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Original Research

Kosovo's Pharmaceutical Regulation: A Comparative Study with Croatia on Medicine Availability, Regulatory Frameworks, and EU Compliance

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Abstract

Introduction: Kosovo and Croatia share a common regulatory and historical background, yet their pharmaceutical systems have developed along different trajectories. Croatia's EU membership and strategic investments have enabled full regulatory integration, while Kosovo continues to face structural and institutional challenges despite aligning its legal framework with EU standards. Key differences are evident in marketing authorization procedures, medicine availability, and regulatory implementation. Thus, this study highlights these gaps that Kosovo must strengthen and adopt EU-aligned best practices. **Objectives:** This study aims to analyze Kosovo's current pharmaceutical regulatory system, particularly its alignment with EU standards, using Croatia's well-established system as a benchmark. In addition, the aim of this paper is to evaluate the marketing authorization procedures in Kosovo compared to Croatia and also assess the availability and diversity of marketing-authorized medicines in both countries. Furthermore, a key focus area is the availability of New Molecular Entities in both countries and identifying the gaps in Kosovo's pharmaceutical market. **Materials and Methods:** A comparative and analytical approach to the pharmaceutical regulatory framework of Kosovo and Croatia is used in this study. Data were collected from national and EU legislation, and the official regulatory agency databases from September 2024 to January 2025. Data were analyzed using thematic content analysis to identify regulatory themes and a quantitative comparison to assess the number and diversity of marketing-authorized medicines in both countries. The study further examines the differences in NME registration, using databases from the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA). **Results:** Our study finds that while Kosovo is taking steps to align its pharmaceutical regulations with EU standards, significant gaps remain, particularly in clinical trials, public engagement and digital infrastructure. On the other hand, Croatia exemplifies full EU compliance, with a transparent, efficient, and operational regulatory system that provides better market access, regulatory enforcement, and public interaction. Additionally, the number of marketing-authorized medicines is 26% higher in Croatia compared to Kosovo. One of the most notable findings of this study is the huge contrast between the availability of NMEs in Kosovo and Croatia. The results show that Kosovo has registered only six EMA-approved NMEs and four FDA-approved NMEs between 2021 and 2024. While Croatia counted 33 out of 46 EMA-approved NMEs in 2024 alone. **Conclusion:** This study presents the first comparative analysis of the pharmaceutical regulatory systems of Croatia and Kosovo, using Croatia as a model for EU-aligned practices. While Croatia has achieved streamlined medicine approvals and broader access through EU integration, Kosovo continues to face implementation challenges. Strengthening digital infrastructure, regulatory enforcement, and EU collaboration are crucial for Kosovo to close the access gap and modernize its system. Croatia's experience offers valuable guidance for Kosovo's regulatory development.

Keywords: Pharmaceutical Regulation, EU standards, Marketing Authorization (MA), New Molecular Entities (NMEs), Kosovo, Croatia

INTRODUCTION

Both Kosovo and Croatia, as part of the Western Balkans, share the same historical and regulatory background, which makes them valuable for comparison in the development of pharmaceutical regulation. However, their trajectories have differed substantially[1]the Soviet Union, and Yugoslavia demonstrates that the process is not irreversible. I argue that in the case of Yugoslavia, (1. Croatia, a member of the European Union (EU) since 2013, succeeded in aligning its drug regulatory framework with EU standards, building on its already well-established institutions before accession. Strategic investment in pharmaceutical infrastructure, digitalization, and market integration has further strengthened Croatia's regulatory landscape. In contrast, Kosovo, being the youngest country in Europe, is still in the early stage of developing its regulatory framework, facing multiple institutional and structural challenges in harmonizing with EU pharmaceutical regulation. Croatia's advantage lies in its full integration within the EU's pharmaceutical system, including access to centralized EMA procedures and facilitation of EU legislation adoption[2]. Its regulatory evolution is further supported by initiatives like the EU Pharmaceutical Strategy for Europe, which aims to ensure access to affordable medicines, foster innovation, and strengthen supply chain resilience[3].

Kosovo, by contrast, has made substantial efforts to align its

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regulatory framework with the EU acquis and international good practices. However, enforcement, institutional capacity, and market surveillance remain major challenges. Significant legislative steps have been taken in pricing, licensing, market surveillance, and public health protection, yet regulatory implementation remains weak[4–10]. Moreover, the ongoing revision of EU pharmaceutical legislation, currently under discussion in the European Parliament, underscores the importance of reforms that should be made in Kosovo. These reforms, such as restructured data exclusivity frameworks, accelerated procedures for innovative treatments, and improved coordination in addressing medicine shortages, are vital benchmarks[3,11]. Without institutional readiness and legislative coherence, Kosovo risks falling further behind as the EU regulatory system becomes more advanced and integrated.

Achieving full implementation of EU-aligned regulation in Kosovo will require more than legislative harmonization; it will depend on building robust regulatory capacity. Current challenges include unstructured Marketing Authorization (MA) data, the absence of clinical trials, and weak pharmacovigilance systems. In contrast, Croatia has continued modernizing its pharmaceutical system through strategic investments in infrastructure and digital solutions, such as the Central Health Information System (CEZIH) and the AI4Health Cro project, reflecting its strong commitment to effective regulatory control [12,13].

Considering the current challenges and developments, this study aims to analyze the overall pharmaceutical regulatory system of Kosovo, focusing on key legislation that regulates medicines and medical devices, evaluating their alignment with EU standards and best practices. This study will also examine the procedures for the Marketing Authorization (MA) and their implementation, using Croatia as a benchmark. In addition, this study includes an analysis of the availability of marketing-authorized medicines in Kosovo, assessing the number and diversity of active ingredients, and comparing these findings with Croatia to identify gaps in availability, variability, and market demand. Furthermore, the study will examine the approval procedures of New Molecular Entities (NMEs), defined by the Food and Drug Administration (FDA) or the European Medicine Agency (EMA) as medicines containing an active substance not previously authorized in the EU[14], in both countries, and compare the presence of NMEs in their respective pharmaceutical markets. Finally, based on the findings, this study will provide recommendations to address identified gaps in Kosovo's pharmaceutical regulatory framework. These recommendations will focus on promoting greater harmonization with best practices and standards, enhancing effective implementation to contribute to the advancement of Kosovo's pharmaceutical market.

MATERIALS AND METHODS

This study compares pharmaceutical regulatory alignment between Kosovo and Croatia, assessing their adherence to EU legislation and best practices. A comparative and analytical analysis was performed for evaluation of the harmonization of both countries with the EU standards. The collected data were analyzed using thematic content analysis and quantitative comparison. The study integrates several data sources and analytic approaches to analyze the progress, challenges, and gaps in pharmaceutical regulation. The primary focus is on regulatory practices in medicines and medical devices, continuing with an in-depth analysis of marketing authorization processes and the availability of marketing-authorized medicines, including NMEs. By comparing these components, the study highlights the main differences and similarities between the two countries.

Data Collection and Sources

Data were collected from publicly available sources between September 2024 and January 2025, such as: National legislation that regulates pharmaceutical activities in Kosovo and Croatia. EU legislation and guidelines were analyzed to examine how these standards have been applied to national laws. To analyze the availability of marketing-authorized medicines and NMEs, quantitative data were extracted from the official regulatory agency database: Kosovo Medicines Agency (KMA) for Kosovo[15] and the Agency for Medicinal Products and Medical Devices of Croatia (HALMED) for Croatia[16]. These data include information on the number of medicines that have marketing authorization in both countries, categorized by therapeutic areas and active ingredients, based on the Anatomical Therapeutic Classification (ATC) system[17]. The extracted data were systematically organized and processed using Microsoft Excel and GraphPad Prism 9 to facilitate accurate comparison and analysis.

