# Key Tailwinds and Headwinds Impacting the Major Developed Markets

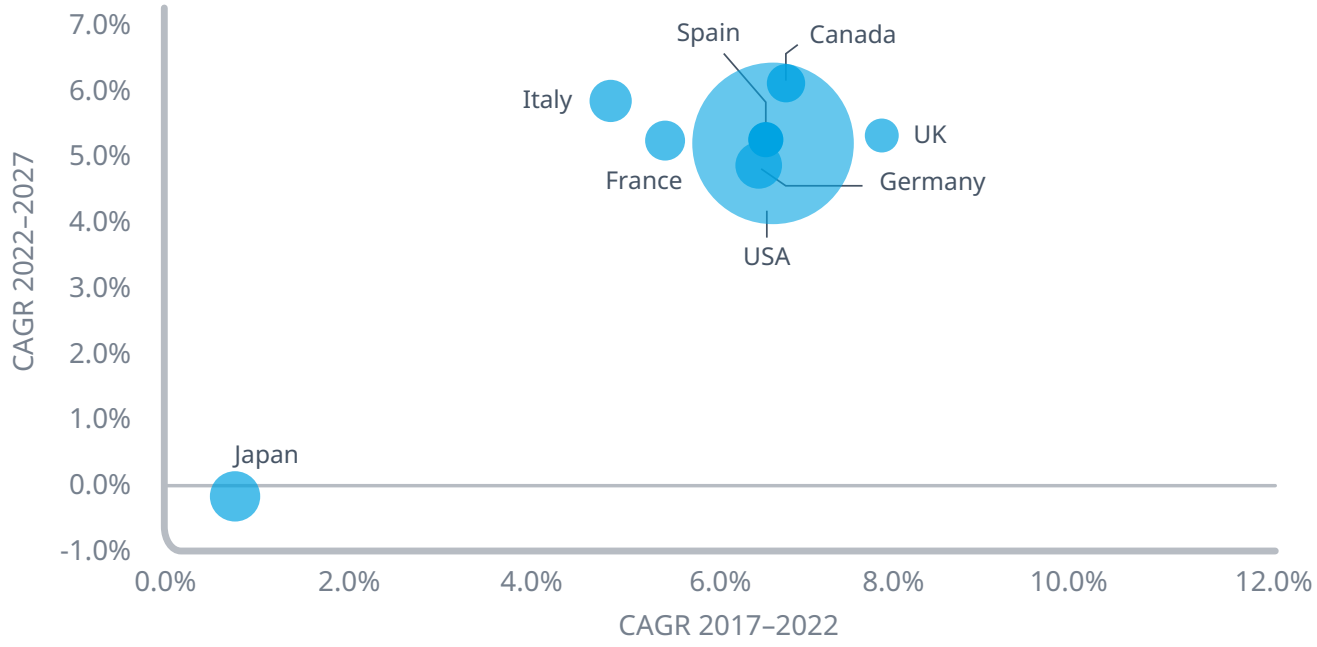
## *IQVIA Market Prognosis*

This article reviews the latest pharmaceutical forecasts from IQVIA's Market Prognosis and presents an overview of key tailwinds and headwinds impacting the eight major developed pharmaceutical markets over the next five years. The analysis is based on findings from Canada, France, Germany, Italy, Japan, Spain, UK and the USA, which are covered in IQVIA's Market Prognosis edition published in March 2023.

In the aftermath of the COVID-19 pandemic and under the impact of increased pressure on healthcare budgets, ongoing economic challenges and stretched healthcare systems, pharmaceutical sales growth in the combined eight major developed markets is forecast to slow to a compound annual growth rate (CAGR) of 4.9% over 2022–2027, from 6.1% over 2017–2022.

Of the eight markets, seven are forecasted to post CAGRs of around 5-6% (in constant dollar terms), while Japan, the second largest market in the group, is projected to contract by -0.1% over the 2022–2027 period. Italy is the only market where growth in 2022–2027 period is forecast to be faster than over 2017–2022.

