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Marketing authorisation of pharmaceuticals in Austria and in Slovakia

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Abstract

PÉTERY, Ivan: *Marketing authorisation of pharmaceuticals in Austria and in Slovakia*. [Mater Thesis]. University Of Vienna. Supervisor: Univ.-Prof. i.R. Dr. Dr. h.c. Peter Fischer. Vienna, 2024, 51 p.

The main focus of this master thesis is on marketing authorisation of medicinal products. The aim of the thesis is to analyse the legislation and procedural steps of the marketing authorisation of medicinal products in the European Union, specifically in Austria and Slovakia. The thesis aims to provide an overview of the historical evolution of pharmaceutical legislation and briefly summarise the current procedures. The main purpose of the work is to examine the level of harmonisation of European pharmaceutical legislation and to find differences in the legislation of Austria and Slovakia. At the end of the work, a reader should have a basic understanding of the extent of harmonisation of the legislation and be able to tell to what extent member states have a free hand in drafting their laws.

Key words: marketing authorisation, medicinal products, pharmaceuticals, Slovakia, Austria, European Union.

Abstrakt

PÉTERY, Ivan: *Die Zulassung von Arzneimitteln in Österreich und der Slowakei*. [Masterarbeit]. Universität Wien. Betreuer: Univ.-Prof. i.R. Dr. Dr. h.c. Peter Fischer. Wien, 2024, 51 S.

Der Schwerpunkt dieser Masterarbeit liegt auf der Zulassung von Arzneimitteln. Ziel der Arbeit ist es, die Gesetzgebung und die Verfahrensschritte bei der Zulassung von Arzneimitteln in der Europäischen Union, speziell in Österreich und der Slowakei, zu analysieren. Die Arbeit soll einen Überblick über die historische Entwicklung der Arzneimittelgesetzgebung geben und die aktuellen Verfahren kurz zusammenfassen. Das Hauptziel der Arbeit besteht darin, den Grad der Harmonisierung der europäischen Arzneimittelgesetzgebung zu untersuchen und Unterschiede in der Gesetzgebung Österreichs und der Slowakei festzustellen. Am Ende der Arbeit sollte der Leser ein grundlegendes Verständnis für das Ausmaß der Harmonisierung der Rechtsvorschriften haben und in der Lage sein zu sagen, inwieweit die Mitgliedstaaten bei der Ausarbeitung ihrer Gesetze freie Hand haben.

Schlüsselwörter: Zulassung, Arzneimittel, Slowakei, Österreich, Europäische Union.

Content

Introduction

A free market, where prices are created on the basis of demand and supply, is considered the perfect economic system. This system, called a market economy, is the economic system of all member states of the European Union, including Austria and Slovakia. The underlying principle of a free market is the freedom to provide almost any type of service without the interference of state authorities.

In some cases, however, state intervention in the free market is necessary to ensure a fair distribution of essential resources. Health care is one of the sectors in which the state must regulate the activities of providers of goods and services in order to secure access to health care for every person without major differences.

State drug policy as a part of the health care system usually involves a number of legislative, scientific, and technical procedures designed to ensure the safety and efficacy of medicinal products. State drug policy includes regulations on clinical trials, registrations, reimbursements, and marketing of medicinal products, by which it interferes with the free market in a significant way.

This master thesis provides a comparative analysis of the legal regulation of medicinal products in Austria and Slovakia. The main focus of this work is on marketing authorisation of human medicinal products, with a few sub-chapters pointing out facts regarding veterinary medicinal products. The aim of the thesis is to analyse the level of harmonisation of the legislation for marketing authorisation of medicinal products and look at how many of the competencies are still in the hands of member states.

The first chapter of this work focuses on the historical reasoning for today's extensive regulation of medicinal products and provides an overview of the evolution of legislation in the European Union and in Austria and Slovakia separately. The European Medicines Agency, as well as the national competent authorities of these two countries, are introduced in the chapter. The evolution of veterinary medicinal products legislation is provided, too.

In the second chapter, marketing authorisation procedures with a cross-border element, i. e. where more than one member state is concerned, are described. The three procedures are reviewed in terms of their legal basis and basic procedural steps. For each procedure, the work also informs of their frequency among all procedures.

The last chapter analyses national marketing authorisation procedures in Austria and Slovakia. In this chapter, national marketing authorisation procedures in both of these countries are described, and we introduce statistics about medicinal products registered in these countries. At the end of the chapter, we analyse whether the level of harmonisation regarding medicinal products in the European Union is high or whether the member states can easily diverge from the European legislation and impose their own rules and procedures in this industry.

1 Definitions, history, and legal basis

The current definition of a medicinal product can be found in European legislation, and this thesis works with this definition when mentioning medicinal products. It is defined as "*any substance or combination of substances presented for treating or preventing disease in human beings*" or "*any substance or combination of substances which may be administered to human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings is likewise considered a medicinal product.*"[1]

The other important term that will be largely dealt with in this work is marketing authorisation. Marketing authorisation is the approval of a regulatory body given to a pharmaceutical company to market and sell medicinal products on the relevant market.[2, 3] To obtain such approval, a company has to undergo a long and strict procedure, which ensures that any medicinal product that is placed on the market is safe and efficacious.

European Union has quite an extensive set of rules regulating the marketing authorisation of medicinal products, with member states having additional complex regulations reflecting European legislation, but at the same time containing their own set of national rules. The current regulation has been around for approximately twenty years, but the beginning of pharmaceutical legislation in the European Union dates back to the 1960s.[4]

In this chapter, we look at the historical and present pharmaceutical legislation in the European Union as a whole and in Austria and Slovakia, too.

[1] Article 1(2) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use [2001], OJ L 311, p. 67–128.
[2] From the definition of EMA. Website of the European Medicines Agency [online] [2/6/2024]. Available at: https://www.ema.europa.eu/en/glossary/marketing-authorisation-application.
[3] SHORTHOSE, S. et al.: *Guide to EU and UK Pharmaceutical Regulatory Law*. The Netherlands : Kluwer Law International, 2023. p. 147. ISBN 9789403530253.
[4] The first legislation on pharmaceutical industry being Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by Law, Regulation or Administrative Action relating to proprietary medicinal products [1965], OJ 22, p. 369–373.

1.1 European Union

Multiple major historical events that occurred in the 20th century were the main factors triggering the never-ending chain of pharmaceutical legislation in Europe. The constant need for health care and pharmaceuticals resulted in the widespread usage of drugs without proper safety or efficacy testing. This usually led to many side effects, such as poisoning, often leading to severe impairment of health or even death.

In 1937, a medication called Elixir Sulfanilamide started to circulate among patients in North America. The medication was a liquified version of already known and used antibiotics with added diethylene glycol to mask the taste of the antibiotics. As the medication was not tested for toxicity, it was not a known fact that diethylene glycol was a poison for the human body. Over 100 patients, of which most were children, died of poisoning. Nowadays, diethylene glycol is used as an antifreeze.[5, 6]

Between the years 1957 and 1962, thalidomide, a drug intended to help with anxiety, insomnia, and most importantly, to relieve morning sickness, has been widely spread, mainly among pregnant women in Europe. As this drug has never been tested on pregnant women, years that followed this widespread usage of thalidomide came as a big surprise, and the incident has been known since then as a thalidomide disaster. Thousands of children across Europe have been born with a congenital disease called phocomelia, in which the long bones of the limbs develop incorrectly or do not develop at all. Long months of searching for the cause of the sudden spike in phocomelia resulted in the prohibition of thalidomide as the most probable cause.[7, 8]

With the thalidomide disaster finally came the need to properly regulate the market for medicinal products. A few European states have already had some legislation regulating this aspect, but the circumstances of the previous years have finally made it a higher priority in Europe. The first legislative act regarding medicinal products made by the legislators of the

[5] BALLENTINE, C.: *Taste of Raspberries, Taste of Death: The 1937 Elixir Sulfanilamide Incident*. In FDA Consumer magazine, No. 6, 1981. [online]. Available at: https://www.fda.gov/about-fda/histories-product-regulation/sulfanilamide-disaster.
[6] RAGO, L., SANTOSO, B.: *Drug Regulation: History, Present and Future 1*. In Drug Benefits and Risks: International Textbook of Clinical Pharmacology, revised 2nd edition. IOS Press, 2008. p. 65. ISBN 9781586038809.
[7] VARGESSON, N.: *Thalidomide-Induced Teratogenesis: History and Mechanisms*. In Birth Defects Res C Embryo Today, No. 105(2), 2015, p. 140–156. [online]. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4737249/pdf/BDRC-105-140.pdf.
[8] BREN, L.: *Frances Oldham Kelsey: FDA Medical Reviewer Leaves Her Mark on History*. In FDA Consumer magazine, 200. [online]. Available at: https://permanent.access.gpo.gov/lps1609/www.fda.gov/fdac/features/2001/201_kelsey.html.

European Union was adopted in 1965. Council Directive 65/65/EEC on the approximation of provisions laid down by Law, Regulation or Administrative Action relating to proprietary medicinal products established the first harmonised rules for the production, evaluation, and marketing of medicinal products in order to safeguard public health. This gave the member states of the European Economic Community (now European Union) the first somewhat consistent regulatory framework.[9, 10]

In the following decades, many more directives, regulations, and other type of legislation (guidelines, opinions, etc.) have been introduced, and the pharmaceutical industry has now become one of the best-regulated in the European Union. The following overview is by no means exhaustive and only contains the most relevant legislation for the purpose of this work.

