White Paper

Unlocking Value in Canada's LOE Wave

Emerging trends, competitive dynamics, and strategic implications

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The upcoming LOE wave in Canada

Loss of exclusivity (LOE) for pharmaceutical products is an inevitable part of the product lifecycle that fundamentally reshapes competitive dynamics and value creation across the industry. The 2026-2030 period marks a global wave of LOE, with a mix of both small and large molecules, including several cornerstone medications, approaching or reaching patent expiry. While this poses a substantial revenue risk for innovator companies, it also unlocks growth opportunities for generic and biosimilar manufacturers, intensifying competition across therapeutic areas (TAs).

In Canada, the dynamic is especially pronounced. The market entered its peak LOE window in 2026, with approximately 180 products across various TAs expected to lose exclusivity over a five-year period. Those products collectively represent roughly $10B in annual sales in Canada, as of 2025. Among the 20 best-selling innovator drugs in Canada in 2025, more than half are already off-patent or will reach LOE by 2031. These molecules currently contribute up to 70% of affected companies' current total revenues in Canada [Exhibit 1, 2, 3].

With a smaller population and market size relative to global markets, Canada presents a uniquely complex LOE landscape. The regulatory environment, reimbursement frameworks, and stakeholder dynamics differ meaningfully from other markets, often resulting in distinct patterns of generic entry and market erosion. These distinctions create both additional challenges and differentiated strategic opportunities for market participants.

This white paper examines the evolving LOE landscape in Canada, outlines key strategic considerations for industry stakeholders (both innovator and generic companies), and guides companies in making informed decisions to prepare for the future by leveraging real-world data.

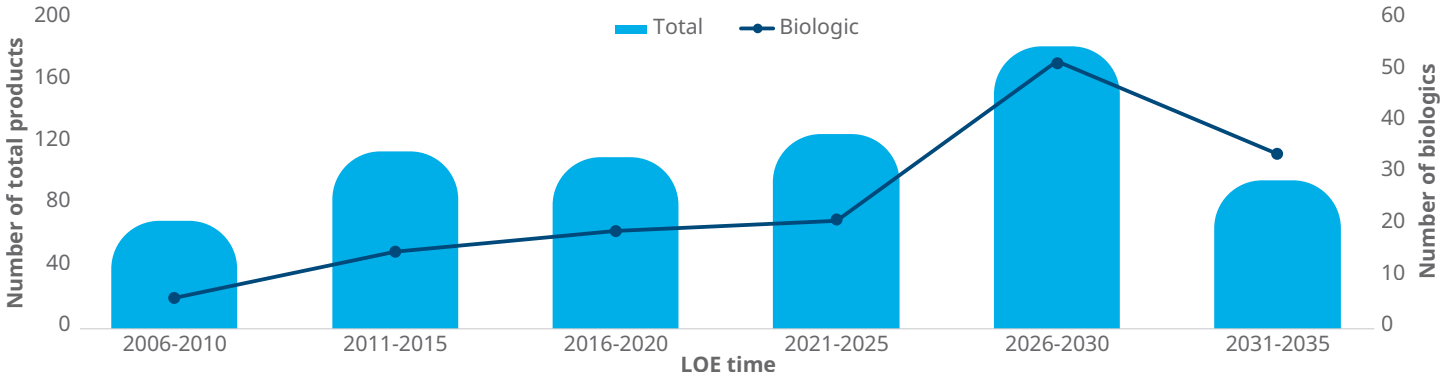
Canadian LOE market landscape

The number of drugs that reach patent expiry changes from year to year, but the 2026-2030 period is expected to see the highest five-year LOE count in more than two decades. Approximately 180 products in Canada are anticipated to lose exclusivity during this time, with biologic LOEs contributing a larger share than historically seen [Exhibit 1].

Even though non-biologic products make up the majority of LOE events, the impact of biologic products on sales has been growing. As of 2025, biologics account for nearly half of the annual sales at risk, driven by patent expiry on major products such as ustekinumab (Stelara), aflibercept (Eylea), and omalizumab (Xolair) [Exhibit 2].

