Arh. farm. 2025; 75: 101 – 113 *Review article/Pregledni rad*

A Comparative Study of the Procedures for Medicine Approval in the European Union and the United States

Blagoj Gjeorgiev, Dijana Miceva, Dino Karpicarov*, Paulina Apostolova, Krume Bogevski, Marija Arev, Biljana Gjorgjeska

Faculty of Medical Sciences, Goce Delcev University, Stip, Krste Misirkov, 10A, Stip, North Macedonia

*Corresponding author: Dino Karpicarov, e-mail: dino.karpicarov@ugd.edu.mk

Received: 20 December 2024; Revised in revised forme: 12 February 2025; Accepted: 17 February 2025

Abstract

Medicine registration refers to evaluating a medical product's safety, efficacy, and quality, leading to the granting of a Marketing Authorization. Given the intense globalization of the pharmaceutical industry, harmonizing regulatory procedures between the European Medicines Agency (EMA) and the United States's Food and Drug Administration (FDA) is critical for accelerating the availability of new medicines. The EMA oversees three different procedures for medicine registration: Centralized, Decentralized and Mutual Recognition Procedure. Conversely, the FDA offers three registration applications – Investigational New Drug Application, New Drug Application and Abbreviated New Drug Application. A comparison between the FDA and EMA reveals numerous discrepancies within each system and highlights opportunities for harmonization. While both agencies achieve high concordance in their final decisions, the FDA is faster and more streamlined, benefiting from a centralized authority and expedited pathways. The EMA's structured approach ensures thorough evaluations but can delay approvals. Efforts to harmonize procedures, such as the FDA-EMA Parallel Scientific Advice program and the Mutual Recognition Agreement, aim to enhance alignment and reduce development resources, creating a global regulatory environment to streamline the registration of new medicines.

Key words: harmonization, regulation, authorization, evaluation

https://doi.org/10.5937/arhfarm75-55555

Introduction

The term "medicine registration" refers to reviewing and evaluating evidence regarding the safety, efficacy, and quality of a specific medical product, ultimately leading to the granting of Marketing Authorization (MA). The relevant authority conducts this process within a clearly defined legal framework, which outlines the requirements for submitting a registration application. It also details the evaluation procedures and the conditions under which an MA may be revoked or modified (1).

Given the intense globalization of the pharmaceutical industry, harmonizing regulatory procedures for medicine registration between the United States (US) and the European Union (EU) has become increasingly important to accelerate the development and availability of new medicines to the public. Globally, the regulatory bodies overseeing medicine registration in these regions – the Food and Drug Administration (FDA) in the US and a coalition of federal bodies, including the European Medicines Agency (EMA), the European Commission (EC), and the national authorities of EU member states in the EU – are among the most rigorous and influential, accounting for 49% of the total share of medicines on the global market (2).

However, the regulatory bodies in these regions often need to revise their interpretation of data regarding the safety and efficacy of medicines during the registration process. In the US, experts consider the registration procedures slow, risky, and expensive, while in the EU, there are concerns that medicines are approved too quickly, potentially compromising patients' health (3). These differences raise uncertainties regarding costs and the time required to obtain an MA in both regions.

A comparison between the FDA and EMA reveals numerous advantages and disadvantages within each system. This growing awareness of their differences underscores the challenges in their regulatory procedures and highlights significant opportunities for harmonization. Bridging these gaps could help resolve ambiguities during the registration process of new medicines in the US and EU, ultimately benefiting global health outcomes.

Regulatory Framework for Medicine Registration in the EU

The EMA is a decentralized body of the EU tasked with evaluating, overseeing, and monitoring the safety of medicines. It plays a crucial role in safeguarding public and animal health across EU member states and the European Economic Area (EEA) by ensuring that all medicines available in the EU are safe, effective, and high-quality (4).

A medicine for human or veterinary use must receive an MA before it can be introduced to the market. The medicine can only be marketed if it fulfills the conditions outlined in the granted authorization. In the EEA, the Marketing Authorization Holder (MAH) is responsible for placing a medicinal product on the market, but only after the relevant authority of a member state has issued a national authorization for its territory or when a Union authorization has been granted under Regulation (EC) No 726/2004. The MAH must also be established within the EEA (5).

