HEALTH ECOSYSTEM INSTITUTE

PATENT CLIFFS 2026

When exclusivity is lost but brand value doesn't expire

2026-2030 Update — AIFA/OsMed data, 2026 Budget Law, Farmindustria

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July 2026

ABOUT THIS REPORT

Methodology, classification, and analytical framework

Field	Detail
Date of analysis	July 2026
Outcome type	Competitive Intelligence & Scenario Analysis
Data period	MAT Oct 2022-2025 (sell-in); MAT Q1 2020-2025 (biologics); Regulatory updates through July 2026
Sources analyzed	BHAVE DATA PLATFORM; National pharmaceutical sell-in data; National health observatory reports (OsMed); Regulatory agency communications and determinations; Industry association reports; Sector press and legal databases
Classification	CONFIDENTIAL DOCUMENT — C-Level Distribution

- Analytical framework: BHAVE Framework (5 Lenses: Dual System Theory, JTBD, Gains/Pains, Symbolic Interactionism, COM-B) applied through the GBDS-SSC model (Stimulus–Sign–Context). All data points follow the Descriptive → Predictive → Prescriptive triad. Analysis author: BHAVE TRUST ADVISOR TEAM & Research Collective. Analysis tool: BEATRIX©® BHAVE Behavioural Intelligence Platform.
- Audience: C-Level management, Market Access, Commercial Excellence, Medical Affairs. Purpose: cross-cutting scenario document providing an integrated view of patent cliff dynamics, regulatory governance shifts, and post-LOE brand value retention in the Italian pharmaceutical market 2026–2030. This report does not constitute legal or regulatory advice.

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THE MARKET IN 5 SEGMENTS

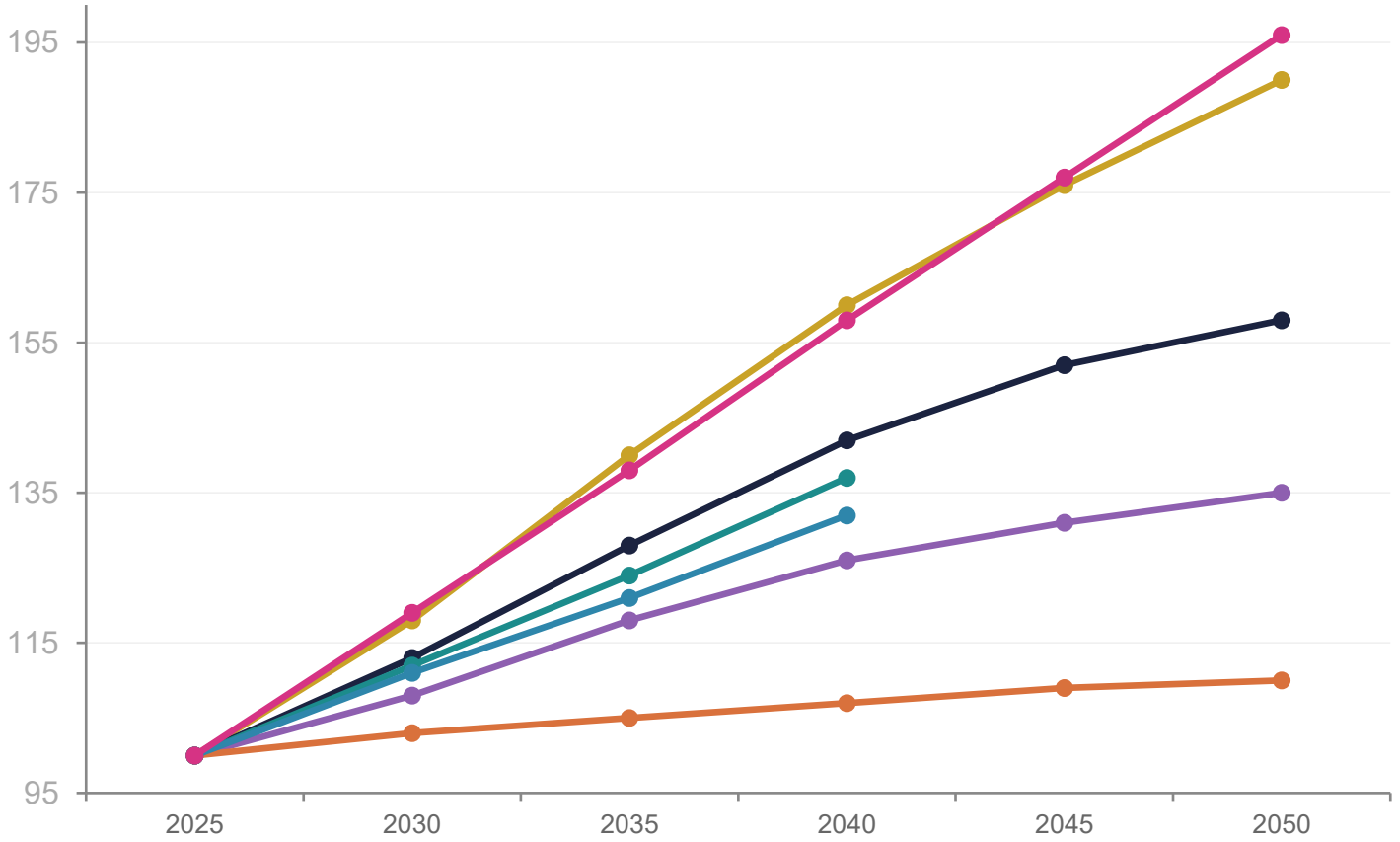
Primary segmentation of the pharmaceutical market

- The Italian pharmaceutical market remains divided into 5 primary segments, based on initial prescriber, prescription requirement, reimbursability, and distribution channel.
- 2026-2033 projection: market estimates converge on a CAGR between 3.6% and 5.4%, with biologics/biosimilars as the fastest-growing component — Hospital and Direct Specialty will continue to absorb the growing share of spending.
- In the most likely system scenario for 2030 (“Ecosistemi Ibridi”, BHAVE Osservatorio Scenario Salute), public and private sectors collaborate structurally and market access shifts from price negotiation to value ecosystem building.
- New cross-cutting element: the Pharmacy of Services, recognized since 2026 as an NHS healthcare facility, redraws the boundary between reimbursed Primary Care and Self-Medication.

Source: AIFA OsMed Report 2024; 2026 Budget Law; BHAVE Group, Italian Pharmaceutical Scenario 2026-2030.

LONGEVITY CLUB — IF WE DON'T INVEST IN PREVENTION IT WILL BE A DISASTER

A wave of diseases is coming



- **Cardiovascular diseases**
  62 mln → ~118 mln **+90%****
- **Dementia / Alzheimer's**
  9,1 mln → 14,3 mln **+58%**
- **Cancer**
  2,7 mln → 3,7 mln/anno* **+38%**
- **COPD**
  36,6 mln → 49,5 mln **+35%**
- **Diabetes**
  65,6 mln → 72,4 mln **+10%**
- **Ophthalmology (AMD)**
  196 mln → 288 mln*** **+47%**
- **Obesity (adults)**
  880 mln → 1.950 mln**** **+122%**

** Cancer: ECIS projection to 2040 (base 2.7M new cases/year EU27). ** Cardio: +90% European projection 2025-2050, not Italy estimate. *** AMD: base 2020, Wong et al. 2014. **** Obesity: base 2022 (NCD-RisC/WHO, Lancet 2024), target 2050 (GBD 2021 Study, Lancet 2025) — two different studies. See notes.*

Source: OECD 2025; Alzheimer Europe 2025; ECIS/AIOM; GOLD/WHO; IDF Diabetess Atlas 2025; Wong et al. 2014 (AMD); NCD-RisC/WHO 2024 and GBD 2021 Study/Lancet 2025 (obesity) — data verification in separate note.

COMPARISON BY DISEASE: WORLD/EU TRENDS VS ITALIAN PROJECTIONS

The wave in Italy

Disease	World / EU (today → projection)	Italy (today → projection)	Italy Source
Cardiovascular diseases	62M → ~118M EU (+90%)	9M (15%) → 15-16M by 2050 (+72%)	P. Perrone Filardi (SIC) / OECD, Mar. 2026
Dementia / Alzheimer's	9.1 → 14.3M EU (+58%)	1.43M (2025) → 2.2M by 2050 (+54%)	Alzheimer Europe / Italian Alzheimer Fed. 2025
Cancer	2.7M new cases/year EU (2020-22 data)	New cases/year stable (~390k, slight decline); prevalence 3.7 → 4M (2030, +8%)	AIOM/AIRTUM 2025; BHAVE Scenario 2026-2030
COPD	36.6 → 49.5M worldwide (+35%)	3.5M (5.6%) today — Italian projection not found (also verified on ISS EpiCentro)	ISTAT 2019 / ISS EpiCentro / Cittadinanzattiva
Asthma	260-300M worldwide (data not consistent across sources)	~3-3.5M (5% adults) today, 300,000 severe asthma; adult prevalence +38% in 2000-2010 decade (last documented trend) — long-term Italian projection not found	Ministry of Health/ISSalute; GINA Italy (Univ. Verona)
Diabetes	65.6 → 72.4M region (+10%)	3.9M (6.6%) → 10% of population by 2040 (+51%)	Italian Barometer Diabetes Report / ISTAT 2024
Ophthalmology (AMD)	196 → 288M worldwide (+47%, base 2020)	~1M today → doubling (~2M) by 2040 (+100%)	ClinicalPractice.it, IT epidemiological data
Obesity (adults)	880M → 1,950M worldwide (+122%)	6M (11.8%) today → 31% adults by 2035 (~15.5M, +163%)	World Obesity Atlas 2023 (WOF); IBDO/ISTAT; ANSA

PURCHASING CENTRALS, TENDERS, AND THE NEW ROLE OF PHARMACIES

The access driver

PURCHASING CENTRALS AND TENDERS

- Fragmented procurement: each Region operates with its own purchasing central (Soresa Campania, AreaCom Abruzzo, Aria Lombardia, Estar Toscana, Intercenter Emilia-Romagna, CUC Sicilia), with non-harmonized platforms and specifications.
- EU directives push toward advanced instruments (competitive dialogue, framework agreements, innovation procurement), but adoption remains uneven across contracting authorities.
- Central tension: many regional tenders favor a single top awardee to maximize immediate discount, at the expense of supplier plurality — a risk flagged by AIFA's 3rd Position Paper and the S.A.V.E. study (Egualia/IBG, June 2026).
- Reference case: the multi-supplier framework agreement of AreaCom Abruzzo (186 firms invited, over €3B ceiling over 4 years, appeals to the administrative court rejected) is cited as a model to extend to other aggregating entities.

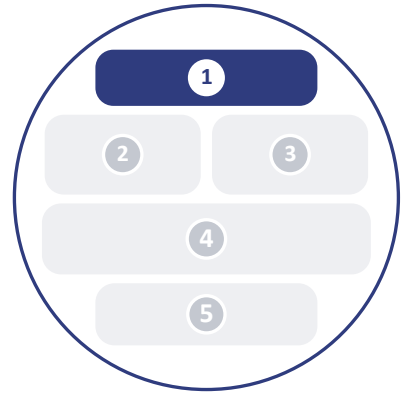
THE NEW ROLE OF PHARMACIES

- The Pharmacy of Services (DM 77/2022) redefines the pharmacy's role from passive dispensing to a proximity healthcare hub: vaccinations, screening, telemedicine, CUP access.
- 2025 funding: €25.3M for the pilot phase, with approximately 14,000 pharmacies (70% of total) already participating; most advanced Regions: Lombardia, Veneto, Emilia-Romagna, Toscana.
- Average investment required per pharmacy: €40,000-100,000 (spaces, diagnostics, digital, training), estimated payback in 3-5 years. Those who don't invest risk revenue and relevance erosion.
- Upstream, intermediate distribution is under structural pressure (margins at 0.3% in 2023): the 2025 Budget Law transferred a +0.65% remuneration to wholesalers, shifting the burden onto the industry.

Source: sector press, June-July 2026; sector journal, July 2026 (biosimilar governance); DM 77/2022; BHAVE Scenario Report 2025-2028.

SEGMENT 1 OF 5

Hospital and Direct Specialty



- Confirmed as the fastest-growing segment: public spending on direct purchases (ASL, RSA, prisons) increasing at double digits.
- Purchasing goes through regional procurement centrals and aggregating entities (Soresa, Aria, Estar, Intercenter, CUC...), with growing demand aggregation across ASLs intensifying lot competition and price pressure.
- Therapeutic drivers: antineoplastics/immunomodulators, advanced/gene therapies, orphan drugs, GLP-1/obesity category in very strong growth.
- Spending cap systematically exceeded: new 2026 instruments — AIFA price renegotiation on pre-LOE biotech drugs, annual Formulary update.

