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**Quality Control Systems in the Generic Pharmaceutical
Industry and Their Role in Enhancing Consumer Trust
Case study of the SAIDAL Group (Dar El-Beida Unit)**

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LIST OF ABBREVIATIONS :

Abbreviation	Meaning
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
IMPD	Investigational Medicinal Product Dossier
IND	Investigational New Drug
INN / DCI	International Nonproprietary Name / Dénomination Commune Internationale
IPA	Pasteur Institute of Algeria
IPQC	In-Process Control
MS	Mass Spectrometry
NTI	Narrow Therapeutic Index
OOS	Out of Specification
OOT	Out of Trend
PSUR	Periodic Safety Update Report
RMP	Risk Management Plan
RPV	Responsible Person for Pharmacovigilance
SPC	Supplementary Protection Certificate
SOP	Standard Operating Procedure

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Introduction

Introduction:

Quality control in the pharmaceutical industry is the cornerstone of ensuring drug safety and efficacy, as the integrated regulatory system constitutes the protective shield that safeguards patients from the risks of substandard products and ensures that medicines comply with stringent international standards. In a sector characterized by a high degree of information asymmetry between the manufacturer and the consumer, quality control systems—embodied in Good Manufacturing Practices (GMP) certifications, bioequivalence tests, and marketing authorizations—become a pivotal mechanism for bridging the knowledge gap and building bridges of trust between the patient and the healthcare system.

However, trust in this context does not arise automatically simply because technical guarantees are in place; it is a complex phenomenon shaped through a dynamic interaction between cognitive, affective, and institutional dimensions. The patient, being technically unable to evaluate drug quality independently, resorts to what is known as "perceived quality"—a subjective judgment based on extrinsic cues such as price, packaging appearance, laboratory reputation, and the recommendation of the physician or pharmacist. This underscores the importance of quality control systems not merely as supervisory tools, but as "reassurance signals" that transform quality from a theoretical promise into a tangible reality, thereby creating a cognitive rupture with the state of "structural ignorance" experienced by the healthcare consumer.

In this framework, regulatory institutions (such as the National Agency for Pharmaceutical Products - ANPP) play a crucial role in reinforcing trust by exercising technical sovereignty on behalf of the patient and providing institutional guarantees that compensate for their cognitive limitations. Additionally, healthcare professionals (physicians and pharmacists) serve as essential intermediaries in translating this systemic trust into individual conviction, through their direct communication with the patient and their clarification of the concepts of bioequivalence and pharmaceutical safety.

➤ **Research Problem:**

Building upon the foregoing, and in order to operationalize the contrast between technical guarantees and the consumer's mental perceptions, the central problem of this

research crystallizes into a fundamental inquiry regarding the mechanisms of trust-building in the pharmaceutical sector. This can be formulated through the following overarching research question:

"To what extent do quality control systems implemented in the generic pharmaceutical industry contribute to enhancing consumer trust toward generic medicines in Algeria?"

To comprehensively address this problem and answer it, the following sub-questions stem from it:

➤ SQ1: Does consumer trust in generic medicines depend more on their certified quality — ensured by control systems — or on the consumer's subjective perception of their effectiveness and safety?

➤ SQ2: To what extent do pharmacist and physician recommendations contribute to building consumer trust toward generic medicines in Algeria?

➤ SQ3: How does the regulatory oversight exercised by national agencies such as the ANPP enhance consumer confidence in the quality and safety of generic medicines?

➤ **The Hypotheses**

To answer these research questions, the following hypotheses are formulated:

- **General Hypothesis (H):**

Quality control systems for generic medicines positively influence the trust of Algerian consumers.

- **Sub-Hypotheses:**

- Hypothesis 1 (H1): The consumer's perceived quality of the generic drug has a direct and positive effect on their trust.
- Hypothesis 2 (H2): Pharmacist recommendation positively influences consumer trust toward generic medicines.
- Hypothesis 3 (H3): Trust in health authorities (ANPP, Ministry) reinforces the positive effect of quality controls on trust in generic medicines.

➤ **Significance of the study**

The importance of this study lies in its provision of an analytical framework that bridges the technical dimension of quality control systems and the behavioral dimension of

consumer trust, and in its field-testing of this relationship through a model that explains how institutional mechanisms translate into psychological conviction. Its practical value is reflected in its potential to assist pharmaceutical institutions in optimizing their communication strategies by identifying the quality signals that most influence patient perception. Strategically, the study supports national policies aimed at pharmaceutical sovereignty and healthcare cost rationalization, recognizing that consumer trust is a prerequisite for the successful adoption of generic medicines and enhanced therapeutic adherence.

➤ **Study Objectives:**

This study aims to achieve the following objectives:

- Highlight the theoretical concepts related to quality control systems, generic medicines, and consumer trust in the healthcare sector.
- Determine the impact of perceived quality of generic medicines—in terms of therapeutic efficacy, safety, and bioequivalence—on consumer trust.
- Evaluate the contribution of doctors' and pharmacists' recommendations to building the trust of Algerian consumers in generic medicines.
- Analyze the impact of trust in regulatory authorities (ANPP, Ministry of Health) on enhancing the perceived effectiveness of quality control systems from the consumer's perspective.
- Provide practical recommendations for pharmaceutical institutions and regulatory bodies to enhance consumer trust and improve the quality of healthcare services.

➤ **Justification for Topic Selection:**

- The societal stake of this study, given that enhancing consumer trust in generic medicines contributes to achieving equity in access to essential treatments, curbing the impact of rumors and misinformation, and ultimately improving patients' therapeutic adherence.
- The study of consumer trust in generic medicines has become a strategic imperative for Algeria's pharmaceutical sovereignty policy, as persistent consumer skepticism regarding the safety and efficacy of local generics poses a significant obstacle to the success of the national import reduction strategy.

- The noticeable research gap, characterized by an abundance of technical studies on quality control on the one hand, and a scarcity of field studies linking these systems to Algerian consumer behavior specifically on the other.
- The availability of a suitable field research environment for conducting the study, through the access provided by the SAIDAL Group (Dar El-Beida unit) to empirical data on quality control systems and the possibility of reaching a sample of consumers, which facilitated the transition from the theoretical framework to field application.
- The personal commitment of the researcher to contribute, however modestly, to supporting the national healthcare sector, stemming from her awareness of the strategic importance of generic medicines in Algerian pharmaceutical policy, by providing recommendations grounded in actual field data.

➤ **Research Methodology:**

This study adopts a quantitative, descriptive-analytical approach. The theoretical framework was developed through a comprehensive literature review encompassing specialized books, academic theses, legal texts, and official websites. For the empirical component, a questionnaire was administered to a sample of pharmaceutical consumers in Algeria, with the aim of measuring the extent to which quality control systems reinforce consumer trust in generic medicines.

➤ **Previous Studies:**

-Firstly: Algerian Studies (National Context):

- In the Algerian context, previous studies focused on analyzing the reality of generic medicines and obstacles to their acceptance. The study by ABBAD and BOUCHAKOR (2023) assessed the status of generics versus originator drugs, revealing trust barriers related to therapeutic efficacy and lack of patient information. It confirmed that pharmacists are the primary information source for patients, supporting the hypothesis on healthcare professionals' influence.
- The study by KHEDIM and TABET DERRAZ (2022) analyzed consumer resistance to generics despite governmental incentives. It demonstrated a strong link between low price and resistance (the "psychological price" effect), and confirmed that lack of health literacy and mistrust among healthcare actors increase resistance. These findings support the role of perceived quality and institutional trust.

-Secondly: International Studies (Theoretical and Conceptual Framework):

- At the international level, studies focused on establishing the concept of trust in healthcare. The study by Goold (2001) established the concept of institutional trust, demonstrating that transparency, procedural justice, and honesty are the pillars of building trust in healthcare institutions, and that self-regulation is more effective than strict external oversight. These findings align with the role of the ANPP in enhancing consumer trust.

- The study by Calnan and Rowe (2007) analyzed trust as a multi-level phenomenon, distinguishing between the micro-level (patient-physician trust) and macro-level (public trust in the system). It emphasized that modern policies transform trust from blind to "informed and conditional trust." This aligns with our model, which posits that trust in generic drugs is influenced by both individual recommendations and institutional credibility.

- The doctoral thesis by Sacha Tolila (2018), entitled "Amélioration du système qualité pharmaceutique opérationnel" (Improvement of the Operational Pharmaceutical Quality System), examined pharmaceutical quality systems in manufacturing plants, focusing on the regulatory framework (GMP, ISO, ICH), quality risk management (ICH Q9 and ICH Q10 using FMEA and Pareto tools), and a case study at Septodont laboratories. Implementation included creating a Product Quality Assurance Technician (AQP) position, Log-book systems, periodic audits, and AQL controls. The study concluded that continuous improvement of quality systems through risk management is essential for patient safety and organizational sustainability, providing a technical foundation that complements our research on the relationship between quality systems and consumer trust.

➤ **Study Structure:**

- Chapter 1: This chapter examined the concept of pharmaceutical quality as a holistic framework integrating technical standards with international and national regulatory requirements. It affirmed that the stringency of quality control measures applied to generic medicines—and the demonstration of their bioequivalence—constitutes the objective foundation upon which consumer trust can be built.

- Chapter 2: explored the complex psychological and social nature of patient trust, highlighting the gap between objective and perceived quality, and confirming that the formation of this trust essentially depends on the role of professional intermediaries and the credibility of regulatory institutions.

- Chapter 3: This chapter operationalizes the theoretical framework through an empirical investigation conducted at the Dar El-Beida unit of the SAIDAL Group. It presents the methodology employed for data collection—using a questionnaire as the primary instrument—followed by an analysis of the extracted findings and the results of hypothesis testing concerning the relationship between quality systems and consumer trust.

Chapter I : Quality control systems within the pharmaceutical industry

Introduction:

Quality is a fundamental concept in any organization, having evolved over time to become a key pillar for excellence and sustainability. In the pharmaceutical sector, quality holds exceptional importance due to its direct impact on patient health and safety. Pharmaceutical quality relies on an integrated system of procedures and controls to ensure the effectiveness and safety of medicines, in compliance with international regulatory standards. Within this framework, quality control plays a vital operational role in verifying those raw materials and finished product conform to specifications and are free from defects. This importance is particularly evident in the context of generic medicines, where quality control ensures bioequivalence and therapeutic efficacy with originator drugs, making generics reliable, effective, and safe alternatives that contribute to promoting equity in access to treatment.

For these reasons, we have dedicated the first chapter of this research as a theoretical framework, divided into three complementary sections aimed at providing a comprehensive overview of the subject. The chapter is structured as follows:

Section 01: Concepts and Standards of Pharmaceutical Quality – This section reviews the evolution of the quality concept in the pharmaceutical industry and its theoretical approaches, with a focus on its two essential pillars (Quality Assurance and Quality Control) and the international regulatory frameworks governing them (GMP, ISO, ICH).

Section 02: Specificities of Quality Control for Generic Medicines – This section focuses on the technical and regulatory characteristics applied to generic medicines, highlighting the precise scientific criteria (such as bioequivalence, dissolution tests, and stability) that grant them approval and legitimacy as reliable therapeutic alternatives.

Section 03: Pharmaceutical Regulatory Authorities in Algeria – This section provides a comprehensive overview of the national regulatory and institutional framework, tracing the evolution of the pharmaceutical sector from independence to the reforms of Law 18-11, while highlighting the roles of key regulatory and oversight bodies.

I. Section 01: Concepts and Standards of Pharmaceutical Quality:

1. Definition of Quality Pharmaceutical :

1.1. Definition of Quality:

Quality constitutes one of the most important concepts in management, economics, and industry, and this concept has witnessed continuous development over time. Today, it represents a fundamental axis for every organization, and is also considered a strategic asset that gives it a clear competitive advantage.

From a linguistic point of view, the origin of the word “quality” comes from the Latin term “qualitas”, which means “The essence, nature, and properties of something.”¹

From an academic point of view, definitions of quality are many and diverse:²

According to the international standard, quality is defined in the following manner: “Totality of characteristics of an entity that bears on its ability to satisfy stated and implied needs (of customers) “.

This definition includes two main elements:

- Inherent characteristics: measurable natural attributes (e.g., performance, durability, reliability) that do not depend on others' opinions.
- Requirements: needs and expectations (explicit or implicit) originating from the customer, stakeholders, laws, and internal organizational rules.

1.1.1. The Multiplicity of Conceptual Approaches to Quality:

¹¹ مأمون سلمان، إدارة الجودة الشاملة وخدمة العملاء، عمان، دار الطباعة والنشر والتوزيع، 2006، ص. 19..

² POTDAR Manohar A., *Concepts of Quality Management in Pharmaceutical Industry*, Hyderabad, PharmaMed Press, 2014, p 4.

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There are multiple perspectives through which quality is viewed. Researchers (notably Garvin, 1984, 1988; Reeves and Bednar, 1994; Seawright and Young, 1996) have classified these views into five main approaches that reflect the evolution of management thought:¹

➤ The Transcendent Approach: Quality is defined as an absolute, innate excellence that cannot be precisely measured but is perceived through intuition and personal judgment; it is "known when seen." This approach has its roots in Greek and Latin philosophy, which link quality to perfection and idealism.

➤ The Product-Based Approach: This approach treats quality as an objective, measurable variable linked to tangible technical characteristics (such as performance and durability). This perspective leads to two conclusions: first, improving quality necessarily requires an increase in costs; second, quality is an inherent property of the product itself, independent of the observer's perception.

➤ The User-Based Approach: This concept is based on "fitness for use" as developed by Joseph Juran, where quality is determined by the extent to which customer needs and expectations are met. Despite its importance in serving the customer, it remains subjective and difficult to operationalize due to the diversity of market preferences.

➤ The Manufacturing Approach (Conformance to Specifications): Quality is defined as "the degree to which a product conforms to specified standards and rules." This perspective directs the organization toward internal performance and defect-free production. Philip Crosby established its foundations with the principles of "zero defects" and "quality is free," considering that high quality saves costs in the long run, and defining quality as: "*Conformance to requirements.*"

➤ The Value-Based Approach: This perspective links quality to cost, balancing performance and price to achieve the best value for the customer. According to Feigenbaum,

¹ GARVIN David A., « What does "product quality" really mean? », *Sloan Management Review*, vol. 26, n° 1, automne 1984, pp. 25-28.

Carol A. REEVES and David A. BEDNAR, « Defining Quality: Alternatives and Implications », *Academy of Management Review*, vol. 19, n° 3, 1994, pp. 420-430.

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quality here does not mean "best" in its absolute sense, but rather "best for certain customer conditions" in terms of actual use and selling price.

It is important to note that these five approaches do not contradict each other. Instead, they fit according to the nature of each organization and the type of its activities. For example, large commercial companies and distributors tend to adopt the user-based approach, while heavy industrial companies prefer the production-based approach that focuses on compliance with specifications.¹

However, these approaches are not completely independent. In most cases, they are interconnected and overlap. Even within the same organization, different departments may apply the concept of quality in different ways, even if they all agree on the same general definition of quality.

1.2. Definition of Pharmaceutical Quality:

Quality is the cornerstone of the pharmaceutical industry; it is the strategic goal ensuring the safety and efficacy of medicines and their compliance with official regulatory standards.

Despite the diverse definitions provided by international organizations, they all converge on fundamental principles aimed at protecting the patient.²

In this context, the U.S. Food and Drug Administration (FDA) asserts that: "Pharmaceutical quality is the foundation that allows patients and consumers to have

¹ Yvon PESQUEUX, « Définition de la notion de qualité, chronologie et fondements de la gestion de la qualité », cours de Master, France, 2020, pp. 3-4. Disponible sur : <https://shs.hal.science/halshs-02615732/document> (Accessed on February 18, 2026).

² Léa BUISINE, « La qualité et son management en industrie pharmaceutique : s'imposer un cadre restrictif ou plutôt s'ouvrir à de nouveaux horizons ? », PhD Thesis in Pharmaceutical Sciences, University of Lorraine, 2016, p. 14. Available at: <https://hal.univ-lorraine.fr/hal-01731751/document> (Accessed: February 20, 2026).

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confidence in the safety and effectiveness of their medications."¹ To clarify this concept operationally, the FDA provides a complementary definition that links quality to therapeutic performance, defining it as: "a product that reliably delivers the therapeutic benefit promised on the label to the patient and is free of contamination" (as defined by Janet Woodcock, Director of the Center for Drug Evaluation and Research - CDER).²

From this perspective, "achieving quality" is based on ensuring that the pharmaceutical product meets four pre-determined essential characteristics that guarantee the required levels of safety and efficacy:³

- Identity: Confirming that the active ingredient is exactly the one intended.
- Strength: Ensuring the concentration of the active ingredient matches the approved specifications.
- Purity: Ensuring the product is free from impurities and contaminants.
- Stability: Maintaining these characteristics unchanged throughout the entire shelf life.

2. Quality assurance (AQ):

2.1. Definition of Quality assurance:

¹ U.S. Food and Drug Administration, « Pharmaceutical quality resources » [online]. (n.d.). Available at: <https://www.fda.gov/drugs/development-approval-process-drugs/pharmaceutical-quality-resources> (Accessed: February 20, 2026).

