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Competition in the Healthcare Sector – Contribution from Italy

- Session II -

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Competition in the Healthcare Sector

- Contribution from Italy -

1. Introduction

1. The Italian National Health Service (NHS), established in 1978, provides universal healthcare coverage to all citizens and legally resident foreigners. The central government defines the national benefits package and allocates funding to the regional health systems, while the regions are responsible for financing, planning, and delivering healthcare services through local health authorities. Hospital and specialist outpatient care are provided either directly by these local authorities, through semi-autonomous public hospitals (known as hospital trusts), or by accredited private providers operating within the public system. Approximately three quarters of total health expenditure in Italy is publicly financed through government or compulsory schemes. However, persistent fiscal constraints have gradually increased the share of private health spending, primarily in the form of out-of-pocket payments by households, which now account for around one fifth of total health expenditure, while the role of private health insurance remains marginal[1].

2. This multi-layered governance structure and the coexistence of public and private providers create unique challenges, where regional disparities, procurement practices, and mixed public–private arrangements require careful monitoring. The Authority has consistently promoted competition as a tool to enhance efficiency, quality, and innovation while preserving the fundamental principles of universality and solidarity that characterise the Italian healthcare system. The AGCM's role in this complex landscape extends beyond traditional enforcement to encompass market studies, advocacy interventions, and collaboration with sector regulators.

3. This submission summarises the AGCM's recent practice and perspectives along the three themes identified by the OECD Global Forum on Competition roundtable on competition in the healthcare sector: the evolving role of competition authorities in healthcare markets, addressing non-price dimensions such as quality and equity, and managing competition risks spanning the pharmaceutical value chain.

2. The Role of the AGCM in Shaping Accessible Healthcare Markets

4. As illustrated in more detail below, the Authority's mandate has consistently reflected a dual function that combines strict enforcement with proactive advocacy.

[1] In 2022, health expenditure represented 9% of GDP: most of the health spending in Italy (74%) was financed through government or compulsory schemes. Household out-of-pocket (OOP) spending on healthcare represented 23% of total health expenditure in 2022, with outpatient medical care and pharmaceuticals being the most substantial categories. Private (voluntary) health insurance plays a minor role, accounting for only about 3% of total health expenditure. See De Belvis AG, Meregaglia M, Morsella A, Adduci A, Perilli A, Cascini F, Solipaca A, Fattore G, Ricciardi W, D'Agostino M, Maresso A, Scarpetti G. Italy: Health System Summary, 2024. Copenhagen: European Observatory on Health Systems and Policies, WHO Regional Office for Europe; 2024. Licence: CC BY-NC-SA 3.0 IGO.

5. Over the years, the AGCM enforced competition rules to address exclusionary practices linked to the strategic use of patents and licences, preventing the entry of generic medicines and deploying proportionate remedies and injunctive powers in emergencies to safeguard supply security. It also curbed exploitative abuses in the supply of essential or orphan drugs and monitored compliance with its cease-and-desist orders overseeing the subsequent negotiation processes between pharmaceutical companies and the National Medicines Regulator (AIFA), ensuring that remedial measures translate into tangible benefits for the Italian National Health Service (NHS) and patients. In merger control cases involving hospitals or pharmaceutical distribution chains, the AGCM considered non-price dimensions such as quality, accessibility, and continuity of service (see section 2.2 below).

6. On the advocacy front, the Authority regularly advises policymakers on market design and on the governance of local health authorities, particularly in relation to procurement systems. It conducted in-depth market studies, including its comprehensive inquiry into the vaccine for human use in 2016, prior to the outbreak of the Covid-19 pandemic in 2020. In parallel, the AGCM maintained close cooperation with other competition agencies, exchanging investigative assistance and market information to ensure consistent enforcement and proportionate sanctioning across jurisdictions in cases of parallel investigations.

7. The Authority's experience in enforcement and advocacy underscores the complexity of competition dynamics in healthcare markets. Highly concentrated segments such as vaccines and biologics often give rise to concerns of exclusionary conduct and excessive pricing, requiring vigilant monitoring of dominant positions. At the opposite end of the spectrum, collusive arrangements or restrictions on resale that ultimately harm consumers can also be found in markets such as those for pharmacies and drug wholesalers that are still fragmented in Italy. These structural characteristics call for a balanced approach in which competition enforcement and advocacy operate in close alignment with public health objectives to ensure open, fair, and sustainable healthcare markets.

2.1. Antitrust enforcement

8. The AGCM enforces Articles 101 and 102 TFEU and Law No. 287/1990 to prevent agreements and abuses that restrict competition in national markets. Its enforcement activity has covered pharmaceuticals, medical devices, and healthcare services, sectors where public procurement and intellectual property (IP) regulation intersect strongly with competition dynamics.

9. Since 2012, the AGCM's enforcement record has established Italy as a reference jurisdiction for antitrust intervention in the pharmaceutical sector (see BOX 1 below). These cases collectively demonstrate the AGCM's ability to integrate competition law with health regulation, applying economic analysis sensitive to the clinical and ethical dimensions of access to medicines.

10. Key enforcement cases include:

- Merck (2006) and Glaxo (2007), concerning refusals to grant export licenses despite patent expiry in destination markets. In both cases, the AGCM closed the investigations by accepting compulsory license as commitments; in Merck (2006), the AGCM, for the first time, adopted interim measures to order compulsory license.
- Pfizer/Xalatan (2012), where the AGCM found a misuse of patent rights aimed at delaying generic entry for a glaucoma drug. The case – which constitutes a leading precedent in Europe on "abuse of rights" in the patent system – led in 2024 to a

compensation for damages of about €13 million awarded to the Italian Ministry of Health.

- Roche/Novartis (2014), addressing collusive behaviour between two originator firms that allegedly misled healthcare authorities to favour a more expensive drug over an equally effective off-label alternative. In relation to this decision, the Court of Justice of the European Union (CJEU) ruled that dissemination of misleading information on safety may amount to a restriction of competition by object under Article 101 TFEU.
- Aspen Pharma (2016), the first EU-level finding of excessive pricing for off-patent oncology drugs.
- Leadiant (2022), another excessive pricing case in orphan drug markets, confirming the AGCM's analytical capacity in assessing cost structures and regulatory barriers.

11. In 2024, the Authority also launched an investigation involving alleged anticompetitive agreements between Samsung/Biogen and Roche/Novartis concerning Byooviz, a biosimilar of Lucentis[2].

12. During the pandemic, the AGCM issued guidance allowing temporary cooperation between distributors to ensure continuity in the supply of essential products, aligned with the European Commission's 2020 framework on COVID-19 cooperation. The AGCM applied its notice on 27 May 2020, to a cooperation project for the distribution of disposable surgical masks through pharmacies and para-pharmacies (i.e., pharmacies with fewer requirements and limited authorisation to sell certain drugs) submitted by two national associations of pharmaceutical distributors[3].

[2] Case No. I868 - BYOOVIZ/MANCATA COMMERCIALIZZAZIONE, decision No. 31213, published in AGCM Bulletin 23/2024. See the English version of the press release and decision opening the investigation (unofficial translation). In May 2024, the AGCM opened proceedings against eight pharmaceutical companies belonging to the Samsung, Biogen, Roche, and Novartis groups to investigate a suspected anticompetitive agreement in breach of Article 101 of the Treaty on the Functioning of the European Union (TFEU). The case concerns the marketing of Byooviz, a biosimilar of Lucentis (ranibizumab), developed by Samsung and Biogen. Byooviz obtained market authorisation from the European Medicines Agency (EMA) in August 2021 as the first biosimilar referencing Lucentis, a drug marketed by Roche/Genentech and Novartis for the treatment of serious ophthalmological diseases such as age-related macular degeneration. The Italian Supplementary Protection Certificate (SPC) for Lucentis expired in July 2022, which should have permitted immediate market entry of biosimilars thereafter. The Authority suspects that Samsung and Biogen may have entered into a collusive arrangement with the originator companies, aiming to delay the commercialisation of Byooviz in Italy beyond the expiry of the SPC, in exchange for early entry of the same product in the United States prior to the expiration of corresponding IP rights. If confirmed (the investigation is still ongoing as at November 2025), such conduct would constitute a serious restriction of competition by object, depriving the Italian National Health Service and patients of the benefits of earlier biosimilar competition and lower prices.