€17.8B
direct purchase spending 2024 (+10%)

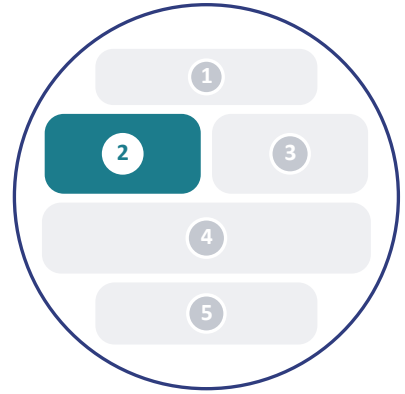
12%
actual incidence 2025 vs 8.3% cap

+€4.7B
2025 cap overshoot

Source: AIFA OsMed Report 2024; Startmag and QuotidianoSanità, Dec. 2025-Jan. 2026; Siciliamedica.it, June 2026.

SEGMENT 2 OF 5

Territorial Specialty



- New competition rules for non-biological generics: multi-supplier framework agreements with more than 3 equivalents; competitive comparison open within 60 days from the first generic on the market.
- Rechanneling of some categories from Direct Distribution to retail (e.g., antidiabetic gliptins and SGLT2), shifting volumes toward this segment.
- 2026-2028 projection: the risk of concentration on a single awardee in regional tenders threatens the sustainability of the generics/biosimilars supply chain — AIFA (3rd Position Paper) and Egualia call for a return to the plurality of framework agreements provided by Law 232/2016.

60 gg

competitive comparison opening from 1st generic

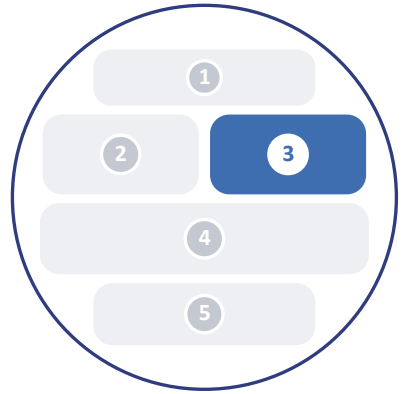
>3

equivalents to activate multi-supplier framework agreement

Source: 2026 Budget Law; Slowpharmacy, January 2026; NCF, July 2026.

SEGMENT 3 OF 5

NHS-Reimbursed Primary Care



- Public territorial pharmaceutical spending: €13.7B in 2024 (+5.1%); 2026 cap at 6.85% of NSF (~€9.79B) — historically met, unlike direct purchases.
- Abolition of the suspension of the 5% ex-factory discount from January 1, 2026: full reduction returns on public prices of affected drugs.
- Regional payback 1.83% abolished for companies from 2026 (burden transferred to other state resources).

€13.7B

public territorial spending 2024 (+5.1%)

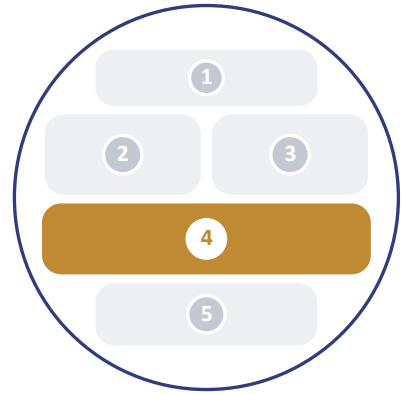
€9.79B

2026 agreed-upon cap (6.85% NSF)

Source: AIFA OsMed Report 2024; AIFA, communication 31/12/2025.

SEGMENT 4 OF 5

Private-Expenditure Primary Care



- Class C drug spending in 2024: over €7B (-1.96% vs 2023), of which 52% prescription-required and 48% self-medication — slight trade-down vs 2023 (54%/46%).
- Total private spending (co-payment + class C + private purchase of class A): €10.2B in 2024, down 2% after years of sustained growth 2019-2023.
- First trend reversal after a five-year growth period: a signal to monitor for pricing strategies on mature brands.

€7B

class C spending 2024 (-1.96%)

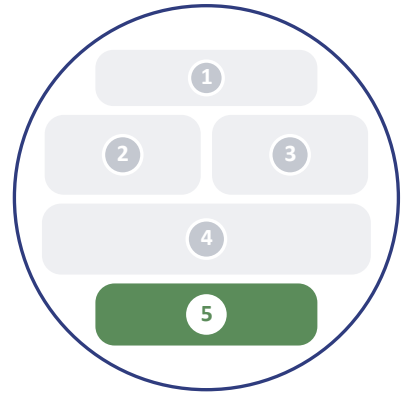
€10.2B

total private spending 2024 (-2%)

Source: AIFA OsMed Report 2024.

SEGMENT 5 OF 5

Self-Medication and the New Role of the Pharmacy



- Pharmacy revenue 2024 (€26.6B, +2.2%) splits between ethical drugs (~60%, €16B, stable growth +1.8%) and commercial sector OTC/supplements/dermocosmetics (~40%, €10.6B, +3.8% in value).
- The Pharmacy of Services (DM 77/2022) shifts the model from transactional selling to ongoing care relationships: from shop to health hub, with multidisciplinary teams (pharmacists, nurses, technicians).
- Investment required for the transition: €40,000-100,000 per pharmacy, payback 3-5 years — pharmacies that don't invest risk losing relevance in the territorial healthcare system.

€26.6B

pharmacy revenue 2024 (+2.2%)

14.000

pharmacies participating in Pharmacy of Services (70%)

40-100k €

average investment per pharmacy

Source: REPORT_SCENARIO_2025-2028_ (BHAVE); DM 77/2022; Federfarma, January 2026.

METHODOLOGY AND 2026-2033 PROJECTION

Forecasts and spending caps 2026

- The forecasting model considers: GDP trends, public cap constraints, patent expirations and biosimilar entry, private spending responsiveness, 2026 Budget Law measures.
- Overall NHS cap: from 15.3% to 15.55-15.65% of the National Health Fund — the highest increase ever recorded, yet estimated insufficient to cover the structural overshoot on direct purchases.
- 2026-2033 projection: expected CAGR between 3.6% and 5.4%, with the market progressively shifting from high-volume/low-cost drugs toward specialty care, biologics, and advanced therapies (ATMP).

€22.37B

overall NHS cap 2026 (+7.13%)

€12.29B

direct purchases cap (8.6% NSF)

€9.79B

agreed-upon cap (6.85% NSF)

Source: 2026 Budget Law; QuotidianoSanità, January 2026; BHAVE Group, Italian Pharmaceutical Scenario 2026-2030.

AIFA 2026 GOVERNANCE: THREE CONVERGING LEVERS ON PRICES

The new pricing and formulary framework

ALREADY IN FORCE (2026)

- 5% ex-factory price cut reinstated (AIFA Det. 1/2026, effective Jan 1, 2026): the option for pharma companies to suspend the reduction has been abolished. All NHS-reimbursed drugs are affected, generating immediate savings for the SSN.
- Biotech pre-LOE renegotiation (Art. 78, Budget Law 2026): when no biosimilar procedure is underway at patent expiry, AIFA can either renegotiate or apply an automatic 20% discount on the originator's reimbursement price.
- TAR Lazio ruling (Feb 2026): the 0.65% margin transfer to wholesalers does NOT apply to generics — AIFA's circular extending it to equivalents was annulled, limiting the extra-margin to branded products only (~€20M/year impact).
- Regional payback 1.83% abolished for companies from 2026, burden transferred to state resources (€166M/year). Competitive comparison open within 60 days from first generic entry.

UNDER DEVELOPMENT (deadline: Nov 30, 2026)

- Annual Formulary Revision (Art. 1, cc. 376-380, Budget Law 2026): AIFA must revise the National Formulary annually by Nov 30. Criteria: clinical efficacy, safety, cost-benefit, access. AIFA can include, reclassify, or exclude drugs and renegotiate prices.
- Therapeutic cluster pricing (Il Sole 24 Ore, Jun 16, 2026): AIFA is working on setting reimbursement prices not by individual active ingredient, but across broader therapeutic groups. First targets: statins, sartans, PPIs. Estimated savings up to €1B.
- Political uncertainty: AIFA has written to Minister Schillaci requesting political and legal endorsement. The Ministry has asked for more robust scientific-technical documentation. The dossier is described as a methodological framework, not yet a fully supported proposal.
- The paradox flagged by Il Sole 24 Ore: the revision targets agreed-upon spending (in surplus, +€459M in 2025), not direct purchases (structurally overshooting by €4.7B). The measure compresses a segment that works within its cap.

Source: AIFA Det. 1/2026; Budget Law 2026 (L. 199/2025, Art. 1 cc. 365, 376-380, Art. 78); TAR Lazio Feb 2026; Il Sole 24 Ore, Jun 16, 2026; QuotidianoSanità, Jun 2026; BHAVE Scenario 2026-2030.

SCENARIO IMPACT — HOW THE NEW AIFA GOVERNANCE CHANGES THE POST-LOE GAME

Accelerated erosion, compressed margins, and the cluster pricing risk

IMPACT ASSESSMENT

- **SMALL MOLECULES** - Therapeutic cluster pricing could compress brand value retention further. If reimbursement is set at the cheapest active ingredient in a therapeutic group (e.g., the cheapest statin, not the cheapest rosuvastatin generic), the co-pay gap for the patient widens dramatically. Brands retaining 20-60% of value post-LOE (as shown in the 2025 basket) face accelerated erosion because the out-of-pocket cost for staying on the originator increases beyond current levels.
- **BIOSIMILARS** - The automatic 20% price cut on pre-LOE biotechs introduces “pre-erosion”: the originator’s price drops BEFORE patent expiry, reducing the starting gap that biosimilars exploit at launch. For molecules like Eylea (biosimilars expected 2025-26), this means the competitive field is already compressed at Day 1. Combined with tender-driven hospital channels, the window for originator defense shrinks from 12-24 months to potentially under 12.
- **THE STRUCTURAL PARADOX** - All three levers target the agreed-upon spending segment (territorial/pharmacy), which is in surplus (+€459M in 2025). The real overshoot sits in direct purchases (€4.7B over cap). This asymmetry creates a scenario where generics manufacturers face margin compression on a functioning market, potentially reducing supply chain resilience — the very risk AIFA’s 3rd Position Paper and the S.A.V.E. study (Egualia/IBG, Jun 2026) have warned about.
- **GEOPOLITICAL OVERLAY** - The US Most Favored Nation policy has coincided with a 40% decline in new drug launches in Europe. In this context, additional price pressure on the Italian market risks accelerating the already slow access timelines (~400 days from EMA approval) and could discourage investment in biosimilar development programs — over 75% of biologics expiring by 2032 may face no biosimilar competition.
- **NET SCENARIO** - The convergence of 5% cut + cluster pricing + 20% biotech pre-LOE discount + MFN geopolitical drag creates a price compression vortex with no historical precedent in the Italian market. Brand defense strategies must now factor in not just LOE timing and co-pay dynamics, but also the regulatory pricing trajectory set by AIFA’s annual Formulary revision cycle (first deadline: Nov 30, 2026, effective Jan 1, 2027).

Source: BHAVE analysis on AIFA governance measures 2026; Il Sole 24 Ore, Jun 16, 2026; QuotidianoSanità, Jun 2026; Pharmaretail, Jun 2026; TAR Lazio, Feb 2026; Egualia/IBG S.A.V.E. study, Jun 2026; BHAVE Scenario 2026-2030.

