

A REGULATORY AND PRICING DIVERGENCE IN PHARMACEUTICAL MARKETS: EU, SLOVENIA, U.S.

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Abstract This paper examines the chosen aspects, circumstances and frameworks in the field of pharmaceuticals. The Authors first investigate the role of the U.S., Slovenian and the EU bodies that regulate, monitor and supervise the functioning of the pharmaceutical industries. Both, the EU's agency EMA and the U.S.'s administration FDA, try to achieve the same purpose – to establish and maintain public health and safety. With their qualifications and power, they greatly contribute to the quality of medicinal products on both markets. However, there is one big difference between them. That is the power over making the medicines available and the setting of prices. While the EMA and for example JAZMP, the Slovenian competent authority, have the control over this financial aspect, FDA does not. The paper further examines, what are the checks and boundaries for the setting of prices and in this regard, what is regulated within the legislative framework of Slovenia, the EU and the U.S. The fact that health is a fundamental right in EU Member States, but not in the U.S., alone explains the striking divergence in the cost of drugs in the EU as compared to the U.S.

Keywords

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EU and Slovenian legal
framework

1 Introduction

Prior to the turn of the twentieth century most medicines were derived from natural remedies (Cabrera et al., 2026). Indeed, before then there was limited understanding of infectious diseases. That changed drastically in the post-World War II era which was characterized by rapid progress in research and technology (Cabrera et al., 2026). These authors refer to the 1960s as the ‘Golden Age’ of pharmaceutical medicine – a time when there were major advancements in discovery of new drugs together with transformative analytical techniques and pharmaceutical manufacturing that led to the development of numerous ground-breaking medicines “for contraception, mental health, blood pressure regulation, and disease prevention” (Cabrera et al., 2026, p. 11). Scientists in the public and private sectors have continued to build on those early successes in the ensuing decades. Today, the pharmaceutical market is one of the largest in the world: hence, BigPharma. Laurent writes that “the global pharmaceutical industry is on track to reach unprecedented scale, with spending projected to hit approximately \$1.6 trillion by 2025” (Laurent, 2025). The global pharmaceutical companies are concentrated in Europe and the U.S., with the top ten companies accounting for roughly 40% of global pharma sales (Laurent, 2025). This market will continue to grow, and thrive, in the face of both ongoing innovation and the need for pharmaceutical drugs required because of the world’s aging population, outbreaks of pandemics etc. (Laurent, 2025).

The drugs we all use to save and prolong lives, combat misery are generally very safe, at least when used according to manufacturers’ and physicians’ directives. But none of this has happened by accident. The industry has evolved along with stringent oversight of drugs from the research and development stage, through circulation into the market, and indeed during the entire life cycle of the drugs. This article analyzes the functions of the bodies tasked with trying to ensure the highest standards of quality and safety for the public throughout the European Union (hereinafter: EU) and one country in the EU particularly, Slovenia, as well as the United States (hereinafter: U.S.). In the first chapter, we compare and contrast three authorities that regulate, monitor and supervise the medicinal products, one being an authority in the U.S., the second in Slovenia and the third one, the authority for the area of the EU. The remaining chapters explore the pricing of drugs across the EU and the U.S. The U.S. has, by far, the most expensive drugs in the world. Drugs throughout the EU are, in contrast, much less expensive. We will explore the reasons

for this disparity. We conclude that this is the case because while health is a fundamental right in the EU countries such that the government plays a significant role in establishing pricing mechanisms, health is not a fundamental right in U.S. Health care in the U.S. is extremely fragmented, both in terms of the provision of health care itself and drugs. The system is largely privatized, meaning the goal of those developing drugs is primarily to make a profit for themselves and their shareholders. The government has played little role in setting prices, instead yielding to corporations to set their own market prices. The article explores in detail other root causes of the sky-high prices of drugs in the U.S., possible solutions to these causes, along with current developments to lower those prices.

Mainly, this article is a comparative piece and uses the methodologies of both legal and comparative analyses. It circles around the hypothesis that *“compared to the U.S., the EU and its Member States, Slovenia in particular, have structured a better legal framework for the field of Pharmaceuticals, enabling lower drug prices”*, which corresponds with the following research questions: i) has the EU successfully harmonized the field of pharmaceuticals and in any way legally limited the setting of drug prices in the EU Member States; and ii) does the U.S. have a certain legal gap in the legislation or is there some other contingency, which explains the sky-rocketing drug prices in the U.S. Throughout the article, Authors discuss different arguments and aspects of the subject matter and finally, elaborate their findings in the concluding chapter.

2 Comparison Between the FDA and EMA

The pharmaceutical industry, both in the EU and the U.S., is subject to stringent pharmaceutical regulations¹ that are designed to ensure that all drug products meet high safety, efficacy², and quality standards. As we shall see, the principal regulatory bodies that oversee virtually every aspect of the pharmaceutical industry is the European Medicines Agency (hereinafter: EMA) in the EU and the Food and Drug Administration (hereinafter: FDA) in the U.S. The EMA and FDA are similar in that they both work to ensure all drug products meet safety and efficacy standards before they are approved for public use and because they continue to monitor approved

¹ When we refer to regulations, we mean various laws, guidelines, and standards that govern the varied aspects of the pharmaceutical industry, all the way from drug development through to marketing and sales.

² In the context of pharmaceutical drugs, when we refer to efficacy, we mean their ability to produce a desired or intended result.

drugs once they enter the market place through adverse event reporting and periodic reviews, to help ensure that drugs initially approved as safe and effective remain that way. There are also key differences – and we discuss those in section 2.3.

2.1 The Development of the U.S. Authority (FDA)

Pharmaceuticals were not regulated in earnest in the U.S. until the twentieth century. The first federal law concerning consumer protection and pharmaceuticals was the Vaccine Act of 1813³ which was designed to encourage vaccination against smallpox. The Biologics Control Act of 1902,⁴ also known as the Virus-Toxin Law, was the first law implementing federal regulations of biological products such as vaccines. It was enacted in response to two incidents involving the deaths of over twenty children that had contracted tetanus from contaminated vaccines (Milstien, 2004). This Act paved the way for one of the most important pieces of legislation in this field, the Pure Food and Drug Act of 1906.⁵ Its primary purpose was to ban foreign and interstate traffic in adulterated or mislabeled food and drug products. The Act required that the names of active ingredients be placed on the label of a drug's packaging and that drugs could not fall below the purity levels established by the United States Pharmacopeia.⁶ This Act was passed in response to a significant decline in the quality of food in the US in the late 1800s, as the U.S. became more urbanized and because the time it took for food to get from rural farms to cities increased. Food producers often used dangerous preservatives such as formaldehyde to keep food appearing fresh. Likewise, there were serious problems with the quality of drugs at that time as many were addictive and dangerous without actually providing curative effect. Initially, the Act directed the U.S. Department of Agriculture's Bureau of Chemistry to inspect products and to make referrals of any offenders to prosecutors. This department was renamed the U.S. Food and Drug Administration (FDA) in 1930.

³ Vaccine Act of 1813, Pub. L. 12-37, 2 Stat. 806 (1813). This Act was signed into law by President James Madison February 27, 1813, but repealed a mere 9 years later, in 1822, and the authority to regulate vaccines given to the States. Act repealed Pub. L. 17-50, 3 Stat. 677 (1822).

⁴ Biologics Control Act of 1902, Pub. L. 57-244, 32 Stat. 728, Chapter 1378. This Act was signed into law by President Theodore Roosevelt on July 1, 1902.

⁵ Pure Food and Drug Act of 1906, Pub. L. 59-384, 34 Stat. 768, Chapter 3915.

⁶ The United States Pharmacopeia (USP) is a compendium of drug information for the United States published annually for over 200 years. The USP is published in a combined volume with the National Formulary as the USP-NF. If a drug ingredient or drug product has an applicable USP quality standard, it must conform to use the designation USP or NF.

The next major piece of legislation, the Food, Drug, and Cosmetic Act of 1938 (FDCA),⁷ was enacted in response to another national health crisis. A major pharmaceutical company Massengill had released a new antibacterial sulfa drug under the name Elixir Sulfanilamide. Although the drug had undergone various quality and safety tests, when Massengill produced a liquid form of the drug it failed to test the solvent known as diethylene glycol, better known as antifreeze, which adversely affected human kidneys. More than a hundred people, including many children, died after ingesting the drug, before the product was recalled.

The U.S. Constitution⁸ does not provide the federal government with the explicit authority to regulate drugs. However, in this field as in others, the federal government found such power under the Commerce Clause.⁹ The FDCA is a compilation of detailed laws and regulations granting the FDA broad powers to oversee and regulate the production, sale, and distribution of food, drug, medical devices, and cosmetics. The FDA is tasked, *inter alia*, with issuing and enforcing quality standards for food, drugs, medical devices, and cosmetics; inspecting facilities where such products are manufactured, processed, packaged, and stored; recalling and/or seizing products it deems unsafe or not FDCA-compliant; regulating advertising of prescription drugs and medical devices; issuing regulations for product labeling and claims; and approving new drugs, medical devices along with food and color additives.

A key aspect of the FDCA was that it authorized the FDA to require drug manufacturers to submit evidence of new drugs' safety and effectiveness before marketing and distribution to the general public. The FDA performed this aspect of its brief by requiring manufacturers to provide it with what was known as a New Drug Application (NDA).¹⁰ The NDA had to comprise information including the proposed drug's composition, the results of testing on the drug's safety, and how the new drug was manufactured and quality controlled. If the FDA found no reason

⁷ Federal Food, Drug, and Cosmetic Act. June 25, 1938, P.L. 75-717, 52 Stat. 1040, codified into United States Code at 21 U.S.C. §§ 301 *et seq.*

⁸ The Constitution of the United States. National Archives. Retrieved from: www.archives.gov/founding-docs/constitution (accessed: January 14, 2026).

⁹ The Commerce Clause refers to Article 1, Section 8, Clause 3 of the U.S. Constitution, which gives Congress the power "to regulate commerce with foreign nations, among states, and with Indian tribes." As a general proposition, over the years the courts have broadly interpreted this clause so as to allow Congress to regulate activities, such as the pharmaceutical industry, that substantially affect interstate commerce.

¹⁰ Code of Federal Regulations, Title 21 U.S.C. 321; Part 312 'Investigational New Drug Application'.

to object, the NDA was automatically approved within sixty days. Over the decades there have been numerous amendments to the FDCA, too many to cover in this article, so here we mention only a few of the most important. One was the so-called Kefauver-Harris Bill of 1962,¹¹ enacted in response to thousands of children born with congenital disabilities resulting from maternal thalidomide used to combat morning sickness. This law requires drug manufacturers to provide evidence of both the efficacy and safety of new drugs before approval. Additionally, it requires product advertising to disclose drug side effects and prohibits cheaper generic drugs from being marketed as more expensive drugs under new trade names.¹² The 1962 amendments also gave the FDA authority over clinical research and development. They also required new drug sponsors (hereinafter: sponsors) to file what is known as an Investigational New Drug Application (IND) and obtain FDA approval for all investigational studies involving humans.