[3] See the AGCM's contribution on "The Role of Competition Policy in Promoting Economic Recovery" submitted for Item 2 of the 134th OECD Competition Committee meeting on 1-3 December 2020.

Box 1. AGCM enforcement in the pharma sector

This box summarises the principal enforcement actions undertaken by the Authority in the pharmaceutical and healthcare sector, covering both anticompetitive agreements and abuses of dominance[4].

Merck (2006) and Glaxo (2007) cases – Compulsory licences and generics entry

In two early landmark cases, Merck (2006) and Glaxo (2007)[5], the AGCM examined refusals to grant licences for the production of active pharmaceutical ingredients (Imipenem Cilastatin and Sumatriptan Succinate) to chemical firms supplying generic producers in other European countries where patents had already expired.

Both cases arose in the context of Italy's Supplementary Protection Certificate (SPC) regime, which extended patent protection beyond the standard duration to compensate for regulatory delays in marketing authorisation. The Italian SPC rules at the time provided no automatic obligation to grant export licences but allowed voluntary licences subject to ministerial review.

After receiving documentation from the competent ministry, the AGCM held that the right to refuse a licence was not absolute and must be balanced against the need to preserve competition where intellectual property rights (IPRs) had expired abroad. The Authority found that the refusals constituted abuses of dominance because they restricted the supply of essential inputs to potential competitors in markets where no IPRs protection remained.

Both investigations concluded with commitments establishing compulsory licences to enable generics production. In Merck, the Authority also adopted an interim measure, its first ever, to impose a temporary compulsory licence during the investigation, justified by the risk of serious and irreparable harm to consumers from delayed entry of generics[6].

Pfizer/Xalatan (2012): misuse of the patent regulatory framework

In Pfizer/Xalatan[7], the AGCM found that Pfizer had engaged in a complex strategy to artificially extend patent protection for its glaucoma drug Xalatan from September 2009 to July 2011. This was achieved through the late filing of a divisional patent and the subsequent request for a Supplementary Protection Certificate[8].

[4] For a more detailed description of these cases, see the AGCM's contributions to the 2014 OECD Roundtable on Generic Pharmaceuticals and the 2018 OECD Roundtable on Excessive Pricing in Pharmaceutical Markets.

[5] AGCM, Case A363 – Glaxo-Principi Attivi, decision No. 15175 of 8 February 2006, published in Bulletin No. 6/2006; Case A364 – Merck-Principi Attivi, decision No. 16597 of 21 March 2007, published in Bulletin No. 11/2007, together with the licensing agreement.

[6] For Merck's: see AGCM's press releases of June 21, 2005, available at and March 26, 2007; for Glaxo case: press release of February 21, 2006.

[7] AGCM case A431 – Ratiopharm/Pfizer, decision No. 23194 of 11 January 2012, published in Bulletin No. 2/2012. See press release of January 17, 2012.

[8] A divisional patent application is a patent application which has been divided out of an earlier filed patent application (known as the parent application). Supplementary protection certificates (SPC) are a type of patent extension, beyond the usual duration, introduced to allow to recover, after a patent has been obtained, for the time lost before the conclusion of process of authorisation to commercialisation.

The Authority did not question the legality of the patent itself but found that its timing and purpose were not linked to any genuine innovation. Pfizer also sought to deter generic entry by sending warning letters and threatening litigation, effectively delaying competition and imposing estimated additional costs of about €14 million on the Italian National Health Service (NHS).

The Italian Council of State upheld the AGCM's decision, stressing that the abuse lay not in the existence of patent rights but in the manner of their exercise, when used solely to exclude competition rather than to reward innovation. The case remains a leading precedent in Europe on "abuse of rights" in the patent system.

Shortly thereafter, the Ministry of Health and the Ministry of Economy and Finance brought an action before the Court of Rome seeking compensation for the losses suffered by the National Health Service (NHS) as a result of having paid higher reimbursement prices for Xalatan during the period in which the entry of generic equivalents was delayed. The claim sought damages in the amount estimated by the AGCM — approximately €14 million — corresponding to the additional expenditure incurred by the NHS. The Rome Court of Appeal upheld the claim, awarding damages in the requested amount with a 5% reduction. In 2024, the Italian Civil Supreme Court confirmed the award, recognising the NHS's right to recover the overcharge resulting from Pfizer's abusive conduct and holding that the AGCM's quantification of harm was adequately supported by evidence[9].

Roche/Novartis (2014): misleading information and market sharing

The Roche/Novartis case concerned an anticompetitive arrangement between two originator companies relating to the ophthalmic drugs Avastin (Roche) and Lucentis (Novartis)[10]. The AGCM found that the firms colluded to artificially differentiate the two medicines (though they were therapeutically equivalent for certain eye diseases) by spreading misleading information about the safety of Avastin's off-label use.

The Authority concluded that this conduct was intended to shift demand towards the far more expensive Lucentis, from which both firms profited: Roche through royalties on sales and Novartis through direct revenues. The AGCM imposed fines of €90.5 million and €92 million on Roche and Novartis respectively. The estimated additional cost to the Italian healthcare system was approximately €45 million in 2012 alone.

Following a preliminary reference from the Italian Council of State, the Court of Justice of the European Union (CJEU) clarified that (i) in principle off-label medicines can be considered in competition with authorised medicines, and (ii) dissemination of misleading information on safety may amount to a restriction of competition by object under Article 101 TFEU[11]. Following the referral, the Italian Council of State upheld the AGCM decision in 2019. This ruling was subsequently confirmed by the Italian Supreme Court of Cassation in 2021 and reaffirmed by the Council of State in 2023 during review proceedings that included a further request for a preliminary ruling from the Court of Justice[12].

[9] Cassazione Civile, judgement No. 9, 2 January 2024.

[10] See AGCM Case I760 – Roche-Novartis/Farmaci Avastin e Lucentis, decision No. 24823 of 27 February 2014, published in AGCM Bulletin No. 11/2014.

[11] Judgment of the Court of Justice of 23 January 2018, F. Hoffmann-La Roche Ltd and Others v Autorità Garante della Concorrenza e del Mercato, C-179/16.

[12] Judgment of the Court of Justice of 7 July 2022, *F. Hoffmann-La Roche Ltd and Others v Autorità Garante della Concorrenza e del Mercato*, C-261/21.

Aspen (2016) – excessive prices for essential drugs

In Aspen, the AGCM fined the Italian subsidiary of the South African group Aspen €5.2 million for abuse of dominance under Article 102 TFEU[13]. The company had increased prices for four off-patent cancer drugs by between 300% and 1,500% and threatened to withdraw supplies unless the price hikes were approved by the Italian Medicines Agency (AIFA).

The Authority ordered Aspen to cease the abusive conduct and report on compliance measures within 60 days. When Aspen delayed negotiations and withheld relevant cost information, the AGCM reopened proceedings for non-compliance. After further investigation and pressure, Aspen and AIFA reached an agreement that reduced prices by 30–80% compared to 2014 levels, applied retroactively to the date of the infringement decision.

As a result, the Italian NHS achieved annual savings of around €8 million. The decision was upheld by the Regional Administrative Court in 2017 and confirmed by the Council of State in 2020. The Aspen case became a European benchmark for excessive pricing enforcement in the pharmaceutical sector.

Leadiant (2022): excessive prices for orphan drugs

In May 2022, the AGCM fined Leadiant Biosciences Ltd and Essetifin S.p.A. (both part of the Leadiant Group) a total of €3.5 million for abusing their dominant position in the market for chenodeoxycholic acid (CDCA), used to treat cerebrotendinous xanthomatosis (CTX), an ultra-rare and life-threatening disease[14].