² Janet WOODCOCK, « LIVE FROM PDA/FDA: Compliance to Quality », *Healthcare Packaging* [online], 2014. Available at: <https://www.healthcarepackaging.com/home/news/14215543/live-from-pdafda-compliance-to-quality-part-1> (Accessed: February 20, 2026).

³ ICH Harmonised Tripartite Guideline, « Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances (Q6A) », *International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use*, 2000.pp. 8-9, 20.

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Quality assurance is the strategic pillar of the pharmaceutical management system; it goes beyond limited technical control to include a system of preventive measures aimed at building "certainty" in product quality

The International Organization for Standardization (ISO 9000:2015) defines quality assurance as: «a part of quality management that focuses on providing confidence that quality requirements will be met».¹

For its part, the World Health Organization (WHO / OMS) provides a more comprehensive definition of the pharmaceutical industry as: «A broad concept that covers all matters that individually or collectively affect product quality, which is the sum of measures taken to ensure that medicines are of the quality required for their intended use».²

In the same regulatory context, Nally (2007) also defines quality assurance in the pharmaceutical industry as: « The sum of all the organized arrangements made with the object of ensuring that medicinal products are of the quality required for their intended use and that they consistently meet the specifications and regulatory requirements.».³

Finally, the French Agency for Drug Safety (ANSM) as: «"Quality Assurance (QA): The set of all provisions taken within the pharmaceutical quality system, aimed at ensuring that medicinal products are of the quality required for their intended use ».⁴

Based on the fundamental intersections between the previous definitions, a comprehensive and inclusive definition of quality assurance in the pharmaceutical environment can be formulated as follows: "Quality Assurance is an integrated

¹ BUISINE, *op. cit.*, p. 15.

² U.S. Food and Drug Administration, *op. cit.*

³ J. D. NALLY (ed.), *Good Manufacturing Practices for Pharmaceuticals*, 6th ed., Informa Healthcare, 2007, p. 45.

⁴ ANSM, « Decision No. 2015-29 relative to Good Manufacturing Practices », NOR: AFSM1600529S, Chapter 1 "Pharmaceutical Quality System", December 29, 2015. Available at: <https://ansm.sante.fr> (Accessed: February 21, 2026).

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administrative and preventive system. It includes a set of planned, organized, and documented activities that accompany the pharmaceutical product throughout its entire lifecycle; from research and design, through manufacturing, to distribution and post-marketing. This system aims to build quality into the product itself and ensure a constant state of process control. This guarantees the delivery of safe, effective medicines that comply with international standards, which strengthens the trust of both consumers and regulatory authorities in the pharmaceutical system. »

2.2. Core Tasks and Responsibilities of the Pharmaceutical Quality Assurance:

Quality Assurance (QA) plays a pivotal role in ensuring regulatory compliance and the delivery of safe, effective medicines. The following table outlines the key technical and procedural responsibilities essential to maintaining the integrity of pharmaceutical operations:¹

Tableau 1: Tasks and Responsibilities of the Pharmaceutical Quality Assurance

Responsibility	Brief Description
Quality Oversight & Product Release	Ensuring all products meet safety, efficacy, and quality standards before market release.
Documentation & Traceability Control	Reviewing and approving all quality documents (SOPs, protocols, records) to ensure complete auditability.
Process Validation & Compliance	Managing process validation and ensuring full adherence to GMP and regulatory guidelines (FDA, EMA, WHO).

¹ Scilife, « The full guide to QMS in pharma for quality assurance professionals » [online], updated April 22, 2026. Available at: <https://www.scilife.io/blog/qms-in-pharma-guide> (Accessed: May 26, 2026).

SimplerQMS, « Pharmaceutical Quality Assurance (QA): Definition and Processes » [online], July 16, 2024. Available at: <https://www.simplerqms.com/pharmaceutical/pharmaceutical-quality-assurance/> (Accessed: May 26, 2026).

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Deviations & CAPA Management	Investigating defects and deviations, determining root causes, and implementing corrective/preventive actions.
Internal Audits & Quality Reviews	Conducting periodic self-inspections, internal audits, and Product Quality Reviews (PQR).
Complaint Management	Addressing customer complaints and integrating feedback into the quality system.
Personnel Training & Development	Training staff on quality procedures and GMP requirements to maintain operational standards.

Source: Elaborated by the author based on Scilife (The full guide to QMS in pharma for quality assurance professionals 2026) and SimplerQMS (Pharmaceutical Quality Assurance (QA): Definition and Processes 2024).

3. Quality Control (QC) :

3.1. Definition of Quality Control (QC):

Quality Control (QC) is the practical and analytical component of the pharmaceutical quality system. It serves as the primary tool for verifying, through physical and laboratory testing, that products meet established standards.

According to the World Health Organization (WHO): «All measures taken, including the setting of specifications, sampling, testing and analytical clearance, to ensure that raw materials, intermediates, packaging materials and finished pharmaceutical products conform with established specifications for identity, strength, purity and other characteristics. »¹

¹ World Health Organization (WHO), « Glossary » [online], in *WHO Prequalification of Medical Products (IVDs, Medicines, Vaccines and Immunization Devices, Vector Control)*, n.d., s.v. "Quality". Available at: <https://extranet.who.int/prequal/glossary-acronyms/q> (Accessed: February 26, 2026).

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In alignment with this, ISO 9000 describes QC as: «A part of quality management focused on fulfilling quality requirements. It involves monitoring aspects of producing and testing the output to identify and classify any defects that have occurred. »¹

Furthermore, within Good Manufacturing Practices (GMP), Sharp (2005) defines QC as: «That part of Good Manufacturing Practice which is concerned with sampling, specifications and testing, and with the organization, documentation and release procedures which ensure that the necessary and relevant tests are actually carried out and that materials are not released for use, nor products released for sale or supply, until their quality has been judged to be satisfactory. »²

According to Chapter 6 of Good Manufacturing Practices (GMP), Quality Control (QC) functions as an informational support tool for manufacturing, serving as the first line of defense in detecting non-conformity to support batch release decisions and reduce the costs associated with external failures. Its operational flow can be summarized as follows: Based on the provided sources, Quality Control (QC) is a comprehensive function that ensures pharmaceutical materials and products are not released for use, sale, or distribution until their quality has been judged satisfactory.³

Based on the common elements of the definitions above, a comprehensive definition of Quality Control can be formulated as follows: « Quality Control (QC) is the analytical and operational function of the pharmaceutical quality system. Its aim is to directly and objectively verify that raw materials, intermediate products, and finished products meet

¹ Sayali Dilip PATIL, Mayuri Kaduba RAUT and Nikhil Prakash RATHOD, « Quality Control and Quality Assurance in Pharmaceuticals », *International Journal in Pharmaceutical Sciences*, vol. 1, n° 11, 2023, p. 91. DOI: <https://doi.org/10.5281/zenodo.10066235>.

² John SHARP, *Good Pharmaceutical Manufacturing Practice: Rationale and Compliance*, CRC Press, 2005, p. 12.

³ Agence Fédérale des Médicaments et des Produits de Santé (AFMPS), « Chapitre 6 : Contrôle de la qualité (partie I) » [PDF], pp. 1-6, specifically p. 1. Available at: https://www.afmps.be/sites/default/files/content/INSP/partie_i-chapitre_6_frdefdocx.pdf (Accessed: June 17, 2026).

approved specifications. This is achieved through sampling, setting standards, and carrying out chemical, physical, and biological tests according to documented and organized procedures, ensuring that no material or product is released until its quality, safety, and effectiveness have been fully confirmed. »

3.2. Core Objectives and Responsibilities of QC:

The primary mission of Quality Control is to ensure product safety and efficacy by rigorously verifying that materials (raw and finished) comply with standard specifications, while prohibiting the release of any product before its quality has been assessed. To achieve this, the department operates with complete independence from Production, supported by equipped laboratories and qualified resources that enable it to participate in all quality-affecting decisions.¹

In the area of investigations and documentation, the department is committed to documenting and tracing all tests, conducting thorough investigations into any abnormal results: Out-of-Specification (OOS) results that exceed permissible limits require immediate batch rejection, while Out-of-Trend (OOT) results that show an unjustified deviation from the usual pattern call for proactive monitoring to prevent future defects.²

On the technical side, the department adopts risk-based sampling plans, validates analytical methods, and ensures the accuracy of laboratory inputs (such as reagents and solutions). The department completes its role with post-marketing stability monitoring programs, analyzing integrated data—including production conditions and in-process control results—to ensure continuous process improvement throughout the product's shelf life.³

¹ *Ibid.*, p. 1.

² *Ibid.*, pp. 2-3.

³ *Ibid.*, pp. 3-4.

3.3. Operational Phases of Pharmaceutical Quality Control:

The quality control process in the pharmaceutical industry is a systematic, multi-stage approach that ensures every step of manufacturing meets precise standards; from the sourcing of raw materials to the release of the final product onto the market. This framework includes the following operational phases :¹

- **Raw Material Testing:** All inputs (such as APIs, excipients, and packaging materials) are examined before use to verify their identity, purity, and safety. Advanced analytical techniques such as liquid chromatography (HPLC/UPLC) and mass spectrometry (MS) are used in this phase to detect any potential contaminants and assess physicochemical and microbiological properties.
- **In-Process Control (IPQC):** Quality control teams monitor critical process parameters (e.g., temperature, pressure, pH, mixing speed) in real time. This procedure aims to detect deviations early, thereby reducing the risk of reprocessing and maintaining batch consistency.
- **Finished Product Testing:** Before any batch of a drug is released, rigorous tests are conducted to verify its compliance with specifications (identity, strength, purity, and performance) using advanced techniques. These tests include content uniformity, dissolution, sterility, and impurities. Stability studies are also conducted according to ICH guidelines (long-term and accelerated) to ensure the safety and efficacy of the drug throughout its shelf life, and to confirm audit readiness and compliance before the product reaches patients.
- **Environmental Monitoring:** The quality of the manufacturing environment (air quality, humidity, and microbial contamination) is continuously verified to ensure a clean, non-

¹ Pharma Now, « Quality Control in Pharmaceutical Manufacturing » [online], 2025. Available at: <https://www.pharmanow.live/pharma-manufacturing/quality-control-in-pharmaceutical-manufacturing> (Accessed: February 27, 2026).

negotiable environment, with HVAC systems activated in production areas to prevent product deterioration and ensure compliance with Good Manufacturing Practices (GMP).

- **Compliance and Documentation Reviews:** This phase includes regular audits of processes, equipment, training, and documentation to ensure full compliance with GMP standards. These reviews help identify gaps and maintain high levels of quality, as the Quality Control department oversees the consistency of documentation and testing across all stages.

This framework forms the operational core of any Quality Control department and serves as a fundamental pillar in protecting product safety, efficacy, and ensuring patient safety.

4. Relationship Between QA and QC in the Pharmaceutical:

Quality Assurance (QA) and Quality Control (QC) are two vital pillars of the pharmaceutical system. QA focuses on processes and proactive error prevention through organized procedures throughout the product lifecycle, while QC focuses on the product and the reactive detection of defects through technical testing to ensure conformity before release—a distinction essential for enhancing patient safety and reducing operational risks.¹

In short, it can be said that Quality Assurance focuses on the process, while Quality Control focuses on the product. The following table illustrates the essential differences between them:²

¹ V. SHINDE, « Quality Assurance (QA) vs Quality Control (QC) in the Pharmaceutical Industry », *PharmiWeb* [online], May 14, 2025. Available at: <https://www.pharmiweb.com/article/quality-assurance-qa-vs-quality-control-qc-in-the-pharmaceutical-industry> (Accessed: May 30, 2026).

² SimplerQMS, « Quality Assurance vs Quality Control: Differences, Relations » [online], 2024. Available at: <https://simplerqms.com/quality-assurance-vs-quality-control/> (Accessed: February 27, 2026).

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Tableau 2: the main differences between QC, QA

Comparison Criterion	Quality Assurance (QA)	Quality Control (QC)
Nature	Proactive: focuses on establishing processes and procedures to prevent issues before they occur.	Reactive: involves activities that detect and correct issues in the product or service lifecycle.
Focus	Process-oriented: focuses on establishing and maintaining processes to ensure consistent quality.	Product-oriented: involves activities that verify and evaluate the quality of products or services.
Coverage	System-oriented: focuses on processes to ensure overall quality.	Part-oriented: focuses on inspecting and testing individual products or components.
Responsibility	Cross-functional: involves activities across all products, services, and processes.	Dedicated personnel: teams responsible for inspecting, testing, and verifying the quality of specific products.
Primary Objective	Prevent: preventing defects and issues before they occur through systematic processes.	Verify, Control, Detect: verifying quality, controlling it, and detecting issues through inspection and testing.
Lifecycle	Activities across the entire lifecycle , from planning to post-marketing.	Periodic activities: focus on specific points in the product lifecycle to verify quality.
Tool	Managerial tool: due to its systematic approach to ensuring and improving quality.	Operational tool: handles specific tasks for testing and controlling quality.

Source: Elaborated by the author based on SimplerQMS (Quality Assurance vs Quality Control: Differences, Relations 2024).

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The integration relationship between Quality Assurance (QA) and Quality Control (QC), according to the ICH Q10 framework, is embodied in continuous technical communication. QC data (test results and deviations) feed into the governance processes led by QA to activate the Corrective and Preventive Action (CAPA) system and drive continuous improvement. Thus, QA establishes the regulatory frameworks, while QC verifies their actual application, thereby ensuring that products comply with international standards in accordance with WHO recommendations.¹

5. The regulatory framework for quality in the pharmaceutical industry:

5.1. Historical Reasons for the Emergence and Development of Regulatory Frameworks:

A series of drug disasters and health crises gradually pushed societies and authorities to build regulatory frameworks for pharmaceutical quality.

- Early beginnings:

Federal drug oversight in the United States began in 1848 with the Drug Importation Act, which was limited to inspecting imported drugs. However, the real catalyst for more comprehensive legislation came with the Elixir Sulfanilamide disaster of 1937, when a drug dissolved in diethylene glycol (a toxic antifreeze substance) caused the deaths of 107 people, most of them children. This tragedy directly led to the enactment of the Federal Food, Drug, and Cosmetic Act in 1938, which established for the first time the requirement to prove product safety before marketing.²

¹ Susan SCHNIEPP, « Frequently Asked Questions About Quality Control vs. Quality Assurance », *Pharmaceutical Technology*, vol. 45, n° 12, December 2021, p. 50. Available at: <https://www.pharmtech.com/view/frequently-asked-questions-about-quality-control-vs-quality-assurance> (Accessed: February 27, 2026).

² Shayne Cox GAD (ed.), *Pharmaceutical Manufacturing Handbook: Production and Processes*, Hoboken, NJ, John Wiley & Sons, 2008, p. 38.

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- The thalidomide disaster and the proof of efficacy:

Decades later, the thalidomide disaster in the early 1960s added a new dimension: the proof of efficacy. The drug caused severe birth defects in more than ten thousand newborns worldwide. This resulted in the Kefauver-Harris Amendment of 1962, which for the first-time required proof of efficacy alongside safety, and gave the U.S. Food and Drug Administration (FDA) broad powers to establish and inspect good manufacturing practices¹.

- European harmonisation and the first GMP standards:

-At the European level, the need to harmonise quality standards was a key driver. Before the 1960s, each European country had its own national pharmacopoeia, leading to significant differences in drug quality and composition. This fragmentation led to an agreement among European countries in 1964 to create a unified European Pharmacopoeia, the first edition of which was published in 1969, aiming to ensure a single quality level for all medicines sold in Europe.².

As for good manufacturing practices (GMP), they were first introduced in the United States as part of the 1938 Food, Drug, and Cosmetic Act regulations, but were not finalised in their definitive form until 1978.³

¹ U.S. Food and Drug Administration, « Milestones in U.S. Food and Drug Law » [online]. (n.d.). Available at: <https://www.fda.gov/about-fda/fda-history/milestones-us-food-and-drug-law> (Accessed: February 28, 2026).

²C. STAINIER, « Rôle et fonctions de la Pharmacopée européenne » [Role and functions of the European Pharmacopoeia], *Annali dell'Istituto superiore di sanità*, vol. 11, n° 3-4, 1975, pp. 211-219.

Pharmacy Standards, « Section 6.3: Good Manufacturing Practices (GMP): The Legal Framework (CRAS Course Material) » [online]. (n.d.). Available at: <https://pharmacystandards.org/cras/section-6-3-good-manufacturing-practices-21-cfr-210-211-eu-gmp/> (Accessed: March 1, 2026)..

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-At the global level, the World Health Organization (WHO) published its first GMP standards in 1969, spreading these concepts internationally.¹

- Modern developments:

On November 14, 2001, the member states of the World Trade Organization (numbering 142 countries at the time) unanimously adopted the "Ministerial Declaration on the TRIPS Agreement and Public Health" (known as the Doha Declaration), which affirmed the right of member states to use the full "flexibility" of the TRIPS Agreement, including the granting of "compulsory licenses" to override pharmaceutical companies' patents, in order to promote access to medicines for all.²

Then came the FDA's 21st Century Initiative in 2004 to support a risk-based and innovation-driven approach. This evolution culminated in the issuance of the International Council for Harmonisation (ICH) guidelines Q8, Q9, and Q10, which introduced advanced concepts such as Quality by Design (QbD), risk management, and a comprehensive quality system throughout the product lifecycle.³

5.2. The Regulatory Framework Governing Quality in the Pharmaceutical Industry:

5.2.1. Pharmacopoeia:

¹ World Health Organization, « Good Manufacturing Practices (GMP) » [online]. (n.d.). Available at: <https://www.who.int/teams/health-product-policy-and-standards/standards-and-specifications/norms-and-standards/gmp> (Accessed: March 1, 2026).