The investigational new drug application process is rigorous. The sponsors must file the IND before testing a new drug on humans. And before sponsors can file an IND they first must develop detailed information concerning the drug's chemistry to allow it to be produced in batches of known strength and purity. Sponsors must conduct animal studies to enable them to produce information on both the pharmacology and toxicology of the drug. These tests are designed to secure information about the proposed new drug's absorption, distribution, metabolism, and excretion properties (The Kefauver-Harris Bill of 1962). Sponsors must also submit detailed protocols for testing on human subjects. Additionally, since 1971, the FDA has required that all proposed clinical studies be reviewed by an institutional review board (IRB), whose task is to review, approve, and monitor research involving human subjects to evaluate the ethical acceptability and the scientific validity of any such studies.¹³

¹¹ The Kefauver-Harris Bill of 1962, Public Law, 87-781, also known as the 1962 Amendments to the Food, Drug, and Cosmetic Act of 1938, required pharmaceutical firms to wait for FDA approval prior to marketing their product. The FDA by law is supposed to review an NDA within 180 days. However, there are no penalties for the FDA failing to meet this deadline, and in practice it often takes the FDA years to approve an NDA. Read more about it here: American Institute for Medical and Biological Research, no date; Glossary FDAReview.org., no date.

¹² This amendment was a response to the thalidomide tragedy, which led to severe birth defects in thousands of children around the world. The amendment was meant to tighten drug regulation by requiring proof of efficacy in addition to safety, and it mandated that clinical trials be conducted to assess both these aspects. Importantly, this marked a change in regulatory approach by emphasizing the need for rigorous scientific evidence to support drug claims.

¹³ An IRB is formally designated by an institution in which research takes place, such as a hospital or university. The IRB must be comprised of at least five members including at least one scientific member, one nonscientific member, at least one person not affiliated with the research institution, no members with conflicts of interests, both genders,

The IND drug approval stage is broken down into three clinical testing phases.¹⁴ The FDA is heavily involved in each phase of the clinical trial process and has the discretion at any point along the way to request additional clinical trials or to request modifications to the testing protocols. The following is a summary of the three phases. Phase 1 – short-term clinical tests of the proposed drug on twenty to eighty healthy volunteers to determine basic pharmacological and toxicological information in humans, especially as regards safety. The FDA can halt further clinical testing if they deem the drug unsafe after phase one. Phase 2 – consists of small-scale, longer-term tests for efficacy and safety. The proposed new drug is typically tested in one hundred to three hundred patients. Dosage levels are experimented with to find optimal dosage levels, and further information on safety is collected. Phase 3 – consists of large-scale testing for both safety and effectiveness. This phase usually involves testing on between one thousand and three thousand patient volunteers. The FDA uses information developed during Phase 3 to determine whether the proposed new drug satisfies its benefit-risk relationship. Phase 3 is of variable lengths and can take anywhere from several months to several years to complete.

The FDA's role has continually evolved over the decades to adapt to changing technological and public health conditions. Its regulatory framework has set a global standard. Introducing the Current Good Manufacturing Practices Guidelines (CGMP) was a key aspect of its evolution. The FDA web page¹⁵ states that the FDA ensures the quality of drug products by *“carefully monitoring drug manufacturers’ compliance with its CGMP regulations /.../ which contain minimum requirements for the methods, facilities, and controls used in manufacturing, processing, and packing of a drug product. The regulations make sure that a product is safe for use, and that it has the ingredients and strength it claims to have.”* The web page also states that the FDA's approval process for both new and generic drug marketing applications includes a review of the applicants' compliance with the CGMP. The approval process includes assessing whether the firm has the

if possible, among other things. Research cannot begin until the IRB approves. See more at the FDA's official website: [FDAREview.org](https://www.fda.gov/oc/foia), no date.

¹⁴ Code of Federal Regulations, Title 21, § 312.21 'Phases of an investigation'. The regulations governing the process sponsors of a proposed new drug are required to comply with are exceedingly specific and complex. They are also very interesting, but beyond the scope of this paper, which is intended as only a primer. For more, see: Part 312, Investigational New Drug Applications, Retrieved from: Electronic Code of Federal Regulations (2024). Title 21, Chapter I, Subchapter D, Part 312 – Investigational new drug application. U.S. Government Publishing Office. <https://www.ecfr.gov/current/title-21/chapter-I/subchapter-D/part-312> (accessed: September 9, 2025). As of the writing of this article, this title had last been amended 09.04.2025.

¹⁵ Official FDA web page can be found at U.S. Food and Drug Administration, 2025.

necessary facilities, equipment, and ability to manufacture the drug it intends to market. CGMP is mandatory for all pharmaceutical drugs.¹⁶

Two other important U.S. legislative enactments bear brief mention. Congress passed the Orphan Drug Act in 1983.¹⁷ The Act incentivizes the development of so-called ‘orphan drugs’ to treat rare diseases such as cystic fibrosis, amyotrophic sclerosis, and Huntington Disease. Incentives include tax benefits, expedited regulatory reviews, clinical research subsidies, and extended market exclusivity. Before this Act passed, only ten orphan drugs were available for patient use. According to the National Center for Biotechnology Information (2023), as of 2015, the FDA has approved over 550 orphan drugs to treat 227 rare diseases. The second is the Prescription Drug Marketing Act¹⁸ of 1987, which implements a legal framework to help ensure prescription drugs are distributed both safely and effectively. It is intended to establish legal safeguards and discourage the sale of adulterated, misbranded, compromised, and expired prescription drugs. The Act’s introduction was influenced by the growth of the so-called ‘diversion market’, a wholesale submarket for the illegal distribution of prescription drugs (Clinton & Preeti, 2023).¹⁹

¹⁶ FDA’s portion of the Code of Federal Regulations (CFR) is contained in Title 21, which in turn interprets the Federal Food, Drug and Cosmetic Act and related statutes. 21 CFR Part 210 is entitled: Current Good Manufacturing Practice in Manufacturing Processing, Packing, or Holding of Drugs. 21 CFR Part 211 is entitled: Current Good Manufacturing Practice for Finished Pharmaceuticals. 21 CFR Part 600 is entitled: Biological Products: General. Accordingly, we can see that the FDA regulations stringently govern pharmaceutical drugs from the time of application and throughout the entire time an approved drug is sold in the marketplace. 1983 Orphan Drug Act P.L. 97-414.

¹⁷ Orphan Drug Act, Pub. L. No. 97-414, 96 Stat. 2049 (1983). See more also Więckowski, 2021.

¹⁸ Prescription Drug Marketing Act of 1987, P.L. 100-293.

¹⁹ Americans spend an estimated \$60 billion annually on dietary supplements, many of which contain plant-based or ‘botanical’ ingredients and other natural products, and many of which are of questionable benefit (see Pasiakos, 2024). There are over 100,000 different supplements available, and it’s unclear what is safe to take. Notably, the FDA lacks the authority to review dietary supplement products for safety and efficacy before they are marketed, because while we might consider them as a subcategory of medication, the FDA instead regulates them as a subcategory of food under the Dietary Supplement Health and Education Act of 1994 (DSHEA) (Public Law 103-417, found in the U.S. Statutes at Large at 108 Stat. 4325, amending the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §301 *et seq.*) Instead, manufacturers are responsible for ensuring products are safe and accurately labeled, with the FDA only stepping in post-market to address adulteration, misbranding, and adverse events, focusing on stopping false disease claims. In other words, while the FDA plays a very active role in ensuring drug safety and efficacy *before* such drugs can go to market, with supplements the FDA’s oversight largely happens *after* a product is sold, focusing instead on preventing unsafe products and unsubstantiated health claims (e.g., claims to cure or ‘treat’ a disease) (for more, see Berg, 2025).

2.2 The Development of the Slovenian Authority (JAZMP)

There are many aspects of pharmaceuticals, and each has its own beginnings and its own path to progress. Notably, in Slovenia the transfusion pharmacy had already begun in the midst of World Wars I and II. The transfusion service was for the first time organised in 1936 in Yugoslavia, Belgrade (Obreza et al., 2017, p. 11). The field of Slovenian clinical-pharmaceutical law started emerging around 1970. Particularly on the 29th and 30th of May 1970, the Union of Pharmaceutical Societies of Yugoslavia held the Plenary Session in Novi Sad, where the president of the Slovenian Pharmaceutical Society (SFD), Prof. Dr. Franc Kozjek, gave the keynote speech entitled ‘The Pharmacist in the Healthcare Team’, in which he emphasized the role of pharmacists in the current healthcare (Kozjek, 1970, pp. 192-197; Kozjek, 2018, p. 3). Slovenia, however, is one of those EU Member States that had to create a new national administrative body responsible for medicinal products from scratch in the transition period between its independence and accession to the EU (Primožič, 2014). For both political and organizational reasons, and because of the professional challenges that Slovenia encountered during the transition period from 1991 to 2004, the Medicinal Products Commission provided expert support in the administrative review and decision-making process for the authorisation of medicinal products (Primožič, 2014). This body was composed of experts from the medical and pharmaceutical fields and has remained an advisory expert group to this day (Primožič, 2014). The first sectoral negotiations for EU accession began in the late 1990s, and six years later, Slovenia adopted its first law on medicinal products, introducing new categories of medicines, dividing them in groups A (prescription), B (non-prescription), C (herbal), and also included medical devices in category D.²⁰ Later on, the succeeding laws regulated medicinal products and medical devices separately, because the progressively relevant EU guidelines and rules demanded so. While the European *acquis communautaire* had to be incorporated into the legislation on medicinal products, the field of medical devices needed to be treated separately and in accordance with the ‘new approach’ directives (Primožič, 2014). Additionally, Slovenia's accession to the Council of Europe Convention on the Preparation of the European Pharmacopoeia in 1993 was one of the first milestones following this development (Primožič, 2014).

²⁰ Zakon o zdravilih (ZZdr), Official Gazette RS no. 9/1996.

In parallel, the Urad RS za zdravila (Eng. Authority for medicines of RS) was developed, representing the national authority in this field that remained a part of the Ministry of Health until 2007 (Primožič, 2014). Its jurisdiction and duties continued to evolve until it reorganised itself into a sectoral structured, agency called Agencija Republike Slovenije za zdravila in medicinske pripomočke (ARSZMP). The European Commission has simultaneously developed the European Medicines Evaluation Agency (EMA), today known as the European Medicines Agency (EMA). This agency has then ensured the successful implementation of the competent Slovenian authority and of national authorities of other ten candidate countries into the existing and rapidly developing EU regulatory scheme (Primožič, 2014).