In 1975, a set of two directives and a council decision were passed. The directives 75/318/EEC, 75/319/EEC, and Council Decision 75/320/EEC laid down the first common rules on the pharmaceutical, toxicological, and clinical standards that the medicinal products needed to meet in order to be granted marketing authorisation in the European Union. This wave of regulation also introduced the predecessor of today's mutual recognition procedure and set up the Committee for Proprietary Medicinal Products (which later became a part of the European Medicines Agency – EMA).[11, 12, 13]

The concentration procedure, a predecessor of today's centralised procedure, was first introduced by Directive 87/22/EEC. The directive made it obligatory for all products derived from biotechnology to be registered in the European Economic Community via this procedure, and to this day, this obligation is still in place.[14]

Council Regulation (EEC) No 2309/93 came into force in 1995 and replaced Directive 87/22/EEC. The concentration procedure was changed to centralised procedure and became

[9] SAINT-RAYMOND, A., HUMPHREYS, A.J.: *Human medicinal products in the European Union: Regulations, Directives and structures.* In The Textbook of Pharmaceutical Medicine, Seventh Edition. John Wiley & Sons, Ltd., 2013. p. 363. ISBN 9780470659878.
[10] Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by Law, Regulation or Administrative Action relating to proprietary medicinal products [1965], OJ 22, p. 369–373.
[11] Council Directive 75/318/EEC of 20 May 1975 on the approximation of the laws of Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of proprietary medicinal products [1975], OJ L 147, p. 1–12.
[12] Second Council Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by Law, Regulation or Administrative Action relating to proprietary medicinal products [1975], OJ L 147, p. 13–22.
[13] 75/320/EEC: Council Decision of 20 May 1975 setting up a pharmaceutical committee [1975], OJ L 147, p. 23–23.
[14] Council Directive 87/22/EEC of 22 December 1986 on the approximation of national measures relating to the placing on the market of high-technology medicinal products, particularly those derived from biotechnology [1987], OJ L 15, p. 38–41.

more precise. Article 1 of this regulation also established the European Agency for the Evaluation of Medicinal Products (EMEA). This is also when the Committee for Proprietary Medicinal Products (CPMP) became a part of EMEA.[15, 16]

In 1993, the European Union was formed with the Maastricht Treaty as a successor of the EEC (later known as the European Communities – EC). In 1995, Austria joined the EU, which meant that the legislation mentioned so far has become binding in Austria, too.[17]

In preparation for the fifth, and so far the largest, enlargement of the European Union in 2004, a large review of the legislation took place in the preceding years. After being in force for almost five decades, Directive 65/65/EEC was repealed and replaced by the new Directive 2001/83/EC in 2001. It has been in force with certain amendments ever since, and today, it is the main source of European law regarding medicinal products. Apart from Directive 65/65/EEC, directives 75/318/EEC and 75/319/EEC have been repealed by this directive, too.[18]

In addition to the centralised procedure and the mutual recognition procedure, the decentralised procedure was introduced in 2004. Directive 2004/27/EC added this procedure to the European legislation by amending Directive 2001/83/EC. Both the mutual recognition procedure and the decentralised procedure are now to be found in the 2001 directive.[19, 20]

The European Agency for the Evaluation of Medicinal Products was replaced by the European Medicines Agency (EMA) as we know it today in 2004, too, and the Committee for Proprietary Medicinal Products (CPMP) was changed to Committee for Medicinal Products for Human Use (CHMP). Regulation (EC) No 726/2004 repealed the former Council Regulation (EEC) No 2309/93 and serves as the legal basis for the functioning of EMA until now. For the second time, the centralised procedure has been reviewed and

[15] Recitals, and Articles 5 and 49 of Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products [1993], OJ L 214, p. 1–21.
[16] SAINT-RAYMOND, A., HUMPHREYS, A.J.: *Human medicinal products in the European Union: Regulations, Directives and structures.* In The Textbook of Pharmaceutical Medicine, Seventh Edition. John Wiley & Sons, Ltd., 2013. p. 364–365. ISBN 9780470659878.
[17] KARAS, V., KRÁLIK, A.: *Právo Európskej únie*, *1. vydanie* [European Union Law, 1st edition]. Prague : C. H. Beck, 2012. p. 14–19. ISBN 9788071792871.
[18] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use [2001], OJ L 311, p. 67–128.
[19] Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use [2004], OJ L 136, p. 34–57.
[20] Title 3, Chapter 4 of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use [2001], OJ L 311, p. 67–128.

improved and can now be found in this regulation, too.[21] In this year, Slovakia joined the European Union, and the European legislation started to slowly make its way into the country's law.[22]

Since then, many new laws amending the existing legislation were introduced, incorporating the newest scientific and technological inventions and improving the safety of European consumers. However, no new large piece of legislation has replaced the previous. Directive 2001/83/EC and Regulation (EC) No 726/2004 are now the main legislative acts regulating marketing authorisation in European Economic Area.

1.1.1 Veterinary medicinal products regulation in the European Union

The regulation of medicinal products for veterinary use in the European Union came many years after Directive 65/65/EEC. The first law on veterinary medicinal products was introduced in 1981 as a set of directives 81/851/EEC and 81/852/EEC. The directives laid down the common analytical, pharmaco-toxicological, and clinical standards for veterinary medicinal products, as well as administrative rules, such as marketing authorisation regulation.[23, 24]

When concentration procedure (now centralised procedure) was introduced in 1987, medicinal products for veterinary use also fell under its scope, provided that they met the requirements for being derived from biotechnology. Council Regulation (EEC) No 2309/93 and Regulation (EC) No 726/2004 covered the concentration (centralised) procedure throughout the years for both human and veterinary medicinal products, up until 2019, when

[21] Recitals, and Articles 5 and 55 of Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency [2004], OJ L 136, p. 1–33.
[22] KARAS, V., KRÁLIK, A.: *Právo Európskej únie*, *1. vydanie* [European Union Law, 1st edition]. Prague : C. H. Beck, 2012. p. 14. ISBN 9788071792871.
[23] Council Directive 81/851/EEC of 28 September 1981 on the approximation of the laws of the Member States relating to veterinary medicinal products [1981], OJ L 317, p. 1–15.
[24] Council Directive 81/852/EEC of 28 September 1981 on the approximation of the laws of the Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of veterinary medicinal products [1981], OJ L 317, p. 16–28.

the centralised procedure for medicinal products for veterinary use was moved to different legislation.[25, 26, 27, 28]

With the big novelisation wave of harmonised legislation in 2001, veterinary medicinal products got their own uniform directive, similarly to medicinal products for human use (which is still in use today). The two directives of 1981 were replaced by Directive 2001/82/EC. More complex rules and a better structure could be found in this directive. The mutual recognition procedure and the decentralised procedure (since 2004) were part of this directive, too.[29]

In 2019, Directive 2001/82/EC was repealed, and new Regulation (EU) 2019/6 was introduced. The regulation of veterinary medicinal products can now be found mostly in this regulation, as it lays down both substantive and procedural rules. All three marketing authorisation procedures in relation to medicinal products for veterinary use are incorporated in this regulation.[30]

1.1.2 European Medicines Agency

European Medicines Agency was formed in 1995 by Council Regulation (EEC) No 2309/93 under the name European Agency for the Evaluation of Medicinal Products. It has gotten its current form and name in 2004 by Regulation (EC) No 726/2004. [31, 32, 33]

[25] Council Directive 87/22/EEC of 22 December 1986 on the approximation of national measures relating to the placing on the market of high-technology medicinal products, particularly those derived from biotechnology [1987], OJ L 15, p. 38–41.
[26] Title 3 of Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products [1993], OJ L 214, p. 1–21.
[27] Title 3 of Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency [2004], OJ L 136, p. 1–33.
[28] Articles 42 to 45 of Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC [2019], OJ L 4, p. 43–167.
[29] Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products [2001], OJ L 311, p. 1–66.
[30] Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC [2019], OJ L 4, p. 43–167.
[31] Website of the European Medicines Agency [online] [2/6/2024]. Available at: https://www.ema.europa.eu/en/about-us/history-ema.
[32] Article 49 of Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products [1993], OJ L 214, p. 1–21.
[33] Article 55 of Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency [2004], OJ L 136, p. 1–33.

After being headquartered in London, UK, for 25 years, EMA relocated to Amsterdam, the Netherlands, in 2020 following the UK's withdrawal from the European Union. [34]

Despite popular beliefs, EMA has been formed as (and still is) a purely scientific agency. Its main purpose is to give scientific evaluations of medicinal products that are currently in the process of obtaining marketing authorisation, as well as to coordinate activities of national competent authorities (NCA)[35]. It is not a regulatory body, as it does not issue any binding decisions; in relation to medicinal products, this competence belongs to the European Commission (EC).[36, 37, 38]

Structurally, EMA is divided into a number of committees and working parties. The committees are responsible for the scientific evaluation of medicinal products, i. e. testing their safety and efficacy. Each committee is responsible for different types of medicinal products. Currently, there are seven committees that are a part of EMA: Committee for Medicinal Products for Human Use (CHMP), Pharmacovigilance Risk Assessment Committee (PRAC), Committee for Medicinal Products for Veterinary Use (CVMP), Committee for Orphan Medicinal Products (COMP), Committee on Herbal Medicinal Products (HMPC), Committee for Advanced Therapies (CAT), and Paediatric Committee (PDCO). The working parties are either independent groups of professionals responsible for a certain task, or they can be a part of a certain committee and be responsible for a partial task within the committee or a specific type of medicinal products (e. g. Cardiovascular Working Party as a part of CHMP).[39]

EMA, together with NCAs and the EC form the European medicines regulatory network. The goal of this network is to enhance the cooperation between its members and to align (or potentially fully harmonise) the requirements and processes across all EEA member states in order to make it easier for pharmaceutical companies to bring new medicinal products to the market, and ultimately to simplify the access to medicinal products for

[34] Website of the European Medicines Agency [online] [2/6/2024]. Available at: https://www.ema.europa.eu/en/about-us/history-ema/relocation-amsterdam.
[35] National competent authority (NCA) is the national institution responsible for overseeing of drug policies in a member state. A member state may have more than one NCA.
[36] Website of the European Medicines Agency [online] [2/6/2024]. Available at: https://www.ema.europa.eu/en/about-us/what-we-do.
[37] Article 55 of Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency [2004], OJ L 136, p. 1–33.
[38] Articles 9(3), 10(1) and 10(2) of Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency [2004], OJ L 136, p. 1–33.
[39] Website of the European Medicines Agency [online] [2/6/2024]. Available at: https://www.ema.europa.eu/en/committees.

patients. The network currently has approximately 50 members across all EU and EEA member states. Prior to Brexit, the British NCA MHRA was a part of this network, too.[40]

It is important to note that EMA does not only perform its competencies in regard to human medicinal products but also medicinal products for veterinary use. In the 50+ NCAs that form the European medicines regulatory network, many of them are specialised in veterinary medicinal products.[41, 42]

1.1.3 Territorial scope of the EU legislation

When talking about the European legislation and the European market in regard to medicinal products, it is important to note that this includes not only the member states of the European Union but also Norway, Iceland, and Lichtenstein, i. e. the European Economic Area (EEA).[43]

The United Kingdom of Great Britain and Northern Ireland has been a part of the European Union since the 1970s up until 2020. For more than 40 years, European legislation has governed the pharmaceutical industry in the United Kingdom. After Brexit, the rules for marketing authorisation of medicinal products in the UK have not changed dramatically. Although the national competent authority in the UK, the Medicines and Healthcare products Regulatory Agency (MHRA), is no longer a part of the European medicines regulatory network, it still respects and recognizes EMA's previous evaluation of medicinal products. This means that all medicines that have already been authorised under centralised, decentralised, and mutual recognition procedures remain intact. However, the results of new centralised procedures are no longer effective in the UK, and medicinal products registered within the EU this way need to obtain separate marketing authorisation from MHRA.[44, 45]

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[40] Website of the European Medicines Agency [online] [2/6/2024]. Available at: https://www.ema.europa.eu/en/about-us/how-we-work/european-medicines-regulatory-network.

[41] Article 6(2) of Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC [2019], OJ L 4, p. 43–167.

[42] Website of the European Medicines Agency [online] [2/6/2024]. Available at: https://www.ema.europa.eu/en/partners-networks/eu-partners/eu-member-states/national-competent-authorities-veterinary.

[43] Agreement on the European Economic Area [1994], OJ L 1, p. 3–522.

[44] Notice of Medicines and Healthcare products Regulatory Agency published on the website of the UK government [online] [2/6/2024]. Available at: https://www.gov.uk/guidance/variations-to-marketing-authorisations-mas.