Data Analysis

The collected data was analyzed using a combination of thematic content analysis and quantitative comparison. Thematic analysis of legislative documents, guided by a structured coding framework based on key EU laws and best practice, was used to identify key regulatory themes like EU harmonization and stakeholder engagement. Manual coding was performed to ensure consistency, focusing on the updating of legislation, compliance measures, and practices related to regulatory enforcement. Comparative analysis was conducted to examine regulatory differences and similarities between Kosovo and Croatia, focusing on specific indicators such as legal alignment with EU legislation, approval timelines, and therapeutic classes covered. To support this, the core EU legal frameworks that were used includes Directive 2001/83/EC (relating to medicinal products for human use), Regulation (EC) No 726/2004 (authorization and supervision procedures), and key policy documents such as the Pharmaceutical Strategy for Europe and the 2023 legislative reform package currently under revision.[3,18,19(p726)]. These instruments formed the basis for assessing Kosovo's legislative and institutional alignment with EU pharmaceutical standards. In parallel, both thematic and quantitative methods were employed to analyze the available data, enabling a multi-dimensional assessment of regulatory structure and medicine availability.

A structured quantitative analysis was performed to assess the availability and characteristics of medicines with marketing

authorization in Kosovo and Croatia. Key aspects analyzed included the number of MA medicines by therapeutic class to reflect treatment diversity, and by active ingredients to assess availability and identify gaps in essential medicines. A comparative analysis examined the differences in NME registration and updates between Kosovo and Croatia. Lists of NMEs approved by EMA and FDA were used to evaluate the accessibility of these medicines in Kosovo's list of medicines (last updated on 17.01.2025) and Croatia's online database for medicinal products. Microsoft Excel and GraphPad Prism 9 were used to categorize, analyze, and visualize the quantitative data through descriptive statistics, pivot tables, and graphical representations. Moreover, the usability and functionality of the official regulatory agency websites were evaluated based on established web accessibility guidelines, including WCAG 2.1 standards[20]. The evaluation focused on several key criteria, such as accessibility and language support for different stakeholders, as well as the availability of data on MA medicines in both countries. Additionally, the assessment evaluated the accessibility of important information, including summaries of product characteristics (SmPCs), and examined the overall user experience, focusing on website navigation, real-time updates, and multilingual support.

Ethical Considerations

In this study, only publicly available data were used and properly cited. No human subjects were involved.

RESULTS

Comparison of Pharmaceutical Regulation Framework in Kosovo and Croatia

The fundamental law regulating pharmaceutical activity in Kosovo is the Law on Medicinal Products and Medical Devices (Law No. 04/L-190), adopted in 2013[21]. The law establishes the regulatory framework for manufacturing, quality assurance, classification, marketing authorization, import, trading, pharmacovigilance, and clinical trials of medicinal products and medical devices in Kosovo. The authority that regulates the activities related to medicinal products and medical devices is the Kosovo Medicines Agency (KMA). Kosovo's law is partially aligned with several key EU directives, ensuring a degree of regulatory harmonization. The main Directive 2001/83/EC[18] is incorporated into the law, which defines the basic framework for human medicinal products covering marketing authorization, labeling, and pharmacovigilance, ensuring that only products that meet stringent requirements for quality, safety, and effectiveness can enter the market. Regarding the production and control of medicinal products, the law complies with Directive 2003/94/EC, ensuring high-quality production standards. Furthermore, the requirements of Directive 93/42/EEC[22] on medical devices are also incorporated into the law, addressing standards for the design, manufacturing, and market placement of medical devices. Other specific EU directives reflected include Directive 98/79/EC[23(p98)] on in vitro diagnostic devices, and Directive 90/385/EEC[24(p90)] on active implantable medical devices, ensuring that specialized categories of medical devices meet stringent EU standards. In addition to EU directives, Law No. 04/L-190 also specifies requirements for compliance with international standards, including those of Good Clinical Practice (GCP) in the performance of clinical trials and the protection of participants' rights, safety, and well-being. The law also incorporates Good Distribution Practice (GDP) standards, which are critical for maintaining product quality throughout the supply chain[21]. Furthermore, the law refers to World Health Organization (WHO) guidelines, specifically those concerning the donation of medicinal products, to ensure compliance with quality and safety standards.

However, despite the comprehensive legal structure, several gaps remain in the implementation of the Law on Medicinal Products and Medical Devices. While it covers key areas like licensing and pharmacovigilance, there is insufficient focus on public engagement and transparency. Specifically, there is a lack of feedback mechanisms among the general public on inspection procedures and outcomes, together with compliance reports. Moreover, there are no available guidelines for stakeholders and the public on reporting systems for adverse reactions. While the law includes provisions for clinical trials, no such trials have been conducted in Kosovo to date. The regulatory framework includes requirements for ethical approval, sponsor responsibilities, and protection of participants following international standards such as GCP. However, this legal framework has not been operationalized. Contributing factors include the lack of infrastructure, the lack of incentives for research, and low public awareness about clinical trials and their potential benefits.

Meanwhile, the KMA website has notable limitations. Although it provides licensing forms and price lists for services, it does not support public comments or interaction with stakeholders, lacks real-time updates, and updates are available only in the Albanian language. Navigation is not user-friendly, and important regulatory information may be difficult to access.

In contrast, Croatia, as an EU member state, has a regulatory system fully harmonized with European Commission standards. The Medicinal Products Act and Medical Devices Act[25,26] ensure strict compliance with EU directives, including Good Manufacturing Practice (GMP), Good Clinical Practice (GCP), and Good Distribution Practice (GDP). Croatia's Agency for Medicinal Products and Medical Devices (HALMED) oversees pharmaceutical regulation, ensuring efficient enforcement and transparency. HALMED and the Ministry of Health ensure compliance with Good Clinical Practice (GCP) standards[27–29]. HALMED ensures strong engagement with the public through real-time updates on procedures for regulation and compliance data, increasing transparency in the pharmaceutical environment. In Croatia, the regulatory bodies support the robust implementation of clinical trial procedures, guaranteeing compliance with GCP standards[30]. Croatia has also fully implemented the Medical Device Regulation and In Vitro Diagnostic Regulation (IVDR), whereas Kosovo is still following the older EU directives without the inclusion of modern regulatory updates[27].

Marketing Authorization

Comparison of Marketing Authorization Procedures and Organization in Kosovo and Croatia

The Marketing Authorization (MA) procedures and organization of medicines in Kosovo and Croatia show considerable differences in regulatory approach, EU harmonization, and access to authorized product data.

