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Review Article

**A Comparative Analysis of Drug Marketing Authorization Procedures in Canada and the European Union****Vinuthna. Rallapalli^{a,*}, Sundar Sankaralingam^b, Vengalasetti Nikita Devi^c**^{a, c} Department of Regulatory Affairs, Vijaya Institute of Pharmaceutical Sciences for Women, Enikepadu, Vijayawada, Andhra Pradesh, India-521108^b Department of Pharmaceutics, Vijaya Institute of Pharmaceutical Sciences for Women, Enikepadu, Vijayawada, Andhra Pradesh, India-521108**Abstract**

The current study will offer an extensive comparison of drug marketing authorization systems within the European Union (EU) and Canada. It examines and compares the regulations, submission procedures, the availability of scientific advice, the type of review, the approving authorities, and the post-review requirements followed in Health Canada and the European Medicines Agency (EMA). Even though both territories adhere to ICH conventions and require CTD/eCTD formats, there are essential distinctions between accelerated approval programs, including Canada Priority Review and Notice of Compliance with Conditions (NOC/c), and the EU Accelerated Assessment, Conditional Approval, and PRIME programs. An overall comparison of procedures is in the form of a table showing differences in structure. In order to evaluate the real-life implementation, three case studies with the most common diseases, Keytruda (oncology), Spinraza (orphan/rare disease), and Humira biosimilar (biologic), were chosen, comparing regulatory approaches and approval dates. The results can be confirmed with the tables and graphs to prove the trends in the approval timelines. It can be concluded that Canada had earlier access to the oncology treatment given in advance through Priority Review, as happened with Keytruda, and the EU was ahead in approval of orphan and biosimilar drugs, having Spinraza and Humira as their representatives. What is captured by these trends is the various strategic focuses and maturity of the regulatory systems. A further analysis of their differences and resulting regulatory planning, when to submit, and the commercial launch of products is also discussed. The insights can help pharmaceutical companies customize region-specific regulatory approaches on the basis of the type of drug and therapeutic area. The recommendation at the end is the adaptability and cross-regional knowledge in the regulations to allow more efficient access for patients to innovative therapies.

Conclusion: This review article eventually offers a useful guide to interested parties in terms of international drug development, regulatory relations, and market access strategy.

Keywords: Marketing Authorization; Health Canada; European Medicines Agency (EMA); PRIME programs; Notice of Compliance (NOC); CHMP; CTD/eCTD

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1. Introduction

Marketing authorization is an important type of regulation as it guarantees the safety, efficacy, and quality of pharmaceutical products before they appear in the market. Health Canada and the European Medicines Agency (EMA) are among the regulatory agencies working under ICH standards, and they utilize the Common Technical Document (CTD/eCTD) to simplify the process of drug submission. In addition to the harmonized aspects, they also differ in the procedural terms, especially in the timeframes, flexibility of approval, and access to tools in the form of regulations. (1,2) Due to the increasing complexity of drug development, particularly of biologics,

oncology agents, and orphan drugs, jurisdictional differences have been gaining importance as far as global regulatory planning is concerned. (3)

It is stressed in recent literature that Canada has fast-track programs like Priority Review and Notice of Compliance with Conditions (NOC/c) programs, but drugs to treat serious illnesses appear to be the greatest beneficiaries of such fast-track approaches to review, including cancer drugs. (4) The centralized process of the EU, on the contrary, is closer to wider regional access and evidences maturity in, e.g., orphan drug designation and biosimilars regulation, with the help of such instruments as accelerated assessment and conditional approval. Such differences are

not just procedural but strategically important to pharmaceutical companies, discarding effective, efficient, region-specific launch strategies. (5,6) Thus, the study offers an overview of the marketing authorization processes in both Canada and the EU that authorize the drug registration in the countries on the basis of selected case studies that aim at comparing the timeframes, the responsiveness of the regulations, and the impact on the development of marketing plans associated with the drug launch.

2. Marketing Authorization Procedure in Canada

2.1 Regulatory Authority

The federal agency that controls the evaluation of drug safety, efficacy, and quality before they are marketed in Canada is Health Canada through its Health Products and Food Branch (HPFB). (7)

2.2 Pre-Submission Activities

Health Canada promotes pre-submission meetings with the sponsors, especially those of novel, complex, or high-priority drugs. These appointments are not compulsory, yet they give information about data requirements, the structure of the dossier, and any issues likely to arise with regulations.

Though having no formal scientific advice procedure as in the EU, sponsors have the option of asking for clarifications at the pre-submission stage in order to prevent any future delay or deficiency.