[45] Notice of Medicines and Healthcare products Regulatory Agency published on the website of the UK government [online] [2/6/2024]. Available at: https://www.gov.uk/guidance/converting-centrally-authorised-products-caps-to-uk-marketing-authorisations-mas-grandfathering-and-managing-lifecycle-changes.

1.2 Austria

In 1906, Austria passed the Pharmacy Act[46], a law regulating the pharmacy system in the country. The act regulates the profession of pharmacists, the requirements for pharmacies, as well as the handling of medicinal products after they have already been placed on the market (their dispensing). Even after more than a hundred years, the law is still in force, although it has been amended numerous times.[47]

The first legislation regulating medicinal products was a decree of the Federal Ministry of Social Administration[48] (now the Federal Ministry of Labour, Social Affairs, Health and Consumer Protection[49]) called the Specialties Ordinance[50], which was passed in 1947. The decree was based on Section 7 of the Pharmacy Act, as well as on Section 1 of the Act on the Organization of the Public Health Service[51] of 1870.[52]

The term "*medicinal products*" was not yet to be found in the Specialities Ordinance. As the name suggests, the decree operated with the term "*pharmaceutical specialties*"[53] but the term had a very similar meaning to today's definition of medicinal products. The main focus of the decree was on the registration of the pharmaceutical specialties, which was a very simple and quick process compared to currently existing rules.[54]

The Specialities Ordinance was repealed by the Medicines Act[55] in 1983. The Medicines Act became the first complex Austrian act regulating medicinal products. It contains the rules on manufacturing, clinical trials, marketing authorisation, and post-registration processes regarding medicinal products.[56]

Austria joined the European Union in 1995, but they have been preparing for the accession long before. The Medicines Act of 1983 was already incorporating European standards even before Austria was a part of the EU. The act is still in force now and has been amended a large number of times, especially reacting to new European legislation.

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[46] Translated from German "*Apothekengesetz*". [RGBl. Nr. 5/1907].
[47] Pharmacy Act (RGBl. Nr. 5/1907) [Translated from German "*Apothekengesetz*"]
[48] Translated from German "*Bundesministeriums für soziale Verwaltung*".
[49] Translated from German "*Bundesministerium für Soziales, Gesundheit, Pflege und Konsumentenschutz*".
[50] Translated from German "*Spezialitätenordnung*". [BGBl. Nr. 99/1947].
[51] Translated from German "*Gesetzes betreffend die Regelung des Apothekenwesens*". [RGBl. Nr. 68/1870].
[52] Specialties Ordinance (BGBl. Nr. 99/1947) [Translated from German "*Spezialitätenordnung*"].
[53] Translated from German "*pharmazeutische Spezialitäten*".
[54] Specialties Ordinance (BGBl. Nr. 99/1947) [Translated from German "*Spezialitätenordnung*"].
[55] Translated from German "*Arzneimittelgesetz*". [BGBl. Nr. 185/1983].
[56] Medicines Act (BGBl. Nr. 185/1983) [Translated from German "*Arzneimittelgesetz*"].

1.2.1 Veterinary medicinal products regulation in Austria

Austria passed their first Animal Welfare Act[57] in 2004, uniting the inconsistent regulation from multiple Federal Provinces. The act has been amended numerous times and is still in force.[58]

Medicinal products for veterinary use have fallen under the scope of medicinal products as described in the Medicines Act since 1983 and were regulated with almost identical rules as human medicinal products.[59]

In 2023, a new act has been passed. The Veterinary Medicines Act[60] is now in force and reacts to the introduction of new legislation on veterinary medicinal products in the EU, especially Regulation (EU) 2019/6. The Veterinary Medicines Act mostly copies the regulation, which is understandable, considering that regulations are directly applicable in member states, and in case of any discrepancy between the national legislation and the European legislation, the European shall prevail.[61]

1.2.2 Austrian supervisory authorities

In the Austrian health care system, there are multiple institutions that are responsible for regulating and supervising health care, including the pharmaceutical market. Each of these authorities has different sets of rights and obligations, and they often work closely together.

The main executive and supervisory authority in the health care system in Austria is the Federal Ministry of Social Affairs, Health, Care and Consumer Protection[62] (BMSGPK). The ministry is mainly responsible for providing legislative acts and for supervising the health care in the country.

In 2006, two new institutions were created by the Health and Safety Act[63] of 2002. The Austrian Federal Office for Safety in Health Care[64] (BASG) was established as the new

[57] Translated from German "*Tierschutzgesetz*". [BGBl. I Nr. 118/2004].
[58] Website of the Austrian Federal Ministry of Agriculture, Forestry, Regions and Water Management [online] [10/6/2024]. Available at: https://info.bml.gv.at/en/topics/agriculture/agriculture-in-austria/animal-production-in-austria/animal-welfare-act.html.
[59] Medicines Act (BGBl. Nr. 185/1983) [Translated from German "*Arzneimittelgesetz*"] – version before 2023.
[60] Translated from German "*Tierarzneimittelgesetz*". [BGBl. I Nr. 194/2023]
[61] Veterinary Medicines Act (BGBl. I Nr. 194/2023) [Translated from German "*Tierarzneimittelgesetz*"].
[62] Translated from German "*Bundesministerium für Soziales, Gesundheit, Pflege und Konsumentenschutz*".
[63] Translated from German "*Gesundheits- und Ernährungssicherheitsgesetz*". [BGBl. I Nr. 63/2002].
[64] Translated from German "*Bundesamt für Sicherheit im Gesundheitswesen*".

official authority responsible for medicinal products, taking over the responsibilities that previously belonged to the Ministry.[65]

At the same time, The Austrian Medicines and Medical Devices Agency[66] (AGES MEA) was established as a division of the already existing Austrian Agency for Health and Food Safety[67] (AGES). AGES is the institution responsible for risk minimisation in health, food safety, and consumer protection. It serves as a competent authority for overseeing the market, ensuring its compliance with the legal requirements, mainly consumer rights. This also relates to market surveillance in the field of medicinal products.[68]

AGES MEA was created as a division of AGES, responsible for the scientific evaluation of medicinal products for the purposes of marketing authorisation. BASG and AGES MEA work in close cooperation, where BASG issues binding decisions in the marketing authorisation procedures that are based on evaluations provided by AGES MEA (similar to the relationship between the European Commission and EMA).[69, 70]

Regarding medicinal products for veterinary use, BASG is also the national competent authority for marketing authorisation procedures. However, veterinary care (unlike human health care) does not fall under the BMSGPK but under the Federal Ministry of Agriculture, Forestry, Regions and Water Management (BML)[71].[72]

1.3 Slovakia

Slovakia as a sovereign state was formed in 1993 after the dissolution of Czechoslovakia. Even as a part of Czechoslovakia, the laws were different in Slovakia and in Czechia. This sub-chapter takes into account both pre and post-federation regimes and provides an overview of historical legislation of approximately the last 60 years.

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[65] Website of the Austrian Federal Office for Safety in Health Care [online] [10/6/2024]. Available at: https://www.basg.gv.at/en/about-us.

[66] Translated from German "*Geschäftsfeld Medizinmarktaufsicht der Agentur für Gesundheit und Ernährungssicherheit*".

[67] Translated from German "*Agentur für Gesundheit und Ernährungssicherheit*".

[68] Website of the Austrian Agency for Health and Food Safety [online] [10/6/2024]. Available at: https://www.ages.at/en/ages/departments/medical-market-surveillance.

[69] Website of the Austrian Federal Office for Safety in Health Care [online] [10/6/2024]. Available at: https://www.basg.gv.at/en/about-us.

[70] Website of the Austrian Agency for Health and Food Safety [online] [10/6/2024]. Available at: https://www.ages.at/en/ages/departments/medical-market-surveillance.

[71] Translated form German "*Bundesministerium für Land- und Forstwirtschaft, Regionen und Wasserwirtschaft*"

[72] Website of the Austrian Federal Ministry of Agriculture, Forestry, Regions and Water Management [online] [10/6/2024]. Available at: https://info.bml.gv.at/en/topics/agriculture/agriculture-in-austria/animal-production-in-austria/animal-welfare-act.html.

The first complex health care act was created in 1966. The act unified regulations on many aspects of Slovak health care, such as the professions of doctors, pharmacists, or nurses, the rules for work hygiene, the territorial distribution of health care, and more. Regulations on medicinal products could have also been found in this then-complex act.[73]

In 1969, the Ministry of Health of the Slovak Socialist Republic passed a decree regulating the registration process for mass-produced medicinal products. For the first time in Slovakia, medicinal products needed to be registered by a state authority before they could be placed on the market. The state authority responsible for the assessment of applications for the registration of medicinal products, as well as for maintaining the registry of medicinal products, was, at the time, the Ministry of Health.[74]

The decree was replaced by a new decree in 1987, which introduced a bit more complex rules on the marketing authorisation of medicinal products in Slovakia but didn't change the requirements or process drastically. The biggest change lay in the new requirement to register serums, vaccines, and biological medicinal products, which up until then relied on the sole approval of the chief hygienist.[75]

The first health care act was replaced by a new one in 1994, and in 1998, legislation regulating medicinal products was taken out of the health care act completely and put into the brand-new medicines act. It also repealed the decree of 1987 that regulated the registration of medicinal products. The Act no. 140/1998 Coll. Medicines Act was the first complex body of law regulating all aspects of medicinal products, including their manufacturing, clinical trials, registrations, and placement on the market.[76, 77]

In preparation for joining the European Union, the Medicines Act was already drafted with this in mind. The act was also taking into account that the national competent authority would become a part of the European medicines regulatory network. The State Institute for Drug Control[78] became the new state authority competent for granting the marketing

[73] Act no. 20/1966 Coll. on the Care of Public Health [Translated from Slovak "*Zákon č. 20/1966 Zb. o starostlivosti o zdravie ľudu*"].
[74] Decree of the Ministry of Health of the Slovak Socialist Republic no. 102/1969 Coll. on the registration of mass-produced medicinal preparations [Translated from Slovak "*Vyhláška Ministerstva zdravotníctva Slovenskej socialistickej republiky č. 102/1969 Zb. o registrácii hromadne vyrábaných liečivých prípravkov*"].
[75] Decree of the Ministry of Health of the Slovak Socialist Republic no. 72/1987 Coll. on the registration of mass-produced medicinal preparations [Translated from Slovak "*Vyhláška Ministerstva zdravotníctva Slovenskej socialistickej republiky č. 72/1987 Zb. o registrácii hromadne vyrábaných liečivých prípravkov*"].
[76] Act no. 277/1994 Coll. Health Care Act [Translated from Slovak "*Zákon č. 277/1994 Z. z. o zdravotnej starostlivosti*"].
[77] Act no. 140/1998 Coll. on Medicines and Medical Devices (Medicines Act) [Translated from Slovak "*Zákon č. 140/1998 Z. z. o liekoch a zdravotníckych pomôckach*"].
[78] Translated from Slovak "*Štátny ústav pre kontrolu liečiv*".

authorisation for medicinal products and maintaining the registry of all approved medicinal products, taking these responsibilities from the Ministry of Health.[79]

Slovakia joined the European Union in 2004, and in that same year, a major reform of health legislation (among others) took place. The Medicines Act better implemented the European legislation, especially reacting to the introduction of Directive 2001/83/EC and Regulation (EC) No 726/2004.