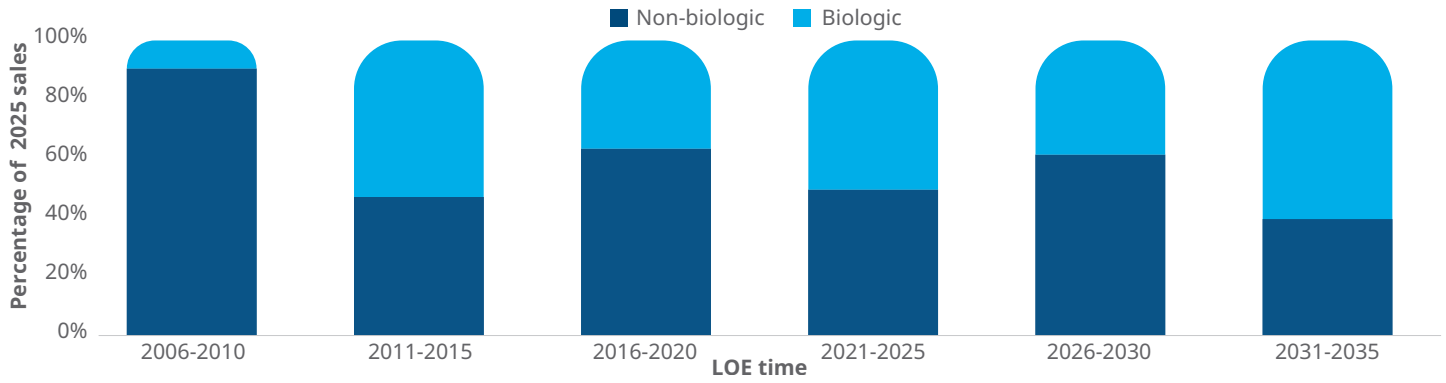
While upcoming patent expiries span a broad range of therapeutic areas, over 90% of the revenue at risk is concentrated in products for oncology, diabetes and anti-obesity, cardiovascular diseases, immunology, and respiratory conditions. Oncology products that will lose exclusivity between 2026 and 2030, as a group, account for 34% of all revenue at risk as of 2025. Diabetes therapy and anti-obesity products, when combined, account for another 34% [Exhibit 3].

Exhibit 1. Canada faces its highest five-year LOE product volume since 2005, with biologics reaching a record share of upcoming LOE events



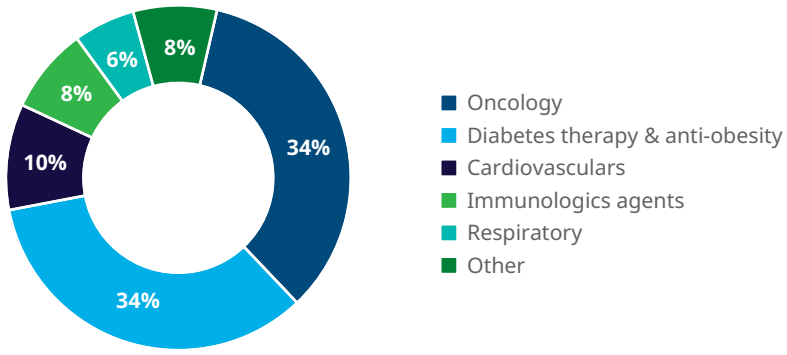
Source: IQVIA Analytics Link, IQVIA MIDAS Audited Value, IQVIA CDH Dec. 2025
Source: Health Canada Patent Register
Notes: The number of products is subject to data availability in the IQVIA database. The products in the analysis exclude MedTech products and vaccines. Upcoming LOE is based on IQVIA MIDAS Audited Value and Health Canada Patent Register

Exhibit 2. Biologics represent ~50% of annual sales at risk in recent years despite accounting for a minority of LOE events