2.3 Submission of Information

Provided that the results of all the preclinical experiments and the trial clinical results indicate that the therapeutic potential of a drug is more than the risk (side effects, toxicity, etc.), and the dossier on the chemistry and manufacturing of the medication is complete, then the sponsor might choose to submit an NDS to the corresponding HPFB Directorate so that it might grant him a license to sell the drug in Canada. Whether the clinical trials were conducted in Canada or elsewhere, a sponsor may file an NDS. The NDS should contain results of the quality (chemistry and manufacturing) and preclinical and clinical trials carried out in or out of Canada. Data on the drug's efficacy and safety is analysed, a risk/benefit analysis is conducted, and the decision is made. The details submitted by Health Canada as part of an NDS application should be specific such that Health Canada is able to fully conclude on the safety and effectiveness of the new drug. Health Canada must receive all submissions in an electronic Common Technical Document (eCTD) format. The documents should be posted in English or French.

2.4 Review Process

The review timelines by Health Canada are between 7 months (accelerated review/ANDS) and 1 year (standard NDS), although the amount of time spent in actual review varies depending on the type of drug, the quality of a dossier, and sponsor delays in responses to the questions raised by Health Canada. The entire drug development and approval procedure, on average, will require 8-15 years.

The HPFB looks into the NDS and everything that was known about the drug throughout the process of development (quality, preclinical, and clinical) and makes an analysis of the risks of the drug against the benefits to the Canadian population. To be more particular, HPFB examines data on manufacturing, packaging, and labelling of the drug; the data on therapeutic claims about the drug; and the description of side effects of the drug. The information that doctors and patients will be told about the drug will also be addressed through the monographs and information sheets of the drug. Any drugs that can be sold within Canada are checked, and their purpose is to make sure that they satisfy the demands of the Food and Drugs Act and Regulations. After the warranty of these requirements, a sponsor (usually the Marketing Authorization Holder) would be issued a Notice of Compliance, ascertaining that a dossier meets the requirements of the Food and Drugs Act and its Regulations.

2.5 Authorization Outcomes for New Drugs

Notice of Compliance: In case the useful effect of the drug overrides the harms and the dossier meets the Food and Drugs Act and Regulations, Health Canada grants the Notice of Compliance (NOC) and Drug Identification Number (DIN), and the drug may appear on the market.

Notice of Non-Compliance: The submission is issued the Notice of Non-Compliance (NON) in case it contains insufficient evidence of safety, efficacy, or quality. The sponsor may give some more information, offer it later, or ask for a reconsideration.

Accelerated Review Process or Priority Review Process

- **Priority Review:** Drugs that have an indication of great evidence of efficiency in the case of severe or life-threatening conditions after clinical testing are subjected to this review.
- **Notice of Compliance with Conditions (NOC/c):** In the case of promising, though preliminary, evidence of effectiveness on drugs. They are approved conditionally, and more confirmatory studies are needed.

The drug should either be a treatment when the treatment is not available in Canada, or should provide better treatment than the currently available treatments. Under the NOC/c, the manufacturer is a provider of constant updates in matters relating to safety. When this condition is fulfilled, the status of "with condition" is eliminated.

2.6 Post-Marketing Phase

After a health product is approved and, on the market, the HPFB needs a sponsor to make sure that its drug is used in line with its market authorization. Besides, life cycle management undertakings (submissions made after approval to Health Canada, new indication, new dosage forms, new strength, manufacturing change, and so on) must be performed to guarantee that the product license with its justifications is maintained. In short, the sponsors should also guarantee they remain compliant with the Food and Drug Regulations as long as their products are in the market.

Canadian pharmacovigilance is coordinated by the Canadian Vigilance Program. As a sponsor, one must have a schedule of ingredients and report certain adverse drug reactions (ADRs) and, in some instances, file:

- Periodic Safety Update Reports (PSURs)
- Risk Management Plans (RMPs)

Important commitments: The NOC/c approval requires additional clinical trials or safety monitoring to be done. (8)

3. Marketing Authorization Procedure in The European Union

3.1 Regulatory Authority

In the EU, the European Medicines Agency (EMA) is in charge of marketing authorization at the central level. Scientific evaluation is the remit of the Committee for Medicinal Products for Human Use (CHMP), while the final approval is carried out by the European Commission

(EC). National regulatory agencies in member states may be involved in certain procedures depending on the extent.