Leadiant's drug CDCA-Leadiant was the only product available in Italy for CTX, conferring a monopoly position reinforced by orphan drug exclusivity. The Authority found that, from 2017 onwards, Leadiant pursued a dilatory and obstructive negotiation strategy with the Italian Medicines Agency (AIFA), exploiting AIFA's weak bargaining position to impose unjustifiably excessive prices on the NHS. The evidence showed that Leadiant's behaviour formed part of a long-term plan to foreclose competition and secure supra-competitive margins.

The AGCM decision was coordinated with parallel investigations by competition authorities in Spain and The Netherlands to ensure proportional and consistent sanctions. In particular, the AGCM decided not to add a specific increase for deterrence to the basic amount of the fine, even though the Authority deemed that this case deserved it. Following enforcement, AIFA and Leadiant renegotiated the price of the drug, achieving a significant reduction from approximately €5,000–7,000 per pack to €2,000–4,000 per pack as of March 2024, a level broadly consistent with the pre-abuse price[15].

In 2024, the Council of State, Italy's top administrative court, confirmed the AGCM charge of excessive pricing against Leadiant and upheld the AGCM fine of €3.2 million, deeming it proportionate despite its high value relative to the Italian market. The court stressed that Leadiant's excessive pricing endangered patients' rights to health and access to essential medicines for a rare, life-threatening disease, and that the company exploited AIFA's weak bargaining position as it sought to ensure timely, affordable supply.

[13] See AGCM Case A480 - INCREMENTO PREZZO FARMACI ASPEN, decision of 29 September 2016, published in AGCM Bulletin No. 36/2016. For a detailed description of the case see section 3.2 of the AGCM submission to the 2018 OECD Roundtable on Excessive Pricing in Pharmaceutical Markets.

[14] See AGCM Case No. A524 - LEADIANT BIOSCIENCES/FARMACO PER LA CURA DELLA XANTOMATOSI CEREBROTENDINEA, decision No. 30156 of 17 May 2022, published in AGCM Bulletin No. 21/2022. See AGCM press release of 31 May 2022 here.

[15] See AGCM Case No. A524B, decision No. 31262 of 18 June 2024, published in AGCM Bulletin No. 26/2024. See AGCM press release of 26 June 2024 here.

2.2. Merger control

13. In the field of merger control, the AGCM examined transactions involving hospital operators and pharmaceutical distribution networks. In 2025, the Authority assessed the merger between CEF and Unico, respectively the second and third largest pharmaceutical wholesalers in Italy, which led to the creation of QFarma, the country's largest pharmaceutical distribution group[16]. The case represented a significant test of competition policy in a sector that, under the Italian regulatory framework, is defined as an essential public service: the wholesale distribution of medicines plays indeed a critical role in ensuring that pharmaceutical products are available nationwide within hours, a requirement that is fundamental to the continuity of patient care.

14. In its analysis, the Authority emphasised that the geographic location of warehouses is a key parameter of competition, as distance directly affects costs, delivery times, and logistical efficiency. These factors are particularly relevant in regions with complex geography or limited infrastructure, where rapid supply is vital for pharmacies and healthcare facilities. Competition in wholesale distribution largely takes place on the basis of price and delivery speed, parameters that directly influence the availability of medicines at local level.

15. The investigation concluded that the merger would have eliminated competitive pressure between the first two distributors in several local markets, corresponding to seven distinct catchment areas where pharmacies relied heavily on their services. The AGCM found that such consolidation risked reducing choice for pharmacies, weakening their bargaining power, and ultimately affecting the diversity and resilience of supply chains.

16. To address the competition concerns identified during the investigation, the Authority authorised the transaction subject to a combination of structural and behavioural remedies. The structural measures required the divestiture of two warehouses together with the associated business assets, ensuring the continued presence of independent competitors in the affected areas. The behavioural remedies complemented these measures by eliminating preferential purchasing clauses, reducing quantitative restrictions, and limiting the duration of affiliation contracts to one year. The Authority also prohibited the imposition of penalties or sanctions on pharmacies in the event of early termination of such contracts.

2.3. Market studies and advocacy opinions

17. The Authority's mandate extends beyond enforcement. It includes market studies and advocacy opinions to ensure that the Italian National Health Service (Servizio Sanitario Nazionale, NHS) benefits from efficient and transparent supply chains.

18. In 1997, the Authority first studied the pharmaceutical sector which was subsequently targeted in numerous advocacy opinions. Well before the Covid-19 pandemic outbreak, the AGCM had already recognised the strategic importance of vaccines for human use. In 2016, it concluded a market study with an analysis of the structure of global vaccine supply and national procurement, identifying high concentration, dependence on few suppliers, and regional fragmentation as key obstacles to competition. In particular, the lack of transparency regarding prices and the data needed to assess the comparative viability and essentiality of vaccines was deemed problematic. The Authority therefore

[16] See AGCM Decision No. 31648 in Case C12722 – *COOPERATIVA ESERCENTI FARMACIA/UNICO LA FARMACIA DEI FARMACISTI/NEWCO*, published in AGCM Bulletin No. 32/2025 of 18 August 2025.

called for coordinated action at both national and EU levels to enhance transparency, facilitate the entry of equivalent vaccines, and strengthen the balance between innovation incentives, affordability, and public health objectives (see BOX 2 below).

19. In 2024, the AGCM conducted a study of the hearing aid market, revealing a lack of transparency in the commercial conditions offered to the public as well as difficulties in public procurement procedures[17].

Box 2. The AGCM Sector Inquiry on Vaccines for Human Use (2016) [18]

In May 2015, the AGCM launched a fact-finding inquiry into the markets for vaccines administered through the National Health Service (NHS), excluding seasonal influenza vaccines. The inquiry, concluded in May 2016, identified structural and behavioural features affecting competition in both industrial and public-procurement dimensions.

The investigation found that the global vaccine industry had undergone profound transformation. Once a low-margin niche, it had become a highly profitable and innovation-driven segment, dominated by four multinational groups—GSK, Merck Sharp & Dohme (MSD), Sanofi Pasteur, and Pfizer—holding over 80 per cent of the global market. High technological barriers, extensive patent protection, and the absence of an effective "generic" or biosimilar pathway for vaccines limited the entry of alternative suppliers. Product differentiation—particularly differences in serotype coverage—often meant that vaccines targeting the same disease were not considered therapeutically or commercially substitutable, resulting in many de facto monopoly markets.

The Authority emphasised that scientific and regulatory bodies, not manufacturers, should determine therapeutic equivalence among vaccines to ensure competition where possible. At European level, it urged consideration of a harmonised regulatory framework to facilitate faster entry of equivalent or follow-on vaccines.

The inquiry also highlighted pricing strategies and information asymmetries. The leading firms applied global "tiered-pricing" policies, differentiating prices by countries' presumed ability to pay. However, the criteria and resulting prices were opaque, often protected by confidentiality clauses in bilateral contracts, preventing public purchasers from benchmarking and negotiating effectively. The AGCM called for greater price transparency and data sharing across jurisdictions to restore balance in procurement negotiations.

In Italy, vaccine demand is shaped by the National Vaccination Plans (PNPV) and the list of Essential Levels of Care (LEA). Inclusion of a vaccine in these programmes confers a decisive competitive advantage amounting to a guaranteed purchase by the NHS. The Authority recommended that decisions on inclusion and maintenance be made transparently, based on scientific evidence and cost-effectiveness analysis (e.g. health-technology assessment). It also supported clear communication strategies to enhance citizens' understanding of vaccine programmes.

Regarding procurement, Italy historically relied on numerous local contracting authorities, but consolidation into regional or central purchasing bodies was under way. The AGCM viewed aggregation of demand positively as a means of countervailing the strong supplier power,

[17] See AGCM Sector Inquiry No. IC55 - *MERCATI DEGLI APPARECCHI ACUSTICI*, decision No. 31149 of 26 March 2024. English press release is available here, executive summary in English is available here.