Source: IQVIA Analytics Link, IQVIA MIDAS Audited Value, IQVIA CDH Dec. 2025
Note: 2025 sales are used to calculate the product revenue at risk

Exhibit 3. Oncology and metabolic therapies dominate LOE exposure in Canada from 2026-2030



Source: IQVIA Analytics Link, IQVIA MIDAS Audited Value, IQVIA CDH Dec. 2025
Notes: 2025 sales are used to calculate the product value and sales distribution

Stakeholder dynamics

In 2023, generic medications accounted for 76.6% of all prescriptions filled in Canada and continue to increase their share of the market, outpacing the growth of brands[1]. Yet attitudes toward generics still vary across key stakeholders, including patients, physicians, payers, and pharmacies/pharmacists. Each group plays a role in shaping adoption and substitution patterns, which in turn influence post-LOE market evolution and commercialization outcomes. By understanding how stakeholder perceptions, behaviours, and interactions differ, pharmaceutical companies can better anticipate risks and opportunities. For innovator companies, identifying the stakeholders most likely to remain brand loyal supports a smoother transition and helps sustain market presence amid generic competition.

Table 1. Overview of stakeholder perspectives and drivers of generic adoption[2,3,4]

Patients

- Mixed perceptions of generics; cost-driven but often hesitant to switch due to perceived differences between brand and generics.
- Influenced by affordability, familarity, trust in efficacy, and insurance coverage.

Physicians

- Prescribing gatekeepers, some maintain brand preference while others switch readily.
- Patient mix, reimbursement considerations, and brand-loyalty can materially influence timing and the extent of switching.

Payers

- Gatekeepers through reimbursement, pro-generics, and enforce substitution policies.
- Cost containment, formulary management, and sustainability of drug plans drive the decisions.

Pharmacies/pharmacists

- Generally pro-generics, with some variability across regions and therapeutic areas.
- Economic incentives, formulary listings, provincial switch policies, and supply agreements heavily influence dispensing behaviors.

1. Source: IQVIA PharmaFocus 2027
2. Source: Kesselheim, A. S., Gagne, J. J., Franklin, J. M., Eddings, W., Fulchino, L. A., Avorn, J., & Campbell, E. G. (2016). Variations in Patients' Perceptions and Use of Generic Drugs: Results of a National Survey. *Journal of general internal medicine*, 31(6), 609–614.
3. Source: National Prescription Drug Utilization Information System (NPDUIS). Feb 2025. Private Drug Plans in Canada: Expenditure report, 2018-2023
4. Lynas K. (2012). Private insurers implementing policies making generic substitution mandatory. *Canadian pharmacists journal : CPJ = Revue des pharmaciens du Canada : RPC, 145*(6), 245.

Generic competition

Generic entry

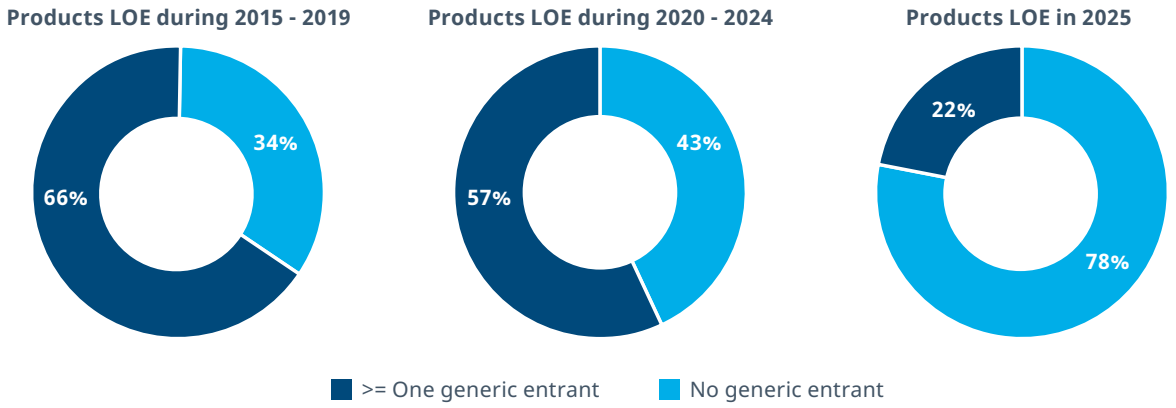
While it is commonly assumed that commercially attractive products will inevitably face generic or biosimilar competition following loss of exclusivity, recent evidence suggests this is not always the case.