According to (6) and (7), MAs within the EU are initially granted for five years. Following this initial term, the authorization can be renewed based on a reassessment of the medicine's benefit-risk ratio. This reassessment includes reviewing any new data collected since the medicine was first authorized, including information from pharmacovigilance systems, thus confirming that the MA remains valid. Typically, the authorization is granted indefinitely after the first renewal, although in some instances, the MAH may be required to renew it again after another five years.

There are three different legal routes for medicine registration in the EU: Centralized Procedure (CP), Decentralized Procedure (DP), and Mutual Recognition Procedure (MRP). Each member state can also register medicines nationally, according to their National Procedure (NP). The CP is mandatory in specific cases, such as for most new, innovative medicines evaluated by the EMA and authorized by the EC for marketing in the EU. Conversely, most generic and over-the-counter (OTC) medicines are assessed and authorized through a relevant national procedure. Additionally, many older medicines, which were available before the establishment of the EMA, were also authorized nationally. Medicines that do not fall within the mandatory scope of the CP can seek MA in one or several EU countries through the DP or MRP. In these cases, member states' competent authorities grant the authorizations (8).

Centralized Procedure (CP)

The CP is a standard European medicine registration procedure that obtains a centrally registered medicine with a single MA valid in all member states (3), including EEA member states. The applicant sends the medicine registration application to the EMA for validation and scientific evaluation. The Committee for Medicinal Products for Human Use (CHMP) at the EMA will review the application and recommend whether the medicine should be authorized. The decision in the form of a proposal is sent to the EC, which has to decide whether or not the medicine will receive an MA (5).

The CP is required for certain medicines and optional for others. It is mandatory for medicines derived from biotechnology processes, including genetic engineering. It is also required for medicinal products used for treating HIV/AIDS, cancer, diabetes, neurodegenerative disorders, autoimmune diseases, and other immune dysfunctions. Additionally, the procedure is compulsory for orphan medicinal products (medicines used for rare diseases) and veterinary medicines primarily used as performance enhancers to promote animal growth or increase yields from treated animals. On the other hand, the CP is not mandatory for medicines containing a new pharmacologically active substance with indications different from those requiring mandatory CP. It can also apply to medicines representing significant therapeutic, scientific, or technical innovations and medicines whose registration is essential for public or animal health in the EU territory (9).

National Procedure (NP)

Each EU member state can establish its NP to authorize medicines that do not require registration through CP (10).

A national competent authority implements the NP, granting an MA. There is usually only one competent authority, but sometimes, two institutions can perform this function. For example, the Spanish Agency for Medicines and Health Products is the competent authority for implementing the NP in Spain, while in Germany, two authorities are responsible for implementing this procedure: the Federal Institute for Drugs and Medical Devices and the Paul Ehrlich Institute. National competent authorities for the registration of medicines in EU member states differ because they have different management forms. Thus, according to the abovementioned examples, the competent authority in Spain is an agency; in Germany, two different institutes act as competent authorities. In Luxembourg, on the other hand, this procedure is under the competence of the line ministry, i.e., the Ministry of Health. In addition to the Healthcare and Youth Care Inspectorate within the Ministry of Health, Welfare, and Sport, a specially formed board, the Medicines Evaluation Board, holds this competence in the Netherlands. In Greece, the National Organization for Medicines appears as a competent authority, which means that an organization can sometimes be a form of competent authority as well (11).

Decentralized Procedure (DP)

The DP applies when the medicine needs to be registered in more than one member state. However, the medicine should not be authorized in any other member state when submitting the registration application (12). Therefore, with this procedure, medicines that do not meet the mandatory scope of the CP can be registered with the DP (9).

When registering a medicine according to the DP, the member state that performs the initial assessment of the medicine, which results in the preparation of a draft assessment report, is referred to as a Reference Member State (RMS). The other member states where the medicine should be registered in parallel are called Concerned Member States (CMS). They can immediately approve the draft assessment report or initiate additional expertise if they think a particular problem exists. The final assessment report is drawn up after the CMS gives the green light to the draft report. Based on this, the member states involved in the medicine registration process simultaneously issue an MA, enabling the medicine to be placed on the market in the RMS and CMS (8).

Mutual Recognition Procedure (MRP)

Like the DP, the MRP applies when the medicine must be registered in more than one member state. However, when submitting for registration, the medicine is already registered in at least one member state (12).