[18] See AGCM Sector Inquiry No. IC50 - *Indagine conoscitiva relativa ai vaccini per uso umano*, decision No. 26015 of 11 May 2016. See also: Pitruzzella, Giovanni and Arnaudo, Luca, *On Vaccines, Pharmaceutical Markets, and a Role for Competition Law in Protecting* (Also) Human Rights (7 September 2017). European Competition Law Review, vol. 38, issue 8, pp. 347-352, August 2017.

provided it was accompanied by solid market intelligence, open data on tenders, and standardised procedures. It rejected the notion that centralisation risked creating a harmful public monopsony.

Analysis of 2010–2015 procurement data (about €300 million annually) showed that effective price competition could occur when multiple products were tendered in the same lot. For example, competition between Cervarix (GSK) and Gardasil (MSD) for HPV vaccines reduced average prices by roughly 30 per cent, while the entry of Hexyon (MSD) into the hexavalent vaccine market lowered Infanrix Hexa (GSK) prices. By contrast, the pneumococcal vaccine Prevenar 13 (Pfizer) achieved a 95 per cent market share and rising prices, due to broader serotype coverage and its inclusion in national vaccination plans—illustrating how essentiality status can reinforce market power.

Finally, the AGCM noted that most vaccines in Italy were still classified as "Class C" drugs, with prices freely set by manufacturers, even though they were almost exclusively purchased by the public sector. The Authority proposed shifting essential vaccines to reimbursable classes (A or H) so that prices could be negotiated centrally by AIFA (Italian Medicines Agency), based on transparent reference prices and cost structures. This reform would ensure consistency, limit excessive pricing, and strengthen oversight of equivalence assessments.

Overall, the inquiry portrayed a rapidly evolving global industry with persistent market concentration and limited contestability. It called for coordinated action—nationally and at EU level—to promote transparency, facilitate entry of equivalent vaccines, and reinforce the balance between innovation incentives, affordability, and public health objectives. Following the AGCM's inquiry, some regional health authorities introduced competitive tenders to improve transparency and efficiency in procurement.

20. Since its establishment, the AGCM has issued over 140 advocacy opinions concerning the pharmaceutical and healthcare sectors (about 6% of the total). Roughly half of these address discriminatory or restrictive measures adopted by health authorities, while around 40% focus on tender procedures, such as rules on lot design, participation conditions, and award criteria.

21. One of the main areas where the AGCM advisory role to Government and Parliament had an impact was the liberalisation of pharmaceutical distribution (see BOX 3 below). With respect to the restrictions imposed on the opening of pharmacies, a law passed in 2017 eliminated certain ownership restrictions and that has increased interest from chains and investors. This has allowed the creation of pharmacy chains which accounted for 7% of value in 2024, and has resulted in a varied landscape in terms of pharmacy ownership and aggregation.

22. With regard to the pricing of medicines paid directly by patients (those not reimbursed by the NHS, including those still requiring a doctor's prescription), the Authority has continued to monitor the implementation of the 2006 liberalisation reform. In doing so, it has advocated for the removal of the requirement to provide "adequate information" on discounts to customers, a provision that has created interpretative uncertainty over whether differentiated discounts are permissible (see BOX 3 below). The Authority has stressed that promoting competition and allowing commercial practices such as loyalty schemes and targeted discounts would not compromise public health safeguards, since medical professionals remain responsible for monitoring the use of prescription-only medicines.

23. Moreover, the AGCM has also promoted the elimination of discriminatory measures between pharmacies and para-pharmacies in the retail sale of self-medication and non-prescription medicines (see BOX 3). It criticised the unjustified exclusion of para-pharmacies from offering ancillary services, such as booking medical appointments, home care, and public awareness campaigns, which limits an important access channel for

citizens. Restricting these services exclusively to pharmacies was deemed to provide them with an undue competitive advantage, depriving para-pharmacies of legitimate revenue opportunities and hindering potential improvements in service quality and efficiency.

Box 3. AGCM Advocacy for a New Regulatory Framework for Pharmacies

Restrictions on the opening and ownership of Pharmacies

Law No. 124 of 4 August 2017 (converted from Decree-Law of 2 August 2017) liberalised several ownership restrictions for retail pharmacies, based on several AGCM recommendations[19]. Previously, only individual pharmacists or associations of pharmacists could own pharmacies. Under Law No. 124/2017, corporations may now own retail pharmacies, provided certain conditions are met.

Despite this liberalisation, several restrictions remain in force. Pharmacies must still be managed by a pharmacist, meaning that the "director" of the pharmacy must hold a pharmacist's qualification even when the owner is a company. Moreover, manufacturers of medicines, scientific informers, and health professionals are prohibited from holding ownership or shareholdings in pharmacies, as laws on incompatibility continue to apply.

There are also ownership concentration limits: a company or corporate entity cannot directly or indirectly control more than 20% of the pharmacies within the same region or autonomous province. Previously, there was a cap of up to four pharmacies per company within the province of its headquarters, but Law No. 124/2017 effectively removed this restriction, subject to varying interpretations.

From a geographical and demographic standpoint, the opening of new pharmacies remains subject to planning rules. The law establishes a ratio of roughly one pharmacy per 3,300 inhabitants (Law No. 27/2012) and maintains a minimum distance of 200 meters between pharmacies. New openings also require authorisation from local health authorities and must comply with standards concerning premises, staffing, and technical requirements, as set out in the Codice del Farmaco (Legislative Decree No. 219/2006) and Law No. 362/1991 on pharmacy authorisations.

In addition, transferability of pharmacy authorisations remains regulated: transfers are permitted only after a certain period following the initial grant, although Law No. 124/2017 has modified some of these conditions.

Overall, the 2017 reform has paved the way for greater concentration of pharmacy ownership, allowing corporate entities to enter the sector and operate multiple pharmacies, within the limits of the 20% regional ownership cap.

Liberalisation of retail drug prices

The liberalisation of pharmaceutical pricing in Italy began with the Bersani Decree (Law No. 223/2006, converted into Law No. 248/2006), which allowed pharmacies to freely determine discounts on over-the-counter (OTC) and non-prescription (SOP) drugs. These discounts had to be clearly displayed and applied uniformly to all customers, a framework reiterated by the 2007 Finance Act. The process advanced with the Save Italy Decree (Law No. 214/2011), which extended discount freedom to all medicines that are not reimbursed by the NHS and whose prices are freely set by producers), including prescription-only ones, while maintaining the same transparency and uniformity requirements.

[19] See AGCM opinion No. *AS1137 - PROPOSTE DI RIFORMA CONCORRENZIALE AI FINI DELLA LEGGE ANNUALE PER IL MERCATO E LA CONCORRENZA ANNO 2014*, published in AGCM Bulletin No. 27/2014.

A major shift occurred with the Cresci-Italia Decree (Law No. 27/2012), which further liberalised pricing by allowing pharmacies to apply discounts on all medicines and products paid for directly by consumers, including the category of essential medicines when purchased privately (that is, outside the NHS reimbursement scheme). This reform removed the prior obligations to offer identical discounts to all purchasers and to display them in a specific format, replacing these with the more flexible requirement of providing "adequate information" to customers. The aim was to promote market openness and competition, enabling practices such as loyalty schemes or targeted discounts, without compromising public health safeguards, since doctors continue to oversee prescription use. To fully align with this liberalisation goal, in 2024 the AGCM suggested that the law should explicitly confirm the freedom to apply differentiated discounts across all medicines and sales outlets, noting that even the more flexible requirement of providing "adequate information" to customers has created uncertainty[20].

Discrimination between pharmacies and para-pharmacies

The Authority has repeatedly highlighted that excluding para-pharmacies from offering services available to pharmacies, such as booking specialist medical appointments (CUP)[21]., referral collection, and payment of co-payments, creates an unjustified competitive disadvantage. This exclusion limits the range of services para-pharmacies can provide, reducing consumer choice and depriving citizens of an additional access channel to essential health services. The Authority has consistently underscored the pro-competitive role of para-pharmacies in the pharmaceutical distribution sector, noting their contribution to market efficiency and accessibility.