² World Trade Organization, « Declaration on the TRIPS Agreement and Public Health » [online], WT/MIN(01)/DEC/2, November 20, 2001. Available at: https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm (Accessed: March 1, 2026).

³Pharmacy Standards, « Section 6.2: Quality by Design (QbD) Principles (CRAS Course Material) » [online]. (n.d.). Available at: <https://pharmacystandards.org/cras/section-6-2-quality-by-design-qbd-principles/> (Accessed: March 1, 2026).

A pharmacopoeia is a binding scientific and regulatory reference that ensures the quality and safety of human and veterinary medicines. It has evolved from a manual of recipes into a cornerstone of the pharmaceutical industry. In practice, Quality Control (QC) verifies that raw materials and finished products comply with the precise specifications laid out in pharmacopoeial monographs – analytical protocols that must be strictly followed.

Pharmacopoeias are legally binding (*référentiel opposable*) for manufacturers and regulators, and vary by region (e.g., European, US, Japanese, Chinese). Compliance is mandatory for manufacturing and marketing, including respect for the importing country's regulations.

To help countries lacking their own pharmacopoeia, the WHO publishes the International Pharmacopoeia (Ph. Int.). This common reference framework can be adapted to national contexts. It focuses on essential medicines (especially for low- and middle-income countries, including paediatric forms), ensuring globally harmonised quality standards.¹

5.2.2. The International Organization for Standardization (ISO):

The International Organization for Standardization (**ISO**) is an independent, non-governmental international organization. Established in 1946 and headquartered in Geneva, Switzerland, it comprises a network of 176 national standards bodies, with one representative per country. To date, ISO has developed more than 26,264 international standards and related documents. Unlike **ICH** guidelines, ISO standards cover a vast range of sectors, including technology, security, food safety, agriculture, and healthcare.²

¹M. YABRE, « Méthodes d'analyses innovantes et peu polluantes pour le contrôle qualité des médicaments essentiels : application aux antipaludiques », PhD Thesis, Université de Bordeaux & Université Joseph Ki-Zerbo, 2020, pp. 27-28. Available at: <http://www.theses.fr/2020BORD0246> (Accessed: June 17, 2026).

² International Organization for Standardization (ISO), « About ISO » [online]. (n.d.). Available at: <https://www.iso.org/about> (Accessed: March 1, 2026).

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It is important to note that ISO itself does not issue certificates of conformity; instead, it develops consensus-based standards, while certification is performed by independent bodies, such as **IANOR** in Algeria or **AFNOR** in France.

Being ISO-certified offers several major advantages: it serves as a mark of quality and a competitive asset, a guarantee of providing safe, reliable, and high-quality products, and a token of trust for both customers and regulatory agencies.

In the pharmaceutical industry, ISO standards are a strategic tool to enhance operational efficiency and patient safety. Their importance can be summarized in five key points:

- Integration with Good Manufacturing Practices (GMP): ISO standards (such as ISO 15378) integrate GMP requirements to ensure an effective management system alongside sound manufacturing control.
- International recognition and trade facilitation: ISO certificates act as a "technical passport" giving laboratory results (e.g., ISO/IEC 17025) global credibility, reducing the need for retesting when medicines are exchanged.
- Enhancing credibility: Third-party independent audits increase the confidence of regulatory agencies and partners in products, thereby raising their market value.
- Securing the supply chain: Standards impose precise traceability of products from the manufacturer to the patient, with stringent requirements for packaging materials to ensure drug safety and facilitate the recall of defective batches.
- Shifting from correction to prevention: The ISO approach adopts "risk-based thinking," helping organizations anticipate and prevent errors before they occur, which reduces waste and saves resources.

5.2.3. Good Manufacturing Practices (GMP):

Good Manufacturing Practices (GMP), referred to in French as BPF, are defined as a fundamental standard system for pharmaceutical quality assurance. The World Health Organization defines them as "that part of quality assurance which ensures that products are consistently produced and controlled according to quality standards appropriate to their

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intended use and as required by the marketing authorization."¹ From a broader academic perspective, these practices represent a set of regulatory, organizational, and technical principles that ensure medicines are manufactured, controlled, and released in a reproducible manner, in compliance with specified specifications and the requirements of competent health authorities.

These practices are based on a fundamental global principle that "quality cannot be assured solely through testing of the finished product; it must be built into every stage of the manufacturing process." This principle represents a fundamental epistemological shift from previous practices that relied exclusively on final product testing, as GMP introduces the logic of "quality by design," where compliance is the result of a controlled process rather than mere subsequent verification. Importantly, these rules are not merely recommendations; they constitute a legally binding framework subject to accountability and inspection by health authorities.

To ensure the quality and safety of pharmaceutical processes, Good Manufacturing Practices (GMP) are organized into three main parts and nineteen technical annexes:²

- Part One: Covers the manufacture of human medicinal products through nine chapters including personnel, buildings, equipment, documentation, production, and quality control, with most of its rules also applying to veterinary medicinal products.
- Part Two: Focuses on quality and traceability requirements for active substances (starting materials) from the receipt stage until their incorporation into the finished product.

¹ World Health Organization (WHO), « Good Manufacturing Practices (GMP) » [online]. (n.d.). Available at: <https://www.who.int/teams/health-product-policy-and-standards/standards-and-specifications/norms-and-standards/gmp> (Accessed: March 1, 2026).

²European Commission, « EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines » [online]. (2018). Available at: https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-4_en (Accessed: March 1, 2026).

➤ Part Three: Compiles documents and internationally harmonized regulations, particularly references issued by the International Council for Harmonisation (ICH).

In addition to GMP, other good practices govern pharmaceutical activity. These include Good Distribution Practices (GDP) which ensure product quality throughout the supply chain, Good Pharmacovigilance Practices (GVP) which monitor adverse effects after marketing, as well as Good Laboratory Practices (GLP) which govern non-clinical safety studies.

5.2.4. The International Council for Harmonisation (ICH):

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) is the fundamental global pillar for unifying scientific and technical standards for drug registration. The urgent need for its establishment emerged following the Thalidomide disaster in the 1960s and the subsequent rapid globalization of the pharmaceutical industry. It was officially launched in 1990 through a joint initiative by Europe, the United States, and Japan, with the aim of ensuring drug safety, quality, and efficacy while reducing duplication of testing and accelerating global approval processes.¹

Although ICH principles are classified as “strong recommendations” intended to facilitate global trade (unlike legally binding Good Manufacturing Practices – GMP), the integration of advanced standards such as ICH Q9 (Quality Risk Management) and ICH Q10 (Pharmaceutical Quality System) into international regulatory guidelines has made them a mandatory reference that complements GMP. This integration ensures the highest levels of oversight and continuous improvement in the modern pharmaceutical industry.

¹ International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), « History » [online]. (n.d.). Available at: <https://www.ich.org/page/history> (Accessed: March 1, 2026).

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The guidelines of the International Council for Harmonisation (ICH) are divided into four main categories aimed at harmonizing pharmaceutical standards globally, as follows:¹

- Category Q (Quality): Includes 12 guidelines covering critical aspects of drug quality, such as stability studies, impurity threshold settings, pharmaceutical quality system, and quality risk management approach.
- Category S (Safety): Consists of 11 guidelines focusing on the detection of potential hazards, including carcinogenicity studies, genotoxicity, and reproductive toxicity.
- Category E (Efficacy): Comprises 18 guidelines related to the design, conduct, safety, and reporting of clinical trials, as well as standards for biotechnology derived and targeted medicines.
- Category M (Multidisciplinary): Includes 8 guidelines covering cross cutting topics that do not fall within the previous categories.

5.2.4.1. The Common Technical Document (CTD)

The Common Technical Document (CTD) is an internationally harmonised format for submitting drug registration dossiers to regulatory authorities worldwide. It was developed under the ICH M4 guideline. Since 2003, this format has become mandatory and widely adopted in most countries, replacing previously used national and regional formats (such as the US NDA and the European EU-CTD).

The CTD aims to standardise the structure of drug registration dossiers globally to ensure transparency, accelerate regulatory review, reduce resource and time waste, and facilitate efficient market access for safe and effective medicines.²

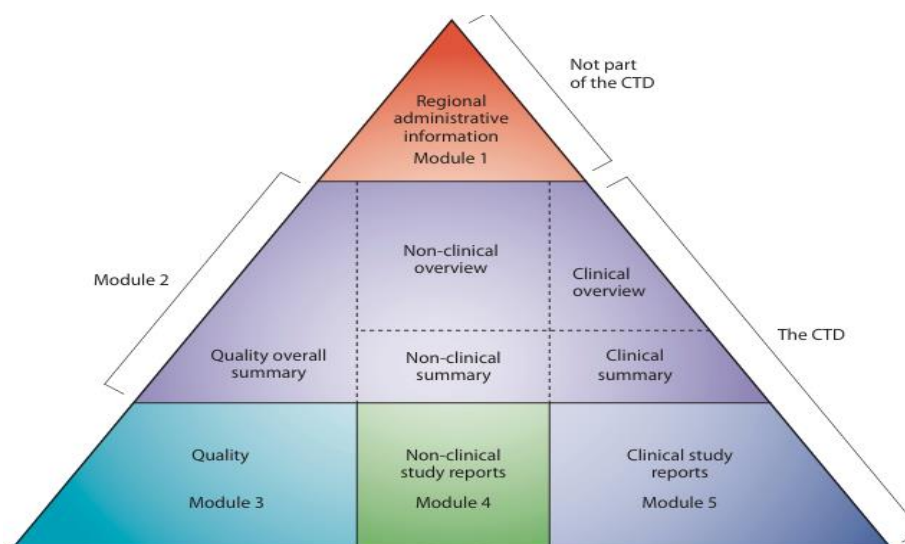
¹International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), « ICH guidelines » [online]. (n.d.). Available at: <https://www.ich.org/page/ich-guidelines> (Accessed: March 1, 2026).

² International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), « CTD (Common Technical Document) » [online]. (n.d.). Available at: <https://www.ich.org/page/ctd> (Accessed: March 2, 2026).

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The CTD is divided into **five modules**, each focusing on a specific type of information. Modules 2 through 5 are harmonised internationally; Module 1 is region-specific.

Figure 1:CTD Triangle



Source : <https://www.ich.org/page/ctd> Retrieved March 2, 2026

The Common Technical Document (CTD) is the traditional paper version, which evolved into the eCTD system: the unified electronic format for drug registration files. This system relies on an XML structure for data organization, PDF files for document presentation, as well as an advanced file lifecycle management system. Its adoption has become mandatory for major regulatory authorities, such as the U.S. Food and Drug

Administration (FDA) and the European Medicines Agency (EMA), in order to streamline review procedures, accelerate drug approvals, and reduce administrative errors.¹

6. The Pharmaceutical Quality System (PQS) according to ICH Q10:

6.1 Definition and Objectives of the PQS :

The Pharmaceutical Quality System (PQS) is a comprehensive model for an effective quality management system in the pharmaceutical industry, developed under the ICH Q10 guideline. This system applies to the entire product lifecycle – from initial pharmaceutical development, through technology transfer and commercial manufacturing, to product discontinuation.²

According to ICH Q10, the PQS is defined as “the sum of all parts of an organization that define and implement quality policy and objectives, and their interrelated responsibilities, to ensure that products are of the quality required for their intended use.”

The fundamental objectives of the PQS are threefold:³

- Achieve product realisation: ensure that medicines are manufactured in a way that consistently meets the quality standards required by the marketing authorisation (MA).
- Establish and maintain a state of control: through effective systems for monitoring process performance and product quality, thereby ensuring continued compliance and process capability.

¹International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), « Multidisciplinary guidelines (ICH M Guidelines) » [online]. (n.d.). Available at: <https://www.ich.org/page/multidisciplinary-guidelines> (Accessed: March 2, 2026).

²SimplerQMS, « ICH Q10 Pharmaceutical Quality System: Definition, Guideline, and Compliance » [online]. (n.d.). Available at: <https://simplerqms.com/ich-q10-pharmaceutical-quality-system/> (Accessed: March 2, 2026).

³ J.C. Famulare, "Pharmaceutical Quality Systems, PQS, Enhanced by QbD for the Product Life Cycle," presented at the ISPE PQLI Workshop, Crystal City, VA, June 2007.

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➤ Facilitate continual improvement: enabling systems to consistently meet quality needs and to innovate throughout the lifecycle.

The PQS applies to active pharmaceutical ingredients, excipients, and finished products, including biotechnological and biological products. It draws on quality management concepts from the International Organization for Standardization (ISO) and complements ICH Q8 (Pharmaceutical Development) and ICH Q9 (Quality Risk Management).

6.2. Components of the PQS:

The PQS rests on two enablers that facilitate the achievement of its objectives and on four structural elements that form the operational core of the system.

➤ 6.2.1 Enablers:¹

These two enablers are presented by ICH Q10 as essential pillars for effective PQS implementation, although they are not formal regulatory requirements

Tableau 3:Description of ICH Q10 Enablers

Enabler	Description
Knowledge Management (KM)	A systematic approach to acquiring, analysing, storing and disseminating information related to products, manufacturing processes and components. KM enables the exploitation of knowledge gained from development and technology transfer to improve process performance and robustness during the commercial phase. It is not a formal regulatory requirement, but its appropriate use is expected by authorities.
Quality Risk Management (QRM)	A systematic process for assessing, controlling, communicating and reviewing risks to quality throughout the product lifecycle (link with ICH Q9). QRM proactively identifies

¹ Scilife, « How to create an ICH Q10 pharmaceutical quality system » [online]. (n.d.). Available at: <https://www.scilife.io/blog/ich-q10-pharmaceutical-quality-system> (Accessed: March 2, 2026).

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	potential risks to product and process quality and implements appropriate measures using a structured, science-based approach.
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Source: Elaborated by the author based on Scilife (ow to create an ICH Q10 pharmaceutical quality system)

➤ 6.2.2 PQS Elements:¹

The following four elements constitute the operational structure of the PQS, each with a specific role in maintaining quality. These elements are interconnected and act synergistically throughout the product lifecycle:

➤ Process Performance and Product Quality Monitoring System:

It focuses on continuous monitoring of manufacturing performance and product quality, aiming to ensure permanent process control, early detection of deviations, and identification of opportunities for proactive improvement.

➤ Corrective Action and Preventive Action (CAPA) System:

A formal system for addressing the root causes of problems, including corrective actions to eliminate the causes of detected non-conformities and preventive actions to prevent potential non-conformities. It relies on a structured investigation to determine the root cause according to the level of risk (ICH Q9).

➤ Change Management System:

It ensures that any change (innovation, CAPA outcomes, or monitoring results) is evaluated, approved, and implemented in a controlled manner, based on quality risk management, in order to maintain the integrity of the "state of control" and avoid unforeseen consequences.

➤ Management Review:

A periodic process conducted by senior management to verify that the PQS remains

¹ Scilife, « What is a Pharmaceutical Quality System (PQS)? » [online]. (n.d.). Available at: <https://www.scilife.io/glossary/pharmaceutical-quality-system-pqs> (Accessed: March 2, 2026).

appropriate, adequate and effective, to evaluate the performance of the system itself, to identify necessary actions, and to allocate resources for maintenance and continuous improvement.

6.3. Lifecycle Approach:

According to ICH Q10, the Pharmaceutical Quality System (PQS) is based on a quality management approach covering the complete product lifecycle, which consists of four interconnected stages, each with a specific objective¹ :

- **Pharmaceutical Development:** Designing the product and its manufacturing process to consistently achieve the intended performance, identifying Critical Quality Attributes (CQAs) and Critical Process Parameters (CPPs), and integrating risk management from the outset.
- **Technology Transfer:** Transferring the knowledge acquired about the product and process from development to manufacturing sites, with the aim of achieving reproducible production that meets specifications.
- **Commercial Manufacturing:** Maintaining a state of control throughout the production period, continuously monitoring process performance and product quality, addressing deviations, managing changes, and implementing continuous improvements to ensure consistent and reliable quality.
- **Product Discontinuation:** Managing the end-of-life stage effectively, by retaining documentation and reference samples in accordance with regulatory requirements, and carrying out necessary post-discontinuation assessments.

This comprehensive approach strengthens the link between development and manufacturing activities, facilitates innovation and continuous improvement, and ensures that quality is not just a final inspection but an ongoing process throughout the product's life.

¹ *Ibid.*

Section 02: Specificities of Quality Control for Generic Medicines:

1. The Originator Drug (Princeps):

.1.1 Definition of the originator drug (princeps)

A drug, according to European Directive 2001/83/EC and the World Health Organization (WHO), is defined as any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.¹

A drug essentially consists of:²

- Active ingredient: the molecule responsible for the therapeutic effect.
- Excipients: pharmacologically inert substances that give the pharmaceutical form (tablet, capsule, syrup), ensure stability, improve taste or preservation, and may affect the release and absorption of the active ingredient.
- Packaging materials: which protect the product and guarantee its safety until use.

