emergency situation a physician will often not have enough time to verify this and his duty to provide assistance will take precedence.

G. Rights Related to the Patient's Medical Record

1. The Right to a Medical Record

211. The patient has the right to a medical record, carefully updated and safely stored by the health professional (Article 9, 1°). The law does not provide a definition of a medical record. It is a factual notion: The medical records are the set of all facts related to health, documents, attachments, and so on, that relate to a single patient, maintained and stored by a health professional, sometimes in various places and on various media (paper, electronic, etc.). The law does not provide any norms to which the medical record must adhere.

2. The Right to Addition

212. At the request of the patient, the health professional adds any documents supplied by the patient to the medical records (Article 9, 1°, second paragraph), for instance an advance directive drafted by the patient.

3. The Right to Access

213. Patients have the right to access their own medical records (Article 9, 2°). The explanatory report thoroughly discusses the reasons for having a right to access. It is not primarily intended to satisfy the patient's information needs: These needs are addressed by the right to information about one's state of health (Article 7) and to information preceding consent or refusal (Article 8). The decision to provide this information lies with the health professional, and this should be done anytime there is a need for it, if necessary several times per day (e.g., an acute hospitalization). The right of access is not a substitute or remedy for poor information delivery. If the patient needs to exercise his right of access in order to obtain information that he should already have been given, then there is something wrong with the initial information delivery. The main reason for having a right of access is to protect the patient's privacy. On the basis of this right, the patient can exercise control over personal data included in a medical record, thus protecting his privacy.

A patient's request to access his medical record shall be granted as soon as possible and not later than fifteen days following the request (Article 9, 2°, second paragraph). The health professional's personal notes and information relating to third parties are excluded from the right of access to medical records (Article 9, 2°, third paragraph). According to the explanatory report, personal notes are the annotations made by the health professional, which are kept separately and which are never accessible to others, not even to the other members of the medical care team. The moment health professionals show these notes spontaneously to a colleague, they lose their qualification as 'personal notes' and can therefore no longer be excluded from the right to access.

Patients may request to be assisted by or to exercise their right of access through a close confidant designated by them. If the latter is a health professional, he or she

shall also have the right to access the personal notes referred to earlier (Article 9, 2°, fourth paragraph).

4. The Right to a Copy

214. Patients have a right to obtain a copy of their medical records, in whole or in part, in accordance with the provisions of Article 9, 2° (i.e., by request, as soon as possible, and not later than fifteen days following the request, excluding personal notes and data concerning third parties, with the assistance of a confidant by request). The maximum price for each copy has been determined by Crown Order of 7 February 2007 (*Moniteur belge*, 7 March 2007). Each copy shall clearly indicate that it is strictly personal and confidential (Article 9, 3°, first paragraph). The health professional can refuse to supply such a copy if there are clear signs that the patient has been pressured to ask a copy of his medical record at the instigation of a third party (Article 9, 3°, second paragraph).

5. Access by Next of Kin after the Death of the Patient

215. Article 9, 4° determines the conditions under which the next of kin may consult elements of the deceased patient's medical records. Only the patient's spouse, legally cohabiting partner, and relatives up to and including the second degree, have this right of consultation. Access must take place via a health professional designated by the person making the request, and the health professional has access to the personal notes. The request must be adequately reasoned and specified and the patient must not have expressly opposed it when he was alive.

This indirect consultation right for the next of kin under strict conditions comes in response to a request from the Commission for the Protection of Privacy in its recommendation of 15 June 2000. As an example of adequate reasoning and specification, the Commission mentions a case where the next of kin have a suspicion that a medical error was committed. The Commission also learned that it is important for the next of kin to receive information about the cause of a family member's death in order to come to terms with the death. Consultation may also be justified for medical reasons, for instance in order to determine if a specific condition has antecedents within the family of the person making the request.

The next of kin have only a right to consult the file of the deceased patient but not a right to make a copy of it.

H. The Right to Protection of Privacy and Intimacy

216. Patients have the right to the protection of their privacy in any medical service, particularly with respect to the information about their health (Article 10, 1°, first paragraph). There shall be no interference with regard to the exercise of this right unless it is provided by law and is necessary for the protection of public health or for the rights and liberties of others (Article 10, 2°).

Patients have the right to the protection of their intimacy. No other persons than those whose presence is required for the delivery of medical services shall be allowed to assist in the provision of care, the examinations, and treatment without the patient's consent (Article 10, 1°, second paragraph).

Article 19 of the patient rights act introduced significant changes to Article 95 of the law of 25 June 1992 on insurance contracts. The draft bill even went so far as to suggest rescinding the article's first paragraph, which provided that the physician chosen by the beneficiary would, at the beneficiary's request, provide the medical declarations necessary for closing or executing the insurance contract. In the explanatory report, this was justified by referring to the provision's patient-unfriendly character. As far as the content and time limitations of the information were concerned, it placed an unlimited requirement on the physician. The Commission for the Protection of Privacy agreed with this line of reasoning. The Council of State, on the other hand, suggested 'investigating if there is not some alternative to simply scrapping the clause in question'. It occurred to the council that the interests of patients are not always served by merely rescinding the provision. In order to deal with this, the government introduced an amendment to Article 95. The first, second, and fifth paragraphs are new, whereas the third and fourth remained unaltered. Under the provisions of the first paragraph, the physician chosen by the beneficiary is no longer required to provide the requested medical declarations; he is permitted to do so. In addition, these declarations must restrict themselves to a description of the current state of health. What the patient's state of health was in the past (e.g., an addiction that has since been cured) may not be mentioned. The second paragraph provides that the declarations may only be given to the insurance company's advisory physician. This immediately implies that every insurance company will need to have such a physician at its disposal. This advisory physician may not give the insurance company any information that is not relevant to the risk for which the declarations are made or which concerns anyone other than the beneficiary. Under the provisions of the fifth paragraph, when there is no longer any risk to the insurance company, the advisory physician returns the declarations to the beneficiary at his or her request or to the beneficiary's next of kin in the event of death.

I. The Right to Representation in the Event of Incompetence

217. The law contains rules to protect the rights of patients who are legally (Article 13) or factually (Article 14) not capable of exercising their rights as a patient.

The rights of adult patients who have the legal status of 'extended minority' or have been declared incompetent are exercised by their parents or guardians. Such patients have to be involved as much as possible and, depending on their comprehension, in the exercise of their rights (Article 13, §1-2).

The rights of adult patients who do not belong to one of the categories mentioned in Article 13 and who are not capable of exercising their rights as a patient are exercised by the person previously designated by said patients to act on their behalf when and for as long as they are unable to exercise these rights themselves. This

so-called *patient-designated representative* has to be designated using a specific written mandate, dated and signed by the patient and by this person, clearly showing the latter's consent. Patients or patient-designated representatives may revoke this mandate (Article 14, §1).

If there is no patient-designated representative or if he fails to act, the rights of the incapable adult patient can be exercised by the cohabiting spouse, the legally cohabiting partner, or the actual cohabiting partner. If this person refuses or if there is no such person, the rights can be asserted, in descending order, by an adult child, a parent, or an adult brother or sister of the patient. If these persons refuse or if there are no such persons, the health professional concerned has to take care of the patient's interests, possibly after multidisciplinary consultation. This is also the case when there is a conflict between two or more representatives of equal rank, for instance a conflict between two children of the patient (Article 14, §2).

An adult, incapacitated patient has to be involved as much as possible and, depending on his comprehension, in the exercise of his rights (Article 14, §3).

Whereas a patient may take 'irrational' decisions, the legal representative of an incapacitated patient has always to act in the interests of the patient. In order to guarantee this, the law provides for a possibility and sometimes even an obligation for the health professional concerned to deviate from the decision taken by the representative.

To protect the patient's privacy the health professional concerned may reject the request, in whole or in part, of a legal representative for having access to the medical records of the patient or for having a copy of it. In such a case, the right to access the medical records or to get a copy has to be exercised by a health professional chosen by the representative (Article 15, §1).