TREND BY SECTOR

2025 pre-final accounts of pharmaceutical spending

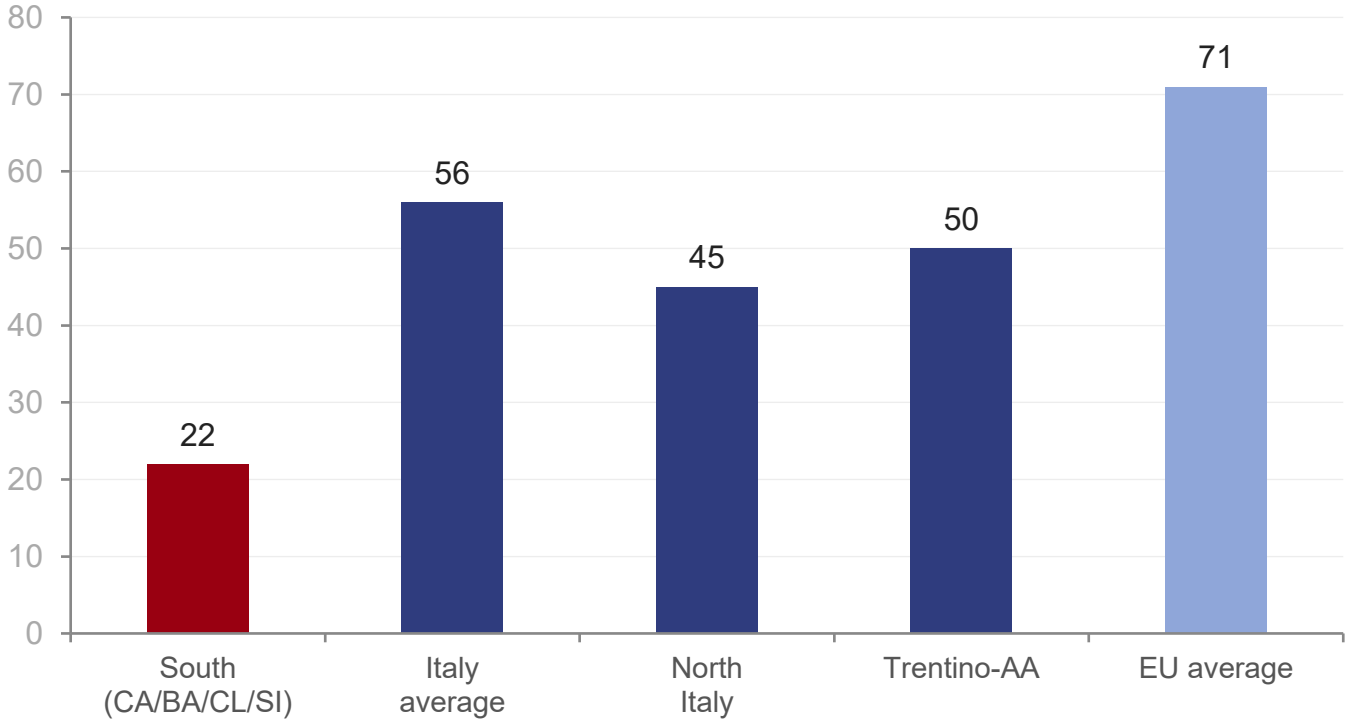
Sector (€B)	2023	2024	Δ 24/23	2025 pre-final*	Δ 25/24*
GRAND TOTAL	36,2	37,2	+2,8%	~39,5	+6/7%
NHS public spending	24,9	26,8	+7,7%	~29,0	+~8%
of which direct purchases	16,2	17,8	+10,0%	~19,5	+~10%
of which public territorial	13,0	13,7	+5,1%	~14,3	+4/5%
Private spending (citizen)	10,6	10,2	-2,0%	~10,3	stable

** 2025: pre-final/projection built on AIFA statements January-October 2025 (growth pace 6-7%/year) — not yet final data.*

Source: AIFA OsMed Report 2024 (Nov. 2025) for 2023-2024; Startmag, December 2025 for 2025 projection.

NORTH-SOUTH AND EUROPEAN GAP

The role of generic drugs in spending control

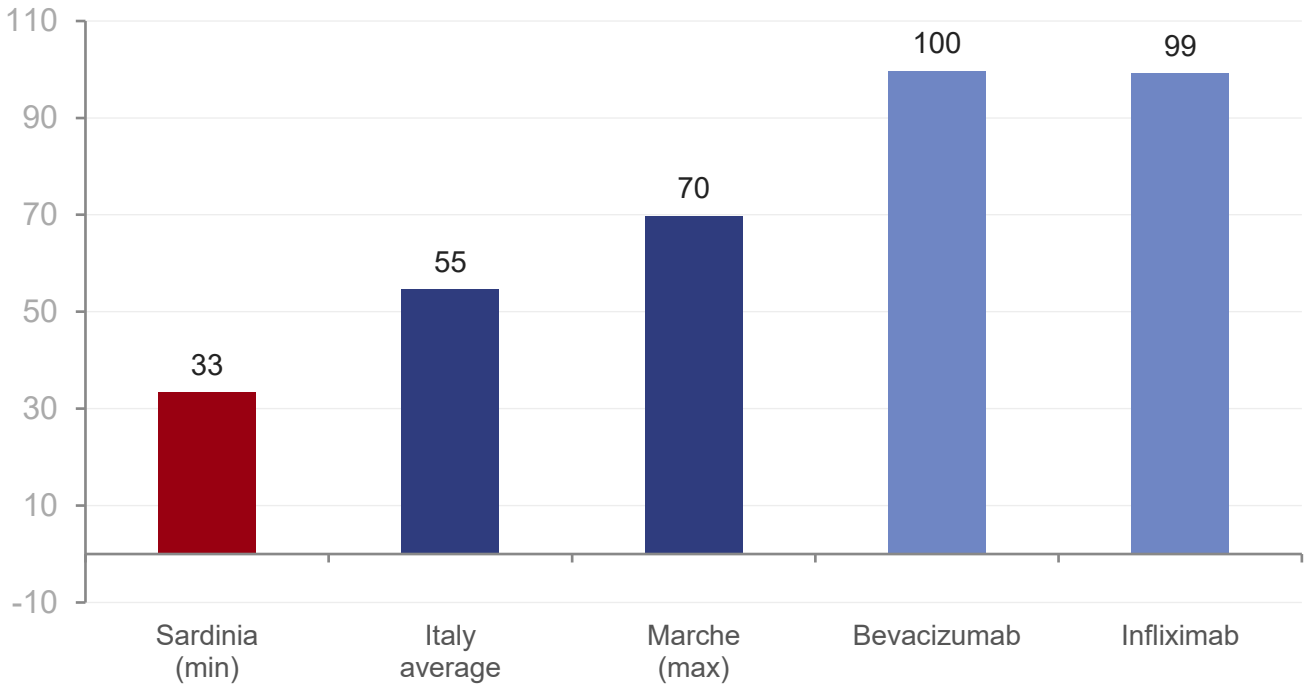


- Italy remains among the lowest in the EU for generic penetration in community care: 56% vs a European average of 71%.
- The North-South gap persists: North ~45% (peaks of 50% in Trentino-Alto Adige) vs ~22% in Campania, Basilicata, Calabria, and Sicily.
- Counterweight: Italy is the EU leader for biosimilars in hospital (1st place for spending 59.8% and consumption 72.2%). The gap is therefore mainly in territorial/pharmacy care.

Note: the two metrics (national share 56% and regional North/South data) come from slightly different calculation bases in the original source — to be harmonized with OsMed Interactive extraction for precise comparison.

Source: AIFA OsMed Report 2024; Ilpunto.it, February 2025 (OsMed 2023 data).

Biosimilars: the new competitive landscape



- In 2025, biosimilars reached 54.5% of the reference market (21 molecules monitored), surpassing originators (45.5%) for the first time — up from 51.2% in 2024.
- 9 molecules have passed 80% substitution by volume: Bevacizumab at 99.6%, Infliximab at 99.1%.
- Regional penetration remains heterogeneous: from 69.7% in Marche to 33.3% in Sardinia — a 36-point gap linked more to regional policies than epidemiological differences. Only Abruzzo and Emilia-Romagna have not yet adopted resolutions favoring lower-cost biologics.
- Structural risk to monitor: over 75% of biologics with patents expiring by 2032 may face no biosimilar competition, due to a lack of clinical development programs — a consequence of regional tenders oriented toward maximum discount/single awardee.

Source: Egualia — Research Center, Biosimilars Report 2025 (Italian Biosimilars Group), via BHAVE, Italian Pharmaceutical Scenario 2026-2030; sector journal, July 2026.

SCENARIO "ECOSISTEMI IBRIDI" (BHAVE)

Pharmaceutical spending forecast 2026-2028

Item	2025*	2026	Note
Overall NHS cap	€20.88B	€22.37B	+7.13% — highest increase ever recorded
Direct purchases cap	€11.33B	€12.29B	8.6% of NSF; expected overshoot ~€4.4B
Agreed-upon cap	€9.28B	€9.79B	6.85% of NSF; historically met
Total NSF	€136.5B	€142.9B	+4,7%
Italian pharmaceutical market	$37.7-40.6B	toward $48-53B in 2030-31	CAGR 3.6-5.4% 2026-2033 (source range)

- ✦ 2026-2030 projection: in the "Hybrid Ecosystems" scenario (the most likely according to the BHAVE Health Scenario Observatory), market access shifts from point-of-sale price negotiation to value ecosystem building — real-world data, digital services, evidence of care burden reduction.
- ✦ Geopolitical risk to monitor: the US Most Favored Nation policy coincided with -40% in new drug launches in Europe in the 10 months following its announcement; Italian access timelines ~400 days from EMA approval.

Source: BHAVE Group, Italian Pharmaceutical Scenario 2026-2030;

PROSPECTIVE IMPACT — EFFECTIVE JULY 9, 2026

The respiratory system: the new Note 99

REGULATORY REFORM

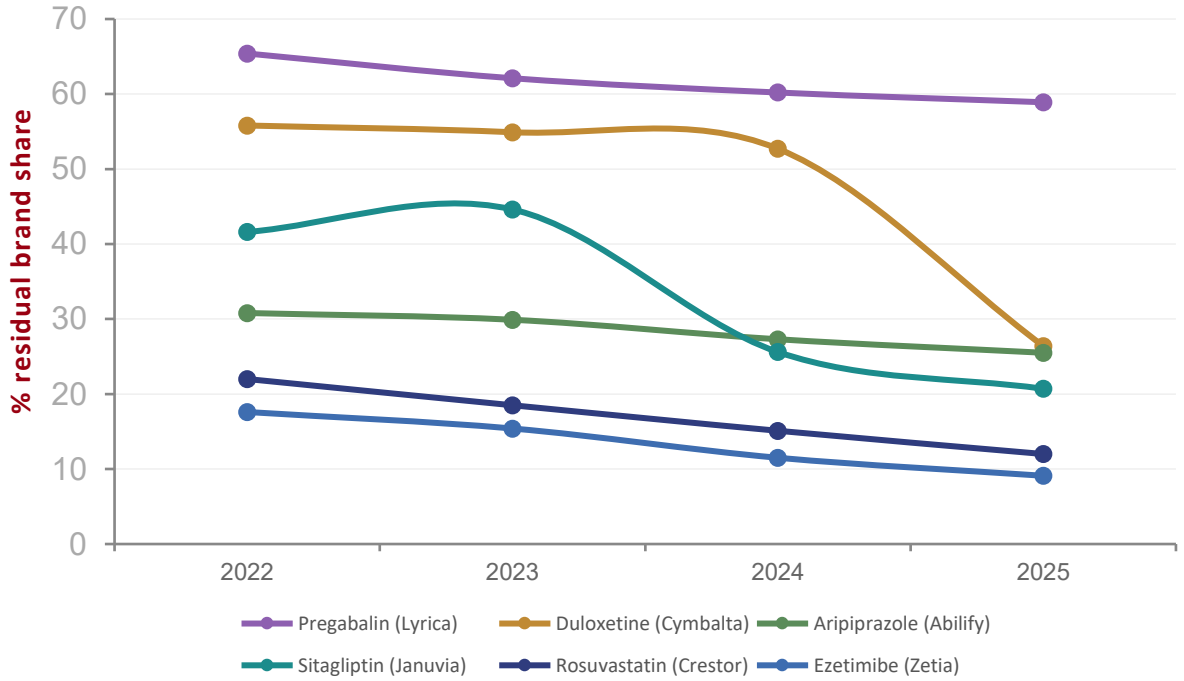
- With AIFA determination no. 822/2026, effective July 9, 2026, Note 99 is updated incorporating GOLD guidelines and abolishes the Specialist Evaluation and Prescription Form for triple inhaled combinations LABA+LAMA+ICS, with reclassification of the supply regime from RRL to RR.
- Expected impact: triple therapy prescription — previously the domain of pulmonologist/internist specialists via Therapeutic Plan — opens to General Practice, strengthening territorial COPD management.
- AIFA will monitor spending and consumption at 6 and 12 months from implementation; in case of significant deviations, it reserves the right to reopen price renegotiation for affected medicines.
- 2026-2028 projection (indicative): expected volume shift from the specialist channel toward Primary Care, with possible consumption acceleration (adherence currently only 22-33%) but also risk of lower diagnostic appropriateness without adequate access to second-level spirometry.
- The real competitive landscape remains severe asthma/COPD with eosinophilia: anti IL-5, IL-4/13, TSLP, and IgE biologics compete on reducing exacerbations and resource consumption — a segment untouched by Note 99, which concerns only COPD.

Source: AIFA, determination no. 822/2026 and Note 39/74/97/99 communication (Jun-Jul 2026); SIMG, July 2026; BHAVE, Italian Pharmaceutical Scenario 2026-2030, par. 4.4.

