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Original Article

How Do Stakeholders Perceive Canada's Drug Pricing Reforms? An Analysis of Submissions to Canada's Patented Medicine Prices Review Board

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Abstract

Background: Canada's Patented Medicine Prices Review Board (PMPRB) regulates pharmaceutical prices to prevent excessive pricing. In June 2024, the PMPRB proposed major reforms including international price comparison (IPC) screening, annual re-benchmarking of existing medicines, and new complaint processes. Understanding how stakeholders responded to these proposals reveals the competing interests and strategic positioning that shape pharmaceutical price regulation.

Methods: We conducted a systematic qualitative content analysis of all 54 public consultation submissions to the PMPRB's 2024-2025 consultation on its Draft Guidelines. Using NVivo software, we coded submissions according to stakeholder type, main concerns, policy recommendations, and positions on specific regulatory mechanisms. We coded concerns and recommendations separately to compare them across stakeholder groups. Thematic analysis identified patterns within and across stakeholder groups.

Results: Pharmaceutical companies and patient advocacy organizations raised different concerns yet converged on several of the same recommendations. Industry submissions described the proposals in constitutional and economic terms, characterizing annual re-benchmarking as jurisdictional overreach and warning of market exit. Patient organizations described the same proposals in terms of access and health equity, emphasizing delayed drug launches and impacts on vulnerable populations. Despite raising different concerns, some organizations in both groups recommended greater transparency in the review process and restricted, validated complaint eligibility, and complaint validation. Five concerns were dominant, raised primarily by pharmaceutical organizations: retroactive application of guidelines to existing medicines (21 of 34), expanded complaint eligibility risking strategic misuse (21 of 34), unclear compliance guidance (18 of 34), limited transparency in in-depth reviews (17 of 34), and insufficient transition periods (13 of 34). Patient organizations primarily sought inclusion in the PMPRB's review processes, recommending patient participation in both therapeutic class comparison (TCC) and the complaint process.

Conclusion: Pharmaceutical stakeholders positioned the proposed PMPRB guidelines as fundamental regulatory problems rather than technical refinements. Industry and patient organizations converged on a number of similar recommendations, highlighting the need for policy-makers to assess the evidence underlying shared recommendations.

Keywords: Pharmaceutical Pricing, Canada, Drug Price Regulation, Stakeholder Engagement, Qualitative Research, PMPRB

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Background

Brand-name prescription drugs are sold by single manufacturers after regulatory approval; these drugs are often protected by patents that block direct competition and allow manufacturers to set high prices.[1] The Patented Medicine Prices Review Board (PMPRB) is an independent federal body in Canada established to ensure the prices charged by rights holders for patented medicines are not excessive.[2] It is one of the principal federal mechanisms for pharmaceutical price oversight, with jurisdiction over all patented prescription and non-prescription medicines sold in Canada.[3] Its assessment of whether a drug's price is excessive has historically relied on two types of comparisons: how the drug's list price aligns with that of the same drug in a group of reference countries and how the drug's list price compares to the list prices of similar treatments already available in Canada.[4] The federal government periodically amends the Patented Medicines Regulations, and the Board periodically revises its Guidelines. Reforms in the 2010s and 2020s introduced new international reference pricing methods and expanded review processes that have generated considerable stakeholder debate.[5,6]

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Key Messages

Implications for policy makers

- Prior research found no negative impact of the 2018-2021 Patented Medicine Prices Review Board (PMPRB) policy uncertainty on drug launches in Canada relative to comparator countries, except for medicines with major therapeutic benefit, suggesting that industry warnings about market exit may function partly as strategic rhetoric.
- Establishing independent clinical expert panels for therapeutic class comparisons (TCCs) would address both industry concerns about unpredictable staff discretion and patient organizations' calls for incorporating clinical expertise into regulatory decisions.
- Phased implementation, beginning with new market entrants before applying annual re-benchmarking to existing medicines, would test whether predicted harms occur while providing transition time for supply chain adaptation.
- Implementing evidence-based complaint validation processes would address concerns about strategic misuse while maintaining accountability for both complainants and the regulatory body.

Implications for the public

Although Canada has some of the highest brand-name drug prices among wealthy countries, the Patented Medicine Prices Review Board (PMPRB) works to ensure Canadians do not pay excessive prices for brand-name medications. When the Board proposed new rules to strengthen price oversight in 2024, pharmaceutical companies and patient groups pushed back, yet for different reasons. Drug companies argued the rules went too far and would discourage them from selling medicines in Canada. Patient groups worried the rules might delay access to new treatments, particularly for patients with rare diseases. Our analysis of 54 formal responses to these proposed rules found that despite using different arguments, both groups recommended some of the same changes: greater transparency in how prices are reviewed and tighter limits on who can trigger price investigations. For those concerned about drug costs and access – both in Canada and globally – this research highlights how different groups influence pharmaceutical pricing policy and why distinguishing genuine access concerns from business strategy matters for achieving affordable medicines.

The PMPRB is not the only body that shapes what Canadians pay for patented drugs, and the relationship between it and the pan-Canadian Pharmaceutical Alliance (pCPA) bears on how the Board's relevance should be understood. Established in 2010, the pCPA now negotiates confidential rebates with manufacturers on behalf of federal, provincial, and territorial public drug plans, which has reduced the PMPRB's influence over the net prices those plans actually pay.[7] The two bodies perform different functions: the PMPRB caps the legal maximum price for patented drugs. The pCPA negotiates confidentially with manufacturers to determine what public drug plans actually pay. But the PMPRB has outsized impacts on particular areas of drug pricing; because the pCPA negotiates for public plans alone, its rebates do not reach private insurers or the uninsured. In its own submission to a 2023 PMPRB consultation, the pCPA stated that private insurers and the uninsured account for 56% of prescription drug spending in Canada and, being more likely to pay list prices, would benefit more than public plans from the PMPRB's oversight.[8]

The 2024-2025 PMPRB consultation followed an earlier reform cycle that shaped how stakeholders approached it. In 2019, the federal government amended the Patented Medicines Regulations to add pharmacoeconomic value, market size, and gross domestic product as factors the Board could consider under section 85 of the Patent Act in applying the statutory "excessive price" standard, to revise the comparator-country basket, and to require manufacturers to report prices net of confidential third-party rebates.[9] Innovative Medicines Canada (the brand-name pharmaceutical industry association), Merck Canada, and other manufacturers challenged the amendments in both court systems, and the outcomes were mixed: the Federal Court upheld the new economic factors and the revised basket while striking the net-of-rebate reporting requirement as beyond the federal patent power,[10] while the Quebec Court of Appeal struck both the net-of-rebate reporting requirement and the economic factors, upholding only the comparator-country change.[11] In 2022, the federal government abandoned the contested provisions and proceeded only with the revised basket and with reduced reporting requirements for medicines at low risk of excessive pricing; both changes took effect on July 1, 2022.[12] This history of contested reform and partial judicial reversal informs the adversarial positioning documented below.

