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IQVIA Market Prognosis 2026–2030

Italy

Published March 2026

Introduction

IQVIA and CPHI are pleased to bring you our special Market Prognosis report sharing our view of the future of the Italian pharma market. Both CPHI and IQVIA consider that such information is key for the growth and development of the pharma industry and believe that this report will provide valuable insight as you look to develop your business in Italy.

The report offers an evidence-based outlook on the healthcare and pharmaceutical industry, leveraging robust quantitative and qualitative methodologies, along with country-specific expertise, to deliver gold-standard market forecasts.

We are excited to share this valuable country information with you and look forward to welcoming you to CPHI Milan.

CPHI and IQVIA team

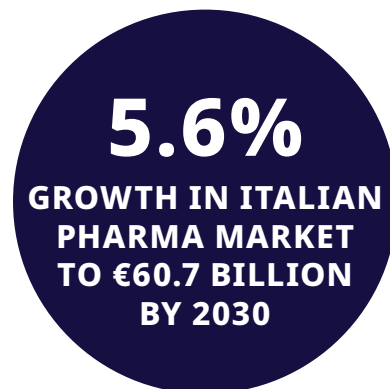


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Market overview and forecasts: Italy

Market synopsis

The Italian pharmaceutical market is forecast to grow at a CAGR of 5.6% ($\pm 1.5\%$) during the period 2025–2030, reaching €60.7 billion by 2030.

At the time of publication, the ongoing US-Israel conflict with Iran, affecting the Middle East region and leading to significant uncertainty in the global macroeconomic outlook, gave rise to downside risks to the assumptions in the prognosis.

Business environment

Real GDP growth in Italy is forecast to grow by 0.8% in 2026 (up from 0.6% in 2025), supported by low unemployment, easing financing conditions and low inflation. Despite ongoing uncertainty about the US trade policy, GDP growth will remain relatively stable during the 2026–2030 period and average 0.8% growth per year. Growth will be underpinned by lower financing costs and support from the EU-funded National Recovery and Resilience Plan (NRRP). Inflation will slow to 1.4% in 2026 owing to a strong euro and a slowdown in wage growth, and average 1.9% per year in 2027–2030. The euro is forecast to appreciate against the dollar in 2026 partly due to continued US policy volatility, before depreciating again, to be valued at an average of €0.86:US\$1 in 2030.

Political stability has improved since a right-wing coalition led by the far-right Fratelli d'Italia (FdI) won a parliamentary majority in 2022. Italy's government, the most right-wing since the end of the Second World War, is led by the country's first female prime minister, Giorgia Meloni in coalition with the far-right Lega and the center-right Forza Italia. The government continues to benefit from the fragmentation of the opposition. Given strong support for Ms Meloni's FdI in opinion polls and the lack of incentives for the FdI's coalition partners to pull out, the government is likely to remain in place for its full term until 2027. The NRRP (about €200 billion) remains the government's main economic policy anchor, although its implementation has been fraught with delays.

Healthcare provision

Despite ranking as one of the most comprehensive healthcare systems in Europe, Italy's healthcare system continues to struggle with long waiting lists and regional disparities, which have worsened due to population aging and persistent healthcare staff shortages. Albeit with limited effect, efforts to address these challenges have intensified since the COVID-19 pandemic, including increased funding, also supported by the EU funded National Recovery and Resilience Plan to strengthen territorial care.

The 2026 Budget Law increases National Health Fund financing to €142.9 billion (up by 4.6% from 2025) – and builds on previous multi year allocations that will inject additional resources through 2028. Funding priorities include workforce strengthening, outsourcing to reduce waiting lists, tariff updates for acute inpatient and outpatient services, and prevention and care programs, particularly in oncology, mental health, and dementias. Pharmaceutical spending caps have been slightly raised. Despite this increased investment, Italy's public health expenditure remains low at 6.3% of GDP in 2024, below OECD and EU averages.