From 2023 to 2025, the IQVIA Institute for Human Data Science has examined the biologic market in Europe and the US, highlighting classes of biologics that are at risk of failing to attract biosimilar competition, a concept called "the biosimilar void". The findings challenge the legacy perception that all biologics facing LOE will automatically experience competition from biosimilar medicines[5]. In fact, in the US, only 14 of 62 biologics without patent protection had biosimilars by the end of 2024 and only 12 molecules set to lose patent protection between 2025 and 2034 have biosimilars in development[6,7].

A similar pattern is observed in Canada, where over half of biologic products that lost exclusivity between 2015 and 2019 did not have biosimilar entrants by the end of 2025. The proportion of biologics with no impending biosimilar competitor exceeds 70% for more recent LOE cohorts (i.e., products with LOE between 2020 and 2024). These gaps in competition are driven by multiple barriers, including high development costs, long development timelines, regulatory complexity, emerging treatment classes, and orphan drug indications, all of which reduce commercial attractiveness for generic players. Beyond biologics, generic entry across all product types is less certain than traditionally assumed.

Historical data from IQVIA indicates that approximately 35% of products losing exclusivity between 2015 and 2019 did not attract any generic entrants, as of 2025. This increased to 43% for products that experienced LOE between 2020 and 2024. These findings reinforce that competition at patent expiry is not always guaranteed [Exhibit 4]. Non-biologic products with annual sales exceeding $100M CAD ('high sales') at the time of LOE appear to attract high levels of generic development, reinforcing scale as a key trigger for generic entry [Exhibit 5].

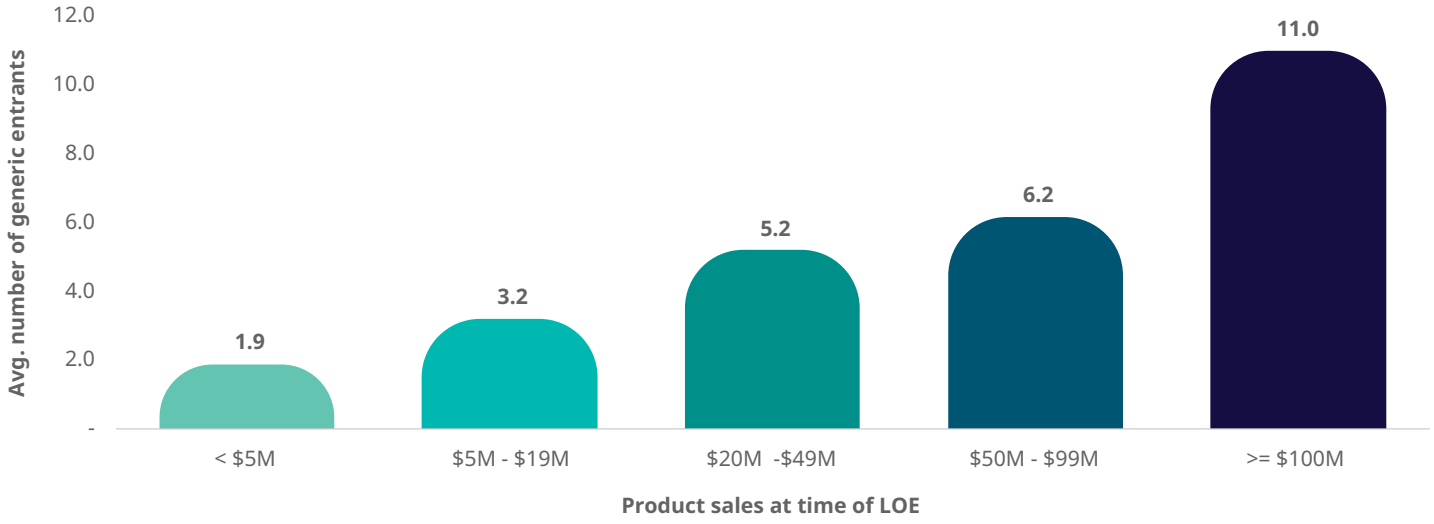
Exhibit 4. Generic entry is not guaranteed and has become increasingly selective in recent LOE cohorts