Most recently, in June 2024, the PMPRB released a Discussion Guide proposing several major structural changes to the price review process.[13] In December 2024, it released Draft Guidelines that put these proposals into operational form.[12] First, the Board proposed annual screening against changing international reference prices, with selective in-depth reviews. Second, the PMPRB proposed screening each medicine's list price against the highest international price (HIP) among the 11 comparator countries adopted by regulation in 2022, a basket that excludes the US, where prices have long been higher than in Canada. Third, for the review process, it outlined a two-phase structure, beginning with a preliminary screen based on international price comparison (IPC) criteria and reserving in-depth reviews for cases that raised concerns. Fourth, the guidelines repositioned the role of the Consumer Price Index factor, shifting it from a general consideration to a specific trigger for identifying problematic price increases, and proposed that complaints from approved parties would automatically launch in-depth reviews. Finally, patented over-the-counter, generic, and veterinary medicines would be reviewed only on complaint, and medicines already on the market would be subject to annual re-benchmarking beginning 1 year after the Guidelines took effect.

The PMPRB requested written feedback on the Discussion Guide by September 11, 2024,[13] and on the Draft Guidelines by March 19, 2025[12]; the final Guidelines took effect on January 1, 2026.[14] The Draft Guidelines consultation, which we analyzed, attracted responses from across the

pharmaceutical ecosystem. The final Guidelines narrowed complaint eligibility relative to the Draft Guidelines: complaint-triggered review was restricted to Ministers of Health and senior officials of public drug programs, leaving private insurers and the uninsured unable to directly trigger a review.[14]

Qualitative analysis of stakeholder submissions to regulatory consultations offers valuable insights into policy positions, strategic framing, and areas of consensus or conflict that quantitative methods alone cannot capture.[15-17] Researchers analyzing health policy consultation responses have used these documents to identify stakeholder priorities,[17,18] map policy positions across multiple dimensions,[19-21] and understand how different groups frame problems and solutions.[22,23] This approach has proven particularly useful in the pharmaceutical policy arena,[24-26] in which competing interests shape how stakeholders frame evidence, interpret data, and construct arguments about access, affordability, and innovation.[27] Document analysis and thematic coding of submissions reveal stakeholders' advocacy goals, as well as the underlying values, concerns, and strategic interests that shape their engagement with regulatory processes.[28-30]

The structure of the PMPRB impacts drug pricing decisions, pharmaceutical investment, and patient access to medicines.[31-33] This is of particular importance because Canadian list prices for patented medicines were the fifth highest among 31 Organisation for Economic Co-operation and Development countries in 2024.[7] The closest previous study of stakeholder views on PMPRB guidelines comes from Foroutan et al,[6] who examined Canadian stakeholder perspectives on updates to the PMPRB's 2007 budget impact analysis (BIA) guidelines. They gathered feedback from 35 participants through semi-structured interviews with policy-makers and a survey of pharmaceutical manufacturers and industry reimbursement consultants. The interview and survey instruments were built around a list of recommendations the research team derived from a review of 16 Canadian and international BIA guidelines. The data were researcher-elicited responses to methodological proposals from a stakeholder universe limited to payers and pharmaceutical industry respondents; patient organizations did not participate. By contrast, the PMPRB's 2024 Draft Guidelines differ in both substance and process: they proposed contested structural reforms (annual re-benchmarking, retroactive application, and expanded complaint eligibility) and drew unsolicited submissions from across the pharmaceutical ecosystem, including the patient advocacy organizations absent from Foroutan's design. It therefore remains unclear how cross-sectoral stakeholders engage with contested PMPRB reforms in a live public consultation, and how industry and patient framing relate when both have direct access to the same regulatory channel.

To identify stakeholders' main concerns, policy recommendations, and strategic positioning during the most recent update of the PMPRB's Guidelines, we conducted a systematic qualitative content analysis of public consultation submissions.

Methods

All consultation submissions were extracted from the publicly available online portal (https://www.canada.ca/en/patented-medicine-prices-review/services/consultations/draft-guidelines-pmprb-staff.html). The consultation process was open. We translated non-English submissions via DeepL, a machine translation tool.[34]

We employed a qualitative content analysis approach to examine stakeholder priorities and perspectives on the proposed PMPRB guidelines.[35] We coded each submission along two dimensions: the concerns stakeholders raised about specific proposed mechanisms, and the changes they recommended. Coding these separately allowed us to compare concerns and recommendations across stakeholder types, and to identify cases where stakeholders raised different concerns but recommended similar changes.

Each submission was imported into NVivo qualitative data analysis software and systematically coded. Our coding scheme included deductive categories derived from the consultation's stated priorities and inductive themes that emerged from the data. Deductive coding categories were derived a priori from the topic areas the PMPRB Discussion Guide specifically invited stakeholder feedback on, including IPC, therapeutic class comparison (TCC), complaint eligibility, in-depth review procedures, and retroactive application. Inductive themes emerged from iterative analysis of submissions and were added to the codebook as they recurred. Coding proceeded until no new themes emerged from additional submissions. Specific coding categories included the following: (*i*) stakeholder type and organizational affiliation; (*ii*) main concerns regarding the proposed guidelines; (*iii*) key policy recommendations; (*iv*) overall position toward the Draft Guidelines; (*v*) guidance on regulatory processes; (*vi*) risk identification; (*vii*) IPC mechanisms; (*viii*) TCC approaches; (*ix*) in-depth review processes; and (*x*) hearings and settlement procedures.

All coding was conducted by one researcher (SN), with coding decisions reviewed iteratively by the lead author (DEK). Disagreements regarding code assignment or theme interpretation were resolved through discussion until consensus was reached. The absence of formal intercoder reliability testing represents a methodological limitation; however, the use of explicit coding categories derived from the PMPRB Discussion Guide's stated topic areas provided structural consistency, and the lead author's review of all coded segments offered a secondary check on systematic bias.