A health professional, possibly after multidisciplinary consultation, has an obligation to deviate from the decision taken by the legal representative of the patient, in the interest of the patient, to avert a threat to the patient's life or serious damage to his health. However, when the decision was taken by a so-called patient-designated representative, the health professional may deviate from this decision only insofar as this representative is unable to refer to the patient's express will, such as an express refusal of a lifesaving treatment (Article 15, §2).

In the cases provided for in paragraphs 1 and 2 of Article 15 the health professional adds a written motivation to the patient's records (Article 15, §3).

See for the legal representation of minor patients, below, paragraph 269.

J. The Right to Lodge a Complaint

218. The patient has the right to register a complaint regarding the exercise of rights granted by this law with the competent ombudsperson's office (Article 11, 1°). The responsibilities of the ombudsperson's office are established in Article 11, 2°. In addition to a preventive (preventing complaints and preventing the shortcomings that gave rise to them) and mediating function, the ombudsperson also has a two-fold informative function: to provide information about alternate possibilities for dealing with a complaint in the event that mediation fails and to provide information about the organization and functioning of the ombudsperson's office.¹

Under the hospital legislation, and following the set standards, every hospital must appoint an ombudsperson. Every health care professional must comply with the patients' rights legislation. Hospitals are also obliged to comply with the stipulations of the law on patient rights with regard to the medical, nursing, and other health care professional aspects of the legal relationship with patients. In addition, hospitals must ensure compliance by health care professionals and access to a hospital ombudsperson for patients with complaints.

A federal ombuds service has been established in the Ministry of Public Health. This service is responsible for handling complaints of patients concerning the exercise of their rights, granted by the Law on Patient Rights, by referring patients to the appropriate local ombudsperson. The complaint is treated by the federal ombuds service if there is no appropriate local ombudsperson. It concerns, for example, GPs, dentists, pharmacists, independent nurses and physiotherapists. The federal ombuds service must also deal with complaints concerning the way in which mediation has taken place by the local ombudsperson. However, the federal ombuds service is not a substantive profession-wide agency for complaints that have been dealt with by local ombudspersons.

A Crown Order of 15 February 2007 (*Moniteur belge*, 20 March 2007) has established specific rules for the representation of incompetent patients in case they want to lodge a complaint. In this case the stringent rules (see paragraph 217) determining the order between relatives who may represent the incompetent patient do not have to be respected.

1. This chapter is based on H. Nys, *Geneeskunde. Recht en medisch handelen* (Mechelen: Kluwer, 2005), 306-448.

K. *The Right to Palliative Care and Pain Relief*

218bis. Article 2 of the Law of 24 November 2004 (*Moniteur belge*, 17 October 2005) has inserted a new Article 11*bis* in the law on patient rights. According to Article 11*bis* everyone has a right to the most appropriate treatment to prevent pain and the right to have his pain evaluated and treated. In the light of Article 5 of the law on the rights of patients (above, paragraph 199) Article 11*bis* adds nothing. According to Article 5 every patient has already a right to receive qualitative health care according to his or her needs. There is even a danger that Article 11*bis* might lead to a restricted interpretation of Article 5.

II. The Legal Duty to Help

A. *Law on the Health Care Professions*

219. According to Article 8, 1 of the Law on the Health Care Professions no physician may knowingly and without legitimate reason and on his own authority discontinue a course of treatment unless he has previously made all the necessary arrangements for it to be continued by another physician. The Councils of the Order of Physicians have to ensure that this obligation is observed.

220. According to Article 9, §1 of the Law on the Health Care Professions, the professional organizations representing the medical profession or organizations established for this purpose may establish a system of turns of duty so as to ensure the regular and normal provision of health care to the population, both in inpatient institutions and at home. The competence to establish a system of turns of duty also implies the competence to determine closing hours for medical practices.¹

1. Cour de Cassation, 28 Apr. 1978, *Arr. Cass.*, 1978, 1002.

221. As such Article 9, §1 does not contain a legal obligation for a physician to participate in a system of turns of duty. The question has arisen whether a professional organization that has established such a system may oblige a physician to participate in it. This question has led to some jurisprudence with respect to pharmacists. *Mutatis mutandis* this jurisprudence is applicable to physicians. When a pharmacist is a member of a professional organization representing pharmacists that has established a tour of duty and closing hours, he may not systematically and without justified reason refuse to respect the closing hours. Otherwise he may be sanctioned by the Order of Pharmacists.¹ The question is more difficult when it concerns a pharmacist or physician who is not a member of the professional organization.

No legal disposition enables such an organization to apply its rules on persons not belonging to its membership.² The freedom to exercise a profession implies that pharmacists or physicians who are not members of such an organization are not obliged to participate in a tour of duty or to respect the closing hours. However, this freedom is not unlimited. A physician may not use this freedom in such a way as deliberately impeding the good functioning of a tour of duty. Otherwise he may be disciplined by the Councils of his order.³

1. *Ibid.*
2. Cour de Cassation, 12 Jan. 1973, *Arr. Cass.*, 1973, 490.
3. *Ibid.*

222. With respect to the organization of a system of turns of duty, Article 9 of the Law on the Health Care Professions delegates several competences to the provincial medical boards. Every organization establishing such systems has to inform the competent provincial medical board of the duty roster that it has drawn up as well as any change that may be made in it (Article 9, §1, 2). Also, the provincial medical boards determine the requirements in respect of a system of turns of duty and supervise its operation. When the rules concerning a system of turns of duty are laid down in the code of professional ethics drawn up by the National Council of the Order of Physicians and made compulsory by the Crown (above, paragraph 124), the medical boards have to take them into account in carrying out these competences (Article 9, §2, 2). In cases where there is no system of turns of duty or where it is inadequate, a medical board, on its own initiative or at the request of the provincial governor shall call upon the professional organizations concerned to collaborate in the establishment or extension of such a system (Article 9, §2, 3).

223. If, on the expiry of the period determined by the provincial governor in the request mentioned in the previous paragraph the system of turns of duty is not

operating in a satisfactory manner, the health inspector of the province concerned has to take all the necessary measures for the organization or extension of the system. The health inspector takes into account such needs as may have been determined by the medical board, which, on this occasion, shall be under the chairmanship of the provincial governor. One of the measures that can be taken by the health inspector consists in a legal obligation for all or several physicians to participate in the turns of duty. Non-compliance with this obligation without legal justification is punishable according to Article 38, §1, 3 of the Law on the Health Care Professions. Legal justifications are in this respect the fulfilment of a more important professional obligation, a serious motive and the replacement by another physician who is at that moment not under a legal obligation to participate in a system of turns of duty.

224. Articles 8 and 9 of the Law on the Health Care Professions have in common that both guarantee the availability and disposability of physicians. Article 10 relates to the same purpose. It provides that no person may prevent or hinder, whether by assault or violence, the legal and normal practice of medicine by a person who satisfies the requirements imposed. Criminal sanctions are provided in Article 38, §1, 4. The exact meaning of Article 10 is difficult to discern. This article, and also Articles 8 and 9, have to be interpreted in the light of the tentious relations between the Belgian government and the professional organizations of physicians between 1964 and 1967. These dispositions are, inter alia, meant as a weapon against medical strikes or against actions of physicians against colleagues who still want to continue their medical activities during a medical strike. According to Anrys, however, it is doubtful whether Article 10 offers a sufficient ground to prosecute medical 'picketeers'.¹

1. H. Anrys, *Les professions médicales et paramédicales dans le Marché Commun* (Bruxelles: Larcier, 1971), 277.

B. Articles 422bis and 422ter Criminal Code

1. Article 422bis

a. Applicability to physicians

225. This article has, together with Article 422ter, been inserted in the Belgian Criminal Code by the Law of 6 January 1961, making punishable some cases of omissions, *Moniteur belge*, 14 January 1961. There can be no doubt that this article is applicable to physicians. Because physicians have been educated to help people, one can even expect more of them when confronted with someone in grave danger than of laypeople. This has also been the attitude taken by the courts. The first sentence of the Cour de Cassation making application of Article 422bis indeed concerned a physician.¹

1. Cour de Cassation, 9 Nov. 1964, *Pas.*, 1965, I, r. 242; *R.D.P.*, 1964-1965, 1502.

226. Apart from the general problems that pose the interpretation of Article 422bis, its applicability to physicians has given rise to specific problems relating to the

organization of services of turns of duty. One question is whether this article also applies to a physician who is not on duty. Another is whether a physician who is on duty in a hospital has still an obligation to rescue under Article 422*bis*, which may force him to leave the hospital in order to help a person in grave danger outside the hospital. According to the Cour de Cassation, the obligation of Article 422*bis* is applicable to a physician who is not on duty.¹ The least one may expect of this physician is that he personally contacts the waiting service to see whether immediate help is available. Where this is not the case, this physician should himself provide the required help.