3.2 Authorization Procedures

There are 4 types of procedures by which a drug gets authorized in the European Union.

a) Centralized Procedure: This is the procedure that is central and gives the applicant the market authorization that is valid throughout the European Union. Such permission is acceptable in the European Union, Norway, Iceland, and Liechtenstein. The registrar of applications is deemed competent to analyse applications; hence, the EMA sends its evaluation within 210 days, and the application is sent to the European Commission to give the ultimate approval. Centralized procedure is mandatory for medicines for cancer, diabetes, autoimmune disease, and orphan medicines. The procedure for approving through a centralized procedure is as given in the following flowchart.

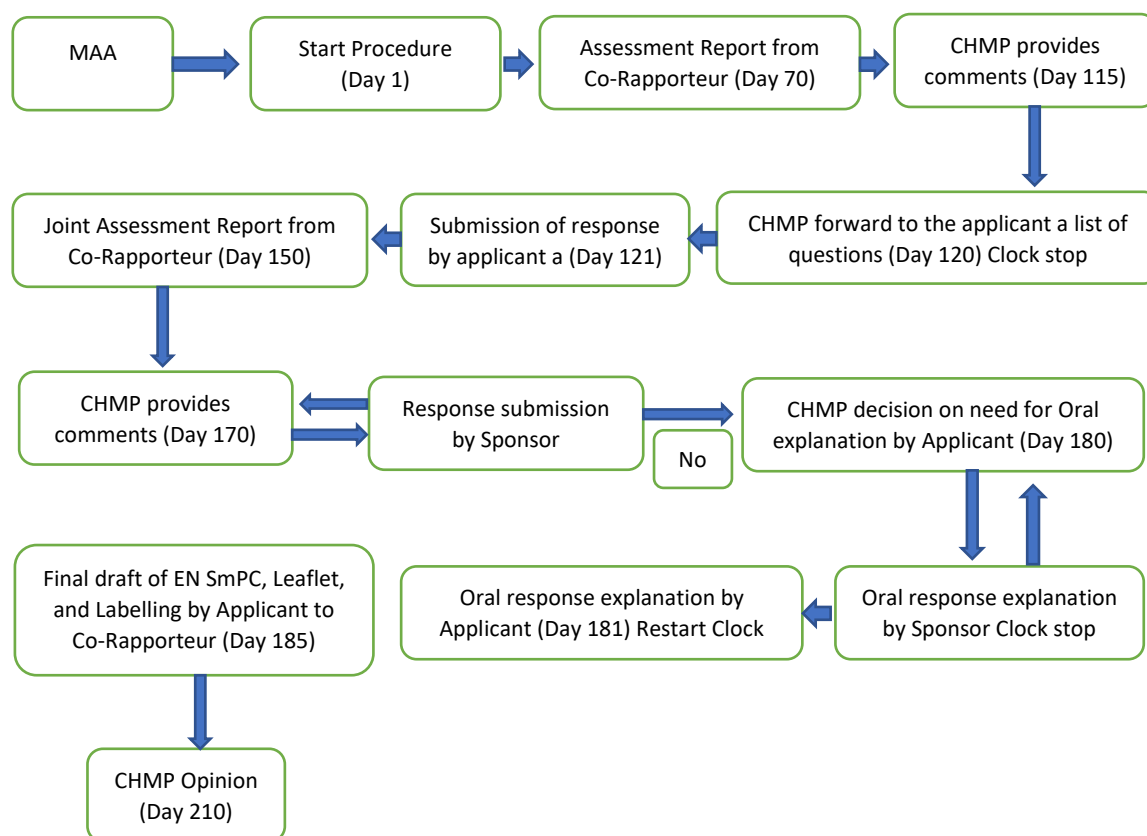


Figure 1. Centralized Procedure

b) Decentralized Procedure - In this process, the applicant may seek authorization for marketing in more than one state of the European Union for those goods that have not been authorized in any country in the European Union, as well as those that do not lie within the list of drugs under the Centralized Procedure.

The report is evaluated by the reference member state and concerned member state, and according to that evaluation,

some comments are provided, and based on those comments and their decision, the marketing authorization is provided. The entire procedure may be as long as a period of 210 days. Approval Process of decentralized procedure: The flowchart below gives details of the process of the decentralized procedure.