The EU funded NRRP territorial care reform aims to reduce hospital pressure by shifting non acute care, post discharge patients, and chronic disease management to multidisciplinary primary care hubs. However, implementation is lagging, with only a small share of planned interventions completed, and wide regional disparities in the progress attained. Delays are driven by infrastructure gaps and shortages of GPs and nurses. Lack of funding provisions beyond the period covered by the NRRP (until 2026) could limit the plan's effectiveness.

Preventive care and chronic disease management are gaining policy attention. The 2026 Budget allocates €238 million for disease prevention to enhance screening services including genomic tests and tests for the detection of rare diseases. Further resources have been earmarked for the implementation of the

National Mental Health Plan, and the vaccination program. The National Plan for Chronic Diseases has been extended to include obesity, endometriosis, and epilepsy, with additional funding allocated for the treatment of dementias and Parkinson's.

Although small compared with other countries, Italy's private health sector has expanded in recent years, largely due to long waiting lists in the public system. This trend has led to a rise in household spending for private consultations (in private or public hospitals) and an increase in spending for privately prescribed medicines which are not reimbursed. While smaller in comparison with other countries, Italy's private healthcare sector is gaining in importance and could generate growth opportunities for the industry in the long term.

Prescribing and dispensing

The roll-out of e-prescriptions is advancing, while efforts to improve access to treatments are intensifying with a recent provision extending prescription validity for chronic conditions to one year, reducing the need for repeat consultations. While prescription volumes have stabilized post-COVID, high levels of poly medication among elderly patients have prompted regional reviews to minimize risks of errors and adverse effects. Meanwhile, private prescriptions have declined for the second consecutive year, though private healthcare remains a common route for timely care.

The simplification of prescribing requirements to improve patients' treatment access remains a long-standing mission of Italy's Medicines Agency AIFA (Agenzia Italiana del Farmaco). In June 2025, AIFA removed the requirement for therapeutic plans (TPs) when prescribing gliflozins. This change follows the transfer of these drugs from the distribution on behalf

(Distribuzione per Conto, DPC) to the retail pharmacy channel to accelerate patient access. The amendment is part of AIFA's broader review of prescribing guidelines and TPs launched in 2024 to simplify processes and ensure financial sustainability.

Pricing and reimbursement

Innovative manufacturers welcome AIFA's new innovation criteria and the work of the newly formed Scientific and Economic Commission (CSE), though delays in pricing and reimbursement (P&R) decisions persist. The new criteria for assessing innovation as part of the P&R process for including new drugs in the Innovative Drug Fund (IDF) prioritize access for treatments for serious diseases with low or medium epidemiological impact and grant innovative status to drugs showing at least 'moderate' therapeutic value and quality of evidence. Orphan drugs scoring 'low' may be admitted in certain circumstances. Drugs partly developed in Italy may gain preferential status.

Population aging and the increased availability of costly innovative treatments will continue to drive up hospital pharmaceutical spending, triggering industry paybacks. While of limited reach, industry stakeholders unanimously welcome the government's decision to raise the hospital target spending ceiling by 0.3% from 8.5% to 8.8% of total annual healthcare funding. The measure, which was introduced in the 2026 budget, allocates over €140 million in additional resources to the hospital drug budget.

The 2026 budget has also raised the target ceiling for the retail sector pharmaceutical expenditure, bringing it from 6.80% to 6.85%. The ceiling was lowered in the 2024 budget law, but it has been increased again to accommodate existing and future transfers of drugs from the DPC to the retail channel.

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The 2026 Budget Law has also introduced some changes to the IDF following the extension in 2024 of IDF coverage to drugs with conditional innovation status — demonstrating moderate innovation status under the new criteria published in 2025 — and reserve antibiotics. IDF funding has been reduced by €140 million to a total of €1.16 billion, to free resources for the general pharmaceutical spending ceiling and in light of the consistent underutilization of the fund.