Besides the regulation of medicinal products for human use at the national level, ARSZMP also assumed responsibility for regulating medicinal products for veterinary use (Primožič, 2014). Moreover, it assumed responsibility for pharmaceutical supervisory tasks that had previously been under the jurisdiction of the Health Inspectorate of the Republic of Slovenia (Primožič, 2014). Intriguingly, pharmaceutical inspection and pharmacovigilance became key priorities in developing the authority responsible for medicinal products and it remains so at present. While the role of the EMA in regulating medicinal products throughout the EU has expanded over time, these are two aspects of administratively regulating medicinal products that are of particular territorial importance and can only be effectively implemented within the EU framework with the active participation of the national competent authority (Primožič, 2014). Today this agency is called Javna agencija za zdravila in medicinske pripomočke – JAZMP. In connection with its supervisory powers, JAZMP has a direct impact on the operations of most economic entities in the pharmaceutical sector and thus also on the supply of medicines to the Slovenian market and *vice versa*, to the populations of many countries that import medicines produced in Slovenia.

2.3 The Development of EU Authority (EMA)

The EMA, the European counterpart to the FDA, is the central regulatory authority responsible for evaluating, supervising, and monitoring safety of medicines throughout the EU. The EMA was established in 1995, and as with the FDA, is briefed with ensuring that all pharmaceutical products available in the EU also meet

the highest standards of safety, efficacy, and quality. The EMA has an excellent and easy to understand home web page and in particular the subsection entitled ‘Human regulatory’ has a list of drop-down menus that explains how the EMA regulates pharmaceutical drugs from the investigative and approval phase through what it calls the entire human medicines product lifecycle.²¹ Similar to the new applicant process in the U.S., the EMA operates through a centralized new drug approval process. Pharmaceutical companies may submit a single marketing authorization application (MAA) and if approved by the European Commission becomes valid across all EU Member States, as well as Iceland, Norway and Liechtenstein.

The EMA’s Committee for Medicinal Products for Human Use (CHMP) is tasked to conduct rigorous scientific assessments to evaluate both the benefits and the risks associated with proposed new medicines, ultimately guiding the decision on whether a product should be approved for the European market. The EMA home web page provides step-by-step guidelines of how an applicant for a new drug must apply. The marketing authorization section states that assessing a marketing authorization for a new medicine takes up to 210 active days, a period used by EMA experts to evaluate the evidence provided by the applicant in support of a marketing authorization application. During this period the CHMP assessment team may from time-to-time forward questions to the applicant to answer. These question-and-answer periods basically ‘stops the clock’ on the 210-day standard, and overall, assessing a new medicine usually takes around a year.

The EMA also provides continuing scientific and regulatory guidance to pharmaceutical companies whose medicinal products have been authorized in Europe throughout the entire lifecycle of a drug. Known as the post-authorization stage of the product lifecycle, the EMA provides robust information regarding the responsibilities of marketing authorization holders in areas such as pharmacovigilance, applying to vary a marketing authorization, submitting product data to EMA and reporting product defect and recalls. The EMA also collaborates with national regulatory authorities and international bodies such as the FDA to harmonize standards and share critical safety information.

²¹ European Medicines Agency web page can be accessed as follows: <https://www.ema.europa.eu/en/homepage> (accessed: January 14, 2026).

In particular, the tasks and obligations of the EMA are defined pursuant to Regulation (EU) 2022/123, dealing with crisis preparedness and management for medicinal products and medical devices.²² One of the aims of this Regulation is to ensure a strengthened framework to monitor and report on shortages of medicinal products during public health emergencies and major events (Regulation (EU) 2022/123, Recital 58).

EMA establishes different work groups and platforms to facilitate functioning, collaboration and supervision. One of these is the Executive Steering Group on Shortages and Safety of Medicinal Products, known as MSSG. It consists of representatives of the national competent authorities for medicinal products, who as so-called “single points of contact” enable the MSSG to monitor events and preparedness, provide recommendations and even reports on the matter, especially in cases of public health emergencies or major events of such calibre (Regulation (EU) 2022/123, Articles 3, 4, 7 and 8). EU Member States or their competent national authorities are, vice versa, obliged to report to the EMA about the events that are likely to lead to a public health emergency or major event, including actual or potential drug shortages, and to provide the relevant information received from marketing authorisation holders. Such information is not only necessary for the EMA or MSSG for the reasons of preventing some major public health emergency, but also for fulfilling their tasks, such as concluding evaluations of information and with providing recommendations on action in relation to the quality, safety and efficacy of medicinal products as well as crafting lists of critical medicinal products and escorting information (Regulation (EU) 2022/123, Articles 5 and 6).

In order to fulfil the tasks previously referred to, EMA provides a detailed list of working methods and information on medicinal products in accordance with the Article 9 of the Regulation (EU) 2022/123 (Regulation (EU) 2022/123, Recital 58), including some of the previously mentioned obligations, such as creating MSSG and appointing single points of contact for each EU Member State. However, the EMA is not the only party with such obligations and tasks - national authorities and authorisation holders are given their duties too. If requested for the relevant information, the marketing authorisation holders must share it by the given

²² Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices PE/76/2021/REV/1, OJ L 20, 31.1.2022.

deadlines, through the single points of contact, and by using the monitoring and reporting methods and systems previously referred to (Regulation (EU) 2022/123, Article 9, para. 2). Pursuant to the Article 10 of the Regulation (EU) 2022/123, marketing authorisation holders for medicinal products that are authorised in the EU area are obliged to provide the relevant information electronically and update it when that is deemed necessary. For the purposes of monitoring medicinal products from the critical medicines' lists, EMA has the authority to request marketing authorisation holders to provide the relevant information via single points of contact (Regulation (EU) 2022/123, Articles 9 and 10). In case of a failure to provide any information requested, or if there is a delay in providing it by the deadline set by the Agency, marketing authorisation holders must give a proper justification (Regulation (EU) 2022/123, Article 9, para. 3). If any relevant actor in the supply chain for medicinal products possesses any information regarding an actual or potential shortage of medicinal products, they are bound to immediately share such information with the EMA (Regulation (EU) 2022/123, Article 9, para. 5). Likewise, EU Member States have similar obligations to EMA as authorisation holders. For instance, EMA may request the EU Member State to submit the set of information or even data on volume of demand and demand forecasts in the same way as the authorisation holders;²³ indicate the existence of any commercially confidential information; explain why certain information is of a commercially confidential nature; and explain the basis for any failure to provide requested information (Regulation (EU) 2022/123, Article 11, para. 1).

Wholesale distributors and other persons or legal entities that are authorised or entitled to supply medicinal products included on the critical medicines lists to the public shall provide that Member State with relevant information and data, including information and data on the levels of stock of those medicinal products at the request of that Member State. Member States are also obliged to notify MSSG whenever it has knowledge of medicines shortages. Additionally, because of the importance and severe damage medicines shortages may have, and to facilitate monitoring and communicating these issues, the EMA has established the European shortages monitoring platform (hereinafter: ESMP). ESMP is used to facilitate the collection of information on shortages, supply, and demand for medicinal products,

²³ In the same way – meaning, through the single point of contact while using the reporting methods and systems previously referred to.

which includes the information on whether the medicinal product is placed or ceases to be placed on the market in a particular Member State (Regulation (EU) 2022/123, Article 11, para. 1).²⁴

While the EU pharmaceuticals framework with EMA's guidance is already very comprehensive, it does not primarily focus on the rules of launching a medicine on the market. In this regard, many preliminary steps must be taken on the national level before the national authorities. In accordance with Slovenian and many other legislations, medicinal products must attain marketing authorisation before their actual placement on the market. The procedure for granting marketing authorisation starts with an application submitted by a legal entity or natural person established within the borders of the European Economic Area. There are different procedures, according to which such marketing authorisation can be achieved, namely national procedure, mutual recognition procedure (also called decentralised procedure), or centralised procedure.²⁵

At this point, it may become clear why separating 'medicinal products' and 'medicinal devices' is of such importance. Devices are not subjected to the complex procedures and marketing authorisation that medicinal products are, which is why regulations carefully separate the jurisdiction and rules for medicinal devices from those of medicinal products. In a recent judgment of the case C-589/23²⁶, the Court of Justice of the European Union (CJEU) clarified this delicate border between regulatory qualifications for the two and with that, impacted both sectors (Anonymous, 2025). The case revolved around two German life science companies, dealing with the sale and promotion of a medicinal product, which was promoted as a medical device that prevents or tries to prevent cystitis and other urinary tract infections. A German association, Verband Sozialer Wettbewerb (VSW), which was advocating for fair competition within the local market, complained about the qualification of this product. The VSW claimed the product these companies are selling should be qualified as a medicinal product, not as a medical device, which translates to the fact that they would be required to obtain marketing authorisation, but then, of course, they did not have it. While the first and the second instances of

²⁴ For more, see the official website of JAZMP: <https://www.jazmp.si> (accessed: September 6, 2025).

²⁵ JAZMP, Obtaining Marketing Authorisation, Official page of JAZMP: <https://www.jazmp.si/en/human-medicines/regulatory-information/marketing-authorisation/> (accessed: September 10, 2025).

²⁶ *Cassella-med GmbH & Co.KG and MCM Klosterfrau Vertriebsgesellschaft mbH v Verband Sozialer Wettbewerb eV*, C-589/23, of the date March 13, 2025, ECLI: ECLI:EU:C:2025:173.

German courts agreed with the VSW, the Federal German Court of Justice referred the matter to CJEU, asking for clarification of the definition of the term ‘medicinal product’. The CJEU held that the products in dispute work mainly through a pharmacological effect, which could mean reclassifying the device as a medicinal product. The already invalidated EU Community Code²⁷ defined the term “medicinal product” broadly, as a product, which includes any substance that can restore, correct or modify physiological functions through pharmacological, immunological or metabolic actions. Even though this Code was invalidated with a directive, the CJEU nevertheless reinforced its broad interpretation purposely for safeguarding the goals of the European pharmaceutical legislation, in particular health and safety. The CJEU also reasoned that interpreting the term too narrowly would contravene previous EU court decisions. This decision coincides with the ongoing revision of the Community Code, which aims to integrate new definitions into EU legislation including drug-device combinations and combinations with a product other than a medical device (Anonymous, 2025).

2.4 The Comparison Between the FDA and EMA at a Glance

Although the FDA and EMA share common traits, there are still differences. The FDA follows a more centralized approach, where it directly manages all drug approvals and regulations. The EMA, on the other hand, since it serves the EU, coordinates with various national regulatory agencies across the EU Member States, using a centralized process for high-impact drugs, and a decentralized process for others, involving national agencies. Another key difference is that while the FDA places a strong emphasis on post-market surveillance through its Risk Evaluation and Mitigation Strategies (REMS) program, the EMA focuses heavily on pharmacovigilance²⁸ across the EU. The following chart provides an excellent summary of the important differences between roles played by the FDA and EMA.²⁹

²⁷ Community code relating to medicinal products for human use (OJ 2001 L 311, p. 67), as amended by Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 (OJ 2004 L 136, p. 34) (‘Directive 2001/83’).

²⁸ Pharmacovigilance, also known as drug safety, is the pharmaceutical science relating to the collection, detection, assessment, monitoring, and prevention of adverse effects with pharmaceutical products. This is explained in the EMA home web page.