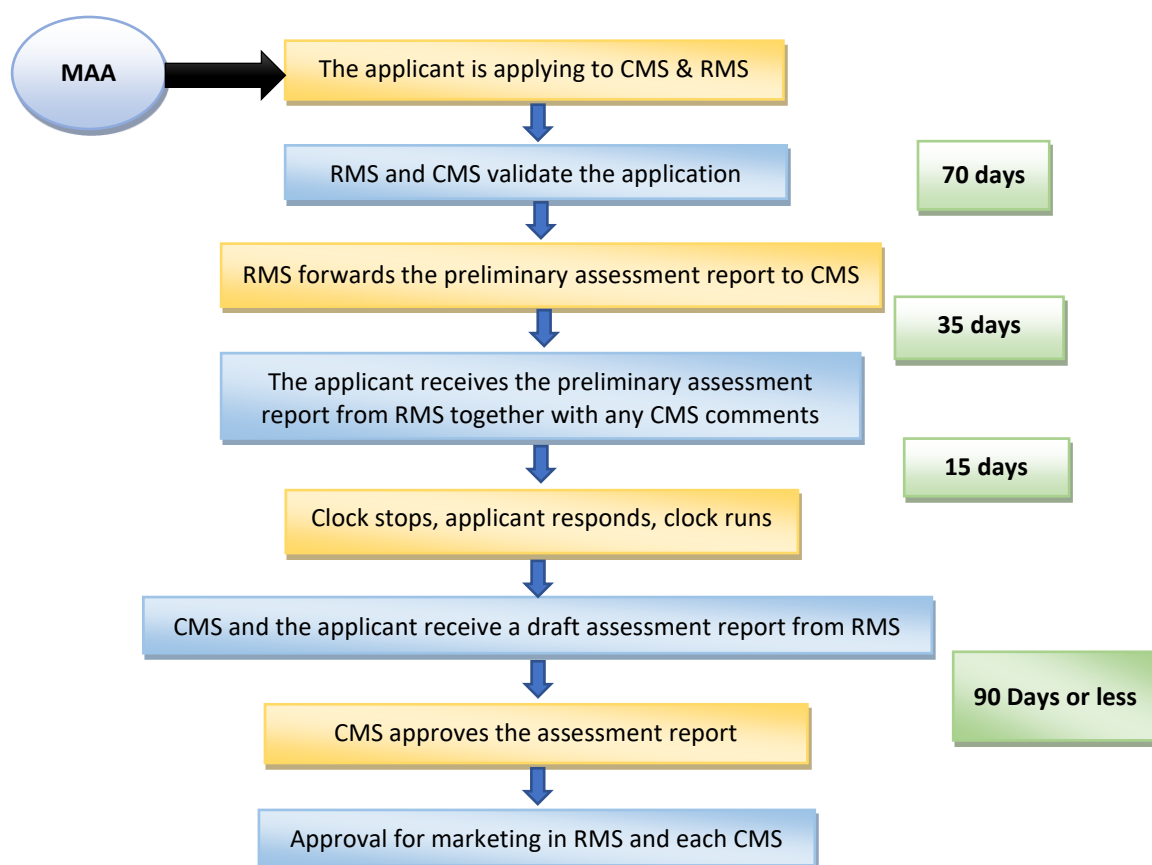
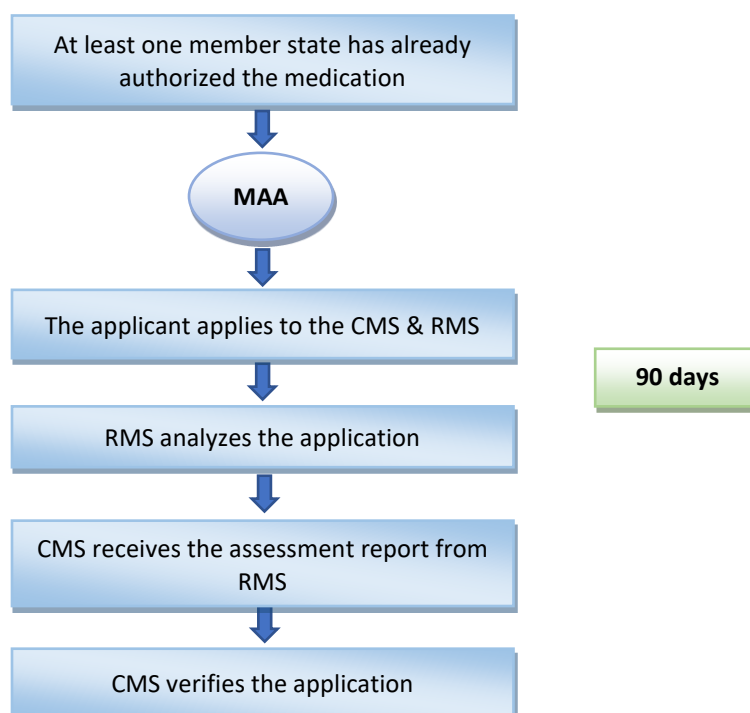


