



Prescription Authority of Pharmacists

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Germany • Portugal • Spain

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AUSTRIA

PRESCRIPTION AUTHORITY OF PHARMACISTS

Executive Summary

In Austria, prescription drugs can be prescribed only by physicians, dentists, or veterinarians and most drugs are prescription drugs.

Austria has statutory health insurance that is part of the social security system. For wage earners and most self-employed, participation in the system is mandatory. In fact, ninety nine percent of the Austrian population is covered by the statutory health insurance.¹

In Austria, prescription drugs are governed by the Prescription Requirement Act of 1972.² It provides that prescription drugs can be dispensed only as prescribed by physicians, dentists, and veterinarians, with the notable exception that midwives do not need a prescription to obtain the drugs they need in the exercise of their profession. The same exception applies to licensed professionals who castrate livestock.³

The Prescription Requirement Act defines drugs that require a prescription as those that could endanger life or health of human beings or animals if they were to be used without the supervision of a physician, dentist, or veterinarian,⁴ and this broad definition is implemented by a regulation of the Austrian Minister of Health. The Regulation on Prescription Drugs⁵ is very comprehensive. It employs the International Nonproprietary Names [INN] nomenclature of the World Health Organization⁶ and it is updated periodically.

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¹ Allgemeines Sozialversicherungsgesetz, Sep. 9, 1955, BGBl no. 189/1955, as amended, §§ 1-4. These provisions apply to wage earners and some self-employed, and separate laws apply to special groups such as farmers, artists, and those engaging in a trade. See U. Braumüller, *Krankenversicherung in Österreich*, at the non-official Web site http://64.233.169.104/search?q=cache:wWiV0DKi2AAJ:www.vvo.at/index2.php%3Foption%3Dcom_content%26do_pdf%3D1%26id%3D271+Krankenversicherung+in+%C3%96sterreich+Braum%C3%BCller&hl=de&ct=clnk&cd=1&gl=us&lr=lang_de (last visited April 11, 2008).

² Rezeptpflichtgesetz [RezPflG], Oct. 25, 1972, BUNDESGESETZBLATT [BGBl, official law gazette of Austria] no. 413/1972, as amended.

³ RezPflG, § 1.

⁴ *Id.*

⁵ Rezeptpflichtverordnung, Aug. 230, 1973, BGBl no. 475/1973, as frequently amended.

⁶ World Health Organization, *Guidance on INN*, at the official Web site <http://www.who.int/medicines/services/inn/innguidance/en/index.html>. (last visited April 11, 2008).

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ENGLAND

PRESCRIPTION AUTHORITY OF PHARMACISTS

The United Kingdom¹ has a comprehensive health care system that it provides based on need through the National Health Service (NHS).² The main statute governing prescription drugs is the Medicines Act 1968 (the 1968 Act).³ The Act regulates a wide range of issues concerning medicinal products, including imports, exports, manufacturing, sales, and supply. The Minister for Health in England, the Secretaries of State for Scotland and Wales, the Department of Health and Social Services in Northern Ireland, the Minister for Agriculture Fisheries and Food, and the Minister of Agriculture for Northern Ireland are responsible for the enforcement of the Act.

There have been two models of pharmacists prescribing medicine in England – the supplementary prescribing model that was introduced in 2003, and the pharmacist independent prescriber, introduced in 2006.⁴ Under the supplementary prescribing model, a voluntary partnership is formed between the doctor, the pharmacist and the patient to “implement an agreed patient-specific clinical management plan.”⁵ Under the pharmacist independent prescribing model, pharmacists with additional training have the ability to prescribe licensed medicines to patients and are responsible for the “assessment and consequent management, including prescribing of both undiagnosed and diagnosed conditions.”⁶

Pharmacists that wish to be able to prescribe medicine must complete an additional accredited course that is at least twenty six days in duration over a three to six month period. This must be supplemented with twelve additional days of practice supervised by a medical practitioner.⁷ The

¹ While the NHS is nationwide across the UK, devolution has granted control of some aspects of health services back to Scotland, Wales, and Northern Ireland, so there are some differences between these areas. For the purposes of this paper, where there are distinctions, the system in England will be used.

