Manual

Manual for

Competition compliance and health sector

UN trade & development

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Note

The project “Fostering competition law and policy and competition culture in Albania” aims to strengthen the effective implementation of competition law and promote a culture of compliance among public institutions and private sector stakeholders in Albania. Implemented by UNCTAD in cooperation with the Albanian Competition Authority, the initiative contributes to enhancing market efficiency, consumer welfare, and sustainable economic development.

A key component of the project is capacity-building and advocacy, including the organization of specialized training activities for judges and public officials, and awareness-raising activities targeting the business community.

As part of its advocacy and outreach efforts, the project has developed sector-specific competition compliance manuals for the telecommunications and health sectors, as well as for business associations. These manuals provide practical guidance to companies on identifying and preventing anti-competitive conduct, implementing internal compliance programmes, and aligning business practices with national and international standards.

The manuals are the result of over 30 interviews with Albanian stakeholders, including representatives from public institutions, business associations, and private enterprises, lawyers and academics ensuring that the recommendations reflect the specific realities and challenges of each sector.

AUTORITETI I
KONKURRENCËS

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More information on the project is available at https://unctad.org/project/fostering-competition-law-and-policy-and-competition-culture-albania. (email: ccpb@unctad.org)

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Foreword

This guide provides practical advice for businesses on how to implement effective competition compliance programs, with a specific focus on the health sector. It provides practical recommendations tailored to companies present in the health sector, namely the hospitals services and the pharmaceutical distribution, on how to prevent and detect competition infringements.

!? Common misconceptions about competition compliance

- “Are we really concerned by competition law? We provide a public interest service and some of our prices are regulated”
- “Are we obliged by law to design and implement a compliance program? It is costly and takes time”
- “Is it worth? In my opinion, there is no anticompetitive behaviour in our sector”

But…

Why compliance still matterse

- “Pharma distributors and hospitals can be held liable for anticompetitive conduct even if they comply with health and pharma-specific regulations”
- “Investors, business partners, exporters and manufacturers ask questions about the measures we have implemented to prevent competition and other infringements”
- “Other companies in the pharmaceutical and hospital sectors have been sanctioned in the European Union, and in Albania these markets are subject to close scrutiny by the Albanian Competition Authority”.

Companies active in the pharmaceutical and hospital sectors do not have a legal obligation to design and implement a competition compliance program, but have an interest in doing so:

- A strong compliance program helps building trust with investors, business partners, exporters, manufacturers and regulators.
- It has a positive impact on your reputation and, therefore, on clients' and patients' retention.
- It enhances your ability to attract talent – staff feels more committed to companies that have values, such as respecting a competition level playing field, and act accordingly.
- The consequences of an infringement of competition law can be very costly (high fines, civil damages, etc.) and, yes, regulated companies serving a public interest, such as health, can also be held liable for competition law infringements.
- It ensures understanding of a company's risk landscape for informed business decisions;
- It guarantees that all departments apply competition rules consistently and coherently.

1. What is competition law?

Competition law protects the competitive process (i.e. a fair level playing field). It is not about protecting specific companies or specific competitors.

By protecting the competitive process, competition rules maximise consumer welfare, this means:

- **Lower prices for all**: Companies generally aim at profit maximization, and can sell more goods by lowering prices.
- **Better quality:** Businesses can attract more customers and expand their market share, by improving their quality of goods and services. Quality can mean various things: products that last longer or work better, better after-sales or technical support, or also or friendlier and better service.
- **More choices**: In a competitive market, businesses will try to make their products stand out from the rest. This results in greater choice for customers, which allows them to select the product that offers the right balance between price and quality.
- **Innovation**: To produce new and better products, businesses need to be innovative in their product concepts, design, production techniques, and services, among other things.

- **Better competitors in global markets:** Competition within national markets also helps make national companies stronger outside the country — and able to hold their own against global competitors.

In Albania, competition is regulated by Law no. 9121, the Albanian Competition Law, first adopted in 2003 and last amended in 2010. This framework aligns with international and European Union competition law principles, aiming to promote market efficiency and protect consumer welfare.