Following initial coding, thematic analysis was conducted to identify patterns within and across stakeholder groups. Code frequencies were calculated and ranked to identify the most prominent issues raised during the consultation. Illustrative quotes were extracted to demonstrate each coded theme and provide context to the quantitative findings.

Reflexivity Statement

As researchers primarily focused on whether the regulation of prescription drugs serves the public interest in affordable access to medicines, we attended to how stakeholders defined regulatory problems and which interests their recommendations served. No author holds personal financial

relationships with pharmaceutical or medical device manufacturers.

Results

A total of 54 submissions were received and analyzed, with two requiring translation from French. Submissions were made by pharmaceutical industry organizations, patient advocacy groups, professional associations, public sector entities, and one member of the public (a rare-disease physician, writing in a personal capacity) (Table 1).

Thematic analysis revealed five major areas of concern. All five were raised predominantly by pharmaceutical organizations: retroactive application of guidelines to existing medicines (21 of 34), opposition to expanded complaint eligibility (21 of 34), unclear guidance for rights holders to assess prices (18 of 34), limited transparency in in-depth reviews (17 of 34), and insufficient transition periods (13 of 34). The most common recommendations, again concentrated among pharmaceutical organizations, were grandfathering existing medicines (23 of 34), restricting complaint eligibility (20 of 34), limiting annual reviews to CPI adjustments (20 of 34), and increasing transparency in the review process (19 of 34) (Table 2). Patient advocacy organizations, by contrast, most commonly recommended incorporating patient perspectives into the Board's review processes (5 of 9), while professional organizations most often raised tariff-related destabilization (5 of 7) and recommended grandfathering existing medicines (3 of 7).

Public sector entities did not oppose the reforms: Alberta Health Services and the pCPA endorsed the proposals, and Canada's Drug Agency raised only procedural concerns about implementation. This informed our decision to focus on five key themes: IPC and annual re-benchmarking, TCC methodology, complaint processes and eligibility, in-depth review procedures, and retroactive application and transition periods.

International Price Comparison and Annual Re-benchmarking

The proposed guidelines would screen each medicine's list price against the highest international price among the 11 comparator countries adopted in 2022 (a basket that excludes the United States) and would establish annual re-benchmarking of existing medicines against international prices. The proposed annual re-benchmarking would reassess prices against changing international benchmarks throughout a medicine's patent lifecycle. Industry submissions thus shifted the focus from regulatory method to regulatory authority: rather than contesting whether annual re-benchmarking produced accurate prices, they contested whether the PMPRB possessed the constitutional power to conduct it at all. This move shifted the burden of justification onto the Board and placed the proposal's legality, not its technical merit, at the center of the response.

Table 1. Stakeholder Categories

Stakeholder Type	Frequency
Pharmaceutical organizations	34 (total)
Biosimilars	2
Brand name	31
Generics	1
Non-pharmaceutical organizations	19 (total)
Patient advocacy organizations	9
Professional organizations	7
Public sector	3
Individual member of the public	1
Total	54

Pharmaceutical stakeholders characterized annual re-benchmarking as constitutional overreach (Table 3). These concerns centered on the transformation of the PMPRB's mandate from prevention of market exclusivity abuse to general price control. The Constitutional Coalition explicitly warned about potential overreach of the PMPRB's mandate beyond patent abuse regulation, turning it into a general price control body. Boehringer Ingelheim similarly characterized re-benchmarking of existing medicines as "an unconstitutional exercise of the PMPRB's excessive pricing mandate," while BioCryst identified annual price reviews against the HIP as a fundamental boundary violation.

The international price comparison mechanism also generated widespread technical concerns, particularly regarding limited availability of comparator-country prices and currency volatility beyond manufacturer control. Roche Canada noted challenges in determining the HIP when a price is available from only one comparator country at the initial review, while Johnson & Johnson warned that such limited data "may lead to misleading conclusions about whether a New Medicine's introductory list price reflects an abuse of patent monopoly." Currency fluctuations compounded these technical concerns, with Daiichi Sankyo Canada emphasizing difficulties in providing certainty and clarity on pricing in the context of rapid currency fluctuations.

In connection with the international comparison, stakeholders also argued that external economic pressures, particularly US-Canada trade tensions and tariff threats, created volatility that guidelines failed to address. The Canadian Pharmacists Association characterized implementation as problematic "due to the ongoing trade dispute between the United States, China, and Canada," while McKesson Canada referenced "the current global upheaval in the pharmaceutical industry caused by volatile US tariff policy, which will lead to an unpredictable pricing & supply environment." Bristol Myers Squibb explicitly connected tariff volatility to compliance difficulties:

> *"Furthermore, the recent implementation of US tariffs on Canadian products has increased the cost of medicines entering Canada. As the trade war escalates in the coming months, the risk of Canadian counter-tariffs on US pharmaceutical imports continues to rise. If imposed, Rights Holders will need to pass these uncontrollable increases onto Canadian payers in the form of sudden List Price increases to maintain the inflow of necessary medicines into Canada."*

The Neighbourhood Pharmacy Association of Canada quantified the scale of potential disruption, noting that pharmaceutical products under tariff consideration were