When registering a medicine according to the MRP, the member state that first authorized, that is, registered the medicine, acts as an RMS. As such, the RMS sends the final assessment report to the other member states that have yet to authorize it. Accordingly, the rest of the member states are CMS. After reviewing and adopting the final assessment report from the evaluation of the authorized medicine, they issue an MA, which enables the marketing of that medicine (8).

Regulatory Framework for Medicine Registration in the US

The competent authority for the registration of medicines within the US is the FDA, i.e., the Center for Drug Evaluation and Research (CDER), the largest of the FDA's six centers (10). The CDER does not test medicines. However, within this center, there is an Office of Testing and Research, which can only conduct limited research on medicine quality, safety, and efficacy (13).

The CDER appropriately evaluates each medicine before it is authorized for marketing in the US. A unique team of experts capable of performing an independent and impartial evaluation carries out this process. The medicine is authorized if the health benefits exceed its known risks. So, the MA issued by the FDA confirms that the CDER has evaluated the medicine and that the health benefits from the specific medicine outweigh the known and potential risks of using it in the human population (14).

There are three types of medicine registration applications that can be submitted to the FDA: Investigational New Drug (IND) Application, New Drug Application (NDA), and Abbreviated New Drug Application (AND). The distinction between a New Drug and an Investigational New Drug is primarily based on their regulatory status and stage of development. A New Drug is a medicine that has completed clinical trials and received approval for marketing from the FDA, while an Investigational New Drug is a medicine that is still undergoing clinical trials to evaluate its safety and efficacy and has not yet been approved (13).

Investigational New Drug (IND) Application

Before receiving authorization, a company or institution acting as a sponsor must conduct clinical trials on the medicine. For this purpose, the sponsor submits an IND application to the FDA and should receive permission to start clinical trials if preclinical trials determine that the medicine is safe (15). Under the current federal law in the US, a medicine can be distributed between different states only if it is previously authorized. By submitting an IND application, the sponsor can be exempted from this legal requirement to conduct clinical trials in different states (16).

New Drug Application (NDA)

Since 1938, an NDA must be submitted for every medicine before it is marketed within the US (17). This application serves as the sponsor's formal request to the FDA for permission to introduce the medicine to the market. Additionally, the data gathered from preclinical and clinical trials conducted under the IND process becomes vital to the NDA (18).

Abbreviated New Drug Application (ANDA)

A reference medicine is defined as a medicine produced by the original developer. Generic medicine has the same qualitative and quantitative active ingredient composition(s). It possesses the same dosage form as the reference medicine, with bioequivalence established through a suitable bioavailability study. To secure approval

for a specific generic medicine, an ANDA is submitted to the FDA, and, upon approval, the applicant is permitted to manufacture and distribute it. This process guarantees that patients in the US have access to a safe, effective, and more affordable alternative to the reference medicine (19).

Results and Discussion

Institutional Differences: Centralization vs. Decentralization

In the EU, the scientific evaluation of new medicines is carried out by the EMA, which assesses data from clinical trials and other studies to determine the safety and quality of a medicine. However, the ultimate decision on whether a medicine is authorized for registration is made by the EC, which bases its decision on the EMA's recommendations. This indicates that the EMA does not possess executive authority, meaning its role is strictly advisory and evaluative (20).

As previously stated, medicine registration in the EU follows one of four possible procedures, categorizing medicines into three groups: centrally registered, approved across all EU member states through the CP; nationally registered, approved individually by each member state through the NP; and mutually recognized medicines, approved in multiple EU countries based on prior authorization in one member state, through the DP or MRP.

The primary benefits of the CP include the ability to register medicines successfully across all EU member states. Furthermore, the CP establishes a centralized system for monitoring the safety of medicines, which enhances post-marketing surveillance. This procedure also ensures that comprehensive information about medicine usage is available in all EU-recognized languages (4).

The DP offers substantial advantages due to the ability to submit a single MA application across multiple EU member states simultaneously for medicines that have not yet been authorized and do not fall under the scope of the CP (21). The DP enables manufacturers to save time and resources by simultaneously reducing the administrative burden of obtaining authorization in several countries. This process benefits generic drugs, facilitating faster market entry and broader availability of more affordable medicines (9).

The MRP allows a manufacturer with an MA in one EU member state to seek authorization in other member states, significantly reducing the time and resources required for approval. By relying on the assessment conducted by one member state, the MRP streamlines the regulatory process. Furthermore, this process supports the free movement of goods, contributing to a more integrated market while respecting the regulatory frameworks of each nation (22).