Source: IQVIA CDH data, Dec. 2025
Notes: Analyses are based on 242 products that lost exclusivity between 2015 and 2025

5. IQVIA Institute for Human Data Science. *Assessing the Biosimilar Void: Achieving Sustainable Levels of Biosimilar Competition in Europe*, October 2023. Available from www.iqviainstitute.org
6. As of September 2024.
7. IQVIA Institute for Human Data Science. *Assessing the Biosimilar Void in the U.S.: Achieving Sustainable Levels of Biosimilar Competition*, February 2025. Available from www.iqviainstitute.org

Exhibit 5. Generic development is highly concentrated in large, high-value markets for non-biologics



Source: IQVIA CDH data, Dec. 2025 data month
Notes: Analysis is based on 90 non-biologic products with initial generic entry between 2015 and 2023

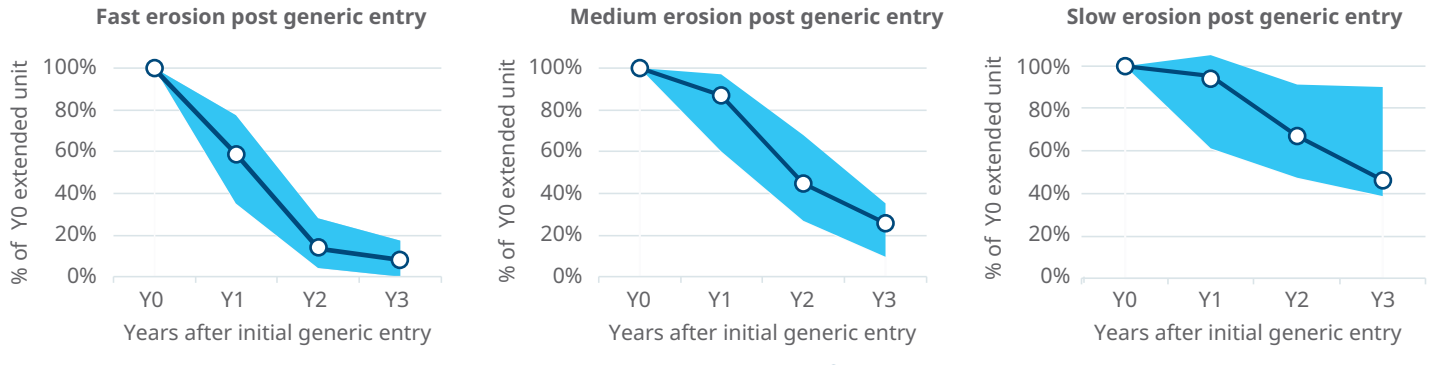
Brand volume erosion and generic uptake patterns

Following generic entry, the lower price of generics creates strong economic incentives for key stakeholders to shift prescriptions from innovator drugs to generics/biosimilars. In most cases, a rapid decline in innovator drug volume is seen, creating significant concern for an innovator company when facing product LOE. However, the speed and pattern of the sales erosion vary across brands.

Analysis of 66 post-LOE drugs with initial generic entry between 2015 and 2021 reveals three distinct volume erosion patterns [Exhibit 6]: fast, medium, and slow erosion. Furthermore, there are multiple distinct brand-to-generic transition trajectories within each category [Exhibit 7].