Table 2. Theme Frequency

Category	Theme	Stakeholders (by Subgroup)
Retroactive application	Retroactive application of guidelines to existing medicines	23 (21 pharmaceutical, 2 professional)
	Unclear retroactivity of excess revenues	10 (10 pharmaceutical)
Main concerns	Opposes allowing complaints from various parties	23 (21 pharmaceutical, 2 patient advocacy)
	Unclear guidance for rights holders to assess their prices	22 (18 pharmaceutical, 3 patient advocacy, 1 professional)
	Lack of transparency of in-depth review	18 (17 pharmaceutical, 1 individual)
	Insufficient transition period for new guidelines	15 (13 pharmaceutical, 2 professional)
	Criticizes excessive subjectivity of in-depth reviews	13 (13 pharmaceutical)
	Concerns around destabilization as a result of tariffs	12 (5 pharmaceutical, 2 patient advocacy, 5 professional)
	Fear of PMPRB jurisdictional overreach	10 (10 pharmaceutical)
Key recommendations	Grandfather existing medicines from new guidelines	26 (23 pharmaceutical, 3 professional)
	Increase transparency in the review process	24 (19 pharmaceutical, 2 patient advocacy, 1 professional, 1 public sector, 1 individual)
	Restrict complaint eligibility	22 (20 pharmaceutical, 2 patient advocacy)
	Limit annual price reviews to CPI adjustments only	20 (20 pharmaceutical)
	Increase length of transition period	17 (15 pharmaceutical, 2 professional)
	Implement complaint validation process	17 (15 pharmaceutical, 2 patient advocacy)
	Eliminate retroactive liability for excess revenues or limit it to a defined period	13 (13 pharmaceutical)
	Implement tolerance margins on prices	13 (12 pharmaceutical, 1 patient advocacy)
	Reinstate complaints-based review for low-risk products	10 (9 pharmaceutical, 1 patient advocacy)
	Avoid expanding beyond the PMPRB's mandate	8 (8 pharmaceutical)
Guidance on the process	Requests clearer procedural guidance	22 (18 pharmaceutical, 3 patient advocacy, 1 public sector)
	Requests greater transparency	19 (18 pharmaceutical, 1 patient advocacy)
	Recommends working groups	12 (12 pharmaceutical)
	Include patient perspectives	5 (5 patient advocacy)
In-depth review	Criticizes subjectivity of in-depth review	9 (8 pharmaceutical, 1 individual)
	Unclear and time-consuming	8 (6 pharmaceutical, 2 patient advocacy)
IPCs	Supports using HIP at initial review only, opposes using only one comparator country	12 (12 pharmaceutical)
	Supports using HIP with no changes	10 (4 pharmaceutical, 3 patient advocacy, 3 professional)
	Supports using HIP at initial review and annual review, opposes using only one comparator country	3 (3 pharmaceutical)
	Requests greater HIP clarity	2 (1 pharmaceutical, 1 individual)
Risk identification	Delay the launch of new drugs in Canada	17 (13 pharmaceutical, 4 patient advocacy)
	Hinder patient access to existing drugs	11 (6 pharmaceutical, 2 patient advocacy, 3 professional)
	Disruption to long-term investments in the industry	8 (7 pharmaceutical, 1 patient advocacy)
	Hinder business operations	4 (3 pharmaceutical, 1 professional)
	Disproportionate impact on rural and remote communities	3 (3 professional)
Therapeutic class comparisons	Criticizes subjectivity of TCC	17 (13 pharmaceutical, 3 patient advocacy, 1 individual)
	Recommends TCC be used only to justify prices above the HIP	5 (5 pharmaceutical)
	Opposes using only generics and biosimilars as comparators	4 (4 pharmaceutical)
	Supports proposed use of TCC	3 (2 patient advocacy, 1 professional)

Abbreviations: IPCs, International Price Comparisons; PMPRB, Patented Medicine Prices Review Board; CPI, consumer price index; HIP, highest international price; TCC, therapeutic class comparison.
Note. Counts show the number of submissions within each stakeholder subgroup that raised the theme; a submission could raise several themes.

"estimated at $4.4 billion, which is over 50% of all US-imported prescription drug products dispensed by Canada's pharmacies." Multiple stakeholders called for exempting drugs from tariffs entirely, with the Best Medicines Coalition arguing that "in the interest of protecting patient care, the BMC calls for exemptions of drugs and related treatments from tariffs and other trade measures."

Stakeholder recommendations focused on constitutional compliance mechanisms and pricing stability through CPI-only adjustments. Multiple pharmaceutical companies proposed restricting annual reviews to CPI adjustments only, with Eli Lilly Canada and the Constitutional Coalition arguing CPI restrictions would keep the PMPRB within its stated mandate rather than expand it into general price control. Astellas Pharma argued that "once a medicine's ceiling price is established at launch, it should be reassessed only in relation to CPI adjustments, rather than ongoing IPCs." Bristol Myers Squibb recommended "tolerance margins, such as a 5% FX

Table 3. Price Review Methodology and Constitutional Mandate

Subtheme	Stakeholder Position	Illustrative Quotation or Paraphrase
Concern: Annual re-benchmarking instability and constitutional overreach	Annual re-benchmarking against international prices creates business uncertainty while exceeding PMPRB's constitutional mandate to address patent abuse	*"It is important to ensure the PMPRB does not overstep its mandate by acting as a general price control entity. ... instead, it is to prevent excessive pricing flowing from patent abuse"* - Eli Lilly Canada (Pharmaceutical Manufacturer). Janssen Inc. (Johnson & Johnson) argued that the PMPRB's role is to assess whether an introductory price is excessive and permit subsequent CPI-related changes without a fuller inquiry, and that using this role to drive prices below non-excessive levels would exceed federal patent authority. - Janssen Inc. (Johnson & Johnson) (Pharmaceutical Manufacturer).
Solution: CPI-based stability and constitutional compliance	Limit annual reviews to CPI adjustments and/or allow tolerance margins to reduce price instability	*"Implement tolerance margins on prices (such as +/- 10%) to ensure that minor price fluctuations do not trigger an in-depth review."* [Innovative Medicines Canada (Brand-Name Pharmaceutical Industry Association)].

Abbreviations: PMPRB, Patented Medicine Prices Review Board; CPI, consumer price index.

[foreign exchange] rate lenience, that would account for transient issues and prevent too many reviews from being triggered by uncontrollable factors." Overall, pharmaceutical stakeholders proposed that the PMPRB's mandate remain focused on market exclusivity abuse, rather than price control.

Therapeutic Class Comparison Methodology

The proposed guidelines would reserve TCC methodologies exclusively for in-depth reviews, with PMPRB staff having discretion to determine therapeutic equivalence and appropriate comparators when assessing whether prices exceed acceptable thresholds. As a result, rather than comparing medicines to similar drugs from the very beginning, the PMPRB would first use a simpler international price screen, and only if a price were flagged as a concern would it then conduct a more detailed review that includes an analysis of other drugs in the same therapeutic class. Stakeholders positioned this methodology as fundamentally flawed due to excessive staff discretion and inadequate clinical expertise in comparative assessments (Table 4).

But some industry and patient organizations built the same critique of staff discretion from different premises: pharmaceutical companies treated unpredictability as a threat to investment planning, while patient groups treated it as a threat to timely access. Both arguments, however, depended on the shared assumption that discretion is a flaw, rather than a feature that allows case-specific clinical judgment.