Within this framework, the original (innovator) drug, or reference medicinal product, is defined as an innovative pharmaceutical product developed for the first time by a research-based company. It is based on a full marketing authorization (MA) supported by a detailed dossier of clinical and preclinical studies demonstrating its quality, safety, and efficacy. It is

¹ European Parliament and Council of the European Union, *Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use*, Official Journal L 311, 28.11.2004, pp. 67-128, Article 1(2).

²T. M. CHAOUCHE, « Pharmacologie : Médicament, Pharmacocinétique, Pharmacodynamique », Course material (Polycopié), Université Abou Bekr Belkaïd – Tlemcen, Faculté des sciences de la nature et de la vie, Département de biologie, 2024, pp. 1-5. (Designed for Licence and Master students in Biological and Food Sciences).

characterized by containing a new active ingredient, protected by a patent that guarantees a period of commercial exclusivity, during which no other company may legally produce or market the same molecule.¹

The concept of the innovator drug has evolved to include, alongside radical innovation, incremental innovations such as improving pharmaceutical forms (e.g., from a standard tablet to an extended-release tablet) or adding new therapeutic indications, with the aim of enhancing patients' quality of life and improving healthcare systems.

1.2. Drug Lifecycle:

The "drug lifecycle" is defined as the complex scientific, regulatory, and commercial path of a molecule, from research laboratories to its withdrawal from the market. This concept represents the fundamental pillar for understanding the quality, safety, and efficacy standards that both innovative and generic medicines are required to meet.

-This lifecycle includes the following stages:

- Research and Development (R&D) Stage:

This stage is the beating heart of the lifecycle and the most costly and risky. It begins with basic research and molecule discovery by identifying a biological target associated with a specific disease and screening thousands of compounds, noting that the success rate of discovered molecules does not exceed 1%. This is followed by preclinical studies to test the toxicological and pharmacological profile using in vitro and in vivo models, in accordance with Good Laboratory Practices (GLP) and ICH guidelines (S1–S9), concluding with the preparation of the IND/IMPd dossier for submission to regulatory authorities. The scientific core of this stage is clinical development, which lasts from 6 to 10 years and is divided into three phases: Phase I to test safety and tolerability in 20–80 healthy volunteers; Phase II to

¹J. PINEL, « Les médicaments de contrefaçons et sous standards : un danger de mort (-exceptionnel dans les pays industrialisés-commun dans les pays en développement) », 2014, pp. 6-7. Available at: http://remed.org/wp-content/uploads/2016/11/Les_medicaments_de_contrefacons_sous_standards_Un_danger_de_mort.pdf (Accesed: June 17, 2026).

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evaluate preliminary efficacy and determine the optimal dose in hundreds of patients; and Phase III, which involves large-scale randomized trials in thousands of patients to demonstrate the benefit-risk ratio according to Good Clinical Practices (ICH E6).¹

- Marketing Authorization (MA) Stage:

Once the data are complete, the laboratory submits a dossier structured according to the Common Technical Document (CTD) format to the competent authorities, such as the National Agency for Pharmaceutical Products (ANPP) in Algeria or the European Medicines Agency (EMA). This dossier undergoes a rigorous evaluation process typically lasting one to two years, including an inspection of manufacturing sites to ensure compliance with Good Manufacturing Practices (GMP). This process establishes the legal framework for the prescription and dispensing of the medicine.²

- Marketing and Pharmacovigilance Stage:

After obtaining authorization, the drug enters the industrial production phase with continuous compliance with GMP and strict quality control for each batch (batch release) before market launch. In parallel, the manufacturer is required to activate a pharmacovigilance system to monitor adverse effects that may appear late under real-world usage conditions (Phase IV), and to submit Periodic Safety Update Reports (PSURs) enabling health authorities to take corrective decisions, thereby ensuring the sustainability of the medicine's benefit-risk balance.³

¹ G. BIALA, E. KEDZIERSKA, M. KRUK-SLOMKA, J. ORZELSKA-GORKA, S. HMAIDAN, A. SKROK, J. KAMINSKI, E. HAVRANKOVA, D. NADASKA and I. MALIK, « Research in the field of drug design and development », *Pharmaceuticals (Basel, Switzerland)*, vol. 16, n° 9, 2023, article 1283, pp. 1283-1300. DOI: <https://doi.org/10.3390/ph16091283>.

² Agence nationale de sécurité du médicament et des produits de santé (ANSM), « Médicaments princeps » [online]. (n.d.). Available at: <https://ansm.sante.fr/qui-sommes-nous/notre-perimetre/les-medicaments/p/medicaments-princeps> (Accessed: March 2, 2026).

³ Jordi BOTET, *Good Quality Practice (GQP) in Pharmaceutical Manufacturing: A Handbook*, Barcelona, Bentham Science Publishers Ltd, 2015, pp. 403-404, 481.

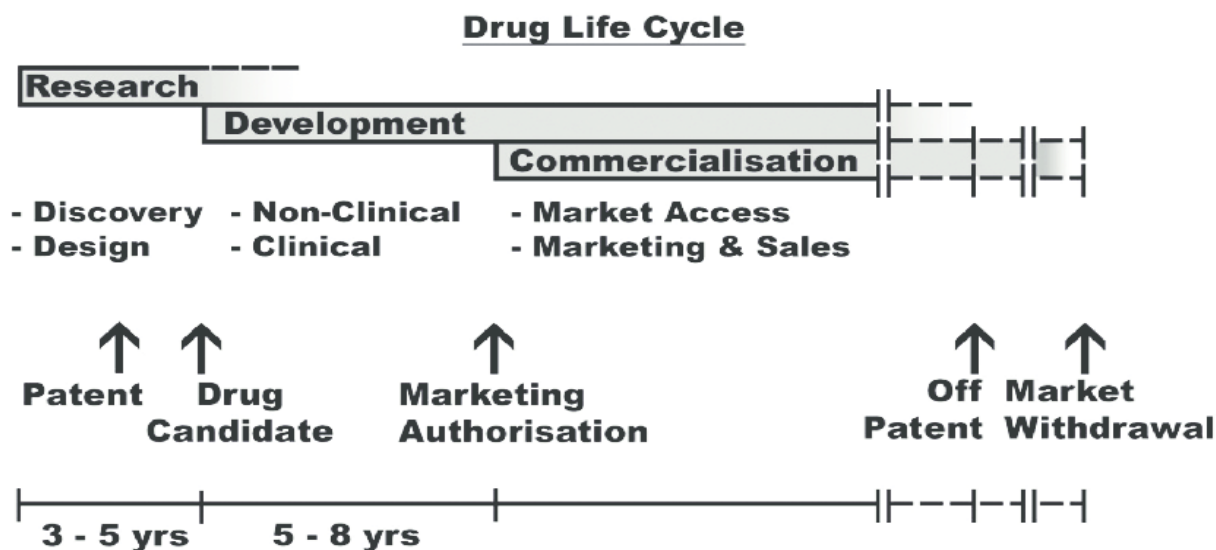
- Patent Expiry and Market Entry of Generic Medicines Stage:

The end of legal protection (typically after 20 years) represents a turning point known as the "patent cliff," opening the door to competition. To face this challenge, innovative companies adopt various strategies such as "evergreening" (minor modifications to extend monopoly), entering into strategic agreements with generic laboratories, or exerting administrative influence to cast doubt on the quality of competitors.¹

In conclusion, the relationship between the innovator and the generic is characterized by both mutual dependence and competition: patents stimulate innovation of new molecules, while generic drugs break the monopoly, reduce costs, and expand access to treatment, achieving a vital balance between supporting innovation and ensuring the right to affordable medicines.

¹ ¹Matthieu THEAU, « Une stratégie face aux génériques : l'innovation galénique et sa protection », Thèse de doctorat en pharmacie, Université de Poitiers, Faculté de Médecine et de Pharmacie, 2016, pp. 9-14. Available at: <https://dumas.ccsd.cnrs.fr/dumas-05421742> (Accessed: March 3, 2026).

Figure 2 : Drug Lifecycle



Source: Thomas, Josse & Schravendijk, Christiaan & Smit, Lucia & Saso, Luciano. (2016). Job and Career Opportunities in the Pharmaceutical Sector (Chapter from the book Special Topics in Drug Discovery).

2.The Generic Drug:

2.1 Definition of Generic Drug:

The legal definitions of generic medicines are clearly evident in the national legislations of Algeria and France, which in turn align with international standards issued by the World Health Organization (WHO), the U.S. Food and Drug Administration (FDA), and the European Directive (2001/83/EC).

According to Article 4 of Executive Decree No. 92-284 in Algeria, a generic medicine is defined as any specialty with a composition essentially similar to an original product, possessing the same qualitative and quantitative composition of the active substance, presented in the same pharmaceutical form, with bioequivalence to the original product

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demonstrated when necessary¹. Similarly, the European Union defines a generic medicine as "a medicinal product which is legally marketed (after expiry of the corresponding patents, if any) and which is identical to an existing medicinal product, being a product similar to it in terms of the same qualitative and quantitative composition of the active substance, the same pharmaceutical form, and bioequivalent in accordance with the recommendations of Council Directive 87/176/EEC of 9 February 1987."²

Based on these two definitions, which are consistent with international references, three essential and integrated criteria can be extracted upon which any legal definition of a generic medicine is based:

- Identity of the active substance: Qualitative and quantitative matching of the active ingredients.
- Identity of the pharmaceutical form: Matching of the drug formulation (tablets, solution, etc.).
- Demonstration of bioequivalence: Through bioavailability studies that confirm the equivalence of the drug's pharmacokinetic performance.

Based on the above, a generic medicine can be defined as a copy of the original drug that can be legally manufactured and marketed as soon as the patent covering the original active substance expires. These medicines are products whose exploitation is not subject to any patent, either because they have entered the public domain or because no patent was ever filed on them from the beginning. The generic medicine is manufactured by a

¹ *Journal officiel de la République algérienne démocratique et populaire*, Décret exécutif n° 92-284 du 6 juillet 1992 relatif à l'enregistrement des produits pharmaceutiques à usage de la médecine humaine, 12 juillet 1992, p. 1201. Available at: https://www.invest.caci.dz/fileadmin/template/recueil/pdf/Dcret_excutif_92-284.pdf (Accessed: March 3, 2026).

² Council of the European Communities, *Council Recommendation of 9 February 1987 concerning tests relating to the placing on the market of proprietary medicinal products (87/176/EEC)*, Official Journal of the European Communities, L 73, 17 March 1987. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:31987H0176> (Accessed: March 3, 2026).

pharmaceutical laboratory licensed by the public authorities, and it is required to meet the same quality, efficacy, and safety standards applicable to the reference product, and is subject to the same regulatory controls by the drug agency of the country concerned. However, it should be noted that a generic medicine does not necessarily have to be an exact replica of the original product in terms of appearance characteristics such as shape, colour, or size.¹

2.2. Regulatory and Economic Dimensions of Generic Drugs:

2.2.1. Legal and Regulatory Characteristics:

Generic drugs are subject to a strict legal framework that ensures a balance between protecting innovation and the right of access to medicines. Their most prominent characteristics are as follows:

- Expiration of protection and onset of competition: Marketing of a generic is only permitted after the patent of the original drug expires (usually 20 years). However, actual market entry may be delayed by additional mechanisms such as data exclusivity, which prevents competitors from using the original's clinical trial data for a specified period, or a Supplementary Protection Certificate (SPC) which extends commercial protection to compensate for lengthy development periods.²
- Abridged authorisation pathway: The generic drug licensing pathway relies on an abbreviated system that accelerates market access while ensuring quality. The Hatch-Waxman Act (1984) made it possible to bypass full-scale clinical trials, requiring only proof of equivalence in active ingredients and therapeutic efficacy compared to the reference

¹M. OUAZOUAZ, « Etude d'un produit pharmaceutique, médicament générique à usage humain », PhD Thesis, Université d'Annaba, 2014,p 21.

² THEAU, *op. cit.*, pp. 73-74.

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product. Globally, bioequivalence studies are considered the critical standard in this simplified registration process to guarantee drug quality and pharmacokinetic equivalence.¹

- The right of substitution (Droit de substitution): refers to the pharmacist's legal authority to dispense a generic medicine instead of the prescribed original drug in order to break the monopoly and reduce costs, provided that the pharmacist does not change the pharmaceutical form or the dosage specified in the prescription. To ensure the safety of this process, the following controls must be observed:²

- Compliance with the nomenclature: Substitution is only permitted for drugs officially listed under the same International Nonproprietary Name (INN) group.

- Caution with narrow therapeutic index (NTI) drugs: Substituting medicines such as antiepileptics or anticoagulants requires extreme caution due to the patient's sensitivity to any change in dose concentration.

- Patient consent and documentation: The patient must be informed of the therapeutic equivalence and their right to refuse must be respected, while the dispensed drug must be recorded on the prescription to ensure medical traceability.

- Substitution is strictly prohibited if the physician has noted "non-substitutable" on the prescription, or when a suitable alternative is not available for the patient's medical or demographic condition.

Basic characteristics of the drug: The characteristics of a medicine, essential for ensuring the safety and efficacy of treatment, rely on three main aspects:³

¹U.S. Food and Drug Administration, « 40th Anniversary of the Generic Drug Approval Pathway » [online], 2024. Available at: <https://www.fda.gov/drugs/cder-conversations/40th-anniversary-generic-drug-approval-pathway> (Accessed: March 3, 2026).

²*Journal officiel de la République algérienne démocratique et populaire*, Décret exécutif n° 92-276 du 6 juillet 1992 portant code de déontologie médicale [Executive Decree No. 92-276 of July 6, 1992 on the code of medical ethics], JORADP, n° 52, 1992, p. 1419.

³ZOUANTI née SNOUSSI Z., « L'accès aux médicaments en Algérie : Une ambiguïté entre les brevets des multinationales et le marché du générique », Thèse de doctorat, Université Hassiba Ben Bouali de Chlef, 2013,p

➤ Drug Name: It consists of two elements:

a-Trade name: Chosen by the manufacturer or the holder of the marketing authorization (MA) to identify and market its product, it is subject to legal rules to prevent confusion.

b-International Nonproprietary Name (INN/DCI): A global standardized name for the active substance adopted by the World Health Organization (WHO) to unify language and reduce errors.

➤ Dosage: The quantity of active substance in the pharmaceutical unit (e.g., mg per tablet), essential for ensuring accurate administration.

➤ Pharmaceutical Form: The physical form of the medicine (solid, liquid, or semi solid) that determines the route of administration and optimal use.

2.2.2. Economic Characteristics of Generic Drugs:

Generic drugs represent the most effective tool for rationalising health expenditure without compromising quality of care:

- Competitive cost: Generic prices are 20% to 80% lower than those of the original. This reduction is a natural consequence of the absence of huge research and development (R&D) costs and the intense competition among several manufacturers for the same molecule.

- Sustainability of healthcare systems: Generics contribute to reducing the overall health bill, allowing social security funds to reallocate resources towards covering other diseases or new therapeutic innovations, thus supporting universal health coverage strategies.

- Breaking monopolies and securing supply: These drugs end the monopoly of innovator companies over markets and also ensure "drug security" by providing available alternatives in cases of shortage or unavailability of imported original medicines.

5. Available at: <https://biblio.univ-alger.dz/jspui/bitstream/1635/16695/1/Mas.1316-.ALLALI%20et%20DAOUD.pdf> (Accessed: June 17, 2026).

- Improving equity in access to treatment: Thanks to their low price, generics enable vulnerable groups and those with limited income to access essential treatments for chronic diseases (such as diabetes and hypertension), thereby reducing health disparities among different segments of society.

3. Types of generic drugs:

Generic drugs are classified into four main categories based on their degree of similarity to the original drug:¹

- Identical/Full generic (Copie-copie): An exact copy of the original drug in terms of active substance, dosage, pharmaceutical form, and excipients. It is often produced by the same pharmaceutical laboratory.
- Equivalent generic (Équivalent): Matches the original in active substance, dosage, and form, with possible differences in excipients. Bioequivalence must be demonstrated.
- Related generic (Apparenté): Differs in composition (e.g., salt form) or pharmaceutical form, while belonging to the same chemical/pharmaceutical family. It must not compromise safety or efficacy.
- Improved generic (Amélioré): An enhanced version that provides better bioavailability or improvements in absorption rate, stability, or reduced side effects compared to the original.

4. Quality, Efficacy, and Safety of Generic Medicines:

To ensure that a generic medicine represents a reliable, effective, and safe alternative to the original drug, regulatory authorities rely on three integrated scientific pillars: quality, efficacy, and safety. These pillars work together to guarantee that every pharmaceutical

¹ABBAD ABD EL MADJID and BOUCHAKOR ERRAHMANI ISLAM, « Les médicaments génériques : Situation actuelle en Algérie », Mémoire de fin d'études (Doctorat en Pharmacie), Université Saad Dahleb – Blida 1, Faculté de Médecine, Département de Pharmacie, July 2023, pp. 38-39.

product reaching the patient fulfills its therapeutic purpose without exposing them to additional risks: ¹

4.1. Quality:

In the pharmaceutical industry, quality goes beyond merely maintaining facility cleanliness; it constitutes a documented and precise commitment to every step of the production chain, from raw materials to final packaging. To obtain a Marketing Authorization (MA), the company must submit a complete technical dossier that includes:

- Identification of the source of raw materials and their chemical characteristics (origin, purity, specifications).
- Provision of validated and fully documented manufacturing procedures.
- Conducting rigorous stability tests to determine the expiry date.
- Verification of product sensory specifications, packaging quality, and accuracy of information in the patient leaflet.