Under competition law there are different types of infringements:

1.1 Restrictive horizontal agreements – illegal relations with competitors

Agreements between two or more competitors (real or potential) are prohibited when their purpose or effect is to restrict competition. As a general rule, the following agreements between competitors are considered to have such purpose or effect:

- Price fixing or setting harmful commercial conditions.
- Market sharing (products, customers, or geographic zones) or sources of supply.
- Limiting production, capacities, investments, or technical progress.
- Boycotting a supplier, customer, or business partner.

For competition purposes, the term “agreement” is very broad. It includes not only a formal written agreement (for example, a contract or letter of intent), but also an oral declaration of intentions, a verbal agreement, gentlemen’s agreements, a tacit agreement (for example, exchange of opinions or information), or uniform and conclusive conduct by two or more parties.

1.2 Restrictive vertical agreements – relations with distributors, suppliers and manufacturers

Vertical agreements are arrangements between companies operating at different stages of the production, distribution, or supply chain—such as manufacturers and retailers, or suppliers and distributors.

Not all vertical agreements are illegal—only the ones that seek to restrain competition are problematic. Therefore, the assessment of pro-competitive and anti-competitive effects of vertical agreements is complex and must be done on a case-by-case basis.

In general, vertical agreements where the supplier’s and buyer’s market share exceed 30 per cent may be considered harmful and should be carefully assessed. Moreover, competition law prohibits vertical relations involving hard-core restrictions, such as:

- **Resale price maintenance** - when working with distributors or other third-party retailers, competition laws generally prohibit companies from fixing resale prices for their products or services to end customers. Maximum or recommended prices are permitted.
- **Restrictions on sales to certain customers or in specific territories** - in general, and with some exceptions, competition rules prohibit suppliers from imposing restrictions on the customers or territories where a distributor can resell their products.
- **Preventing effective use of the Internet** - In general, and with some narrow exceptions, competition law does not permit the supplier to prevent the effective use of the Internet by the buyer or its customers for selling the acquired goods or services.

1.3 Abuse of dominant position

Competition law also prevents companies that have a dominant position in a relevant market from engaging in practices that can distort competition.

A company holds a dominant position when it can significantly influence market conditions — such as prices, output, or innovation — without needing to align its behaviour with what other market players do. The existence of a dominant position derives from a combination of several factors that, taken separately, are not necessarily determinative:

- **The existence of large market shares**. In particular, this is the case where an undertaking business or other actor holds a market share of 40 per cent or above.1
- **The existence of barriers to market expansion and entry** that prevent competitors from expanding their activities in the market or that prevent potential competitors from entering the market.2 Barriers to expansion and entry may consist, for example on the existence of tariffs or quotas, sector-specific regulations, licensing requirements, authorisation requirements, intellectual property rights, an established distribution and sales network, economies of scale and scope, vertical integration, access to critical raw materials or high sunk costs.

[1] Guideline on the applicability of articles 8 and 9 of Law 9121 dated 23.07.2003 «On the Protection of Competition»; Guidance on the Commission's enforcement priorities in the application of Article 82 of the EU Treaty to abusive conduct by dominant undertakings (2009/C 45/02) (OJ C 45, 24.2.2009, p. 7–20). Available at: https://caa.gov.al/wp-content/uploads/2023/05/Udhezimi_per_poziten_dominuese.pdf

[2] Judgment of 14 February 1978, United Brands and United Brands Continental v Commission, Case 27/76, EU:C:1978:22, paragraphs 122 and 124; judgment of 13 February 1979, Hoffmann-La Roche v Commission, Case 85/76, EU:C:1979:36, paragraph.

- **Customers with countervailing buyer power.** Countervailing buyer power can prevent even an undertaking with a high market share from acting to an appreciable extent independently of customers.