In the US, the FDA's CDER holds executive authority to determine whether a medicine is approved for registration. The registration process is highly centralized, offering two main types of MA: standard and accelerated. To obtain one of these MAs, applicants must submit one of three applications: IND, NDA, or ANDA. As a centralized

federal agency, the FDA oversees the regulation of biomedical products, including clinical trials, marketing approval, and risk management. Before any testing on human subjects can begin, the manufacturer must engage the FDA to ensure compliance and approval for clinical studies (13).

The INDA is the first step in the approval process for medicines without prior approval or with new indications. It is submitted before the clinical trials, which allows the FDA to assess study protocols and investigator details. After the trials, an NDA containing comprehensive safety and efficacy data is submitted for marketing approval. In contrast, the ANDA is submitted in case of generic medicines, allowing manufacturers to use existing NDA data without new clinical trials. In summary, the INDA initiates trials, the NDA seeks marketing approval, and the ANDA supports generic medicine approval (23).

The process of medicine registration in the US is streamlined through its centralized system, which lacks an added layer of state-level regulations, simplifying the entry of new medicines and ensuring uniformity across the country (2). In contrast, the EU allows individual member states to impose national requirements, adding complexity to the process and creating variations in medicine availability. Although the structured approach of the EMA ensures the safety and effectiveness of medicines, some argue that it may slow access compared to the more flexible system of the FDA, which often utilizes expedited pathways (24).

Differences in Approval Timelines: From Development to Authorization

The reduced timeline from discovering and developing new medicines to their marketing is equally crucial for patients and manufacturers. For manufacturers, this period is often characterized by significant costs, mainly due to the extensive resources allocated to clinical trials. During this time, manufacturers incur expenses without generating revenue, which can significantly impact their financial resources (25).

While the overall regulatory process seems similar between the EMA and FDA, notable differences in approval timelines persist. The regulatory process of the FDA is considerably quicker and more streamlined as it consolidates evaluation and decision-making under a single federal agency. In contrast, the regulatory process of the EMA involves two steps: an initial scientific opinion provided by the CHMP and a formal decision issued by the EC (24).

For the EMA, once an application is submitted, the review process begins with the CHMP conducting a scientific evaluation and issuing a recommendation, followed by a decision from the EC within 67 days. Overall, the entire process can take several months, depending on the complexity of the application and any additional information that may be required. In contrast, the FDA typically reviews NDAs within 10 months under the standard process or 6 months for priority reviews (20).

According to Downing et al. (26), the FDA processes applications faster than the EMA, challenging commonly held assumptions. Specifically, average time required for

the FDA to complete the initial review of novel medicines is 303 days compared to an average of 366 days in case of the EMA, while the full review takes an average of 322 days for the FDA and 366 days for the EMA. This efficiency is particularly significant given that the EMA typically approves applications after just one review cycle, while the faster review times of the FDA are achieved despite often involving multiple review cycles.

The average time elapsed after applying for an MA is 39 weeks for the FDA compared to 44 weeks for the EMA. Furthermore, the EMA requires an additional 3.7 weeks, on average, to evaluate a new medicine compared to the FDA, further underscoring the differences in the efficiency of their regulatory timelines (27).

While the timelines for medicine registration vary significantly between the FDA and EMA, their final decisions to grant authorization show a high level of concordance, aligning in 91 – 98% of cases. This substantial agreement highlights the shared commitment of both agencies to ensuring the safety and efficacy of medicines. The minor discrepancies are due to the differences in the clinical evidence each agency requires and the distinct organizational structures of the regulatory authorities (28).

Harmonization Efforts: Future Steps for Alignment

Regulatory authorities are becoming more aware of these concerns and are working together to address them. Organizations such as the International Council for Harmonization (ICH), the Pharmaceutical Inspection Convention (PIC), and the Pharmaceutical Inspection Co-operation Scheme are critical in setting standards and guidelines. Additionally, the International Coalition of Medicines Regulatory Authorities, a voluntary group of regulatory agencies, seeks to establish a formal framework to enhance regulatory alignment. However, it is essential to note that none of these organizations possesses the authority to enforce harmonized legislation or ensure uniform regulatory practices worldwide (29).