To ensure actual compliance, inspectors from regulatory authorities carry out periodic factory visits to verify the application of Good Manufacturing Practices (GMP) standards. These standards cover a broad system including staff training, building cleanliness, and documentation of all production pathways. In this context, the National Academy of Pharmacy (2012) explains that all drugs intended for the market undergo strict physical, chemical, and microbiological analyses to ensure they are free from toxic residues or infection risks, as well as verifying proper storage and packaging.

However, the World Health Organization (2008) warned that a GMP certificate and quality control (QC) results are not absolute guarantees, as relying on them alone may create a false sense of security. Quality control remains a technical tool linked to a specific reference standard, and there is no substitute for the integration of the three fundamental criteria of any medicine: quality, efficacy, and safety.

¹ OUAZOUAZ, *op. cit.*, pp. 26-30.

4.2. Efficacy:

Efficacy is the cornerstone for the approval of generic drugs. Because chemical identity alone is insufficient to guarantee therapeutic effect (due to the impact of different excipients and manufacturing methods on how the active substance reaches the bloodstream), regulatory bodies rely on three integrated scientific criteria to ensure the quality and equivalence of a generic drug:

a. Bioavailability: It is defined as the ability of a pharmaceutical formulation to ensure absorption and distribution of the active substance into the bloodstream to reach target organs in the same way as the original drug. This measurement is influenced by internal factors (properties of the active substance such as particle size and solubility) and external factors (excipients, manufacturing method, packaging). It is measured using two key indicators:¹

- **Area Under the Curve (AUC):** Reflects the total amount of active substance absorbed, ensuring the patient receives the required therapeutic dose without waste.
- **Maximum plasma concentration (C_{max}):** Reflects the intensity and timing of the effect, ensuring the drug reaches its maximum concentration at the same speed and pattern as the original, thus preventing delayed treatment or side effects.

b. Bioequivalence: is the primary regulatory and scientific standard that proves a generic drug provides the same clinical outcome and therapeutic efficacy as the original. Its importance lies in being an effective regulatory tool that ensures the safety of generic drugs and eliminates the need for long, costly clinical trials, thereby directly contributing to reducing healthcare costs and rationalizing expenses.

Bioequivalence is established through rigorous comparative studies on healthy volunteers using a crossover design. A drug is considered bioequivalent if the absorption ratios (AUC and C_{max}) fall within the internationally accepted statistical range (80% –

¹ Arthur J. ATKINSON Jr., « Drug absorption and bioavailability », in *Atkinson's Principles of Clinical Pharmacology*, Academic Press, 2022, pp. 43-59.

125%). Studies have shown that the actual average difference for generic drugs within this range is typically no more than 3.5%.

This standard constitutes the "scientific fingerprint" that grants a generic the status of "interchangeable" and legitimizes the pharmacist's right of substitution. However, because bioequivalence is demonstrated between each generic and the original individually, and not between two different generics, caution is necessary when switching between different generic products, especially for narrow therapeutic index drugs, to avoid therapeutic failure or toxicity. Without this proof, a generic drug remains an unreliable chemical copy.¹

c. Dissolution Tests — Ensuring continued efficacy

If a bioequivalence study is the drug's "birth certificate", the dissolution test is the "periodic check-up" that ensures every production batch maintains the performance approved at the time of licensing. It measures the amount of active substance released from the drug over time in a medium that simulates the digestive tract. These tests serve two essential functions in the quality control system:

- **Routine production control:** A mandatory test for each batch before it enters the market, ensuring that every tablet or capsule releases the active substance at the same speed and degree as approved. Any deviation from acceptance criteria yields an "Out of Specification" (OOS) result, immediately stopping the batch and triggering a mandatory investigation to ensure continued efficacy.

- **Biowaiver:** For highly soluble and permeable drugs (BCS Class I), authorities rely on laboratory dissolution data as a substitute for expensive clinical studies, thereby speeding up drug availability without compromising safety or efficacy.²

¹ABBAD ABD EL MADJID and BOUCHAKOR ERRAHMANI ISLAM, *op. cit.*, pp. 38-39.

² Sabrina BENYAHIA et Ahlem BOUMALA, « Le contrôle de la qualité des produits pharmaceutiques », Mémoire de fin d'études (Diplôme d'ingénieur d'État en Biochimie moléculaire et cellulaire, Option :

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4.3. Safety:

Safety concerns the evaluation of risks associated with "excipients". These are auxiliary substances that, although having no therapeutic effect, play vital roles in stabilizing the active substance, improving its solubility, and controlling its release. The danger lies in the fact that differences in excipients between the original drug and a generic may completely alter how the drug works. This has led the European Medicines Agency (EMA) to require companies to declare the effect of these substances on gastrointestinal transit, absorption, and dissolution.

Excipients may contain components such as sucrose or sodium that pose a threat to diabetic or kidney patients. There have been documented cases of therapeutic failure or adverse effects when switching between original and generic drugs due to such differences. Therefore, distinguishing between quality (ensuring the drug contains what it should) and safety (ensuring no additional risks) is essential for health managers when making substitution decisions, in order to build trust in generic drugs through comprehensive control of both active substances and excipients.

5.Differences and similarities between brand-name and generic drugs:

The following table presents the main similarities and differences between the originator medicine and the generic medicine, focusing on the regulatory, technical and economic dimensions.

Tableau 4:Key Similarities and Differences Between Princeps and Generic Drugs

Aspect	Originator medicine (Princeps)	Generic medicine (Générique)
I. Research & Development	New molecule discovery; preclinical studies and three phases of	Development from a known molecule; absence of full clinical

Contrôle de Qualité et Analyses), Université de Jijel, Faculté des Sciences, Département de Biologie Moléculaire et Cellulaire, juillet 2007, p. 23.

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	clinical trials; average duration 10 to 15 years; cost exceeding US\$ 2.6 billion.	trials; proof of bioequivalence; average duration 2 to 4 years; cost about 90% lower.
II. Regulatory framework (Algeria)	• Full CTD dossier (Modules 1-5) with original safety/efficacy data. • Registration decision (DE) from ANPP under Law 18-11.	• Abbreviated CTD dossier (same format) relying on originator data. • Same legal pathway to obtain DE; mandatory bioequivalence.
III. Composition	Innovative active substance protected by patent; excipients fixed during initial development.	Same active substance, same strength and same route of administration; excipients may differ provided they do not alter quality, safety or efficacy.
IV. Standards and control (ANPP)	• Specifications based on in-house or recognised pharmacopoeia. • Subject to GMP and GLP issued by ANPP. • Stability studies (ICH Q1A).	• Conformity to any recognised pharmacopoeia (Ph. Eur., USP, BP, etc.). • Same GMP/GLP requirements; inspections by ANPP. • Same stability requirements (ICH Q1A). • Bioequivalence interval 80-125%.
V. Pharmacovigilance	Mandatory reporting of adverse effects and continuous post-marketing monitoring.	Same pharmacovigilance obligations and post-marketing follow-up.
VI. Pricing	High price (recoups R&D investment).	On average 30 to 80% cheaper owing to the absence of initial

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		research costs and competition among manufacturers.
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Section 03: Pharmaceutical regulatory authorities in Algeria:

1. Evolution of the pharmaceutical sector and stakeholders:

1.1. Evolution of the pharmaceutical sector in Algeria (1962 to present):

1.The Monopoly Period (1962–1990):¹

This period is considered the era of foundation and general state control over the pharmaceutical industry sector, characterized by total reliance on imports and central monopoly. After independence, Algeria inherited a pharmaceutical system that relied on imports for more than 90% of its needs, in the near-total absence of local production. In 1969, the "Algerian Central Pharmacy" (PCA) was established as a single monopolistic entity responsible for the import, manufacture, and distribution of all human medicines. With the issuance of Decree No. 82/161 in 1982, a structural transformation occurred by separating production activities from distribution, leading to the establishment of the "National Pharmaceutical Production Enterprise" (ENPP) to ensure the state monopoly over production and to meet the needs of the local market. By 1985, the enterprise was renamed "SAIDAL," which became the sole public industrial hub, before being transformed in 1989 into a state-owned economic enterprise (EPE) with administrative independence. These stages led to the consolidation of absolute state control, as import and pricing operations remained centralized, and local production was limited to essential medicines through SAIDAL, while the "Algerian Central Pharmacy" retained its monopoly over distribution and import operations.

¹ نبيلة حدوي، « ممارسة المسؤولية الاجتماعية في المؤسسة الجزائرية - مجمع صيدالال »، *المجلة الجزائرية للعلوم الاجتماعية والإنسانية*، مجلد 8، عدد 2، 2020، ص. 488.

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2. The Liberalisation and Opening-up Period (1990–2010):¹

Between 1990 and 2010, the pharmaceutical sector in Algeria underwent radical structural transformations, shifting from a monopoly system to liberalization and regulatory development. This period began with the end of the state monopoly on foreign trade under Laws 90-10 and 90-16, followed by the establishment of legal foundations for drug registration and the definition of the "generic drug" through Decree 92-284, as well as the encouragement of foreign investments via Decree 93-12. To strengthen quality control, the National Laboratory for the Control of Pharmaceutical Products (LNCPP) was established between 1993 and 1995. Additionally, 43 implementing decisions were issued between 1995 and 1997, linking import operations to the necessity of investing in local manufacturing. In a move to support the emerging national industry, Algeria adopted the World Health Organization (WHO/GMP) standards of 1992 with flexibility, before expanding its regulatory frameworks in 1997 to include Good Clinical Practices (GCP). Despite the dynamism brought by the emergence of new private sector actors, the sector faced structural challenges, including an inflated import bill, a multiplicity of intermediaries, and difficulties in quality control oversight, leading to a decline in the market share of SAIDAL in the face of imported products, despite its continued leadership.

3. Major Reforms: Law 18-11 and the ANPP (2010 – today)²:

Between 2018 and 2021, Algeria implemented major structural changes to strengthen pharmaceutical sovereignty. Law No. 18-11 (2018) defined generic drugs and bioequivalence, strengthened quality control, and established the National Agency for

¹Rachid GHEBBI, « Historique de la législation du médicament en Algérie », 2018, pp. 1-9. Available at: https://www.academia.edu/39163761/HISTORIQUE_DE_LA_LEGISLATION_DU_MEDICAMENT_EN_ALGERIE (Accessed: June 17, 2026).

²Chahinez NEHAL, « Histoire de la pharmacie en Algérie », Course material, Université des Sciences de la Santé, Faculté de Pharmacie, 2025, pp. 1-5. (Designed for pharmacy students).

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Pharmaceutical Products (ANPP) to oversee drug registration, medical devices, and product safety (operational 2019-2020). A dedicated Ministry of Pharmaceutical Industry was created in 2020 to accelerate generic drug registration and GMP inspections. The National Laboratory for the Control of Pharmaceutical Products (LNCPP) was dissolved, transferring all its tasks to the ANPP, making it the sole authority for drug registration and quality control. The period ended with Decree 21-82 (2021) aiming to reduce the pharmaceutical import bill and boost local production.

2. Fundamental Legal Texts: From Law 85-05 to the "Health Constitution" 18-11:

Health Law 18-11 (2018): Known as the "Health Constitution" as it is the modern replacement for Law 85-05. It established legal foundations for modernizing the health system and ensuring the quality, safety, and efficacy of pharmaceutical products. It also focused on rationalizing social security expenditures by promoting generic drugs, noting that the first legal framework for generics appeared in 1992 under Decree 92-284.

Mechanisms to support production and regulation:¹

- Article 206: supports local production and encourages generic drugs.
- Article 205: obliges manufacturers and importers to ensure the availability of essential medicines.
- Article 219: regulates the distribution of medicines to guarantee their accessibility.
- National Agency for Pharmaceutical Products (ANPP): Chapter Four of Law 18-11 is dedicated to the ANPP. Article 223 provides for its creation as an administrative body with financial autonomy, tasked with drug registration and control. This step unifies regulatory oversight following the dissolution of the former national laboratory (LNCPP).

¹People's Democratic Republic of Algeria, *Law No. 18-11 relating to health*, Official Journal No. 46, July 29, 2018, pp. 19-22, Article 11.

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- Alongside Law 18-11, the legal framework consists of a set of complementary texts that specify its implementation mechanisms, the most important of which are:
 - Order 20-02 (2020): Amended Law 18-11 and transferred supervisory authority over the ANPP to the Ministry of Pharmaceutical Industry to strengthen coordination between regulatory and industrial sides.¹
 - Decree 21-82 (2021): A strategic tool reorganizing pharmaceutical establishments (manufacturing, import, distribution) and precisely defining their responsibilities. It aims to enhance health sovereignty by encouraging national production, reducing the import bill, and imposing international quality standards under the supervision of the ANPP.²
 - Decree 23-105 (2023): Defines the tasks of the Intersectoral Economic Committee for Medicines, a mechanism for cross-sector coordination on drug pricing and market regulation.³
 - Decree 22-247 (2022): Resulted in the publication of the national Good Manufacturing Practices (GMP) guide in September 2022. This is the first official document issued by a competent Algerian authority, serving as a regulatory tool that translates legal requirements into binding technical recommendations for manufacturers and importers.⁴

¹People's Democratic Republic of Algeria, *Order No. 20-02 of August 30, 2020, amending Law No. 18-11 on health*, Official Journal No. 50, 2020, pp. 4-5.

²Algeria, *Decree No. 21-82 of February 23, 2021 (approval of pharmaceutical establishments)*, Official Gazette No. 14, 2021, pp. 10-13.

³ Algeria, *Executive Decree No. 23-105 Amending Decree No. 20-326 on the Medicines Economic Committee*, Official Gazette, 2023. Available at: <https://dgpp.industrie.gov.dz> (Accessed: March 6, 2026).

⁴République algérienne démocratique et populaire, *Décret exécutif n° 22-247 du 30 juin 2022 relatif aux règles de bonnes pratiques de fabrication des produits pharmaceutiques à usage humain*, Journal officiel n° 46, 2022, pp. 15-18.

3. Regulatory and Control Institutions:

3.1. Ministry of Health:

The Algerian Ministry of Health, based on Executive Decree No. 11-379 and Law No. 18-11, ensures the conduct and coordination of national health policy through three integrated axes:¹

Strategic regulation: The Ministry develops strategic orientations for public health, drafts legislative and regulatory texts, and ensures their effective implementation at the national level.

Institutional supervision: The Ministry exercises its administrative and regulatory control over public health establishments and the decentralized directorates of the wilayas, while taking into account the legal transfer of supervisory authority over the National Agency for Pharmaceutical Products (ANPP) to the Ministry of Pharmaceutical Industry under Order No. 20-02.

Strengthening health security: The Ministry is responsible for managing the pharmaceutical market, assessing its needs, ensuring the availability of essential medicines, as well as regulating and controlling the sector through the issuance of practice licenses.

3.2. Ministry of Pharmaceutical Industry and Production:

The ministry was established in June 2020 (under Presidential Decree 20-163), representing a strategic shift making the pharmaceutical industry an independent sector supporting the national economy. In November 2023 (under Executive Decree 23-412), its

¹People's Democratic Republic of Algeria, *Executive Decree No. 11-379 of November 21, 2011, defining the attributions of the Minister of Health, Population and Hospital Reform*, Official Gazette No. 63, 2011. Available at: <https://www.joradp.dz/FTP/jo-arabe/2011/A2011063.pdf> (Accessed: March 6, 2026).

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scope expanded to become the "Ministry of Pharmaceutical Industry and Production," leading an integrated economic and industrial vision for national pharmaceutical policy.¹

3.2.1. Core Missions:²

Supervision and Regulation: Regulating the entire pharmaceutical sector chain, from manufacturing to distribution, to ensure drug quality and safety.

- Local Production Development: Developing strategies for local industry growth, increasing its market share, and supporting R&D in innovative drugs and biotechnology.
- Investment and Export: Attracting local and foreign investments and encouraging the export of pharmaceutical products and medical supplies.
- Drug Security: Ensuring the availability of medicines and medical supplies in the national market and preventing shortages through needs analysis and the regulation of imports and distribution.
- Licensing and Control: Granting licenses to institutions, overseeing drug registration, and issuing Good Manufacturing Practices (GMP/BPF) certificates.
- Digitalization and Traceability: Managing the digital transformation of the sector and establishing a traceability system for pharmaceutical products and medical devices.

3.2.2. Supervisory Authority:

The ministry exercises its supervisory authority over the following bodies:

¹Algeria, *Presidential Decree No. 20-163 of June 23, 2020, forming the government – Establishment of the Ministry of Pharmaceutical Industry*, Official Gazette, 2020. Available at: <https://miph.gov.dz> (Accessed: March 7, 2026).

²Algeria, *Executive Decree No. 25-188 of July 13, 2025, on the organization of the central administration of the Ministry of Pharmaceutical Industry*, Official Gazette No. 45, 2025, arts. 2-6.