Figure 2. Decentralized Procedure

c) Mutual Recognition Procedure -The mutual recognition procedure enables the holder of a marketing authorization in one state (reference member state (RMS)) to receive the same in the other states (concerned member states (CMS)) where the drug has already been approved. All of the European Union member states where the applicant desires an issue of a marketing authorization must be provided with a dossier. A decision to appraise the

medicinal product is made by one of the member states, and notification will be made to other member states where the application has also been made. The reference member states will then provide their report to other states, and the entire process may consume a maximum time duration of 390 days. The approval process of the mutual recognition procedure is as shown in the following flowchart.



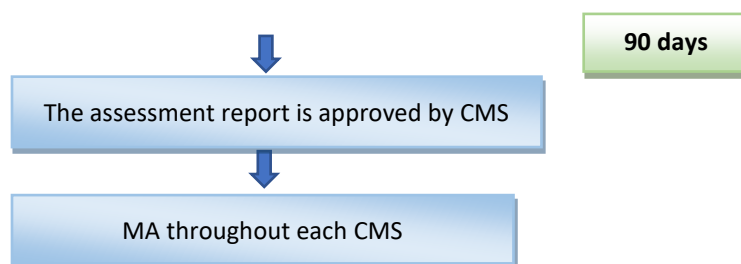


Figure 3. Mutual recognition procedure

d) Nationalized Procedure - In this process, the applicant has a chance to apply in several member states within the European Union for products whose marketing authorization has not been acquired in any European Union country, and also that are not included in the list of drugs under the Centralized Procedure.

What happens is that a report is assessed by the reference member state and the concerned member state, and some comments are provided by these members, on the basis of which the marketing authorization is granted. The entire procedure may take up to a 210-day period. The approval of the decentralized procedure is as depicted in the flowchart below. (9)

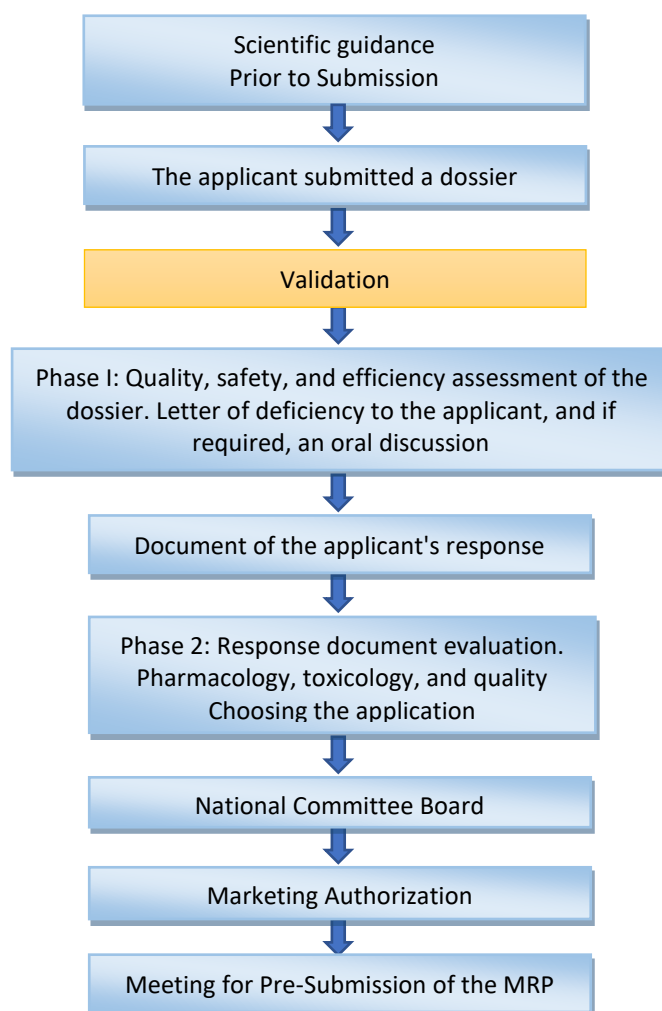


Figure 4. National Procedure

3.3 Key Stages of the Marketing Authorization Process

a) Pre-submission activities

The first step that the applicants should undertake is an eligibility request to make sure the product in question has the right to undergo centralized assessment (187 months before MAA). A notice of intent to apply should be made 7 months before. CHMP and PRAC appoint rapporteurs.