Manufacturer stakeholders (13 of 34) raised concerns about the subjectivity of TCCs. Amgen Canada noted:

> *"Using different rules, depending on factors like the range of prices within an IPC or within a TCC, will result in excessive subjectivity. It will be impossible for a manufacturer to know what price level would trigger a recommendation for a hearing once an in-depth review is initiated."*

Patient advocacy organizations, by contrast, criticized TCCs from access perspectives, while supporting clinical expertise integration. The pricing methodology generated particular concern for rare disease treatments for which therapeutic comparisons can be more complex, with the Chronic Myelogenous Leukemia Society of Canada warning that implementation uncertainty could "delay the launch of new drugs in Canada, hindering timely patient access to critical chronic myelogenous leukemia therapies." The Mood Disorders Society of Canada criticized the "subjectivity of TCC due to unclear guidelines for evaluation" while emphasizing mental health treatment needs. Several patient groups advocated for meaningful participation in TCC determinations, with the Gastrointestinal Society

Table 4. Therapeutic Class Comparison Methodology

Subtheme	Stakeholder Position	Illustrative Quote
Concern: excessive subjectivity and inadequate clinical expertise	Staff discretion in determining therapeutic equivalence creates unpredictable regulatory outcomes without sufficient clinical input	*"The introduction of therapeutic comparability tiers appears to rely on subjective decisions made by PMPRB staff. This introduces uncertainty for rights holders throughout the in-depth review process as there is no way for a rights holder to predict the outcome of an in-depth review"* - LEO Pharma (Pharmaceutical Manufacturer). *"The level of Board staff discretion apparent in the overall approach detailed in the Discussion Guide, particularly for the proposed in-depth reviews are of concern. Absent appropriate direction, the unpredictable use of transient or context-specific compliance interpretations would run counter to the stated objective of predictability. Under the current proposals, there is no clear sense to patentees to predict the outcome of an in-depth review and PMPRB should provide written clarity to staff and patentees"* - Pfizer (Pharmaceutical Manufacturer).
Solution: clinical expertise integration and objective criteria	Use technical working groups to clarify assessment methods and criteria	*"[Our company] suggests that the PMPRB work together with technical working groups to identify a clearer path forward"* - LEO Pharma (Pharmaceutical Manufacturer). Lundbeck recommended that *"additional discussions with experts representing Rights Holders, in the form of technical working groups, be conducted on this topic"* - Lundbeck Canada (Pharmaceutical Manufacturer).

Abbreviation: PMPRB, Patented Medicine Prices Review Board.

recommending that "patient perspectives be incorporated in TCC" alongside clinical expertise to ensure that comparative assessments reflect real-world treatment experiences and patient outcomes.

Stakeholder policy recommendations focused on clinical expertise integration to address technical methodology problems and access concerns. RAREi, the Canadian Forum for Rare Disease Innovators, a pharmaceutical industry coalition, proposed that "an independent expert panel of clinicians should be responsible for identifying the appropriate comparator." Stakeholders recommended standardized assessment criteria to reduce subjectivity. They placed particular attention on specialized treatment pathways for rare diseases and vulnerable populations. This convergence on independent clinical panels, however, obscured disagreement about what such panels were for: industry submissions positioned them as a constraint on staff discretion, whereas patient organizations positioned them as a channel for incorporating clinical and patient experience.

Complaint Processes and Eligibility

The Draft Guidelines would have allowed complaints from federal, provincial, and territorial health ministers, publicly funded drug programs, and Canadian life and health insurers and their trade associations, with each complaint automatically triggering an in-depth review. Stakeholders argued that allowing more parties to file complaints would harm the PMPRB's credibility and effectiveness, as for-profit insurance companies could abuse the complaint system (Table 5). Industry submissions therefore framed expanded complaint eligibility as a problem of motive rather than evidence, attributing strategic intent to private payers.

Complaint eligibility expansion in particular generated concerns about strategic misuse and resource misallocation. AstraZeneca warned about the potential to weaponize this system, calling for "an efficient complaints process that minimizes the impact on resources of examining spurious or tactical 'complaints' from eligible parties." Manufacturer stakeholders proposed that validation should verify complaints against the HIP standard, arguing that prices already below this threshold should not trigger further review regardless of who filed the complaint.

Patient advocacy organizations approached complaint eligibility from fundamentally different principles, emphasizing access and inclusion while acknowledging misuse risks. The Mood Disorders Society of Canada warned about unintended consequences of broad complaint eligibility, noting it could create "a multitude of unnecessary complaints," while simultaneously advocating for patient group involvement in legitimate complaint processes. Cystic Fibrosis Canada called for the PMPRB to work with patients and patient groups to determine their involvement in the complaints process.

Stakeholder recommendations focused on restricting complaint eligibility to democratically accountable officials and implementing strict validation protocols to distinguish substantive pricing concerns from strategic complaints. Save Your Skin Foundation, for instance, recommended that the PMPRB commit to validating each complaint against the HIP before opening a review (Table 5).

In addition to calling for changes to complaint eligibility, industry stakeholders advocated for reinstating a complaints-only review process for low-risk medicines. They argued that products such as vaccines, blood products, generics, and hospital-only medicines warranted a distinct risk-adjusted standard due to their funding structures and lower likelihood of excessive pricing. Innovative Medicines Canada argued, "all tendered products (including vaccines and blood products) [should be] considered on a complaints-only basis." Similar recommendations were echoed by Merck Canada, Pfizer, and Vertex, who positioned a complaints-based approach as a pragmatic means that would focus PMPRB resources on

Table 5. Complaint Processes and Eligibility

Subtheme	Stakeholder Position	Illustrative Quote
Concern: expanded eligibility and regulatory weaponization	Allowing for-profit insurance companies to file complaints threatens democratic accountability and enables strategic misuse of complaint mechanisms	*"There is concern that complaints from private payers could lead to an increase in unwarranted requests due to competing business interests or strategic positioning. To prevent this, clear criteria, strict evidence requirements, or a review process to filter out meritless submissions should be implemented before any [in-depth reviews] are triggered"* - Bristol Myers Squibb (Pharmaceutical Manufacturer). *"Both public and private drug plans actively negotiate reimbursement criteria and prices for medicines. Allowing complaints from these parties to automatically trigger In-Depth Reviews risks inappropriate use of the system and unnecessary use of resources. This could create potential conflicts of interest, particularly for private payers, who represent for-profit interests and may be incentivized to leverage the PMPRB's complaint process as a negotiation tactic"* - Bayer (Pharmaceutical Manufacturer).
Solution: restrict eligibility and implement validation	Limit complaints to Ministers of Health and establish strict screening mechanisms to prevent misuse	*"[We propose that] the PMPRB state explicitly that it will validate an excessive price [complaint] to ensure that it [does] in fact meet the criteria for a complaint i.e. it is higher than the HIP"* - Save Your Skin Foundation (Patient Advocacy Organization). *"[T]he right to make a complaint should be limited to the federal minister of health or any of his/her provincial or territorial counterparts only. Others who believe that a product price should be reviewed could submit those concerns to the minister(s) for consideration and rely [on] them to determine if there is a case to be made to the board via an official complaint. The ministers are the best positioned to assess whether a complaint is relevant to the board's limited mandate"* - RAREi (Pharmaceutical Industry Coalition).