Having a dominant position is not illegal under competition law. However, when a company uses that position to eliminate competition, exploit customers, or prevent others from entering the market, it is considered abusive. This can manifest is several ways:

- **Excessive or predatory pricing:** A company may set unreasonably high prices to extract significant profits unjustly. Alternatively, it might set prices very low to drive competitors out of the market (known as predatory pricing), intending to raise prices once competition is weakened or eliminated.
- **Exclusive dealing and loyalty rebates:** Dominant firms might tie customers to exclusive deals or offer rebates conditional on buyers purchasing exclusively or primarily from them. This practice can limit the ability of competitors to access the market.
- **Refusal to supply:** A dominant company could refuse to supply essential products or services to competitors, or sell them at unfairly high rates.
- **Tying and bundling:** This involves forcing buyers to purchase a non-core product when buying a core product.
- **Limiting production or development:** A dominant firm may limit production, supply, or technical development to gain an advantage, affecting innovation and consumer choice adversely.

2. What is compliance?

Compliance encompasses all actions taken by a company around three fundamental axes:

- **Prevention**. involves all initiatives aimed at establishing clear policies and building awareness and compliance culture inside an organization to deter potential violations before they occur.
- **Detection**. The “risk zero” does not exist and violations may still occur despite prevention effort. Compliance will, therefore, also focus on detecting any wrongdoing.
- **Remediation**. Compliance must also serve to correct identified problems, refine policies, and take action to minimise harmful impact.

For many companies, compliance goes beyond respect for the law, it includes also a commitment to business ethics, integrity and sustainability.

According to best practices, competition authority guidelines, and international standards, an effective compliance program should include several key elements. However, there is no one-size-fits-all approach; a compliance program designed for one company may not be effective if simply implemented in another. A compliance program must be tailored over time to the specific context and particular compliance risks of the organization. Therefore, the first step in creating and implementing a context specific program is to use a risk assessment.

The elements of a compliance program are the following[3]:

- **Risk assessment.** A firm should identify and evaluate its compliance risks by considering their likelihood and potential impact on the company's activities. Risk assessments should be reviewed regularly, especially when a company enters a new market. Companies must prioritize risks, determine appropriate treatment actions (mitigation, acceptance, avoidance, transfer) and assign responsibility to units and individuals. This approach enables the organization to allocate resources effectively, address specific vulnerabilities, and implement targeted measures.
- **Positive tone at the top.** Effective compliance programs require clear and visible support from the company's leadership—including the President, Board of Directors and Chief Executive Officer. The commitment of resources to a compliance program, such as a dedicated and empowered compliance officer in larger firms, exemplifies this commitment. When leadership shows its support, it reinforces the importance of compliance and encourages employees to adhere to established policies and practices
- **Clear policies and controls.** The company must put in place guidelines and directives on how to conduct business processes and manage relations with stakeholders (including clients, competitors, suppliers and distributors) to avoid violations of competition law and unethical behaviour.
- **Training and communication.** Mandatory compliance training is a critical component of any effective compliance program. Compliance training should be required for all staff in positions with identified risks, as well as part of new employee training process. The training content must be adapted to reflect the company's unique risk profile. In addition to training, the company and its leadership should communicate regularly on the company's commitment towards compliance engage in zero tolerance for any of competition law violations. Compliance with competition law can sometimes be complex, and companies often designate a contact person through whom staff can raise concerns or questions regarding the alignment of business decisions and practices with competition regulations.

[3] OECD (2021), Competition Compliance Programmes, OECD Competition Committee Discussion Paper. Available at: http://oe.cd/ccp

- **Whistleblowing channel.** The company should create a whistleblowing channel where staff and other stakeholders can confidentially report suspicions of competition law infringements. Under this program, people who report potential violations must be protected from retaliation.
- **Disciplinary regime.** The organisation must establish a set of rules, procedures, and sanctions for misconduct. Disciplinary measures to address violations of compliance policies must be consistently enforced.
- **Auditing and evaluation.** A commitment to continuous improvement should be central to the compliance program. Regular monitoring is essential to ensure the program remains current, effective, and aligned with its core objectives, which should also be regularly evaluated. Program effectiveness can be assessed through surveys, training evaluations, and interviews with key personnel to gauge their knowledge and attitudes toward compliance and illegal conduct.