It wasn't until 2011 that the Act no. 362/2011 Coll. Medicines Act was introduced. The new Medicines Act consolidates and modernises the rules set out in the former Medicines Act and better adheres to European standards. It is still in force now, and it is the primary source of regulation for medicinal products in Slovakia.[80]

1.3.1 Veterinary medicinal products regulation in Slovakia

The legislation on veterinary care in Slovakia has always been different from the one on human health care. In 1961, the first Veterinary Care Act was passed. Throughout the years, several new veterinary care acts were introduced – in 1987, 1998, 2002, and finally in 2007 that is still in force now.[81]

On the other hand, medicinal products for veterinary use usually shared the same legislation with human medicinal products. The first legislation on marketing authorisation of mass-produced medicinal products (for veterinary use and human use) was introduced in 1969 in the form of a decree of the Ministry of Health. The decree was replaced by a new decree in 1987.[82, 83]

With the introduction of the first Medicines Act in 1998, the legislation of 1987 was replaced. The act was in force until 2011 when the new Medicines Act was introduced. This

[79] Section 21(2) of Act no. 140/1998 Coll. on Medicines and Medical Devices (Medicines Act) [Translated from Slovak "*Zákon č. 140/1998 Z. z. o liekoch a zdravotníckych pomôckach*"].
[80] Act no. 362/2011 Coll. on Medicines and Medical Devices (Medicines Act) [Translated from Slovak "*Zákon č. 362/2011 Z. z. o liekoch a zdravotníckych pomôckach*"].
[81] Act no. 66/1961 Coll. Veterinary Care Act; Act no. 87/1987 Coll. Veterinary Care Act; Act no. 337/1998 Coll. Veterinary Care Act; Act no. 488/2002 Coll. Veterinary Care Act; Act no. 39/2007 Coll. Veterinary Care Act [Translated from Slovak "Zákon č. 66/1961 Zb. o veterinárnej starostlivosti; Zákon č. 87/1987 Zb. o veterinárnej starostlivosti; Zákon č. 337/1998 Z. z. o veterinárnej starostlivosti; Zákon č. 488/2002 Z. z. o veterinárnej starostlivosti; Zákon č. 39/2007 Z. z. o veterinárnej starostlivosti"].
[82] Decree of the Ministry of Health of the Slovak Socialist Republic no. 102/1969 Coll. on the registration of mass-produced medicinal preparations [Translated from Slovak "*Vyhláška Ministerstva zdravotníctva Slovenskej socialistickej republiky č. 102/1969 Zb. o registrácii hromadne vyrábaných liečivých prípravkov*"].
[83] Decree of the Ministry of Health of the Slovak Socialist Republic no. 72/1987 Coll. on the registration of mass-produced medicinal preparations [Translated from Slovak "*Vyhláška Ministerstva zdravotníctva Slovenskej socialistickej republiky č. 72/1987 Zb. o registrácii hromadne vyrábaných liečivých prípravkov*"].

act is still in force now and is the legal basis for medicinal products for veterinary use in Slovakia.[84, 85]

However, it is important to note that veterinary medicinal products are complexly regulated by Regulation (EU) 2019/6, which is directly applicable in Slovakia. The Medicines Act, therefore, must be read together with this regulation in order to fully understand veterinary medicinal products regulation in Slovakia.[86]

1.3.2 Slovak supervisory authorities

The first institute for drug control for the territory of Slovakia was founded in 1918 under the name Institute for the Study of Medicines[87], having its seat at the Charles University in Prague, Czechia. The institute only studied medicinal products individually made in pharmacies and did not evaluate mass-produced medicinal products before their placement on the market.

In 1952, the State Institute for Drug Control in Prague was created. Although it was seated in Czechia, the evaluation of Slovak medicinal products fell under its scope, too. The first institute for drug control in Slovakia was created in 1964, and it was a subsidiary of the institute in Prague. At this time, the institutes were not yet regulatory bodies but only scientific, as their main purpose was to evaluate the medicinal products before they could be placed on the market. The placement on the market, however, did not lie upon the institutes; decisions on whether a medicinal product could be placed on the market in either Czechia or Slovakia were in the hands of the respective Ministry of Health.

As Slovakia became an independent state, the two institutions separated as well. The State Institute for Drug Control (ŠÚKL)[88] became the only drug control institute in Slovakia, and in 1998, it acquired new competencies from the Ministry of Health regarding the marketing authorisation of medicinal products.[89, 90]

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[84] Act no. 140/1998 Coll. on Medicines and Medical Devices (Medicines Act) [Translated from Slovak "*Zákon č. 140/1998 Z. z. o liekoch a zdravotníckych pomôckach*"].
[85] Act no. 362/2011 Coll. on Medicines and Medical Devices (Medicines Act) [Translated from Slovak "*Zákon č. 362/2011 Z. z. o liekoch a zdravotníckych pomôckach*"].
[86] Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC [2019], OJ L 4, p. 43–167.
[87] Translated from Slovak "*Ústav pre skúmanie liečiv*".
[88] Translated from Slovak "*Štátny ústav pre kontrolu liečiv*".
[89] Website of the Slovak State Institute for Drug Control [online] [14/6/2024]. Available at: https://www.sukl.sk/hlavna-stranka/slovenska-verzia/o-nas/historia-a-sucasnost?page_id=161.
[90] Website of the Czech State Institute for Drug Control [online] [14/6/2024]. Available at: https://www.sukl.cz/sukl/historie-a-soucasnost.

Nowadays, the State Institute for Drug Control is the only institution with the authority to oversee all aspects of medicinal products, with the exception of reimbursement, which still belongs to the Ministry of Health.[91, 92]

Veterinary care in Slovakia belongs to the Ministry of Agriculture and Rural Development [93] as the main authority responsible for overseeing veterinary care and implementing regulations. Responsible for veterinary inspections is the State Veterinary and Food Administration[94], with a number of regional veterinary and food administrations as its first instance.[95]

The State Institute for Drug Control (ŠÚKL) is not responsible for medicinal products for veterinary use. An independent authority, the Institute of State Control of Veterinary Biologicals and Medicaments (ÚŠKVBL) is the national competent authority. The two authorities are totally independent of each other while sharing the same competencies, ŠÚKL for human medicinal products and ÚŠKVBL for veterinary.[96, 97]

[91] According to Sections 6(2), 46(1), 110, 125 of Act no. 362/2011 Coll. on Medicines and Medical Devices (Medicines Act) [Translated from Slovak "*Zákon č. 362/2011 Z. z. o liekoch a zdravotníckych pomôckach*"].
[92] According to Section 6(1) of Act no. 363/2011 Coll. on the Scope and Conditions of Reimbursement of Medicines, Medical Devices and Dietetic Foods on the Basis of Public Health Insurance [Translated from Slovak "*Zákon č. 363/2011 Z. z. o rozsahu a podmienkach úhrady liekov, zdravotníckych pomôcok a dietetických potravín na základe verejného zdravotného poistenia*"].
[93] Translated from Slovak "*Ministerstvo pôdohospodárstva a rozvoja vidieka*".
[94] Translated from Slovak "*Štátna veterinárna a potravinová správa*".
[95] Section 4(1) of Act no. 39/2007 Coll. Veterinary Care Act [Translated from Slovak "*Zákon č. 39/2007 Z. z. o veterinárnej starostlivosti*"].
[96] According to Sections 84(1) and 125 of Act no. 362/2011 Coll. on Medicines and Medical Devices (Medicines Act) [Translated from Slovak "*Zákon č. 362/2011 Z. z. o liekoch a zdravotníckych pomôckach*"].
[97] Website of the Slovak Institute of State Control of Veterinary Biologicals and Medicaments [online] [14/6/2024]. Available at: https://www.uskvbl.sk/?page_id=27.

2 Marketing authorisation process in the European context

As was demonstrated in the previous chapter, the European Union strongly regulates the pharmaceutical industry, including the marketing authorisation of medicinal products. There are multiple routes that pharmaceutical companies may take in order to get the authorisation to place their products on the market. It is not always up to the pharmaceutical companies to decide which route they will take.

The procedures for marketing authorisation of medicinal products may be divided into two groups – those in the hands of the European Union, and those in the hands of national competent authorities (NCA). In this chapter, an overview of marketing authorisation procedures with a cross-border element is provided.

2.1 Centralised procedure

The centralised procedure was introduced in 1987 as the concentration procedure. The concentration procedure required every medicinal product derived from biotechnology to be registered centrally through the European Commission for the whole territory of the European Union.[98] In 1995, the concentration procedure was renamed to centralised procedure by new legislation. In the same year, the European Medicines Agency was established.[99] Today's rules regulating the centralised procedure can be found in Regulation (EC) No 726/2004.[100]

The centralised procedure is currently the only European-level procedure, meaning it is the only procedure carried out by European institutions – jointly by the European Commission and the European Medicines Agency. This procedure allows pharmaceutical companies to get a single authorisation for marketing their products in all member states of the European Economic Area.[101]

[98] Council Directive 87/22/EEC of 22 December 1986 on the approximation of national measures relating to the placing on the market of high-technology medicinal products, particularly those derived from biotechnology [1987], OJ L 15, p. 38–41.
[99] Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products [1993], OJ L 214, p. 1–21.
[100] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency [2004], OJ L 136, p. 1–33.
[101] Website of the European Commission [online] [5/6/2024]. Available at: https://health.ec.europa.eu/medicinal-products/legal-framework-governing-medicinal-products-human-use-eu/authorisation-procedures-centralised-procedure_en.

Obtaining marketing authorisation for a certain medicinal product through the centralised procedure is obligatory in some cases; in others, it is optional or not possible at all. Article 3(1) of Regulation (EC) No 726/2004 is the legal basis for the obligation to obtain marketing authorisation via the centralised procedure. The article states that "*no medicinal product appearing in the Annex may be placed on the market within the Union unless a marketing authorisation has been granted by the Union in accordance with the provisions of this Regulation*."[102] In the annex referred to by the Article 3(1), three types of medicinal products are stated as follows:

"*a) products derived from biotechnology*

b) orphan medicinal products

c) medicinal products for human use which contain an active substance authorised in the Union after 20 May 2004 and which are intended for the treatment of AIDS, cancer, neurodegenerative disorders or diabetes."[103, 104]

If a pharmaceutical company decides to apply for marketing authorisation at the European level and does not meet the requirements of Article 3(2), the medicinal product seeking an authorisation must comply with at least one of the following rules of Article 3(2) of Regulation (EC) No 726/2004:

"*a) the medicinal product contains an active substance which, on 20 May 2004, was not authorised in the Union; or*

b) the applicant shows that the medicinal product constitutes a significant therapeutic, scientific or technical innovation or that the granting of authorisation in accordance with this Regulation is in the interest of patients' health at Union level"[105]

[102] Article 3(1) of Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency [2004], OJ L 136, p. 1–33.