Abbreviations: PMPRB, Patented Medicine Prices Review Board; HIP, highest international price.

higher-risk products.

Overall, some patient organizations and industry reached the same recommendation – restriction in addition to validation – but patient submissions grounded the validation requirement in democratic legitimacy and patient participation, whereas industry grounded it in resource protection and the risk of regulatory weaponization.

In-Depth Review Procedures and Timeline

The proposed guidelines would establish in-depth reviews examining the statutory factors, including international prices, TCCs, and CPI changes, with PMPRB staff having discretion to determine how to balance and weigh these factors when recommending whether to proceed to excessive pricing hearings. Stakeholders argued that in-depth review procedures would deter companies from entering the market and meeting regulatory requirements because the processes lack transparency and give PMPRB staff too much individual decision-making power (Table 6). They argued that this lack of clear, predictable criteria would make it difficult for companies to comply with regulations and plan their business strategies. Johnson & Johnson reinforced these concerns, noting that "the In-Depth Review process in the Draft Guidelines lacks the clarity needed to uphold the principles of fairness, transparency, openness, and predictability." These submissions likened the absence of guaranteed outcomes to an absence of fair process, often treating predictability and procedural fairness as interchangeable: the Draft Guidelines' statement that the guidelines were "not intended to provide certainty on ultimate outcomes for particular cases" was read as an admission of unfairness rather than as a description of how discretionary regulatory review ordinarily operates. Stakeholders particularly emphasized that the lack of clear procedures extended beyond compliance issues to broader concerns about the PMPRB's regulatory power and the role companies would play in pricing decisions.

Beyond transparency concerns, stakeholders argued that procedural uncertainty would deter companies from launching medicines in Canada altogether (Table 6). Life Sciences Ontario asserted these concerns to documented patterns, noting that "pharmaceutical companies are hesitant to launch new drugs in Canada due to uncertainty about how the PMPRB will enforce new pricing regulations. This uncertainty has led companies to delay or reconsider introducing innovative medicines in the country." Multiple rare disease patient organizations also echoed these access concerns, with the Canadian Organization for Rare Disorders warning that "overly restrictive pricing measures can make it financially unviable for manufacturers to introduce these therapies in Canada, resulting in limited availability and delayed access."

The procedural guidance concerns extended beyond therapeutic comparisons to fundamental questions about how companies could assess their own compliance. Innovative Medicines Canada noted that "the Guideline appendices on *Patent Act Section* 85 direct staff to consider over 30 broad and open-ended questions – many of which may extend beyond the scope of the *Patent Act*. However, the Guidelines offer little guidance on how to assess, prioritize, or resolve conflicting answers." Eli Lilly Canada reinforced this self-assessment problem, arguing that "the absence of any guidance to aid rights holders in assessing their prices creates uncertainty and hinders the ability of rights holders to provide Canadians with patented medicines at non-excessive prices in an effective manner."

Stakeholder recommendations centered on transparency mechanisms and timeline restrictions to address both procedural fairness and market access concerns. AbbVie advocated for full disclosure mechanisms, arguing that "procedural fairness requires that Rights Holders are afforded an explanation for the decision that is coherent, logical, and that accounts for relevant facts and context." Multiple companies requested access to both scientific and price review reports, positioning transparency as essential for preventing regulatory error and reducing unnecessary escalation to hearings.

Stakeholders also proposed working groups as mechanisms for addressing procedural uncertainty. Multiple companies requested working groups specifically for TCC methodology, with Lundbeck Canada arguing that "additional discussions

Table 6. In-Depth Review Procedures and Timeline

Subtheme	Stakeholder Position	Illustrative Quote
Concern: process opacity and excessive timelines	Guidelines lack clear, predictable criteria while lengthy review timelines create market access barriers	*"Business is loath to operate in an environment of uncertainty and unfortunately, uncertainty is exactly what is being proposed in the Draft Guidelines for PMPRB Staff. In fact, the document itself states that '... the guidelines are not intended to provide certainty ....' Rights holders need certainty through the duration of patent life of new medicines as not having a price certainty would impact decisions to launch innovative and life saving therapies in Canada"* - Boehringer Ingelheim (Pharmaceutical Manufacturer).
Solution: enhanced transparency, streamlined timelines, and the establishment of working groups	Provide full access to review documents, establish clear time limits to enable meaningful participation	*"Transparency in the in-depth review process is essential. BIOTECanada recommends full access to the scientific review report and the price review report, to help prevent errors or misunderstandings from escalating unnecessarily into a hearing"* - BIOTECanada (Biotechnology Industry Association). *"Given the extent of outstanding and unanswered practical questions, Pfizer would strongly support the design and tasking of joint working groups to explore options on various technical and operational matters that would be both effective and workable for all parties. This model has been used with great success in past instances and has enhanced the effectiveness of patentee compliance with Board Guidelines"* - Pfizer (Pharmaceutical Manufacturer).

Abbreviation: PMPRB, Patented Medicine Prices Review Board.

with experts representing Rights Holders, in the form of technical working groups" were necessary because "PMPRB staff may not have the scientific expertise to consider and weigh relevance of comparators during in-depth reviews."

Retroactive Application and Transition Periods

Arguably the most substantial reform involved applying the new rules retroactively to medicines already on the market that previous rules had deemed compliant, subjecting existing medicines to annual re-benchmarking against new international price criteria. Stakeholders argued that retroactive application violated basic fairness and created uncertainty that would discourage pharmaceutical investment and market participation (Table 7). As Merck Canada noted, "the risk of retroactive liability could create uncertainty and discourage pharmaceutical companies from launching new products in Canada." The Constitutional Coalition noted that retroactive changes would undermine the predictability essential for pharmaceutical investment decisions, while the Canadian Association for Pharmacy Distribution Management (CAPDM) emphasized that "existing products were already compliant and therefore non-excessive with the applicable legislation and guidelines." This objection characterized prior compliance as a settled entitlement: because existing medicines had been judged non-excessive under earlier rules, stakeholders situated re-benchmarking as the withdrawal of an established right.