²⁹ We discussed the U.S. Orphan Drug Act in connection with the timeline of key pharmaceutical legislation in the U.S. Similarly, the EMA has a detailed section on its home page that discusses that same topic: Orphan designation: post-authorisation. As with the U.S. Orphan Drug Act, EU law provides various orphan status incentives, referred to as ‘protocol assistance’ a form of scientific advice specifically for orphan medicines.

Table 1: Key Differences Between FDA and EMA

Aspects	FDA (U.S. Food and Drug Administration)	EMA (European Medicines Agency)
Regulatory Scope	Regulates pharmaceutical products within the United States.	Oversees drug regulation across the European Union.
Approval Process	Centralized process; all drug evaluations and approvals managed by the FDA.	Hybrid process: centralized process for high-impact drugs; decentralized for others.
Review Process	Direct, continuous communication with companies during the review process.	More formal, structured communication primarily through CHMP.
Post-Market Surveillance	Emphasizes the REMS (Risk Evaluation and Mitigation Strategies) program.	Focuses on EU-wide pharmacovigilance and monitoring of drug safety.
Labeling Requirements	Strict, detailed labeling requirements specific to the U.S. market.	Labeling must accommodate multiple languages and EU healthcare systems.
Collaboration	Primarily focused within the U.S. but collaborates internationally.	Actively collaborates with international bodies like the FDA for harmonization.

Source: The Ultimate Guide to Pharmaceutical Regulations – Compliance & Standards (Adgros Pharma, no date)

3 Establishing Pharmaceutical Drug Prices in the U.S. and Europe – a Comparative Analysis

3.1 Brief Overview of Drug Pricing Worldwide; Drug Pricing in the U.S. and Discussion of Why Americans Pay So Much for Drugs; Possible Solutions to the Problem

Elsewhere, your American author has sarcastically written about areas where the U.S. can boast of extreme exceptionalism: the highest incarceration rate in the world; the greatest number of guns in the world; the highest rate of homelessness (Heller, 2024). Relevant to this article, we can add to this rather ignominious list that it also boasts paying the highest costs for prescription drugs and the highest per capita expenditure on pharmaceuticals in OECD countries. And the others are not even close.

In February 2024, the Assistant Secretary for Planning and Evaluation (ASPE), U.S. Department of Health & Human Services issued a report entitled “Comparing Prescription Drugs in the U.S. and Other Countries: Prices and Availability” (Assistant Secretary for Planning and Evaluation (ASPE) U.S. Department of Health

& Human Services, 2024). The ASPE contracted with RAND Health Care to perform three studies analyzing data on U.S. prescription drug prices and availability in comparison to drug prices and availability in other Organization for Economic Co-operation and Development (OECD) countries. The study yielded the following key findings.³⁰ In 2022, U.S. prices across all drugs (brands and generics) were nearly three times as high as prices in 33 OECD comparison countries. For every dollar paid in other countries for drugs, consumers in the U.S. pay \$2.78. And even worse news is that this gap continues to widen over time as the prices of drugs in the U.S. continue to grow faster than drug prices in other countries.

Analyzing prescription drug statistics from 2025, Single Care (SingleCare Team, 2025) reports that in the U.S. and indeed around the world, prescription drug use continues to rise. In the U.S., national and per capita spending on prescription drugs has risen significantly over the last several years and is likely to continue on that upward trajectory (SingleCare Team, 2025). There were 6.7 billion total prescriptions written across the U.S. in 2022, up from 6.1 billion in 2018 (SingleCare Team, 2025). 61% of Americans reported currently taking at least one prescription medication, and 27% reported taking four or more. The therapeutic areas with the highest spending in the U.S. are antidiabetics, oncologic, autoimmune, and respiratory diseases (SingleCare Team, 2025). Pharmaceutical spending increased 13.6% from 2022 to 2023, hitting \$722.5 billion total. The prices of 4,264 medicines increased between 2022 and 2023 (SingleCare Team, 2025). Pharmaceutical companies launched new drugs in 2023 at prices 35% higher than in 2022 (SingleCare Team, 2025). The average out-of-pocket prescription drug spending is \$1,432 per capita (SingleCare Team, 2025). Around three out of every ten Americans surveyed have reported skipping doses, foregoing refills, or substituting an over-the-counter medication because of high prices (SingleCare Team, 2025).

McCay (2024) gathered example prices for a range of common medicines from ten different nations and compared their prices. McCay's findings confirm that the U.S. indeed can boast of exceptionalism when it comes to the exorbitant costs of prescription drugs. McCay states, the "USA is the most expensive country for prescription medication by a country mile" (SingleCare Team, 2025). McCay gave the stark example of Viagra. This commonly prescribed drug for men costs a

³⁰ The ASPE study used 2022 data.

staggering US\$2,771.36 for a box of a mere 30 tablets in the U.S. while Canada was the second most “expensive” coming in at US\$115.62. The following chart, compiled by McCay, compares the costs of twelve commonly prescribed drugs among the ten countries examined.

Table 2: Example cost of selected medicines across the world

Branded Drug	Australia	USA	Canada	France	UK	South Africa	Portugal	Sweden	Finland	Mexico
Viagra	\$38.70	\$2,771.36	\$115.62	\$287.76	\$12.77	\$21.81	\$40.83	\$41.27	\$46.88	\$18.99
Lyrica	\$16.62	\$648.87	\$72.30	\$25.62	\$12.77	\$16.15	\$20.12	\$73.68	\$20.70	\$130.93
Lipitor	\$14.12	\$1,761.02	\$101.15	\$4.27	\$12.77	\$1.73	\$3.55	\$28.25	\$21.66	\$24.99
Ventolin	\$20.12	\$33.42	\$78.72	\$8.31	\$12.77	\$2.14	\$6.74	\$6.16	\$4.21	\$25.00
Zithromax	\$5.16	\$103.55	\$68.41	\$8.00	\$12.77	\$7.04	\$6.23	\$8.31	\$10.22	\$5.63
Lantus	\$21.17	\$77.16	\$185.95	\$41.73	\$12.77	\$6.84	\$64.10	\$51.31	\$35.89	–
Prograf	\$21.17	\$765.98	\$116.57	\$157.13	\$12.77	\$205.15	\$26.11	\$251.49	\$240.04	\$388.99
Yasmin	\$18.98	\$416.38	\$127.79	\$0.00	\$12.77	\$5.25	\$12.30	\$22.94	\$37.20	\$65.99
Prozac	\$21.17	\$1,503.55	\$120.97	\$2.39	\$12.77	\$2.07	\$15.17	\$11.47	\$6.33	\$198.68
Xanax	\$18.52	\$96.30	\$75.81	\$1.79	–	\$1.38	\$1.22	\$4.57	\$1.95	–
Zestril	\$17.35	\$423.00	\$81.56	\$3.46	\$12.77	\$1.73	\$15.37	\$6.47	\$4.34	\$38.99
Vircead	\$21.17	\$1,329.44	\$151.45	\$245.63	\$12.77	\$16.02	–	\$735.93	\$292.46	–

Source: Cost of Insulin by Country 2025 by the World Population Review (Anonymous, no date-a)

World Population Review (Anonymous, no date-a) investigated the cost of insulin (SingleCare Team, 2025)³¹ in 32 western countries. The United States came in ‘first place’ with the cost at \$98.70. Chile came in a distant second, at \$21.48. At only \$2.64, insulin in Turkey was the cheapest. Slovenia was twenty-seventh on the list, with insulin costing only \$7.43. Austria was twenty-second on the list - \$7.92 while Germany was in seventh place, with the cost at \$11.

There is simply no denying that Americans, using President Donald Trump’s favorite line when defending his tariff policies, are indeed being ‘ripped off’ by the pharmaceutical companies with the ever-increasing and exorbitant prices they charge U.S. consumers for the drugs they produce. But the question is, why is this the case? Why does Xanax, a commonly prescribed anti-anxiety medication, cost \$96.30 in the U.S. as compared to \$1.79 in France? Why does Lipitor, another commonly prescribed medication to treat high cholesterol, cost an astounding \$1,761 in the U.S.

³¹ Insulin is a hormone, made by the pancreas, which enables the body's cells to absorb sugar (glucose) from the bloodstream and consume it for energy. Roughly 10% of the world's population suffer from diabetes, a condition caused when the body's ability to produce and utilize insulin is disrupted (Anonymous, no date-a). Diabetes caused 6.7 million deaths in 2021. *Ibid.* Type-1 diabetes, in which the pancreas fails to produce enough insulin, can usually be treated by injecting man-made insulin. However, insulin drugs (as with all other drugs) are of no value if they are so expensive that persons suffering from Type 1 diabetes are unable to afford them. Insulin prices skyrocketed in the U.S. over the past two decades and continue to rise. The cost of a one-month supply of the insulin Humalog cost \$21 in 2006, but \$275 in 2010 – a 1200% increase, while actual inflation during that same period was only 63.67%.

and only a paltry \$3.55 in Portugal? To try to get answers we turned to the transcript from a March 23, 2021, United States Senate hearing before the U.S. Subcommittee on Primary Health and Retirement Security of the Committee on Health, Education, Labor, and Pensions. The topic was Why the U.S. Pays the Highest Prices in the World for Prescription Drugs (hereinafter: Senate Hearing, 2021).

Bernie Sanders, a senator from Vermont since 2007, and one of the standard-bearers of the modern American progressive movement, was the chairman of the hearing. The Committee heard testimony from several experts including Dr. Aaron Kesselheim, a professor of medicine at the Brigham and Women's Hospital and Harvard Medical School; Dr. Nav Persaud, who is the Canada Research Chair in Health Justice at the University of Toronto; and, Alex Brill, a research fellow at the American Enterprise Institute. This section of our article draws heavily upon testimony provided at the hearing.

The Constitution of the Republic of Slovenia, in Article 51, guarantees the right to healthcare, with the specific conditions and access to public funding determined by law. Article 35 of the EU Charter of Fundamental Rights guarantees access to preventative healthcare and medical treatment under national laws and mandates a high level of human health protection in all EU policies. The World Health Organization's Constitution also recognizes the right to health and other health-related human rights. These are legally binding commitments enshrined in international human rights instruments. In the U.S., by contrast, the Constitution does not guarantee citizens the right to health. Americans are essentially left to their own devices to care for their health. The entire healthcare system is, with some limited exceptions, privatized. Senator Sanders, and many others of his political persuasion, have bemoaned this situation. Senator Sanders has long advocated legislating measures that would provide Americans with a more robust safety net, along the lines of many European countries. Included in that net would be things as seemingly basic as universal health care, free or certainly cheaper higher education, a higher minimum wage, paid time off for pregnant women, affordable housing for all, and as it relates to this article, much more affordable prescription drugs.³² In his

³² For more information about it, see a recent book by Sanders entitled "It's OK to be Angry About Capitalism" (2024). In his book, Sanders discusses that while the U.S. Constitution and Bill of Rights (collectively, the first ten Amendments to the Constitution) guarantee Americans the right to vote, to express opinions, to assemble, and other important political rights, "*they do not guarantee us the right to a decent job, health care, education, food and shelter. They do not guarantee us the right to basic necessities that allow human beings to live decent and secure lives.*" After then referencing

opening statement Sanders laid bare the main obstacle to reducing the high costs of prescription drugs, and one that frankly may be impossible to overcome: the virtually unlimited political “donations” that the Supreme Court gave its explicit imprimatur to in *Citizens United v. Federal Election Commission*.³³ There, in a 5-4 decision, the Court found, in reviewing campaign finance laws, that any laws restricting the political spending by corporations are inconsistent with the Free Speech Clause of the First Amendment. Conservatives saw this as a resounding victory for ‘free speech’ while others, generally progressives, saw it as a defeat for common sense and victory for special interest groups.

