

Original Article

Overview in EMA and FDA Approved Novel Drugs in the Years 2020, 2021 and 2022.

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ABSTRACT

Introduction: the drug approval is essential to any drugs to get in the market for use by patients. The current overview have been focuses on novel drugs approvals by European medicine agency (EMA) and food and drug administration (FDA). **Objective:** The researchers have been focused on the different between the EMA and FDA novel drugs approval during three years. **Method:** Throughout extracts the data from EMA and FDA and other sources and analyze the results like orphan drugs, dosage form, number of approvals, route of administration, pharmacotherapeutic class of novel drugs in both agencies. **Result:** In 2020, the EMA and FDA approved 39 and 53 new drugs, respectively. In 2021, the EMA approved 54 drugs, while the FDA approved 50 drugs for 2022 EMA approved 41 drugs, while the FDA approved 37. For orphan drug designation FDA had higher orphan designation than the EMA, in term of route of administration the vast majority of FDA approved drugs were parenteral drugs. Over the last three years. On the other hand, EMA approved parenteral drugs were also the highest percent. Likewise in terms of dosage form, the solid dosage forms in both EMA and FDA had the upper hand except for 2021 in the FDA. in the pharmacotherapeutic class of the EMA and FDA show high percent of antimicrobial agents, antineoplastic agents, and endocrine agents. **Conclusion:** The drug approval processes of the EMA and FDA exhibit similarities and differences. This Variations highlight the distinct regulatory considerations and priorities of each agency. Understanding these factors is vital for company, healthcare providers and general knowledge

Keywords: European Medicine Agency, drug approval, Food and Drug Administration, novel drugs, regulatory bodies.

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INTRODUCTION

The journey of pharmaceuticals from raw material to the hand of customer difference from country to country and from time to time and it is considered one of the most precise and highly regulated industries to ensure the best quality must be first approved before gets into shelves and patient the approval process must be under laws and limits by a specialist into a wide range of scientists in general pharmaceuticals approved by the pharmaceutical's authority organization or agent.

Every country has its own regulatory body that is responsible for enforcing laws, putting limits on quality, ensuring the quality of the product, inspect the safety of the consumer every organization is different from each other in terms of responsibility ability and they have a common rule of regulations related to drug product registration, manufacturing, distribution, price control, marketing, research, and development, and improve overall public health the purpose of the pharmaceutical regulatory body ensures the safety and quality of pharmaceutical products to the customer and enforce stander and limits for pharmaceuticals use, marketing, and production, and help people to make independent, safe choice ([Van Norman, 2016](#)).

The US Food and Drug Administration (FDA):

The Food and Drug Administration (FDA) is an agency within the U.S. Department of Health and Human Services It consists of the Office of the Commissioner and four directorates overseeing the core functions of the agency: Medical Products and

Tobacco, Foods and Veterinary Medicine, Global Regulatory Operations and Policy, and Operations (US food and drug administration, 2021).

The Rules of FDA

In general mission does not limit to pharmaceuticals some examples of FDA regulate:

Foods, including dietary supplements, Drugs, Biologics, Medical Devices, Electronic Products that give off radiation, Cosmetics, Veterinary

Products, Tobacco and Nicotine product, Marketing, Drugs of Abuse, Meat and Poultry, Pesticides, Water (US food and drug administration, 2022).

FDA Clinical Trial

Then the sponsor begins the clinical trials that include multiple introduce general phase 1, phase 2, and phase 3 are conducted to collect data before the drug gets approval, phase 4 is directed when a drug gets approval

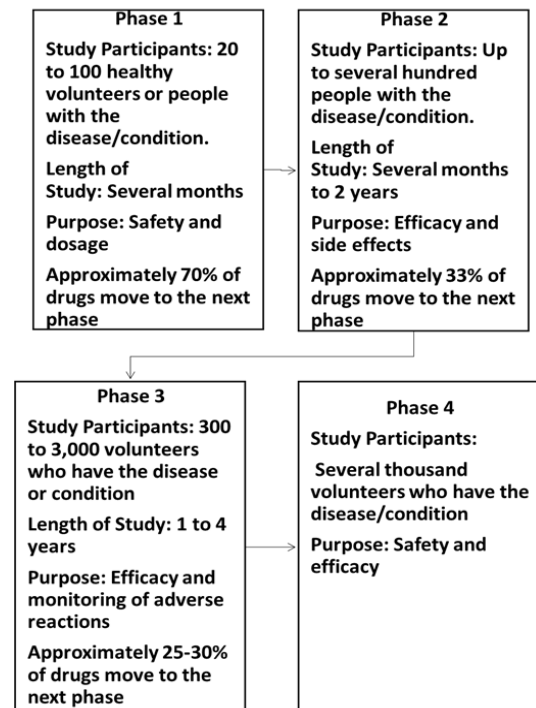
- A. Phase 1 clinical test study on the vary of twenty to eighty volunteers to urge basic pharmacologic and metabolic impact, drug execrated the doable facet impact on the human subject typically it's the single-blind study and it has worn out little to reduce the risks when the study and gathering the data then decide if the drug will pass to phase 2 ([Ciociola et al., 2014](#); [Van Norman, 2016](#)).
- B. In phase 2 clinical test studies are conducted on volunteers with specific illnesses to confirm the effectiveness and also the impactive dose with the best profit-to-risk profile in a manner to gather preliminary information on the effect of a drug on the patient with illness or condition and compare it with the patient

with alternative treatment or placebo (inactive substance typically it is conducted with many hundred volunteers (Ciociola et al., 2014; Van Norman, 2016).