**Major developed markets compound annual growth rates LC$ 2017–2022 and 2022–2027**




Source: IQVIA Market Prognosis, March 2023.
Notes: Sales growth based on LC$ at constant exchange rate – (Q4 2022 IQVIA). Bubble size represents the market size in 2022 in LC$ at ex-manufacturer prices.

# Tailwinds

## RECENT AND NEW PRODUCT LAUNCHES

Pharmaceutical market growth in the eight major developed markets will primarily be driven by launches of innovative new drugs. The launch of specialty medicines such as therapies for cancer, rare diseases and chronic diseases, including novel biologics, as well as cell and gene therapies and other innovations will raise average drug prices, thereby fueling market growth in value terms over the forecast period.

However, since 2020, launches of innovative new drugs have, with certain exceptions, under-performed pre-pandemic benchmarks of launch sales performance, according to the IQVIA whitepaper *"Overcoming Pharma's Launch Performance Problem"* published in October 2022. Contributing factors include disruption in patient journey to diagnosis and prescription, reduced company interaction time with healthcare professionals (HCPs) and a reluctance by HCPs to prescribe new drugs to patients without face-to-face interaction.

## MEASURES TO ACCELERATE ACCESS TO INNOVATION

Recognizing the importance of ensuring timely access to innovative new drugs for patients, governments in the major developed markets are implementing various initiatives to expedite access to these drugs.

Confidential agreements between manufacturers and payers are widely used to facilitate access to innovation, while managing uncertainty around their financial impact or performance. These agreements also serve as a valuable tool for payers to secure rebates on medicines, generating savings. In **Germany**, confidential discount agreements, based on tenders, are struck between manufacturers and the federal association of health insurance funds (GKV). In the **USA**, an executive order signed by President Joe Biden in October 2022 required the Health and Human Services (HHS) Secretary to consider exploring new ways, including a cell and gene therapy access model and a new payment model, to deliver and pay for better access to drugs for Medicare and Medicaid beneficiaries.

Schemes such as the new early access (AP) and compassionate access (AC) system in **France**, and the Early Access to Medicines Scheme (EAMS) and Innovative Licensing and Access Pathway (ILAP) in the **UK** aim to provide early access to innovative medicines. The Voluntary Scheme for Branded Medicines Pricing and Access (VPAS) and the Statutory Scheme in the **UK**, also aim to encourage faster market access for medicines.

In **Japan**, the *Sakigake Shinsa Shitei* system fast-tracks the review of selected 'breakthrough' drugs. Additionally in **Japan**, price premiums are granted to innovative medicines to compensate for price declines resulting from National Health Insurance (NHI) price revisions.

To meet the increasing expenditure from high-cost innovative drugs, extra funding has been allocated in **Italy**; provisions included in the 2022 Budget Law allocated an additional €100 million for the Innovative Drugs Fund (IDF) in 2022, rising to €200 million in 2023, and to €300 million in 2024.

## REFORMS AND MEASURES TO IMPROVE ACCESS TO HEALTHCARE

The COVID-19 pandemic has exacerbated pre-existing deficiencies in healthcare systems in many countries, including the major developed markets. In response, governments are implementing reforms aimed at enhancing the quality and efficiency of healthcare provision and addressing social and geographical disparities in access to healthcare. Moreover, governments in the major developed markets are seeking ways to make healthcare systems more resilient to the pressures created by demographic developments, where the elderly population in need of treatment is expanding, and the working age population is shrinking.

Strengthening primary care is a priority across most developed markets. In **France**, objectives for the new medical contract under discussion between the doctors' unions and the national health insurance fund include ensuring that all citizens have access to a referring GP; guaranteeing access to care in all regions; raising the number of medical assistants; increasing the number of groups of healthcare professionals that coordinate primary (and, to an extent, secondary) care in a given area (CPTSs); and making greater use of digital technology. In **Spain**, the approved 2022–2023 Primary Care Action Plan aims to strengthen quality of care provided by primary care physicians.