Such discrimination, the Authority argues, lacks legal justification under the current framework, which originally encouraged competition and consumer freedom through liberalisation measures introduced by the Bersani (2006) and Save Italy (2011) decrees. While existing laws, such as Legislative Decree No. 502/1992, allow pharmacies to provide CUP-related services, they do not expressly prohibit other qualified entities, like para-pharmacies, from doing so. The Authority therefore recommends legislative intervention to harmonise national and regional regulations, explicitly enabling para-pharmacies to offer booking and related services. This reform would align with the objective of ensuring the widest possible access to healthcare services and fostering a more competitive and consumer-oriented market.

For instance, the AGCM advocated the amendment of provisions in the 2020 Budget Law that allowed only pharmacies, excluding para-pharmacies, to provide certain public health services funded by the NHS[22]. These services included participation in home-care programmes, collaboration on health education and disease prevention campaigns, the delivery of specialised patient services, and the booking of medical visits and tests. The AGCM argued that this exclusion unjustifiably restricted competition by preventing para-pharmacies from offering these services, thereby removing an important access channel for citizens and granting pharmacies an undue competitive advantage, to the detriment of service quality and efficiency.

The Authority also expressed concerns about regional restrictions preventing para-pharmacies from selling, on behalf of the NHS, medical devices, diabetic products and foods for special medical purposes. In 2018, the AGCM issued an opinion to all Regions and the Ministry of Health highlighting the inconsistent regional approaches to authorising para-pharmacies to

[20] See for instance AGCM opinion No. *AS2045 - PROPOSTE DI RIFORMA CONCORRENZIALE AI FINI DELLA LEGGE ANNUALE PER IL MERCATO E LA CONCORRENZA - ANNO 2024*, published in AGCM Bulletin No. 1/2025.

[21] See the above footnote.

[22] See AGCM opinion No. *AS1652 - OSSERVAZIONI IN MERITO ALLA LEGGE DI BILANCIO 2020*, published in AGCM Bulletin No. 12/2020.

supply these products[23]. The Authority stressed that excluding para-pharmacies from offering such products reduces consumer choice and weakens competitive pressure on traditional pharmacies. It further noted that the refusal by certain Regions to enter into agreements with para-pharmacies amounted to unjustified discrimination between distribution channels, with adverse effects on consumer welfare. The AGCM concluded that such exclusions could not be justified on public-health grounds, given that para-pharmacies are also required by law to have a licensed pharmacist on their premises.

2.4. 2.4 Strengthening the AGCM toolkit and partnering with national authorities

24. Some recent legislative reforms that have considerably enhanced the AGCM's enforcement and advocacy toolkit are of particular relevance for the healthcare sector.

25. In 2022, the introduction of Article 16(1-bis) of Law No. 287/1990 expanded the Authority's powers to review mergers falling below notification thresholds when there are plausible risks to competition. This measure is especially relevant to so-called killer acquisitions in the biotech and pharmaceutical sectors, where dominant firms may acquire innovative start-ups to pre-empt future competition[24].

26. Furthermore, a 2023 reform empowered the AGCM to impose structural or behavioural remedies following market studies that identify competition concerns even in the absence of infringements. This new Competition tool seem particularly suitable for fast-moving, innovative industries like those belonging to the healthcare sector[25].

27. Institutional cooperation remains a crucial element of the AGCM's approach, ensuring that competition policy complements broader healthcare policy objectives, such as universal access and service quality. Key partnerships include a Memorandum of Understanding with AIFA (2017), providing for information sharing, joint investigations, and coordinated remedies, exemplified by the Aspen case, which showcased the synergy between competition enforcement and price regulation. The AGCM also engages in regular consultations with the Ministry of Health on legislative and regulatory developments.

28. Looking ahead, the Authority aims to: (i) strengthen coordination with AIFA and regional health authorities on pricing and procurement; (ii) enhance analytical tools to assess innovation and sustainability alongside price impacts; (iii) intensify scrutiny of mergers and strategic partnerships in digital health and biotechnology; and (iv) integrate competition principles into public health policy design through systematic advocacy.

2.5. Consumer Protection

29. The AGCM also applies consumer-protection powers alongside its competition mandate to tackle misleading commercial practices, unfair contract terms and unlawful online sales in the pharmaceutical and health sector. These consumer-oriented interventions became particularly salient during the COVID-19 emergency, when the Authority used

[23] See AGCM opinion No. *AS1536 - CONVENZIONAMENTO DELLE PARAFARMACIE AI FINI DELLA VENDITA DI DISPOSITIVI MEDICI E DI ALIMENTI PER FINI MEDICI*, published in AGCM Bulletin No. 39/2018.

[24] For more information, see sections 1.4 and 2.2.3 of "Annual Report on Competition Policy Developments in Italy - 2024".

[25] See AGCM submission to the December 2025 OECD Roundtable on "Market Studies and Other Market Analysis Tools".

interim measures and its power to suspend websites that promoted unproven antiviral remedies or sold medical products with misleading claims, and significant fines for companies exploiting pandemic fears through deceptive health claims[26].

30. Beyond COVID-era measures, the AGCM has consistently intervened against misleading advertising of health products, unfair commercial practices in online sales by pharmacies, aggressive marketing of medical devices and false claims regarding therapeutic efficacy of food supplements and medical devices[27], with special attention to practices targeting the most vulnerable segments of the population, specifically young people and children, who can fall into the trap of health-related practices spread through social media[28].

31. Overall, the AGCM integrates consumer-protection and competition instruments where appropriate. The Authority's pandemic practice illustrates how consumer protection (removing misleading offers and ensuring truthful information) and competition enforcement (preventing exploitative pricing and ensuring fair procurement) can be deployed in tandem to preserve both market integrity and public health.

3. Beyond Price in Healthcare Markets – Access, Quality, and Equity

32. While price competition is essential, the AGCM recognises that access, quality, and innovation are equally critical, notably in a sector that involves a fundamental value such as health. The Authority's enforcement and advocacy actions have consistently linked economic efficiency to broader social outcomes.

[26] For instance, see AGCM press releases of 27 February 2020 available here and 17 March 2020 available here.

[27] For instance, in October 2025, the Authority launched an investigation into Philip Morris' promotional campaign of its innovative "smoke-free" products (see AGCM press release of 15 October 2025, available here). In February 2024, the AGCM imposed fines of €6 million on British American Tobacco Italia S.p.A. and €1 million on Amazon EU SARL for misleading advertising practices concerning the tobacco-related devices Glo Hyper X2 and Glo Hyper Air. The Authority found that the advertising campaigns failed to provide adequate warnings on the health risks associated with the use of these products, particularly for minors, due to the presence of nicotine in the tobacco consumables. According to the AGCM, the absence of clear and specific health warnings capable of promoting conscious use constituted a seriously misleading practice, as it could induce consumers to purchase products posing potential health risks and whose sale is prohibited to minors. See AGCM Case No. *PS12524 - GLO HYPER X2*, decision No. 31053 of 30 January 2024, published in AGCM Bulletin No. 7/2024. See AGCM press release of 14 February 2024 available here.

[28] In February 2024, the AGCM adopted a decision concerning the so-called "Hot Chip Challenge", a social media phenomenon involving the commercialisation of a highly spicy snack promoted as an online challenge among young consumers. The investigation established that the distributor of the product failed to disclose critical information on health risks, omitted essential safety warnings, and provided incomplete details about the product's composition and intended use. These omissions were deemed likely to mislead consumers, particularly minors, and to encourage unsafe consumption behaviours. To remedy these concerns, the company offered a set of commitments accepted by the AGCM, including the immediate cessation of sales, the discontinuation of all promotional activities on digital and social media platforms, and the removal of the product from online and physical listings. See AGCM Case No. *PS12661 - HOT CHIP CHALLENGE*, decision No. 31067 of 27 February 2024, published in AGCM Bulletin No. 9/2024. See press release of 4 March 2024 available here.