3. Why should pharmaceutical companies and hospitals have a compliance program?

The benefits of designing and implementing a competition compliance program for pharmaceutical companies are as follows.

- **Building and maintaining trust with investors and business partners.** A strong compliance framework demonstrates the company's commitment to ethical business practices and adherence to competition law, reducing the risk of legal penalties and reputational damage. This proactive approach reassures investors and business partners that the company is managing risks effectively, which fosters confidence in the company's stability and long-term viability. A proven track record of compliance can enhance the company's credibility in the financial markets, attracting further investment. Similarly, it can be a catalyser to attracting business partnerships. Pharmaceutical originators and manufacturers relying on pharmaceutical wholesalers for distributing its products in Albania also pay attention to how the latter manage compliance risks that could ultimately damage their brand name.
- **Building a strong reputation.** Building a competition compliance program significantly enhances the company's reputation by demonstrating a commitment to ethical and fair business practices. This creates trust among customers, who are more likely to stay loyal to a brand that is perceived as transparent and responsible. Failure to comply with competition law can have particularly severe consequences in the healthcare sector, given its role in serving the public interest and its significant reliance on taxpayers' money.

- **Building trust with the public authorities.** Companies in the health sector regularly interact with public authorities, namely the Ministry of Health in relation to price regulation and service standards. A strong commitment to competition compliance to prevent potential competition law infringements, including anticompetitive pricing behaviour or unfair trading conditions, helps to build and maintain a trustworthy relationship with the public authorities. This can lead to more constructive engagement.

The consequences of non-compliance with competition law can be very costly.

- **Fines** of up to 10 per cent of the annual turnover in the previous financial year.

Example of pharmaceutical wholesalers being fined for an anti-competitive conduct

In September 2015, the Hungarian Competition Authority (GVH) imposed fines totalling approximately HUF 2.5 billion (around €8 million) on three pharmaceutical wholesalers and two consulting firms for engaging in a cartel that manipulated a public procurement process for the supply of medicines to hospitals in Budapest.

The GVH investigation found that the companies colluded in connection with a large public tender launched in November 2011 for supplying medicines to 12 metropolitan hospitals. The anti-competitive conduct consisted of bid rigging, a serious infringement of competition law.

Specifically, the wholesalers coordinated to manipulate the tender requirements so that only their companies could meet the conditions, effectively excluding other potential competitors. In addition, before submitting bids, the companiesexchanged confidential pricing information, aligned offers based on each other's intentions, and agreed to divide the supply of 919 active pharmaceutical ingredients among themselves. Two consulting firms facilitated and organised this collusion.

- **Sanctions** on individuals up to 5 million lek [4]
- **Civil damages for anti-competitive conduct**. Any person or company affected by the anti-competitive conduct can claim damages before the competent court to members of the trade association and to the association itself.

Example of private hospitals being fined for an anti-competitive conduct

In July 2022, the Portuguese Competition Authority (AdC) imposed fines totalling approximately €190 million on five major private hospital groups and their trade association for engaging in concerted practices that restricted competition in negotiations with the ADSE, Portugal's public health subsystem for civil servants.

The AdC's investigation found that the hospitals, through their association — the Portuguese Association of Private Hospitals (APHP) — colluded between 2014 and 2019 to coordinate their commercial strategy when negotiating prices and conditions with ADSE. This conduct amounted to a serious infringement of competition law.

Specifically, the hospital groups and the APHP shared commercially sensitive information and aligned their negotiating positions, effectively eliminating their freedom to negotiate individually with ADSE. They also collectively threatened to terminate or suspend contracts if ADSE did not meet their demands, using their coordinated market power to put pressure on the public health system.

Sources: Hungarian Competition Authority, Case Vj/28/2013.
https://www.gvh.hu/pfile/file?path=/en/press_room/press_releases/press-releases-documents/press_releases_2015/sk_28_2013_lezart_gyogyszer_kartell_a&inline=true
Portuguese Competition Authority, Case PRC/2019/2.
https://extranet.concorrencia.pt/PesquisAdC/PRC_OR_INC_OR_PCC_Page.aspx?Ref=PRC_2019_2&isEnglish=True

[4] According to Article 78 of the Albanian Competition Law the Commission may impose fines on individuals not exceeding 5 million lek on individuals, if they, intentionally or negligently, carry out or co-operate to carry out actions sanctioned in accordance with article 73, paragraph 1 and article 74, paragraph 1.