Regulatory clarity is guaranteed by a pre-submission meeting. Reconfirmation should be done 2-3 months prior to application by the applicants regarding the date of submission.

b) Submission of the Application

Marketing Authorization applications (MAAs) should be filed in eCTD format through the EMA portal called

eSubmission. The process EMA flags technical validation checks prior to the commencement of scientific review.

c) Scientific Assessment (Day 1-210)

The scientific evaluation is thus carried out by the CHMP within up to 210 days (without clock-stops), including the assessment of the PRAC and CAT. Assessment includes:

- Assessment report preparation
- On-site inspection (in case it is required)
- RMP review
- Finalization in the form of peer review of question lists

d) Clock Stops

- Clock Stop 1 (Day 120): Applicant answers the first set of questions by CHMP (typically within 3 months).
- Clock Stop 2 (Day 180): Applicant solves leftover problems (generally within 1 month), possibly including oral clarification.

e) Opinion Final and Re-examination

By 210 days, CHMP takes an opinion. In case it is negative, the applicant is given the right to appeal for a re-examination to be done within 15 days. A new group of rapporteurs is designated, and an ultimate opinion is delivered in 60 days.

f) Scientific Opinion CHMP

The CHMP scientific recommendation is passed over to the European Commission by the EMA.

g) Decision of the Commission

It is then provided with the final legally binding marketing authorization meant to be available across the EU/EEA, given by the European Commission. EMA is, in turn, responsible for publishing the European Public Assessment Report (EPAR) or a similar summary (in case of a rejection). (10)

3.4 Post Authorization Phase

Table 1. Comparative Overview of General Marketing Authorization Procedures in Canada and the European Union

Regulatory Aspect	Canada	European Union (EU)
Regulatory Authority	Health Canada	European Medicines Agency (EMA) + European Commission
Application Types	NDS, SNDS, ANDS, SANDS	Centralized, Decentralized, Mutual Recognition, National
Submission Format	CTD/eCTD (mandatory)	CTD/eCTD (mandatory in centralized)
Scientific Advice	Optional (pre-submission meetings)	Available via formal EMA channels
Review Pathways	Standard (300 days), Priority (180 days), NOC/c	Standard (210 days), Accelerated (150 days), Conditional Approval, PRIME, Orphan Designation
Evaluation Committees	Internal review committees, BRDD/TPD experts	CHMP, PRAC, CAT (depending on product)
Decision Authority	Health Canada (issues NOC)	European Commission (issue EU-wide MA)
Approval Validity	Valid in Canada only	Valid across EU member States
Post-Marketing Surveillance	RMP, Vigilance Reporting	RMP, EudraVigilance, PSURs

The EU has a well-designed pharmacovigilance system that is managed by the Pharmacovigilance Risk Assessment Committee (PRAC). Requirement of:

- Risk Management Plans (RMPs)
- The Post-Authorization Safety Studies (PASS)
- Detection of signal through EudraVigilance.

4. Methodology

This review used a qualitative comparative method to determine the drug marketing authorization process in Canada and the European Union. Official delegations of regulatory data were obtained using official sources, i.e., the Health Canada Drug Product Database (DPD) site, the European Medicines Agency (EMA) site, and publicly accessible guidance documents. Additional information was found in peer-reviewed journals, policy reports, sponsor press releases, and regulation filings. Some of the key regulatory parameters, such as the types of submission, review process, designation, and post-approval requirements, were studied to develop a structural comparison of the two jurisdictions.

Phase two is done to compare three selected case studies, namely, Keytruda (pembrolizumab), Spinraza (nusinersen), and Humira (adalimumab biosimilar), to show practical variations at different regulatory processes and timeframes. The date of approval was verified based on official databases offered by Health Canada and EMA, and comparison tables were constructed so that the procedural aspects of each product could be summarized. The interregional comparisons of years of approval were also graphically portrayed in a bar graph that was generated in Microsoft Excel. The regulated analysis assisted in the review of responsiveness in regulations, therapeutic orientation, and strengths in the process in both Canada and the EU.

5. Results

A comparative analysis of the drug marketing authorization process in Canada and the European Union in terms of regulatory structure, review systems, and significant procedural aspects follows:

Analysis: Canada and the EU adhere to all harmonized principles and submission formats (CTD/eCTD), but the regulatory flexibility and regulatory approval efficiencies differ. The EU provides a centralized mode of access to greater bandwidth at large and more support for orphan and biosimilar products. Canada, though within a smaller geographical jurisdiction, has a prompt review with the Priority Review or NOC/c of some therapeutic domains.