3.1. Promoting Access and Quality

3.1.1. Ensuring Access Through Drug Price Reductions

33. The Leadiant and Aspen cases (see BOX 1 above) reaffirmed the AGCM's commitment to safeguarding patient access and the financial sustainability of the national healthcare system by tackling exploitative pricing in highly concentrated, innovation-driven pharmaceutical markets. In both cases, the Authority's intervention led to a significant reduction in drug prices and substantial savings for the NHS, demonstrating how competition policy can advance not only market efficiency but also equity and public value by ensuring that patients and the healthcare system have access to essential medicines at fair and sustainable prices.

34. The remedies applied in both cases underscored the role of competition enforcement as a complement to sectoral regulation. The AGCM's cease-and-desist orders do not impose specific price mandates, as pricing falls within AIFA's remit. However, the Authority can facilitate regulatory price negotiations subsequently by opening proceedings to monitor compliance with its decisions. Additionally, retroactive price adjustments are incorporated into final agreements where relevant.

35. Building on this enforcement experience, the Authority has advocated for changes in the regulatory framework to address distortions that undermine the negotiation of drug reimbursement prices between AIFA and pharmaceutical companies. Those changes intend to strengthen AIFA's leverage in negotiations, accelerate the conclusion of reimbursement agreements, prevent prolonged negotiation impasses and safeguard patient access.

3.1.2. Product Access Through Generic and Biosimilar Competition

36. The AGCM has consistently acted to remove barriers to generic and biosimilar entry, recognising their importance in reducing healthcare costs and improving patient access[29]. In particular, the Authority has promoted key reforms, including:

- the elimination of administrative restrictions on the registration of equivalent medicines prior to patent expiry (see section 4.1 below on patent linkage);
- therapeutic equivalence recognition in tenders, allowing biosimilars to compete on equal terms (see Box 4 below);
- mandatory use of International Non-Proprietary Names (INNs) in tenders, introduced through 2018 regulatory changes, to foster generic competition; and
- mandatory indication of the generic alternative drug by doctors when prescribing medicines to patients.

37. The AGCM also actively pursues anticompetitive agreements in the pharmaceutical and healthcare sectors, particularly where public procurement and reimbursable medicines are concerned. A notable example is the 2016 case on home-care ventilation and oxygen therapy services, in which sixteen companies coordinated their bids across Milan, as well

[29] See for instance, AGCM opinions: *AS057 - INTRODUZIONE E SVILUPPO SU LARGA SCALA DEI FARMACI GENERICI*, published in AGCM Bulletin No. 41/1995; *AS239 - DURATA DELLA COPERTURA BREVETTUALE COMPLEMENTARE DEI FARMACI*, published in AGCM Bulletin No. 21/2002; AS760 - *PROCEDURE DI AUTORIZZAZIONE PER L'IMMISSIONE IN COMMERCIO DI FARMACI GENERICI*, published in AGCM Bulletin No. 36/2010; AS819, *NUOVE DISPOSIZIONI IN MATERIA DI FARMACI BIOSIMILARI*, published in AGCM Bulletin No. 11/2011.

as the Marche and Campania regions. The Authority imposed €46 million in fines, concluding that the collusive conduct distorted competition, raised costs for the NHS, and undermined fair and efficient tendering processes for essential patient services[30].

Box 4. Competition between biologics and biosimilars in public tenders

The AGCM has long advocated for greater competition in the biologics and biosimilars market, given its significant impact on public healthcare expenditure. The Authority supports a framework based on therapeutic equivalence, appropriately adapted to the specific nature of biological medicines.

Reducing the cost of high-priced treatments, particularly biologics used in hospitals, and improving patient access, require a regulatory framework that facilitates interchangeability and therapeutic comparability among drugs, thereby enhancing competition in public tenders.

Article 15(11-quater) of Decree-Law No. 95/2012 currently restricts competition by prohibiting automatic substitution between biological and biosimilar drugs and by preventing drugs with different active ingredients, even if therapeutically equivalent, from being tendered in the same lot.

While biological compounds differ from chemically synthesised drugs and true equivalence cannot always be established, clinical evidence shows instances of therapeutic overlap among certain biosimilars. Accordingly, the AGCM considers the blanket ban under Article 15(11-quater) unnecessarily restrictive. To foster competition and cost savings while safeguarding patient health, in 2023 the Authority recommended repealing this provision and aligning the treatment of biologics with the general rules on therapeutic equivalence set out in Article 15(11-ter) of the same Decree-Law. [31]

3.1.3. Ensuring Access of Private Healthcare Facilities

38. In Italy, private healthcare facilities can complement public ones in delivering services under the NHS, provided they meet regulatory requirements and obtain the necessary authorisations.

39. The COVID-19 pandemic placed exceptional pressure on the NHS, highlighting the need for reforms that enhance efficiency and balance rising healthcare needs with limited public funding. The AGCM has recommended a more efficient use of public resources, advocating measures to broaden access for private providers, including those offering additional services that are not reimbursed by the NHS. Greater public–private cooperation could help expand healthcare capacity and its geographical reach, and improve service quality without additional fiscal burden.

[30] See AGCM Case No. I792 – *GARE OSSIGENOTERAPIA E VENTILOTERAPIA*, decision No. 26316 of 21 December 2016, published in AGCM Bulletin No. 2/2017. In Milan, companies engaged in bid-rigging through bid suppression, submission of inadmissible offers, and identical bids at the auction's base price. Evidence showed coordinated efforts to pressure the contracting authority to increase auction prices by refusing contract extensions and aligning responses to tender requests. In the Marche Region, companies colluded to abstain from participating in the tender after being consulted on its design, which led the contracting authority to forgo future tenders and extend existing contracts under more favourable conditions. In Campania, the firms jointly sought to delay the tender and later agreed to divide lots among themselves, using cover bids to disguise the allocation.

[31] See AGCM opinion No. AS1893 - *PROPOSTE DI RIFORMA CONCORRENZIALE AI FINI DELLA LEGGE ANNUALE PER IL MERCATO E LA CONCORRENZA ANNO 2023*, published in AGCM Bulletin No. 26/2023.

40. In this perspective, in 2021 the Authority called for initiatives to increase supply and efficiency in healthcare services[32]. First, it recommended removing unnecessary barriers restricting private operators from offering non-contracted services, currently limited by regional assessments of healthcare needs designed for publicly funded care[33]. Second, the authorisation process for private providers wishing to operate under NHS contracts should be selective, transparent, periodic, and non-discriminatory, ensuring fair access through regular regional selection procedures and systematic reviews of existing providers. Finally, to strengthen patient choice and accountability, the AGCM emphasises the importance of greater transparency on provider performance, including financial data, quality indicators, and waiting times across public and private facilities. Making such information publicly available would help steer demand toward more efficient providers, fostering competition based on quality and efficiency within the healthcare system.

41. Law No. 118/2022 partly reflected the AGCM's proposals. It modified the system of NHS accreditation of private providers, establishing the following criteria to be taken into account cumulatively by regional health authorities in charge of the authorisation process: (i) quality and volume of the services to be provided; (ii) results of any activities already carried out; (iii) results of control, supervision and monitoring activities for the evaluation of the activities provided in terms of quality, safety and appropriateness. However, the implementation of this reform has been repeatedly postponed due to difficulties of its application by the Regions, often lacking planning capabilities and resources.

42. Finally, the Authority raised concerns over the criteria used to allocate NHS budgets to accredited private healthcare providers[34]. The AGCM questioned the exclusive reliance on the historical expenditure method adopted by some regions, noting that it discourages competition on quality and innovation among accredited operators and entrenches the position of incumbents. The Authority recommended that budget allocations be based not only on past expenditure but also on objective, performance-based criteria, such as non-discrimination, operational efficiency, and the effective capacity of each provider to meet patient needs.

[32] See AGCM opinion No. AS1730 - *PROPOSTE DI RIFORMA CONCORRENZIALE AI FINI DELLA LEGGE ANNUALE PER IL MERCATO E LA CONCORRENZA ANNO 2021*, published in AGCM Bulletin No. 13/2021.