Despite easing inflation and stable energy prices, industry margins remain under pressure due to fixed reimbursed drug prices and high input costs. Generic manufacturers are most vulnerable due to competitive tenders and the limited ability to offset losses. While the 2026 Budget Law's removal of the 1.83% payback offers some relief, the updated EU Urban Wastewater Treatment Directive imposes costly environmental compliance sparking strong opposition.

Regulatory environment

In October 2025, AIFA adopted a new regulation reorganizing the agency into two divisions -administrative and technical-scientific. The new framework, which is part of the recent structural reform of the agency, aims at improving access to treatments, although stakeholders remain skeptical about its effectiveness. While dialogue with industry has improved, limited interaction with the industry, and resource constraints remain a challenge and may hinder AIFA's ability to lead at EU level, particularly as the implementation of the EU HTA is under way.

In December 2025, the Council and the European Parliament reached an agreement on the revised EU pharmaceutical legislation. Initial reactions from the industry have been positive. Innovators welcomed the removal of the original proposal to reduce data exclusivity from eight to six years, while the generics industry supported the 11-year cap on exclusivity and the clarification on patent linkage, which will ease the market entry of generics. The reform package also incentivizes early product launches, and is expected to be formally adopted in late 2026.

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Pharmaceutical business environment

The US most-favored-nation (MFN) pricing policy featured in the executive order 14297 of May 2025 is generating uncertainty among Italian innovators. The policy benchmarks US drug prices against developed nations with low pricing levels like Italy applying the mechanism of international reference pricing and could complicate pricing and reimbursement negotiations in Italy, possibly delaying new launches as companies seek to agree prices with the US first. A scenario where the MFN policy could boost launch prices in Italy is highly unlikely due to budgetary constraints.

The US is Italy's second-largest export market after Germany, accounting for 10.4% of Italian goods' exports in 2024. Pharmaceutical products are one of Italy's key exports to the US, and accounted for 19.3% of the total exports to the US in 2024 (Italian Statistical Office). The industry remains concerned about the potential 15% tariff on patented drugs, although as of March 2026, these are pending the outcome of the Section 232 investigation on pharmaceuticals, while a US Supreme Court ruling has temporarily upheld the validity of further trade tariffs.

Although generic uptake has shown consistent growth over the past five years, it remains limited, and the sector's sustainability is under threat. Margin erosion, rising costs, and supplier concentration with 46% of critical generics supplied by only one or two manufacturers — are heightening the risk of shortages.

While the industry welcomes the removal of the 1.83% payback included in the 2026 Budget Law, it is calling for urgent measures to support the sector.

Unlike the generics market, biosimilar uptake has surged over the past decade, making Italy the largest biosimilar market in Europe — a trend driven by regional prescription quotas and competitive tendering. However, a steady decline in biosimilar margins due to increasingly competitive tendering practices could threaten this success. This downward pressure could intensify as a result of the provision in the 2026 Budget Law mandating an automatic 20% discount on biologics upon patent expiry when there is no biosimilar alternative.

While still dominated by independent outlets, Italy's retail pharmacy market has seen the gradual expansion of chains, with major groups such as Lafarmaciapunto, Benu and Dr. Max leading the segment. Retail pharmacies are also increasingly benefiting from the expansion of the 'services pharmacy' model following the 2025 Simplification Decree, supported by €50 million in annual funding. In addition to publicly funded services, pharmacies are offering a range of non-dispensing services, boosting footfall and driving sales growth.

Italy's OTC market continued to stabilize in 2024, reflecting a gradual normalization following the COVID-19 pandemic. If approved, provisions contained in the draft revision of EU pharmaceutical legislation would reclassify antimicrobials as prescription-only negatively impacting future OTC growth. Italy's 'Sanità Trasparente' public register, expected by March 2026, will increase scrutiny of manufacturers' promotional activities as part of Italy's delayed Sunshine Act. The 2022 law mandates the disclosure of transfers of value to prevent conflicts of interest and corruption.