1. Cour de Cassation, 7 Oct. 1981, *Arr. Cass.*, 1982, 200.

227. The other question is less easy to answer. A surgeon who was on duty in a hospital refused to administer urgent medical care to a gravely injured patient outside the hospital and was consequently prosecuted for not adhering to Article 422*bis*. He argued that one of the conditions of this article, that is, not endangering other persons, was not fulfilled: If he had left the hospital, this would have deprived potential emergency cases brought into the hospital from necessary help. The Cour de Cassation did not follow his reasoning: A real and acute danger always has priority over a potential danger whose gravity is not known beforehand.¹

1. Cour de Cassation, 28 Mar. 1972, *Arr. Cass.*, 1972, 721.

b. Constitutive factors of Article 422*bis*

i. *Great danger*

228. Article 422*bis* requires the victim to be in 'great danger'. This implies a serious and real threat to his life or his physical integrity. The seriousness of the danger has to be judged at the moment that the great danger arises. The cause of the danger is of no importance: This can be bad luck, a suicide attempt, a criminal act, or something else.

With regard to the dying patient and the suicide attempt see also below, paragraph 316.

ii. *Knowledge of the great danger*

229. Article 422*bis* requires that the physician has knowledge of the great danger either because he personally has ascertained this danger or because it has been described to him by the person calling for help. Especially in this respect Article 422*bis* requires more of a physician than of a layperson, because a physician is supposed to make a greater effort to ascertain the danger personally. This is especially the case when a physician is called upon for a presumed emergency case by phone. Mostly, the description of the danger will not contain sufficient elements to enable the physician to evaluate the seriousness of the danger. In cases of doubt, the only way to evaluate the danger, therefore, consists in personally going to the victim. This, however, imposes on the physician an obligation not contained in Article 422*bis*. During the parliamentary preparation of this article the

members of parliament have expressed their hope that the tribunals and courts would handle this kind of case with wisdom and prudence. This means that, if a physician has reasonably come to the conclusion that no great danger existed although some doubt remained, this doubt has to be interpreted to the advantage of the physician and not against him.

iii. Refusal to help

230. Article 422*bis* requires that the physician has knowingly refused to deliver help. This article does not punish merely the omission to help, but the omission to help although one knew that one had the obligation to procure help.

iv. No serious danger for oneself or others

231. No obligation to help under Article 422*bis* exists if there is a serious danger for oneself or others. The legislature does not expect a physician to behave like a hero.

2. Article 422*ter*

232. Article 422*ter* of the Criminal Code makes it a crime to refuse or omit help to a person in danger after a requisition for it by a legal authority, if one has the opportunity to help without serious danger to oneself or others. Like Article 422*bis*, this article has a general field of application, thus not limited to physicians.

3. Law on Emergency Medical Care

233. Article 4 of the Law of 8 July 1964 concerning emergency medical care, *Moniteur belge* 25 July 1964, requires a physician to respond to the requisition of a competent authority to go to an indicated place and to provide the first emergency care to a person whose situation requires immediate care due to an accident or illness. Non-compliance with this obligation can be punished with criminal sanctions.

A refusal can only be justified by more urgent professional duties or another exceptional serious reason. This sentence has been added to Article 4 at the request of the Council of State to leave to the physician concerned a certain but small margin of judgment, under control of the courts and tribunals. In contrast to Articles 422*bis* and 422*ter* of the Criminal Code, Article 4 of the Law on Emergency Medical Care is only applicable to physicians.

III. Respect for the Privacy of the Patient

234. In this paragraph we only deal with the so-called privacy of information of the patient and the obligation of the physician to respect this aspect of the patient's privacy (see for the obligation to medical secrecy paragraph 241).

235. Since 1992, Belgium has general legislation protecting the individual with regard to automatic or manually processing of personal data. Belgium also ratified Convention No. 108 of the Council of Europe of 28 January 1981.

Before 1992, the only protection came from the rules concerning medical secrecy. But it is generally accepted that medical secrecy alone cannot solve all the problems raised by automatic processing of medical personal data. Firstly, medical secrecy refers to an individual relationship between a patient and a physician while automatic processing of medical personal data involves also non-physicians. Secondly, medical data can be collected and stored in a short period and on a large scale. The privacy of the patient is at stake. Therefore, the patient has to be protected. One of the instruments thereto is a right to information. However, this right of information does not result automatically from the provisions concerning medical secrecy. Thirdly, in Belgium medical secrecy does not protect the individual against negligence of the physician. A physician will only be punished under criminal law when he knowingly and willingly exposes confidential data (below, paragraphs 241 et seq.).

236. For all these reasons, a privacy act with specific provisions for medical personal data was desperately needed. The proposal for a Council Directive of 27 July 1990 concerning the protection of individuals in relation to the processing of personal data¹ also has put severe pressure on Belgium to approve a privacy law. The Law of 8 December 1992 on the protection of personal data contains specific rules as to the protection of personal health-related data. This law has been amended by the law of 11 December 1998 in order to comply with Directive 95/46.

1. Proposal for a Council Directive concerning the protection of individuals in relation to the processing of personal data, OJ C 277/3, 27 Jul. 1990.

A. General Rule for Processing of Personal Medical Data

237. Article 7, §1 prohibits the processing of health-related personal data.

B. Exceptions

238. Article 7, §2 provides for exceptions in the following cases:

- (a) if the data subject has given his written consent to the processing of those data, on the understanding that the consent may be withdrawn by the data subject at any time; the King may lay down in a decree agreed upon in the Council of Ministers after advice of the Commission for the protection of the privacy, in which cases the prohibition of processing health-related data may not be lifted by the explicit consent of the data subject;
- (b) if processing is necessary for the purposes of carrying out the specific obligations and rights of the controller in the field of employment law;
- (c) if the processing is necessary for the realization of an objective laid down by or by virtue of the law in view of the application of social security;

- (d) if processing is necessary for the promotion and protection of public health, including examination of the population;
- (e) if processing is made obligatory by or by virtue of a law, decree, or ordinance for reasons of an important public interest;
- (f) if processing is necessary to protect the vital interests of the data subject or another person, provided that the data subject is physically or legally incapable of giving his consent;
- (g) if processing is necessary for the prevention of a concrete danger or the suppression of a specific criminal offence;
- (h) if processing relates to data that are apparently made public by the data subject;
- (i) if processing is necessary for the establishment, exercise, or defense of legal claims;
- (j) if processing is necessary for the purposes of preventive medicine or medical diagnosis, the provision of care or treatment to the data subject or to one of his relatives, or the management of health care services operating in the interest of the data subject, and if those data are processed under the supervision of a health professional;
- (k) if processing is necessary for scientific research and carried out under the conditions established by the King in a decree agreed upon in the Council of Ministers after advice of the Commission for the protection of the privacy.

C. Guarantees with Respect to the Processing of Personal Health-Related Data

239. According to Article 7, §4 health-related personal data shall only be processed under the responsibility of a health professional, except for the written consent of the data subject or if the processing is necessary for the prevention of a concrete danger or for the suppression of a specific criminal offence.

The King may lay down in a decree agreed upon in the Council of Ministers after advice of the Commission for the protection of the privacy, which categories of persons are to be considered health professionals in the meaning of this law.

The health professional and his appointees or agents shall be obliged to secrecy with regard to the processing of personal data.

According to Article 7, §5 health-related personal data shall be collected from the data subject.

They may solely be collected from other sources if this is in compliance with paragraphs 3 and 4 of this article and necessary for the purposes of the processing or if the data subject is incapable of procuring the data.