In Kosovo, administrative instruction No. 01/2015 provides different types of authorization, including independent review for new medicinal products and simplified procedures for generics, well-established medicines, and those already approved in the EU, Schengen states, or the U.S[31]. Advanced and innovative medicinal products, such as biologics and biosimilars, require pre-approval by EMA or FDA since the high standards on safety and efficacy have to be fulfilled. However, mutual recognition agreements have not been yet applied in practice**.** On the other hand, Croatia has adopted the complete EU system as stated in the Medicinal Products Act and the Ordinance on Granting Marketing Authorizations for Medicinal Products. Under MA procedures, new medicinal products also go through the process of full dossier submission using the Common Technical Dossier (CTD) format in order to maintain strict assessment. Similarly to Kosovo, Croatia employs simplified procedures for generics, traditional herbal medicines, and homeopathic products, relying on quality data, bioequivalence studies and well-established scientific data

While the regulatory framework in Kosovo allows potential mutual recognition agreements, such agreements remain in an early stage of development. The authority responsible for establishing arrangements concerning the recognition of foreign marketing authorizations is the Ministry of Health, but these are not yet systematically applied. On the other hand, Croatia is an EU member state that participates in full mutual recognition and decentralized EU procedures either as a Reference Member State (RMS) or a Concerned Member State (CMS). This simplifies the approval process and speeds up market entry for high-quality medicinal products.

Kosovo grants marketing authorization to local pharmaceutical manufacturers if they obtain a valid manufacturing license issued by KMA and provide documentation, including GMP certificates, product samples, and packaging information in Kosovo's official languages. This supports domestic industry while maintaining safety and quality. In Croatia, local manufacturers must comply with EU GMP regulations and demonstrate adherence to EU quality, safety and efficacy requirements. HALMED performs inspections and guarantees that manufacturing facilities meet very stringent EU-aligned quality control standards, positioning Croatia's pharmaceutical industry as a fully integrated EU entity.

Kosovo has a 120-day timeline for the KMA to issue an MA decision once all the required documentation is submitted. This shows the country's attempt to ensure effective regulatory processing. However, due to limited capacity, delays are common**.** On the other hand, Croatia's marketing authorization procedure runs in parallel with EU timelines. Thus, the evaluation is performed effectively and in line with the broader European pharmaceutical regulatory practices.

The major difference between the two countries lies in the organization and accessibility of authorized medicines. The KMA of Kosovo maintains an Excel-based list of authorized medicines, updated weekly. It does not have structured search tools, multilingual support, or real-time update notifications. Additionally, the SPC of the approved medicines is not publicly available, limiting usability for professionals and patients**.** Croatia's HALMED provides a highly accessible online database. It contains therapeutic indications, ATC classification, SPCs, package leaflets, and risk management plans. Searching and filtering functions in this system are highly developed, hence increasing its usability. Moreover, the regulatory updates of HALMED are synchronized with the EMA databases on a real-time basis concerning variations, suspensions, and revocations. A summarized comparative overview of pharmaceutical regulatory systems is presented in Table 1.

Table 1. Comparative Overview of Pharmaceutical Regulatory Systems in Kosovo and Croatia

Aspect	Kosovo	Croatia
Legal Framework	Law No. 04/L-190 on Medicinal Products and Medical Devices (2013)[10]	Medicinal Products Act & Medical Devices Act[16,17]
EU Integration	Partially aligned; follows some EU directives but lacks full implementation	Fully aligned with EMA and EU standards
Regulatory Authority	Kosovo Medicines Agency (KMA) https://akppm.rks-gov.net/	HALMED (Agency for Medicinal Products and Medical Devices) https://www.halmed.hr/en/O-HALMED-u/
Clinical Trials	Legislation in place but not operationalized due to lack of infrastructure	Fully operational with clear ethical and regulatory guidelines
Marketing Authorization	Independent, simplified, and reliance-based approvals	Full dossier (CTD), simplified, and mutual recognition
Mutual Recognition	Limited agreements in place	Fully functional within the EU mutual recognition system
Local Manufacturer MA	Requires KMA manufacturing license	Requires GMP compliance and EU regulatory adherence
Decision Timeline for MA	120 days for approval	Synchronized with EMA timelines (~210-277 days)
Data Accessibility for MA	Excel list, basic categorization, available only in Albanian	Structured online database in Croatian and English
SmPCs, PL & Risk Plans	Not publicly available	Available via HALMED's online registry

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Evaluation of Medicines with Marketing Authorization (MA) in Kosovo

Based on the latest available list from the KMA (https://akppm.rks-gov.net/DocumentsAndPublications/SinglePublication/8317; last accessed on 09.01.2025, there are currently 4,227 authorized medicines in Kosovo. The classification by therapeutic class (ATC first-level classification) is presented in Table 2.

Table 2. Classification of MA Medicines in Kosovo based on the therapeutic class

Therapeutic class	Number of MA medicines
Alimentary tract and metabolism	468
Antiinfectives for systemic use	585
Antineoplastic and immunomodulating agents	225
Antiparasitic products, insecticides and repellents	17
Blood and blood forming organs	245
Cardiovascular system	708
Dermatologicals	206
Genito urinary system and sex hormones	168
Musculo-skeletal system	331
Nervous system	585
Respiratory system	392
Sensory organs	134
Systemic hormonal preparations (excl. Sex hormones and insulins)	104
Various	59
	4227

Evaluation of Medicines with Marketing Authorization (MA) in Croatia:

According to the most recent data available on HALMED's website https://www.halmed.hr/en/lijekovi/baza-lijekova/, last accessed on 13.01.2025, there are currently 5,337 authorized medicinal products for use in Croatia.

Classification by therapeutic class for medicines in the Croatian market is presented in Table 3.

Comparison of MA Medicines Between Kosovo and Croatia

A comparison of the number of MA medicines in Kosovo and Croatia reveals significant differences across several therapeutic classes. Croatia has 1,110 more authorized medicines than Kosovo, which reflects a 26% higher availability of medicines in Croatia.

Figure 1 shows these differences in graphic form, presenting the total number of MA medicines found in each country and their distribution across therapeutic classes, while the detailed breakdown of these differences is provided in Table 4.

The biggest disparities are found in the category of Antineoplastic and Immunomodulating Agents, where Croatia has 672 more approved medicinal products (897 in Croatia vs. 225 in Kosovo). Such a large gap indicates substantially broader access to cancer and immune-related treatments in Croatia.

Table 3. Classification of MA Medicines in Croatia based on the therapeutic class

Therapeutic class	Number of MA medicines
Alimentary tract and metabolism	478
Antiinfectives for systemic use	599
Antineoplastic and immunomodulating agents	897
Antiparasitic products, insecticides and repellents	5
Blood and blood forming organs	476
Cardiovascular system	861
Dermatologicals	100
Genito urinary system and sex hormones	254
Musculo-skeletal system	180
Nervous system	889
Respiratory system	197
Sensory organs	104
Systemic hormonal preparations (excl. Sex hormones and insulins)	123
Various	174
	5337

Table 4. Comparison of the number of MA Medicines in Kosovo and Croatia based on the therapeutic class

Therapeutic Class	Kosovo	Croatia	Diff (Cro-Ks)
Alimentary tract and metabolism	468	478	10
Antiinfectives for systemic use	585	599	14
Antineoplastic and immunomodulating agents	225	897	672
Antiparasitic products, insecticides, and repellents	17	5	-12
Blood and blood forming organs	245	476	231
Cardiovascular system	708	861	153
Dermatologicals	206	100	-106
Genito urinary system and sex hormones	168	254	86
Musculo-skeletal system	331	180	-151
Nervous system	585	889	304
Respiratory system	392	197	-195
Sensory organs	134	104	-30
Systemic hormonal preparations (excl. sex hormones & insulins)	104	123	19
Various	59	174	115
Total	**4,227**	**5,337**	**1,110**