² The National Health Service is currently provided for under the National Health Service Act 1977, c. 49 (as amended), <http://www.statutelaw.gov.uk/legResults.aspx?LegType=All+Legislation&title=National+Health+Service+Act+&Year=1977&searchEnacted=0&extentMatchOnly=0&confersPower=0&blanketAmendment=0&TYPE=QS&NavFrom=0&activeTextDocId=2254451&PageNumber=1&SortAlpha=0> (unofficial source).

³ Medicines Act 1968, c. 67 (as amended), <http://www.statutelaw.gov.uk/legResults.aspx?LegType=All+Legislation&title=medicines+act&Year=1968&searchEnacted=0&extentMatchOnly=0&confersPower=0&blanketAmendment=0&TYPE=QS&NavFrom=0&activeTextDocId=1662209&PageNumber=1&SortAlpha=0> (unofficial source).

⁴ Prescription Only Medicines (Human Use) Order 1997 SI 1997/1830 (as amended by the Prescription Only Medicines (Human Use) Amendment Order 2003 SI 2003/696, <http://www.opsi.gov.uk/si/si2003/20030696.htm> (official source); the Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2006 SI 2006/915, <http://www.opsi.gov.uk/si/si2006/20060915.htm> (official source); and the Prescription Only Medicines (Human Use) Amendment Order 2008 SI 2008/464, http://www.opsi.gov.uk/si/si2008/pdf/uksi_20080464_en.pdf (official source). These regulations are made under the Medicines Act 1968, c. 67 (as amended), <http://www.statutelaw.gov.uk/legResults.aspx?LegType=All+Legislation&title=medicines+act&Year=1968&searchEnacted=0&extentMatchOnly=0&confersPower=0&blanketAmendment=0&TYPE=QS&NavFrom=0&activeTextDocId=1662209&PageNumber=1&SortAlpha=0> (unofficial source).

⁵ Department of Health, Supplementary Prescribing, Feb. 2007, http://www.dh.gov.uk/en/Healthcare/Medicinespharmacyandindustry/Prescriptions/TheNon-MedicalPrescribingProgramme/Supplementaryprescribing/DH_4123025.

⁶ A.P. Tonna et. al, *Pharmacist prescribing in the UK - a literature review of current practice and research*, Journal of Clinical Pharmacy & Therapeutics, Vol. 32: 6, Dec. 2007 at 545-556.

⁷ Royal Pharmaceutical Society of Great Britain, *Pharmacist Prescribing*, <http://www.rpsgb.org/worldofpharmacy/currentdevelopmentsinpharmacy/pharmacistprescribing/> (last visited Apr. 10, 2008).

pharmacist must then apply to the Royal Pharmaceutical Society of Great Britain to have their entry in the Register of Pharmaceutical Chemists annotated before they can prescribe medicines.⁸

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⁸ *Id.*

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FRANCE

PRESCRIPTION AUTHORITY OF PHARMACISTS

All legal residents of France are covered by public health insurance, and patients are free to choose among health care providers. A majority of physicians are in private practice. Physicians, surgical dentists (for dental purpose), midwives (within the limits of the law), directors of analysis laboratories of medical biology (within the limits of the law), and veterinarians (for veterinary medicine) are authorized to prescribe medicines. Prescriptions must be in writing.¹

As a general rule, pharmacists in France enjoy a monopoly in the dispensing of medicines.² They cannot prescribe medicines. In the case of the treatment of a chronic illness, however, they exceptionally may dispense the necessary dosage to avoid an interruption in the treatment when a renewable prescription has expired, after notifying the physician who prescribed the medicine in the first place.³

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¹ CODE DE LA SANTE PUBLIQUE, art. R. 5132-6. (Daloz 2007) (commercial source used by judges and attorneys).

² *Id.* art. L. 4211-1.

³ *Id.* art. L. 5125-23-1.

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GERMANY

PRESCRIPTION AUTHORITY OF PHARMACISTS

Executive Summary

In Germany, prescription drugs can only be sold if prescribed by a physician, dentist, or veterinarian. Germany has a mandatory health insurance system for everyone except high income earners and most prescription drugs are covered in this insurance scheme.