[33] The AGCM has systematically challenged discretionary criteria in healthcare facility authorisation procedures. For instance, in a case concerning the Puglia Region, the Authority successfully challenged a denial of authorisation for private operators to install diagnostic equipment outside the NHS. See section 3.2 and Box 1 of the written contribution from Italy (Designing publicly funded healthcare markets – Note by Italy) submitted for Item 4 of the 66th OECD Working Party 2 meeting on 26 November 2018.

[34] See section 3.3 and Box 2 of the written contribution from Italy (Designing publicly funded healthcare markets – Note by Italy) submitted for Item 4 of the 66th OECD Working Party 2 meeting on 26 November 2018. See also AGCM more opinion No. AS1916 - *ACCREDITAMENTO E CONVENZIONAMENTO DELLE STRUTTURE SANITARIE PRIVATE*, published in AGCM Bulletin No. 39/2023.

3.1.4. Promoting Quality

43. The above-mentioned Roche/Novartis case highlighted to what extent manipulating perceptions of quality and safety can amount to anticompetitive conduct. The AGCM systematically incorporates quality assessment into its competition analysis, recognising that healthcare outcomes depend not only on efficiency but also on service standards, accessibility, and innovation. In merger review, non-price dimensions such as timely delivery of drugs to retail pharmacies are also considered (see section 2.2 above).

44. In its advocacy activities, the AGCM has also promoted the inclusion of quality-based competition criteria in public procurement, encouraging tender designs that prioritise innovation, long-term efficiency, and patient outcomes rather than lowest-price bidding alone.

3.2. Promoting Equity and Inclusion

45. The AGCM's competition interventions consistently integrate equity considerations. The Aspen case safeguarded access to life-saving drugs for children and elderly patients; hospital merger reviews evaluated the effects on underserved and rural areas; and procurement reforms aimed to prevent "cherry-picking" of profitable services, ensuring a fair distribution of care across all patient groups.

46. The COVID-19 pandemic underscored the importance of coordinated enforcement and advocacy to ensure equitable access to essential healthcare goods and services. In 2020, the AGCM issued guidance on cooperative agreements, allowing temporary collaboration in the distribution of masks and essential medicines strictly limited to arrangements that were objectively necessary, proportionate, and time-bound.

47. The Authority also intervened against national rules excluding para-pharmacies from delivering publicly funded services, highlighting that competition can enhance both geographical and social accessibility (see BOX 2 above). Building on this approach, the AGCM has promoted greater public–private integration in healthcare delivery (see section 3.1.3 above) and recognition of the third sector as a service provider.

4. Competition Risks Across the Pharmaceutical Value Chain

4.1. Interplay Between Competition and Intellectual Property

48. The AGCM's experience confirms the complementary relationship between intellectual property (IP) rights and competition law. Both instruments serve the public interest through different mechanisms: IP protection rewards and encourages innovation, while competition law ensures the spread of innovation, promotes affordability, and prevents the abuse of exclusive rights[35].

49. In assessing the interface between IP and competition, the Authority considers the following factors: the timing and purpose of patent applications, their relationship to genuine innovation, the potential foreclosure effects on competitors, and the resulting impact on consumer welfare. The analysis distinguishes between the legitimate exercise of IP rights, characterised by genuine innovation, proportionate enforcement, and a reasonable period of exclusivity, and abusive conduct, where rights are used strategically to delay entry

[35] See AGCM submission to Item 6 of the 131st OECD Competition committee meeting on 5-7 June 2019, Licensing of IP rights and competition law – Note by Italy.

or obstruct market access. Examples of such conduct include the unjustified filing of defensive or duplicative patents, vexatious litigation, and other forms of regulatory gaming.

50. This analytical framework was central to several cases. As described in Section 2.1, the AGCM examined refusals by Merck and Glaxo to grant licences for the production of active pharmaceutical ingredients (APIs) destined for generic manufacturers in European markets where all relevant patents had already expired[36]. In light of the very specific circumstances of these cases, and considering the peculiarities of the Italian legal framework governing supplementary protection certificates, the Authority found no objective justification for the refusals. In the Merck (2007) case, the AGCM adopted a compulsory licence as an interim measure, subject to the payment of appropriate remuneration, to permit the manufacture of the APIs at issue, given that the refusal was capable of causing serious and irreparable harm to the competitive process[37]. Both investigations ultimately concluded with binding commitments by the parties to grant licences for the APIs concerned.

51. In the Pfizer/Xalatan (2012) decision, the Authority found that Pfizer misused secondary patents and litigation to delay the market entry of generics, constituting an abuse of dominance under Article 102 TFEU. The case showed that the lawful acquisition of a patent does not preclude competition law scrutiny when its exercise serves no innovative purpose and instead aims solely at market foreclosure. A further development occurred in January 2024, when the Italian Supreme Civil Court (Judgment No. 9/2024) confirmed the award of damages to the NHS for the overcharge resulting from this abuse, marking the first time such compensation was granted in Italy following an AGCM antitrust finding.

52. In terms of regulatory developments, the Authority supports flexible application of IP law through mechanisms such as Article 70-bis of the Industrial Property Code (IPC), introduced by Law No. 108/2021, which allows a fast-track procedure for compulsory licensing of patents for essential medicines and devices during national health emergencies. This instrument can complement competition enforcement by preventing artificial scarcity.

53. Another significant legislative development concerns the reform of the patent linkage mechanism, an issue that has long been scrutinised by both European and national competition authorities. Patent linkage refers to regulatory schemes that tie the marketing authorisation, pricing, reimbursement eligibility, or other administrative approvals for a generic medicine to the patent status of the corresponding originator drug. Such mechanisms can delay the market entry of therapeutically equivalent medicines, extend the period of *de facto* exclusivity beyond legitimate patent protection, and increase healthcare expenditure for both citizens and public health systems.

54. Since 2012, the AGCM has consistently advocated for the elimination of patent linkage practices, arguing that they create unjustified regulatory barriers and distort competition between originator and generic manufacturers. These efforts culminated in a legislative reform adopted in 2022 under Article 17 of Law No. 118/2022, which introduced a decisive change to the Italian regulatory framework. The new provision allows

[36] AGCM, Case A363 – Glaxo-Principi Attivi, decision No. 15175 of 8 February 2006, published in Bulletin No. 6/2006; Case A364 – Merck-Principi Attivi, decision No. 16597 of 21 March 2007, published in Bulletin No. 11/2007, together with the licensing agreement. For a more detailed description in English of these two cases, see the AGCM's contributions to the 2014 OECD Roundtable on Generic Pharmaceuticals.

[37] In case of failure to find an economic agreement in relation to the compulsory license, the AGCM envisaged the intervention of an expert appointed by the Authority. See AGCM case A364 Merck Principi Attivi, decision of 15 June 2005.

manufacturers of equivalent medicines to obtain reimbursement classification even while the originator's patent remains in force, ensuring that generics can be immediately reimbursed once the patent expires. This reform significantly shortens the time required for the commercialisation and public reimbursement of generics, thereby enhancing competitive pressure at the moment of market entry and contributing to more sustainable pharmaceutical spending.

4.2. Vertical Integration and Distribution

55. Vertical structures in the pharmaceutical value chain can both enhance efficiency and create exclusionary risks.

56. As discussed in section 2.1, in Roche/Novartis case, the Authority addressed collusion between two originator companies designed to discourage off-label use of a cheaper drug in order to sustain sales of a more expensive alternative. The case underscored the delicate interplay between competition law, pharmacovigilance, and health regulation, highlighting the need for clear boundaries between legitimate scientific communication and coordinated commercial strategies that distort market outcomes.

57. Experience across these and other cases suggests several lessons for enforcement:

- timely intervention is essential to prevent lasting market harm; indeed, in the mentioned Merck case the AGCM adopted interim measures with a view to preserving competition while investigations proceeded;
- coordination with sectoral regulators is crucial to ensure consistency between competition and public health objectives; and
- international cooperation among competition authorities is increasingly necessary in view of the cross-border structure of pharmaceutical markets.