The pandemic has underscored the significance of pharmacists and their potential to offer additional primary care services. Expanding the scope of pharmacists' services can aid primary care professionals by alleviating some of their workload. In **Canada**, pharmacists in Ontario have been allowed to prescribe medications for common medical ailments from 1 January 2023. In **Italy**, pharmacists' role in primary healthcare provision is set to expand further if the reform of territorial care as outlined in the EU-funded National Recovery and Resilience Plan (NRRP) is successfully implemented by 2026, while in **France**, retail pharmacists' involvement in the provision of primary care services will grow under the new national pharmacy contract.

In the **UK**, Integrated Care System (ICS), which came into statutory footing on 1 July 2022, aims to improve the health of the population by tackling inequalities in outcomes, improving experience and access, enhancing productivity and value for money. Similarly, in **Japan** the gradual emergence of an integrated community care system (ICCS) will deliver a greater proportion of services outside of the hospital sector.

The digitalization of healthcare is also expanding patient access to care. Although most developed markets had promoted the use of telehealth to improve access to healthcare over the past decade, remote consultations and the use of telemedicine expanded dramatically since the onset of the pandemic. Developments in digitization could also lead to improvements in efficiency of care by reducing waiting times and eliminating duplication of work.

## PRICE ADJUSTMENTS DUE TO INFLATION IN THE SHORT TERM

Higher inflation rates globally have resulted in most pharmaceutical manufacturers experiencing higher raw material and energy costs, which are consequently squeezing profit margins, with the generics industry particularly affected. Although inflation is expected to ease in short term, deteriorating margins have worsened drug shortages.

Authorities across several countries are taking steps to provide some respite to pharmaceutical manufacturers. In **Italy**, effective January 2023, retail prices for non-reimbursed (Class C) prescription drugs increased slightly above consumer price index, following authorization by the national medicines' agency *(Agenzia Italiana del Farmaco; AIFA)*. On similar lines, in **Canada**, for patented drugs a higher price adjustment factor is anticipated for 2023 compared to previous years.

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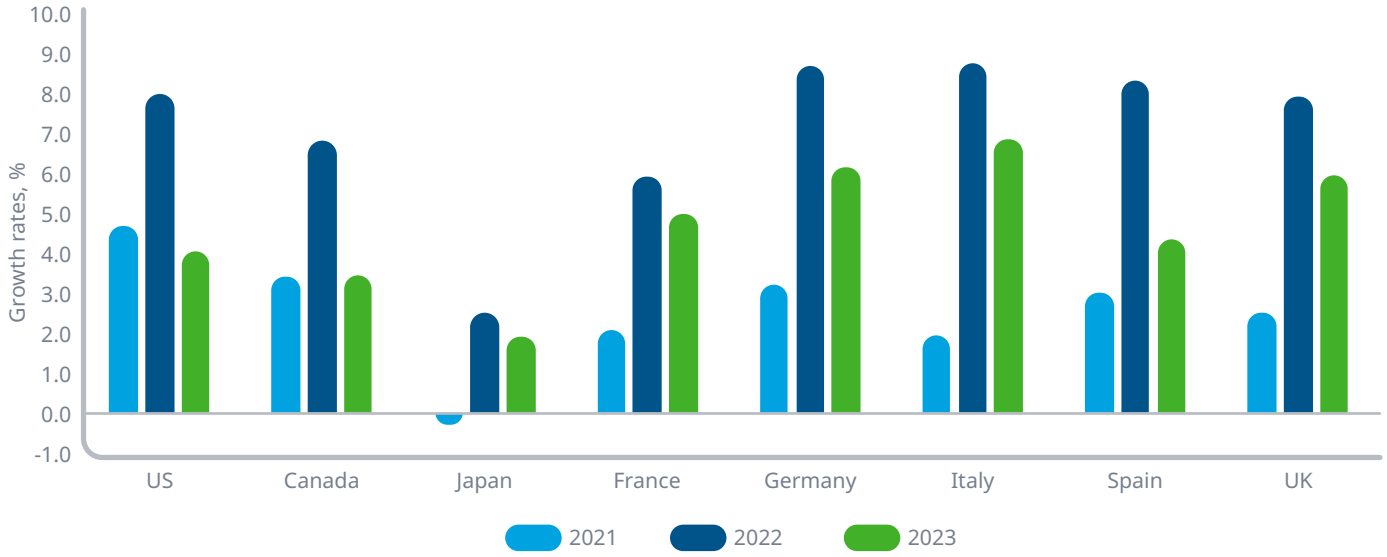
In **France**, in view of recurring drug shortages, the government announced in February 2023 a moratorium on price reductions for "strategic generics on the industrial and health level". In addition, it advocated targeted price increases for some strategic generics produced in Europe in exchange for a commitment to supply the French market. In **Germany**, manufacturers are in discussions with the authorities to allow more frequent adjustments of drug prices subject to the extended price freeze and within the reference pricing system.