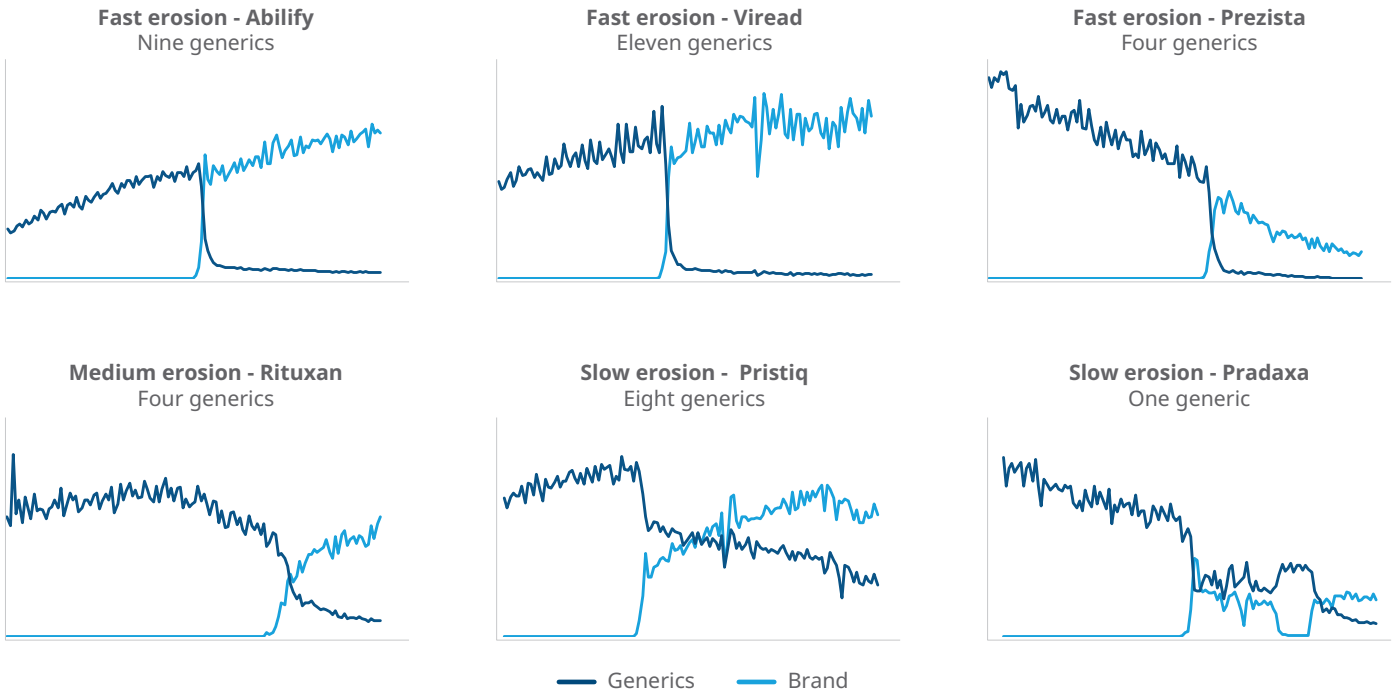
- **Fast erosion** occurs when generics capture at least 80% of brand units within two years of entry, indicating rapid displacement of the innovator drug.
- **Medium erosion** reflects a more gradual decline, where the brand preserves meaningful unit share at year one post-LOE but falls below 40% by year three post-LOE.
- **Slow erosion** demonstrates sustained brand resilience, with the brand maintaining over 40% unit share three years after generic entry.

Exhibit 6. Out of 66 studied products, 36% experienced fast volume erosion, 27% showed medium erosion, and the remaining 37% demonstrated a slower, more sustained decline in brand volume in the first three years following a generic entry.