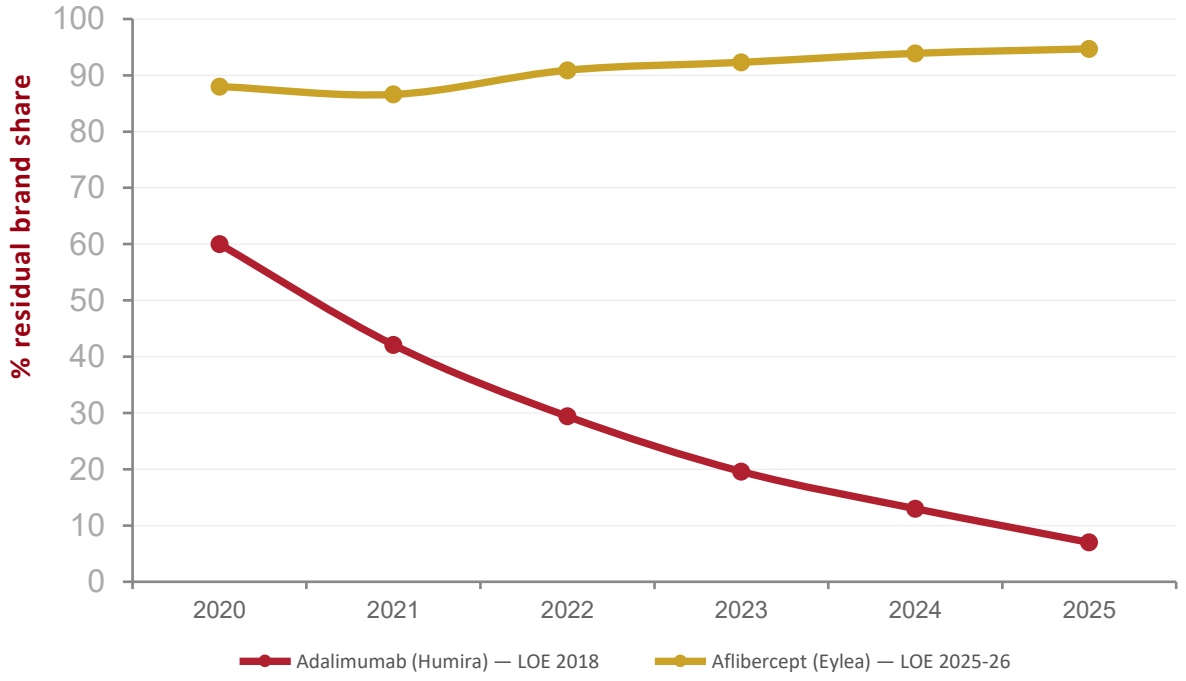
2025 UPDATE — RESIDUAL VALUE SHARE OF ORIGINATOR BRAND POST-LOE

Why do genericized brands still make sense in Italy?

SMALL MOLECULES (generics)



BIOLOGICS (biosimilars)



Reading: Small molecules erode slowly and heterogeneously — the brand can retain 20-60% of value even years after LOE (prescriber loyalty, contained co-pay). **Biosimilars** erode the originator much faster where the channel is hospital and tender-based: Humira from 60% to 7% in 5 years. Eylea is not yet in LOE (biosimilars expected 2025-26): it is the next big ophthalmology wave.

Source: BHAVE analysis on Italian sell-in data (MAT Oct 2022-2025, EUR MNF with discount) for small molecules; pan-European sales database, Italy (MAT Q1 2020-2025, EUR MNF) for biologics.

A REAL CASE BY THERAPEUTIC AREA — ITALIAN MARKET 2025

Pricing & timing remain key factors — but at two speeds

Area · Molecule (brand)	Type	Market 2025	Brand share residual 2025	Erosion dynamics
Cardio-Metab. · Ezetimibe (Zetia)	Small mol.	€322M	**9.1%**	Slow and deep erosion: brand nearly zeroed out, but over 5+ years
Cardio-Metab. · Rosuvastatin (Crestor)	Small mol.	€207M	**12.0%**	Mature genericization, stable residual brand ~12%
Metabolic · Sitagliptin (Januvia)	Small mol.	€38M	**20.7%**	Recent LOE (2022-23): drop 42%→21% in 2 years
CNS · Duloxetine (Cymbalta)	Small mol.	€29M	**26.4%**	Late erosion: stable until 2024, then -50% in 2025
Respiratory · Fluticasone comb. (Seretide)	Small mol.	€132M	**11.7%**	Inhalers: slower erosion (device+adherence provide protection)
Immunology · Adalimumab (Humira)	Biosimilar	€481M	**7.0%**	Rapid and vertical erosion: 60%→7% in 5 years (tender)
Ophthalmology · Aflibercept (Eylea)	Biosimilar	€163M	**94.7%**	Pre-LOE: biosimilars expected 2025-26 — future wave

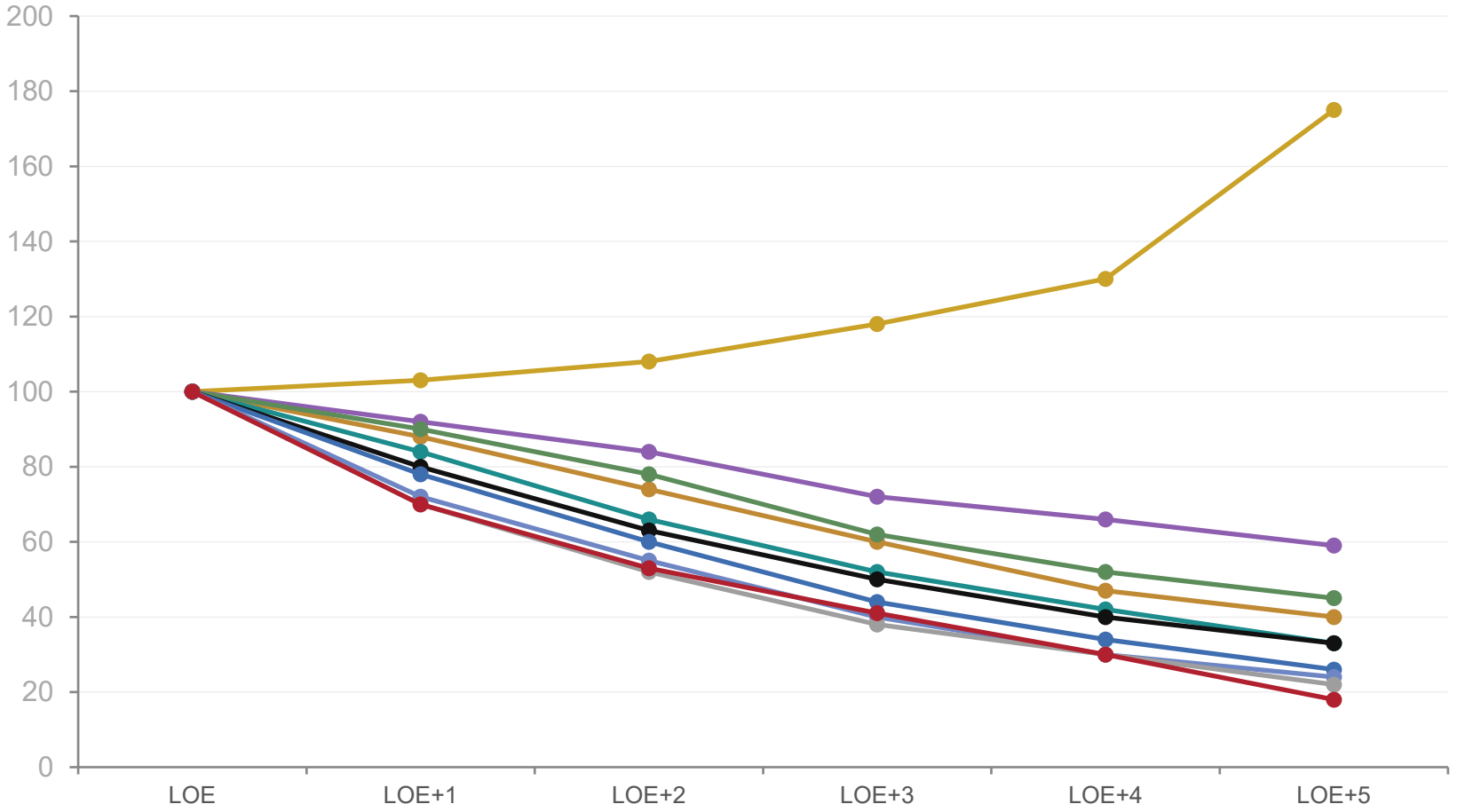
Opportunity (small molecules): the first 6-12 months post-LOE and the price differential (co-pay) remain the key predictors of value defense. **Risk (biosimilars):** where the channel is hospital and tender-based the window closes in 12-24 months — the defense strategy must be set before LOE, not after.

Source: BHAVE analysis on sales data. "Residual brand share" = MNF value of the originator brand over the total molecule.

BRAND VALUE RETENTION POST-LOE — 2025 BASKET (SMALL MOLECULES + BIOSIMILARS)

Why genericized brands still make sense in Italy

Brand value retention (%)



Brand value retention
5 years post-LOE (%)

Eylea (aflibercept)*	pre-LOE
Lyrica (pregabalin)	59%
Abilify (aripiprazolo)	45%
Cymbalta (duloxetina)	40%
Italy Median	33%
Januvia (sitagliptin)	33%
Crestor (rosuvastatina)	26%
Seretide (fluticasone)	24%
Zetia (ezetimibe)	22%
Humira (adalimumab)**	18%

* *Eylea not yet in LOE (biosimilars expected 2025-26).*
** *Humira: biologic in hospital/tender channel — much faster erosion than small molecules.*

Source: BHAVE analysis on sales data. Small molecule curves anchored to 100 at LOE; biosimilars indexed on originator brand value.

POST-LOE ITALIAN MARKET SUMMARY — 2025 UPDATE

Pricing & timing remain key success factors, but…

LOE SUMMARY — 2025 BASKET Italian market · multi-therapeutic area	Pre-LoE	LoE+1	LoE+2	LoE+3	LoE+4	LoE+5
BRAND SHARE RETENTION **(small molecules, basket average)**	100%	82%	69%	58%	48%	38%
BRAND PRICE EROSION **(brand list price, actual sell-in)**	n.s.	~0%	-1%	-1%	-1%	-2%
BRAND-Gx PRICE DIFFERENCE **(co-pay)**	0%	-24%	-19%	-22%	-27%	-33%
BIOSIMILAR — BRAND RETENTION **(e.g. Humira, tender channel)**	100%	**70%**	**53%**	**41%**	**30%**	**18%**
BIOSIMILAR — LUCENTIS (ranibizumab) **(ophthalmology, biosimilars since 2022)**	100%	~90%	~78%	~62%	**~50%**	n.a.*

Opportunity — two speeds. The brand **defends its list price** (brand price nearly flat, ~−1%/year in real terms): it cedes share, not price. The game is played on **volume e timing** in the first 6-12 months. **Biosimilars:** where the channel is hospital and tender-based, share drops much faster (Humira 18% at 5 years); Lucentis eroded more slowly (biosimilars only since 2022).

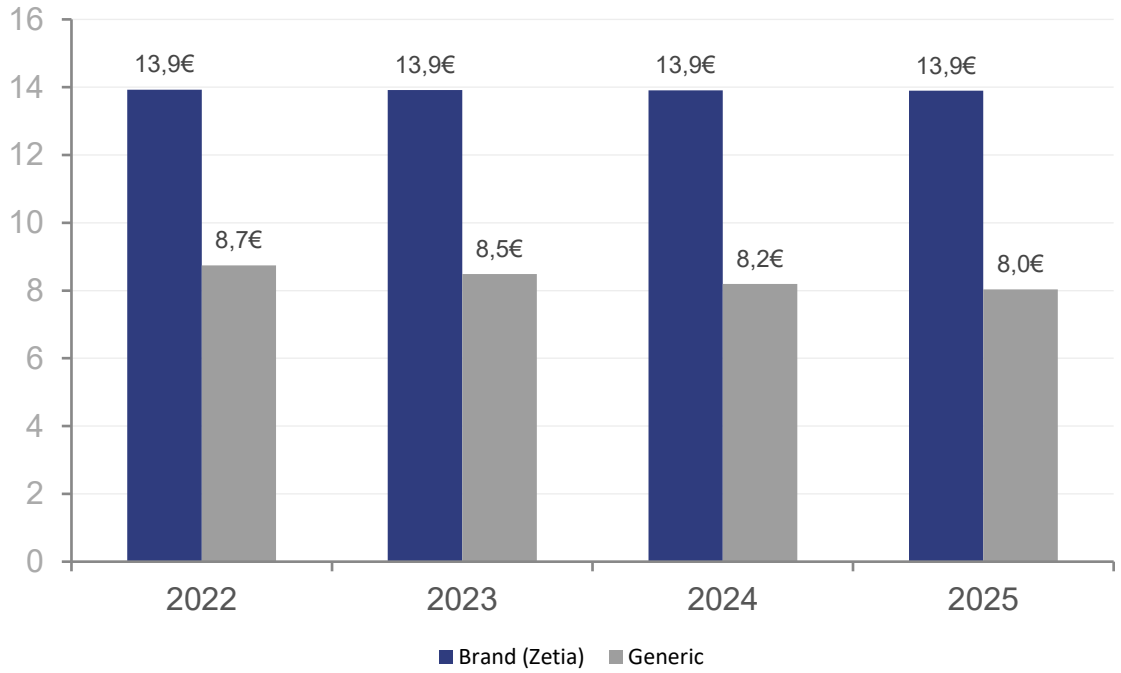
Source: BHAVE analysis on sales data. Brand price erosion recalculated on actual data (average brand price ≈ −0.5%/year), not on the historical S. Remiddi 2004-2011 analysis (−31% at LoE+1). Biosimilar row = adalimumab (Humira); Lucentis = ranibizumab (pan-European sales database).