In **Japan**, the the Ministry of Health, Labor, and Welfare (MHLW) has implemented a one-off concession for 150 patented medicines that would otherwise have been subject to price cuts in April 2023 had the price maintenance premium (PMP) rules been applied. Similarly, around 1,100 unprofitable generic medicines will be granted a price increase.

While inflation-driven price adjustments will result in slight upward pressure on the average list price per standard unit, they are unlikely to fully compensate for the deterioration in margins, and the impact on overall market growth at list prices will be marginal.

**Major developed markets inflation rates, 2021–2023**




Source: Economist Intelligence Unit, Q1 2023.
Notes: Inflation measured by Consumer Price Inflation (CPI).

# Headwinds

### COST-CONTAINMENT MEASURES

The premium pricing of innovative new drugs places a substantial strain on pharmaceutical budgets. Authorities are exploring ways to generate savings that can be used to finance these high-priced products and to limit their impact on already stretched budgets. Moreover, the current inflationary pressures are resulting in additional payer constraints, thereby increasing the emphasis on cost-effectiveness of innovative drugs.

In **Germany**, the GKV Financial Stabilization Act, formalized in October 2022, requires increased discounts from the industry and tighter pricing and reimbursement for high-cost drugs. In **Italy**, AIFA plans to step up cost-containment measures, which include renegotiation of contract renewals to reduce drug prices by an average of 20% and introducing prescribing restrictions in response to overconsumption or new scientific evidence among others.

In **Japan**, the government has stepped up efforts to curb spending on 'long-listed' products (LLPs: off-patent original brands) through the imposition of the Z2 (additional price cuts at each 'on year' NHI price revision), G1/G2 (price caps) and Category C (price reduction) rules.

In **Canada**, private payers are increasingly adopting cost-containment strategies including: the use of restrictive criteria for formulary listings; prior authorization requirements; generic substitution; multi-tier drug plans; shifting costs to patients; implementing preferential listings of biosimilars; and adopting step therapy initiatives where costly drugs are listed as second- or even third-line treatments.

### PRICING REVIEWS

Another important tool to cut down on spending are routine or ad-hoc price reviews and price cuts. In **France**, the 2023 Social Security Financing Law (LFSS) seeks price cuts worth €800 million on reimbursed drugs. In **Japan**, the second off-year NHI price revision was implemented in April 2023. The price adjustment exposed almost 70% of NHI listed products, far higher coverage than the industry had hoped for off-year revisions. Additionally, amendments to the re-pricing rule and changes to new product cost calculation methodology will put downward pressure on average prices.

In **Canada**, reform of guidelines that direct the framework for determining the prices of patented medicines partially came into force in July 2022. This led to the creation of a new basket of reference countries for the assessment of patented medicine prices by the Patented Medicine Prices Review Board (PMPRB). The change in the basket of countries will drive down average prices.

In the **USA**, by amending the 'non-interference' clause that has historically ruled out government intervention in Medicare drug prices, the 2022 Inflation Reduction Act (IRA) will enable the Department of Health & Human Services (HHS) to negotiate 'maximum fair prices' (MFPs) for some single-source branded drugs, although the first batch of MFPs will not take effect until 2026. In addition, Medicaid rebates, which are triggered when the price of a drug increases at rates in excess of inflation, are currently capped at 100% of the average manufacturer price (AMP). The cap will be removed from 1 January 2024. Further, the 2022 IRA will trigger the expansion of rebate requirements into the Medicare market. Insulin producers have already cut the price of some leading brands in a bid to avoid falling foul of the new rebating provisions. However, as of early 2023, it remained unclear if other companies will follow suit.