5.1 Comparative Analysis based on Case Studies

To evaluate practical application, three high-impact pharmaceutical products will be chosen:

- Keytruda (pembrolizumab)—an anti-cancer cell immunotherapy
- Spinraza (nusinersen) is a therapy for spinal muscular atrophy (SMA)
- Humira (adalimumab), a monoclonal antibody, includes its biosimilar

All drugs were approved both in Canada and the European Union, which enabled the comparison of the approval period and regulatory processes.

5.2 Case study 1: Keytruda (Pembrolizumab)

Table 2. Comparative Marketing Authorization Details for Keytruda in Canada and the European Union (11-12)

Feature	Canada	European Union
Regulatory Authority	Health Canada –BRDD	EMA – CHMP
Procedure Type	New Drug Submission (NDS)	Centralized Procedure
Review Type	Priority Review	Standard Review
Approval Date	19-05-2015 (NOC/c) (11)	17-Jul-2015 (12)
Designation	-	-
Post-Approval Requirements	RMP, Pharmacovigilance, NOC conditions	RMP, EudraVigilance, PSUR

Analysis: In Canada, Keytruda received approval in the Priority Review and NOC/c pathway, and this flexibility shows that the oncology drugs are not a foregone conclusion. The EU went by the book (a typical centralized-based procedure), so it came to a thorough scientific review process, but it slowed down over time. Both areas applied structured post-approval safety surveillance, but Canada has a conditional approval, which implies an adaptive early access solution.

Analysis: The EU has previously granted Spinraza accelerated assessment and orphan drug designation, which indicates that Europe is very process-friendly with regard to rare disease treatments. Canada employed a typical biologic review without special designations, which made the process of approval slightly behind that of other countries. The EU did even better by organizing the orphan support and coordinating centrally to grant quicker entry.

5.3 Case Study 2: Spinraza (Nusinersen)

Table 3. Comparative Marketing Authorization Details for Spinraza in Canada and the European Union (13-14)

Parameter	Canada	European Union
Regulatory Authority	Health Canada – BRDD	EMA – CHMP
Procedure Type	Biologic Drug Submission	Centralized Procedure with Orphan Designation Drug
Review Type	Standard Review	Accelerated / Orphan Drug Pathway
Approval Date	01-Jul-2017 (13)	01-Jun-2017 (14)
Designation	None	Orphan Drug, Accelerated
Post-Approval Requirements	RMP, Early access program, PSP	RMP, PRAC, EU registry

Table 4. Comparative Marketing Authorization Details for Humira Biosimilar in Canada and the European Union (15-16)

Aspect	Canada	European Union
Regulatory Authority	Health Canada –TPD/BRDD	EMA – CHMP
Procedure Type	NDS (original), ANDS (biosimilar)	Centralized Procedure
Review Type	Standard Review	Standard (originator), Accelerated (Biosimilar)
Original Approval Date	17-Oct-2006 (15)	08-Sep-2003 (16)
Biosimilar Approval Date	04-Nov-2020	17-Mar-2017
Designation	None	Biosimilar
Post-Approval Requirements	RMP, bridging studies, Pharmacovigilance	RMP, Eudravigilance, interchangeable approval

5.4 Case Study 3: Humira (Adalimumab) and Biosimilar

Analysis: The EU had the most advanced legislation in the authorization of biosimilars because it approved the

originator and biosimilar earlier and carried out biosimilars through accelerated pathways. Canada used a common process for originator (NDS) and biosimilar (ANDS), but the approval of the biosimilar was observed to be delayed. The measures of the EU illustrate the high

level of regulatory development in the area of biosimilar policy, whereas Canada reflects a rather conservative rate of implementation being performed.

To aid the comparative analysis, the next bar graph shows the year of approval in Canada and the European Union of

Keytruda, Spinraza, and Humira biosimilars. The graphical representation is an indication of the responses of each regulatory authority to these two vital drug applications over a period of time.