I. Prescribing drugs

Section 48 of the Act on Pharmaceutical Drugs¹ provides that prescription drugs can be dispensed only upon a prescription by a physician, dentist, or veterinarian. The only exception from this rule applies to merchant ships sailing under the German flag.² These must maintain a ship's pharmacy which has to be stocked with certain drugs (including prescription drugs) that are listed in a Regulation on the Care of the Sick on Merchant Ships.³ According to this Regulation, ships below a certain size need not be manned with a physician, so it appears that prescription drugs must be dispensed under these circumstances without the benefit of a prescription. A pharmacist, however, has to be involved in the stocking of the ship's pharmacy, and this process is also supervised by the public health authorities.⁴

Section 48 of the Act on Pharmaceutical Drugs defines prescription drugs as those containing certain substances that are listed in a regulation. This list is provided in the Regulation on Prescription Drugs,⁵ which in its section 1 reiterates the prohibition of dispensing drugs without a prescription of a physician, dentist, or veterinarian. The list of substances that cause a drug to become a prescription drug is lengthy.⁶

II. Non-prescription drugs

Drugs are generally defined very broadly as preparations that contain substances intended to cure human beings or animals or diagnose their illnesses, or free them from parasites, or have effects on the mental state of human beings.⁷ For all preparations that serve these purposes and that are not merely food, approval is required by the German or European drug agencies.⁸ In addition to prescription drugs,

¹ Arzneimittelgesetz [AMG], repromulgated Dec. 12, 2005, BUNDESGESETZBLATT [BGBl, official law gazette of the Federal Republic of Germany] I at 3394, as amended, available at the official Web site http://www.gesetze-im-internet.de/amg_1976/index.html#BJNR024480976BJNE007811310.

² AMG § 48.

³ Verordnung über die Krankenfürsorge auf Kauffahrteischiffen, repromulgated Sept. 5, 2007, BGBl I at 2221.

⁴ *Id.*

⁵ Arzenimittelverschreibungsverordnung [AMVV], Dec. 21, 2005, BGBl I at 3632, as last amended by Bekanntmachung, Mar. 20, 2008, BGBl I at 484, , available at the official Web site http://www.gesetze-im-internet.de/amvv/_1.html.

⁶ AMVV, Anlage, at the official Web site http://www.gesetze-im-internet.de/amvv/anlage_1_9.html.

⁷ AMG, § 2.

⁸ AMG § 21. Homeopathic drugs, however, merely require registration and not an approval process [AMG, §§ 38-39 d].

however, a regulation differentiates between two other types of drugs, and these are non-prescription drugs that can be dispensed only in pharmacies, and non-prescription drugs that can be sold in other retail establishments.⁹ In recent years, this regulation and the underlying statutory provisions have been changed¹⁰ by increasing the number of drugs that can be sold only in pharmacies,¹¹ thus leaving very few substances or preparations that can be sold in other retail settings;¹² the latter, however, are further restricted by requiring a knowledgeable sales staff,¹³ so that in fact Germany does not have much of an over-the-counter drug market.

II. Health Care System

Germany has a statutory health insurance system that covers close to 90 percent of the population. This is part of the German social security system and participation in the statutory health insurance plan is mandatory for wage earners up to a certain income level and for certain categories of the self-employed.¹⁴ Statutory health insurance coverage, some mandatory, some on a voluntary basis, is also extended to retirees, the disabled, the unemployed, welfare recipients, college students, and interns. Coverage also extends to the dependents of the insured.¹⁵ In addition, 10.6 percent are privately insured, either through primary or supplemental coverage. Another three percent of the population enjoys other health insurance coverage, and among these is a special system for government employees. Only 0.3 percent of the German population is uninsured.¹⁶

The statutory health insurance provides coverage for prescription drugs that are prescribed by a physician while generally denying coverage for non-prescription drugs. However, even some prescription drugs are exempted from coverage, unless exceptional circumstances prevail.¹⁷

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⁹ Verordnung über apothekenpflichtige und freiverkäufliche Arzneimittel, Nov. 24, 1988, BGBl I at 2105, as last amended Dec. 19, 2006, BGBl I 3276.