4. What is ACA's policy regarding compliance programs?

The Albanian Competition Authority (ACA) views the adoption of competition compliance programs by businesses positively. Reflecting a broader trend among European Union competition authorities, the ACA issued guidelines in 2017 encouraging companies to develop robust competition compliance programs. The 2017 guidelines offer numerous practical tips for designing and implementing effective compliance measures. The present guide complements ACA's 2017 compliance guidelines by providing further practical tips on how to tailor compliance programs to business associations most common competition risks.

The ACA does not offer immunity or fines reductions solely for adopting of compliance programs as may be the case in other jurisdictions. Instead, it believes that the reward for a well-implemented compliance program is the early detection of anti-competitive conduct and the possibility for companies to leverage the leniency program to obtain immunity or reduced fines. This approach aligns with the policy adopted by the European Commission.

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LINIENCY PROGRAM:

WHO, WHY, WHAT, HOW

Who can apply for leniency

- Companies operating in the market that are part of anticompetitive agreements

Why apply for leniency

- Inmunity from hine - first applicant and not a leader of the cartel
- Reduction of fines (50% to 20%)

What is required to apply for liniency

- Application before the investigation initiated
- Commission deso not have sufficient data
- Immediately make the evidence available

How to apply for leniency

- Via the form www.caa.gov.al
- Email us: competition@caa.gov.al
- Call us : +355 4 22 34 504

Source : https://caa.gov.al/wp-content/uploads/2023/06/Fine_Leniency_Programme.pdf

5. What are the competition compliance risks in the health sector?

5.1 Competitive dynamics in the health sector

For the purposes of these guidelines, Albania's health sector encompasses hospital services and pharmaceutical products.

Most hospitals in Albania belong to the public healthcare system. There are 413 public healthcare clinics and 42 public hospitals. The number of private healthcare services has grown over the last decade. There are 13 private hospitals, as well as dozens of private multi-disciplinary diagnostic clinics and laboratories, mostly located in urban areas.5

Prices in public hospitals are regulated by law and private hospitals set their prices freely. Private hospitals must compete with public hospitals in terms of quality and variety of services. Albania's hospital services market present high barriers to entry due to strict licensing requirements, costly investments in facilities and advanced medical equipment, and special rights for certain services such as dialysis.

Regarding pharmaceutical products, Albania imports all medical equipment and devices, and around 90 per cent of its medicines.6 There is only one major Albanian manufacturer of generic drugs, which sells most of its products in the country, and there is no originator company (i.e., a pharmaceutical company that develops and brings a new drug to market). Pharmaceutical products are distributed in Albania through wholesalers, who purchase and import from manufacturers and sell to pharmacies and hospitals. Sales to hospitals are organised through public tenders.

The major barrier to entry in the pharmaceutical distribution market is the authorisation license necessary to sell pharmaceutical products in Albania. Other barriers include investments in developing the distribution network (warehouses, distribution centres, transportation, inventory, etc.)

The pharmaceutical distribution market in Albania comprises more than 20 wholesalers, with around five major players holding significant market shares.7 All wholesalers must hold a valid distribution licence from the Ministry of Health to operate and supply medicines to pharmacies and hospitals.

5 Available at: https://www.trade.gov/healthcare-resource-guide-albania

6 ibid

7 ibid

Prices for medicines are regulated in Albania by a Decision of the Council of Ministers.8 Price regulation consists of maximum margins set at the three levels of the supply chain:

1. The maximum margin for the manufacturer or importer (primary wholesaler)
2. The maximum margin for the distributor (secondary wholesaler)
3. The maximum margin for the pharmacy, but the retail price in the pharmacies for each medicine is fixed.

Maximum level of margins ensures that, while companies can compete by offering lower prices or lower margins within the allowed thresholds, they cannot exceed the statutory ceiling that protects patients from excessive prices.