Source: IQVIA CDH data, Dec. 2025 data month
Notes: Analyses are based on 66 products with initial generic entry between 2015 and 2021
Y0 refers to the year before first generic entry and is set to be the base level of the product's volume (extended units)
Y1 refers to the year of the first generic entry

Exhibit 7. Six distinct brand-to-generic switch trajectories are observed among the studied products



Source: IQVIA CDH data, Dec. 2025 data month
Notes: Analyses are based on 66 products with initial generic entry between 2015 and 2021

These findings highlight that product performance post-LOE varies significantly, reflecting a broad range of underlying market dynamics. Switching behaviors are influenced by multiple factors including therapeutic area, stakeholder preferences, pricing dynamics, and competitive intensity. LOE dynamics require a broad look across many dimensions and markets to identify the appropriate curve(s) that matches the unique aspects of the product and manufacturer strategy[8].

Strategic considerations

Strategic considerations to maximize innovator product value

When approaching patent expiry, innovator companies typically consider three core LOE strategies: defend, maximize, and optimize. Even when opportunities to extend exclusivity are limited or no longer viable, companies can preserve meaningful value through a well-designed LOE commercialization strategy, often initiated two years in advance of an anticipated loss of exclusivity.

To effectively navigate this transition, brand teams must address several critical business questions pre- and post-LOE:

- What is the likelihood and timing of generic entry?
- How can the impact of generic competition be accurately forecasted?
- How will different stakeholders respond following generic entry?
- How can brand value be maximized in a competitive, post-LOE environment?
- Which promotional strategies can be deployed to slow down the erosion of sales and market share?

Strategic considerations to identify business opportunities for generics

Canadian generic drug manufacturers face a range of challenges, including cost pressures, constrained profitability, complex regulatory requirements, and increasing competition from both established players and new entrants. Before making the strategic move of entering a market, generic manufacturers must take a disciplined, data-driven approach to evaluating opportunities, focusing on key dimensions such as market attractiveness, strategic fit, feasibility, and competitor dynamics.

8. IQVIA, *The Rules of Loss of Exclusivity are Being Rewritten*. 2025 Aug. Available from: https://www.iqvia.com/locations/united-states/insights

Table 2. Framework for assessing generic market entry opportunities

Market attractiveness

- What is the overall market size? What share and scale will the brand have pre-LOE?
- Is the brand's growth trajectory stable, growing, or declining?
- Are emerging therapies likely to disrupt demand?

Strategic fit

- Does this opportunity align with our existing portfolio or enable diversification?
- Can the molecule be integrated into our current generic pipeline?

Feasibility

- Do we have the required development and manufacturing capabilities?
- Does the cost and development timeline align with our capability?
- Do we have appropriate distribution capabilities? (i.e., hospital, retail, specialty pharmacies, etc.)

Competitor dynamics

- Who are the expected generic competitors at launch?
- Is there an opportunity to secure first-to-market advantage?

Case study 1: Evaluating brand retention potential with a data-driven approach

- **Situation:** A leading pharmaceutical company engaged with IQVIA in advance of a key product's LOE. The objective was to assess potential for brand retention and inform engagement strategies across physicians and pharmacy outlets, both before and after generic entry.
- **Solution:** IQVIA applied a data-driven approach, leveraging multiple proprietary datasets, including outlet prescription data for all prescribers (Geographic Prescription Monitoring), physician-level prescription data (Xponent), and the InnoviCares database that tracks copay card behavior of physicians and pharmacy outlets. This enabled analysis of prescribing behavior, dispensing patterns, and financial support utilization. IQVIA also identified comparable analogue products and generated a comprehensive view of stakeholder behaviors and segments.
- **Impact:** The analysis uncovered distinct stakeholder segments based on overall prescribing volume, likelihood of retaining the brand, payer split within their practice, and utilization of copay cards. These insights informed differentiated engagement strategies: defend, maintain, switch, and evaluate. This allowed the client to optimize its commercial strategy and preserve brand value in the face of generic competition.