C. After phase 2, the office meets with a sponsor to debate the arrangement to begin phase 3, Then if the drug is accepted to allow phase 2 it goes to giant scale studies in phase 3 clinical test studies in a vary of many volunteers and aim to gather a lot of data concerning drug safety, efficacy, completely different doses, different population with volunteers up to thousands (Ciociola et al., 2014; Van Norman, 2016).

D. After phase 3 if the office approves the drug observation does not stop when it gets within the vend keep underneath phase 4 that is postmarked studies square measure essential of or in agreement to buy a sponsor, and are directed when the office has approved a product for selling. The food and Drug Administration need that the sponsor to submit updates on drug safety in figure1 flow chart visualize the process (Ciociola et al., 2014; Van Norman, 2016).

The sponsor then collects all information from the human and animal study and also the chemical, and physical characteristic of the drug including the pharmacodynamics and pharmacokinetic information into the new drug application (NDA) to decide if the drug gets approval to market into the USA when NDA comes in FDA has sixty days to decide to file it (Ciociola et al., 2014; Van Norman, 2016)



The European Medicines Agency (EMA):

The EMA is a decentralized agency of the European Union. It is located in Amsterdam and primary is responsible to monitor and evaluate the quality and the safety of medicine and manufacture. EMA defends community and animal health in the EU member states, as well as the countries of the European Economic Area (EEA), by confirming that all medicines existing on the EU market are safe and effective and high quality (European Medicines Agency, 2022).

EU law continues to apply The EMA is a more complex agency than FDA or other drug authorization agencies because it does not include just one country as most other agencies and its primary goal is to make harmonization the existing drug agency under its responsibilities (European Medicines Agency, 2020, 2021; Garattini & Curto, 2016).

1.3.2 The Role of EMA:

EMA is responsible for evaluating marketing authorization of medicine of both human and animals, supervising on medicine on the EU market after approved, gives scientific advice on drug development, application evaluation of orphan drug, inspect pediatric investigation, gives transparent good quality information about drugs to practitioner and public, systematic guidelines on necessities for the quality, safety and efficacy testing of medicines (European Medicines Agency, 2019).

Before medicine get on the shelves, they must get authorized and approved. There are two main systems for drug authorization: a centralized route and a national route.

The centralized route is when the pharmaceutical company submits one marketing-authorization application to get market approval throughout the country under EMA under one product name and product information (European Medicines Agency, 2019).

EMA's Committee for Medicinal Products for Human Use (CHMP) or Committee for Medicinal Products for Veterinary Use (CVMP) carry out a scientific assessment of the application and give a recommendation on whether the medicine should be marketed or not. The centralized procedure is necessary for human medicine containing a new active substance for cancer, diabetes, neurodegenerative disease, auto-immune and other immune diseases, (HIV)/(AIDS), viral disease, drugs derived from biotechnology procedures, advanced-therapy medicine, orphan medicines (European Medicines Agency; Pignatti et al., 2011).

The mutual-recognition procedure, that a marketing authorization approved in one Member State can be recognized in other EU countries through decentralized procedure (European Medicines Agency, 2019).

Drug Development Designations of EMA:

EMA does not fund or sponsor new drug development however it publicizes the area in which it has more interest in public health like medicine for rare diseases or life-threatening illnesses to encourage it. EMA primary responsibility is for the scientific evaluation of applications for centralized marketing authorizations in the country under EMA. This approved procedure lets pharmaceutical companies market the medicine through the European Economic Area on the basis of a single marketing authorization.

The sponsor attempts to collect the most possible data on the drug safety, quality, and efficacy to give to EMA for drug authorization with Information about any possible safety concerns with the medicine and follow up plan for risk management after authorization which is called the 'risk management plan' (RMP). The RMP is evaluated by EMA's safety committee, Pharmacovigilance Risk Assessment Committee PRAC, to ensure its suitability must too be provided by the developer and is studied and agreed upon by the CHMP (European Medicines Agency, 2019; Mazzaglia et al., 2018).