D. Rights of the Data Subject

240. Article 10, §1 states that the data subject has the right to obtain from the controller:

- (a) confirmation as to whether or not data relating to him are being processed and information at least as to the purposes of the processing, the categories of data concerned, and the categories of recipients to whom the data are disclosed;

- (b) communication in an intelligible form of the data undergoing processing and of any available information as to their source;
- (c) knowledge of the logic involved in any automatic processing of data concerning him in the case of automated decisions referred to in Article 12*bis*;
- (d) knowledge of the possibility to lodge an appeal referred to in the Articles 12 and 14 and, possibly, to consult the public register referred to in Article 18.

For that purpose the data subject shall submit a signed and dated request to the controller or to any other person indicated by the King.

The information shall be communicated immediately and no later than forty-five days after receipt of the request.

The King may specify the modalities relating to the exercise of the right referred to in the first section.

Notwithstanding the right to access his medical file (see Article 9 of the law on the rights of patients; above, paragraph 213) any person has according to Article 10, §2 the right to get knowledge of the personal data that are processed relating to his health, either directly or with the assistance of a health professional.

Upon request of the controller or of the data subject, communication may be done through mediation of a health professional who has been chosen by the data subject.

If there is apparently no risk of offending against the privacy of the data subject and if the data are not used for taking measures and decisions with regard to an individual data subject, communication may be postponed if the health-related data are processed for purposes of medical scientific research. However, this is done only to the extent that communication would interfere seriously with the research and no later than the moment on which the research is terminated.

In that case the data subject must have given in advance his explicit consent to the controller that the personal data relating to him may be processed for purposes of medical scientific research and that communication of the personal data relating to him may be postponed for that reason.

According to Article 10, §3 no effect shall be given to a request referred to in §1 and §2 but after expiration of a reasonable period, counting from the date of a prior request of the same person that has been answered or from the date on which the data have been disclosed to him on own initiative.

IV. Duty of Medical Secrecy

A. General Principle

241. One of the most important legal obligations owed by a physician to a patient is the protection of confidences revealed by the patient to the physician. Article 458 of the Criminal Code lays upon a physician a legal obligation not to disclose confidential information concerning a patient that he learns in the course of his professional practice.

The doctor's obligation of non-disclosure applies not only to information acquired directly from the patient, but also to information concerning the patient which the doctor learns from other sources in his character as the patient's doctor.

242. The duty of medical secrecy is not limited to physicians who are in a relationship *ad sanandum* with their patients. A physician who medically investigates a person at the request of a third party, for example, an employer or insurance company, is also bound by the duty to medical secrecy, although he may inform his principal (*opdrachtgever*) within the limits of his mission.

243. Article 458 of the Criminal Code has a large field of application in that it not only applies to physicians but to everyone who in the course of his professional practice is being informed of confidential information. Therefore, it is generally accepted that not only physicians but also nursing and paramedical personnel are bound to a duty of secrecy. Because all the members of a medical team are obliged to respect the confidentiality of the patient's information, one accepts that this information may circulate within the team. This is often called the 'shared medical secret'.

B. Exceptions

244. Article 458 of the Criminal Code provides for two exceptions to the duty of professional secrecy of a physician. There is no offence if a physician discloses confidential information during a testimony before a court or before a Parliamentary Committee, neither when a law obliges him to divulge such information.

1. Testimony in a Court or Before a Parliamentary Committee

245. When a physician is summoned to testify in a court, he has a right (some call it a mere possibility) to speak: He cannot be sanctioned for a breach of his duty to medical secrecy. It is generally recognized that the physician has in such a case also a right to silence or testimonial privilege; this is a permission for the physician to refuse to disclose medical information in court. This right has been expressly recognized by Article 929 Civil Procedure Code. The Criminal Procedure Code does not contain a similar disposition, but in criminal affairs the testimonial privilege is generally accepted. The decision to testify or not to disclose medical information rests upon the physician, having regard to the interests of the patient. The testimonial privilege applies only to confidential disclosures made to a physician.

2. Statutory Obligations to Disclose Confidential Information

246. In certain circumstances the law requires disclosure of information about a patient without his consent and even in face of his refusal.

247. The Crown Order of 1 March 1971 concerning the prophylaxis of communicable diseases (*Moniteur belge*, 23 April 1971; *IDHL*, 1972, 452) makes the notification of any case, either confirmed or suspected, of a disease enumerated in Article 1 compulsory. Note that human immunodeficiency virus (HIV) infection is

not in this enumeration. This Crown order has been abolished for the Flemish Community by a Community Decree of 5 April 1995 on the prophylaxis of communicable diseases (*Moniteur belge*, 19 July 1995) that meanwhile has been replaced by the Flemish Community Decree of 21 November 2003 regarding preventive health care policy (*Moniteur belge*, 3 February 2004).

248. Health insurance legislation further contains specific exceptions to the duty to medical secrecy.

249. The Law on the Prophylaxis of Venereal Diseases of 24 January 1945, *Moniteur belge*, 26 January 1945, imposes an obligation to notify any of the four venereal diseases mentioned in Article 1 of this act. Also this law has been repealed and replaced by the Community Decrees mentioned in paragraph 247.

C. Notification of Criminal Acts

250. There is no legal obligation for a physician to notify a criminal act, whether a patient is the author or the victim of it. Article 20 of the Crown Order of 31 May 1885 approving new instructions for physicians, pharmacists, and druggists provides that a physician has to notify any case that may give rise to a prosecution, for example, poisoning, to the competent authorities. However, this Crown order does not contain penal provisions. Moreover, the Cour de Cassation has judged that the duty imposed by Article 20 does not contain a limitation of the duty to medical secrecy in Article 458 Criminal Code.¹ The discussion has moreover become without any subject since the Crown Order of 31 May 1885 has been abolished by Article 47 of the Crown Order of 21 January 2009 containing instructions for pharmacists, *Moniteur belge*, 30 January 2009. In another judgment the Cour de Cassation judged that Article 458 Criminal Code prohibits a physician to notify facts that may give rise to a prosecution against a patient.² Another article that may at first sight be relevant in this respect is Article 30 Code of Criminal Procedure that imposes upon every citizen a duty to notify any crime of which he has been a witness. However, in most cases, a physician is not a witness of the crime committed by a patient or of which a patient is a victim. Moreover, no penal sanctions exist in case of non-observation of this article.

1. Cour de Cassation, 30 Oct. 1978, *Arr. Cass.*, 1979, 235.

2. Cour de Cassation, 9 Feb. 1988, *Arr. Cass.*, 1988, 720-721.

251. Article 458 Criminal Code may not be considered independently of the general principles of Belgian penal law. Next to the exceptions to the duty of medical secrecy provided for in this article itself (testimony in a court and statutory obligations to disclose), other exceptions may in specific cases arise from grounds of justification. Grounds of justification are special circumstances that make an act or omission lawful, that justify the conduct, although they violate the literal terms of criminal law.¹ One of these grounds of justification is the so-called (state of) necessity. Necessity is:



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an emerging situation in which a person is faced with the threat of serious harm that can only be avoided by violating a criminal statute. Necessity confronts a person with the dilemma of allowing the threatened harm to occur or committing what would otherwise – if such necessity did not exist – be a criminal offence. The rationale of this justification is that, faced with a choice of evils, it is better to do the lesser evil (e.g. violation of the speed limit laws by an ambulance driver) in order to avoid the greater (as a result of complying with the law he arrives at the hospital too late to save a wounded man).²

1. L. Dupont & C. Fynaut, 149.
2. *Ibid.*, 169.

252. In two judgments the Cour de Cassation has approved decisions of the Court's indictment division of the Court of Appeal of Liege not to prosecute a physician who had broken his duty of medical secrecy and had notified the competent authorities of facts committed by his patient (an illegal drug user in the first case; bankrupters and kidnappers in the other case), because the protection of medical secrecy was outweighed by higher values and interests.¹

1. Cour de Cassation 8 May 1985, *Arr. Cass.*, 1985, 1219; Court of Cassation 13 May 1987, *Arr. Cass.*, 1987, 1203.

253. When the patient is a victim of a crime, for example, in case of child abuse, the same reasoning is often made in the literature. The conflict between the duty to medical secrecy and the duty to rescue a person in great danger may result in a right (not an obligation) to notify a case of child abuse to the competent authorities. However, in a judgment of 9 February 1988 the Cour de Cassation has followed another reasoning. Article 458 Criminal Code intends to protect the interests of the patient.