The FDA and EMA have initiated several harmonization efforts to streamline approval processes. One significant initiative is the FDA-EMA Parallel Scientific Advice (PSA) program, established in 2009. This program allows manufacturers to receive simultaneous guidance from both agencies, reducing development time and resources. Under this framework, sponsors submit identical documentation to both agencies, which conduct independent assessments before aligning their perspectives. The process culminates in a joint meeting where formal advice letters are provided, offering coordinated feedback to the manufacturers (30).

However, the impact of this program is limited by low participation, procedural inefficiencies, and regulatory differences, with only 22 completed procedures over a five-year period between 2017 and 2021. While the PSA program often leads to regulatory convergence, full harmonization still remains a challenge, and many sponsors lack awareness or engage too early in development. Addressing these challenges could significantly improve the PSA’s potential to accelerate patient access to innovative treatments (31).

The ICH has implemented several key initiatives to enhance the regulatory framework for medicine registration. These efforts include establishing guidelines (e.g., the Common Technical Document) that cover critical areas such as clinical trial design, data integrity, and pharmacovigilance. The ICH also promotes collaboration among regulatory authorities through forums facilitating discussions on essential topics such as developing pediatric and oncologic medicines and expedited pathways for innovative therapies (28).

Another harmonization effort is the Mutual Recognition Agreement (MRA), established between the FDA and EMA to streamline the inspection processes, enhance efficiency, and reduce costs in bringing medicines to the market. Initiated in late 2017 and fully implemented by July 2019, the MRA allows for mutual acceptance of Good Manufacturing Practice (GMP) inspections, which is expected to increase the competitiveness of both the US and EU pharmaceutical sectors and enhance regulatory efficiency by minimizing redundant inspections (32).

Although the MRA reduces duplicate inspections, both agencies still retain the right to inspect independently, which limits efficiency. Furthermore, because inspections are only a snapshot in time, reliance on these reports can lead to discrepancies due to inherent differences in inspection methodologies between the two agencies (33).

Looking ahead, the FDA and EMA are focusing on expanding the MRA to include veterinary medicines and considering the inclusion of vaccines and plasma-derived products. They are also exploring cooperation on individualized treatments for ultra-rare diseases and the use of real-world evidence to support regulatory decisions (34). These efforts aim to enhance the efficiency of medicine development and ensure timely access to safe and effective treatments for patients in both regions.

Conclusion

The process of medicine registration is quite complex and subject to continuous evolution, aimed at ensuring that only medicines with a high degree of safety, efficacy, and quality reach the market. Due to the varying categories of medicines, registration processes are not standardized and can differ significantly. For example, the FDA's centralized approach in the US contrasts significantly with the EMA's decentralized framework in the EU, reflecting broader disparities in their regulatory philosophies and operational structures. Furthermore, differences in timelines for obtaining an MA represent additional challenges for pharmaceutical companies aiming to market their products in both regions, requiring careful resource allocation and strategic planning. Nevertheless, these challenges could be mitigated by harmonizing regulatory policies between the EU and US, creating a global regulatory environment to streamline the registration of new medicines.

Acknowledgment

The authors of this paper extend their gratitude to all those who contributed to the completion of this study. We thank the regulatory professionals and scholars whose research and insights on medicine registration processes in the EU and US informed and enriched our comparative analysis. Our appreciation goes to the organizations and agencies, including the EMA and FDA, whose publicly available resources provided critical data for this study.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Author contributions

DM and PA: conceptualization and investigation; BG and KB: writing – original draft; DK and MA: writing – review & editing; BG: supervision.

References

1. Aronson JK, Ferner RE. Unlicensed and off-label uses of medicines: definitions and clarification of terminology. Br J Clin Pharmacol. 2017;83(12):2615–25.
2. Sifuentes MM, Giuffrida A. Drug Review Differences across the United States and the European Union. Pharm Regul Aff: Open Access. 2015;4(4):1000e156.
3. Van Norman GA. Drugs and Devices: Comparison of European and U.S. Approval Processes. JACC Basic Transl Sci. 2016;1(5):399–412.
4. Authorizations of Medicines – European Medicines Agency [Internet]. European Medicines Agency [cited 2025 Mar 20]. Available from: https://www.ema.europa.eu/en/about-us/what-we-do/authorisation-medicines.
5. European Commission. EudraLex – Volume 2 – Pharmaceutical legislation on notice to applicants and regulatory guidelines for medicinal products for human use [Internet]. health.ec.europa.eu; 2019 [cited 2025 Mar 20]. Available from: https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-2_en.
6. Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency [Internet]. Official Journal of the European Union. 2004;L 136(47):1–33 [cited 2025 Mar 20]. Available from: https://eur-lex.europa.eu/eli/reg/2004/726/oj.
7. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use [Internet]. Official Journal of the