The data collected for the drug are from experiment and a series of clinical trials by the sponsor After that EMA's Committee for Medicinal Products for Human Use (CHMP) is involved in the assessment of medicines data that submitted by the company and evaluate if the benefit of the

drug can outweigh its risks and bring health advantage CHMP team is holding a variety of expert in wide range of science and nationality when a new drug application is submitted the CHMP team appoint two members as the rapporteur and co-rapporteur their main role is a peer review and scientific evaluation about the data each one of them forms from their national agency or other agencies a team to export to assess the information with the available data each group analyze the data the sponsor submitted and summarize, and judge it to fully understand the advantage of public health and the limitation of data and question that need to answer (European Medicines Agency, 2019).

Drug Approval Time Frame:

This original evaluation lasts over 120 days then paused (first clock stop) while the applicant prepares the responses to the CHMP's questions and updates the drug's threat operation plan The rapporteur and co-rapporteur estimate the information transferred by the applicant in response to the issues raised by the CHMP and include their analysis of the responses in an updated assessment report the CHMP members review and comment on the updated assessment report (European Medicines Agency, 2019).

The updated assessment report is also reviewed and noted by the PRAC members and talked over at an entire meeting of the PRAC. The PRAC may at this stage request that the risk management plan include the conduct of safety studies after authorization.

Commentary from the CHMP and PRAC members are consolidated and integrated into an updated assessment report which

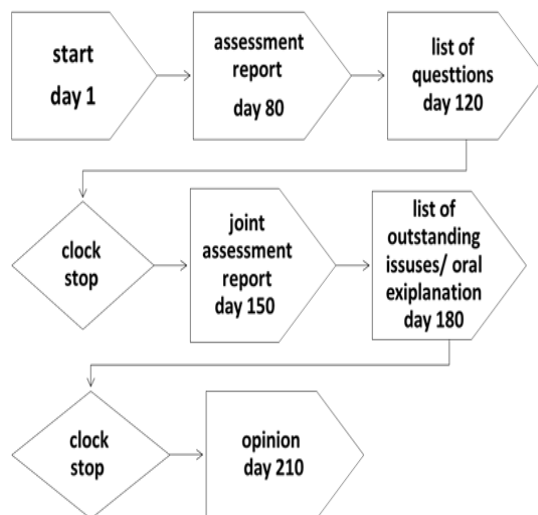
is discussed and adopted at a plenary meeting of the CHMP by day 180 of the active evaluation time. The utmost of the time, this report will contain a new list of questions for the aspirant, called the list of outstanding issues still, the evaluation is paused again (second clock- stop) while the applicant prepares responses If a list of outstanding issues is agreed upon (European Medicines Agency, 2019).

After the second clock stop, an oral explanation in which the applicant directly addresses the commission can be requested either by the applicant or by the CHMP. It's generally organized when the CHMP still has major difficulties with the application. However, the applicant is asked to give explanations of the commission's outstanding issues (European Medicines Agency, 2019).

Once the responses to the outstanding issues are entered and conceivably argued during an oral clarification with the company, the CHMP rapporteur and co-rapporteur assess the revised information from the applicant and include their evaluation in an updated assessment report, as do the PRAC rapporteur and co-rapporteur about the threat operation plan The updated assessment report is reviewed by the members of the two committees and discussed at the CHMP meeting By day 210 of the active evaluation time at the rearmost, the CHMP will adopt an opinion on the operation. The commission will make a recommendation on whether or not a drug should be granted marketing authorization and, if so, under which conditions of use. The commission will also agree on the wording of the product information for healthcare professionals and cases and on any additional data that

the company is needed to give after the drug's authorization (European Medicines Agency, 2019).

The utmost of the time, the commission reaches opinions by agreement. If such an agreement cannot be reached the committee's final opinion will represent the majority view. The divergent opinions and the names of the members expressing them are attached to the opinion of the commission and mentioned in the meeting minutes. The divergent opinions are also published together with the public assessment report and the applicant can request a re-examination of the CHMP's opinion, stating the grounds on which they wish to appeal, within 15 days of receipt of the announcement of the CHMP's opinion. A different rapporteur and co-rapporteur from the original evaluation are also appointed (European Medicines Agency, 2019).



METHODS

The current work studies the difference in new approval novel drugs in both FDA and EMA in the years 2020, 2021 and 2022 by comparing the number of approvals and drug's route of administration, dosage

form, orphan designation and pharmacotherapeutic classes.

This project study novel only and the search obtain the information of approval process of EMA from the searching and analyze only the novel drugs from the main source European public assessment reports (EPARS) which are full scientific assessment reports of medicines authorized at a European Union level and from its website (European Medicines Agency), then FDA from their website (U.S. Food and Drug Administration) and other research papers and sources such as; (Drugs@FDA) and pharma network magazine to obtain more data of novel drugs in the years (2020-2021-2022) (pharma network Magazine).