Pulling no punches, here is what Sanders said in his opening remarks: “*There is an interesting debate among the people in this Country about which powerful special interest has the most clout on Capitol Hill. Some people think it may be Wall Street. Some people may think it’s the military-industrial complex. Some people think it’s the fossil fuel industry. I myself may be wrong, but I would give the nod to the pharmaceutical industry, an industry which charges the American people, by far, the highest prices in the world for prescription drugs and has managed to create a situation where they can raise their prices to any level they want any day of the week*” (Senate Hearing, 2021, p. 1). He was not done. “*Drug companies are an industry which year after year make huge profits, and they pay their CEOs incredibly large compensation packages. It is an industry which is significantly responsible for the fact that in the United States we pay the highest prices in the world for health care, almost double what any other country pays*” (Senate Hearing, 2021, p. 1). Sanders also pointed to corruption in industry. “*This is an industry that has paid \$32 billion in fines for a variety of illegal actions over the last 20 years, including price fixing, overcharging Federal, state, and local governments for their products, bribery, collusion, fraud, and deception. And yet, this is an industry which keeps on its merry way virtually untouchable, year after year*” (Senate Hearing, 2021, p. 2).

Returning to the theme of the *Citizens United* Court giving donors the unfettered green light to make unlimited “campaign contributions” and the problem of lobbyists Sanders was very blunt. “*Now, how do they get away with that? And it is not hard to understand. During the last 23 years, the drug companies have spent \$7.6 billion on lobbyists /.../ They have more than 1,500 lobbyists here in Washington [while there are 435 Members of*

President Franklin D. Roosevelt’s proposed Economic Bill of Rights (which never came to fruition), and his proclamation that, “*True individual freedom cannot exist without economic security and independence,*” Sanders goes on to state “*Roosevelt was right when he made that statement almost eighty years ago, and the principle remains true today. Economic rights are human rights, and true freedom cannot exist without those rights.*” *Ibid*, pp. 11-12.

³³ *Citizens United v. Federal Election Commission*, 558 U.S. 310 (2010).

Congress] /.../ as well as lobbyists in virtually every state capital in this Country. Since 1990 they have spent nearly \$730 million on campaign contributions which have gone to many, many hundreds of Members of Congress, including both political parties” (Senate Hearing, 2021, p. 2). Sanders bemoaned the fact both political parties have failed to summon up the courage to “take on” the pharmaceutical industry and asserted “it is not Congress which regulates the drug companies but the drug companies which regulate Congress, and that has got to change” (Senate Hearing, 2021, p. 2). While many Americans are getting sick or dying because they cannot afford the cost of drugs Sanders cited statistics for the profits of those companies. “[N]ine large drug companies made over \$58 billion in profits last year /.../ while just six pharmaceutical industry CEOs made \$564 million in total compensation over the past 3 years” (Senate Hearing, 2021, p. 2).³⁴

Many Americans live on the margins of being bankrupt and too many still do not have the necessary insurance to pay for the drugs they need to either live a quality life or to stay alive. Testimony from the Senate Hearing chronicles some of the horrendous stories. They are in equal measure both very sad and outrageous, especially when one stops to consider that, as Sanders says, it does not have to be this way. Sanders offers an example of Type 1 diabetes. In 2018, one out of every four Americans suffering from this disease were forced to ration insulin because they could not afford it. Insulin was invented over a century ago by Canadian scientists. Despite being an ancient drug, its price has increased over 300% in the last decade. Sanders stated that with just a short drive to Canada from his Vermont home one can purchase insulin ‘at about one-tenth the price’ Americans pay (Senate Hearing, 2021, p. 3). Citing a Rand study, Sanders stated that “a standard unit of insulin costs \$98 in the United States, \$12 in Canada, \$11 in Germany, \$9 in France, \$7.52 in the UK, and \$6.94 in Australia” (Senate Hearing, 2021, p. 3). He cited similar statistics for the drugs Entocort, used to treat Crohn’s disease, Flovent Diskus, an asthma inhaler, and EpiPens used to treat allergic emergencies.

Kesselheim³⁵ framed his testimony as follows. “We’re here today because the U.S. spends far more on drugs per capita than any other industrialized nation, over \$1,200 in 2018, while the

³⁴ According to NY Requirements – Blog, The revenue of the worldwide pharmaceutical market in 2022 reached \$1.4 trillion. The three largest pharma companies by annual profit were: Pfizer - \$31.17 billion; Johnson & Johnson - \$17.94 billion; and Merck - \$14.52 billion (Tortorice, no date).

³⁵ Dr. Aaron Kesselheim is a physician, attorney, and medical researcher. He is a Professor of Medicine at Harvard Medical School and a faculty member in the Division of Pharmacoepidemiology and Pharmacoeconomics in the Department of Medicine at Brigham and Women’s Hospital. He created and led the program on regulation and an

OECD average was less than \$600. U.S. prices are primarily driven by spending on brand-name drugs, most of which have been on the market for many years, during which time they're subject to astonishing price increases" (Senate Hearing, 2021, p. 6). Kesselheim offered three primary reasons for this disparity and their solutions. The first two problems were alluded to by Senator Sanders while the third were not. The first problem is that the U.S. permits drug makers to set prices after FDA approval at any level they wish and then require Medicare³⁶ and Medicaid³⁷ to pay regardless of the drug's clinical utility. Second, drug manufacturers can raise those prices each year beyond inflation. The third problem is that drug manufacturers have found ways to game the patent mechanisms. They "*extend their patent-protected market exclusivity by building a thicket of dozens or even hundreds of patents to delay generic entry. Other industrialized nations, even some states and payers in the U.S., have strategies that address these issues*" (Senate Hearing, 2021, p. 6).

Kesselheim offered three principal strategies to help address the problem of excessive drug prices. The first is to, what he calls, 'evaluate and negotiate'" (Senate Hearing, 2021, p. 6). He points to what the U.S. Defense Department does when purchasing weapons and what other countries, such as Germany, does when purchasing drugs. This process, called 'health technology assessment', begins once the regulatory agency (here FDA) approves a new drug, and involves an independent organization whose task is to determine a fair price based on how well the new drug performs against other available treatments, that is, its efficacy. He explains, "*only if a drug provides more benefit to patients should it cost more than other options. The U.S. needs to establish a publicly funded body that would determine a price for a drug based on its clinical benefit*".³⁸

interdisciplinary research program focusing on prescription drugs and medical devices, patient health outcomes, and regulatory practices and the law. He has authored over 450 publications in peer-reviewed medical and health policy literature.

³⁶ Medicare is a federal health insurance program for people of the age of 65 or older and younger people with disabilities, established in 1965. Not all persons over 65 are covered by Medicare. Many must look for health insurance in the private market; and some have no health insurance at all.

³⁷ Medicaid, as distinguished from Medicare, is a government program that provides health insurance for adults and children with limited income and resources. The program is partially funded and primarily managed by the State governments which have wide latitude in determining eligibility and benefits, though the federal government sets baseline standards for State Medicaid programs and provides a significant portion of their funding. All States have participated in the program since 1982.

³⁸ He observed that the States of New York and Massachusetts have initiated this kind of review process for their Medicaid programs.

His second proposed strategy is to proscribe or limit drug price increases. He pointed to the drug Gleevec³⁹ as an example of a situation where there had been obnoxious price increases. The drug was introduced in the U.S. in 2001 for a list price of \$26,000 a year and increased to more than \$120,000, a nearly 500% increase, by 2016. Governments of other countries, in contrast, reach agreements with (i.e., negotiate) payers and manufacturers to restrict price increases.

Dr. Kesselheim's final proposal is to reform the problems arising from what he terms 'patent thickets'.⁴⁰ That is, he asserts that generic or biosimilar drugs' entry into the marketplace too often are thwarted in the U.S. due to patent thickets covering trivial attributes of the drug (Senate Hearing, 2021, p. 7). Currently, brand-name manufacturers can delay generic entry by obtaining numerous patents, many of them for trivial changes, and then leverage them to introduce new formulations with only minor clinic effects that can forestall direct competition (Senate Hearing, 2021, p. 19). Reforming this aspect of patent law concerning drugs, in turn, would allow a "more efficient transition to a competitive market" (Senate Hearing, 2021, p. 19). Although the government provides about 6-7 years of guaranteed generic-free marketing periods for new brand-name drugs under the Hatch-Waxman Act of 1984,⁴¹ a study by his research team found that patents actually provide 13-17 years of market exclusivity for some new brand-name, small-molecule drugs, and even more for biological products, keeping much less expensive generic manufacturers from the market long after the exclusivity period ends. The patent system should be reformed to ensure a competitive market once a drug's basic period of patent-provided exclusivity ends. This is necessary to prevent the current practice of drug companies from obtaining numerous extra patents to extend their monopoly powers for years longer than originally expected, often for clinically trivial changes. This patent manipulation has allowed companies to move market share to their newer

³⁹ Gleevec, also known as Glivec, is an anticancer medicine.

⁴⁰ A patent thicket is a dense and overlapping set of patent rights that makes it difficult for competitors to develop or commercialize new technologies without infringing on existing patents. These thickets are often created strategically by companies to prolong their market monopoly, increase prices, and deter competition, particularly in industries like pharmaceuticals, biotechnology, and digital communications. They are used to hinder innovation and access to cheaper alternatives.

⁴¹ The Hatch-Waxman Act, Public Law 98-417, formally known as the Drug Price Competition and Patent Term Restoration Act of 1984, is a federal law that established the regulatory framework for generic drugs and restored some patent time to pharmaceutical innovators. It allows for an abbreviated drug approval process through Abbreviated New Drug Applications (ANDAs) and includes market and patent exclusivities for both brand-name and generic medications. The Act also provides for patent term extensions and can trigger a 30-month stay of generic approval during patent litigation. The Act's two main goals were to facilitate entry of generic drugs into the market and to compensate the original drug developers for regulatory delays by the FDA.

product formulations even if these offer limited or even no clinical advantages but can be sold at higher prices.