Consequently, this article may not impede the prosecution of the author of a crime of which the patient has become a victim. The prohibition to divulge information may therefore not be extended to facts of which the patient has become a victim.¹ This reasoning has been confirmed later on by the legislature in Article 458*bis* of the Criminal Code.

1. Cour de Cassation, 9 Feb. 1988, *Arr. Cass.*, 1988, 720-721.

D. Consent of the Patient or Waiver

254. Some jurisprudence accepts that a physician can be released from the obligation to keep the confidence with the express or implicit consent of the patient. The Belgian jurisprudence remains divided regarding the validity of the consent of the patient in this respect. According to the Cour de Cassation, a physician cannot be released from the duty to secrecy by the circumstance that the patient has consented to the disclosure of confidential information.¹ In the Cour de Cassation's opinion the duty of medical secrecy is of public order; thus it is not to the disposition of the patient. This opinion is completely in accordance with Article 64 of the



code of professional ethics of the Order of Physicians. Lower tribunals and courts of appeal, however, have recognized that the consent of the patient may release a physician of his duty of medical secrecy. The great majority of legal writers defend the same point of view. Important to note in this respect is that the former prosecutor general to the Cour de Cassation, F. Dumon, also has acknowledged that the consent or request of the patient enables a physician to disclose confidential information to a third party.²

1. Cour de Cassation, 30 Oct. 1978, *Arr. Cass.*, 1979, 235.
2. F. Dumon, 'Le secret médical', *Consilio Manuque* (1987), 30.

E. Deliverance of Medical Certificates to Third Parties

255. The attitude of the Cour de Cassation and the Order of Physicians regarding the consent of the patient frequently created problems concerning the validity of medical certificates delivered directly to a third party, for example, an insurance company, at the request or with the consent of the patient. When a legal dispute arose between the insurer and the insured, for example, because the insurer in light of a medical certificate refused a benefit, the judge would consider this certificate as void because it had been delivered to the insurer notwithstanding the duty of medical secrecy. The fact that the insured had signed an insurance policy that contained a clause releasing his physician of this duty was irrelevant because such a clause was in itself void. The Law of 25 June 1992, *Moniteur belge*, 20 August 1992, contained in Article 95 a legal obligation for the treating physician to deliver a medical certificate to the physician of an insurance company concerning the cause of death of the patient provided the patient had consented to this deliverance during his life. The law on the rights of patients has amended this article and replaced the obligation by a mere possibility (see *for details* paragraph 216).

V. Medical Fees

A. Right to Fees or Remuneration for Services

256. Notwithstanding Article 18, §2, a physician has a right to a fee or remuneration for the medical services provided by him, having regard to the rules of professional medical ethics (Article 15, 1 Law on the Health Care Professions). A fee means a payment for service, a remuneration is a salary.

The reference to Article 18, §2 is not entirely clear. This provision stipulates that, without prejudice to Articles 15 and 17, no agreement of any kind whatsoever is permitted between physicians or between physicians and third parties, and in particular manufacturers of pharmaceutical products and suppliers of medical equipment and prostheses, when such agreement has some connection with the practice of their profession and is intended to be profitable, whether directly or indirectly to one or other of them. We will come back to this provision later on (below, paragraph 266).

Part III. The Physician and the Health Care System

Chapter 1. Relations with Other Health Care Providers

§1. PHARMACISTS

I. The Practice of Pharmacy

458. The practice of pharmacy is regulated in Chapter 1 of the Law on the Health Care Professions and by the Crown Decree of 21 January 2009 giving instructions to pharmacists (*Moniteur belge*, 30 January 2009). Pharmacy together with medicine, in which dentistry is included, are called the healing arts (see above, paragraph 64).

459. No person may practice pharmacy unless he holds a legal diploma of pharmacy, obtained in accordance with legislation on the award of academic degrees or unless he has been legally exempted therefrom (Article 4, §1 Law on the Health Care Professions). Moreover, he has to receive a visa from the provincial medical board competent for the place in which he intends to practise (Article 7, §1; see paragraphs 57-62), and an inscription on the list of the Order of Pharmacists (Article 7, §1; see paragraph 63). The Order of Pharmacists has been established by Crown Order No. 80 of 10 November 1967. Its structure and responsibilities are comparable to the Order of Physicians (see paragraphs 86 et seq.).

460. Pharmacists have a legal monopoly for the practice of pharmacy. According to Article 4, §1, 2 of the Law on the Health Care Professions, the following has to be considered as constituting the illegal practice of pharmacy: the habitual carrying out, by a person who does not satisfy all the requirements laid down in this law of any procedure the purpose of which is the preparation, offering for sale by retail and supply, even if free of charge, of medicaments. The Law of 1 May 2006 to guarantee the quality of products sold in pharmacies (*Moniteur belge*, 13 July 2006) has enlarged the legal responsibilities of pharmacists to the so-called pharmaceutical care (Article 3, §2bis of the Law on the Health Care Professions). Pharmaceutical care aims at ameliorating continuously the consumption of pharmaceutical products and to preserve and ameliorate the quality of life of the patient.

461. The simultaneous practice of medicine and pharmacy is forbidden, even in the case of persons holding diplomas authorizing them to practice each of these

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professions (Article 4*bis* Law on the Health Care Professions, as amended by Law of 13 December 1976; see *IDHL*, 1978, 527-528).

Physicians who have been authorized to keep a so-called medicament store may supply medicaments only to patients whom they are treating. They have to obtain these medicaments from a pharmaceutical dispensary that is open to the public in the province where the medicament store is established. Such stores may not be open to the public and must be separate from the consulting rooms (Article 4, §4 Law on the Health Care Professions). The authorization to keep a medicament store is personal and non-transferable. Given the increase of pharmaceutical dispensaries open to the public throughout the whole country, there are almost no authorized medicament stores anymore.

462. A physician may supply medicaments in emergency cases; he may not receive any fee or reward for such supply (Article 4, §2, 2 Law on the Health Care Professions).

463. A physician may also supply free samples of medicaments (*ibid.*).

464. A physician may also supply medicaments for the control of sexually transmittable diseases, provided that he has had them prepared by a pharmacist in the district and that he supplies them to the patient with the pharmacist's label (Article 4, §2, 3 Law on the Health Care Professions).

465. Before 1993, Belgian law did not recognize the right of a pharmacist to substitute the medicine prescribed by a physician by another one. However, in 1993 Article 11 of the Law on the Health Care Professions has been amended in such a way that a pharmacist may substitute a medicine prescribed by a physician on the following conditions. First, the active elements of both products are the same; second, the prescribing physician did not oppose the substitution and third the product delivered by the pharmacist is cheaper for the patient. Up to now, this disposition has remained a dead letter because the implementing Crown decrees have not been taken.

466. Any physician who finds that the medicaments supplied to his patients by a pharmacist are badly prepared, not in conformity with the formula or spoiled, has to seal them and request patients to give them only to those persons sent to collect them on behalf of the competent provincial medical Commission.

The physician has, as soon as possible, to inform the secretary of the Commission to this effect, so that the latter may have the medicaments collected and handed over to the Commission. The provincial medical Commission has to examine the question and take action in accordance with the seriousness of the case (Article 20 Law on the Health Care Professions).

467. The Law on the Health Care Professions only contains minimal dispositions regarding the prescription of medicaments by a physician. According to Article 21, 1, every prescription has to be signed and dated by the physician concerned; as far as possible, the directions for the use of the medicament have to be

stated. Section 2 of the same article stipulates that when a physician prescribes a poisonous medicament in a dose greater than that provided for in the relevant legislation, he has to repeat the dose in words and confirm it with a second signature.

468. [Reserved]

469. According to Article 13, § 1 of the Medicines' Law 1964, a pharmacist has to guarantee the quality and conformity of the medicines delivered by him. According to Article 3, §2^{ter}, §2 of the Health Care Professions (added by Article 2, 4° of the Law of 1 May 2006 to guarantee the quality of products sold in pharmacies, *Moniteur belge*, 13 July 2006) a pharmacist is civilly, criminally, and disciplinary responsible for the pharmaceutical activities. This responsibility is the reverse side of the legal monopoly to deliver medicines.