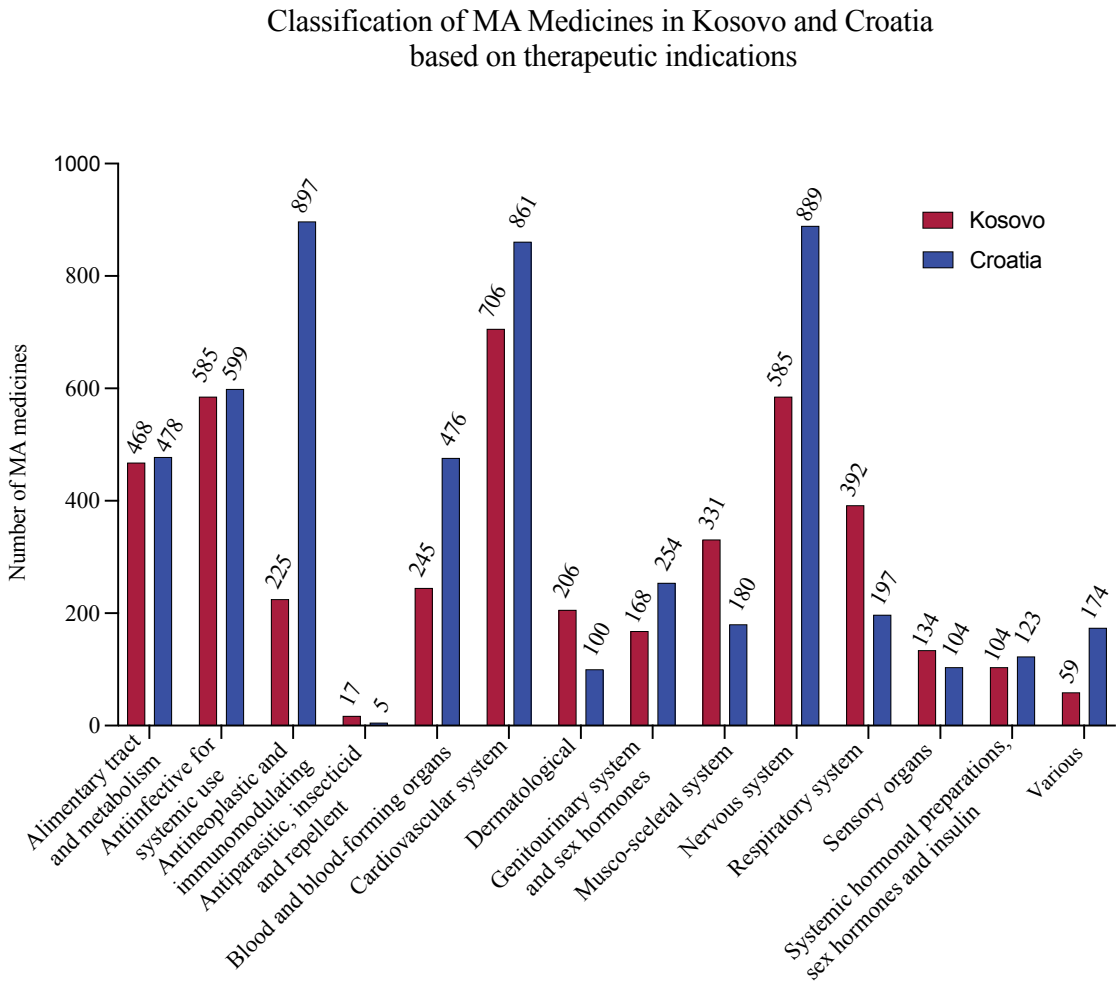

Figure 1. Comparison of the number of MA Medicines in Kosovo and Croatia based on the therapeutic class. The red bars represent Kosovo. The Blue bars correspond to Croatia. The numbers above the bars represent the MA medicines classified by therapeutic class using the ATC classification system. The x-axis shows the therapeutic medicinal products category, while on the y-axis is the number of medicines within each category.

Another notable difference is in medicines used for Nervous System treatment, where Croatia has 304 more medicines than Kosovo (889 vs. 585), which may reflect broader access to treatments for neurological and psychiatric disorders. Similarly, the Blood and Blood-forming Organs category shows a difference of 231 products in favor of Croatia (476 vs. 245), potentially indicating greater therapeutic variety for hematological conditions.

Despite these discrepancies, Kosovo has more licensed medicines in certain therapeutic classes. It outnumbers Croatia in the Musculoskeletal System by 151 medicines, in the Respiratory System by 195, and in Dermatologicals by 106. These areas may reflect regulatory priorities or local market dynamics that favor broader availability of specific treatments.

Comparison of Market-Authorized Medicines in Kosovo and Croatia by Active Ingredients:

A detailed comparison of market-authorized medicines in Kosovo and Croatia, categorized by therapeutic class and active ingredients, is presented in Table 5. A comparative analysis offers an overview of the availability and diversity of medicines within each therapeutic category, highlighting the range of treatment options. These differences are most evident in oncology, immunosuppressive therapy, and treatments for chronic diseases. These variations are further illustrated in Figure 2, offering an overview of the number of MA medicines based on active ingredients available in each country across therapeutic classes. The classification and comparison of MA medicines available in Kosovo and Croatia reveal large discrepancies in the availability of MA medicines classified by active ingredients across different therapeutic classes. These discrepancies are noted in many therapeutic areas, especially in the availability of MA medicines with distinct active ingredients used in oncology treatments, immunosuppressive therapies, and chronic disease management.

The largest gap is observed in antineoplastic agents, with 520 MA medicines classified by active ingredients available in

Table 5. Comparison of MA Medicines in Kosovo and Croatia by Therapeutic Class and Active Substances

Therapeutic Class	**Number of MA medicines based on active ingredient**		
	Kosovo	**Croatia**	**Diff (Cro-Ks)**
Agents acting on the renin-angiotensin system	286	356	70
All other non-therapeutic products	2	7	5
All other therapeutic products	39	78	39
Allergens		9	9
Anabolic agents for systemic use	1		-1
Analgesics	185	166	-19
Anesthetics	55	50	-5
Anthelmintics	6		-6
Anti-acne preparations	16	15	-1
Antianemic preparations	30	27	-3
Antibacterials for systemic use	510	297	-213
Antibiotics and chemotherapeutics for dermatological use	45	14	-31
Antidiarrheals, intestinal anti-inflammatory/anti-infective agents	40	26	-14
Antiemetics and antinauseants	21	18	-3
Antiepileptics	70	120	50
Antifungals for dermatological use	40	15	-25
Antigout preparations	6	15	9
Antihemorrhagics	25	72	47
Antihistamines for systemic use	89	38	-51
Antihypertensives	6	43	37
Anti-inflammatory and antirheumatic products	232	83	-149
Anti-inflammatory/anti-infective agents			0
Antimycobacterials		6	6
Antimycotics for systemic use	22	53	31
Antineoplastic agents	159	520	361
Antiobesity preparations, excl. Diet products		7	7
Antiparkinson drugs	7	57	50
Antiprotozoals	10	5	-5
Antipruritics, incl. Antihistamines, anesthetics, etc.	14		-14
Antipsoriatics		6	6
Antiseptics and disinfectants	9	1	-8
Antithrombotic agents	117	249	132
Antivirals for systemic use	29	113	84
Beta blocking agents	93	71	-22
Bile and liver therapy	7	10	3
Blood substitutes and perfusion solutions	73	111	38
Calcium channel blockers	62	44	-18
Calcium homeostasis	8	27	19
Cardiac therapy	54	90	36
Contrast media	15	42	27
Corticosteroids and anti-infectives in combination	1		-1
Corticosteroids for systemic use	56	39	-17