European Communities. 2001;L 311(44):67–128 [cited 2025 Mar 20]. Available from: https://eur-lex.europa.eu/eli/dir/2001/83/oj.
8. Ghalamkarpour A. Marketing Authorization Procedures in the European Union – Making the Right Choice. Life Science Technical Bulletin. 2009;33:1–5.
9. Young E. Evaluation of the European Medicines Agency – Final report [Internet]. 2010 [cited 2025 Mar 20]. Available from: https://health.ec.europa.eu/.
10. Van Norman GA. Drugs, Devices, and the FDA: Part 1. JACC Basic Transl Sci. 2016;1(3):170–9.
11. National competent authorities (human) – European Medicines Agency [Internet]. European Medicines Agency [cited 2025 Mar 20]. Available from: https://www.ema.europa.eu/en/partners-networks/eu-partners/eu-member-states/national-competent-authorities-human.
12. Kekare A, Jagadish PC, Janodia M, Bhat K, Karande S, Udupa N. Drug product registration and marketing authorization procedures in EU – A perspective. Marmara Pharm J. 2013;1(17):1–6.
13. How Drugs are Developed and Approved [Internet]. U.S. Food and Drug Administration; 2019 [cited 2025 Mar 20]. Available from: https://www.fda.gov/drugs/development-approval-process-drugs/how-drugs-are-developed-and-approved.
14. Ciociola AA, Cohen LB, Kulkarni P, Kefalas C, Buchman A, Burke C, et al. How Drugs are Developed and Approved by the FDA: Current Process and Future Directions. Am J Gastroenterol. 2014;109(5):620–3.
15. Kashyap UN, Gupta V, Raghunandan HV. Comparison of Drug Approval Process in United States & Europe. J Pharm Sci Res. 2013;5(6):131–6.
16. Investigational New Drug (IND) Application [Internet]. U.S. Food and Drug Administration; 2022 [cited 2025 Mar 20]. Available from: https://www.fda.gov/drugs/types-applications/investigational-new-drug-ind-application.
17. New Drug Application (NDA) [Internet]. U.S. Food and Drug Administration; 2022 [cited 2025 Mar 20]. Available from: https://www.fda.gov/drugs/types-applications/new-drug-application-nda.
18. Mahapatra AK, Sameeraja NH, Murthy PN. Drug Approval Process – In United States of America, European Union and India: A Review. Appl Clin Res Clin Trials Regul Aff. 2014;1(1):13–22.
19. Rafi N, Sandeep DS, Narayanan VA. Regulatory Requirements and Registration Procedure for Generic Drugs in USA. Indian J Pharm Educ Res. 2018;52(4):544–9.
20. Navale SA, Basarkar GD. Overview of Drug Approval Process and Post Approval Changes in Europe. Int J Drug Regul Aff. 2023 Dec 15;11(4):1–15.
21. Parvizi N, Woods K. Regulation of medicines and medical devices: contrast and similarities. Clin Med. 2014;14:6–12.
22. Marathe DD, Shahzeb SM. Review on: Dossier submission in the European countries by using mutual recognition procedure and decentralized procedure. J Generic Med. 2022;19(1):4–9.
23. Sambhaji DJ, Tidke PB. Review on “Regulatory Approval Process of INDA, NDA and Anda in India and Foreign Countries (Us, Europe, China, Australia, Canada).” Int J Innov Sci Res Technol. 2024;9(3):545–60.
24. Kühler TC, Bujar M, McAuslane N, Liberti L. To what degree are review outcomes aligned for new active substances (NASs) between the European Medicines Agency and the US Food and Drug Administration? A comparison based on publicly available information for NASs initially approved in the time period 2014 to 2016. BMJ Open. 2019;9(11):e028677.