¹⁰ Decision of Verwaltungsgericht Köln, March 22, 2006, docket no. 7 K 7593/01, available at the subscription database JURIS.

¹¹ AMG, § 43.

¹² AMG § 44.

¹³ AMG § 50.

¹⁴ For an overview of the German health insurance system, see H. Nadolski, Budgeting and Rationing in the German Health Care System.

¹⁵ Sozialgesetzbuch Fünftes Buch – Gesetzliche Krankenversicherung [SGBV], Dec. 20, 1988, BGBl I at 2477, as amended, §§ 5-10.

¹⁶ *Forum Gesundheitspolitik* at the private Web site <http://www.forum-gesundheitspolitik.de/dossier/index409.htm> (last visited April 10, 2008).

¹⁷ SGB, § 31 in conjunction with SGB, § 34.

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PORTUGAL

PRESCRIPTION AUTHORITY OF PHARMACISTS

In 1979, Portugal created a National Health System (*Sistema Nacional de Saúde - SNS*) to enable the government to guarantee the right to health to all citizens.¹ The system involves all integrated health steps, including the advancement and vigilance of health, prevention of diseases, diagnostic and treatment of sick people, and social and medical rehabilitation.² SNS is subordinated to the Ministry of Health and is composed of a body of institutions and official medical care services methodically organized by hierarchy.³

The Portuguese Medicine Statute (*Estatuto do Medicamento*) defines medical prescription (*receita médica*) as a document by which are prescribed, by a physician or, in cases covered by special legislation, by a medical dentist, one or more determined medicines (*medicamentos*).⁴ Additionally, the medical prescription must be signed by a physician in an appropriate paper containing, *inter alia*, the physician's name and place of residence.⁵

No provision allowing pharmacists to prescribe medications was found in the researched legislation.

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¹ História do Serviço Nacional de Saúde, available at the Web site of the Portuguese Ministry of Health at <http://www.portaldasaude.pt/portal/conteudos/a+saude+em+portugal/servico+nacional+de+saude/historia+do+sns/historiadosns.htm>.

² *Id.*

³ Estatuto do Serviço Nacional de Saúde, Decreto-Lei No. 11/93, de 15 de Janeiro, Anexo, art. 1, available at the Web site of the Portuguese Ministry of Health at <http://www.portaldasaude.pt/portal/conteudos/a+saude+em+portugal/servico+nacional+de+saude/estatuto+do+sns/estatuto+sns.htm>.

⁴ Estatuto do Medicamento, Decreto-Lei No. 176/2006 de 30 de Agosto, art. 3(1)(hhh), DIÁRIO DA REPÚBLICA, 1ª Série, No. 167, Aug. 30, 2006, at 6297.

⁵ Código Deontológico, art. 96(2), available at the Web site of the Ordem dos Médicos at <http://www.ordemdosmedicos.pt/?lop=conteudo&op=24b16fed9a67c9251d3e7c7161c83ac&id=67c6a1e7ce56d3d6fa748ab6d9af3fd7>.

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SPAIN

PRESCRIPTION AUTHORITY OF PHARMACISTS

Under Law 44/2003¹, pharmacists are in charge of the production, preservation and provision of medicine. They are also part of the analytical and pharmaco-therapeutic processes and the vigilance of public health. According to Law 29/2006² on the Guarantees and Rational Use of Medicine and Health Products, pharmacists may only provide prescription medicine backed by a physician's prescription.

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¹ LAW 44/2003 OF 21 NOV., 2003 ON HEALTH PROFESSIONS IN BOLETIN OFICIAL DEL ESTADO, (B.O.E) 22 NOV. 2003, ART. 6.2.B. in <http://www.boe.es/boe/dias/2003/11/22/pdfs/A41442-41458.pdf>, JEFATURA DEL ESTADO (BOE N. 280 DE 22/11/2003).

² LAW 29/2006 OF JUL 26, 2006 ON THE GUARANTEES AND RATIONAL USE OF MEDICINE AND HEALTH PRODUCTS IN B.O.E. 27 Jul, 2006, art. 77.2 in <http://www.boe.es/boe/dias/2006/07/27/pdfs/A28122-28165.pdf>.