RESULTS and Discussion

Number of Approved Drugs:

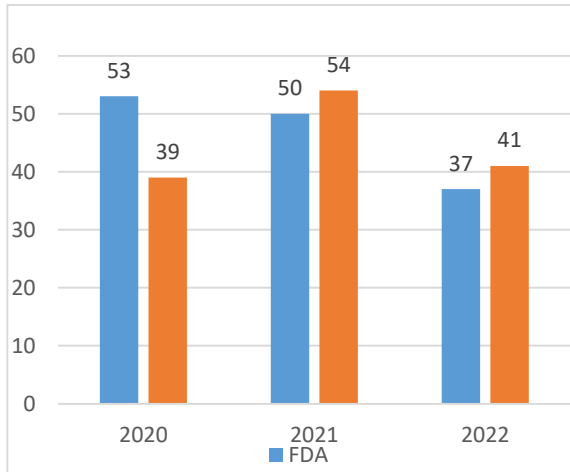
In 2020, the EMA approved 39 new drugs, while the FDA approved 53. However, in 2021, the EMA saw an increase in approvals, with 54 new drugs approved, while the FDA saw a decrease

with 50 approvals Looking ahead 2022, the EMA is projected to approve 41 new drugs, while the FDA is projected to approve 37 the mean approval drug in the last three year of FDA was ≈ 46.67 drugs and ≈ 44.67 drug by EMA and (figure 4) illustrate it.

Orphan Designation:

Orphan designation is granted to drugs that treat rare diseases and conditions, providing incentives to the manufacturers, such as market exclusivity, fee waivers, and tax credits, to encourage the development of

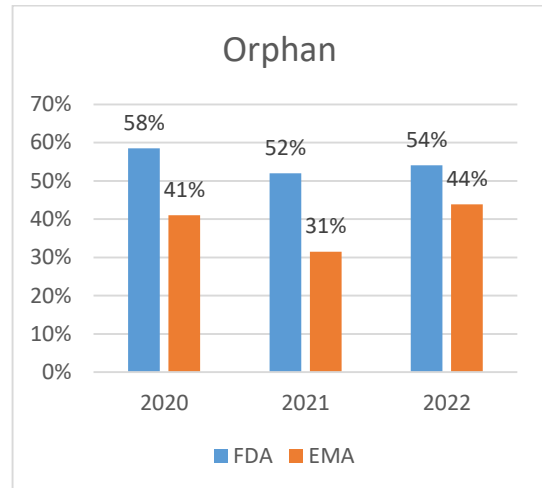
Figure 1. This chart represent the number of approval novel drugs in 2020, 2021 and 2022 in FDA and EMA.



treatments for rare diseases. In this project essay, show the difference in orphan designation and approval of new drugs between the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA) in the years 2020-2022 In 2020, EMA granted orphan designation to 16 out of 39 new drugs, representing a designation rate of 41%. In 2021, this rate decreased to 31%, with 17 out of 54 new drugs receiving orphan designation. In 2022, the orphan designation rate increased to 44%, with 18 out of 41 new drugs receiving orphan designation in contrast, the FDA granted orphan designation to 31 out of 53 new drugs in 2020 (US food and drug administration, 2021). representing a higher designation rate of 58%. However, this rate decreased to 52% in 2021, with 26 out of 50 new drugs receiving orphan designation (US food and drug administration, 2023). In 2022, the orphan designation rate further decreased to 54%, with 20 out of 37 new drugs receiving orphan designation (US food and drug

administration, 2023) (European medicine agency, 2022).

Figure 2 the percent of orphan drugs in both EMA and FDA in 2020, 2021, 2022



3.4 Route of Administration:

The route of administration of a drug plays a critical role in determining its safety and efficacy for use in patients. The way in which a drug is administered can affect the rate and extent of its absorption, distribution, metabolism, and elimination within the body, which in turn can impact its therapeutic effectiveness and potential for adverse effects. Therefore, understanding the differences in route of administration for novel drugs that are approved by regulatory agencies such as the FDA and EMA is of utmost importance for healthcare providers and patients alike, they are classified as (Topical administration, Parenteral administration, Enteral administration)