ACTUAL AVERAGE PRICE (€/UNIT) CALCULATED FROM DATA — ITALY 2020-2025

Does genericization really lower the brand price?

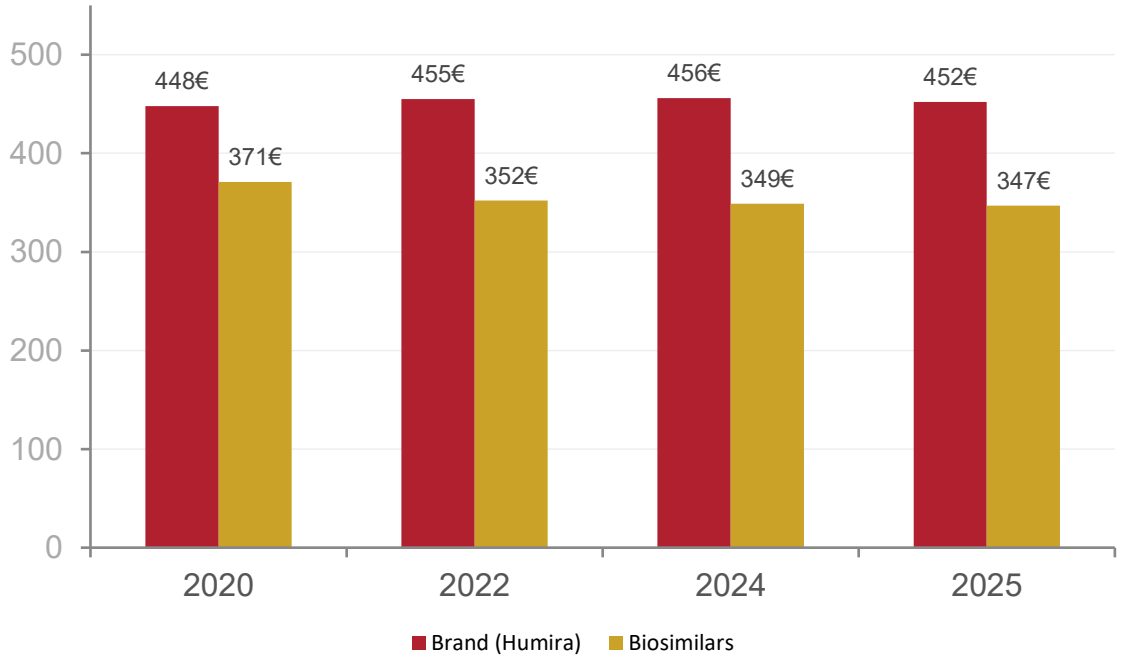
The counterintuitive finding: the originator brand barely lowers its list price. It defends price and cedes volume. It is the **generic/biosimilar** that enters at a lower price and shifts spending.

SMALL MOLECULE — Ezetimibe (Zetia)



Brand flat at ~€14 (–1% in 4 years). The generic enters at ~€8 and keeps falling: gap –42% in 2025.

BIOSIMILAR — Adalimumab (Humira)



Brand flat at ~€450 (+1% in 5 years). Biosimilars enter at ~€350: gap –23%. Erodes volume, not list price.

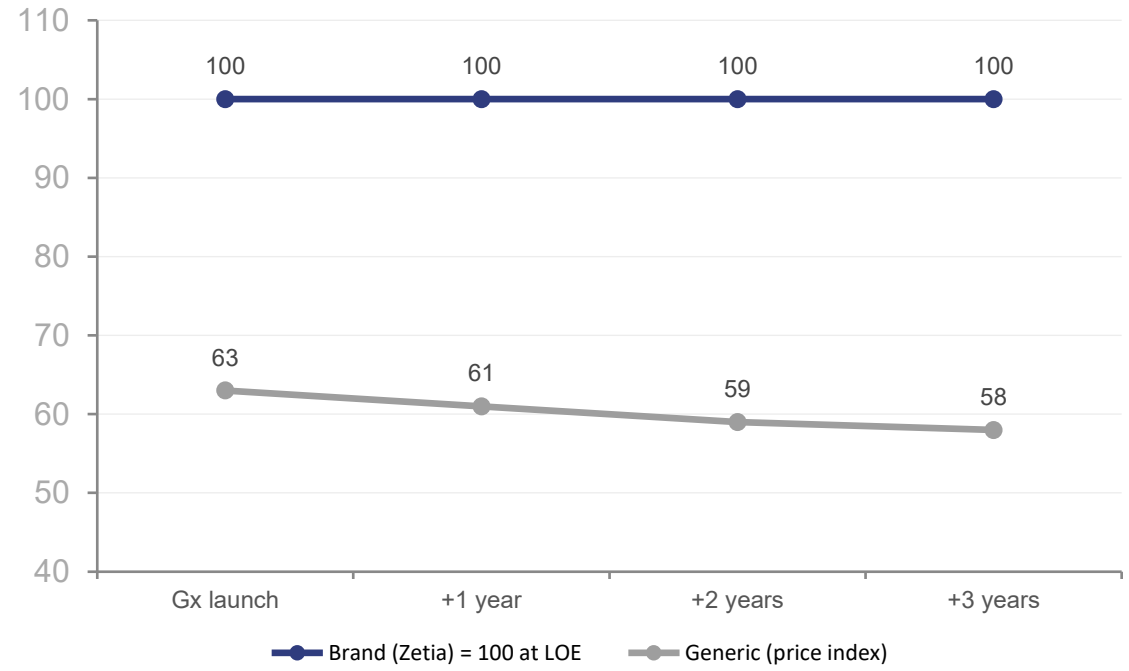
Source: BHAVE analysis: average price = MNF value / unit. Small molecules from Italy sales data (EUR MNF with discount / UN, MAT Oct); adalimumab Italy (EUR MNF / Units, MAT Q1). Average prices at dosage/package mix.

INITIAL DISCOUNT VS BRAND AND DECLINE UP TO +5 YEARS — ITALY (ACTUAL DATA)

What about the generic price? How does it fall after launch

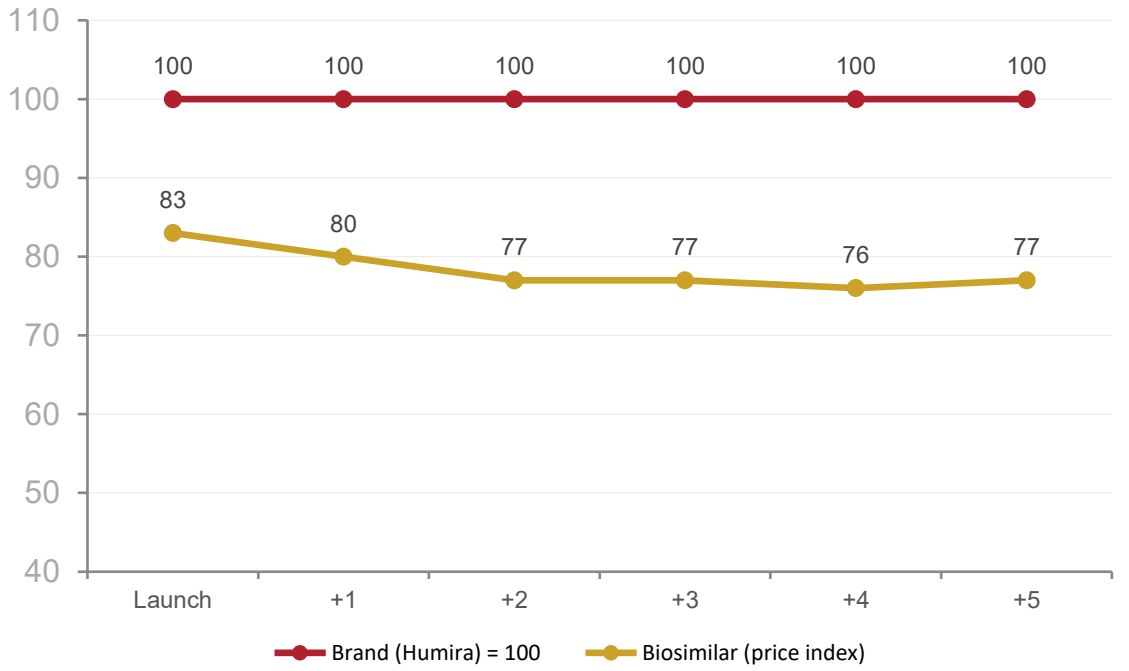
The pattern: the generic/biosimilar enters already discounted (−30/45% small molecules, −17% biosimilars) and then **continues to fall slowly** by a further ~5-8% over 5 years. The bulk of the discount is immediate, not progressive.

GENERIC — Ezetimibe (Zetia)



Enters at −37% (index 63) and drops to **−42%** in 3 years. Discount almost entirely at launch.

BIOSIMILAR — Adalimumab (Humira)



Enters at −17% (index 83), drops to **−23%** in 5 years. Smaller initial discount, but share eroded via tender.

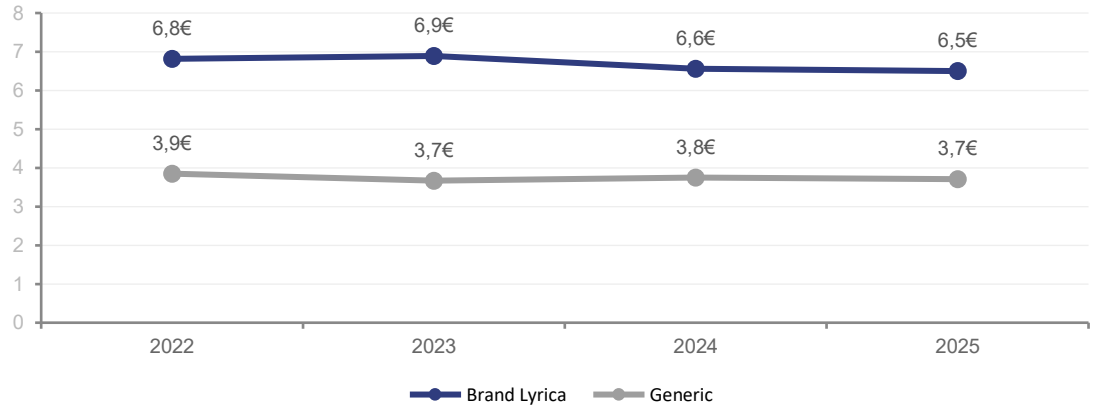
Source: BHAVE analysis: price index = average price (MNF value / unit) of generic/biosimilar relative to pre-genericization brand price (=100). Ezetimibe Italy (MAT Oct 2022-2025); adalimumab Italy (MAT Q1 2020-2025). Average prices at dosage/package mix.

PREGABALIN, ADALIMUMAB BIOSIMILARS (BRAND VS ACTIVE INGREDIENT) AND LUCENTIS — ITALY

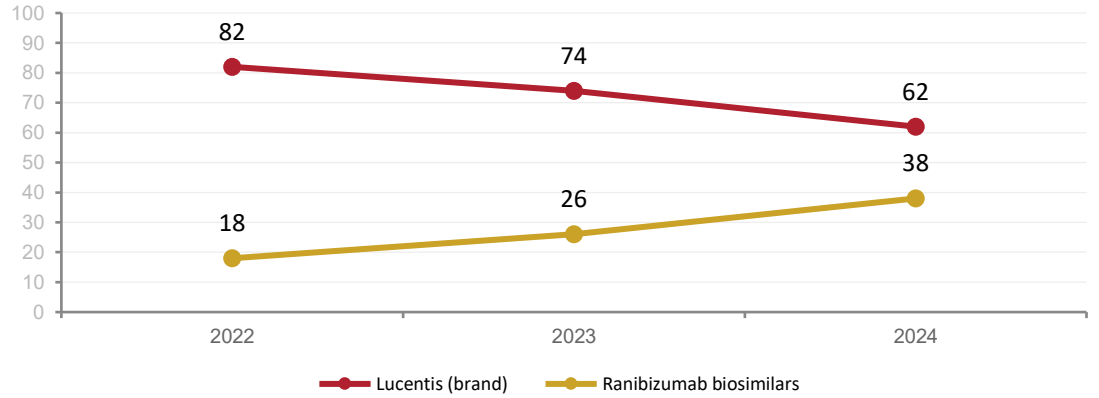
Generic and biosimilars: four price trajectories compared

In Italy the biosimilar competes as a brand, not as a commodity: almost all biosimilars carry a brand name (Amgevita, Imraldi, Ximluci…). Selling under the active ingredient alone (INN) remains marginal.