In addition to concerns about retroactivity, stakeholders argued the transition periods did not provide sufficient time between the introduction of new regulatory rules and the point at which companies, pharmacies, and the broader health system would be required to comply. Professional organizations positioned insufficient transition periods as creating systemic access barriers throughout pharmaceutical distribution systems, with particular attention to rural and underserved communities. The Canadian Pharmacists Association recommended a three-year transition to support pharmacy operations and continuity of care. AstraZeneca reinforced supply chain concerns, arguing that "a three-year transition would be more appropriate for the Canadian pharmaceutical supply chain (eg, pharmacists, distributors, pharmacies and generic manufacturers) which is already struggling due to a variety of cost control policies."

Concerns around supply chain issues were commonly positioned as issues of health equity. CAPDM connected pricing changes to geographic access barriers through distribution economics (Table 7).

The Canadian Pharmacists Association positioned inadequate transition periods as creating access barriers particularly in rural areas: "without adequate time for adjustment, pharmacies may face financial instability, leading to disruptions in patient access to medications, especially in underserved communities where pharmacists serve as the primary healthcare providers." Bristol Myers Squibb argued that grandfathering was necessary because "forcing price reductions, despite previous compliance, devalues past regulatory decisions, creating inconsistency and risking disruptions or delays in treatment options for patients who rely on these medicines."

Stakeholders focused their recommendations on protecting companies from timing-related problems through grandfathering mechanisms that would exempt existing products from new rules and through extended implementation periods that would give the system more time to adjust to new requirements. GSK Canada proposed that existing medicines receive "legacy status" to exempt them from new guidelines entirely, while LEO Pharma requested "a three-year transition period for existing products to allow sufficient time for rights holders to come into compliance and for other stakeholders in the Canadian pharmaceutical supply chain (eg, pharmacists, distributors, and generic manufacturers) to adjust to the new policy environment." Multiple stakeholders advocated for staggered implementation approaches, with CAPDM recommending that the Board stagger annual reviews, reviewing new drugs in odd years and existing drugs in even years to ease the operational burden as a mechanism for reducing supply chain disruption while enabling gradual adaptation to new regulatory requirements. These recommendations framed time-based protections as essential for maintaining both the PMPRB's credibility and

Table 7. Retroactive Application and Transition Periods

Subtheme	Stakeholder Position	Illustrative Quote
Concern: temporal injustice and supply chain disruption	Applying new guidelines retroactively to compliant medicines violates regulatory fairness while insufficient transition periods threaten supply chain stability	*"This retrospective approach is problematic, as rights holders make long-term investment decisions based on the regulatory framework in place at the time of a product's launch"* [Astellas Pharma (Pharmaceutical Manufacturer)]. *"Since the distribution of medications is largely driven by listed drug prices, which are derived from the federally approved maximum price, the equation is simple: reduced distribution funding leads to lower inventory levels, which in turn reduces regional service capacity (particularly for remote communities), ultimately increasing the frequency and duration of drug shortages"* [CAPDM (Distributor Trade Association)].
Solution: grandfathering and extended implementation	Exempt existing medicines from new guidelines and provide longer transition periods for supply chain adjustment	*"To ensure fairness, medicines first sold before July 1, 2022 should be grandfathered so that they would not be subject to an in-depth review, provided they remain within allowable inflation-based price adjustments"* [Astellas Pharma (Pharmaceutical Manufacturer)]. *"A phased implementation over 24 months after the implementation of new Guidelines would allow for smoother adaptation for existing medicines"* [Novartis (Pharmaceutical Manufacturer)].

Abbreviation: CAPDM, Canadian Association for Pharmacy Distribution Management

the healthcare system's ability to function properly.

Discussion

This analysis of 54 stakeholder submissions to the PMPRB's 2024-2025 consultation on its Draft Guidelines found that pharmaceutical stakeholders described the proposed guidelines as fundamental regulatory problems rather than technical issues requiring refinement. The central concerns were annual re-benchmarking creating business uncertainty, excessive staff discretion in therapeutic comparisons undermining predictability, complaint processes risking strategic misuse, in-depth review procedures lacking transparency, and retroactive application violating regulatory fairness.

Our study builds on previous research examining how pharmaceutical market stakeholders engaged with PMPRB reforms – particularly Foroutan and colleagues'[6] analysis of perspectives on updates to the 2007 BIA guidelines. Both studies document persistent concerns about transparency, predictability, and regulatory scope. However, Foroutan et al found that stakeholders approached budget impact analysis guidelines collaboratively, treating them as technical problems requiring methodological refinement. Our analysis revealed adversarial positioning in that stakeholders deployed constitutional arguments, warned about regulatory weaponization, and predicted market exit to constrain regulatory power rather than simply improve technical processes.

Pharmaceutical manufacturers opposed the reforms on procedural, economic, and constitutional grounds, characterizing annual re-benchmarking as jurisdictional overreach, warning about market exit, and emphasizing investment uncertainty.

The two positions rested on different premises about the Board's purpose. Pharmaceutical manufacturers argued that annual re-benchmarking against changing international prices would convert a patent-abuse regulator into a price-control body it has no constitutional authority to be, tying that claim to warnings of market exit and investment uncertainty. Patient organizations primarily emphasized treatment access, formal patient participation and the effects of uncertainty on vulnerable populations. Some also raised concerns about the Board's mandate.

Canadian pharmaceutical manufacturers fought strongly against stricter price controls, building on past arguments that controls would delay or prevent new drugs from entering the country.[32] But these submissions did not engage with the empirical literature on whether earlier predictions of market exit materialized. Zhang et al[36] tested whether warnings that medicines would become inaccessible to Canadian patients were borne out, tracking 349 new molecules across Canada and 13 comparator countries between 2012 and 2021 and specifically examining Canada during the 2018–2021 PMPRB policy uncertainty period (when earlier reforms generated the same industry warnings about market exit). The authors found no negative impact on 2-year launch rates in Canada relative to comparator countries, except for medicines with major therapeutic benefit, whose 2-year launch rate in Canada fell from 45.8% to 31.3%. Thus, industry warnings about wholesale market exit may function as strategic rhetoric rather than credible predictions of actual corporate behavior, but are nevertheless a common feature of public commentary in responding to PMPRB proposals. The omission is consistent with the broader pattern in the documents: stakeholders restated their concerns rather than engaging the empirical record that might contradict them.