§2. DENTISTS

I. The Practice of Dentistry

470. In the eyes of the legislator, dentistry is a part of medicine (see Article 1 of the Law on the Health Care Professions see paragraph 64). The practice of dentistry is regulated by the Law on the Health Care Professions and the Crown Order of 1 June 1934 on the Practice of Dentistry, as amended by subsequent orders. This Crown order has remained in force up to now and may not be amended other than by a law (Article 52 Law on the Health Care Professions).

471. No person may practice dentistry unless he holds the diploma of master in dental science, obtained in accordance with the legislation on the award of academic degrees or unless he has been legally exempted therefrom (Article 3, 1 Law on the Health Care Professions). Moreover, he has to receive a visa from the provincial medical board competent for the place where he intends to practice (Article 7, §1; see paragraphs 57-62). There is no Order of Dentists and consequently no obligation to be on the list of this order. The Law of 19 December 2008 (*Moniteur belge*, 31 December 2008, 3rd edn) has amended the Law on the Health Care Professions in order to give the provincial medical boards a limited disciplinary competence regarding dentists. The date of entering into force of this competence has still to be determined by a Crown order.

472. Dentists have a legal monopoly for the practice of dentistry. According to Article 3, 2 of the Law on Health Care Professions, the following has to be considered as constituting the illegal practice of dentistry: the habitual carrying out by a person who does not satisfy all the requirements laid down in this law of any intraoral operation or manipulation effected on patients, the purpose of which is the preservation, cure, straightening, or replacement of teeth, this term including the alveolar tissue, and particularly in connection with operative dentistry, orthodontics, and bucco-dental prosthetics.

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473. A dentist is competent to prescribe medicines within the limits of the definition of dentistry given in the foregoing paragraph. According to Article 8, Crown Order of 1 June 1934 on the Practice of Dentistry, dentists may prescribe soporifics and narcotics for the treatment of mouth-and-tooth diseases.

II. Professional Relations between Physicians and Dentists

474. Although dentistry forms part of medicine, a physician is legally not competent to practice dentistry (see paragraph 66). Only when a physician also holds a diploma that enables him to practice dentistry is he competent to practice both medicine and dentistry. This physician is called a stomatologist.

475. Although the delimitation of dentistry and medicine *sensu stricto* may be a difficult problem, it has not given rise to any dispute in practice. The Crown Order of 1 June 1934 on the Practice of Dentistry contains some provisions that might be of help in distinguishing dentistry and medicine. According to Article 5, 2, a dentist may not perform a so-called bloody act other than concerning the teeth and surrounding tissues. Nor may he treat mouth diseases, the treatment of which belongs to medicine *sensu stricto*. Further, only a physician is competent to perform a complete anaesthesia in the case of dental surgery.

475bis. Article 3 of the Law of 15 April 1958 on advertising in dental care matters (*Moniteur belge*, 5 May 1958) imposes penalties on those who infringe Article 1 of that law, which is worded as follows:

No person may, whether directly or indirectly, engage in advertising of any kind with a view to treating or providing treatment, whether or not by a qualified person, in Belgium or abroad, for dental or oral ailments, lesions or abnormalities, by means, inter alia, of displays or signs, inscriptions or plaques liable to be misleading as to the lawful nature of the activity advertised, leaflets, circulars, handouts and brochures, via the media of the press, radio or the cinema, by conferring or promising to confer benefits of any kind such as discounts or the provision of free transport for patients, or through the intermediary of canvassers or other such intermediaries.

The act on the part of mutual clinics and hospitals of informing their members of the dates and times of consultations, the names of those holding consultations and any changes to these shall not constitute advertising for the purposes of this article.

The Tribunal de Première Instance de Bruxelles decided to stay the proceedings against a dentist who was charged of having placed advertisements for his dental practice and to refer the following question to the Court of Justice for a preliminary ruling:

Must Article 81 EC, read in conjunction with Article 3(1)(g) EC and the second paragraph of Article 10 EC, be interpreted as precluding a national

law – in the present case the Law of 15 April 1958 – which prohibits (any person or) dental care providers, in the context of professional services or a dental surgery, from engaging in advertising of any kind, whether directly or indirectly, in the dental care sector?

The Court of Justice has answered as follows:

The answer to the question referred must therefore be that Article 81 EC, read in conjunction with Article 3(1)(g) EC and the second paragraph of Article 10 EC, does not preclude a national law, such as the Law of 15 April 1958, which prohibits any person or dental care providers, in the context of professional services or a dental surgery, from engaging in advertising of any kind in the dental care sector.¹

1. Court of Justice EC, 13 Mar. 2008, Case C-446/05 (Ioannis Doulamis).

§3. PHYSIOTHERAPISTS

I. The Practice of Physiotherapy

476. A Law of 6 April 1995 on the Practice of Physiotherapy (*Moniteur belge*, 16 June 1995) has amended the Law on the Health Care Professions so that physiotherapists are no longer considered as practitioners of a paramedical profession (see paragraph 495). But they are neither practitioners of medicine. Their legal status is somewhere in between a paramedical profession and the medical profession. According to Article 21*bis*, §1 of the Law on the Health Care Professions, no one may practice physiotherapy without a license delivered by the federal minister of health. This license can only be obtained after higher education of at least four years, in or outside a university. However, also physicians remain competent to practice physiotherapy.

Article 21*bis*, §4 gives a technical definition of the illegal practice of physiotherapy.

The Law of 19 December 2008 (*Moniteur belge*, 31 December 2008, 3rd edn) has amended the Law on the Health Care Professions in order to give the provincial medical boards a limited disciplinary competence regarding physiotherapists. The date of entering into force of this competence has still to be determined by a Crown order.

II. Professional Relations between Physicians and Physiotherapists

477. A physiotherapist may only practice physiotherapeutical activities on the condition that these activities have been prescribed by a physician (Article 21*bis*, §6). For this reason, physiotherapists are not considered as practitioners of medicine because they cannot act on their own initiative. Professionally they are dependent on physicians. On the other hand, the law attributes more professional autonomy to

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physiotherapists than to paramedical practitioners because they are entitled to deviate from the medical prescription, be it with the approval of the prescribing physician (Article 21bis, §6). Also, the activities that a physician may delegate to a physiotherapist are not enumerated in a limited way in a Crown Order.

§4. NURSING PROFESSION

I. The Practice of Nursing

478. Until the Law of 20 December 1974 concerning the Practice of Nursing that has amended the Law on the Health Care Professions the latter one did not contain any provision as to the practice of nursing. The original title of the Law on the Health Care Professions was indeed:

Crown Order No. 78 of 10 November 1967 concerning the healing arts, the practice of *the professions concerned therewith* and the medical boards.

The professions concerned therewith were dealt with in Chapter 2, entitled: 'Practice of the paramedical professions'. The nursing profession was until 1974 considered as a paramedical profession.

479. For the purpose of Chapter 2 of the Law on the Health Care Professions, the practice of a paramedical profession meant:

- either the habitual carrying out by persons other than physicians or dentists of such auxiliary technical services connected with the establishment of a diagnosis or the application of a treatment, as specified by a Crown order;
- either the habitual carrying out of the procedures mentioned in Article 5, §1.

This section empowered the Crown to determine the conditions under which a physician may, under his responsibility and supervision, entrust so-called auxiliaries with the carrying out of certain preliminary procedures employed in establishing a diagnosis or connected with the application of treatment or the carrying out of certain measures concerned with preventive medicine (Article 22 Law on the Health Care Professions, original version).

480. Article 46 of the Law on the Health Care Professions provided a very detailed and hopelessly complicated procedure for the enactment of the Crown orders referred to in Article 22. In essence, Article 46 attributed to the Royal Academy of Medicine a right to veto these Crown orders.

It soon became apparent that the Royal Academy blocked the implementation of Article 22 of the Law on the Health Care Professions.