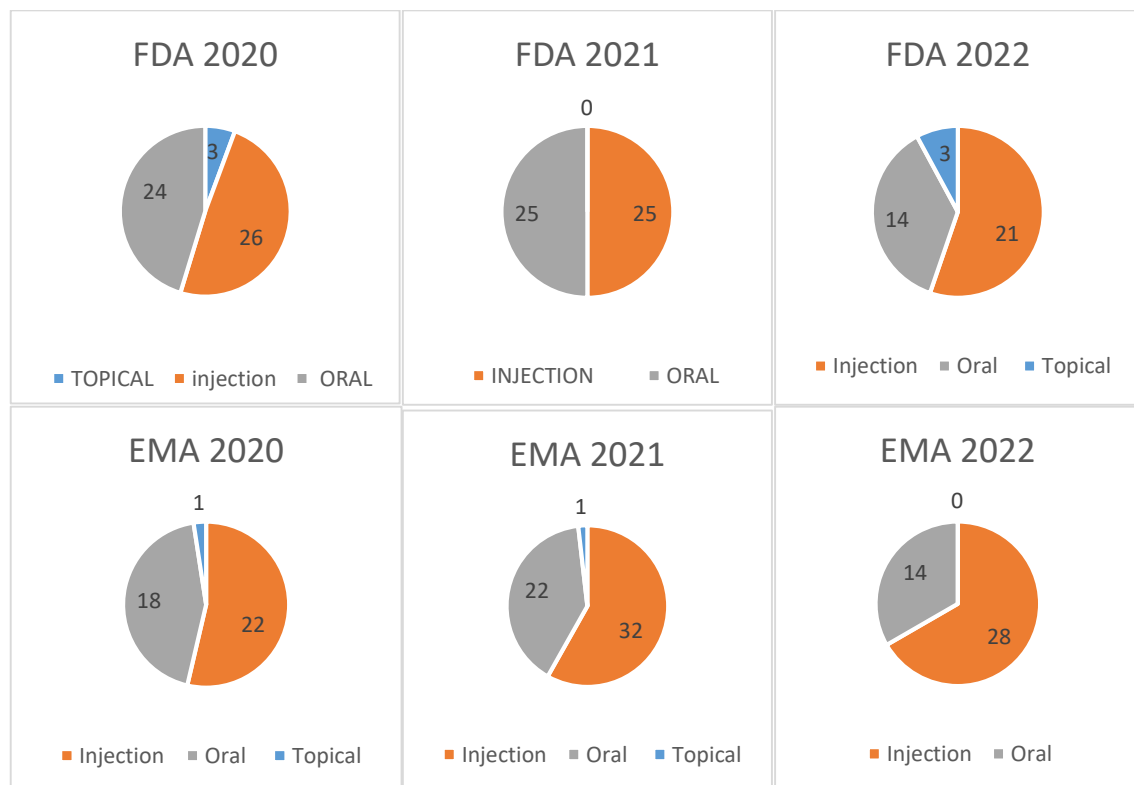
The data shows that in 2020, the FDA approved 26 parenteral drugs, 24 enteral drugs, and only 3 topical drugs. This suggests that the FDA has approved a relatively similar number of drugs for parenteral and enteral administration, which are common routes for chronic

disease management, but has approved fewer drugs for topical administration. In 2021, the FDA approved 25 drugs for both injection and oral administration, but no topical drugs were approved. This indicates a possible preference for more traditional routes of administration, such as injection and oral, over topical administration for drug delivery. In 2022, the number of topical drugs approved increased slightly to three, while the number of injection and oral drugs remained relatively constant in contrast, the EMA approved 22 injection drugs, 18 oral drugs, and only one topical drug in 2020. This suggests that the EMA approved more drugs for parenteral and enteral administration than topical

administration in that year. In 2021, the EMA approved more injection drugs than the previous year, with 32, and also approved more oral drugs with 22, but the number of topical drugs approved remained the same at one. In 2022, the number of injection drugs approved by the EMA decreased to 28, while oral drugs remained at 14, and no topical

drugs were approved Overall, the data shows that both the FDA and EMA have approved more drugs for parenteral and enteral administration than for topical administration.

Figure 3 Pie Charts of EMA And FDA Percent of Different Rout of Administration In 2020, 2021, 2022.



3.5 Dosage Forms:

The dosage form of a drug is an essential aspect of its development and regulatory approval process. The physical properties of the dosage form, such as its solubility, stability, and bioavailability, can affect its efficacy, safety, and patient adherence. The categorization of dosage forms can provide a systematic approach to drug development, formulation, and evaluation, as well as facilitate regulatory approval and clinical use.

They are categorized based on their physical properties such as Solid dosage forms, Liquid dosage forms, Semi-solid dosage forms.

In 2020, the EMA approved 19 solid dosage forms, 20 liquid dosage forms, and 1 semi-solid dosage form. In contrast, the FDA approved 25 solid dosage forms, 26 liquid dosage forms, and 2 semi-solid dosage forms in the same year.

This indicates that the FDA approved slightly more dosage forms overall than the EMA did in 2020, but the difference was not significant. Moving on to 2021, the EMA approved 26 solid dosage forms, 32 liquid dosage forms, and 1 semi-solid dosage form, while the FDA approved 16 solid dosage forms, 28 liquid dosage forms, 0 semi-solid dosage forms, and 1 gaseous dosage form. The EMA approved more dosage forms overall than the FDA did in 2021, with a particular emphasis on liquid dosage forms. In 2022, the EMA approved 16 solid dosage forms, 28 liquid dosage forms, and 0 semi-solid dosage forms. The FDA approved 12 solid dosage forms, 23 liquid dosage forms, 1 semi-solid dosage form, and 1 gaseous dosage form. Once again, the EMA approved more dosage forms overall than the FDA did in 2022, with a particular emphasis on liquid dosage forms.

Figure 4 Chart Shows the Difference in Dosage Forms Approved by FDA In 2020, 2021, 2022.