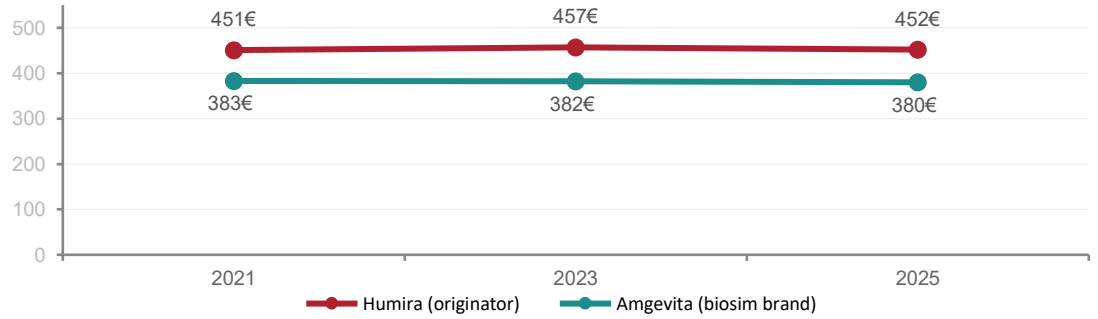
GENERIC — Pregabalin (Lyrica), €/unit



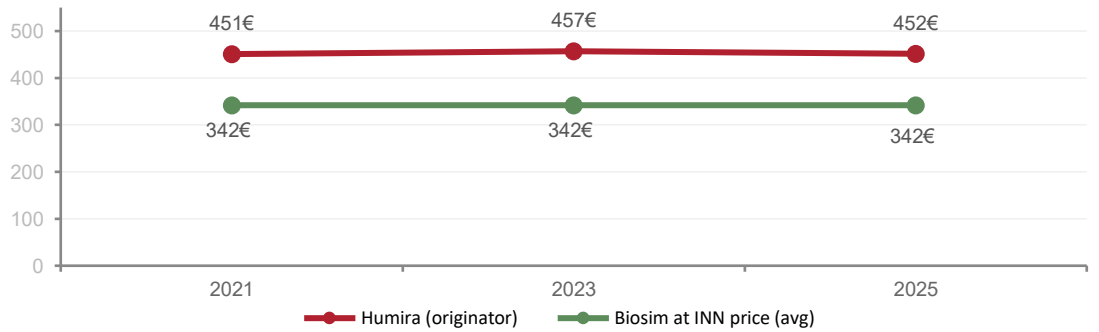
BIOSIMILAR — Lucentis (ranibizumab), share %



BIOSIMILAR 'BRAND' — Amgevita, €/pack



BIOSIMILAR 'ACTIVE INGREDIENT' — €/pack

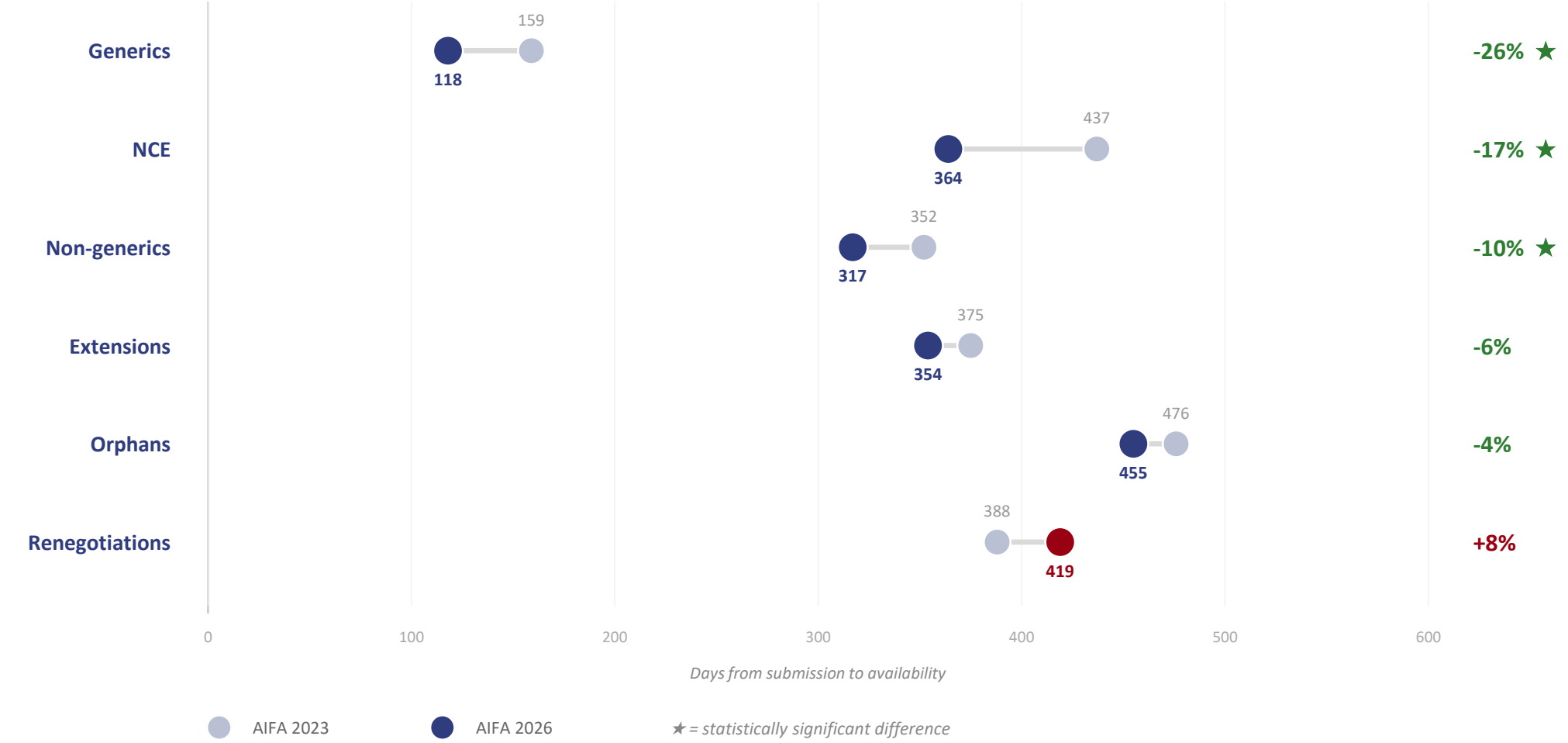


Reading: Pregabalin generic enters at −44% and stays there. Lucentis: brand share yields to biosimilars (62% in 2024). Among adalimumab biosimilars, those positioning 'as a brand' (Amgevita, −16% vs originator) hold a higher price than those competing 'as active ingredient' (Imraldi/Idacio/Hyrimoz, aligned at −24%).

Source: BHAVE analysis: Pregabalin and adalimumab from sell-in data (price = MNF value/unit). Lucentis: volume share from pan-European sales (Standard Units; € prices not available in the file). 'Brand' vs 'active ingredient' = biosimilar naming strategy.

P&R PROCEDURE TIMELINES COMPARED: AIFA 2023 VS 2026 (POST-REFORM)

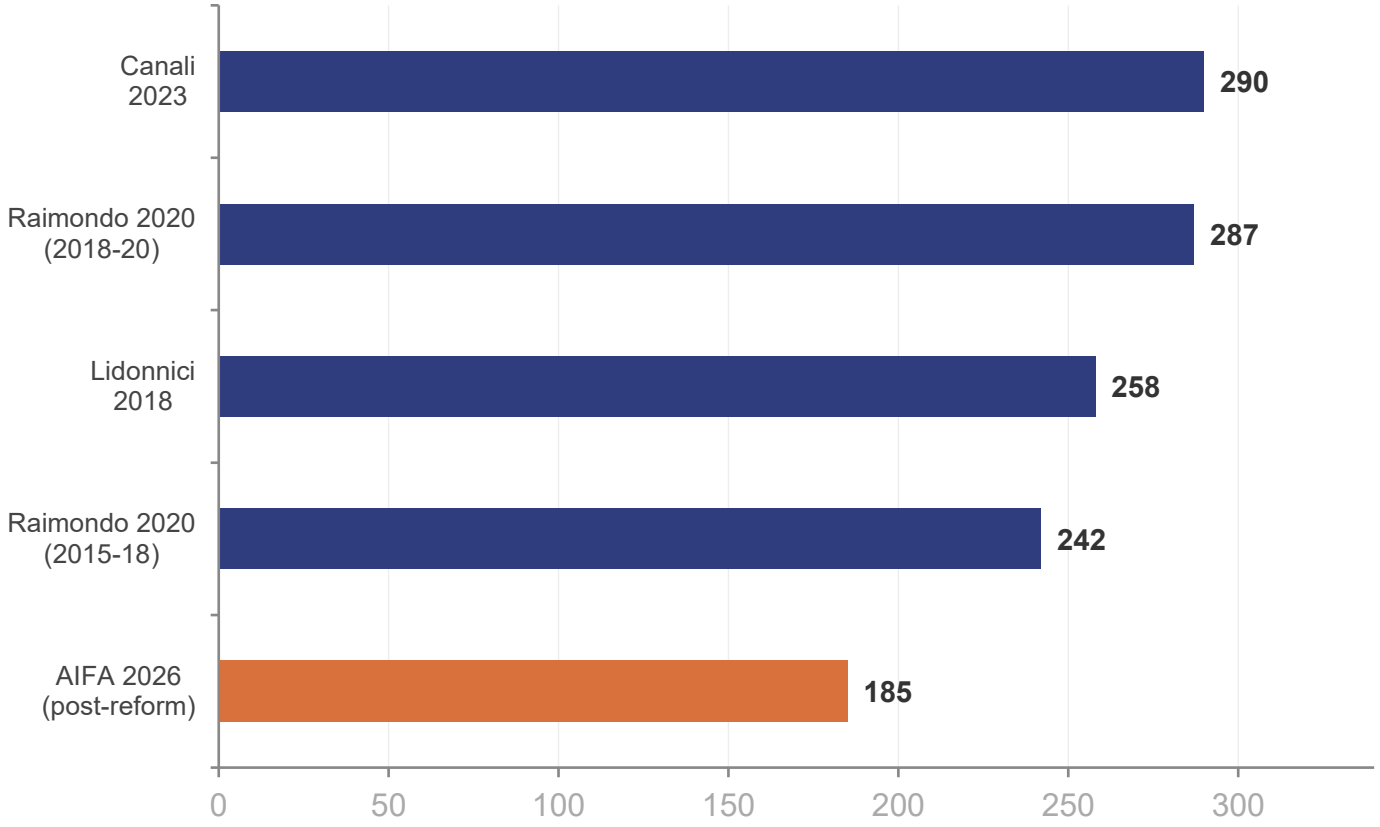
How long from submission to availability to the Regions?



Source: A. Marcellusi, ISPOR Italy-Rome Chapter / DiSFarM (2026): analysis of AIFA 2023 and 2026 reports, full application→regional-availability pathway. Robust reduction for generics/NCE/non-generics; none for renegotiations (+8%).

2026 POST-REFORM TIMELINES COMPARED WITH PUBLISHED PRE-REFORM STUDIES

The AIFA reform has accelerated access



185 days

AIFA 2026 post-reform

vs 242-290 days in pre-reform studies — a 24-36% reduction in assessment and publication time.

Probability that AIFA 2026 is faster

100% on the average system time

72% on the individual drug

Source: A. Marcellusi, ISPOR Italy-Rome Chapter / DiSFarM (2026): Monte Carlo analysis (100,000 iterations), AIFA 2026 vs pre-reform literature (Raimondo 2020, Lidonnici 2018, Canali 2023). Cohorts from different periods: part of the gap may reflect general trends, not the reform alone.

ADDITIONAL DELAY FROM REGIONAL FORMULARIES (PTOR/PTR) AFTER NATIONAL APPROVAL

After AIFA, access goes through the Regions

15
Regions with PTOR/PTR in force (regional barrier)

3
Regions with no formulary (near-immediate access)

up to 270 days
estimated additional delay in the slowest Regions

0-90 days (no formulary)	Lombardia, Veneto, Friuli-VG	**3 reg.**
30-120 days	Abruzzo, Emilia-Romagna, Sardegna	**3 reg.**
60-180 days	Lazio, Liguria, Piemonte, Umbria, Valle d'Aosta	**5 reg.**
150-200 days	Marche, Puglia, Sicilia, Toscana, A.P. Bolzano, A.P. Trento	**6 reg.**
180-270 days	Basilicata, Calabria, Campania, Molise	**4 reg.**

The delay grows from North to South: where no regional formulary exists (North-East/Lombardy) the drug is available almost immediately; in Regions with a PTOR and outcome publication beyond 3 months, the patient waits up to 9 months longer.

Source: BHAVE analysis (June 2026) from public sources: industry association, regional websites, regional gazettes, literature. 21 Regions/APs. Estimated delay = additional time after AIFA national availability for inclusion in the regional formulary.