Each branded medicine typically has an exclusive distribution agreement with a single importer or wholesaler. In the case of generic products, wholesalers distributing different brands compete with one another to supply pharmacies and hospitals within the same therapeutic category. For patented products, there is usually only one wholesaler authorised to distribute the product nationwide. In general, wholesalers handle a portfolio of products that includes both generic and patented brands, and the scope and breadth of this catalogue can serve as a competitive factor.

In 2018, the ACA launched a sector Inquiry in the hospital services market,9 which resulted in recommendations to the Ministry of Health to seek ACA's opinion regarding draft laws affecting market access, exclusive rights, or uniform pricing practices for hospital services. It also advised the Compulsory Health Insurance Fund (FSDKSH) to ensure fair distribution of service packages among private hospitals. The ACA has also investigated the pharmaceutical market between 2020-202110 and recommended to replace the price regulation based on fixed margins by prices set based on maximum margins.

5.2 Competition compliance risks for pharmaceutical market

There are several wholesalers operating in the market and, although they are granted exclusivity to distribute specific brands, they still compete the distribution of different branded generic products within the same therapeutic category. None of the wholesalers appears to hold significant market power in the market for generic medicines. However, for patented drugs, exclusive wholesalers may hold a monopoly position within a specific therapeutic segment.

[8] Available at: https://gcca.gov.ge/uploads_script/publications/tmp/8513d5729ffb4ae891031e5670979865.pdf

[9] ibid

[10] Available at: https://caa.gov.al/wp-content/uploads/2023/05/Vendim_nr._707_dat_23.09.2020.pdf

Even though drug prices are regulated, wholesalers can still compete by offering lower margins within the limits set by law. As a result, pharmaceutical wholesalers may still face risks of coordinating their behaviour — for example, by agreeing not to undercut each other — which would reduce or eliminate price competition despite the regulatory framework. Other types of anti-competitive coordination could also take place among pharmaceutical wholesalers.

Primary wholesalers maintain vertical commercial relationships with secondary wholesalers and should exercise vigilance regarding any conditions or clauses imposed on these entities that may be deemed anti-competitive. For example, a resale price maintenance (RPM) clause that obliges secondary wholesalers to set a fixed margin when selling medicines to pharmacies and hospitals.

In particular, wholesalers could inadvertently or deliberately breach competition law in several ways. The most common include:

- **Price fixing:** Firms may agree on margins below the cap or not to undercut each other below the maximum margin, keeping prices as close as possible to the legal ceiling. This prevents competitive discounting that would otherwise reduce their profit margins.
- **Market/customer allocation:** companies may collude to divide customers, territories, or product lines, reducing rivalry and protecting market shares
- **Bid rigging in public procurement for hospitals:** wholesalers may be tempted to agree in advance who will win tenders and at what prices (still within the allowed cap). This guarantees predictable profits and limits the risks of competitive bidding.
- **Information sharing.** Sharing sensitive information (like future pricing or bidding strategies) helps companies coordinate behaviour, maximise revenues, and limit competitive pressures.
- **Abusive tying or bundling in relation to patented medicines:** By tying or bundling the distribution of patented products — for which a wholesaler holds a monopoly position — with the distribution of other generic products limiting competition in the generic segment, where multiple wholesalers should normally compete
- **Vertical restrictions,** like resale price maintenance or limits on sales to certain customers or territories, can restrict competition by preventing secondary wholesalers or pharmacies from setting their own prices or choosing their clients freely. This reduces price competition, limits market access, and can keep prices artificially high.

5.3 Competition compliance risks for hospitals

Private hospitals in Albania face price competition and may have an incentive to coordinate their pricing practices to maintain prices at high levels. However, competition from public hospitals — whose service prices are regulated by law — can provide a significant competitive constraint that helps to discipline private providers' pricing behaviour.

As noted, private hospitals tend to compete more on the quality and range of services offered rather than on price alone. This means that coordination on non-price factors should not be overlooked.