Several patient organizations, including the Chronic Myelogenous Leukemia Society of Canada, argued that TCC is ill-suited to rare disease drugs that lack close comparators. These concerns about therapeutic assessment warrant consideration even where claims about market withdrawal remain unsubstantiated. For medicines with few suitable comparators, uncertainty about comparator selection and the interpretation of clinical evidence could affect the TCCs used in price reviews. On one hand, this supports transparent explanations of how comparators are selected and evidence is weighed, alongside opportunities for rights holders and clinical experts to identify errors or submit additional evidence. But these concerns do not establish that the proposed approach would systematically undervalue medicines or deter their launch, but they identify procedural safeguards against those risks.

Patient advocacy organizations filed 9 of the 54 submissions, consistent with the more prominent role that patient voices now play in Canadian pharmaceutical policy-making.[37-39] Patient advocacy organizations have become increasingly important stakeholders in pharmaceutical policy-making,[40-42] expressing concerns that policy-makers must now address alongside traditional industry and payer perspectives.

Our analysis has limitations. First, we analyzed only written submissions without access to informal communications between stakeholders and PMPRB officials. Second, we cannot determine whether stakeholder arguments influenced final guideline decisions, which would require examining relationships between those arguments and policy outcomes. Third, we did not systematically code for organizational relationships between patient advocacy groups and pharmaceutical manufacturers, though such relationships might explain some policy position alignment. Fourth, beyond the omission discussed above, we did not systematically analyze what stakeholders chose not to address.

A number of policy directions follow from the convergent recommendations documented above. Where we extend beyond what stakeholders proposed, we flag this explicitly. First, rather than focusing on who can file complaints, the PMPRB could require complainants to submit preliminary evidence before triggering resource-intensive in-depth reviews. Complaints would need to show prices exceed international comparators by meaningful thresholds, or provide market evidence of pricing behavior inconsistent with competitive conditions. Save Your Skin Foundation, AstraZeneca, Bristol Myers Squibb, and RAREi proposed validation mechanisms of this kind. We extend their proposals by suggesting that validation decisions be time-limited and published with explanations of each outcome,

creating accountability for both complainants and the PMPRB. The final Guidelines moved in the opposite direction on eligibility without adopting an evidentiary threshold: complaint standing was confined to Ministers of Health and senior public-drug-program officials, the restriction industry submissions sought, without the evidentiary screening that patient and industry submissions alike proposed.

Second, the final Guidelines already provide a two-year transition before annual review of existing medicines. We propose using this interval to assess effects on access before extending annual re-benchmarking to those products. CAPDM, Novartis, AstraZeneca, and the Canadian Pharmacists Association proposed staggered or phased rollouts on supply chain and transition grounds. We concur and note that sequencing also functions as an empirical test of whether industry warnings about market exit reflect genuine business constraints or strategic positioning, given Zhang and colleagues'[36] finding of no negative impact on launches in Canada, except for medicines with major therapeutic benefit, during the 2018–2021 policy uncertainty period.

Third, the recent US pricing environment has added a further reason for Canada to retain list-price oversight. Executive Order 14297, issued in May 2025, directs US authorities to pursue "most-favored-nation" drug pricing, under which manufacturers would offer US patients prices no higher than the lowest paid in comparably developed countries, and frames lower foreign prices as "freeloading" on US-funded innovation.[43] In December 2025, the Centers for Medicare & Medicaid Services proposed two payment models, the Global Benchmark for Efficient Drug Pricing model for Medicare Part B and the Guarding US Medicare Against Rising Drug Costs model for Medicare Part D, that would tie Medicare drug rebates to prices in 19 reference countries, Canada among them.[44] And in April 2026, a presidential proclamation announced tariffs of up to 100% on patented pharmaceutical imports under Section 232 of the Trade Expansion Act of 1962, with lower rates or exemptions under specified production, jurisdictional and pricing arrangements.[45] If Canadian list prices were used as a most-favored-nation benchmark, manufacturers would face a direct incentive to raise list prices in Canada or delay Canadian launches to avoid setting a low reference point for the much larger US market. This asymmetry strengthens the case for an independent check on Canadian list prices.

Finally, as an extension of these stakeholder recommendations, we propose that the PMPRB establish standing expert panels of clinicians with specialty expertise to assess therapeutic equivalence, removing this determination from staff discretion. RAREi and the Gastrointestinal Society converged on incorporating clinical expertise into TCC decisions, despite reaching that recommendation through different starting concerns. We add that panel recommendations should be published with explicit rationales, creating precedents that guide future assessments.

Future research should examine whether stakeholder arguments influenced the Guidelines that took effect in January 2026, and which arguments proved effective. Whether the revised complaint and price-review processes weaken the Board's effect on prices is an empirical question these data cannot answer. Comparative studies examining how other jurisdictions handle retroactive application of pricing regulations could also provide evidence about whether predicted harms actually occur. Several countries have modified pharmaceutical pricing policies over the past decade; tracking drug availability, launch timing, and supply chain stability in these settings would test whether Canada's stakeholder concerns reflect universal regulatory challenges or context-specific conditions. Finally, studies should examine optimal transition periods for major regulatory changes by analyzing supply chain resilience, market stability, and access disruptions across different implementation timeframes. Stakeholders warned that insufficient transition periods would particularly harm rural communities; testing these predictions would inform future policy timing.

Conclusion

The PMPRB's pricing decisions directly shape pharmaceutical market entry, drug availability, and health care costs across Canada, making stakeholder arguments critical for understanding how different actors seek to influence the balance between affordability and innovation. As Canada's PMPRB revised its approach to pharmaceutical price regulation, this analysis of 54 stakeholder submissions found that pharmaceutical manufacturers fundamentally opposed the reforms, while patient organizations, primarily emphasizing access concerns, converged with industry on several of the same recommendations. This pattern creates a distinct challenge for policy-makers: distinguishing between self-interested arguments designed primarily to constrain regulatory authority, genuine concerns about treatment access, and legitimate technical problems with specific implementation mechanisms.

Disclosure of artificial intelligence (AI) use

The authors used DeepL, an artificial intelligence translation tool, to translate the two French-language submissions into English (See Methods).

Ethical issues

This study did not require institutional review board (IRB) review because it analyzed publicly available consultation submissions and involved no human subjects.

Conflicts of interest

Aaron S. Kesselheim reports serving as a consultant for Alosa Health and as an expert witness on behalf of a payor in a case against Teva regarding marketing Copaxone and on behalf of a group of state attorneys general and payors in a case against multiple generic manufacturers related to alleged price fixing. Daniel Eisenkraft Klein reports serving as an expert witness on behalf of a payor in a case against Teva regarding marketing Copaxone.

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