PREVALENCE AND ACCESS CHANNEL BY DISEASE — WHERE DEMAND CONCENTRATES

The epidemiological weight of therapeutic areas in Italy

Area · Disease	Prevalence / cases Italy	ATC class	Prevalent channel	Specialist
Ophthal. · Glaucoma/ocular hypertension	800,000-1,000,000	S01	Community pharmacy	Ophthalmologist
Ophthal. · Macular degeneration (wAMD)	~280,000-350,000	S01	Hospital direct / DPC	Ophthalmologist
Onco · Advanced melanoma BRAF+	~970-1,300 eligible/year	L01	Hospital direct (regional tenders)	Oncologist
Onco · Ovarian carcinoma BRCA+	~1,300-1,650 eligible/year	L01	Hospital direct / DPC	Oncologist
Cardio-Metab · Type 2 diabetes	~3.9M (prev. 6.6%)	A10	DPC / Community pharmacy	Endocrinologist
Cardio-Metab · Obesity (BMI ≥30)	~6-7M adults	A10	Private / DPC if reimbursed	Endocrinologist
Cardio-Metab · Cardiac amyloidosis (ATTR)	~3,000-5,000/year	C01	Hospital direct (specialist)	Cardiologist
Respiratory · COPD	~1.52M (prev. 2.58%)	R03	DPC / Community pharmacy	Pulmonologist
Respiratory · Severe eosinophilic asthma	~200,000 (SEA pool)	R03	Hospital direct (pulmo/allergo)	Pulmonologist

Two worlds of access: High-prevalence diseases (diabetes, COPD, glaucoma) flow through community pharmacy/DPC — large volumes, contained price. Specialist diseases (oncology, severe asthma, AMD) flow through hospital direct purchasing and regional tenders — small pools, high value, access governed by regional formularies.

Source: BHAVE analysis (June 2026) on public sources: national health institute, AIOM-AIRTUM 2024, Parliamentary Report on Diabetes 2024, SIMG 2024, Orphanet, Ministry of Health. Data at disease/ATC-class level.

AIFA NATIONAL TIME + REGIONAL DELAY = REAL DAYS TO THE PATIENT

The double funnel of drug access

PHASE 1 — NATIONAL (AIFA)

~185-364 days

from submission to national availability (185-day median post-reform; up to 364 for NCEs)

\+

PHASE 2 — REGIONAL (PTOR/PTR)

0-270 days

additional delay for inclusion in the regional formulary (0 where none exists, up to 270 days in the South)

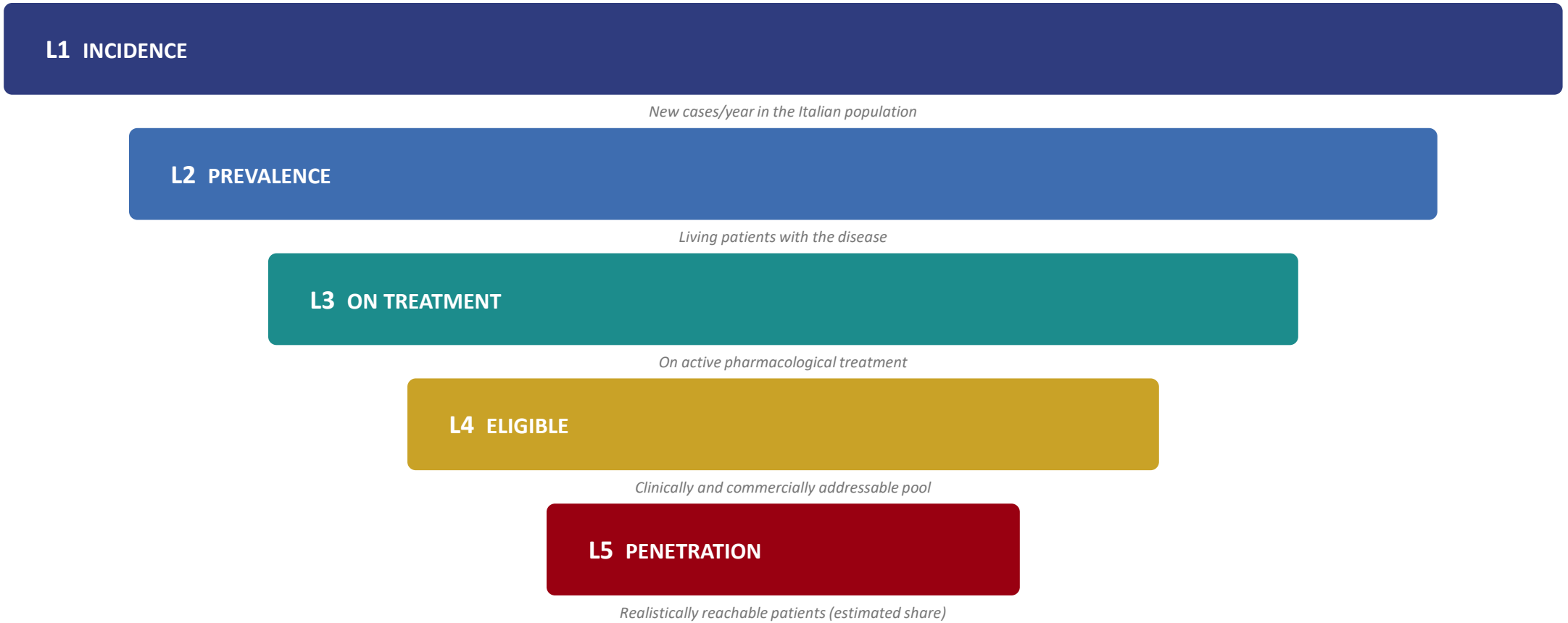
= The real time to the patient
from ~6 months (Regions with no formulary) to over 20 months (NCE + slow Region)

Strategic implication: the AIFA reform shortened Phase 1, but the regional Phase 2 remains the true driver of inequality. For a launch, the map of regional formularies matters as much as the national dossier — and determines in which Regions the patient gains access first.

Source: BHAVE analysis: Phase 1 from A. Marcellusi/DiSFarM (AIFA 2026 report); Phase 2 from regional PTOR/PTR mapping (June 2026). Timelines add up along the submission→patient chain.

L1→L5 METHODOLOGICAL SCHEME TO SIZE THE REAL COMMERCIAL POOL

From population to treatable patient: the funnel



What it's for. Each disease is run through this funnel: from the general population down to the pool of patients that can realistically be reached. Applied with source-of-business (switch / new / add-on) and a confidence rating, it yields a defensible estimate of potential demand — the basis for forecasting, network sizing and area prioritization.

Source: BHAVE methodological framework (Patient Cascade). Generic scheme applicable to any therapeutic area; absolute values depend on the disease and the epidemiological sources.

Distribution Channels, Pricing & 2026 Formulary Revision

COMMUNITY PHARMACY (REIMBURSED)

Class A retail

Pharmacy purchases from wholesaler

NHS reimburses list price minus margins

Regulated price, no tender

DPC (ON-BEHALF-OF DISTRIBUTION)

Class A-PHT

Region purchases via centralized tender

Pharmacy dispenses for a fixed fee

Discount ≥50% + tender → ~24% savings

HOSPITAL / TENDER

Class H · H-PHT

Mandatory discount ≥50% (L.386/1974)

Regional tender: rebate 33–50%+

Net price can fall below 15% of list

Pharmaceuticals in Italy: channels, categories & company net revenue

Key distribution modes and reimbursement classes — company net revenue at list price = 100

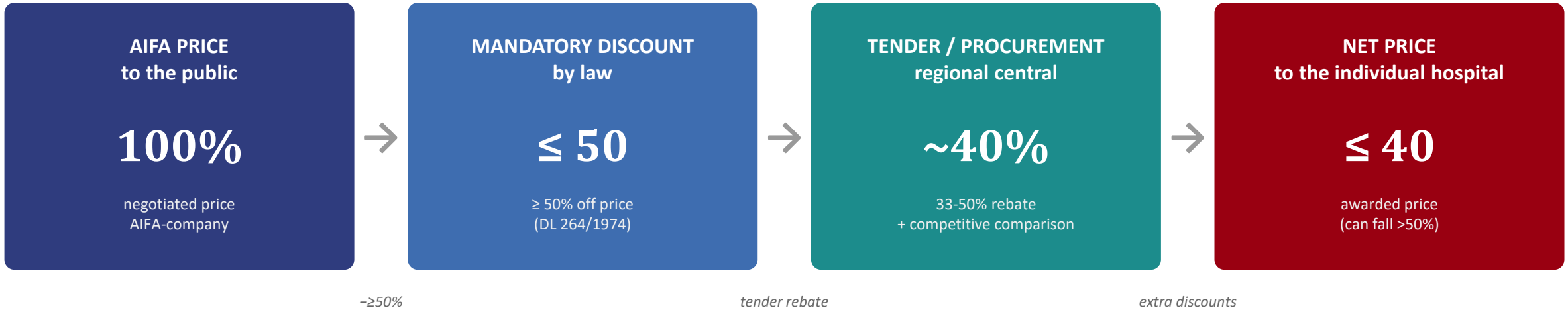
Channel / Category	Who pays	Distribution margins	Company discounts & clawbacks	Company net LP = 100
Community pharmacy (reimbursed) Class A	NHS (minus co-pay & pharmacy discount)	Pharmacy 30.35% Wholesaler 3.65%	Statutory discounts 5%+5%; payback 1.83%; conv. cap 6.85%	**53–59%**
DPC (on-behalf-of) Class A-PHT	NHS — tender + fixed fee	Fixed fee ~€ 6–7 / pack	5%+5% discounts; Direct Purchases cap payback (12–24 mo.); no 1.83%	**52–56%**
Direct / Hospital Class A-PHT · H	LHU / Hospital (direct purchase)	No retail margin	Mandatory ≥50% discount (L.386/1974) + tender (−33/50%+); Dir. Purch. payback	**~50% → <15%**
Class C — prescription	Patient (free pricing)	Commercial supply chain	No payback / NHS discount	**~60%**
SOP / OTC	Patient (OTC, free pricing)	Supply chain + promos	No payback / NHS discount	**50–60%**

KEY POINT: Across all channels the company nets ~50–60% of the list price. In NHS channels, the net is eroded by statutory discounts and payback; in hospital tenders it can fall below 15%. The same neighborhood pharmacy can dispense the same drug under two different regimes: pure reimbursed (regulated price) or DPC (tender price) — the difference is who purchases and at what price.

Base: list price incl. VAT 10% = 100. Sources: L. 662/1996; L. 405/2001; DL 78/2010; Det. AIFA 27/09/2006; AIFA expenditure monitoring Jan–Dec 2025.

FROM AIFA PRICE TO THE INDIVIDUAL HOSPITAL: STEPS AND DISCOUNTS (DIRECT PURCHASES / TENDERS)

The discount chain — Hospital channel



How it works. For direct purchases the company must apply by law a minimum 50% discount off the public price (DL 264/1974). On this basis the procurement central/LHU opens the tender (minimum 33-50% rebate) and obtains further competitive discounts. Where biosimilars/generics exist, the real saving on the purchase price can exceed 50%. The 2026 Budget Law adds: multi-supplier framework agreements above 3 equivalents and competitive comparison within 60 days of the 1st equivalent.

Source: DL 264/1974 art. 9; DL 78/2010; 2026 Budget Law; ANAC survey on drug tenders; SIFO. Indicative values in index form (public price=100).

Retail pricing cascade (community pharmacy / reimbursed)

List price breakdown and NHS discounts: branded, generic, branded-generic

Item (net of VAT)	Branded (in patent)	Branded-generic	Generic (equivalent)
Manufacturer share (ex-factory)	**66.0%**	**58.65%**	**58.65%**
Wholesaler share	3.65%	6.65%*	6.65%*
Pharmacy share (minimum)	30.35%	26.7%*	26.7%*
+ Redistributed 8% share	—	yes	yes
Mandatory NHS discount (regressive)	3.75–19%	3.75–19%	3.75–19%
5% price reduction (reinstated 2026)	−5%	−5%	−5%
List price vs originator	*reference*	*below transp. list*	**−20/45%**

* Equivalents and branded-generics: the manufacturer cedes 8% (from 66.65% to 58.65%), redistributed between wholesaler and pharmacy. The pharmacy share remains a statutory minimum. The generic enters 20–45% below list and activates competition; the branded-generic positions in between, leveraging the 8% share to compete in pharmacy.

Sources: L. 662/1996; Budget Law 2025 (66%/3.65%/30.35%); DL 39/2009 (58.65%+8%); Budget Law 2026 (reinstated 5% discount).

The tender process: from publication to award

Documented real case — Regional procurement agency, biologics and biosimilars

Contracting authority	AreaCom — Regional Procurement Agency, Abruzzo (+ ASREM Molise)
Subject	Biologic and biosimilar drugs, ed. 2-2024
Lots / Amount	42 lots · € 85.08M (net of VAT), 3-year + 12-month extension
Procedure type	Multi-supplier Framework Agreement (DPS); art. 54 para. 4 lett. a D.Lgs. 50/2016
Award	Top 3 bidders — volume shares 50% / 35% / 15% (L. 232/2016 art. 1 para. 407)

1. Notice + Specifications
2. Reserve price & lots
3. Bid submission
4. RUP verification
5. Award decision

PRICE LEVEL EXAMPLE (comparable case, Tuscany)

Awarded at €282/unit (−15% vs reserve, −36% vs previous contract). The originator, not participating, remains at €442.93 (+36%). The supply price is formed in the tender, not from the list.