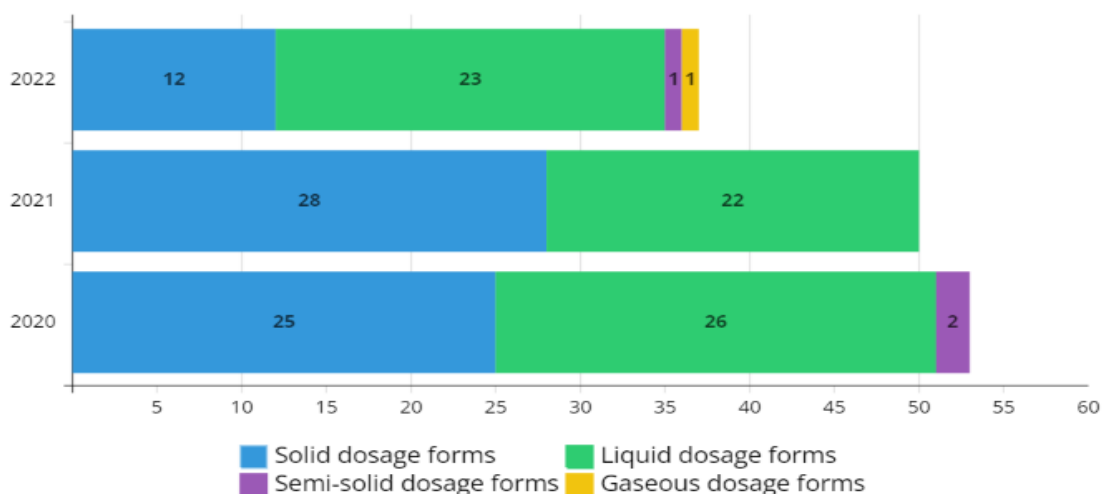
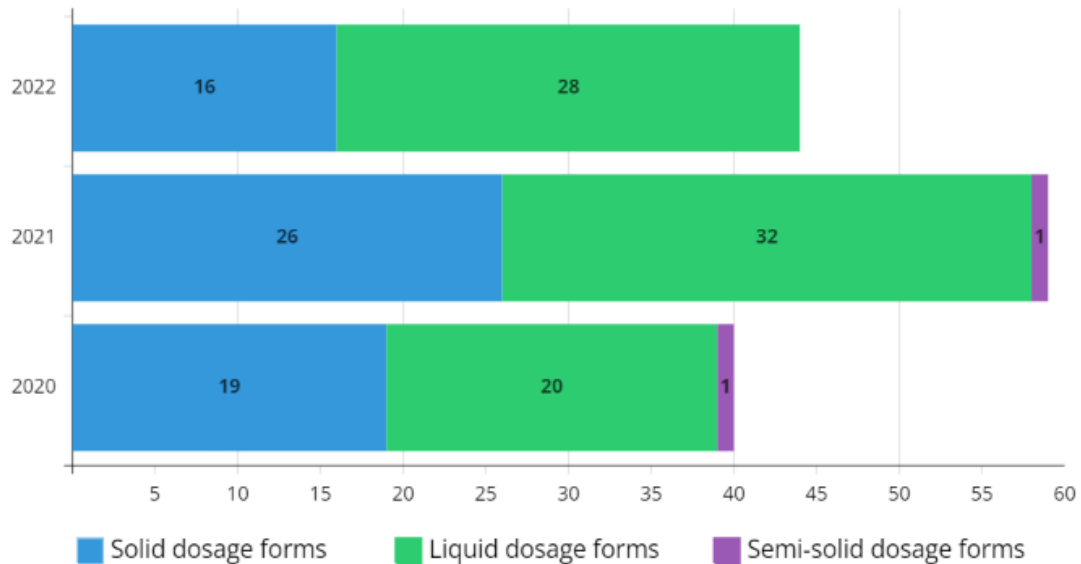


Figure 8 Chart Shows the Difference in Dosage Forms Approved by FDA In 2020, 2021, 2022



Pharmacotherapeutic Classes:

Pharmacotherapeutic classes of FDA and EMA approved pharmaceutical products between 2020 and 2022 have been analyzed. The findings show that the percentage of drugs approved by EMA and FDA in the pharmacotherapeutic classes of antimicrobial agents, antineoplastic agents, endocrine agents, CNS agents, CVS and blood agents varied over the three years.

In 2020, EMA approved 17.95% of drugs in the pharmacotherapeutic class of antimicrobial agents, 35.9% in antineoplastic agents, 2.57% in endocrine agents, 2.57% in CNS agents, and 2.57% in CVS and blood agents. In the following year, the percentages for these pharmacotherapeutic classes for EMA approved drugs were 5.56%,

27.78%, 14.82%, 3.71%, and 5.56%, respectively. In 2022, EMA approved 4.88% of drugs in the pharmacotherapeutic class of antimicrobial agents, 26.83% in antineoplastic agents, 4.88% in endocrine agents, 9.76% in CNS agents, and 4.88% in CVS and blood agents for