[103] Article 3(1) of Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency [2004], OJ L 136, p. 1–33.

[104] Website of the European Commission [online] [5/6/2024]. Available at: https://health.ec.europa.eu/medicinal-products/legal-framework-governing-medicinal-products-human-use-eu/authorisation-procedures-centralised-procedure_en.

[105] Article 3(2) of Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency [2004], OJ L 136, p. 1–33.

2.1.1 Procedure steps

As already mentioned, the legal basis for the centralised procedure is Regulation (EC) No 726/2004. The Regulation contains substantive rules regarding the centralised procedure and the establishment of the European Medicines Agency, but most importantly, the procedural rules on the centralised procedure.

A pharmaceutical company wishing to centrally register its medicinal product submits the application for marketing authorisation directly to the European Medicines Agency.[106] The submission is done via electronic means (an eSubmission client).[107] EMA also recommends that pre-submission steps are taken in order to prepare for the actual authorisation process. This may include an eligibility check, notification of intent to submit an application, and pre-submission meetings of the pharmaceutical company representatives with EMA representatives.[108]

The application for marketing authorisation must include a number of different information and documents, such as information about the applicant, the composition of the medicinal products, the information about where and how the medicinal product was manufactured, the proposed labelling, packaging, draft of the summary of product characteristics (SPC) and the patient information leaflet (PIL) and others.[109]

In the process of granting the marketing authorisation, EMA gives out only the scientific evaluation of the medicinal product, not the binding decision. The submission goes straight to the Committee for Medicinal Products for Human Use, which then performs a scientific assessment and ultimately gives its recommendation on whether or not should be the medicinal product granted marketing authorisation. This part of the process lasts approximately 210 days, as this is the period during which the CHMP is obliged to decide.

[106] Article 4(1) of Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency [2004], OJ L 136, p. 1–33.
[107] Website of the European Medicines Agency [online] [5/6/2024]. Available at: https://www.ema.europa.eu/en/human-regulatory-overview/marketing-authorisation/obtaining-eu-marketing-authorisation-step-step.
[108] Website of the European Medicines Agency [online] [5/6/2024]. Available at: https://www.ema.europa.eu/en/human-regulatory-overview/marketing-authorisation/obtaining-eu-marketing-authorisation-step-step.
[109] Articles 6(1) and 6(2) of Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency [2004], OJ L 136, p. 1–33.

This period may be further extended in case the CHMP needs to ask the applicant additional questions.[110]

Once the Committee for Medicinal Products for Human Use has decided that the medicinal product is safe and should be granted marketing authorisation, they issue an opinion in writing, which is then sent to the applicant, the member states (national competent authorities), and to the European Commission to finish the authorisation process. Along with the opinion, an approved labelling, packaging, summary of product characteristics (SPC), and the patient information leaflet (PIL) are sent.[111]

After receiving the opinion from EMA, the European Commission prepares a draft decision and sends it to the Standing Committee on Medicinal Products for Human Use for approval. The decision is then implemented within 67 days of the issuing of the EMA's opinion. The decision on granting marketing authorisation to the medicinal product is valid for five years, however, it can be renewed for an indefinite period of time.[112]

2.1.2 Centralised procedure in numbers

The European Commission, in cooperation with the European Medicines Agency, has been registering medicinal products centrally for almost 30 years.[113] For the first half of its operation, 401 medicinal products have been granted marketing authorisation by the EC and EMA, which is only a little over a quarter of the total number of registered medicinal products.[114] Approximately the same number (413) of medicinal products have been registered in the past five years.[115] Each year, more and more advanced medicinal products

[110] Article 6(3) of Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency [2004], OJ L 136, p. 1–33.
[111] Article 9(3) and 9(4) of Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency [2004], OJ L 136, p. 1–33.
[112] Website of the European Commission [online] [7/6/2024]. Available at: https://health.ec.europa.eu/medicinal-products/legal-framework-governing-medicinal-products-human-use-eu/authorisation-procedures-centralised-procedure_en.
[113] Website of the European Medicines Agency [online] [7/6/2024]. Available at: https://www.ema.europa.eu/en/about-us/history-ema.
[114] Statistics according to EMA Database of medicinal products centrally registered in the European Union [online] [7/6/2024]. Available at: https://www.ema.europa.eu/en/search?f%5B2%5D=ema_med_status%3A100108&f%5B3%5D=ema_medicine_bundle%3Aema_medicine&f%5B4%5D=ema_search_categories%3A83&f%5B5%5D=ema_marketing_authorisation_date%3A%28min%3A%2Cmax%3A1262304000%29&landing_from=73303.
[115] Statistics according to EMA Database of medicinal products centrally registered in the European Union [online] [7/6/2024]. Available at: https://www.ema.europa.eu/en/search?f%5B2%5D=ema_med_status%3A100108&f%5B3%5D=ema_medici

are developed and registered in the European Economic Area. Nowadays, more than 1,400 medicinal products are registered by the EC and EMA. It is important to note that this number only contains each medicinal product once and does not count different presentations of the same medicinal product separately.[116]

2.2 Decentralised procedure

The youngest marketing authorisation procedure is the decentralised procedure. Introduced in 2004, it is one of the two procedures that pharmaceutical companies may choose if they wish to place their products on the market in multiple EEA member states and do not (or do not want to) meet the requirements for the centralised procedure.[117]

The decentralised procedure is not carried out by European institutions but rather by the national competent authorities of the member states concerned. The legal basis for the decentralised procedure is Directive 2001/83/EC (as amended by Directive 2004/27/EC), as well as the national legislation of member states.[118]

If a pharmaceutical company wishes to obtain marketing authorisation for their medicinal product in multiple member states but hasn't yet obtained one in any, the decentralised procedure is the most efficient way. In practice, this means that they choose multiple member states in which they wish to register their medicinal product and pick one of the member states as the reference state. The NCA of that reference state then leads the registration process.[119]

In the decentralised procedure, the leading NCA is responsible for the evaluation of the safety and efficacy of the medicinal product. The NCA prepares "*a draft assessment report, a draft summary of product characteristics and a draft of the labelling and package*

ne_bundle%3Aema_medicine&f%5B4%5D=ema_search_categories%3A83&f%5B5%5D=ema_marketing_authorisation_date%3A%28min%3A1546300800%2Cmax%3A%29&landing_from=73303.

[116] Statistics according to EMA Database of medicinal products centrally registered in the European Union [online] [7/6/2024]. Available at: https://www.ema.europa.eu/en/search?f%5B0%5D=ema_med_status%3A100108&f%5B1%5D=ema_medicine_bundle%3Aema_medicine&f%5B2%5D=ema_search_categories%3A83&landing_from=73303.

[117] Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use [2004], OJ L 136, p. 34–57.

[118] Title 3 Chapter 4 of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use [2001], OJ L 311, p. 67–128.

[119] Articles 28(1) and 28(3) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use [2001], OJ L 311, p. 67–128.

leaflet". [120] The period within which the reference member state must prepare the documentation is comparatively shorter than the centralised procedure, only 120 days. All of these documents are then sent to the applicant and member states chosen by the applicant.[121]

The member states then have 90 days to approve the documentation received by the reference state. During this period, they may either approve or dispute the assessment of the reference state. If the assessment and all other documentation are approved by a member state, they adopt a binding decision on granting the marketing authorisation for the medicinal product within 30 days.[122]

Should a member state not agree with the reference state NCA's assessment, it may raise concerns. In that case, a coordination group is set up, and the concern is discussed with all relevant member states. The applicant is also asked to comment on the matter. If an agreement is reached after the discussions, the states will approve the agreement and continue as usual. In case of failure to reach an agreement, the matter is forwarded to EMA, which takes over the procedure.[123]

2.3 Mutual recognition procedure

The mutual recognition procedure is very similar to the decentralised procedure. Both procedures share the same legal basis, Directive 2001/83/EC. Pharmaceutical companies choose this procedure once they have already obtained marketing authorisation for their medicinal product in one of the EEA member states.[124]

The medicinal product has already undergone the national marketing authorisation procedure in a certain member state, meaning that the national competent authority of that state has already evaluated the medicinal product and prepared all the necessary documents. On the basis of this marketing authorisation, the pharmaceutical company may ask the NCA

[120] Article 28(3) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use [2001], OJ L 311, p. 67–128.
[121] Article 28(3) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use [2001], OJ L 311, p. 67–128.
[122] Articles 28(4) and 28(5) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use [2001], OJ L 311, p. 67–128.
[123] Article 29 of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use [2001], OJ L 311, p. 67–128.
[124] Article 28(2) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use [2001], OJ L 311, p. 67–128.

of other member state (or states) to register their medicinal product via their national procedure.[125]

After an application has been submitted, the applicant is required to request the assessment of the medicinal product from the NCA of the reference state. The NCA has 90 days to either prepare the assessment or update the existing report. All the relevant documents are then sent to the member state (or states) and to the applicant.[126]

From then, the process is identical to the decentralised procedure. The same periods according to Articles 28(4) and 28(5) of Directive 2001/83/EC apply, as well as the rules on solving the disagreement between the reference state and the member state (or states) concerned.[127]

Both the mutual recognition procedure and the decentralised procedure are based on the national marketing authorisation procedures of the member states. As this thesis focuses on the legislation of Austria and Slovakia, the next chapter provides a comprehensive overview of national procedures in these two countries.

2.4 Procedures for veterinary medicinal products

The legal basis for all European marketing authorisation procedures for veterinary medicinal products is Regulation (EU) 2019/6. Apart from procedural rules, the regulation also contains substantive rules that medicinal products for veterinary use must comply with.

Article 6(1) of the regulation lists the procedures which pharmaceutical companies may (or must) choose in order to obtain marketing authorisation for their veterinary medicinal product. Apart from already known centralised, decentralised, mutual recognition, and national procedures, a fifth marketing authorisation procedure, called subsequent recognition procedure, is added.[128]

[125] Article 28(2) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use [2001], OJ L 311, p. 67–128.
[126] Article 28(2) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use [2001], OJ L 311, p. 67–128.
[127] Articles 28(4), 28(5) and 29 of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use [2001], OJ L 311, p. 67–128.
[128] Article 6(1)(d) of Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC [2019], OJ L 4, p. 43–167.