Additionally, the granting of exclusive rights or concessions for certain healthcare services may create market power for private providers. This market position carries a risk of abuse, such as imposing unfair market conditions on patients.

In particular, private hospitals could inadvertently or deliberately breach competition law in several ways, such as:

- **Market/customer allocation:** Private hospitals could divide the market geographically or by specialisation — agreeing not to compete for certain patients or types of services to avoid rivalry among them.
- **Coordination on non-price elements:** Private hospitals might collude on service quality or technological investments — for example, agreeing not to introduce certain new services to maintain the status quo or restrict patient choice.
- **Abuse of dominance.** Private hospitals holding exclusive rights or concessions for certain services (e.g., dialysis) could exploit this by imposing unfair conditions such as excessive prices.

6. How can pharmaceutical wholesalers and private hospitals mitigate competition compliance risks?

To prevent competition risks, pharmaceutical distributors and private hospitals should focus on fostering a compliance culture of zero tolerance toward anti-competitive conduct and establish clear rules to embed that culture within the company. This guide offers some recommendations for mitigation actions and controls that pharmaceutical distributors and private hospitals could adopt. As mentioned above, there is no "one-size fits all" in compliance, therefore, each company should carefully assess its own context and governance structure in order to adapt these recommendations to suit its unique circumstances:

- ✓ Adopt a **code of conduct** or **competition statement** where the leadership of the company commits to a zero-tolerance policy against anti-competitive conduct.
- ✓ Set-up a **communications strategy** of the zero-tolerance commitment against anti-competitive conduct. For example, by communicating it at strategic business meetings, team building or townhall-type events.
- ✓ Adopt a **competition compliance manual** that clearly sets and explains the internal rules, controls, and procedures to prevent anti-competitive conduct. The manual should set a general statement prohibiting:
  - Coordination of competitive behaviour,
  - Exchange of sensitive commercial information with competitors,
  - Abusive pricing strategies to exclude competitors or exploit patients.
  - Anti-competitive vertical restrictions.
- ✓ Establish internal rules and procedure to prevent anti-competitive agreements or tacit collusion such as **price fixing, coordination on non-price elements** or **sharing of commercially sensitive information**.
  - Implement rules for participating in trade associations, sector-specific events, working groups, business partnerships, and formal or informal meetings where staff may be in contact with your competitor:
    - The competition compliance or legal team should conduct due diligence on trade associations or working groups before joining to ensure that these structures implement adequate competition compliance systems.

- Only staff that have completed competition compliance training may be allowed to represent the company in such meetings.
- For any key meetings, the competition compliance or legal teams should review the agenda to make sure that topics are legitimate and prohibit participation if this is not the case.
- Establish clear rules on communications and on topics that can and cannot be discussed. Prohibited topics may include: (i) current or future prices, margins, pricing strategies;(ii) customer allocation, market shares, or territories; (iii) commercial terms; (iv) quality standards and (iv) technology and innovation strategies.
- Set up a protocol in case prohibited topics are discussed. Request staff to:
  - Immediately object to the discussion.
  - Exit the meeting and ask for this objection and end of the meeting to be recorded in the minutes of the meeting.
  - Report the incident to the competition compliance or legal team without delay.
- Keep internal records of all attended meetings with competitors, including the agenda, a list of the participants, and key discussion points.
- Review or retain official minutes where available, and request corrections if needed.
- For informal contacts, establish a clear prohibition against any "off-the-record" discussions involving commercially sensitive topics.

✓ Establish clear rules on how to act when participating in **public procurement** to prevent bid rigging

- Never discuss bid prices, strategies, or tender conditions with other bidders — directly or indirectly.
- Do not agree with any competitor to submit or withdraw a bid, submit cover bids, rotate winning contracts, or divide markets or customers.
- Never share sensitive information (e.g., cost structures, pricing, planned bids, or margins) with other bidders.
- Keep all bid-related information strictly confidential and restrict access to those with a legitimate need-to-know.
- Joint bidding or consortium arrangements must be:

- Approved in advance by competition compliance or legal team.
- Based on objective and legitimate reasons (capacity, technology)

  - Conduct careful due diligence of joint bidders, consortium partners, consultants, or agents involved in tenders.
  - Require management sign-off for all final bids to ensure compliance checks are performed.
  - To the extent possible, ensure different individuals handle tender preparation, pricing, approval, and submission.
  - Maintain records of all tender processes, approvals, and communications.