Corticosteroids, dermatological preparations	62	32	-30
Cough and cold preparations	97	11	-86
Diagnostic agents		7	7
Diagnostic radiopharmaceuticals		20	20
Digestives, incl. Enzymes	2	6	4
Diuretics	44	39	-5
Drugs for acid related disorders	125	51	-74
Drugs for constipation	20	13	-7
Drugs for functional gastrointestinal disorders	42	15	-27
Drugs for obstructive airway diseases	126	119	-7
Drugs for treatment of bone diseases	20	42	22
Drugs used in diabetes	109	242	133
Ectoparasiticides, incl. Scabicides,	1		-1
Emollients and protectives		2	2
Endocrine therapy	17	89	72
General nutrients	3	1	-2
Gynecological antiinfectives and antiseptics	37	12	-25
Immune sera and immunoglobulins	13	37	24
Immunostimulants	12	39	27
Immunosuppressants	37	249	212
Insecticides and repellents			0
Lipid modifying agents	126	208	82
Mineral supplements	8	6	-2
Muscle relaxants	28	33	5
Nasal preparations	53	17	-36
Ophthalmological and otological preparations	6	1	-5
Ophthalmologicals	119	103	-16
Other alimentary tract and metabolism products	8	57	49
Other dermatological preparations	11	13	2
Other drugs for disorders of the musculo-skeletal system	4	5	1
Other gynecologicals	6	18	12
Other hematological agents		17	17
Other nervous system drugs	30	62	32
Other respiratory system products		12	12
Otologicals	8		-8
Pancreatic hormones	1	3	2
Peripheral vasodilators	4	3	-1
Pituitary and hypothalamic hormones and analogues	19	41	22
Preparations for treatment of wounds and ulcers	9	2	-7
Psychoanaleptics	89	146	57
Psycholeptics	148	288	140
Sex hormones and modulators of the genital system	47	86	39
Stomatological preparations	24	1	-23
Therapeutic radiopharmaceuticals		9	9
Throat preparations	27		-27
Thyroid therapy	20	13	-7

Tonics	1		-1
Topical products for joint and muscular pain	41	2	-39
Urologicals	78	138	60
Vaccines	11	93	82
Various	1	1	0
Vasoprotectives	33	7	-26
Vitamins	60	26	-34
	4227	**5337**	**1,110**

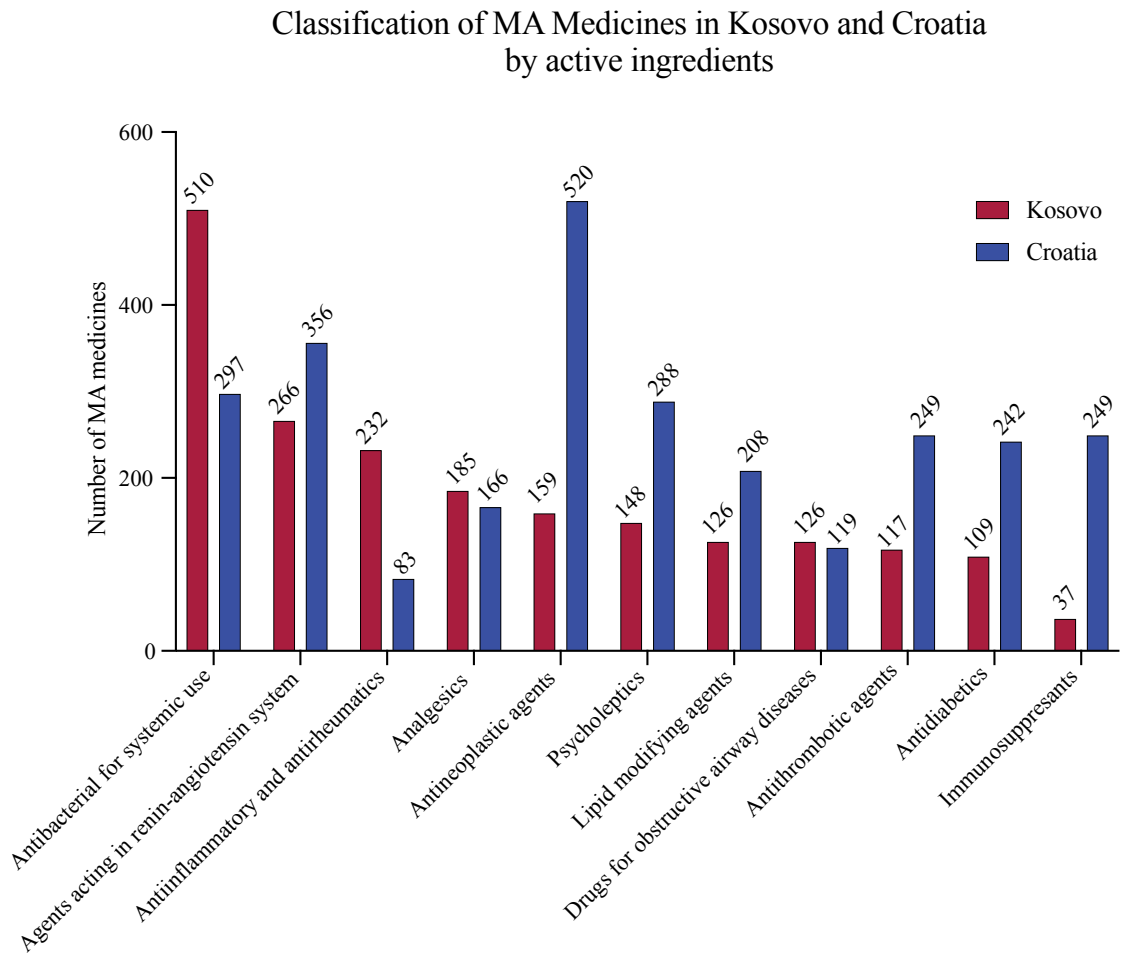

Figure 2. Comparison of MA Medicines in Kosovo and Croatia by Active Ingredients for Different Therapeutic Classes. The red bars represent Kosovo. The blue bars correspond to Croatia. The numbers above the bars represent the MA medicines based on active ingredients across various therapeutic categories. The x-axis represents different therapeutic medicinal product classes, while the y-axis shows the number of medicines classified by active ingredients within each category.

Croatia, while there are 159 in Kosovo (520 vs. 159). Similarly, in immunosuppressant medicines, it is noticed that Croatia has 249 MA medicines with distinct active ingredients compared to 37 for Kosovo (249 vs. 37). In the area of diabetes treatment, there are 242 MA medicines classified by active ingredients in Croatia and 109 in Kosovo (242 vs. 109). Furthermore, the number of MA medicines with different active ingredients for antithrombotic agents is higher in Croatia, at 249 versus 117 in Kosovo (249 vs. 117). Also, under antivirals for systemic use, Croatia has 113 MA medicines classified by different active ingredient, compared to 29 in Kosovo (113 vs. 29). On the other hand, Kosovo has more authorized MA medicines classified by different active ingredients in some therapeutic classes, specifically in antibacterial agents, anti-inflammatory medications, and symptomatic relief medicinal products.