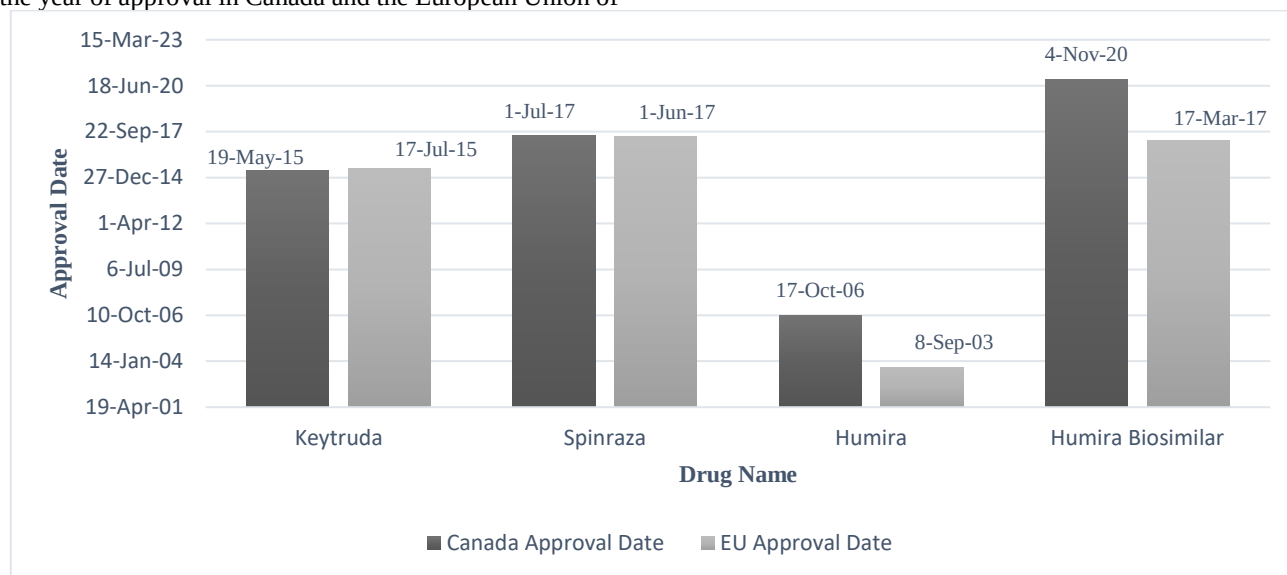


Figure 5. Comparative Approval Dates for Case Study Drugs

Through the chart, one can tell that the European Union tended to approve the chosen drugs sooner than Canada, especially with Spinraza and Humira Biosimilar. This leads to increased regulatory flexibility in the EU for orphan drugs and biosimilars. Nevertheless, Keytruda was authorized in Canada a little bit earlier, which shows that oncology-related expedited reviews are effective. These disparities highlight the role played by regional regulatory regimes and review plans in determining the availability of drugs.

6. Discussion

Assessment of similarity and differences between drug marketing authorization procedures in Canada and the European Union, done as shown in Tables 1 to 4 and Figure 5, depicts harmonization or lack thereof in the regulation systems. Although the two jurisdictions follow ICH-compliant dossier formats (CTD/eCTD), they have differences in procedural speed and flexibility in accommodating unique drug categories such as orphan drugs, oncology agents, and biosimilars. As observed in the case studies, Canada proves to be efficient in its oncology-related drug authorizations, as in the example of Keytruda approval under the Priority Review and NOC/c program. Conversely, the European Union is more regulatorily mature in administering orphan drugs and biosimilars, given that Spinraza and Humira biosimilars were approved in time. Such variations not only indicate possible policy decisions but also indicate the strategic purpose of regulatory systems to meet region-specific community health requirements.

Significance to Pharmaceutical Companies

The results can be found to be strategic to pharmaceutical companies in search of effective regulatory routes. In Canada, priority review gives preference to the accelerated approval of oncology drugs, whereas the centralized and

expedited review procedures of the EU promote the accelerated access to the market of orphan medicines and biosimilars. The knowledge about these regional strengths of companies can be used to better plan submissions, optimize time-to-market, and efficiently allocate regulatory resources. The comparative knowledge helps with informed decisions about launch sequencing, risk management, and global market access planning.

7. Conclusion

In this comparative analysis, the differences in the process and strategy of marketing authorization of drugs in Canada and the EU are pointed out. Although both have taken steps to guarantee stringent assessments, the EU proves its maturity in its aspects of orphan and biosimilar authorizations, and Canada emerges superior in oncology, where fast-tracking is the requisite. Knowledge of these pathways is helpful in the efficient planning of global launches.

Future studies could also examine regulatory convergence and the development of digital submission, and the integration of real-world evidence. Taking the additional step of extending the case studies to other therapeutic areas will also develop the potential to increase the convergence of regulatory strategies among global pharmaceutical players.

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Conflict of Interest

The author declares that there is no conflict of interest regarding the publication of this article.

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