25. DiMasi JA, Wilkinson M. The Financial Benefits of Faster Development Times: Integrated Formulation Development, Real-Time Manufacturing, and Clinical Testing. Ther Innov Regul Sci. 2020;54(6):1453–60.
26. Downing NS, Aminawung JA, Shah ND, Braunstein JB, Krumholz HM, Ross JS. Regulatory Review of Novel Therapeutics — Comparison of Three Regulatory Agencies. N Engl J Med. 2012;366(24):2284–93.
27. Vokinger KN, Serra-Burriel M, Glaus CEG, Rohr UP, Hwang TJ, Dalla S, et al. Regulatory Review Duration and Differences in Submission Times of Drugs in the United States and Europe, 2011 to 2020. Ann Intern Med. 2023;176(10):1413–8.
28. Kashoki M, Hanaizi Z, Yordanova S, Veselý R, Bouygues C, Linares J, et al. Comparison of EMA and FDA Decisions for New Drug Marketing Applications 2014–2016: Concordance, Discordance, and Why. Clin Pharmacol Ther. 2019;107(1):195–202.
29. Zerhouni E, Hamburg M. The need for global regulatory harmonization: A public health imperative. Sci Transl Med. 2016;8(338):338ed6.
30. Hanaizi Z, Kweder S, Thor S, Ribeiro S, Marcal A. Considering Global Development? Insights from Applications for FDA Breakthrough Therapy and EMA PRIME Designations. Ther Innov Regul Sci. 2022;57:321–8.
31. Thor S, Vetter T, Marcal A, Kweder S. EMA-FDA Parallel Scientific Advice: Optimizing Development of Medicines in the Global Age. Ther Innov Regul Sci. 2023;57:656–61.
32. Ernesto LG, Loureiro RM. Pharmaceutical Manufacturing in the EU and the EU-US Mutual Recognition Agreement. PDA J Pharm Sci Technol. 2020;74(6):617–26.
33. Frequently Asked Questions and Answers – U.S.-EU Mutual Recognition Agreement [Internet]. U.S. Food and Drug Administration; 2023 [cited 2025 Mar 20]. Available from: https://www.fda.gov/media/168700/download?attachment.
34. European Commission, EMA and FDA agree new priorities to strengthen their collaboration on medicines – European Medicines Agency [Internet]. European Medicines Agency [cited 2025 Mar 20]. Available from: https://www.ema.europa.eu/en/news/european-commission-ema-fda-agree-new-priorities-strengthen-their-collaboration-medicines?utm_source=chatgpt.com.

Uporedna analiza procedura za odobravanje lekova u Evropskoj uniji i Sjedinjenim Američkim Državama

Blagoj Gjeorgiev, Dijana Miceva, Dino Karpicarov*, Paulina Apostolova, Krume Bogevski, Marija Arev, Biljana Gjorgjeska

Fakultet medicinskih nauka, Univerzitet Goce Delcev, Stip, Krste Misirkov, 10A, Stip, Severna Makedonija

*Autor za korespondenciju: Dino Karpicarov, e-mail: dino.karpicarov@ugd.edu.mk

Kratak sadržaj

Registracija leka se odnosi na procenu bezbednosti, efikasnosti i kvaliteta medicinskog proizvoda, što dovodi do davanja dozvole za stavljanje u promet. S obzirom na intenzivnu globalizaciju farmaceutske industrije, harmonizacija regulatornih procedura između Evropske agencije za lekove (EMA) i Uprave za hranu i lekove Sjedinjenih Država (FDA) je ključna za ubrzanje dostupnosti novih lekova. EMA sprovodi tri različite procedure za registraciju lekova: centralizovanu, decentralizovanu i proceduru uzajamnog priznavanja. Nasuprot tome, FDA nudi tri vrste registracionih prijava: prijavu za novi lek u toku istraživanja, prijavu za novi lek i prijavu za novi lek sa skraćenim postupkom. Poređenje između FDA i EMA otkriva brojne razlike unutar svakog sistema i naglašava mogućnosti za harmonizaciju. Dok obe agencije postižu visoku usklađenost u svojim konačnim odlukama, FDA je brža i efikasnija, ima koristi od centralizovane vlasti i ubrzanih postupaka. Strukturirani pristup EMA-e obezbeđuje temeljne procene, ali može da odloži odobrenja. Napori za harmonizaciju, kao što su FDA-EMA program paralelnih naučnih saveta i Sporazum o međusobnom priznavanju, imaju za cilj da poboljšaju usklađivanje i smanje razvojne resurse, stvarajući globalno regulatorno okruženje za pojednostavljenje registracije novih lekova.

Ključne reči: harmonizacija, regulisanje, ovlašćenje, evaluacija