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The biggest gap is observed for antibacterials for systemic use, as Kosovo has 510 MA with different active ingredients and Croatia has 297 (510 vs. 297). Under the category of anti-inflammatory and antirheumatic products, there are 232 MA medicines classified by active ingredients compared to 83 in Croatia (232 vs. 83). In MA medicines classified by active ingredients used for cough and cold preparations, Kosovo has the largest range in comparison to Croatia with 97 against 11 (97 vs. 11). Similarly, systemic antihistamines have 89 MA medicines with different active ingredients in Kosovo compared to 38 in Croatia (89 vs. 38). In antibiotics and chemotherapeutics for dermatological use, Kosovo has 45 MA medicines classified by different active ingredients compared to 14 in Croatia (45 vs. 14). Despite these differences, some therapeutic categories have comparable availability of MA medicines with distinct active ingredients in both countries. The number of MA medicines with distinct active ingredients against acne is 15 in Croatia and similar in Kosovo (15 vs. 16). On the other hand, diagnostic radiopharmaceuticals are available in Croatia with 20 MA medicines classified by active ingredients, but they are absent in Kosovo (20 vs. 0). In further contrast, the MA medicines with active ingredients used in the treatment of psoriasis are absent in Kosovo and present in six cases in Croatia (0 vs. 6).

Regulatory approaches and availability of New Molecular Entities (NMEs) in Kosovo and Croatia

The regulatory pathways in Kosovo and Croatia are substantially different, which influences the availability of these medicines. The presence of NMEs in Kosovo remains limited, with only a few registered medicinal products that are EMA and FDA-approved during a period of 4 years, from 2021 to 2024. Although the simplified procedure exists for medicines approved in the EU, Kosovo's lack of mutual recognition agreements and structured fast-track approval mechanisms keeps it at a disadvantage in efficiently introducing NMEs. Furthermore, the reliance on independent evaluations of non-EU medicines makes the process even longer.

On the other hand, Croatia benefits from the advantages of full integration into EMA regulatory frameworks, including automatic recognition of centrally authorized medicinal products. This leads to fewer bureaucratic barriers and faster NME access. During the same four-year period, Croatia registered a significant number of EMA and FDA-approved medicinal products.

The number of NMEs registered in Kosovo and Croatia during this time varies considerably. As shown in Table 6 and Figure 3, Kosovo's list of EMA-approved medicinal products in 2021 and 2022 includes only 3 NMEs registered each year, out of 54 and 41 respectively. However, in 2023 and 2024, Kosovo did not register any NMEs from the EMA-approved list. By contrast, Croatia registered 49 out of 54 in 2021, 36 out of 41 in 2022, 38 out of 39 in 2023, and 33 out of 46 in 2024.

Furthermore, the FDA-approved NMEs registered in Kosovo and Croatia follow a similar pattern, as shown in Table 7 and Figure 4. From 2021 to 2024, Kosovo managed to register only 4 NMEs from the FDA-approved list in total. Meanwhile, Croatia registered 24 out of 50 NMEs in 2021, 25 out of 37 in 2022, 32 out of 55 in 2023, and 7 out of 23 in 2024.

DISCUSSION

The findings of this study provide a thorough comparison of the pharmaceutical regulatory frameworks of Kosovo and Croatia, underlining the main differences in their harmonization with EU standards, marketing authorization procedures, availability and diversity of medicinal products. While Kosovo has established the basic legal and institutional framework for pharmaceutical regulation, significant implementation gaps remain when compared to Croatia.

Croatia's integration into the EU pharmaceutical system-built on a well-established regulatory base prior to accession, has resulted in a transparent and structured environment. In contrast, Kosovo continues to face challenges with regulatory enforcement, data management, and the absence of mutual recognition agreements, all of which affect access to both essential and innovative medicines.

Referring to Law No. 04/L-190 adopted in 2013[21], Kosovo has made measurable progress in aligning its pharmaceutical legislation with EU directives. However, the lack of digital infrastructure, technical capacity, and operational mechanisms has limited full implementation. One of the most relevant findings of this study is the inconsistent application of Kosovo's marketing authorization pathways, although independent, simplified, and reliance-based procedures exist, they are not routinely or efficiently applied. This contributes to delays in

Table 6: Overview of EMA-approved New Molecular Entity (NME) in Kosovo and Croatia during a four-year period

EMA-approved NMEs	Kosovo	Croatia
Year 2021	3/54	49/54
Year 2022	3/41	36/41
Year 2023	0/39	38/39
Year 2024	0/46	33/46

Table 7: Overview of FDA-approved New Molecular Entity (NME) in Kosovo and Croatia during 2021-2024.

FDA-approved NMEs	Kosovo	Croatia
Year 2021	1/50	24/50
Year 2022	2/37	25/37
Year 2023	1/55	32/55
Year 2024	0/23	7/23

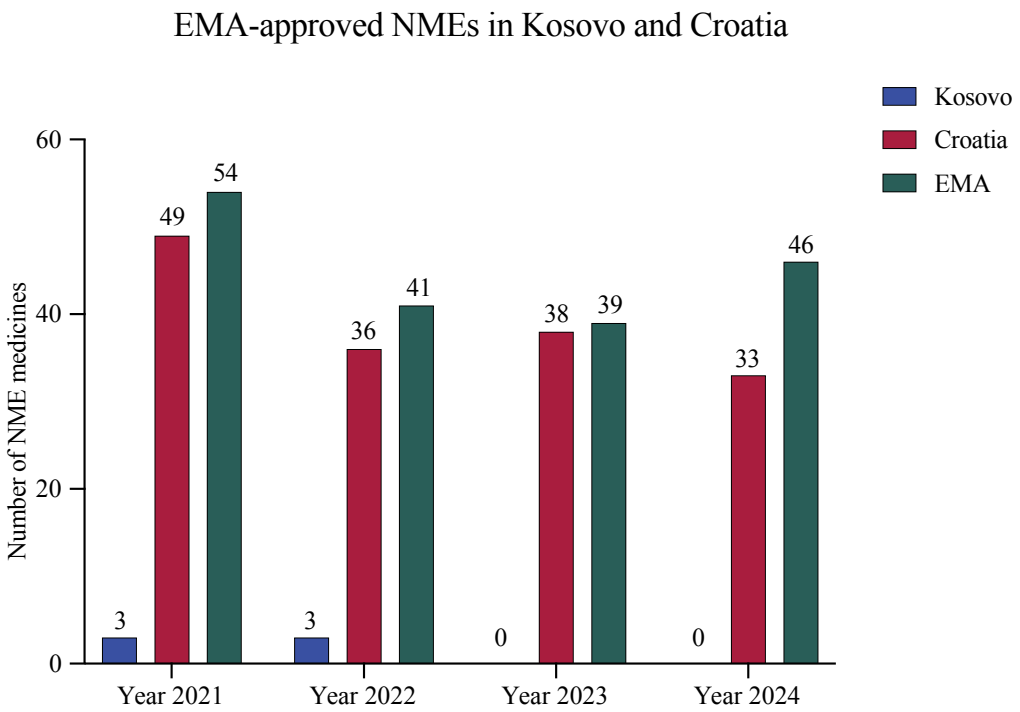

Figure 3. Comparison of NMEs in Kosovo and Croatia. The blue bars represent Kosovo, the red bars represent Croatia and, the green bars the EMA-approved NMEs. The numbers above the bars correspond to the number of NMEs registered in each country compared to the total number of EMA-approved NMEs (green bars) during the four years shown in the x-axis.