Exhibit 8. Physician segments for an innovator drug post generic entry

Engagement strategy

Defend: Priority segment. Proactive retention strategy to maintain competitive advantage.

Switch: Selective engagement strategy, using targeted messaging to slow erosion and preserve brand value.

Maintain: Sustain existing relationships with loyal customers using efficient engagement strategies.

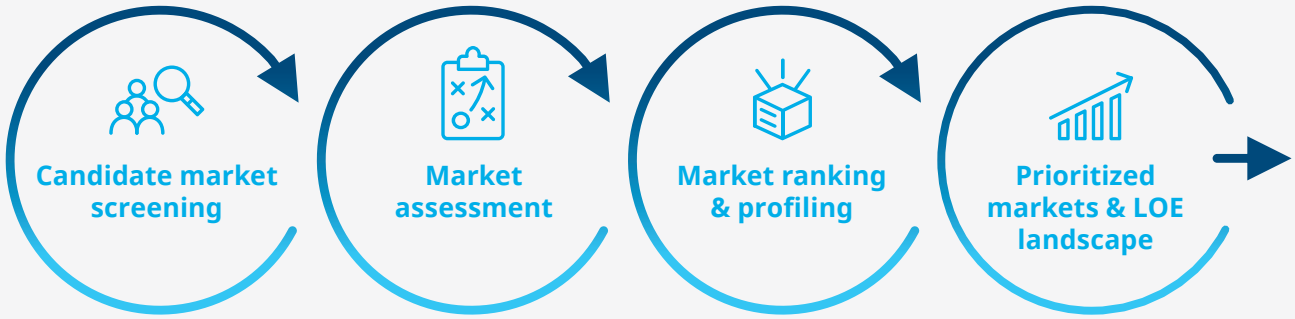
Evaluate: Lower priority; monitor with cost-effective approaches to optimize resource allocation.

Case study 2: Strategic prioritization of generic opportunities

- **Situation:** A generic pharmaceutical manufacturer sought to expand its business beyond Canada as part of its broader strategic vision. The objective was to identify and prioritize attractive international markets and therapeutic areas based on upcoming LOE opportunities and long-term growth potential. The client also wanted to understand the LOE landscape in the next five and 10 years for selected products and markets, respectively.
- **Solution:** IQVIA leveraged its proprietary international MIDAS database and developed a data-driven framework to assess markets across key dimensions, including market attractiveness, entry barriers, competitive dynamics, and strategic fit. The framework includes a novel prioritization and scoring system which considers unique market archetypes in each country and therapeutic area.
- **Impact:** IQVIA helped the client identify a prioritized list of product opportunities that align with their strategic plan and capabilities through a comprehensive assessment of over 300 markets (unique combination of country + therapeutic area + distribution channel).

  Following this, IQVIA Analytics Link and IQVIA Forecast Link were used to investigate the LOE market landscape, including expected competitive outlook for the prioritized list of markets over the next five and 10 years, respectively. In addition, a dynamic and user-friendly Power BI dashboard was developed to ensure ease of use across different stakeholders in the organization.

Exhibit 9. Steps for prioritizing generic opportunities



About the authors

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Ling Ling is a Principal in Canada's Advisory Services practice, which provides customized consulting services with advanced analytics capabilities to support commercial strategy, go-to-market and launch excellence, and salesforce effectiveness. Prior to joining IQVIA, Ling was Director of Strategy and Commercial Operations at a leading Canadian pharmacy chain where she was responsible for strategic planning and the overall P&L performance of the business unit. Previously, she held multiple roles at Canada's largest pharmaceutical company from 2012 to 2020 in global business development, portfolio strategy, and corporate development. Ling holds a Ph.D. degree in Medical Biophysics from the University of Toronto where she held a Vanier Canada Graduate Scholarship. She holds a M.Sc. degree in Anatomy and Cell Biology from Queen's University and a H.B.Sc. degree in developmental biology from the University of Toronto.

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