Persaud,⁴² in striking a defiant tone similar to that of Senator Sanders, lamented that the U.S. has over the years failed to have the strength to stand up to the ‘pharmaceutical companies that rip off Americans’” (Senate Hearing, 2021, p. 21). He offered three ways the U.S. can lower drug prices while promoting access and equitable care. First, he would create a new bureau to set price ceilings for patented medicines, give that bureau the resources and teeth to keep prices low, and empower that bureau to issue compulsory licenses when companies price patented medicines unreasonably. He contends this bureau should be able to cut annual spending by at least \$100 billion. He would also use negotiating power and open tendering processes to secure low prices on a defined set of essential medicines in accordance with international guidance. Lastly, he would use existing legislation and additional political will to discipline the companies currently bloated by high medicine prices that illegally market products (Senate Hearing, 2021, p. 23).

Finally, we want to highlight recommendations offered by Alex Brill.⁴³ *“Congress should protect the intent of existing law but pursue improvements to facilitate more competition, curtail overly long monopolistic periods for brand drugs, and promote the approval of new innovative medicines to compete with existing brand drugs. Finally, biosimilars⁴⁴ have shown initial success and cost savings in the U.S. market, and a more robust biosimilar market should be encouraged”* (Senate Hearing, 2021, p. 35). In his oral testimony, Brill said he also agrees that so-called patent thickets and related patenting strategies have stifled innovation and have effectively blocked access to more affordable biosimilars (Senate Hearing, 2021, p. 35). While acknowledging that there had been past legislative attempts to deal with this serious problem, Brill urged legislators to stay focused on legislative reforms that would simultaneously protect drug manufacturers’ legitimate core

⁴² Dr. Nav Persaud is the Canada Research Chair in Health Justice, Staff Physician in the Department of Family and Community Medicine at St. Michael’s Hospital in Unity Health Toronto, and Associate Professor in the Department of Family and Community Medicine at the University of Toronto.

⁴³ Alex Brill is a senior fellow at the American Enterprise Institute, where among other things, he studies health care reform, pharmaceutical spending and drug innovation.

⁴⁴ Biosimilar drugs are complex biological medicines that are developed to be highly similar to an already-approved original biological medicine, known as the reference product. They are not identical copies but are proven through rigorous scientific review to have no clinically meaningful differences from the reference product in terms of quality, safety, and effectiveness. The benefit of biosimilars is that they increase access to treatments, foster competition, and offer better value in healthcare systems by expanding the availability of essential biological therapies, according to organizations such as the American Cancer Society and World Health Organization.

patents and appropriate patents while at the same time blocking or preventing the ability of innovators to stack patents on top of each other and create, undue, unnecessary, excessive monopoly powers for their products.

In the U.S., so-called direct-to-consumer pharmaceutical advertising (DTCA) also has played a major role both in proliferating drug use (mainly brand names) and in their sky-rocketing costs. As its name implies, DTCA, which has been in existence in the U.S. for as long as prescription drugs have been for sale, started to accelerate in the 1980s due to a combination of factors, including a rise in patient proactiveness in medical decision making, a political environment that favored deregulation, and 1985 FDA guidance establishing the form in which a brief summary of risks associated with prescription drugs could be provided in print media (Wang & Kesselheim, 2013). In the late 1990s, the FDA further scaled back what drug manufacturers were required to disclose in advertisements about their drugs' side-effects. The FDA only required them to provide side effect profiles called 'major statements' as long as sources for more complete information (e.g., a concurrent print advertisement or a toll-free number) were identified (Wang & Kesselheim, 2013). After this regulatory change, pharmaceutical DTCA spending accelerated dramatically, increasing from less than \$1 billion in 1997 to \$5.4 billion in 2006 (Wang & Kesselheim, 2013). A complete analysis of DTCA is beyond the scope of this article. Suffice it to say here that DTCA has generated substantial controversy. On the one hand, DTCA has helped educate patients and perhaps encouraged them to take a more active role in their care (Wang & Kesselheim, 2013). On the other hand, pharmaceutical companies use DTCA, increasingly on digital platforms, to promote brand name, high-cost, patent-protected drugs that patients then ask for when meeting their physicians (Wang & Kesselheim, 2013; see also Parekh & Shrank, 2018). Therefore, DTCA has significantly influenced prescription drug usage by increasing demand, often for the higher-priced brand-name drugs. In sum, DTCA has created a complex trade-off between empowering patients to have increased knowledge of drug options and access to them while at the same time adding to the ever-rising healthcare costs and potential overuse of more costly brand names drugs over generics.

3.1.1 Recent Developments in U.S. Regarding the Costs of Prescription Drugs Reveals a Mixed Picture

Former President Joe Biden's signature legislative accomplishment was the Inflation Reduction Act of 2022 (IRA).⁴⁵ Broad-sweeping legislation, it had multiple goals, including to lower costs while reducing the federal deficit, while at the same time investing in domestic energy production and climate change mitigation; incentivizing movement toward clean energy and electric vehicles; and, as it relates to the topic of this article: lowering prescription drug prices (Anonymous, no date-c). Lovelace reported that prescription drug aspect of the law was designed to lower the cost of prescription drugs for millions of Americans, and to help address the problems of many skipping or delaying filling their prescriptions because of their inability to pay for them (Lovelace, 2022). Citing a Kaiser Family Foundation poll published in the summer of 2022, Lovelace reported that *"nearly 1 in 2 [American] adults report difficulty affording their health care expenses, including their prescribed medications"* (Lovelace, 2022). A key aspect of the IRA was that it allowed the U.S. federal government to negotiate prices for some of the drugs that Medicare spends the most money on. Medicare is a federal health insurance program for people of the age of 65 or older and younger people with disabilities, established back in 1965. Prior to the IRA, the U.S. government was prohibited from engaging in price negotiations with drugmakers on behalf of the U.S. Medicare population. While the IRA does not cover all Americans, as of late 2024, more than 66 million people in the U.S. receive their health coverage from Medicare (Anonymous, no date-b). The IRA also capped costs at \$2,000 per year for those on Medicare and limited the monthly cost of insulin to \$35 for seniors. People on Medicare are expected to benefit the most from the [IRA] though health experts say some of the changes could eventually find their way into the commercial insurance market (Lovelace, 2022).⁴⁶

In late November 2025, under the current Trump administration, pursuant to the IRA, the Centers for Medicare and Medicaid Services announced that it had successfully lowered prices significantly on fifteen costly prescription drugs (Lovelace, 2025).⁴⁷ The following are a few examples, showing the negotiated prices

⁴⁵ Inflation Reduction Act of 2022, Pub. L. 1178-169.

⁴⁶ Many Americans do not have healthcare through Medicare. Many are forced to purchase health care insurance in the private marketplace.

⁴⁷ Pharmaceutical companies have sued over the Medicare drug negotiations enabled by the 2022 Inflation Reduction Act, asserting that price setting for medications is bad public policy, and threatens future medical

for the drugs, based on a 30-day supply, compared to the 2024 list price: 1) Ozempic, Rybelsus and Wegovy, used to treat Type 2 diabetes and weight loss: \$274 negotiated price, down from the \$959 list price; 2) Xtandi, used to treat prostate cancer: \$7,004, down from \$13,480; 3) Ibrance, a drug to treat breast cancer: \$7,871, down from \$15,741 (Lovelace, 2025). This is the second round of negotiations under the IRA. In 2024, the Biden administration reached price-reduction deals on 10 prescription drugs, including several for heart disease and diabetes. Those price cuts are to take effect in 2026 while this latest round of price negotiations will go into effect in 2027 (Lovelace, 2025). Lovelace also reports that although “Drugmakers can choose not to strike deals with the negotiation program, doing so would most likely mean withdrawing their drugs from Medicare – cutting them off from one of the nation’s largest markets. Drugmakers have challenged the program in court but so far have been unsuccessful” (Lovelace, 2025).⁴⁸

Although the most recent price cuts created under the IRA were negotiated under the Trump administration, many Republicans are opposed to the IRA in general. Further, the Trump administration has utilized what he calls a ‘most favored nation’ approach to drug pricing, which relies on his use of executive orders and voluntary deals with drugmakers, as opposed to legislation, to lower drug prices in exchange for tariff relief (Lovelace, 2025). In summary, while it is true that the costs of some important drugs have been and will likely continue to be lowered whether under the IRA or the Trump administration’s most favored nations approach, those reductions will (at least for the foreseeable future) benefit only Medicare beneficiaries. Overall, however, for the many millions of other Americans that rely on prescription drugs for their health through private insurance (Ellis, 2025),⁴⁹ list prices for brand-name drugs and new innovative medications are continuing to rise, often faster than the rate of inflation. The bottom line, then, is that U.S.’s fragmented health care system, coupled with the many problems identified in the 2021 Senate Hearing, will continue to cause drugs in the U.S. to remain excessively high, and a majority of Americans are not likely to benefit much if at all from some of the recent drug price negotiations.

innovation by siphoning billions of dollars from biopharmaceutical research, thus undermining the U.S. economy and ability to compete globally (Swenson, no date).

⁴⁸ The negotiated prices are what Medicare will pay drugmakers for the medicines, not what patients will pay out of pocket. The Center for Medicare and Medicaid Services estimates that the discounts will save taxpayers \$12 billion and its expected to save Medicare enrollees \$685 million in out-of-pocket costs in 2027 (Lovelace, 2025).

⁴⁹ Recent data from U.S. Census Bureau's Annual Health Insurance Survey (2024) shows that 56.2% of the civilian non-institutionalized population held private health insurance; this is roughly 185 million people out of a total population of 330 million.

As this article is being finalized prior to its publication there have been new developments regarding drug pricing in the U.S. in 2026. Although President Trump had struck deals with 16 major drug companies in late 2025 to lower prices on some drugs, in January 2026 those same companies released lists of higher prices on many of their drugs (Lupkin, 2026). Drug companies, including those 16 with whom Trump made deals, have reportedly raised the prices of 872 brand-name drugs in the first two weeks of 2026 (Lupkin, 2026). Included were important drugs used to treat cancer, heart failure, Type 2 diabetes and Covid. (Lupkin, 2026). Pharmaceutical giant Pfizer, which had struck a deal with the Trump Administration only months earlier to reduce the prices on some of its drugs, nevertheless turned around in January 2026 and raised prices on 72 of its products (Lupkin, 2026). The increase in prices came in at a median of 4%, although Pfizer raised the price of its Covid shot by 15% (Lupkin, 2026). Pfizer indicated the new increases were ‘modest’ and necessary so it could invest in new medicines and address added expenses (Lupkin, 2026).

3.2 Setting Prices According to the EU Legislation

The EU is generally known for its rigid legislation and consumer-protective approaches. The pharmaceutical sector exemplifies this approach, and stands in stark contrast to the U.S. approach, at least concerning the pricing of medicinal drugs. In 2020, the EU accepted the EU pharmaceutical strategy,⁵⁰ which prioritizes ensuring the use of pharmaceuticals remains sustainable. With Big Pharma’s rapid development and extensive costs of innovation, prices of medicine rise to the point where people cannot afford them, which precludes many patients from benefitting from these innovations. The strategy has a valid point; however, it is only a strategy and not a fully binding document that would guarantee a complete respect of its provisions.