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About IQVIA Market Prognosis

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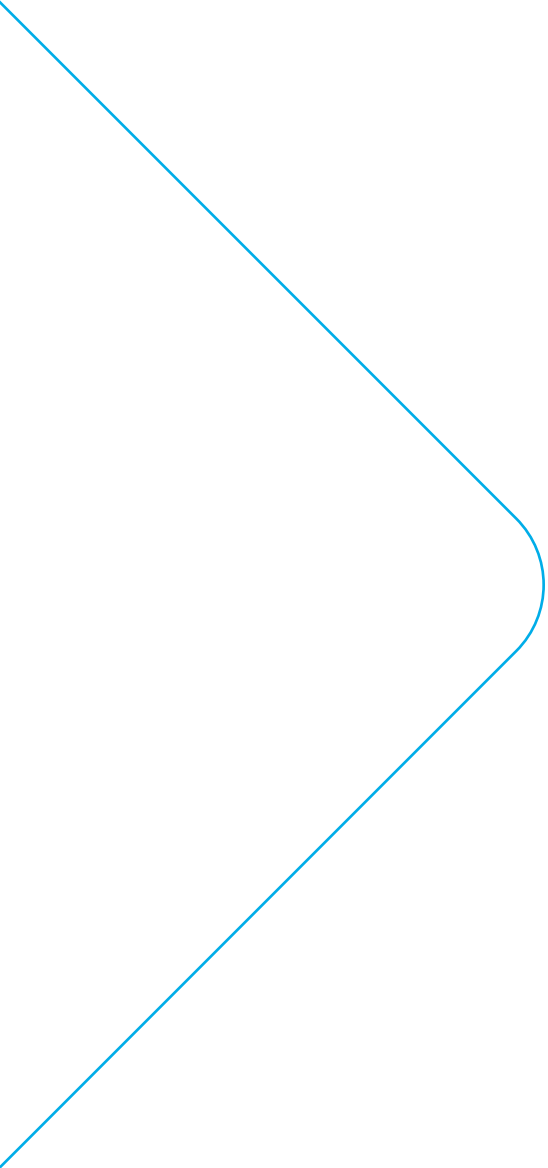


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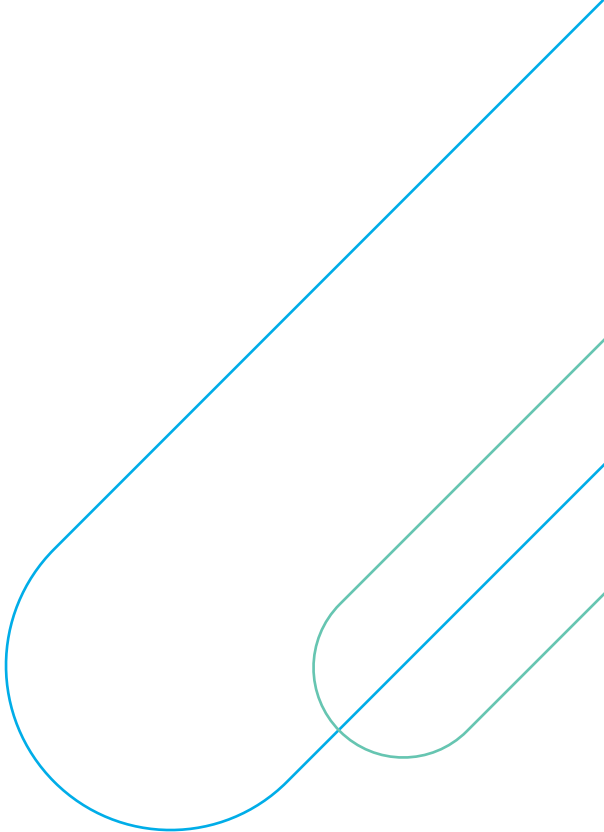
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