The procedures for veterinary medicinal products can be found in the following articles of Regulation (EU) 2019/6:

a) centralised procedure in Articles 42 to 45;
b) national procedure in Articles 46 and 47;
c) decentralised procedure in Articles 48 to 50;
d) mutual recognition procedure in Articles 51 and 52; and
e) subsequent recognition in Article 53.[129]

In principle, the centralised, decentralised, and mutual recognition procedures for medicinal products for veterinary use have almost identical rules to human medicinal products procedures. The analytical, pharmaco-toxicological, and clinical standards for these medicinal products likely vary. Therefore, the documents needed to be submitted along with the application vary as well. However, the process itself, including the periods, is the same.[130]

Similarly to Directive 2001/83/EC, which regulates human medicinal products, Regulation (EU) 2019/6 incorporates some provisions for national marketing authorisation procedures. The difference in veterinary medicinal products regulation is that these rules for national marketing authorisation are more detailed. Probably the most important rule in both of these acts is the period during which the national competent authority of a member state, where the national procedure is taking place, should complete the procedure. In both cases, this period is 210 days.[131]

The most notable difference between the rules on marketing authorisation for human medicinal products and for veterinary medicinal products is the addition of subsequent procedure to Regulation (EU) 2019/6. This procedure allows pharmaceutical companies to ask additional member states for marketing authorisation of their medicinal products after either a decentralised or mutual recognition procedure has already been completed for the same medicinal product.[132]

After the pharmaceutical company submits the application for the subsequent procedure to the reference state and the additional member states, the reference state will send all

[129] Articles 42 to 53 of Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC [2019], OJ L 4, p. 43–167.
[130] Articles 42 to 53 of Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC [2019], OJ L 4, p. 43–167.
[131] Articles 46 and 47 of Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC [2019], OJ L 4, p. 43–167.
[132] Article 53(1) of Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC [2019], OJ L 4, p. 43–167.

necessary documentation, including the binding decision on granting marketing authorisation to the veterinary medicinal product to these member states. The additional member states now have 60 days to grant the marketing authorisation to the medicinal product or alternatively to raise an objection.[133]

If an objection is raised, a coordination group is set up of the member states concerned and the reference state, with the purpose of finding a solution and coming to an agreement. If this is not possible, the case is forwarded to the European Commission to resolve the dispute.[134]

Unlike marketing authorisation for medicinal products for human use, veterinary medicinal products obtain their marketing authorisation for an unlimited period of time. This applies to marketing authorisation obtained via any of the possible marketing authorisation procedures.[135]

[133] Articles 53(2) to 53(4) of Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC [2019], OJ L 4, p. 43–167.
[134] Articles 53(5), 53(8), 54(1), 54(6) and 54(10) of Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC [2019], OJ L 4, p. 43–167.
[135] Article 5(2) of Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC [2019], OJ L 4, p. 43–167.

3 National marketing authorisation procedures

With the harmonisation of legislation on medicinal products and other aspects of drug policies, the status of national competent authorities didn't fall into the background, despite popular beliefs. With the creation of the European Medicines Agency and the centralised procedure, a certain type of medicinal products fell out of the scope of NCAs, but in return, they acquired many other competencies, and their position within the European drug policy has become even stronger.

Almost[136] every national competent authority within the European medicines agencies network possesses very powerful competencies in regard to marketing authorisation of medicinal products. NCAs responsible for marketing authorisation procedures are trusted to responsibly and correctly evaluate the safety and efficacy of the medicinal products in question. Particularly in mutual recognition and decentralised procedures, as described in the previous chapter, other member states trust the scientific opinion of the reference state's NCA (while keeping the right to object) and base their marketing authorisation decisions on these opinions.

Although the European legislation has mostly harmonised the substantive rules on medicinal products, especially regarding pharmacovigilance, each member state has retained its own national rules on certain aspects, including the procedural rules on marketing authorisation. In this chapter, we analyse national marketing authorisation procedures in Austria and Slovakia and shortly compare their differences.

3.1 Austria

Austrian national marketing authorisation procedure is regulated by the Medicines Act, specifically by Sections 7 to 27.[137]

All medicinal products are subject to approval from the national competent authority BASG. This does not apply to medicinal products that are already registered at the European Commission or that are placed on the market in the country on the basis of a different legislative act.[138] Although individually made medicinal products (e. g. in pharmacies or

[136] Some EEA member states have multiple NCAs with different scope of competencies. Marketing authorisation usually only belongs to one NCA in a certain member state. In some member states, human and veterinary medicinal product fall under different NCA.
[137] Sections 7 to 27 of Medicines Act (BGBl. Nr. 185/1983) [Translated from German "*Arzneimittelgesetz*"].
[138] Section 7(1) of Medicines Act (BGBl. Nr. 185/1983) [Translated from German "*Arzneimittelgesetz*"].

hospitals at the time of their need) also fall under the definition of medicinal product according to the Medicines Act, Section 7(3) exempts these medicinal products from authorisation obligation. Other exceptions to the obligation to obtain marketing authorisation are listed in Section 8 of the Medicines Act.[139]

The application for registering a medicinal product is submitted electronically to BASG. In order to be eligible to obtain marketing authorisation for a medicinal product, the applicant must have a residence or registered seat (depending on whether they are a natural or a legal person) in the European Economic Area.[140, 141]

BASG itself does not perform the scientific evaluation of medicinal products seeking marketing authorisation. It works closely with AGES, an agency responsible for market surveillance regarding medicinal products. AGES MEA, a division of AGES, is the one responsible for evaluating whether a medicinal product that is to be registered in Austria is safe and efficacious. After receiving an opinion from AGES MEA, BASG issues a decision based on the opinion and either grants marketing authorisation to the medicinal product or refuses the application.[142, 143, 144]

Multiple different documents are submitted along with the application. This involves all information about the applicant, such as its name or license to manufacture medicinal products (from the manufacturer if the applicant is not the manufacturer). Regarding the medicinal product, the documentation must include information such as the name of the medicinal product, the proposed packaging and labelling, the composition of the medicinal product, and even a sample of the medicinal product for further testing. All documents regarding the pharmaceutical, toxicological-pharmacological, and clinical testing are necessary, too. The applicant is also obliged to submit a draft of the summary of product characteristics (SPC) and the patient information leaflet (PIL).[145]

After receiving the application, BASG has seven months to issue a decision on the matter. As mentioned, BASG processes the application and submits samples of the medicinal product to AGES MEA for scientific evaluation. The safety, efficacy, and quality of the

[139] Section 7(3) of Medicines Act (BGBl. Nr. 185/1983) [Translated from German "*Arzneimittelgesetz*"].
[140] Section 9(1) of Medicines Act (BGBl. Nr. 185/1983) [Translated from German "*Arzneimittelgesetz*"].
[141] Website of the Austrian Federal Office for Safety in Health Care [online] [20/6/2024]. Available at: https://www.basg.gv.at/en/companies/marketing-authorisation-life-cycle/electronic-application.
[142] Website of the Austrian Federal Office for Safety in Health Care [online] [20/6/2024]. Available at: https://www.basg.gv.at/en/about-us.
[143] Website of the Austrian Federal Office for Safety in Health Care [online] [20/6/2024]. Available at: https://www.basg.gv.at/en/companies/marketing-authorisation-life-cycle.
[144] Website of the Austrian Agency for Health and Food Safety [online] [20/6/2024]. Available at: https://www.ages.at/en/ages/departments/medical-market-surveillance.
[145] Section 9a of Medicines Act (BGBl. Nr. 185/1983) [Translated from German "*Arzneimittelgesetz*"].

medicinal product are examined, as well as whether good laboratory practice, good clinical practice, and good manufactory practice standards were met. These standards vary throughout the world, but most big economies have adopted the same rules on good practice. The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) is an initiative uniting multiple countries that have undertaken to follow the same good practice standards prepared by experts of ICH. The European Union is one of the parties to the initiative, and the European Commission and national competent authorities need to verify that ICH good practice standards were met.[146, 147, 148]

After receiving a positive result of the evaluation, BASG can issue a decision and register the medicinal product. On the other, the decision can be negative, and the application refused. This can happen even before AGES MEA carries out the evaluation, for example, if the application or documentation is incomplete or incorrect or the medicinal product cannot be registered according to the national marketing authorisation procedure. Of course, if the results of the evaluation of the medicinal product by AGES MEA are not satisfactory, marketing authorisation is not granted either. The complete list of reasons to refuse the application is listed in Section 19(1) of the Medicines Act.[149]

For generics and biosimilars[150], the national marketing authorisation procedure is much simpler. Generics and biosimilars do not need to submit clinical testing data about the medicinal product, provided that the original brand name medicinal product has already been registered in an EEA member state for at least eight years. However, generics and biosimilars may be marketed in the country only after ten years after the first authorisation for the reference medicinal product has been granted.[151]

Homeopathic medicinal products are considered a part of alternative medicine, but the legislation puts them into the same category as altruistic medicinal products. This is why the legislators need to deal with marketing authorisation of these medicinal products, too. In

[146] Section 18(1) of Medicines Act (BGBl. Nr. 185/1983) [Translated from German "*Arzneimittelgesetz*"].
[147] Website of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use [online] [20/6/2024]. Available at: https://www.ich.org/page/mission.
[148] Website of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use [online] [20/6/2024]. Available at: https://www.ich.org/page/members-observers.
[149] Sections 13(1), 18 and 19(1) of Medicines Act (BGBl. Nr. 185/1983) [Translated from German "*Arzneimittelgesetz*"].
[150] Generics are medicinal products with the same chemical composition as a different medicinal product that is already on the market under a brand name. Biosimilars are medicinal products with the same biological composition as a different medicinal product that is already on the market under a brand name. In Austria, both of these fall under the definition of generic (Translated from German "*Generikum*").
[151] Sections 10(1) and 10(2) of Medicines Act (BGBl. Nr. 185/1983) [Translated from German "*Arzneimittelgesetz*"].

Austria, most homeopathic medicinal products do not require registration, for example, if they are for external or oral use only.[152]

Once the application is reviewed, the medicinal product evaluated, and a positive decision issued, the applicant becomes the marketing authorisation holder (MAH) for the medicinal product. It is now possible to place this medicinal product on the market in Austria. The registration for human medicinal products is valid for five years. The MAH may apply for renewal after four years, but no later than nine months before the marketing authorisation period lapses (i. e. MAH has specified three months for the submission of extension). BASG reviews the renewal application and, if everything is in order, grants the marketing authorisation without a limitation period. Alternatively, BASG may extend the registration by another five years for reasons of pharmacovigilance, but this may only be done once. If the applicant applies for another renewal after this period, the extended marketing authorisation must be granted indefinitely (unless it is refused).[153]

For public health-related issues, or if the MAH decides so, the marketing authorisation of a medicinal product may be suspended or revoked. This is possible if any of the contested facts in the application were untrue or if unknown side effects become obvious throughout time. If the problem is easily fixable, the registration is suspended by BASG, in other cases, it is withdrawn.[154] Should the medicinal product be unavailable on the market for three years after the marketing authorisation was granted, it lapses.[155]

3.1.1 Statistics

BASG is the provider of a database containing all medicinal products that are currently registered in Austria. The database is called the Austrian Medicinal Products Index (AMPI)[156] and contains over 16,000 human medicinal products registered in the country.[157]

Out of the 16,000, approximately 6,800 medicinal products are registered via the national marketing authorisation route, and approximately 6,000 are registered via either the decentralised or mutual recognition procedure. In many of these cases, Austria has played