As fully legally binding, the EU’s predecessor the European Economic Community (hereinafter: ECC) adopted the Council Directive 89/105/EEC⁵¹ (hereinafter: Transparency Directive), which relates to the transparency of measures regulating

⁵⁰ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions Pharmaceutical Strategy for Europe COM/2020/761 final.

⁵¹ Council Directive 89/105/EEC of 21 December 1988, relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems OJ L 40, 11.2.1989, pp. 8–11.

the pricing of medicinal products for human use and their inclusion in the scope of national health insurance systems, remains valid today. While the pharmaceutical market has fundamentally changed, especially the development of generic medicines and the increasingly innovative research-based medicinal products, the Transparency Directive's provisions reflect the pharmaceutical market conditions from decades ago.⁵²

3.2.1 Transparency Directive

Transparency Directive as an Act of harmonizing nature, serves only as a framework and a minimum standard for the setting of medicine prices across the EU Member States.⁵³ It provides the EU Member States with certain procedural rules, e.g. the deadlines, legal protection, guidelines regarding communication among the authorities, information publicity and similar. Even though the Transparency Directive limits EU Member States by harmonizing this important aspect of pharmaceutical law, it also gives them the freedom to set their own medicine prices – however, they must remain in line with its (procedural) requirements (Directorate-General for Health and Food Safety et. al., 2021). Therefore, the specific mechanisms and substantive rules fall within the jurisdiction of the national laws of each EU Member State, which results in differences and even inconsistencies among them.

In September 2024, the EU Health Support Consortium produced an extensive report (EU Health Support Consortium, 2024) on the functioning of the Transparency Directive. The report discussed both stakeholders' and EU Member States' authorities' perspectives on the topic. In contrast to the whole purpose of the Transparency Directive, almost half of the stakeholders (47%) indicated the Directive does not help them increase the transparency of measures that regulate pricing and reimbursement of medicinal products for human use (Directorate-General for Health and Food Safety et. al., 2021, p. 20). Interestingly, both the stakeholders and EU Member States' authorities expressed concerns regarding certain timelines. Some industry delegates lamented that the timelines are not always

⁵² Para. 5 of the Proposal for a Directive of the European Parliament and of the Council relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of public health insurance systems COM/2012/084 final - 2012/0035 (COD).

⁵³ The main function of the Directive is to harmonise a particular field – not to unify the legislation in this field of study for all the EU Member States.

respected by Member States and requested better compliance (Directorate-General for Health and Food Safety et al., 2021, p. 20). On the other hand, approximately half of the EU Member States' authorities voiced concerns relating to the abiding timelines and even confirmed that in a minority of cases, decisions on the prices of medical products are not made within the assigned timeframe (Directorate-General for Health and Food Safety et al., 2021, p. 22). Their reasoning was that the complexity of specific medicinal products does not correspond with such rigid timelines. While the stakeholders ask for better compliance, EU Member States' authorities seek more flexibility. These contradictory perspectives of the two main actors in the market raises questions regarding not only the suitability of the Transparency Directive to the present conditions and demands of the market but also the effectiveness of this legal Act as such. Another shared concern is Transparency Directive's alignment with other legislative frameworks that have an impact on this market, namely the EU's new HTA Regulation 2021/2282.⁵⁴

Although the European Commission made initiatives to reform pharmaceutical legislation on the EU level (in its latest activity its focus was to fight the medicine shortages) (Directorate-General for Health and Food Safety et al., 2021, p. 22), the aspect of setting and calculating prices remains unchanged. Particularly in 2012, the European Commission proposed a new directive⁵⁵ that would replace the Transparency Directive. The aim of the proposed text was to rationalise procedures and reduce the time taken by national authorities to make decisions on the pricing and reimbursement of medicines, which would have been achieved by simplifying procedures and improving legal clarity and certainty for all stakeholders (EUR-Lex, 2024). The European Commission withdrew its proposal in March 2015 (EUR-Lex, 2024), which makes the Transparency Directive the only legally binding Act in this field for 37 years and counting. As odd as this may seem, we must recognize that the Transparency Directive sets only a small, but broad set of procedural rules, whereas 'the real power' on substantive rules lies in each of the EU Member States. Therefore, the longevity of the Transparency Directive does not necessarily suggest that particular national legislations dealing with this field have not evolved. In

⁵⁴ Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment and amending Directive 2011/24/EU (Text with EEA relevance) PE/80/2021/INIT OJ L 458, 22.12.2021, pp. 1–32.

⁵⁵ Proposal for a Directive of the European Parliament and of the Council Relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of public health insurance systems COM/2012/084 final - 2012/0035 (COD).

Slovenia for example, the setting of medicines' prices is regulated in two different legal acts, namely the Medicines Act⁵⁶ (hereinafter: ZZdr-2), which has been modified two times so far, and Rules on the pricing of medicinal products for human use⁵⁷ (hereinafter: Pravidnik), which has been amended five times already. The following section analyses both in detail.

3.2.2 Setting of the Prices According to Slovenian Legislation

Interestingly, GIRP estimated Slovenia's wholesale margins as one of the lowest in the EU (Trgovinska Zbornica Slovenije, 2022). In this chapter, we will try to establish why.

Besides the Transparency Directive, which establishes the basic procedural parameters, the two most important national legal Acts regulating the medicine prices in Slovenia are ZZdr-2 and Pravidnik. Pursuant to the Article 1 ZZdr-2, this Act regulates the field of medicines for both human and veterinary use and further imposes the conditions and measures for ensuring their appropriate quality, safety, and efficacy. It also establishes the conditions and procedures for their testing, manufacture, marketing, and use. It enforces the prices of medicines, official control, the preparation and supervision of implementing it. ZZdr-2 also delegates the tasks and powers to the Public Agency of the Republic of Slovenia for Medicinal Products and Medical Devices (hereinafter: JAZMP), which is a respectable and internationally recognized institution, and the authority that regulates and supervises this particular field and ensures safe, effective, and accessible medicines and compliant medical devices or other products in its field of activity in the public interest.⁵⁸ However, we must not mistake the mere setting of prices of medicines with the public funding of medicines. The latter is regulated by the Health Care and Health Insurance Act⁵⁹ and falls under the jurisdiction of a different authority – the

⁵⁶ Zakon o zdravilih (*en. Medicines Act*) (ZZdr-2) Official Gazette of the Republic of Slovenia, No. 17/14, 66/19, 102/24 – ZZKZ, 24/25 and 27/25 – corr. 102/24 – ZZKZ, 24/25 and 27/25 – corr.

⁵⁷ Pravidnik o določanju cen zdravil za uporabo v humani medicini (*en. Rules on the pricing of medicinal products for human use*) Official Gazette of the Republic of Slovenia, Nos. 32/15, 15/16, 19/18, 11/19, 26/20, 51/21, and 52/21 – corr.

⁵⁸ Official website of JAZMP: <https://www.jazmp.si/o-nas/poslanstvo-vizija-strategija/> (accessed: September 11, 2025).

⁵⁹ Zakon o zdravstvenem varstvu in zdravstvenem zavarovanju (*en. Health Care and Health Insurance Act*) (ZZNVZZ) Official Gazette of the Republic of Slovenia, No. 72/06 – official consolidated text, 114/06 – ZUTPG, 91/07, 76/08, 62/10 – ZUPJS, 87/11, 40/12 – ZUJF, 21/13 – ZUTD-A, 91/13, 99/13 – ZUPJS-C, 99/13 – ZSVarPre-C, 111/13 – ZMEPIZ-1, 95/14 – ZUJF-C, 47/15 – ZZSDT, 61/17 – ZUPŠ, 64/17 – ZZDej-K, 36/19, 189/20 –

Health Insurance Institute of Slovenia (hereinafter: ZZZS) (see ZZZVZZ, Article 1.a and 7). Also, in Slovenia the law distinguishes between setting the price of medicines covered by public funds and medicines paid for by patients themselves. Meaning, the prices of medicines prescribed by and dispensed in hospitals, health centres, and pharmacies on green prescriptions are regulated by the JAZMP (STA, 2019). That is relevant, because the JAZMP sets the maximum permitted price of a medicine, ensuring the price is regulated. Particularly in its Article 156, ZZdr-2 explains that prices of medicines are to be freely determined by market conditions, except in cases specified by this Act – which essentially points to the cases with an element of public funding.

The JAZMP can set the maximum permitted price of a certain medicine by following a legally determined procedure. For certain medicines⁶⁰ for human use that are financed from public funds or are intended to be financed from public funds, the JAZMP determines the maximum permitted price based on application. Even in such a case, there is still a possibility of permitting a higher price, however, but only for specific reasons as set forth in an exhaustive list of cases provided by law.

According to the Article 158, there must be either an additional application for an increase of the maximum permitted price, the opinion of the Commission for determining exceptional higher permitted prices of such medicine, or an established public interest in the field of health and economic justifications (ZZdr-2, Article 158, para. 2).⁶¹ If any of the three preconditions occur, the JAZMP has the authority to confirm an exceptionally higher permitted price. That is done by a special procedure, in which the JAZMP appoints the Commission with seven members, involving representatives of the ministry responsible for health, JAZMP, the OZZ holder, and of the healthcare providers. Although the Commission adopts its procedural rules at

ZFRO, 51/21, 159/21, 196/21 – ZDOsk, 15/22, 43/22, 100/22 – ZNUZSZS, 141/22 – ZNUNBZ, 40/23 – ZČmIS-1, 78/23 and 32/25 – ZZDej-N.

⁶⁰ Any medicine that is marketed in the Republic of Slovenia or if it has a marketing authorization, a marketing authorization for a parallel imported medicinal product or a certificate of notification of parallel distribution, or a compassionate use authorization (ZZdr-2, Article 20, para. 1); a medicinal product that has obtained a marketing authorization through a centralized procedure if the JAZMP assigned it a national medicinal product identifier and the data specified in Article 13 of this Act (ZZdr-2, Article 20, para. 2); a medicine which is, because of its active ingredient, pharmaceutical form and strength, included in the list of essential medicinal products or urgently needed medicinal products referred to in Article 17 ZZdr-2 (ZZdr-2, Article 20, para. 3, subpara. 3).

⁶¹ By justifications the law means, specifically, justifications regarding the risk that would arise due to a disruption in the supply of medicinal products, or on the basis of demonstrable, unavoidable, and disproportionate costs that would arise exclusively because of the need to fulfil public service obligations.

its inaugural meeting, the general rules, such as the methods, criteria, mandatory components of the application, turnover threshold, and procedure for determining the maximum and exceptional higher permitted price of medicines, are determined by the minister (ZZdr-2, Article 158, paras. 2 and 3).