58. The AGCM also applies competition principles to assess co-promotion and co-marketing agreements in the pharmaceutical sector. The Authority examines whether such arrangements unduly coordinate the commercial behaviour of independent undertakings in a manner that appreciably reduces competition on price, quality, or innovation[38].

59. As for merger control, in its QFarma (2024) decision the AGCM assessed the concentration between CEF and Unico, Italy's two largest wholesalers, resulting in the creation of the country's largest pharmaceutical distribution group. The Authority evaluated potential foreclosure of independent pharmacies and the impact on regional supply stability (see section 2.2 above).

[38] See AGCM Case No. I770 - *ARCA/NOVARTIS-ITALFARMACO*, decision No. 25508 of 04 June 2015, published in AGCM Bulletin No. 22/2015, together with the commitments. In this case, the AGCM noted that agreements involving the exchange of commercially sensitive information, close supervision of one party's sales and investment policies by the other, or requirements to achieve and report minimum market shares may restrict competition and must therefore be proportionate to legitimate business objectives. The case, which was closed with commitments, clarified that certain contractual restrictions, such as limited non-compete clauses, can be justified when they are strictly ancillary to protecting the licensor's investments or preventing free-riding by the licensee. More generally, the Authority recognises that a limited reduction in competition between parties to similar cooperation agreements may be acceptable when it is demonstrably necessary to achieve legitimate efficiency or investment goals.

60. Finally, the Authority scrutinises vertical agreements that may restrict price competition downstream or limit parallel trade of medicines[39].

61. The AGCM has also examined vertical restraints in medical device maintenance (see BOX 5 below), clarifying that refusal to supply service software constitutes abuse only if the input is indispensable and non-replicable, thereby protecting both competition and technological innovation. This case shows that the AGCM is well aware of the trade-off between lower prices and accessibility, on the one hand, and the protection of investments in quality and innovation, on the other. The latter represent a key component in the effectiveness of healthcare and should not be unduly frustrated.

Box 5. Refusal to supply in medical devices sector

In the medical devices sector, the AGCM concluded an investigation in March 2021 concerning Siemens Healthcare Srl, Philips SpA, GE Medical Systems Italia SpA and their parent companies[40]. The case addressed an alleged refusal to provide access to maintenance manuals, service software, and spare parts for high-end diagnostic imaging devices. Following a detailed assessment, the Authority ultimately found no abuse of dominant position.

The investigation originated from concerns that the companies, as original equipment manufacturers (OEMs), had limited independent maintenance providers' access to essential inputs, thereby restricting their ability to service "branded" diagnostic imaging equipment. Each OEM offered a basic (or minimum) software package for maintenance, which was available to independent service providers, and an advanced software package reserved for their own technicians or authorised partners. The Authority examined whether the restriction of access to the advanced software constituted an exclusionary practice capable of foreclosing competition in the maintenance market.

In its analysis, the AGCM applied the principles established by the Court of Justice of the European Union (CJEU) in *Magill* and in *IMS Health* on refusals to supply or license intellectual property rights. It endorsed the companies' arguments that the minimum software sets allowed independent service providers to perform basic diagnostic tests and essential maintenance, while granting access to the advanced software would have compromised proprietary technology and infringed IP rights. The Authority also recalled that competition law does not guarantee competitors access to identical inputs or the ability to offer identical quality of service to that of the dominant firm.

[39] For instance, see AGCM case No. I854 - *SOFAR/FORNITURA INTEGRATORI ALIMENTARI*, decision No. 29935 of 03 December 2021, published in AGCM Bulletin No. 50/2021. In May 2021, the Authority opened an investigation following a complaint that SOFAR S.p.A., a probiotic producer, had imposed fixed resale prices for *Enterolactis Plus* and restricted the number of dealers authorised to sell it online. To address these concerns, SOFAR offered commitments, subsequently made binding, undertaking not to impose minimum resale prices, not to restrict online sales, and to inform its distributors of these obligations in writing.

[40] See AGCM Case No. A517 - *MERCATI DI MANUTENZIONE DI DISPOSITIVI DIAGNOSTICI*, decision No. 28620 of 30 March 2021, published in AGCM Bulletin No. 21/2021.

Based on available evidence, the AGCM found that access to the advanced service software was not "indispensable" for independent providers to operate effectively, as the relevant functionalities could be replicated or substituted through alternative technical solutions. The Authority therefore concluded that the OEMs' conduct did not amount to an abuse of dominance. Moreover, it recognised that limiting access to the advanced software could be justified by legitimate considerations related to product safety, innovation, and the protection of intellectual property in the development of diagnostic technologies.

5. Final remarks

62. The AGCM's long-standing experience in enforcing competition law in the healthcare and pharmaceutical sectors confirms that competitive markets are essential to ensuring affordability, innovation, and the long-term sustainability of healthcare systems. Over the years, the Authority's interventions have prevented and sanctioned practices that would have resulted not only in unjustified price increases—thereby reducing accessibility for patients and increasing the financial burden on the National Health Service (NHS), particularly to the detriment of the most vulnerable groups—but also in a decline in quality and in the erosion of incentives to innovate. These aspects are particularly critical in the healthcare sector, where innovation and quality of care directly affect public health outcomes.

63. The AGCM is fully aware of the distinctive nature of the healthcare sector, where the objectives of competition policy must coexist with the overarching goals of public health. The COVID-19 crisis has clearly demonstrated that health is not merely a private good but also a collective value with profound social and economic implications. In this context, ensuring access to healthcare for vulnerable groups must be balanced with preserving adequate incentives for investment in quality, research, and innovation. For this reason, the AGCM considers healthcare a strategic priority and operates in close coordination with policymakers and sectoral regulators. Its objective is to make competition a tool to enhance the spread, efficiency, and accessibility of healthcare services whenever this is both possible and appropriate.

64. Looking ahead, the AGCM will continue to strengthen its cooperation with national regulators and public institutions to improve transparency and efficiency in public procurement, which represents a significant portion of overall healthcare expenditure. Over the years, the Authority has developed extensive expertise in this field, and its cases in the healthcare sector have shown that there is still room for improvement in terms of transparency, proportionality, and openness of tender requirements. In particular, certain technical or economic criteria used in procurement have been found to be excessively restrictive, potentially limiting the participation of producers of generic and bioequivalent medicines, and the fragmentation of competences among contracting authorities remains an area requiring better coordination. In this respect, several AGCM initiatives have proven effective in preventing anticompetitive or collusive behaviours that could have imposed excessive or unjustified costs on the NHS. Furthermore, the Authority's decisions have, in some cases, led to the recovery of damages suffered by the public healthcare system, demonstrating that the complementarity between public and private enforcement can serve as a powerful deterrent against unlawful conduct.

65. Active engagement in international fora will also remain a central component of the AGCM's strategy. International cooperation is essential not only for identifying and addressing cross-border infringements, such as excessive pricing, and regulatory gaming, but also for understanding business strategies that may appear local in scope but have global reach, as illustrated by the Aspen case. International collaboration helps ensure coordinated and proportionate enforcement, while also enabling the exchange of knowledge and experience on emerging trends and technologies. This dialogue is particularly relevant in the context of the ongoing digital transformation of healthcare, which offers significant opportunities for innovation and improved services, but also introduces new risks and challenges for system sustainability and security. In this evolving context, competition authorities must work together to align competition enforcement with broader health policy objectives, with the ultimate goal of protecting consumers, fostering innovation, and supporting the development of resilient, inclusive, and high-quality healthcare systems.

66. Leveraging its power to review below-threshold mergers, the AGCM will also intensify its scrutiny of mergers and strategic partnerships in the digital health and biotechnology sectors. This power is increasingly important to detect and prevent so-called "killer acquisitions," whereby incumbent firms acquire innovative start-ups to suppress potential competition and hinder technological progress.

67. The Italian Competition Authority will continue to devote significant attention and resources to the healthcare and pharmaceutical sectors, reaffirming its conviction that careful and balanced competition enforcement and advocacy are powerful instruments for promoting equitable access to medicines and high-quality healthcare services for all citizens.