## MEASURES TO IMPROVE GENERICS AND BIOSIMILARS UPTAKE

Governments in the major developed markets are adopting pro-generic and biosimilar strategies to increase their uptake, generate savings and offset rising expenses. The wider adoption of biosimilars will make advanced treatments more accessible to a larger number of patients at reasonable prices. Meanwhile, the pro-generic and biosimilar policies will place downward pressure on average price per standard unit.

In the **USA**, the establishment of a Competitive Generic Therapy (CGT) pathway, offering expedited reviews and exclusivity periods, has encouraged the development and approval of generics in areas of the market where generic competition is deemed inadequate. Furthermore, early patent challenges and first-to-file generic exclusivity periods continue to create a competitive generics market. The biosimilar market will gain momentum in 2023 following the launch of multiple adalimumab biosimilars.

In **Japan**, the adoption of generics is driven by generic utilization targets and the government is expected to set a new volume-based target for biosimilar use by early 2024. Furthermore, a special add-on medical fee premium will be applied between April–December 2023 to increase prescribing and dispensing of generics.

The substitution of biosimilars at the pharmacy level is a widely debated topic, whose implementation has been slow owing to concerns from physicians, patients and the industry. In **Germany**, the automatic substitution of biosimilars at the pharmacy level was postponed to August 2023, to allow the Federal Joint Committee (G-BA) more time to assess concerns raised by healthcare staff and industry. In **France**, pharmacy biosimilar substitution has initially been permitted for just two molecules — Neupogen (filgrastim) and Neulasta (pegfilgrastim). Pharmacists hope that the pharmacist-led substitution will be broadened under the 2024 LFSS.

In **Italy**, regional prescribing guidelines, the introduction of hospital biosimilar quotas, and the interchangeability guidelines released in an AIFA position paper in 2018 will continue to contribute to a steady increase in biosimilar prescribing.

In **Canada**, the provincial authorities have been adopting biosimilar switching policies over recent years to support uptake of biosimilars.

## RATIONAL DRUG USAGE AND PRESCRIBING CONTROLS

A more coordinated and standardized approach is being adopted to prescribing policies to prevent overprescribing in light of budgetary restraints, which have been aggravated by the pandemic's after-effects and inflationary pressures.

In **France**, rational and economical prescribing is being encouraged by cost-saving targets set out by the national health insurance fund (CNAM); savings sought annually in the LFSS as part of the controlled and rational approach to medical practice; and incentives for doctors are being set under the performance-based remuneration (ROSP) system. In the **UK**, measures to enhance medicines optimization, implement cost-effective prescribing, and prevent overprescribing are likely to curb demand and NHS drug expenditure growth.

In **Germany**, each year, the GKV and the federal statutory health insurance doctors' association (KBV), agree the general terms and conditions for prescribing, which are incorporated into regional agreements.

# Summary

Healthcare budgets across developed markets are under significant pressure due to the allocation of substantial funds towards the management of the COVID-19 pandemic over the past three years, an ageing population, a shrinking working age population, and healthcare staffing challenges. Furthermore, the ongoing conflict in Ukraine is exacerbating the challenging macroeconomic environment. In these circumstances, authorities are striving to strike a balance between improving access to innovative medicines and allowing for selected price adjustments to limit the impact of inflation, while at the same time generating the necessary savings to finance these measures.

Furthermore, the pandemic has highlighted the inadequacies of healthcare systems, making reforms imperative to provide citizens with quality, efficient, and equitable healthcare. Measures are being implemented to improve primary care provision as an important step towards this objective, while also making health systems more resilient to withstand any future shocks.

**Key tailwinds and headwinds in major developed markets**

## TAILWINDS

- Recent and new product launches
- Measures to accelerate access to innovation
- Reforms and measures to improve access to care
- Price adjustments due to inflation in the short term

## HEADWINDS

- Cost containment measures
- Pricing reviews
- Measures to improve biosimilars and generics uptake
- Rational drug usage and prescribing controls

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