- National Agency for Pharmaceutical Products (ANPP): Placed under the ministry's supervision since August 2020, serving as its technical and regulatory arm. The ministry guides its strategy, while the agency handles registration, quality control, and inspection, ensuring the integration of industrial policy with quality and safety standards.¹
- SAIDAL Group: The supervision of SAIDAL was transferred from the former Ministry of Industry and Mines to this ministerial sector. The ministry oversees SAIDAL's performance, guides its production plans, and works to develop its capacities in generic drug manufacturing, in line with the strategy to achieve health security and self-sufficiency.

3.3. The National Agency of Pharmaceutical Products (ANPP):

The National Agency of Pharmaceutical Products (ANPP) is an independent administrative authority endowed with legal personality and financial autonomy, established under Law No. 18-11 on health. The agency effectively began its operations between 2019 and 2020 pursuant to Executive Decree No. 20-316, which included the dissolution of the National Laboratory for the Control of Pharmaceutical Products (LNCPP) and the transfer of its staff, equipment and missions to the ANPP. The agency is currently under the supervision of the Ministry of Industry and Pharmaceutical Production (in accordance with Order No. 20-02), where it plays a pivotal role combining rigorous technical control and quality assurance with support for the national industrial sovereignty strategy.²

3.3.1. Main missions of the ANPP:

The National Agency of Pharmaceutical Products exercises sovereign missions covering the entire lifecycle of pharmaceutical products. Its main tasks include:³

¹Algeria, *Ordonnance n° 20-02 du 30 août 2020 modifiant la loi n° 18-11 relative à la santé*, Official Journal No. 50, 2020, art. 1.

² National Agency for Pharmaceutical Products (ANPP), « المهام » [Missions] [online]. (n.d.). Available at: <https://anpp.dz/missions/> (Accessed: June 8, 2026).

³ National Agency for Pharmaceutical Products (ANPP), « Presentation of ANPP » [online]. (n.d.). Available at: <https://anpp.dz/presentation-de-lanpp/> (Accessed: June 9, 2026).

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- Drug registration: Granting, renewing, suspending or withdrawing the registration decision (DE) for any medicine intended for the Algerian market, after consulting the competent technical committees, which conduct a precise scientific evaluation of the benefit-risk ratio and therapeutic value.
- Approval of medical devices: Issuing the approval decision for various types of medical devices (instruments, equipment, medical software, etc.).
- Technical and laboratory control: Ensuring medicines comply with national and international standards by carrying out physicochemical and microbiological analyses.
- Inspection and compliance: Conducting on-site audits of manufacturing and distribution sites to verify strict compliance with Good Manufacturing Practices (GMP/BPF).
- Pharmacovigilance and risk management: Coordinating with the National Pharmacovigilance Centre (CNPM) to monitor adverse effects and overseeing the withdrawal of non-conforming batches from the market.
- Economic regulation: Setting medicine prices (ex-works price for locally produced products, FOB value for imported products) and participating in the preparation of the list of medicines reimbursable by social security.
- Research support and cooperation: Giving opinions on applications for clinical trials and bioequivalence studies, and working to align national legislation with international standards (such as ICH and WHO).

3.4. The National Centre for Pharmacovigilance and Materiovigilance (CNPM):

The National Centre for Pharmacovigilance and Materiovigilance (CNPM) is a public administrative institution, endowed with legal personality and financial autonomy, and placed under the supervision of the Ministry of Health. It was established by Executive Decree No. 98-192 (1998) and is the sole national body responsible for monitoring the safety of medicines and medical devices after they are placed on the market in Algeria, within the framework of Law 18-11 and its implementing decrees.

The CNPM works to protect public health through an integrated system for reporting adverse effects, conducting investigations, and proposing corrective actions (such as issuing

recommendations, batch recalls, and updating product information)¹, The centre also participates internationally in the WHO Programme for International Drug Monitoring via the Uppsala Monitoring Centre (UMC), with Algeria being a participating member since 2006.²

3.4.1. Core Missions:

The National Center of Pharmacovigilance and Materiovigilance (CNPM), established by Decree 98-192, is the reference authority for ensuring the safety of health products in Algeria. It acts as a safety valve for the health system along the following axes:

- Monitoring and investigation: Tracking adverse effects of medicines and vaccines, as well as incidents involving medical devices; conducting field investigations to identify the root causes of risks.
- Analysis and intervention: Collecting and evaluating data, submitting immediate reports to the ministry, and imposing corrective measures (such as withdrawals or updates) and Risk Management Plans (RMPs) on laboratories.
- National and international network: Managing the network of field stakeholders locally and coordinating with international organizations (e.g., Vigibase) to exchange scientific alerts.
- Training and awareness: Promoting the rational use of medicines and medical devices by training medical staff (on prescribing and dispensing), disseminating reliable scientific information to professionals and the general public, and participating in scientific and awareness-raising events.

3.4.2. Organization Operation and Reporting System of the Centre:

¹National Center of Pharmacovigilance and Materiovigilance (CNPM), « Presentation of CNPM » [online], June 2025. Available at: <https://cnpm.org.dz/presentation-du-c-n-p-m/> (Accessed: June 9, 2026).

²T. M. ALSHAMMARI, N. MENDI, K. A. ALENZI and Y. ALSWAIDA, « Pharmacovigilance Systems in Arab Countries: Overview of 22 Arab Countries », *Drug Safety*, vol. 42, n° 7, July 2019, pp. 849-868.

The National Center of Pharmacovigilance and Materiovigilance (CNPM) is managed by a Steering Committee chaired by a Director General, assisted by an Advisory Scientific Council of experts, in accordance with internal regulations defined by a joint ministerial decree, ensuring precise institutional governance. To activate its supervisory role, the Center relies on a "participatory reporting system" covering all health products (medicines, vaccines, medical devices, dietary supplements, and cosmetics). The duty to report is assigned to all stakeholders in the health sector, including professionals and reference institutions (such as the Pasteur Institute and the National Poison Control Center), as well as pharmaceutical companies and patients themselves, through standardized tools (electronic and paper) and direct communication channels. This system is further strengthened by a strategic partnership network with key bodies such as the National Agency for Pharmaceutical Products (ANPP) and the Central Hospital Pharmacy (PCH), supported by regional technical collaborators spread across the country's provinces, ensuring an effective flow of information and precise field monitoring to guarantee the safety of the national health system.¹

3.4.3. Obligations Imposed on Pharmaceutical Laboratories:

Algerian health authorities impose strict regulatory obligations on laboratories holding a Marketing Authorization (MA) to ensure drug safety. These obligations begin with the mandatory establishment of an internal pharmacovigilance system and the appointment of a qualified Responsible Person for Pharmacovigilance (RPV) based in Algeria to ensure direct communication with the National Center (CNPM). Laboratories are also required to report adverse reactions immediately (within 15 days for serious cases and 90 days for non-serious cases), and to submit periodic safety reports (PSUR/PBRER) according to specified timelines. In addition, the laboratory must provide a Risk Management Plan (RMP) defining preventive measures to reduce potential risks. The institution is also subject to periodic or

¹ National Center of Pharmacovigilance and Materiovigilance (CNPM), *Algerian guide to pharmacovigilance* [PDF], 2019. Available at: <https://www.miph.gov.dz/en/wp-content/uploads/2025/07/guide-pharmaco.pdf> (Accessed: March 8, 2026).

unannounced inspections by the Center to ensure full compliance with national and international standards, thereby ensuring continuous and effective monitoring of the quality and safety of pharmaceutical products on the national market.

4. Main Actors in the Pharmaceutical Market:

The Algerian pharmaceutical market comprises a variety of institutional, professional, and economic actors, among whom the organisation of the supply chain, production, distribution, and control is distributed. This section aims to provide a brief overview of these categories and their main representatives, while indicating the basic tasks assigned to each, in order to clarify the market structure within which quality control systems operate and through which generic medicines are distributed.

This is what the table below illustrate: ¹

¹ République Algérienne Démocratique et Populaire - Conseil de la Concurrence. (s.d.). *Étude sectorielle sur la concurrentiabilité du marché des médicaments à usage humain en Algérie.*

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Tableau 5: Main Actors in the Pharmaceutical Market

Category	Main Actors	Role Description
Regulatory authorities and bodies	Ministry of Health, Ministry of Industry and Pharmaceutical Production, ANPP, CNPM	Formulating national drug policies, granting marketing authorisations (ANPP), inspecting factories and pharmacies, and monitoring post-marketing drug safety (CNPM).
Producers (manufacturers)	Public sector: SAIDAL Private sector: National laboratories (Biopharm, Frater-Razes) and foreign subsidiaries (Sanofi, Novartis, Pfizer)	Manufacturing originator and generic medicines, complying with Good Manufacturing Practices (GMP), and ensuring product quality before market release.
Importers	LPA, IMA, DISTRIMED, COPHARM	Supplying medicines and raw materials not produced locally, with a mandatory requirement to invest in local production within two years of starting operations.
Wholesale distributors	• 637 distributors registered in the trade register.	Storing medicines under appropriate conditions and distributing them to pharmacies and hospitals in accordance with Good Distribution Practices (GDP).
Retail pharmacies	Private pharmacies: 11,241 pharmacies Public pharmacies (ENDIMED): 800 pharmacies	Direct point of contact with patients, dispensing medicines with prescriptions, applying the substitution right (generic substitution), and educating patients.

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Public supply institutions	PCH (Central Hospital Pharmacy), IPA (Pasteur Institute of Algeria)	Supplying public hospitals with medicines and surgical equipment (PCH), and producing/distributing vaccines, sera, and biological reagents (IPA).
Professional unions and associations	SNAPO, SNECHU, UNOP, FAP, ethics councils	Representing the profession, defending pharmacists' rights, organising continuing education, and overseeing professional ethics.

Source: *Elaborated by the author based on République Algérienne Démocratique et Populaire – Conseil de la Concurrence (s.d.).*

Conclusion of Chapter 1:

This chapter concluded that pharmaceutical quality is an essential and indispensable pillar for ensuring the safety and efficacy of medicines, as its concept has evolved from mere technical specifications to an integrated administrative system combining the preventive dimension of Quality Assurance (QA) and the regulatory dimension of Quality Control (QC). The chapter also highlighted those generic medicines, despite their economic nature, are subject to the same rigorous standards applied to originator drugs, through the adoption of precise scientific criteria such as bioequivalence and dissolution tests, which grant them therapeutic legitimacy and enhance their role in achieving equity in access to medicines.

At the national level, the institutional and regulatory framework of the Algerian pharmaceutical sector, thanks to its recent structural reforms, shows a clear trend towards strengthening oversight and ensuring quality, thereby consolidating patient confidence in marketed pharmaceutical products. This direction is fundamental to understanding how to build effective quality systems, not merely as compliance tools, but as pillars of sustainable trust in generic medicines, which will be the focus of the upcoming chapters of this research.

Chapter II:

Consumer trust and health behavior regarding generic medicines.

Introduction

Trust constitutes a strategic pillar in behavioral and economic sciences, acting as the "glue" that connects individuals to institutions and ensures the stability of relationships. In the pharmaceutical sector, this trust takes on a particular dimension due to the nature of the patient and the uncertainty inherent in therapeutic decisions. Accordingly, consumer trust in generic medicines is not limited to the technical evaluation of quality; it is rather the product of a complex interaction between cognitive, affective, and institutional dimensions that guide health behaviors.

In this context, the second chapter aims to deconstruct the mechanisms underlying the formation of Algerian consumers' trust in generic medicines, based on a multidimensional theoretical framework. It is divided into three integrated sections :

- Section 01: Conceptual foundations of consumer trust in generic medicines
- Section 02: Risk perception and behavioral determinants of the consumer
- Section 03: The relationship between quality control and trust enhancement.

This chapter thus lays the methodological foundations for understanding how negative perceptions can be transformed into sustainable trust, forming an essential basis for analyzing the results of the field study in the following chapters.

Section 01: Conceptual Framework of Consumer Trust in Generic Medicines.

1- Definition and dimensions of trust:

1.1 General definition of trust:

Trust is a strategic pillar in the behavioral and economic sciences, acting as the "glue" that binds individuals to institutions and ensures relational stability. It is an intangible asset that provides a competitive advantage by reducing uncertainty and enhancing customer loyalty. Despite its vital importance, trust remains a complex academic concept due to the multiplicity of theoretical approaches and the diversity of its study contexts.

Despite this diversity, researchers agree on its fundamental essence:

Mayer et al. (1995) define it as "the willingness of a party to be vulnerable to the actions of another party based on the expectation that the other will perform a particular action important to the trustor, irrespective of the ability to monitor or control that other party."¹

In the consumption context, this concept takes on a more nuanced relational dimension, where Moorman, Deshpandé & Zaltman (1993) define it as "a willingness to rely on an exchange partner in whom one has confidence."²

In this regard, Rousseau et al. (1998) summarize the nature of this concept by stating: "Trust would not be needed if actions could be undertaken with complete certainty and no risk,"³ thereby affirming that risk and interdependence are the two pillars without which trust cannot emerge.

¹ Roger C. MAYER, James H. DAVIS, and F. David SCHOORMAN, "An Integrative Model of Organizational Trust", *The Academy of Management Review*, vol. 20, no. 3, July 1995, p. 712.

² Christine MOORMAN, Rohit DESHPANDÉ, and Gerald ZALTMAN, "Factors Affecting Trust in Market Research Relationships", *Journal of Marketing*, vol. 57, no. 1, January 1993, p. 82.

³ Denise M. ROUSSEAU, Sim B. SITKIN, Ronald S. BURT, and Colin CAMERER, "Not so different after all: A cross-discipline view of trust", *Academy of Management Review*, vol. 23, no. 3, July 1998, p. 395.

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Based on this theoretical foundation, trust in exchange relationships rests on four essential characteristics that intertwine to form the structure of this behavioral phenomenon:

State of Uncertainty: This is the primary justification for the existence of trust; we resort to it precisely because we cannot verify everything; it is a means of managing the unknown.

Vulnerability (Risk): The consumer takes a real risk when granting their trust, voluntarily accepting exposure to the consequences of their decision in an environment with uncertain outcomes.

Reliance on Expectations: Trust is based on a firm belief that the other party will act competently and in good faith.

Dynamic Nature: Trust is not a static state, but a process that is built and evolves (or deteriorates) over time based on the accumulation of continuous interaction experiences.

1.2 The Three Dimensions of Trust:

Academic literature agrees that trust is a complex construct consisting of three complementary dimensions that interact to explain how it is formed and how it influences consumer behavior:¹

¹ MCALLISTER Daniel J., "Affect- and cognition-based trust as foundations for interpersonal cooperation in organizations", *Academy of Management Journal*, vol. 38, no. 1, February 1995, pp. 24-59.

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Tableau 6: The Three Dimensions of Trust (Cognitive, Affective, Behavioral)

Dimension	Description	Key Elements	Outcome / Function
Cognitive	Rational and objective evaluation of the other party's competence and reliability.	Credibility, expertise, knowledge, past experiences.	Reduces risk and uncertainty.
Affective	Interpersonal bonds and mutual feelings that go beyond logic.	Benevolence, empathy, psychological security.	Creates a sense of reassurance and safety.
Behavioral	Translating trust into concrete actions and intentions.	Willingness to act, purchase, commitment, recommendation.	Cooperative behaviors resulting from the integration of cognition and affection.

Source: Elaborated by the author based on McAllister (1995).

These dimensions do not operate in isolation; trust, as a psychological variable, emerges from an integrated process that begins with the cognitive evaluation of risks and benefits, is reinforced by emotional bonds based on experience, and ultimately culminates in tangible cooperative behaviors.

1.3. Reference Theoretical Models:

This study is based on two leading theoretical models that complement each other in covering the dimensions of trust at both the individual and institutional levels:

1.3.1. Mayer et al. (1995) Model:

The Mayer et al. (1995) model is the most prominent reference in organizational trust, as it views trust as a rational judgment based on evaluating the other party's characteristics

rather than merely an emotional feeling. An individual's willingness to trust depends on their perception of three interrelated factors:

- Ability: The technical competence and skills necessary to perform what is expected in a given domain.
- Benevolence: The belief that the other party seeks to act in the interest of the trustor, not solely in its own self-interest.
- Integrity: Adherence to a set of ethical principles and values that the trustor finds acceptable.

These factors interact together to form trust; complete trust is only achieved when they are all present, as skill alone is insufficient in the absence of integrity, nor is integrity without the ability to execute.¹

1.3.2. McKnight & Chervany (2002) Model:

The McKnight & Chervany (2002) model is a fundamental contribution to trust studies, as it expanded the scope of research from the individual level to the institutional and structural level. The model presents four complementary components of trust:

Trusting beliefs: Positive convictions about the other party's characteristics (e.g., competence, honesty, benevolence).

- Trusting intentions: The individual's willingness to rely on the other party and accept risk despite the possibility of harm.
- Trusting behaviors: Concrete actions and actual decisions that translate the state of trust into reality.
- Institution-based trust: Trust resulting from formal structures, guarantees, and the surrounding regulatory frameworks.

¹ MAYER, DAVIS et SCHOORMAN, *op. cit.*, pp. 716-720.