FDA approved drugs, in 2020, 9.44% of drugs belonged to the pharmacotherapeutic class of antimicrobial agents, 32.08% to antineoplastic agents, 5.67% to endocrine agents, 9.44% to CNS agents, and 1.89% to CVS and blood agents. In 2021, the percentages for these pharmacotherapeutic classes for FDA approved drugs were 8%, 32%, 8%, 12%, and 4%, respectively. In 2022, FDA approved 10.82% of drugs in the pharmacotherapeutic class of

antimicrobial agents, 37.84% in antineoplastic agents, 5.41% in endocrine agents, 13.52% in CNS agents, and 8.11% in CVS and blood agents. These results suggest that both FDA and

EMA prioritize the approval of drugs in the pharmacotherapeutic class of antineoplastic agents, followed by antimicrobial agents

Figure 9 Chart Shows the Pharmacotherapeutic Classes of Approved Drugs in 2020

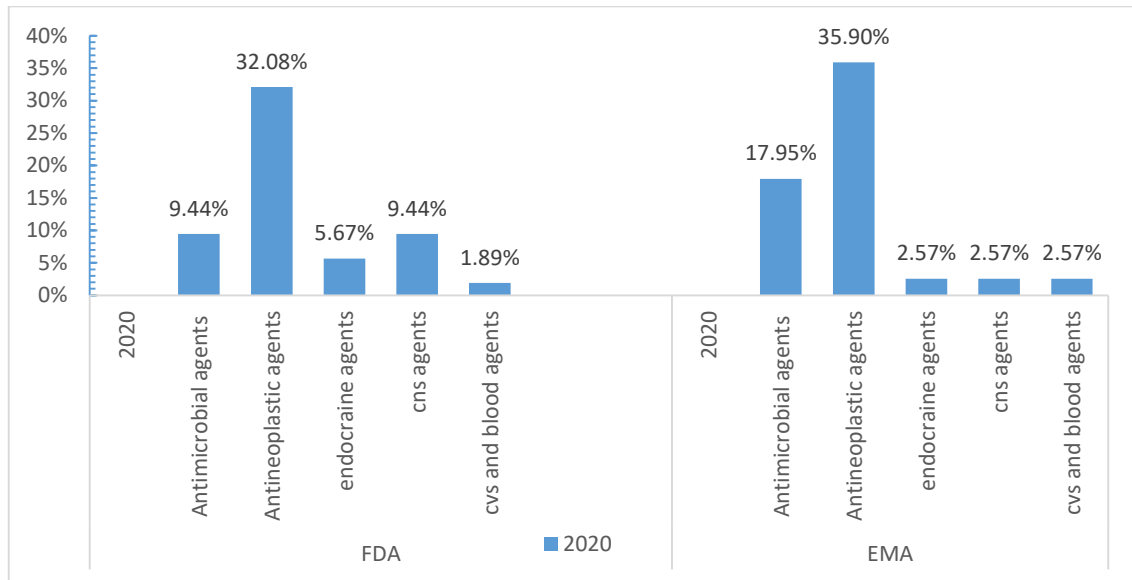


Figure 10 Chart Shows the Pharmacotherapeutic Classes of Approved Drugs in 2021

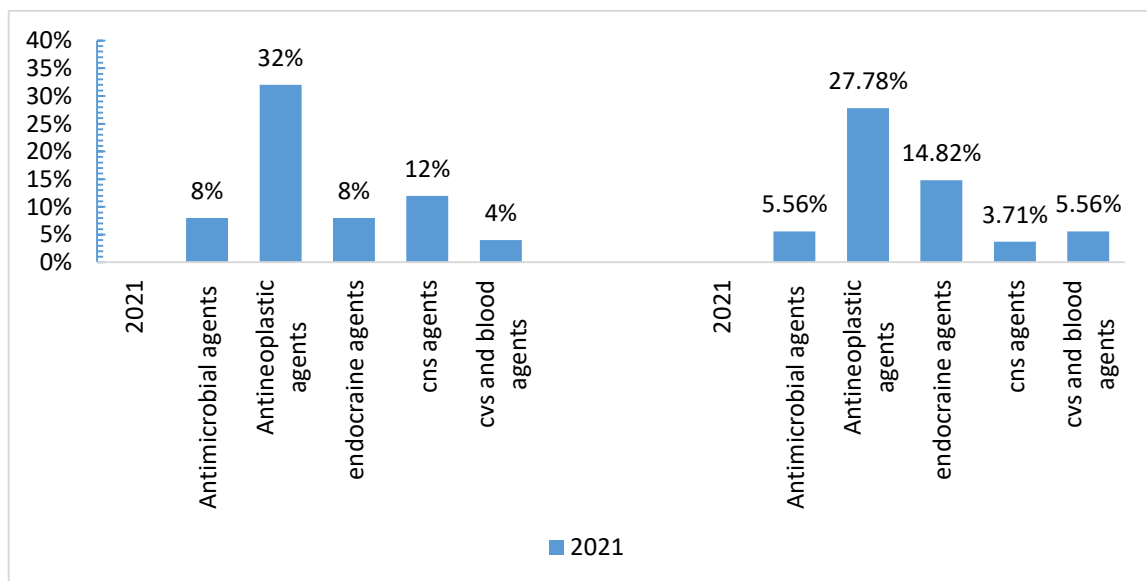
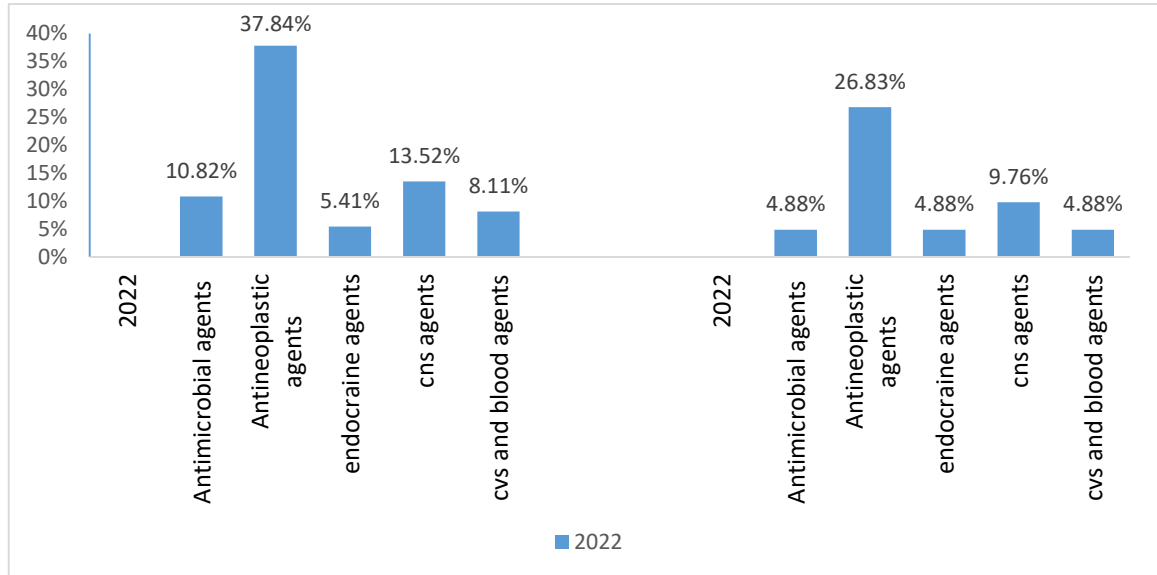


Figure 11 Chart Shows the Pharmacotherapeutic Classes of Approved Drugs in 2022



CONCLUSION

The drug approval processes of the EMA and the FDA share similarities in terms of preclinical studies and clinical trials. However, there are notable differences in the number of drug approvals between the two agencies while the FDA approved more drugs than the EMA in 2020, the EMA experienced an increase in approvals in 2021 and 2022 while the FDA saw a decrease. Projections for 2021 and 2022 suggest that the EMA will continue to have a slightly higher number of approvals compared to the FDA. These variations in approval rates can be attributed to differences in regulatory approaches and review timelines.

Orphan designation, granted to drugs that treat rare diseases, also demonstrates variations between the EMA and FDA. The FDA has higher rates of orphan designation compared to the EMA, indicating a greater emphasis on providing incentives for rare disease drug development in the United States.