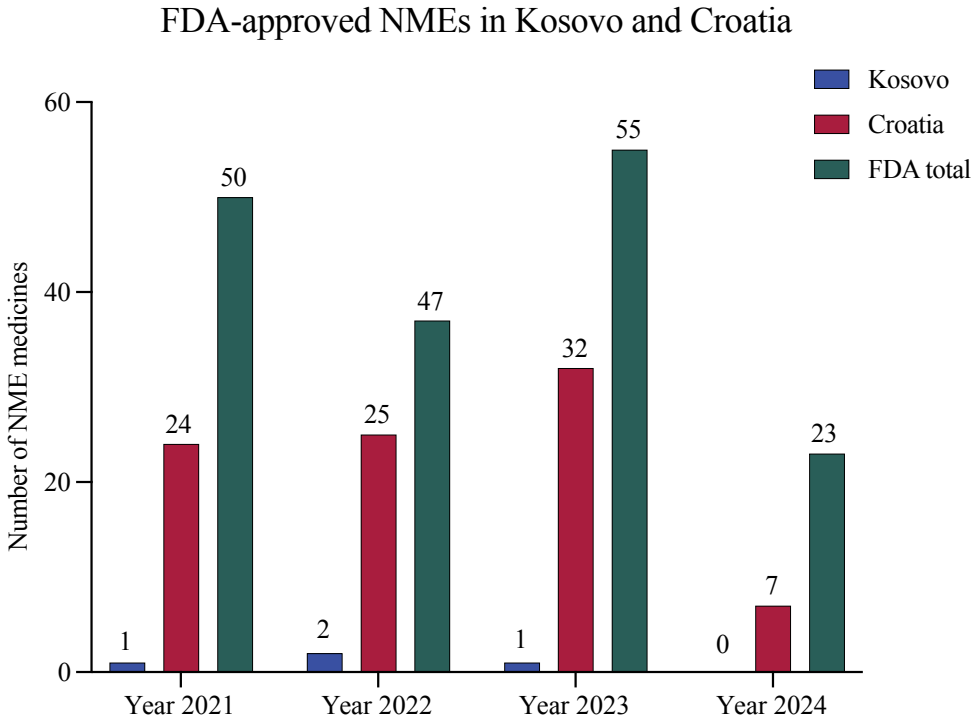

Figure 4. Comparison of NMEs in Kosovo and Croatia. The blue bars represent Kosovo, the red bars represent Croatia and the green bars the FDA-approved NMEs. The numbers above the bars correspond to the number of NMEs registered in each country compared to the total number of FDA-approved NMEs (green bars) during the four years shown in the x-axis.

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market access for new treatments and hinders regulatory performance.

Furthermore, Kosovo has not yet developed streamlined processes for the approval of biologicals, biosimilars, and advanced therapy medicinal products. This regulatory gap limits access to modern treatment options. In contrast, Croatia benefits from full participation in EU centralized, decentralized, and mutual recognition procedures, allowing faster and more predictable entry of innovative medicines into the market. The adoption of the Common Technical Document (eCTD) format and robust post-marketing surveillance systems such as real-time pharmacovigilance and risk management plans, enhances both product safety and public trust. Another major difference lies in how the two countries organize and disseminate regulatory data. Croatia offers a publicly accessible, interactive online database (HALMED) with SmPCs and real-time updates, supporting informed decisions by healthcare professionals. In contrast, Kosovo's KMA provides an Excel-based list of authorized medicines, with limited searchability, no SmPC database, and no multilingual support, which restricts transparency and clinical utility.

A more detailed comparison of authorized medicines reveals notable disparities. Croatia has 5,337 authorized medicinal products, compared to 4,227 in Kosovo, a 26% difference. This discrepancy is most pronounced in therapeutic categories such as antineoplastic and immunomodulating agents, where Croatia has nearly four times as many approved products. This underscores a critical access gap in cancer and immunotherapy treatments in Kosovo. In cardiovascular, hematological, and nervous system drugs, Croatia also shows a broader spectrum of available medicines, likely reflecting its participation in the EMA network. On the other hand, Kosovo shows higher availability in therapeutic areas like antibacterials, anti-inflammatory agents, and symptomatic relief medicines. This pattern may reflect regulatory orientation toward essential public health needs and current market dynamics, rather than innovation-driven priorities.

The deeper analysis by active ingredients reinforces these trends. Kosovo consistently shows a more limited selection in advanced therapeutic classes. For example, in the antineoplastic category, the number of distinct active ingredients available in Kosovo is significantly lower, limiting clinical options. In contrast, Croatia's broader access includes newer targeted therapies and biologics, aligned with EMA-approved treatments. Despite these differences, Kosovo's broader range in some essential medicine categories may reflect effective local procurement strategies and regulatory focus on primary care needs. However, limited access to novel therapeutics highlights a critical gap in the integration of innovation into the national system. Croatia's advantage in this regard is supported not just by EU mechanisms but also by industry engagement and local implementation capacity. One of the most striking findings concerns the availability of New Molecular Entities (NMEs). Kosovo registered only six EMA-approved and four FDA-approved NMEs between 2021 and 2024. This reflects major structural barriers to innovation, including lack of clinical trial infrastructure, weak incentives for industry, and no fast-track or reliance-based approval frameworks.

By contrast, Croatia integrated 33 out of 46 EMA-approved NMEs in 2024 alone, and 32 out of 55 FDA-approved NMEs in 2023. This proactive regulatory approach ensures that Croatian patients have earlier access to cutting-edge treatments. Croatia's performance in NME adoption reflects its seamless participation in EU-wide authorization mechanisms. Kosovo's reliance on independent review processes and the absence of structured acceleration mechanisms continues to delay access to lifesaving therapies. These findings illustrate the need for Kosovo to prioritize regulatory modernization, structured reliance pathways, and collaboration with established regulatory networks like the EMA.

Study Limitations

The study is limited by potential inconsistencies in publicly available data in Kosovo and differences in reporting standards between Kosovo and Croatia, which may affect the comparability of certain indicators. Moreover, while the study was based on complete registry data and not on sampled observations, thus not requiring statistical hypothesis testing, future studies could consider using statistical inference, particularly when working with sampled datasets, time series data, or multi-country comparisons to assess the significance of observed trends and differences.