✓ Establish internal rules and procedures to **prevent anticompetitive tying or bundling** of patented and generic drugs by wholesalers.

  - Require competition compliance or legal team to review and approve all distribution agreements and sales conditions involving patented products.
  - Include a mandatory antitrust compliance check for any rebate schemes, discounts, or conditional sales that could amount to bundling.

✓ Establish internal rules and procedures regarding the conditions for **hospital services under exclusive rights or concession**:

  - Implement a documented pricing procedure for services covered by exclusive rights or concessions.
  - Require competition compliance and legal team to review prices of services covered by exclusive rights or concessions. In particular, whether they are objectively justified, cost-based, and similar to prices charged for comparable services in other regions or by other providers
  - Significant price changes must be reviewed by competition compliance and legal team and be supported by clear, documented business justifications.

✓ Pharmaceutical wholesalers should implement measures to prevent **anti-competitive vertical restrictions**:

  - Establish standard templates for vertical agreements with pharmacies and secondary wholesalers approved by the competition compliance and legal team.

- Any deviations from standard templates should be reviewed by the competition compliance and legal team.
- Commercial teams must be trained to respect the freedom of wholesalers to set their own margins and choose their own clients. Any recommended margin must be clearly labelled as non-binding.
- Conduct audits to verify that no instructions or incentives are given to enforce minimum/maximum or recommended margins or unjustified sales restrictions.

✓ Design and implement a **competition compliance training plan** consisting of:

- Mandatory annual training for all employees (legal, commercial, regulatory, strategy, pricing, marketing, and product development) on the fundamentals of competition with a focus on key risks in the health sector, as well as the dos and don'ts in interactions with competitors and other business strategies.
- Targeted training modules by function, for example
  - Employees involved in tenders should receive specific training on how to prevent bid rigging.
  - Sales and account managers should receive training on how to recognise what constitutes illegal tying or bundling.
- Briefings for any trade association or working groups participation to discuss acceptable conduct, prohibited topics, and what to do if sensitive issues are raised and discussed.
- Onboarding training activities for new employees should include an introduction to the company's competition compliance manual and core competition risks in the pharmaceutical and hospitals sector.

✓ Set up a whistleblowing channel for reporting suspicious patterns:

- Adopt a whistleblowing policy containing at least:
  - The purpose and scope of the whistleblowing channel, including the type of reportable issues (e.g. anti-competitive conduct) and,
  - The rights and protections offered to whistleblowers, including confidentiality, anonymous reporting, and anti-retaliation measures.

- Set up a secure, confidential, and accessible tool that enables the submission of anonymous or identified reports.
- Offer alternative reporting channels: telephone, e-mail, physical mailbox, and in-person reporting.
- Communicate about the whistleblowing channel and whistleblower protection policy to all employees (and possibly external stakeholders such as pharmacies and patients)
- Set up the roles and responsibilities for the handling and follow-up of reports.

7. Consumer Protection and Competition Compliance

Competition law and consumer protection reinforce one another. In markets, where there is effective competition, companies have incentives to align with consumer protection objectives, for example, to attract customers/patients away from rivals they are likely to provide the necessary information to reduce switching costs.

At the same time, when consumers are able to exercise their choices effectively, they can act as a competitive discipline upon companies active in the market. In some jurisdictions, like Spain, competition laws include consumer protection aspects, and it is not uncommon for companies to include consumer protection as part of their competition compliance programs.

Compliance should not operate in silos. Many of the initiatives, actions, and procedures outlined above can be leveraged to address consumer protection concerns. For example, when setting prices for services covered by special rights or concession, hospitals should not only pay attention to not offer them at excessive prices but also respect patients right to have access to essential services, such as health.

Training programs can be designed to cover both compliance and consumer protection topics, ensuring a cohesive understanding across teams.