Understanding the differences in the route of administration for FDA and EMA-approved drugs is crucial for healthcare providers and patients. The data shows that both agencies prioritize parenteral and enteral administration for drug approvals, which aligns with the prevalence of chronic disease management through these routes. Topical administration, often used for localized conditions, receives fewer drug approvals. It is important to consider various factors, including therapeutic benefits, safety profiles, and manufacturing quality, in addition to the route of administration.

The dosage form of a drug also plays a significant role in its development and regulatory approval. Solid and liquid dosage forms receive higher numbers of

approvals compared to semi-solid dosage forms. However, the differences in dosage form approvals between the EMA and FDA are not significant.

The distribution of drugs across different pharmacotherapeutic classes varies over the years for both agencies. Antineoplastic agents receive the highest percentages of drug approvals, followed by antimicrobial agents. However, there are variations in the percentages of approvals within other pharmacotherapeutic classes. Understanding these variations is important for evaluating the availability and effectiveness of drugs for different medical conditions.

In conclusion, the drug approval processes of the EMA and FDA demonstrate both similarities and differences. The varying approval rates, orphan designation rates, route of administration, dosage forms, and distribution across pharmacotherapeutic classes highlight the distinct regulatory considerations and priorities of each agency.

Understanding these factors is crucial for healthcare providers, scientists, R & D pharma companies and patients when assessing the therapeutic options available for different medical conditions. Continued research and collaboration between regulatory agencies worldwide are essential for ensuring timely access to safe and effective treatments for patients.

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Conflict of Interest

The authors declare no conflict of interest

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