[152] Section 11 of Medicines Act (BGBl. Nr. 185/1983) [Translated from German "*Arzneimittelgesetz*"].
[153] Section 20 of Medicines Act (BGBl. Nr. 185/1983) [Translated from German "*Arzneimittelgesetz*"].
[154] Section 23 of Medicines Act (BGBl. Nr. 185/1983) [Translated from German "*Arzneimittelgesetz*"].
[155] Section 22(1) of Medicines Act (BGBl. Nr. 185/1983) [Translated from German "*Arzneimittelgesetz*"].
[156] Translated from German "*Arzneispezialitätenregister*".
[157] Statistics according to BASG Database of medicinal products registered in Austria (AMPI) [online] [20/6/2024]. Available at: https://aspregister.basg.gv.at/aspregister/faces/aspregister.jspx.

the role of the reference state, and BASG is an important NCA in the European medicines regulatory network.[158]

The rest of the medicinal products (approximately 3,200) are medicinal products registered in the EU via the centralised procedure.[159]

3.1.2 National procedure for veterinary medicinal products in Austria

For veterinary medicinal products, Austria does not have a separate national competent authority. BASG and AGES MEA are responsible for marketing authorisation of medicinal products for veterinary use, too.[160, 161] As of the first half of 2024, there are currently more than 2,000 veterinary medicinal products registered in the AMPI.[162]

All veterinary medicinal products in the European Union are governed by Regulation (EU) 2019/6, which is directly applicable in EU member states. The regulation contains provisions on national marketing authorisation procedure as well, which means that the procedure is more or less the same in every member state. In Austria, veterinary medicines are governed by the new Veterinary Medicines Act of 2023, which is directly incorporating provisions of the regulation.[163]

The main difference lies in the fact that veterinary medicinal products have less strict rules when it comes to their testing and, ultimately, their safety and efficacy. Regarding their marketing authorisation, it is valid for an unlimited period of time, as opposed to human medicinal products.[164]

[158] Statistics according to BASG Database of medicinal products registered in Austria (AMPI) [online] [20/6/2024]. Available at: https://aspregister.basg.gv.at/aspregister/faces/aspregister.jspx.
[159] Statistics according to BASG Database of medicinal products registered in Austria (AMPI) [online] [20/6/2024]. Available at: https://aspregister.basg.gv.at/aspregister/faces/aspregister.jspx.
[160] Section 4(1)(1) of Veterinary Medicines Act (BGBl. I Nr. 194/2023) [Translated from German "*Tierarzneimittelgesetz*"].
[161] Website of the Austrian Federal Office for Safety in Health Care [online] [20/6/2024]. Available at: https://www.basg.gv.at/en/about-us.
[162] Statistics according to AMPI. Available at: https://aspregister.basg.gv.at/aspregister/faces/aspregister.jspx [online] [25/6/2024].
[163] Veterinary Medicines Act (BGBl. I Nr. 194/2023) [Translated from German "*Tierarzneimittelgesetz*"].
[164] Section 12(1) of Veterinary Medicines Act (BGBl. I Nr. 194/2023) [Translated from German "*Tierarzneimittelgesetz*"].

3.2 Slovakia

The current rules on marketing authorisation of pharmaceuticals in Slovakia can be found in Sections 44 to 66 of the Act no. 362/2001 Coll. Medicines Act.[165]

In Slovakia, only medicinal products that have obtained marketing authorisation from either the European Commission or the State Institute for Drug Control (ŠÚKL) can be placed on the market.[166]

If we look at the historical legislation for medicinal products in Slovakia, we can find that in relation to marketing authorisation, it mostly regulated the registration of mass-produced medicinal products. This is still true today, although they are no longer called that in the legislation.[167]

Section 46(2) of the Medicines Act contains an exhaustive list of medicinal products (as defined by Sections 2(7) and 2(9) of the Medicines Act) that do not need to obtain marketing authorisation in order to be placed on the market or used in the country for commercial purposes. This applies to individually made medicinal products (in pharmacies, hospitals, etc.), antidotes, investigational medicinal products intended for scientific or research purposes, transfusion medicinal products, and intermediate medicinal products intended for further processing.[168]

The requirements for the application for marketing authorisation of human medicinal products are in Sections 47 and 48 of the Medicines Act. The application is submitted electronically to the ŠÚKL, which performs the scientific evaluation (except in cases of decentralised or mutual recognition procedures where Slovakia is not the reference state) and ultimately decides to either grant marketing authorisation to the medicinal product or refuse the application.[169, 170]

The applicant can be either a natural or legal person and must have a residence or registered seat in the European Economic Area. Each applicant (a pharmaceutical company)

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[165] Sections 44 to 66 of Act no. 362/2011 Coll. on Medicines and Medical Devices (Medicines Act) [Translated from Slovak "*Zákon č. 362/2011 Z. z. o liekoch a zdravotníckych pomôckach*"].
[166] Section 46(1) of Act no. 362/2011 Coll. on Medicines and Medical Devices (Medicines Act) [Translated from Slovak "*Zákon č. 362/2011 Z. z. o liekoch a zdravotníckych pomôckach*"].
[167] *See Chapter 1.3*.
[168] Section 46(2) of Act no. 362/2011 Coll. on Medicines and Medical Devices (Medicines Act) [Translated from Slovak "*Zákon č. 362/2011 Z. z. o liekoch a zdravotníckych pomôckach*"].
[169] Sections 47 and 48 of Act no. 362/2011 Coll. on Medicines and Medical Devices (Medicines Act) [Translated from Slovak "*Zákon č. 362/2011 Z. z. o liekoch a zdravotníckych pomôckach*"].
[170] Website of the Slovak State Institute for Drug Control [online] [24/6/2024]. Available at: https://www.sukl.sk/hlavna-stranka-1/english-version/registration-of-medicinal-product/instructions/submission-of-applications?page_id=6052.

must have a responsible person. This is a person who is responsible for the overview of the medicinal products – their manufacturing, transportation, pharmacovigilance, etc.[171]

The applicant must submit complex documentation relating to the medicinal product seeking to obtain marketing authorisation. This includes administrative facts about the medicinal product, such as its name, labelling, and packaging, as well as scientific information such as when and how was the medicinal product manufactured, its composition, and the complete documentation of pharmaceutical, toxicological-pharmacological, and clinical testing. The ŠÚKL also needs the draft the summary of product characteristics (SPC), the patient information leaflet (PIL), and the proposal for the classification of the medicinal product according to the method of its dispensing (prescription or non-prescription).[172]

After receiving the application with all necessary documentation, ŠÚKL has 30 days to examine whether the documentation is complete. If it is not, the applicant is asked to fix the issue and submit all documentation. The applicant has 180 days to do that, otherwise, the application will be refused.[173]

If the documentation is complete, ŠÚKL now has 210 days to evaluate the medicinal product's properties and decide whether or not to register the medicinal product. The main purpose of the marketing authorisation procedure is to scientifically evaluate medicinal products before they are placed on the market. ŠÚKL will examine the safety, efficacy, and quality of the medicinal product as a part of this procedure. Apart from a scientific evaluation, ŠÚKL examines whether all requirements for good laboratory practice, good clinical practice, and good manufactory practice were met.[174]

Once the ŠÚKL performs the extensive evaluation process, it issues a decision. The decision can be negative if the conditions for safety, efficacy, or quality are not met or if, during the testing and manufacturing process, ICH standards were broken. On the other hand, ŠÚKL may issue a positive decision and grant the applicant marketing authorisation for the medicinal product. Together with the decision, ŠÚKL approves the final labelling and packaging of the medicinal product, the summary of product characteristics (SPC), and

[171] Sections 5, 47(1) and 48(1)(b) of Act no. 362/2011 Coll. on Medicines and Medical Devices (Medicines Act) [Translated from Slovak "*Zákon č. 362/2011 Z. z. o liekoch a zdravotníckych pomôckach*"].
[172] Section 48 of Act no. 362/2011 Coll. on Medicines and Medical Devices (Medicines Act) [Translated from Slovak "*Zákon č. 362/2011 Z. z. o liekoch a zdravotníckych pomôckach*"].
[173] Section 52(1) of Act no. 362/2011 Coll. on Medicines and Medical Devices (Medicines Act) [Translated from Slovak "*Zákon č. 362/2011 Z. z. o liekoch a zdravotníckych pomôckach*"].
[174] Sections 52(1) and 52(2) of Act no. 362/2011 Coll. on Medicines and Medical Devices (Medicines Act) [Translated from Slovak "*Zákon č. 362/2011 Z. z. o liekoch a zdravotníckych pomôckach*"].

the patient information leaflet (PIL) and classifies the medicinal product according to the method of its dispensing.[175]

For certain medicinal products for human use, a simplified marketing authorisation procedure is available. These medicinal products also have lower requirements regarding the documentation that needs to be submitted alongside the application.

Firstly, this is true for generics and biosimilars seeking marketing authorisation. There are already medicinal products with the same or very similar chemical or biological composition placed on the market, which have already undergone a marketing authorisation procedure. This means that for any new generics or biosimilars, less complicated procedure and documentation is needed.[176]

The second type of simplified marketing authorisation procedure is for homeopathic medicinal products. Unlike in Austria, all homeopathic medicinal products in Slovakia must be properly registered with ŠÚKL, but at least it is by a simplified procedure. This is due to the fact that these products are being ingested with the intention to cure the body and, therefore, fall under the legal definition of medicinal products. I believe it is better to have them under control, even though they might not be effective, rather than having uncontrolled substances on the market.[177]

Once the marketing authorisation is granted, the applicant is called the marketing authorisation holder (MAH). Marketing authorisation for a certain medicinal product is valid for a period of five years following its approval. MAH may ask for the authorisation to be extended at least nine months before the authorisation expires. If there are any safety concerns that may become more obvious in the future, ŠÚKL may decide to grant the extended marketing authorisation for another five years. In other cases, however, the extended marketing authorisation is issued without any limitation period.[178]

Other than proper marketing authorisation, Slovakia also has a temporary registration of a medicinal product. The Medicines Act allows the Ministry of Health to grant a medicinal product a temporary exception from the necessity to obtain proper marketing authorisation via national or other procedures. The exception allows the pharmaceutical company to

[175] Sections 53 of Act no. 362/2011 Coll. on Medicines and Medical Devices (Medicines Act) [Translated from Slovak "*Zákon č. 362/2011 Z. z. o liekoch a zdravotníckych pomôckach*"].
[176] Section 49 of Act no. 362/2011 Coll. on Medicines and Medical Devices (Medicines Act) [Translated from Slovak "*Zákon č. 362/2011 Z. z. o liekoch a zdravotníckych pomôckach*"].
[177] Section 50 of Act no. 362/2011 Coll. on Medicines and Medical Devices (Medicines Act) [Translated from Slovak "*Zákon č. 362/2011 Z. z. o liekoch a zdravotníckych pomôckach*"].
[178] Section 53(8) and 53(9) of Act no. 362/2011 Coll. on Medicines and Medical Devices (Medicines Act) [Translated from Slovak "*Zákon č. 362/2011 Z. z. o liekoch a zdravotníckych pomôckach*"].