2026 Budget Law: mandatory multi-supplier framework agreements when 3+ equivalents exist; competitive comparison within 60 days of the 1st equivalent.

Sources: AreaCom (Determination 187/2024); So.Re.Sa.; Egualia/IBG; QuotidianoSanità; L. 232/2016; D.Lgs. 50/2016 & 36/2023.

On-Behalf-Of Distribution (DPC): pathway & real figures

How A-PHT drugs reach the patient — antidiabetics (Nota 100) case study · AIFA/OsMed 2024 data

1 Public procurement (tender)

LHU/Region buys hospital packs via public procurement procedure (art. 8, L. 405/2001).

2 Prescription — Nota 100 + ETP

GP or NHS specialist. Electronic Therapeutic Plan via Health Card (GPs from 12/2022).

3 Dispensing at community pharmacy

Hospital pack dispensed 'on behalf of' the LHU; max 60 days of therapy per prescription.

4 Service remuneration

NHS pays = tender price + pharmacist fee (€ 6–7/pack), set by regional agreement.

5 Reporting

Promofarma/DCR data flow; expenditure outside community reimbursement (falls under Direct Purchases).

KEY FIGURES (ACTUAL DATA)

€ 1,642M	Public spend on antidiabetics 2024
> 51%	Antidiab. + anticoag. share of total DPC
+13.2%	vs 2023 (volumes +4.3%)
€ 2.1B	NHS purchase value in DPC
€ 7.03	Average fee per pack
+€ 343M	Annual service cost

Sources: AIFA — OsMed Report 2024; AIFA Nota 100; DPC art. 8 L. 405/2001; AIFA expenditure monitoring Jan–Dec 2025.

From list price to company net: discounts and payback in DPC

How the list price splits (net of 10% VAT)

In DPC, percentage-based margins do not apply: the Region buys at ex-factory (tender price) and pays the pharmacy a fixed fee (~€ 6–7/pack).

Statutory discounts and payback on ex-factory (base 100)

100	Ex-factory (NHS transfer price)	
95.0	− 5% discount (Det. AIFA 2006 / CIPE)	*at supply*
90.25	− Further 5% (Det. AIFA 27/09/2006)	*at supply/period.*
net	− Payback Dir. Purchases cap overshoot	*deferred 12–24m*

CRITICAL DPC NOTES

The 1.83% payback does NOT apply in DPC (community reimbursement only). A-PHT drugs in DPC fall under the Direct Purchases cap (8.60% of NHS Fund in 2026). Combined effect of statutory discounts ≈ −9.75% on ex-factory; the cap payback is additional and varies yearly.

Direct Purchases clawback: € 1.03B (2021) → € 1.35B (2022) → € 1.64B (2023) → € 521.7M companies (2025, cap 8.30%).

TIMING OF EACH REDUCTION

At supply: VAT 10%; pharmacy fee (DPC); 5% + 5% discounts. **Periodic:** Potential 5% payback if company suspends price reduction. **Deferred 12–24m:** Cap overshoot payback — AIFA rules by Oct 31 following year; payment often delayed due to appeals.

Sources: L. 662/1996; L. 405/2001; Det. AIFA 27/09/2006; DL 78/2010; L. 145/2018; AIFA clawback determinations 2021–2023.

DPC vs Community Reimbursement: two mirror supply chains

Where the list price goes and what the company keeps — the same molecule in two channels

Dimension	DPC (Direct Purchases)	Community reimbursement (retail)
What NHS pays	Tender price + fixed fee	LP − co-pay − pharmacy discount
Distribution	Fixed fee ~€ 6–7 / pack	Pharmacy 30.35% + Wholesaler 3.65%
Statutory discounts	−5% −5% (≈ −9.75%)	−5% −5% (≈ −9.75%)
1.83% payback	NO	**YES (semi-annual)**
Cap payback	Dir. Purch. 8.60% · deferred 12–24m	Community 6.85% · ≈ 0 (2025 surplus)
Company net	Ex-factory − discounts − DP payback	≈ 53–59% of LP

THE CRUCIAL CONSTRAINT: the drug must be 'transferable' to the DPC channel. DPC/DD applies to PHT drugs (A-PHT) and, by regional agreement, to some Class A drugs linked to chronic conditions. In practice, over 99% of DPC consumption is Class A, of which 96% is A-PHT.

Class A in PHT (or regional DPC for chronic care) → yes, can be tendered at ≤50% of list price, while still dispensed at the community pharmacy.
Class A pure, non-PHT, community reimbursement only → no, cannot be tendered: regulated price applies.

This is the economic lever driving Regions to shift volumes from community reimbursement to DPC (~24% savings, rewarded by the LEA indicator).

Reimbursed retail drug supply chain: real-world example

Trimbow (Chiesi) — community reimbursed channel via wholesaler, not DPC · Class A, Nota 99 (COPD) · LP € 81.05

Item	€
List price (incl. 10% VAT)	**€ 81.05**
− VAT 10%	− € 7.37
= List price net of VAT	**€ 73.68**
− Pharmacy margin (30.35%)	− € 22.36
− Wholesaler margin (3.00%)	− € 2.21
= Ex-factory (66.65%)	**€ 49.11**
− 1.83% payback	− € 1.35
− 2006 discounts (−5% −5%)	up to − € 4.79
= COMPANY NET REVENUE	**≈ € 43–48**

KEY DIFFERENCES VS DPC

Real % margins apply

Pharmacy 30.35% and wholesaler 3.65% are actually applied. In DPC they are replaced by a fixed fee (~€ 6–7/pack).

1.83% payback due

Only in community reimbursement (not in DPC). Companies paid € 173.5M in 1.83% payback alone in 2025.

Community cap 6.85%

Not Direct Purchases. In 2025 community reimbursement was in surplus (€ 459M) → cap overshoot payback ≈ 0.

Net ≈ 53–59%

The company nets 53–59% of the shelf price (€ 43–48 on € 81.05).

Sources: AIFA det. 'Trimbow' (OJ 07/03/2023); L. 662/1996; DL 78/2010; Det. AIFA 27/09/2006; AIFA monitoring Jan–Dec 2025.

What is happening: formulary & pricing revision 2026

THE ONGOING DEBATE (June–July 2026)

AIFA is working on a Formulary revision (annual obligation by Nov 30): possible therapeutic-group reimbursement — only the cheapest active ingredient reimbursed, with the difference borne by the patient.

AIFA has already sent price reduction requests; most companies refused. Farmindustria (Cattani): 'reduction is unfeasible'.

Health Minister Schillaci puts up guardrails — patients must not pay more or lose access to innovative therapies.

Trigger: Direct Purchases cap overshoot (~€ 4.1–4.7B). For pre-LOE biologics without a biosimilar: renegotiation or automatic −20% price cut.

IMPACT SCENARIOS BY AREA / CLASS

Area / class	Channel	Risk
Oncology (L01), biologics	Hospital	HIGH
Immunology biosimilars (L04)	Hospital	HIGH
Ophthalmo anti-VEGF (S01)	Hospital	MED-HIGH
Respiratory inhalers (R03)	Retail	MEDIUM
Cardio-metab / PPIs, statins	Retail	HIGH
Diabetes / GLP-1 (A10)	Retail/H	MEDIUM

Risk reading. HIGH where the channel is hospital-tender with biosimilars/generics available (immediate price pressure) or where therapeutic-group reimbursement would hit crowded classes. MEDIUM where device or adherence protect (inhalers) or the category is growing fast (GLP-1).
Implication: monitor the Formulary revision and map the portfolio by class/channel/biosimilar availability. Crowded off-patent classes are most exposed to therapeutic-group reimbursement; pre-LOE biologics to the automatic −20% cut.

Sources: Il Sole 24 Ore (16/6/2026); Sky TG24 (25/6/2026); QuotidianoSanità; Farmindustria Assembly 2026; Budget Law 2026.

Structural shifts: channel migration, revised caps & payback reality

Three converging dynamics reshaping portfolio economics

DPC → COMMUNITY REIMBURSEMENT

The channel shift is accelerating.

The new National Collective Agreement (ACN, OJ 19/3/2025, Art. 15) confirms DPC applies **exclusively to A-PHT drugs**. Non-PHT Class A drugs must be dispensed in community reimbursement at regulated price — no tender.

LMWH precedent: Low-molecular-weight heparins shifting from 77% DPC to community (Veneto, Sardinia). TEHA estimates min. €2.9M/yr NHS savings. This template is replicable to other A-PHT classes.

Gliptins/gliflozins (Nota 100): already reclassified from A-PHT to Class A — €9.7M savings in 2024 alone.

Portfolio impact: Respiratory generics (Note 99) are pure Class A, NOT A-PHT → they remain in the community channel at regulated price, protected from tender pressure. Positive for margin stability.

2026 EXPENDITURE CAPS (REVISED)

	2025	2026
Direct Purch. cap	8.50%	**8.70%**
Community cap	6.80%	**6.85%**
Combined	15.30%	**15.55%**

Despite the increase, the Court of Auditors simulation (May 2025) shows:

Direct Purchases overshoot: €3.8B
Company payback: €1.9B
Community surplus: €793M

All 21 Regions exceed the Direct Purchases cap — even at 8.70%. The structural overshoot is baked in.

2024 actual: Pharm. spend €23.7B, overshoot €3.3B vs available resources. Payback doubled in 3 years to €2.0B.

PAYBACK REALITY & BIOSIMILAR GAP

Payback collection rate: ~30%

(Court of Auditors, Ruling 21/2025)

From 2013 to 2023 companies paid ~€20B total. The mechanism is structurally dysfunctional — massive litigation, confidential discounts, renegotiations.

Budget Law 2026 change: Regional share of payback abolished → 100% falls on companies. Higher nominal exposure, but actual collection still ~30%.

Biosimilar penetration gap:

Country	Biosimilar %
Italy	**~40%**
France	~50%
Germany	**~80%**
UK (NHS)	**~85%**
EU target	*80%*

For a biosimilar portfolio: the ~40-point gap is both a realistic ceiling (EU targets are unlikely short-term) and a growth opportunity (formulary revision + tender pressure will push adoption).

Sources: TEHA Working Paper on LMWH (2025); BHAVE 'Futuro Liquido' (Feb 2026); Court of Auditors Ruling 21/2025; AIFA OsMed 2024; ACN Art. 15 (OJ 19/3/2025); EFPIA WAIT 2024–25.

STATUTORY SOURCES AND ACTS FOR EACH TOPIC IN THE DOCUMENT

Regulatory and administrative references

Topic	Regulatory / administrative reference
Supply-chain shares (66% / 3.65% / 30.35%)	L. 662/1996 art. 1 §40; L. 207/2024 (Budget 2025) art. 1 §324-327; AIFA det. 7/2/2012
Equivalents: 58.65% share + 8% redistributed	D.L. 39/2009 art. 13 (conv. L. 77/2009); AIFA transparency lists
Mandatory NHS pharmacy discount (regressive)	L. 662/1996 art. 1 §40; D.L. 78/2010 art. 11 §6; 2.25% withholding → D.L. 95/2012 art. 15 §2
–5% price discount (reinstated 2026)	AIFA det. no. 26 of 27/9/2006; reinstatement: 2026 Budget Law (repeal of suspension)
Direct purchases / hospital discount ≥50%	D.L. 264/1974 art. 9 §4-5 (conv. L. 386/1974)
Tenders and procurement centrals (33-50% rebate)	D.Lgs. 50/2016 (Procurement Code) and D.Lgs. 36/2023; ANAC survey on drug tenders
2026 spending caps (direct purch. 8.6% / community 6.85%)	2026 Budget Law (§62 ff.); D.L. 78/2010 art. 15; L. 145/2018
Payback and cap-overshoot repayment	D.L. 159/2007 art. 5; D.L. 95/2012 art. 15; abolition of Regional share: 2026 Budget Law
Annual Formulary revision (by 30/11)	2026 Budget Law §376-380; AIFA 2026 activity plan (Board 28/1/2026)
Pre-LOE biologics: renegotiation / –20%	2026 Budget Law; D.M. 2/8/2019 (P&R criteria); D.M. 21/7/2022 (automatic generic/biosimilar negotiation)
Pharmacy of Services (€50M/year)	D.Lgs. 153/2009; DM 77/2022; 2026 Budget Law art. 67; Regional Integrative Agreements
Innovative drugs (Fund)	L. 232/2016 art. 1 §400-401; 2026 Budget Law art. 73 (Fund remodulation)
Respiratory Note 99 (triple COPD)	AIFA det. no. 822/2026 (effective 9/7/2026); GOLD guidelines
Regional formularies (PTOR/PTR) and access delay	D.L. 158/2012 (Balduzzi) art. 10; State-Regions Agreement 2010; regional resolutions
National P&R timelines	D.M. 2/8/2019; AIFA P&R timelines report; AIFA 2023 and 2026 reports

Source: BHAVE analysis. References indicate the primary sources applicable to each topic; for AIFA acts and regional resolutions, see the texts published in the Official Gazette / regional gazettes. Framework updated to July 2026.