This model emphasizes that trust depends not only on the direct evaluation of the other party but is also shaped by the institutional environment (laws, standards, control mechanisms), which enhances individuals' levels of trust.¹

2. Trust in the Healthcare Field:

2.1. Definition of trust in the health domain:

Many researchers have proposed definitions of trust specifically adapted to the healthcare context. Hall et al. (2001) define trust in health as: "the optimistic acceptance of vulnerability by a patient toward a physician or a healthcare system, based on the conviction that the latter will act in the patient's best interest."²

This definition highlights three essential elements that characterize trust in the healthcare field:

Vulnerability: It is the patient's conscious decision to rely on the healthcare provider despite the risks, a necessity arising from a state of weakness and health-related need, whereby the patient places their trust based on the expectation of responsible behavior from the other party.³

Positive Orientation: The acceptance of vulnerability is grounded in expectations that the other party acts exclusively in the patient's interest; these expectations combine technical

¹ D. Harrison McKnight and Norman L. Chervany, "What trust means in e-commerce customer relationships: An interdisciplinary conceptual typology", *International Journal of Electronic Commerce*, vol. 6, no. 2, Winter 2001-2002, pp. 9-19.

²Mark A. HALL, Elizabeth DUGAN, Bing ZHENG and A. K. MISHRA, "Trust in physicians and medical institutions: What is it, can it be measured, and does it matter?", *The Milbank Quarterly*, Vol. 79, No. 4, December 2001, p. 615.

³ Lucy GILSON, "Trust and the development of health care as a social institution", *Social Science & Medicine*, Vol. 56, 2003, p. 1456.

competence (skill and professionalism) with ethical integrity (honesty, fairness, and genuine concern).¹

Trust as a Cooperative Partnership: Trust rises to become an "implicit agreement" and a partnership based on shared treatment goals, thereby giving the patient a sense of security and certainty that both parties will commit to their roles, free from any exploitation.²

In the same context, Thom & Campbell (1997) affirm that trust in the medical domain necessarily involves belief in the healthcare provider's competence and in their motivation to act solely for the patient's benefit, irrespective of any external considerations.³

2.2. The specific characteristics of trust in healthcare:

Trust in the healthcare sector is characterized as a strategic pillar that surpasses commercial exchanges in its complexity, for the following reasons:

Asymmetry of information: Trust arises to bridge the cognitive gap between the patient and the "system of experts," as the patient is forced to rely on institutions and professionals due to their inability to medically assess service quality on their own.⁴

High stakes: Healthcare decisions are irreversible, making trust extremely fragile; any failure can lead to serious consequences that go beyond disappointment to reach moral outrage for the patient.⁵

¹ *Ibid.*, p. 1454.

² Vijayaprasad GOPICHANDRAN, "Trust in healthcare: an evolving concept", *Indian Journal of Medical Ethics*, Vol. 10, No. 2, April-June 2013, p. 79.

³David H. THOM et Bruce CAMPBELL, « Patient-physician trust: An exploratory study », *Journal of Family Practice*, vol. 44, n° 2, février 1997, p. 171.

⁴ Kenneth J. ARROW, "Uncertainty and the welfare economics of medical care", *American Economic Review*, Vol. 53, No. 5, December 1963, p. 965.

⁵ David MECHANIC and Sharon MEYER, "Concepts of trust among patients with serious illness", *Social Science & Medicine*, Vol. 51, No. 5, September 2000, pp. 661-663.

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Networked trust: Trust is not limited to the doctor-patient relationship, but extends to include a chain of actors (pharmacist, manufacturer, regulatory bodies); any flaw in any link affects the credibility of the entire system.¹

Affective dimension: In the face of illness, trust transforms from logical calculations into "faith" and a psychological defense against existential anxiety, making empathy and emotional support an essential part of the success of the treatment plan.²

2.3.Levels of Trust in the Healthcare Sector:

Trust in the healthcare sector is distributed across four interrelated levels that form a "network structure," where each level influences the others (cascade effect)³, and any failure may lead to a complete collapse of trust:

Interpersonal trust: Built on direct encounters between the patient and the healthcare provider, assessing their competence, integrity, and concern. It evolves from "thin trust" at the first meeting to "thick trust" based on experience, and is the primary driver of patient adherence to treatment.⁴

Organizational trust: The patient's perception of an institution's competence (such as a hospital or pharmacy) is based on its reputation and official accreditations, which serve as structural assurances that compensate for the patient's lack of direct information. Institutions seek to enhance this trust in order to reduce uncertainty and risk, thereby ensuring the continuity of the relationship with the customer. Positive impressions transfer from the

¹ ZHENG, Siu Fu HUI and Zhilin YANG, "Hospital trust or doctor trust? A fuzzy analysis of trust in the health care setting", *Journal of Business Research*, 2017, p. 3.

² HALL et al., *op. cit.*, pp. 617-618.

³ GILSON, *op. cit.*, p. 1459.

⁴ Zara J. BENDING, "Reconceptualising the Doctor–Patient Relationship: Recognising the Role of Trust in Contemporary Health Care", *Bioethical Inquiry*, Vol. 12, 2015, p. 194.

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institution to its individuals through the "halo effect," which strengthens overall trust and increases the intention to use the service.¹

System trust: The cornerstone directed toward abstract systems (laws, regulatory bodies). It gives the patient the ability to trust strangers (healthcare providers) thanks to legal and institutional guarantees that compensate for the absence of personal knowledge.²

Trust in medical interventions (medication): Linked to the degree of system transparency in ensuring product quality and safety. Any lack of institutional transparency immediately reflects on the medication, leading patients to question its safety and avoid using it.

To move beyond the traditional view that treats medication as an ordinary consumer good, a conceptual model has been developed that analyzes trust in medication through five interrelated dimensions; these dimensions play a crucial role in shaping patient awareness and acceptance of therapeutic options, particularly generic medicines:³

¹ ZHENG, HUI et YANG, *op. cit.*, p. 2.

² Lucy GILSON, "Trust in health care: theoretical perspectives and research needs", *Journal of Health Organization and Management*, Vol. 20, No. 5, 2006, pp. 360-361.

³ Jean-Claude ANDRÉANI, Jean-Louis MOULINS, Françoise CONCHON, Cendrine FONS et Benjamin BOEUF, « Une approche protéiforme de la confiance du consommateur. Le cas des médicaments », *Décisions Marketing*, vol. 75, n° 3, 2014, pp. 83-86.

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Tableau 7: The five dimensions of trust in medication

Dimension	Core / Definition	Application in the Context of Generic Medicines
1. Reliability	The intrinsic quality of the drug, its therapeutic efficacy, and its benefit-risk balance. This is the most fundamental and influential dimension of general trust.	Directly related to therapeutic equivalence: Does the patient trust that the generic medicine achieves the same results as the original brand-name drug? This dimension represents the greatest challenge to the acceptance of generic alternatives.
2. Investment in Innovation	Reflects the manufacturer's benevolence and good intentions; i.e., the belief that investment in research and development is genuinely aimed at improving patient health, not merely profit.	Although generic medicines rely on prior innovations, patient trust is influenced by the extent to which they perceive that the healthcare system encourages genuine innovation, which may reduce the inferior perception of generic alternatives.
3. Transparency of Information	Clarity and adequacy of information about the drug (package insert, updates on side effects, recommendations for proper use, institutional information).	Lack of clear information about generic approval criteria or the patient's failure to understand the drug leaflet weakens trust. Transparency enhances acceptance of the generic alternative.
4. Credibility of Actors	The integrity of all parties in the supply chain (manufacturers,	If the patient suspects that the physician prescribes the brand-

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	physicians, pharmacists); and the patient's perception that they act ethically and sincerely, not out of purely commercial motives.	name drug for commissions, or that the pharmacist promotes a poor-quality generic, their credibility collapses, and acceptance of the generic declines.
5. Societal Responsibility	The ability of drug actors to build a sound and sustainable relationship with society, including fair exchanges, fulfilling promises, reducing health disparities, and protecting the environment.	This dimension is used as an ethical tool to enhance social acceptance of generic medicines, portraying them as a means to reduce disparities in access to treatment and achieve health equity.

Source : Élaboré par l'auteur à partir de Andréani et al. (2014).

3. Distinction between certified quality and perceived quality:

3.1. The Concept of Certified quality:

Certified quality is defined as the conformity of a medicine to regulatory standards through rigorous scientific processes attested to by competent institutions. It is "objective quality" that exists independently of consumer perception.

Its importance lies in addressing "adverse selection" in pharmaceutical markets: since the consumer is unable to distinguish between quality levels, they automatically assume an average quality, which threatens the withdrawal of high-quality products from the market. Therefore, certification and monitoring systems act as reliable signals that guarantee quality and reduce the information asymmetry gap between the manufacturer and the patient.¹

¹ AKERLOF, George A., "The Market for 'Lemons': Quality Uncertainty and the Market Mechanism", *The Quarterly Journal of Economics*, Vol. 84, No. 3, August 1970, pp. 488-500.

3.2. The Concept of Perceived Quality:

In contrast to objective quality, Zeithaml (1988), in her seminal study "Consumer Perceptions of Price, Quality, and Value," established the reference definition of perceived quality:

"Perceived quality is defined as the consumer's judgment about a product's overall excellence or superiority. It differs from objective quality in that it is a mental abstraction rather than a mere technical attribute, and a comprehensive evaluation that essentially resembles an attitude."¹

This definition identifies three fundamental characteristics that distinguish perceived quality from certified (objective) quality:²

Abstraction: It transcends technical attributes to integrate emotional and symbolic dimensions, distancing itself from the language of laboratory standards.

Holistic Evaluation: It is not measured by discrete indicators, but rather is a global impression that integrates various signals (price, packaging, recommendations) into a single judgment.

Attitude-like Stability: It functions as a stable psychological state that resists change, explaining patients' tendency to reject scientific evidence that contradicts their prior impressions about generic medicines.

Bridging the trust gap requires communication strategies that do not merely provide technical data, but seek to reshape the patient's "psychological attitude" toward generic medicines, transforming their negative impressions into convictions built on trust.

3.3. Determinants of Perceived Quality and the Relationship with Trust:

When technical evaluation of a product is difficult—a structural reality for patients regarding generic medicines—consumers shift their reliance from intrinsic attributes

¹ Valarie A. ZEITHAML, "Consumer Perceptions of Price, Quality, and Value: A Means-End Model and Synthesis of Evidence", *Journal of Marketing*, Vol. 52, No. 3, July 1988, p. 3.

² ZEITHAML, *op. cit.*, pp. 3-4.

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to extrinsic cues. This reliance on "quality surrogates" determines the patient's trust.¹ The primary determinants are:

➤ Price is an ambiguous extrinsic cue with a dual function; it operates simultaneously as a signal of quality (where a high price is associated with superiority and excellence) and as an indicator of financial sacrifice (where a high price represents a greater cost to the consumer). Conversely, while a low price indicates a lower financial sacrifice, it may also be interpreted as evidence of poor quality.²

This ambiguity directly affects generic medicines; the patient tends to associate a "low price" with reduced therapeutic efficacy, thereby generating a trust gap that leads the patient to perceive the lower cost as a negative indicator of the drug's technical value rather than as an economic advantage.

➤ The country of origin: serves as a critical "mental shortcut" for assessing quality in the absence of technical information, operating through three dimensions: cognitive (manufacturing competence), affective (feelings toward the country), and normative (social influence). The importance of this cue increases among experienced consumers or when there is a clear differentiation in countries' manufacturing capabilities, and its strength derives from its "predictive value" (quality expectations) and "confidence value" (certainty of origin). Thus, the country of origin becomes a form of moral capital that compensates for the lack of technical knowledge and reduces risk, making it a fundamental pillar in building trust toward the product³.

➤ Laboratory image (reputation): is a fundamental pillar in an environment lacking information symmetry; it serves as a cognitive proxy that spares the patient from examining technical data, and as a competence indicator that reduces risk by linking the organization's

¹ ZEITHAML, *op. cit.*, p. 6.

² William B. DODDS, Kent B. MONROE and Dhruv GREWAL, "Effects of price, brand, and store information on buyers' product evaluations", *Journal of Marketing Research*, Vol. 28, No. 3, August 1991, p. 308.

³ Johny K. JOHANSSON, « Determinants and effects of the use of "made in" labels », *International Marketing Review*, vol. 6, n° 1, 1989, pp. 49-54.

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name to professional merit. This framework, supported by official certifications and accreditations, grants the product a legitimacy that makes the "manufacturer's name" the primary refuge for reassurance¹. Since building a brand requires huge investments recovered over the long term, laboratories put their reputation forward as a "bond" for their promises; the ease with which this reputation can be destroyed in the event of sanctions acts as an implicit deterrent against any opportunistic behavior².

➤ Continuous availability : a strong indicator of the manufacturer's reliability, based on the concept of "tacit trust" as formulated by Luhmann: "Tacit trust is based on familiarity and regularity: it is formed when the behaviors of one party are stable and predictable enough for the other party to formulate reliable expectations about its future actions".³

Accordingly, the permanent availability of generic medicines is not merely a logistical achievement, but an implicit signal that reinforces the patient's trust in the manufacturer's commitment and stability, thereby providing them with sustained positive expectations that spare them the trouble of reassessing quality with every purchase.

➤ Medicine appearance (intrinsic visual signals): In the absence of direct assessment of pharmaceutical quality, the patient relies on visual and sensory cues to judge the effectiveness and safety of generic medicines. The quality of the outer packaging (carton, printing, security features) reflects the manufacturer's control, while poor packaging reinforces the notion that the drug is "cheap and ineffective."⁴ As for the shape of the tablet, capsules and streamlined designs suggest technological advancement and ease of swallowing, whereas switching from a capsule to a round tablet weakens perceived quality.

¹ ZHENG, HUI et YANG, *op. cit.*, p. 2.

² Amna KIRMANI and Akshay R. RAO, "No pain, no gain: A critical review of the literature on signaling unobservable product quality", *Journal of Marketing*, Vol. 64, No. 2, April 2000, p. 69.

³ Niklas LUHMANN, « Confiance et familiarité : problèmes et alternatives », *Réseaux*, n° 108, 2001, pp. 21-22.

⁴ Mark SPEECE, « Packaging and Purchase Decisions: A Focus Group Study on the Impact of Involvement Level and Time Pressure », *British Food Journal*, vol. 106, n° 8, 2004, p. 610.

Color also has a strong influence: bright colors suggest high efficacy¹, while a difference in the color of the generic tablet from the color the patient was accustomed to in the original drug creates a feeling of unfamiliarity, thereby reducing treatment adherence and undermining trust.

Section 02: Risk perception and behavioral determinants of the consumer:

1. Risk perception and fears related to generic medicines:

The concept of risk perception is central to the psychology of the healthcare consumer. According to Bauer (1960), any consumer behavior involves a form of perceived risk, which is defined as "the uncertainty felt by the consumer regarding the consequences of their purchasing action"². In the pharmaceutical field, this perception takes on a particularly acute dimension because it directly affects health and physical safety. Jacoby and Kaplan (1972) identified several types of perceived risk — functional, physical, financial, social, and psychological — and their combination determines the consumer's ultimate attitude toward a product.³

1.1. Doubts about bioequivalence and therapeutic effect:

Bioequivalence is the scientific basis for the interchangeability of generic medicines, yet it remains an abstract concept that is difficult for patients to grasp. To explain this gap, we draw on the Elaboration Likelihood Model (ELM) by Petty and Cacioppo (1986), which demonstrates that persuasion occurs through two routes: the central route, which relies on

¹ Amel ARABI, « Impact of Packaging' Color on Pharmaceutical Product Perception and Consumer Beliefs », *Annals of the „Constantin Brâncuși” University of Târgu Jiu, Economy Series*, n° 2, 2018, p. 120.

² Jacob JACOBY et Leon B. KAPLAN, « The components of perceived risk », *Proceedings of the 3rd Annual Conference of the Association for Consumer Research*, 1972, pp. 382-393.

³ Jacob JACOBY et Leon B. KAPLAN, « The components of perceived risk », *Proceedings of the Third Annual Conference of the Association for Consumer Research*, éd. M. Venkatesan, Chicago, IL, Association for Consumer Research, 1972, pp. 382-393.

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logical analysis and high cognitive ability, and the peripheral route, which relies on superficial cues such as price and packaging when the ability for deep analysis is lacking.¹

In the pharmaceutical context, the patient faces a cognitive dilemma: while the motivation to ensure health safety is very high, their ability to understand technical complexities (such as bioequivalence) remains limited. This discrepancy unconsciously drives the patient toward the peripheral route, where they transform external indicators such as low price or a change in packaging appearance into mental shortcuts (heuristics) for judging quality, leading them to make decisions based on visual impressions and surface attributes rather than proven scientific efficacy.

This cognitive bias does not stop at the purchasing decision alone, but extends to activate the negative side of psychological expectations; the patient's prior belief that the generic medicine is of poor-quality leads to an actual deterioration in their condition or the appearance of "imagined" side effects, despite its biological efficacy. Thus, the visual attributes of the product are transformed from mere marketing details into critical psychological factors that translate the patient's concerns into tangible clinical outcomes, as associating the generic drug with superficial attributes (such as low price or modest packaging) reinforces negative expectations that activate the nocebo effect. This effect goes beyond the psychological dimension to become a clinical barrier, manifested in reduced therapeutic response, increased "imagined" side effects, and poor treatment adherence; proving that visual cues are fundamental psychological drivers that determine the success or failure of the therapeutic pathway.²

A generic medicine is not limited to the active ingredient alone; it also contains inactive ingredients (excipients) that may differ from their counterparts in the original branded drug. Although these excipients do not theoretically affect efficacy, variations in

¹ Richard E. PETTY et John T. CACIOPPO, « The Elaboration Likelihood Model of persuasion », *Advances in Experimental Social Psychology*, vol. 19, 1986, pp. 141-142.