market its medicinal product in the country for the duration of the temporary registration. The ministry can do so in cases where there is a public health reason. During the COVID-19 pandemic in 2021, the Slovak Ministry of Health allowed the temporary registration and import of the Russian Sputnik vaccine to increase interest in vaccination.[179]

ŠÚKL can not only grant the marketing authorisation to a pharmaceutical company but also suspend or revoke it. After a medicinal product has been placed on the market, ŠÚKL is allowed (and obliged) to perform market controls of medicinal products to ensure everything is in accordance with the law. The pharmaceutical companies and health care workers are also obliged to notify ŠÚKL of any new safety concerns with a certain medicinal product, as well as of any new side effects observed. This is called pharmacovigilance, and it is the basis on which ŠÚKL decides whether a medicinal product is sufficiently safe and efficacious. Marketing authorisation for a certain medicinal product also lapses if the product is not actually marketed in the country within three years of obtaining the authorisation.[180]

3.2.1 Statistics

The national competent authority of Slovakia, the State Institute for Drug Control (ŠÚKL), keeps a database of all medicinal products that have the right to be marketed on the Slovak market. The database includes national marketing authorisations (via all possible procedures) or European marketing authorisation (obtained via centralised procedure). The database is available on the webpage of ŠÚKL.[181]

Around 8,000 medicinal products are currently registered at the ŠÚKL via the national marketing authorisation procedure. More than 9,000 medicinal products have obtained their

[179] Article of the online political news portal Politico.eu [online] [24/6/2024]. Available at: https://www.politico.eu/article/slovakia-approves-russian-vaccine-defying-its-own-regulator/.
[180] Section 56 of Act no. 362/2011 Coll. on Medicines and Medical Devices (Medicines Act) [Translated from Slovak "*Zákon č. 362/2011 Z. z. o liekoch a zdravotníckych pomôckach*"].
[181] Statistics according to ŠÚKL Database of medicinal products registered in Slovakia [online] [24/6/2024]. Available at: https://www.sukl.sk/hlavna-stranka/slovenska-verzia/databazy-a-servis/vyhladavanie-liekov-zdravotnickych-pomocok-a-zmien-v-liekovej-databaze/vyhladavanie-v-databaze-registrovanych-liekov?page_id=242.

marketing authorisation in Slovakia via mutual recognition procedure, where ŠÚKL has recognised the evaluation of the medicinal product of another member state's NCA.[182, 183]

The most used way for registering medicinal products in Slovakia is the decentralised procedure. More than 22,600 medicinal products are currently registered via this procedure. In some cases, Slovakia has been the reference state responsible for the evaluation and preparation of the documentation. Other times, the ŠÚKL has only been the NCA recognising the medicinal product evaluation of a different member state's NCA.[184]

It is important to note that these numbers also include marketing authorisation for multiple different presentations (pack sizes) of the same medicinal product.

3.2.2 National procedure for veterinary medicinal products in Slovakia

The national competent authority for veterinary medicinal products in Slovakia is the Institute of State Control of Veterinary Biologicals and Medicaments (ÚŠKVBL). The ÚŠKVBL is responsible for marketing authorisation of medicinal products for veterinary use, as well as for keeping the database of these medicinal products up to date.[185, 186] The database can be found on the website of ÚŠKVBL. Currently, there are more than 1,300 veterinary medicinal products registered with ÚŠKVBL.[187]

[182] Statistics according to ŠÚKL Database of medicinal products registered in Slovakia [online] [24/6/2024]. Available at: https://www.sukl.sk/hlavna-stranka/slovenska-verzia/databazy-a-servis/vyhladavanie-liekov-zdravotnickych-pomocok-a-zmien-v-liekovej-databaze/vyhladavanie-v-databaze-registrovanych-liekov?page_id=242&lie_nazov=&atc_nazov=&lie_kod=&reg_typ_kod=NAR&atc_kod=&lie_rc=&drz_kod=.

[183] Statistics according to ŠÚKL Database of medicinal products registered in Slovakia [online] [24/6/2024]. Available at: https://www.sukl.sk/hlavna-stranka/slovenska-verzia/databazy-a-servis/vyhladavanie-liekov-zdravotnickych-pomocok-a-zmien-v-liekovej-databaze/vyhladavanie-v-databaze-registrovanych-liekov?page_id=242&lie_nazov=&atc_nazov=&lie_kod=&reg_typ_kod=MRP&atc_kod=&lie_rc=&drz_kod=.

[184] Statistics according to ŠÚKL Database of medicinal products registered in Slovakia [online] [24/6/2024]. Available at: https://www.sukl.sk/hlavna-stranka/slovenska-verzia/databazy-a-servis/vyhladavanie-liekov-zdravotnickych-pomocok-a-zmien-v-liekovej-databaze/vyhladavanie-v-databaze-registrovanych-liekov?page_id=242&lie_nazov=&atc_nazov=&lie_kod=&reg_typ_kod=DCP&atc_kod=&lie_rc=&drz_kod=.

[185] According to Sections 84(1) and 125 of Act no. 362/2011 Coll. on Medicines and Medical Devices (Medicines Act) [Translated from Slovak "*Zákon č. 362/2011 Z. z. o liekoch a zdravotníckych pomôckach*"].

[186] Website of the Slovak Institute of State Control of Veterinary Biologicals and Medicaments [online] [14/6/2024]. Available at: https://www.uskvbl.sk/?page_id=27.

[187] ÚŠKVBL Database of medicinal products registered in Slovakia [online] [24/6/2024]. Available at: https://www.uskvbl.sk/?page_id=319.

Regulation of medicinal products for veterinary use can also be found in the same Slovak legislative act, the Medicines Act. The legal basis for marketing authorisation of these medicinal products are Sections 84 to 98 of the Medicines Act.[188]

For veterinary medicinal products, the same marketing authorisation procedures exist as for human medicinal products. The national procedure for veterinary medicinal products in Slovakia is very similar to the one for medicinal products for human use. The Slovak Medicines Act does not explicitly state the documentation and the procedure that is to be taken in order to obtain marketing authorisation for a veterinary medicinal product. This is due to the fact that all aspects of medicinal products for veterinary use have already been harmonised on the European level by Regulation (EU) 2019/6, and the Medicines Act directly refers to the regulation.[189]

The most notable difference between human and veterinary medicinal products is that the validity of marketing authorisation of veterinary medicinal products is unlimited and does not need renewal as human medicinal product do. Slovak Medicines Act does not contain any provision on the validity of veterinary medicinal product registration, and, therefore, the regulation is applied.[190]

3.3 The comparison of national procedures in Austria and Slovakia

One of the most important aspects of European Union law is its internal market. Although medicinal products are goods like any other, they can have a significant influence on the health of individuals, and, therefore, they need to be regulated more strictly than other goods and services. Finding the right balance between safeguarding public health and ensuring the smooth operation of the internal market has always been the aim of pharmaceutical regulation in the European Union. Years and years of pharmaceutical legislation in the European Union have evolved into the current complex regulation of medicinal products. Most aspects of medicinal products regulation are now harmonised with a number of directives and regulations and unify the rules across all member states, however, some aspects are still in the hands of member states.

[188] Sections 84 to 98 of Act no. 362/2011 Coll. on Medicines and Medical Devices (Medicines Act) [Translated from Slovak "*Zákon č. 362/2011 Z. z. o liekoch a zdravotníckych pomôckach*"].
[189] Section 85 of Act no. 362/2011 Coll. on Medicines and Medical Devices (Medicines Act) [Translated from Slovak "*Zákon č. 362/2011 Z. z. o liekoch a zdravotníckych pomôckach*"].
[190] Article 5(2) of Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC [2019], OJ L 4, p. 43–167.

When analysing the legislation and marketing authorisation procedures in Austria and Slovakia, it is easily noticed that the rules are almost identical. The idea behind allowing the safe functioning of the internal market for medicinal products is that all member states have common rules for their composition and for their registering.

Only the smallest differences could have been noticed between the rules of national marketing authorisation procedures in Austria and Slovakia. Firstly, in Austria, not all homeopathic medicinal products need to be registered with the NCA in order to be marketed in the country. There are some exceptions for homeopathic medicinal products and when they cannot be marketed without proper registration. On the other hand, in Slovakia, every homeopathic medicinal product must undergo a marketing authorisation procedure before its placement on the market.

The most visible difference is in the structure of NCAs in these two countries. In Slovakia, there are two NCAs responsible for marketing authorisation of medicinal products – ŠÚKL for human medicinal products and ÚŠKVBL for veterinary medicinal products. These two institutions perform all activities in connection with medicinal products in the country, from the administrative part of marketing authorisation to the scientific evaluation of medicinal products, to pharmacovigilance. The only exception is the reimbursement of human medicinal products, which belongs to the Ministry of Health.

In Austria, there is only one NCA that performs marketing authorisation of all medicinal products, human and veterinary alike, the BASG. However, this institution does not work alone and only performs the administrative part of the procedure. AGES MEA is the institution responsible for the scientific evaluation of medicinal products in the process of obtaining marketing authorisation. AGES MEA also performs activities of pharmacovigilance (market surveillance) in the country.

These differences are only minor, and it is easily concluded that they are not significant. The harmonisation of European pharmaceutical legislation has significantly influenced the national legislation of member states. Member states do not have free hands in choosing what properties medicinal products entering their market must have. In conclusion, European legislation nowadays rules all aspects of medicinal products in the European Union.

Conclusion

The market for medicinal products in the European Union is largely regulated. Throughout the years, many legislative acts of the European bodies have come in and out of force, and the regulation has only been getting stronger and stronger. Nowadays, the question of the marketing authorisation of medicinal products is almost completely harmonised.

In Austria and Slovakia, legislation regulating medicinal products has existed even before the European legislation had any influence on the legal systems of these two countries. The laws in these two countries have changed throughout the years, and now they are mostly compliant with European legislation.

In the thesis, we discussed the historical evolution of medicinal products legislation in the European Union and in Austria and Slovakia. We could observe that the legislation was constantly becoming more and more complex, reacting to the ever-growing amount of new scientific knowledge.

We analysed all marketing authorisation procedures and found out that decentralised procedure is the most used one. This is most likely due to the fact that it is the most efficient way of registering a medicinal product in multiple member states at the same time. This shows that the internal market of the European Union works for medicinal products just as well as for any other goods or services, even though this area is strongly regulated.

Lastly, we looked at the national legislation and national marketing authorisation procedures in Austria and Slovakia and realised that apart from some little technical details, the legislation and the procedures are very similar. This proves that the European regulation on medicinal products is harmonised at a very high level and leaves only very little to member states to decide.

On the other hand, we demonstrated that national competent authorities gained much more competencies with the evolving legislation, and their position has not been negatively influenced by the harmonisation. Their roles have not been replaced by the European Medicines Agency, and they are trusted with performing difficult scientific evaluations of medicinal products entering the European market.

When we look at the historical tragedies that occurred in Europe and America in the first half of the 20th century, we can conclude that more advanced scientific knowledge and a high level of legislative harmonisation in the field of medicinal products keep not only the internal market safe, but also safeguard the health of all European population.

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