481. Meanwhile, the professional organizations of nurses had begun to exercise pressure upon the government and Parliament to recognize the nursing personnel as a profession apart from the paramedical professions. They also required a clear

and secure legal position. In 1971, the nursing organizations sent an enquiry to doctors asking whether nurses could properly perform a list of medical procedures. The reply was that they could and regularly did. It was, however, illegal for nurses to perform them. An amendment of the Law on the Health Care Professions had become inevitable.

482. This amendment became the Law of 20 December 1974 concerning the Practice of Nursing (*Moniteur belge*, 29 April 1975, *IDHL* 1976, 523). The original title of the Law on the Health Care Professions (see above, paragraph 451) was changed into its actual title (see above, paragraph 68), making a distinction between nursing and paramedical professions.

483. Further, Article 5 of the Law on the Health Care Professions was amended so that the Crown is authorized, in conformity with the procedure laid down in the newly introduced Article 46*bis*, to determine under which conditions certain medical procedures may be entrusted to persons entitled to practice nursing. The new Article 46*bis* enabled the Crown to circumvent the complicated procedure described in Article 46 and the reluctant attitude of the Royal Academy of Medicine. Article 46*bis* requires the so-called identical advice of the Technical Commission on Nursing. This Commission is equally composed of nurses and physicians.

484. The Law of 20 December 1974 also inserted a new Chapter 1*bis*, entitled 'Practice of nursing' in the Law on the Health Care Professions, after Article 21. It became Chapter 1*ter* after the approval of the Law on the Practice of Physiotherapy of 5 April 1995 (see paragraph 476).

485. According to Article 21*quater*, no person may practice nursing as defined in Article 21*quinquies* unless he holds either the professional title of nurse or graduate nurse, and, in addition, fulfils the conditions laid down in Article 21*sexies*. The latter article requires that nurses have their qualifications certified by the provincial medical board having jurisdiction over the place where they intend to practice. There exists no Order of Nurses.

486. For the purposes of the practice of gynaecology, fertility treatment, and neonatology, a person holding the diploma for midwives (see below, paragraph 500) is allowed to practice nursing (Article 21, §4 Law on the Health Care Professions).

487. There are numerous exceptions to the rule that only persons with one of the qualifications mentioned in paragraph 485 are authorized to practice nursing. Physicians, students in medicine as well as students in nursing may practice nursing (Article 38*ter*, 1 Law on the Health Care Professions). The Law of 19 December 1990 amending the Law on the Health Care Professions (*Moniteur belge*, 29 December 1990) has enlarged this to paramedical students. The same Law of 19 December 1990 has also authorized the paramedical professions to practice nursing activities. Another exception can be found in Article 54*bis*, §1 of the Law on the Health Care Professions. Everyone who has not obtained one of the qualifications mentioned in Article 21*bis* but has practiced nursing activities in a

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hospital or a medical or dental office for more than three years on 1 September 1990 (in the original version 1 January 1975) may continue to perform these activities under the same conditions as qualified nurses. According to Article 54*bis*, §2, this vested right gets lost if this person does not makes himself known before a date determined by the Crown. A Crown Order of 8 September 1990 has determined 30 April 1996 as being the ultimate date.

488. Finally, Article 50, §1, final sentence of the Law on the Health Care Professions authorizes the Crown to determine, by way of exemption from the provisions of that law and in accordance with the provisions of Article 46*bis*, the nursing activities that persons not qualified for such practice but who have received special training may perform either in the course of training undergone prior to qualification, when in the absence of a sufficient number of legally qualified persons, military operations, or disasters render the performance of these procedures urgent. The Crown is responsible for determining the existence of a disaster associated with a lack of legally qualified personnel. Up to now, the Crown has not implemented this article.

489. According to Article 21 *quinquies*, nursing means the performance by the persons referred to in paragraph 485, of the following activities:

- (1) The observation, detection, and confirmation of the health status both at physical, psychical, and social level; the description of nursing problems.
- (2) Collaborating in the establishment by the physician of a diagnosis or in the application of medical treatment.
- (3) Continuously assisting in, performing and helping to perform activities through which nurses contribute to the preservation, promotion, or restoration of the health of healthy or unhealthy persons or groups give palliative care.
- (4) Support the dying patient and accompany the relatives in their greaving process:
 - (a) The performance of technical nursing procedures associated with the establishment by the physician of a diagnosis or with the application of the treatment prescribed by the physician or of measures in the field of preventive medicine. The Crown is empowered, in accordance with the provisions of Article 46*bis*, to draw up a list of these procedures and prescribe the manner in which they are to be carried out and the qualifications required;
 - (b) The performance of medical procedures that may be delegated by a physician, in accordance with Article 5, §1 (see paragraph 483).

490. It is generally agreed that the difference between activities mentioned under (b) and those under (c) is almost non-existent.

491. Crown Order of 27 September 2006 determines the list of specific professional titles and specific professional competences for the practitioners of nursing.

II. Professional Relations between Physicians and Nurses

492. In accordance with Article 5 and Article 21 *quinquies* of the Law on the Health Care Professions, a Crown Order of 11 March 1985 prescribed the list of technical nursing procedures and the medical procedures that a physician may delegate to nurses, the manner in which they are to be carried out and conditions regarding the qualifications required (*Moniteur belge*, 22 March 1985). It has been declared void by the Council of State, due to formal defects (Council of State, No. 27.781 in *re Kinart*, 3 April 1987). It has been replaced by a Crown Order of 18 June 1990 prescribing the list of technical nursing procedures and the procedures that a physician may delegate to nurses, the manner in which they are to be carried out and conditions regarding the qualifications required (*Moniteur belge*, 26 July 1990, amended by Crown Order 4 September 1990, *Moniteur belge*, 13 September 1990, Crown Order 25 November 1991, *Moniteur belge*, 21 February 1992, Crown Order 27 December 1994, *Moniteur belge*, 26 January 1995 and Crown Order 21 April 2007, *Moniteur belge*, 14 May 2007).

493. Annex I to the Crown Order of 18 June 1990 contains a list of technical nursing procedures. With regard to the professional relationship between physicians and nurses, the distinction made between technical nursing procedures to be performed on medical prescription or not is of importance. The Crown Order does not specify the exact contents of a prescription, nor the conditions it has to fulfil. The nullified Crown Order of 11 March 1985 was more detailed in this respect: it required a sufficiently detailed prescription, signed by a physician.

494. Annex II to the Crown Order of 18 June 1990 enumerates the procedures that a physician may delegate to nurses. However, no conditions are prescribed as to this delegation. Annex III contains the requirements to be qualified to perform nursing activities, whereas Annex IV enumerates the activities that may only be practiced by holders of a specific professional title or specific professional competence.

§5. PARAMEDICAL PROFESSIONS

495. The original title of the Law on the Health Care Professions (see paragraph 451) used the terms 'professions connected therewith' to indicate both the paramedical and the nursing professions. The Law of 20 December 1974 on the Practice of Nursing has distinguished both professions (see paragraph 478).

496. The definition of a paramedical profession provided for in Article 22 (see paragraph 452) has remained unchanged until now. No person may carry out the services specified pursuant to the provisions of Articles 22 and 23 (see below, paragraph 497) unless he can show that he has the required qualifications and has had them certified by the provincial medical board competent for the place in which he intends to set up practice (Article 24). Also in this case, these are several exceptions to this rule. Physicians as well as students in medicine, in nursing, and in



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a paramedical profession are excluded. Moreover, an amendment by the Law of 19 December 1990 (see paragraph 461) has authorized nurses to perform paramedical activities (Article 39, 1 Law on the Health Care Professions).

3

497. The implementation of Articles 22 and 23 has been impeded by different problems. First, a list of paramedical professions was not available. A Ministerial Order of 12 August 1988, *Moniteur belge*, 7 October 1988, enumerated the paramedical professions. However, it has been declared void by the Council of State¹ due to lack of competence of the minister. The Law of 19 December 1990 has inserted Article 22bis in the Law on the Health Care Professions, authorizing the Crown to establish the list of paramedical professions. Up to now, this Crown order has not been taken yet.