Determining both the maximum and exceptional higher permitted price of medicines is further regulated in *Pravilnik*, a document that is even more specific in this matter than ZZdr-2. According to the Article 5 of *Pravilnik*, maximum permitted prices are established on the basis of comparisons of prices of medicines in comparable countries. For Slovenia, these reference countries are namely Austria, France, and Germany (*Poslovník*, Article 11). The details on calculations of these comparisons of each of the three countries are thoroughly described in Annex 2 to the *Poslovník*,⁶² which is the Slovenian naming of the central act by which the body, company or certain organization, regulates the rules of its own operation.

In his article, Boštjan Koritnik in a concise manner explained the equation behind the actual calculation of a particular medicine's price, which encompasses the manufacturer's price element (hereinafter: PEC), a fixed wholesale margin of 0,50 € and the variable percentage of 1,10% of the PEC that cannot exceed 27 € (Koritnik, 2025; *Poslovník*, Articles 10-15). The calculation of the first factor, PEC, depends on the type of the provided medicine and its actual availability in the reference countries (*Poslovník*, Article 12). For example, the value of a generic medicine will be calculated differently in comparison to the value of original, biological or similarly to biological medicines (STA, 2019). The value of PEC also deviates if the same medicine is available in one reference country instead of being available in all three of them. Pursuant to the first paragraph of the Article 12 of *Poslovník*, the PEC value of the original medicine is determined based on the comparative price of the medicine, which is the lowest calculated price of the same medicine in any of the three reference countries for the original medicine. If a certain medicine is available on the market in only one or two reference countries, only the converted prices in those countries are considered. In any case, the PEC value of the original medicine may not exceed 100% of the reference price of the medicine (*Poslovník*, Article 12, para. 1). However, the PEC value of the generic medicine is more dependent on the availability of the same medicine in reference countries (in some cases, the

⁶² See more in Article 11 of *Poslovník* and Annex 2 to the *Poslovník*.

medicine's price may not exceed 68% of the reference price of the medicine and in other cases, the limit is set at 72%) (Poslovnik, Article 12, para. 2).

Finally, the retail price of the medicine consists, not only of the PEC, wholesale margin (0,50 € plus 1,10% PEC), but also of the payment for the pharmacy margin and the value added tax (hereinafter: VAT), which is mostly 9,50%, but in some cases turns to 22% (Koritnik, 2025). Pharmacy margins are a variable factor (STA, 2019). Meaning, those margins are not limited or provided for by law but instead are set individually by pharmacies. Years ago, the Chamber of Pharmacists determined a uniform amount that pharmacies charged for processing and dispensing non-prescription or white prescription drugs, however, the Slovenian Competition Protection Agency intervened in 2015 (Poslovnik, Article 12, para. 2). Presently, even if pharmacies are free to set particular parts of medicine prices, they are still obliged to report data on wholesale drug prices to JAZMP, which puts the State in some control over the freely set prices (Poslovnik, Article 12, para. 2). Therefore, even when the law does not dictate the direct limits or prohibitions on pharmacies, it still manages to provide enough checks and boundaries to maintain the fair market prices.

Intriguingly, in 2022 the Slovenian Chamber of Commerce highlighted that even in cases of permitting exceptionally higher permitted prices pursuant to Pravilnik, the wholesale margin price does not allow wholesalers to make profits, as it is barely sufficient for covering their costs (Trgovinska zbornica Slovenije, 2022). The head of marketing, communications, and external affairs at Kemofarmacija emphasized the problem is in having laws that are outdated for present market conditions (Rutar Pariš, 2024). Presently, more medications are better developed, biological (for the rare diseases) or even personalized for each patient (as there are more personalized therapies for very rare diseases), and unsurprisingly, these factors have led to more expensive medications (Poslovnik, Article 12, para. 2). While Slovenia has already amended the mentioned legal acts, experts of the field argue more reforms are needed. According to some statistics, the wholesale margin of medicines that cost over 50,00 € per box is only 2,10% or even less (Koritnik, 2025; Trgovinska zbornica Slovenije, 2022). Considering that these medicines present more than two-thirds of the market value of medicines, the profits for pharmacies are negligible. Another interesting example can be viewed in the table, presented by Mrs. Rutar Pariš's article (Rutar Pariš, 2024). The latter shows that 23,70% of medicines on the market are

estimated to be at the wholesale price below 2,50 €. However, by the value that these 23,70% bring to the market presents only 2% of the whole market value. On the other hand, this table also contains some very expensive medicines that can cost more than 2000 € per piece which in quantity represent only 0,20% of the market. Nevertheless, this trivial percentage represents 28,3% of the whole market value – exceeding the value of the cheaper medicines that are sold in much larger quantities (Rutar Pariš, 2024).

Finally, we can confirm Slovenia's wholesale margins may be one of the lowest in the EU due to its strict and thorough framework in this area of pharmaceutical law. While from a business standpoint it may seem the field is too rigidly regulated, which deprives pharmacies from making the profits they might otherwise could, from the consumer's perspective, it would be unconventional for the State to leave this market unregulated, not only because a significant share of different medicines is financed from the public funds, but also because the matter is strongly intertwined with the public interest and public health. While all the listed reasons are valid and credible, we cannot neglect the need to amend the laws so that they allow pharmaceutical companies to profit more from the important medicinal products they offer. The profits that they are allowed to make at present pursuant to the current laws are marginal. Higher drug prices, or marginally higher drug prices would negatively impact patients or consumers. However, this impact must be weighed against the impact of maintaining the status quo. The flip side of the equation is that the failure to modify laws so as to fairly compensate pharmaceutical companies and pharmacies for their vital services to protect the public health, may disincentivize them from making the continual investments required to innovate and to develop and provide new drugs that will provide greater protection for the public - a delicate balance to be sure.⁶³

⁶³ It is interesting to note that in the U.S., pharmaceutical companies oppose reforms, including almost any efforts designed to lower drug prices, claiming that doing so would hamper their research and development efforts. It is certainly true that R & D is expensive; it can take a long while to bring a new product to market; and that many proposed drugs never make it to market. However, when considering the billions of dollars these companies are making annually, these arguments are simply difficult to take very seriously. Is it fair that these obscenely profitable enterprises should earn such profits at the expense of people who are suffering from ill health and cannot afford to purchase drugs?

4 Conclusions

In conclusion, the EU's approach and regulation in the field of pharmaceutical industries may be considered very well structured and detailed. There are many checks and boundaries, additional bodies and platforms that assist the EMA in fulfilling its obligations and goals. Additionally, the EU has its own judicial system with close legislative power, considering that the CJEU's decisions interpret and, in many cases, co-create the EU law. Considering the U.S. and its bodies, we can also confirm the FDA is doing adequate work, very similar to EMA's, not to mention all its relevant, but "supporting" legal acts, which are pointed to basically the same direction as the EU's. Although the FDA boasts longevity and could be considered as more established than the European competent authorities, we can find no significant flaws in the EMA, neither in its structure nor in its functioning. The Slovenian JAZMP, can be in a way viewed as subordinate or inferior to the EMA, however, that is just not the case – their relation is a bit more complicated than that. As a national competent authority, the JAZMP or its employees work closely with the EMA. The EU excels at projects, comparative research and analyses to further advance the healthcare field and in many cases, people from JAZMP are included in them. Therefore, the relevant legislations as well as the work of each body, looking at Slovenian, the EU and the U.S., seem to be established in a correct way, with all the right reasons and objectives. Consequently, the pharmaceutical field has evolved rapidly, efficiently, and the many drugs placed into the market are extremely safe and are doing their job to save lives and to allow citizens both in the U.S. and Europe to live better, healthier lives.

Regarding the hypothesis set out in the very beginning of the article, we can confirm that *"compared to the U.S. the EU and its Member States, Slovenia in particular, have structured a better legal framework for the field of Pharmaceuticals, enabling lower drug prices"*. In EU Member States, including in Slovenia, health is considered to be a fundamental right. Subsumed within this larger right is the right to medicinal drugs, which are readily available and reasonably priced to be available to all citizens. Additionally, because health is a right, in the EU and in Slovenia, governments have the autonomy to and widely do control and regulate the prices of drugs within their national borders. They do this in a variety of ways such as direct price controls and negotiations and through, as in Slovenia external reference pricing. In sum, these government

controls – which have historically been lacking in the U.S. – have been designed to manage public health expenditures and ensure drug affordability and availability.

The U.S. takes a completely contradictory approach. In the U.S., health, including healthcare, is not a public right. Health, like many other rights (e.g., the right to privacy (see more Turnšek, 2024; Turnšek & Kraljić, 2024), is left to the individual, and many struggle with managing this on their own. Because health is not a right, and because the healthcare system is largely privatized (with some exceptions), all actors within the system – healthcare facilities, physicians, drug manufacturers – are incentivized to make a profit, and large profits at that. The body that could at least in a certain way control or even manage these margins is the FDA, however, unlike the EMA or Slovenian JAZMP, its jurisdiction does not extend to such length. Accordingly, the absence of a federal public authority that has the power to regulate and negotiate prices of drugs leaves drug pricing largely unconstrained and permits healthcare actors to extract substantial margins and profits. As a result, in a micro sense those same actors use the political and legislative system to promote their financial interests – these are the many factors identified in the Senate Hearing of 2021. To put it bluntly, the actors in the U.S. health care system have financial motives that do not necessarily align with patients' interests. The capitalist system has been very successful; it has made the U.S. a leader in innovation and has produced the world's strongest economy for many years. However, the downside is that Americans pay exorbitant costs for their healthcare including their medicines. Not to strike an overly pessimistic tone but barring fundamental changes – and it is difficult to see them happening any time soon, if at all because the system is so 'baked in' for lack of a better phrase – it is difficult to discern any clear path to radical changes to the status quo.

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Povzetek v slovenskem jeziku

Članek obravnava izbrane vidike, okoliščine in pravne ureditve na področju farmacevtskih izdelkov. Avtorja najprej preučita vlogo organov ZDA, Slovenije in EU, ki regulirajo, spremljajo in nadzirajo delovanje farmacevtske industrije. Tako agencija Unije EMA kot tudi ameriška agencija FDA si prizadevata za isti cilj – vzpostavitev in ohranitev javnega zdravja in varnosti. S svojimi kompetencami in pristojnostmi pomembno prispevata h kakovosti zdravil na obeh trgih. Med njima pa obstaja ena velika razlika. To je pristojnost za zagotavljanje dostopnosti zdravil in določanje cen. Medtem ko imajo EMA in na primer JAZMP, slovenski pristojni organ, nadzor tudi nad finančnim vidikom, FDA te pristojnosti nima. V nadaljevanju članek preučuje, kakšni so mehanizmi nadzora in omejitve za določanje cen in kako je slednje urejeno v pravnem sistemu Slovenije, EU in ZDA. Že samo dejstvo, da je zdravje temeljna pravica v državah članicah EU, v ZDA pa ne, pojasnjuje izrazito razliko v cenah zdravil v EU v primerjavi z ZDA.