CONCLUSION

To the best of our knowledge, this is the first study to present a comparative overview of the main differences between the pharmaceutical regulatory systems of Croatia and Kosovo, using Croatia as a benchmark for EU-aligned regulatory practice. Croatia's pharmaceutical system, through its organization, implementation, and integration into the EU framework, serves as a model of best practice and offers a potential roadmap for Kosovo's regulatory advancement. A comparison between the pharmaceutical regulatory systems of Croatia and Kosovo illustrates the crucial role that regulatory structures play in ensuring access to medicines. shows how effectively their systems ensure access to medicines. Despite some progress in aligning with European standards, Kosovo still faces significant challenges with practical implementation, particularly with electronic resources, consistent procedures, and international collaboration. On the other hand, Croatia's deeper integration into EU frameworks has enabled medicine approval simplification and wider availability of both essential and novel treatments. In order to progress, Kosovo must move beyond a legislative-centric approach and prioritize robust implementation and enforcement. This includes investments in digital platforms, adopting faster and more accelerated review pathways, and active collaboration with EU regulatory institutions. These reforms would not only enhance the country's capacity to authorize and monitor medicines more efficiently but also strengthen public health outcomes and institutional credibility. Looking ahead, Kosovo would benefit from developing an online database for medicines

and creating mechanisms that facilitate access to important novel medicines. Building regulatory trust through stronger engagement with the pharmaceutical industry and closer alignment with European standards will be essential for closing the current access gap and reinforcing Kosovo's role in the broader European regulatory environment.

Future research should explore the feasibility of introducing reliance-based pathways, assess the long-term effects of regulatory reforms on medicine availability, and develop a phased roadmap for integrating clinical trial activities. Croatia's successful pre-accession regulatory transformation provides valuable lessons that Kosovo can adapt to build a more resilient, responsive, and internationally recognized pharmaceutical system.

AUTHORS' CONTRIBUTIONS

All authors were involved in all parts of the study and manuscript preparation, including literature search, study design, data analysis, manuscript preparation, and review of the manuscript.

CONFLICT OF INTEREST

No conflict of interest.

References

1. Kunitz SJ. The Making and Breaking of Yugoslavia and Its Impact on Health. *Am J Public Health*. 2004;94(11):1894-1904.
2. The European Regulatory System for Medicines.
3. A pharmaceutical strategy for Europe - European Commission. June 6, 2025. Accessed June 12, 2025. https://health.ec.europa.eu/medicinal-products/pharmaceutical-strategy-europe_en
4. Percival V, Sondorp E. A case study of health sector reform in Kosovo. *Confl Health*. 2010;4:7. doi:10.1186/1752-1505-4-7
5. Kosovo Report 2020 - European Commission. Accessed January 25, 2025. https://neighbourhood-enlargement.ec.europa.eu/kosovo-report-2020_en
6. Kosovo Report 2021 - European Commission. Accessed January 25, 2025. https://neighbourhood-enlargement.ec.europa.eu/kosovo-report-2021_en
7. Kosovo Report 2022 - European Commission. Accessed January 25, 2025. https://neighbourhood-enlargement.ec.europa.eu/kosovo-report-2022_en
8. Kosovo Report 2023 - European Commission. Accessed November 25, 2024. https://neighbourhood-enlargement.ec.europa.eu/kosovo-report-2023_en
9. Kosovo Report 2024 - European Commission. Accessed January 19, 2025. https://neighbourhood-enlargement.ec.europa.eu/kosovo-report-2024_en
10. HEALTH SECTOR STRATEGY 2025-2030 AND ACTION PLAN. Accessed February 2, 2025. https://gzk.rks-gov.net/ActDetail.aspx?ActID=99025
11. Parliament adopts its position on EU pharmaceutical reform | News | European Parliament. April 10, 2024. Accessed June 12, 2025. https://www.europarl.europa.eu/news/en/press-room/20240408IPR20308/parliament-adopts-its-position-on-eu-pharmaceutical-reform
12. Karninčić EB. Education on the Central Health Information System of the Republic of Croatia (CEZIH) -. January 12, 2024. Accessed June 17, 2025. https://edihadria.eu/en/edukacija-o-centralnom-zdravstvenom-informacijskom-sustavu-republike-hrvatske-cezih/
13. EDIH - AI for Smart Healthcare and Medicine. Accessed February 2, 2025. https://ai4healthcro.eu/
14. Research C for DE and. Novel Drug Approvals at FDA. FDA. March 14, 2025. Accessed June 12, 2025. https://www.fda.gov/drugs/development-approval-process-drugs/novel-drug-approvals-fda
15. AKPPM. Accessed June 11, 2025. https://akppm.rks-gov.net/
16. HALMED. Medicinal Products Database | Medicinal Products .: HALMED. .: HALMED. Accessed January 25, 2025. https://www.halmed.hr/en/lijekovi/baza-lijekova/
17. Anatomical Therapeutic Chemical (ATC) Classification. Accessed June 12, 2025. https://www.who.int/tools/atc-ddd-toolkit/atc-classification
18. Directive - 2001/83 - EN - EUR-Lex. Accessed November 25, 2024. https://eur-lex.europa.eu/eli/dir/2001/83/oj
19. Regulation - 726/2004 - EN - EUR-Lex. Accessed June 17, 2025. https://eur-lex.europa.eu/eli/reg/2004/726/oj/eng
20. Web Content Accessibility Guidelines (WCAG) 2.1. Accessed February 27, 2025. https://www.w3.org/TR/WCAG21/
21. LAW NO. 04/L-190 ON MEDICINAL PRODUCTS AND MEDICAL DEVICES. Accessed November 25, 2024. https://gzk.rks-gov.net/ActDetail.aspx?ActID=9437
22. Directive - 2003/94 - EN - EUR-Lex. Accessed November 25, 2024. https://eur-lex.europa.eu/eli/dir/2003/94/oj
23. Directive - 98/79 - EN - EUR-Lex. Accessed January 19, 2025. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:31998L0079
24. Council Directive 90/385/EEC of 20 June 1990 on the Approximation of the Laws of the Member States Relating to Active Implantable Medical Devices. Vol 189.; 1990. Accessed January 19, 2025. http://data.europa.eu/eli/dir/1990/385/oj/eng

25. Josipović I. MEDICINAL PRODUCTS ACT.
26. REGULATION (EU) 2017/ 745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL - of 5 April 2017 - on medical devices, amending Directive 2001/ 83/ EC, Regulation (EC) No 178/ 2002 and Regulation (EC) No 1223/ 2009 and repealing Council Directives 90/ 385/ EEC and 93/ 42/ EEC.
27. Law on the Implementation of Regulation (EU) 2017/745 on Medical Products and Regulation (EU) 2017/746 on In Vitro Diagnostic Medical Products. Accessed February 2, 2025. https://narodne-novine.nn.hr/clanci/sluzbeni/2018_11_100_1930.html
28. HALMED. Good Manufacturing Practice | Manufacturing | Distribution, Manufacturing and Inspection .: HALMED. .: HALMED. Accessed January 21, 2025. https://www.halmed.hr/en/Promet-proizvodnja-i-inspekcija/Nadzor-proizvodnja-i-uvoz/Dobra-proizvodacka-praksa/
29. HALMED. National legislation - The legislative framework | The Role Of Halmed And The Legislative Framework | Medical Devices .: HALMED. .: HALMED. Accessed February 2, 2025. https://www.halmed.hr/en/Medicinski-proizvodi/Uloga-HALMED-a-i-zakonodavni-okvir/Zakonodavni-okvir/
30. Act implementing Regulation (EU) No. 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC. Accessed January 21, 2025. https://narodne-novine.nn.hr/clanci/sluzbeni/2019_02_14_270.html
31. ADMINISTRATIVE INSTRUCTION NO.01/2015 MARKETING AUTHORISATION FOR MEDICINAL PRODUCTS. Accessed January 21, 2025. https://gzk.rks-gov.net/ActDocumentDetail.aspx?ActID=10803