1. Council of State, *Chambre Syndicale Dentaires de Wallonie*, 27 Nov. 1989, No. 33.462.

498. Another problem similar to the nursing profession, was the reluctant attitude of the Royal Academy of Medicine, which made the implementation of Articles 22 and 24 impossible. The Law of 19 December 1990 has inserted a solution in the Law on the Health Care Professions that is analogous to the solution in the Law on the Practice of Nursing. This means that instead of an advice of the Royal Academy, the Crown has to seek the advice of a newly established Technical Commission for Paramedical Professions (Article 46bis, §2 Law on the Health Care Professions). This Commission has to give its so-called identical advice; it is equally composed of physicians and members of paramedical professions (Article 35bis).

499. Up to now, the following paramedical professions have been recognized on the basis of the new legal procedure, namely, the medical laboratory technologist (Royal Decree of 2 June 1993, *Moniteur belge*, 10 July 1993), logopedist (Royal Decree of 20 October 1994, *Moniteur belge*, 6 December 1994), ergotherapist (Royal Decree of 8 July 1996, *Moniteur belge*, 4 September 1996), bandagist, orthesist, prothesist (Royal Decree of 6 March 1997, *Moniteur belge*, 16 May 1997), dietist (Royal Decree of 19 February 1997, *Moniteur belge*, 4 June 1997), medical imaging technologist (Royal Decree of 28 February 1997, *Moniteur belge*, 7 June 1997), pharmaceutical assistant (Royal Decree of 5 February 1997, *Moniteur belge*, 2 July 1997), orthoptist (Royal Decree of 24 November 1997, *Moniteur belge*, 25 December 1997), podologist (Royal Decree of 15 October 2001, *Moniteur belge*, 7 December 2001), and audiologist (Royal Decree 4 July 2004, *Moniteur belge*, 9 August 2004).

All these royal decrees contain a limited enumeration of medical activities that may be delegated by a physician to the practitioner of one of these paramedical professions.

§6. MIDWIVES

500. Notwithstanding the provision of Article 2 §1, 1 of the Law on the Health Care Professions – this provision attributes a legal monopoly to physicians for the



practice of medicine (see above, paragraph 68) – any person licensed in accordance to Article 21 *noviesdecies* is authorized to practice normal deliveries, provided she or he has received a visa from the provincial medical board competent for the place where she or he intends to practice (Article 2, §2, 1 and Article 7, §1 Law on the Practice of Medicine). There is no Order of Midwives.

The Law of 19 December 2008 (*Moniteur belge*, 31 December 2008, 3rd edn) has amended the Law on the Health Care Professions in order to give the provincial medical boards a limited disciplinary competence regarding midwives. The date of entering into force of this competence has still to be determined by a Crown order.

501. The legal rules governing the practice of the profession of midwives have been thoroughly adapted by Article 3 of the Law of 13 December 2006 (*Moniteur belge*, 22 December 2006). A new Chapter I *quater* has been incorporated in the law on the Health Care Professions called 'The practice of the profession of midwife'. Article 21 *octiesdecies* §1 of the Law on the Health Care Professions gives a definition of the practice of the profession of midwife. Article 21 *octiesdecies* §2 empowers the Crown to determine the activities that may be performed by practitioners of the profession of midwife, after advice of the federal Council of midwives. Originally Article 2 §2, 2 of the Law on the Health Care Professions empowered the Crown, in accordance with the provisions of Article 46, to determine the rules to be obeyed by midwives when attending deliveries. The Crown Order of 1 February 1991 on the Practice of the Profession of Midwifery (*Moniteur belge*, 6 April 1991 amended by the Crown Order of 8 June 2007, *Moniteur belge*, 20 July 2007) has implemented this. Because the Law of 13 December 2006 has abolished Article 2, §2, 2 of the Law on the Health Care Professions the Crown Order of 1 February 1991 finds its legal basis in Article 21 *octiesdecies* §2.

502-507

Chapter 2. Relations with Health Care Provisions

§1. HOSPITALS

502. Article 2 of the Hospital Law defines a hospital as a health care establishment where examinations and/or treatment are performed specific to medical specialities in the field of medicine, surgery, and in certain cases obstetrics, which may be carried out or applied at any time in a multidisciplinary setting, with the necessary and appropriate conditions of care and medical, medico-technical, allied medical, and logistical framework appropriate in relation to the persons admitted and staying, because their condition requires such care in order to treat or alleviate disease, restore or improve their state of health, or stabilize lesions as quickly as possible.

503. Hospitals are distinguished by their public or private character, their general or academic propensities, and their range of accredited services. A distinction is also made between general hospitals and psychiatric hospitals.

504. Some 62% of all hospital beds are located in private clinics, the majority of which are not for profit. The remainder of the hospital beds are in public hospitals, most of which are the responsibility of the local authority.

505. Teaching or academic hospitals provide highly specialized tertiary care. About 8% of all hospital beds are in a teaching environment. Academic hospitals differ from general hospitals insofar as they undertake medical research and are responsible for the provision of both basic and specialist training for doctors.

506. Hospitals are subdivided because each hospital bed in a department has to be accredited according to published criteria. Some hospitals, for example, are accredited for emergency care or intensive neonatal care, whereas others are not.

507. Hospital accreditation is regulated by the federal government and implemented by the communities. The system of accreditation is primarily concerned with aspects relating to safety, hygiene, quality, and continuity of care. In recent years, hospital planning and accreditation are moving away from considering the hospital as an overall infrastructure towards defining it in terms of its various medical and supportive services. They have coined the descriptive terms *care programme* and *function*. A programme is a coherent intervention for a well-defined target patient group. The programme is first defined by the case treated and the type of care given. Then norms describing infrastructure, number of personnel, minimum activity level, and so on are allocated to this programme. A distinction is made between basic programmes for regular conditions and specialized programmes for more rare conditions, which will not be available in every hospital. A function describes a set of hospital services, which are not aimed at a specific patient group. They are not provided in a defined unit; that is, they are not directly linked to hospital beds and all the programmes and services of the hospital can use them. The idea is that hospitals would be completely made up of a series of basic

programmes and basic functions (which would have to be present in every hospital) as well as some specialized functions and programmes.

508. A system of mandatory hospital planning was introduced in Belgium in 1973. It was intended to remedy an estimated surplus of hospital beds and to re-orient hospital provision towards areas that were underserved. The initiative met with little success but a further attempt in 1982 to combine planning, accreditation, and funding of hospitals succeeded to some extent in reducing and adapting hospital capacity to meet present and future requirements. Special attention was given to hospital mergers in a bid to rationalize bed capacity. Current policy seeks to continue to reduce the stock of hospital beds through a system of continuous budgetary controls.

§2. RELATIONS BETWEEN PHYSICIANS AND HOSPITALS

509. The Hospital Law contains specific provisions regarding the legal status of the hospital physician. These provisions have been introduced into this law by Crown Order No. 407 of 18 April 1986, *Moniteur belge*, 6 May 1986.

510. According to Article 132 Hospital Law, a medical Council has to be established in every hospital. Through this Council, the hospital physicians participate in the decision-making process in the hospital. The medical Council gives advice to the hospital manager on five groups of matters: general regulations (below, paragraph 511), medical activities, relations with other hospital staff, financial means and techniques necessary for medical activity, as well as the organization of the hospital with regard to medical activity. For well-defined matters, this advice obliges the manager to consult an intermediary in case of disagreement on his opinion and the advice of the medical Council.

511. Article 144, §1, 1 Hospital Law imposes an obligation upon every hospital to determine a so-called general regulation on the legal relationship between the hospital and its physician, as well as the organizational, working, and financial conditions.

512. Under reference to this general regulation, the rights and obligations of every hospital physician and the hospital governor and more specific his working conditions have to be laid down in writing, either in an agreement between both parties or in a unilateral act of appointment.

513. The Hospital Law has not determined the legal nature of this agreement. This can be either a labour agreement or a contract of work.

In the former case, the physician performs his medical activities according to the directives of the hospital manager; in the latter case, he performs his activities independently. According to the jurisprudence, the agreement between a hospital physician and the hospital is in most instances a contract of work. The distinction between both agreements may be of importance for the liability of the physician in case of a medical fault (above, paragraph 169).



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514. An agreement between physician and hospital may exist both in a private or a public hospital, where by nature the unilateral act of appointment is limited to public hospitals.

§3. HEALTH INSURANCE

515. Above, paragraph 38 et seq.



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