² Kate FAASSE and Keith J. PETRIE, "The nocebo effect: patient expectations and medication side effects", *Postgraduate Medical Journal*, Vol. 89, No. 1055, September 2013, pp. 540-546, specifically pp. 1-2.

their composition may alter the rate of drug absorption or its impact on patients with sensitivities or chronic conditions requiring high therapeutic precision. According to Meredith, these technical differences raise legitimate medical concerns for certain patient groups and—unfortunately—contribute to fueling broader, less scientifically grounded suspicions about the overall quality of generic medicines, thereby reinforcing the patient's distrustful attitude toward any change in the pharmaceutical formulation.¹

1.2. Doubts about manufacturing conditions and quality standards:

Studies reveal a deep gap between scientific reality and public awareness; patients mistakenly associate lower prices with lower quality, considering branded drugs as the "real" and only trustworthy ones. This skepticism is fueled by superficial factors—such as the country of origin, changes in packaging shape or color, or free availability—thereby reinforcing the impression that the generic drug is less effective². This perception disregards the regulatory truth that generic drugs are subject to the same stringent registration and quality control standards to ensure their bioequivalence. Thus, these doubts, based on external cues, turn into a psychological barrier that prevents acceptance of the generic alternative, confirming that resistance to generics is not a crisis of drug quality but a crisis of "trust and perceptions."³

¹ Peter MEREDITH, « Bioequivalence and Other Unresolved Issues in Generic Drug Substitution », *Clinical Therapeutics*, vol. 25, n° 11, novembre 2003, pp. 2879-2886.

² Alian A. ALRASHEEDY, Mohamed Azmi HASSALI, Kay STEWART, David C. M. KONG, Hisham ALJADHEY, Mohamed Izham Mohamed IBRAHIM et Saleh Karamah AL-TAMIMI, « Patient knowledge, perceptions, and acceptance of generic medicines: a comprehensive review of the current literature », *Patient Intelligence*, vol. 2014, n° 6, 3 avril 2014, pp. 22-26.

³ Barbara M. DAVIT, Patrick E. NWAKAMA, Gary J. BUEHLER, Dale P. CONNER, Sam H. HAIDAR, Devvrat T. PATEL, Yongsheng YANG, Lawrence X. YU, and Janet WOODCOCK, "Comparing Generic and Innovator Drugs: A Review of 12 Years of Bioequivalence Data from the United States Food and Drug Administration", *Annals of Pharmacotherapy*, Vol. 43, No. 10, October 2009, p. 1584.

2. Personal, Cultural, and Social Factors:

According to the Howard and Sheth model (1969), consumers do not make decisions in isolation from their environment; rather, their choices are shaped by the ongoing interaction between external environmental and situational pressures. Environmental influences include circles of social influence (such as culture, social class, and family), which establish the individual's value norms, while situational influences (such as financial status) act as direct constraints or triggers. Thus, the decision-making process transforms from a rational evaluation of the product into the outcome of the interaction of these pressures, which shape the buyer's motives and guide their response¹. This explains the complexity of the patient's decision-making when choosing between branded and generic medicines.

2.1 Past experiences and health literacy (positive / negative):

past experiences and health literacy are two fundamental drivers shaping patient behavior toward generic medicines, acting as psychological and cognitive filters for scientific reality:

The impact of past experiences: Ajzen's Theory of Planned Behavior (TPB) is based on the premise that a patient's intention to use generic medicines is the result of the interaction of three determinants: personal attitude (resulting from past experiences and behavioral beliefs), subjective norms (surrounding social pressures), and perceived behavioral control (the perceived ease or difficulty of adopting the alternative). Negative past experiences, even if only perceived, establish a resistant attitude that is difficult to change with scientific information alone; this personal "cognitive stock" overshadows objective facts, making the patient's intentions and actions dependent on these "salient beliefs" that determine their response to the generic medicine.²

¹ John A. HOWARD et Jagdish N. SHETH, *The Theory of Buyer Behavior*, New York, John Wiley & Sons, 1969, p. 485.

² Icek AJZEN, "The Theory of Planned Behavior", *Organizational Behavior and Human Decision Processes*, Vol. 50, No. 2, December 1991, pp. 188-189.

The role of health literacy: According to Nutbeam (2000), health literacy is the critical variable that determines the patient's ability to access, understand, and intelligently evaluate information. A patient with high health literacy possesses cognitive and social tools that enable them to deconstruct stereotypes, resist surrounding rumors, and make an objective decision based on bioequivalence and reliable data, rather than being swept along by prevailing negative beliefs.¹

Thus, it becomes clear that therapeutic response depends not only on the "drug's efficacy" but also on the "cognitive and experiential stock" carried by the patient, making the enhancement of health literacy a strategic necessity to dispel skepticism toward generic alternatives.

2.2. Demographic factors:

Scientific literature agrees that social and demographic variables play a crucial role in shaping patients' attitudes toward generic medicines. These effects are clearly evident in the "age gap"; younger patients (under 60 years old) show high awareness of the safety of these alternatives and greater acceptance of their use², while older patients display marked resistance that begins to escalate specifically after the age of 57 – a point considered in academic studies as a "turning point" at which the likelihood of accepting brand-name drug substitution decreases.³

This phenomenon is embodied in what can be called the "elderly paradox", where the patient experiences a conflict between two opposing drivers:

¹ Don NUTBEAM, « Health literacy as a public health goal: A challenge for contemporary health education and communication strategies in the 21st century », *Health Promotion International*, vol. 15, n° 3, September 2000, p. 263.

² ALRASHEEDY et al., *op. cit.*, p. 10.

³ David A. MOTT et Richard R. CLINE, « Exploring Generic Drug Use Behavior: The Role of Prescribers and Pharmacists in the Opportunity for Generic Drug Use and Generic Substitution », *Medical Care*, vol. 40, n° 8, août 2002, p. 667.

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Economic necessity: Generic medicine represents a necessary option for this group, as they often rely on a fixed income, making cost savings a strong driver for acceptance.¹

Psychological resistance: This economic driver faces deeply rooted psychological barriers, most notably the "familiarity factor" with the original drug and the fear of visual confusion caused by differences in the drug's shape, color, or packaging.²

Accordingly, acceptance of generic alternatives among the elderly is not a purely medical or scientific decision, but rather a "complex equation" in which psychological convictions intertwine with material circumstances, necessitating the adoption of awareness approaches that take this specificity into account when dealing with the elderly to dispel their fears and enhance their confidence in the therapeutic option.

2.3. Social influence: family environment and word of mouth:

Social influence constitutes a fundamental driver of the patient's decision, as the individual decision is surpassed to become the outcome of a complex social learning process. According to Bandura's theory (1986), individuals rely on "observational learning" and the experiences of those around them, as the family and social environment serve as a living "model" for the patient. This explains the profound impact of "word of mouth": the patient internalizes the outcomes of others' experiences (success or failure) without having to experience them firsthand, thereby shaping their attitudes and reinforcing their trust or doubts in advance.³

This dynamic is embodied in the "two-step flow of communication" model (Katz & Lazarsfeld, 1955), which explains how pharmaceutical information is transmitted through "opinion leaders" (such as trusted relatives or healthcare workers). They receive the information and then translate it according to their personal beliefs before passing it on to

¹ SHARGEL Leon et KANFER Izzy, « Introduction to generic drug product development », in *Generic Drug Product Development*, CRC Press, 2014, pp. 23-38.

² MEREDITH, *op. cit.*, p. 2885.

³ Albert BANDURA, *Social Foundations of Thought and Action: A Social Cognitive Theory*, Englewood Cliffs, NJ, Prentice-Hall, 1986, pp. 47-48.

their family networks. These leaders act as "gatekeepers"; if one of them adopts a negative perception, it creates a "collective trust crisis" that becomes more influential than official medical guidance.¹

In conclusion, pharmaceutical behavior in this context does not require addressing the patient as an isolated individual; rather, it necessitates a communication strategy that targets "opinion leaders" within families, as they are the effective intermediaries who guide the therapeutic compass of patients in their daily lives.

3. The Role of Media and Information:

The media environment plays a crucial role in shaping consumer attitudes, based on the "agenda-setting" theory; the media do not impose on people "what to think", but rather impose "what to think about". Accordingly, the way issues are framed by the media – in terms of frequency and focus on controversy – determines their value and presence in the consumer's mind, making media coverage the most prominent factor in guiding public awareness and decisions.²

3.1. Digital Transformations in the Consumption of Pharmaceutical Information:

The digital age has brought about fundamental changes in the pharmaceutical landscape, which can be summarized in three main axes:

Crisis of information quality and lack of regulation: The internet has become the primary source of medical information amidst sharp contradictions in credibility. In the absence of effective content regulation, patients are exposed to serious health risks due to

¹ Elihu KATZ et Paul F. LAZARSFELD, *Personal Influence: The Part Played by People in the Flow of Mass Communications*, Glencoe, IL, Free Press, 1955, pp. 32-33.

² Maxwell E. McCOMBS and Donald L. SHAW, "The agenda-setting function of mass media", *Public Opinion Quarterly*, Vol. 36, No. 2, Summer 1972, p. 177.

reliance on non-specialized sources, as traditional evaluation tools are unable to keep up with the complexities of pharmaceutical details.¹

From "information scarcity" to "information overload": Excessive information abundance has led to negative psychological effects, including "information anxiety" and information avoidance as a defensive mechanism. Constant exposure to conflicting content on social media platforms has also generated a state of "cyberchondria", a chronic and excessive worry about one's health.²

Evolution of the patient's role (between empowerment and risks): Digital openness has reshaped the patient's identity, as access to information has helped create an "expert patient" more prepared to discuss and understand medical terminology, thereby enhancing the effectiveness of medical consultations.³

3.2 Impact of Rumors and Resistance to Scientific Refutation:

Health rumors lead to complex behavioral and professional consequences, which can be summarized in the following points:

- Trust crisis and disregard for expertise: Digital information undermines the cognitive authority of the physician, as patients tend to trust what they have read online over professional diagnosis, turning the medical consultation into a battleground.⁴

¹ Adel S. ALHLAYL and Haitham A. ALZGHAIBI, "Evaluating the effectiveness and limitations of online health information tools in assessing the quality of medication-related content", *Frontiers in Public Health*, Vol. 13, 2025, Article 1460202, pp. 1-2.

² Saira Hanif SOROYA, Ali FAROOQ, Khalid MAHMOOD, Jouni ISOAHO and Shan-e ZARA, "From information seeking to information avoidance: Understanding the health information behavior during a global health crisis", *Information Processing and Management*, Vol. 58, No. 1, 2021, Article 102440, pp. 1-3.

³ Sharon Swee-Lin TAN and Nadee GOONAWARDENE, "Internet Health Information Seeking and the Patient-Physician Relationship: A Systematic Review", *Journal of Medical Internet Research*, Vol. 19, No. 1, 2017, Article e9, p. 11.

⁴ TAN et GOONAWARDENE, op. cit., p. 2.

- Behavioral contagion of symptoms: The focus of media reports on specific symptoms directs patients to monitor those symptoms and mistakenly attribute them to the drug, creating "suggested symptoms" that did not previously exist.¹
- Refutation resistance (backfire effect and motivated reasoning): Direct confrontation with scientific facts triggers a "backfire effect"; individuals process information through "motivated reasoning" that serves their prior beliefs, making them more entrenched in their rejection (e.g., rejection of generic medicines) the more direct correction attempts are made.²
- The spread of misinformation weakens trust between patient and physician and creates suggestive behavioral symptoms, while psychological mechanisms (such as motivated reasoning) render direct scientific confrontation ineffective, necessitating a more flexible communication approach that goes beyond direct correction.

4. The role of professional recommendation:

4.1. The Physician: Guardian of Trust and Mediator of Knowledge:

The physician represents the cornerstone of healthcare, as their authority extends beyond the technical aspect to encompass an ethical commitment adapted to the challenges of the digital age:

➤ Guardian of Trust (Fiduciary Commitment): Given the state of vulnerability imposed by illness, the physician bears a "fiduciary duty" that places the patient's interest above any financial considerations, thereby giving the profession its ethical character and making the physician the trusted source who fills the patient's "knowledge gap."³

¹ Kate MACKRILL, Greg D. GAMBLE and Keith J. PETRIE, "The effect of television and print news stories on the nocebo responding following a generic medication switch", *Clinical Psychology in Europe*, Vol. 2, No. 2, 2020, Article e2623.

² Brendan NYHAN and Jason REIFLER, "When corrections fail: the persistence of political misperceptions", *Political Behavior*, Vol. 32, No. 2, June 2010, p. 323.

³ BENDING, *op. cit.*, pp. 189-195.

➤ **Guide and Interpreter in the Digital Age:** The physician's role has shifted from a "monopolist of information" to a "participatory guide"; they help the patient filter digital information (which may be misleading) and protect their treatment decisions from rumors. In this context, the patient's online search is not seen as a threat, but as an empowering tool; the patient uses digital knowledge to deepen dialogue with their physician, thereby enhancing informed trust and treatment adherence.¹

4.2. The Pharmacist: "Guardian of Trust" and Strategic Treatment Agent:

The pharmacist's role extends beyond the traditional dispensing function to become the most influential actor in the patient's therapeutic journey, through three dimensions:

➤ **Reference and Credibility:** Thanks to their easy accessibility and deep scientific expertise, patients prefer to consult the pharmacist verbally rather than reading medication leaflets, as this communication provides immediate reassurance and a more accurate understanding of drug formulations.²

➤ **Adherence Assurance and Acceptance of Alternatives:** The pharmacist represents the "critical driver" for the adoption of generic medicines, successfully guiding 83.8% of patients toward them. They also bear the responsibility of protecting the patient from medication errors resulting from changes in drug appearance, through direct education and explaining treatment labels.³

➤ **Human Support:** The pharmacist embodies the "psychological dimension" of care; they do not sell the medicine as a mere commodity, but rather sell "reassurance and

¹ TAN et GOONAWARDENE, *op. cit.*, pp. 2, 11-12.

² Mohamed Azmi HASSALI, David C. M. KONG et Kay STEWART, « Generic medicines: perceptions of consumers in Melbourne, Australia », *International Journal of Pharmacy Practice*, vol. 13, n° 4, 2005, pp. 262-263.

³ MOTT et CLINE, *op. cit.*, p. 662.

hope," thereby creating an emotional bond that is the cornerstone of the patient's adherence to their treatment plan.¹

Section 03: The relationship between quality control and trust enhancement:

1.Economics of Trust in Pharmaceutical Markets:

1.1. The Market Failure Thesis and the Structural Incapacity of the Patient:

Healthcare markets constitute an exceptional case compared to traditional commodity markets. Arrow identified the structural characteristic distinguishing this sector as the "pervasiveness of uncertainty," affirming that the social institutions emerging around healthcare are nothing but structural attempts to cope with this reality—a structural uncertainty inherent in the very nature of health services.²

Within this framework, Akerlof provides a precise explanation of this market failure through "information asymmetry." When buyers are unable to assess quality prior to purchase, markets descend into what he termed a "lemons equilibrium," where dishonest practices lead to the "crowding out" of high-quality products from the market, thereby creating systematic pressure that stifles innovation and quality³. By applying this mechanism to the generic drug market, the absence of verification mechanisms leads the consumer to assume a low average quality, resulting in a collapse of returns on genuine investment in quality.

Market failure is not confined to the supply side; it extends to the patient's incapacity as a 'sovereign consumer', due to their technical ignorance and the pressures of illness

¹ ناجح أشرف، « أثر التغليف على مبيعات الأدوية دون وصفة طبية (دراسة حالة: مؤسسة صيدال) »، دفاتر MECAS، مجلد 17، عدد 2، جوان 2021، ص. 274.

² ARROW, *op. cit.*, p. 441, 446-447.

³ AKERLOF, *op. cit.*, pp. 488-490.

(Culyer, 1971)¹. This structural incapacity assigns quality control systems (such as GMP) the role of a 'surrogate consumer'; they exercise technical sovereignty on behalf of the patient, thereby transforming their choice from a gamble rooted in ignorance into a guaranteed institutional decision.

To counter market failure resulting from information asymmetry and the patient's inability to assess quality, Akerlof (1970) calls for the establishment of "counteracting institutions" such as government regulation and professional licensing.² These institutions are practically embodied in pharmaceutical quality control systems—including Good Manufacturing Practice (GMP) certifications, bioequivalence tests, and marketing authorizations—which go beyond their administrative role to establish a structural framework that guarantees drug quality and safety, thereby transforming trust in generic medicines from an ambiguous choice into a rational and sustainable one.

1.2 The Strategic Dimensions of Certification as a Tool for Governance and Legitimacy:

Certification goes beyond being a mere technical "signal" to become a tool for adjudication that separates marketing discourse from the actual reality of the organization. Its vital roles in building trust can be summarized according to the following themes:³

➤ **Enhancing Transparency and Accountability:** Certifications provide a systematic method to prove the quality of processes. This transparency—according to Rawlins (2008)—is achieved when the organization does not merely disclose achievements but also adopts "accountability" as a cornerstone, by providing information—including

¹ A. J. CULYER, « The nature of the commodity "health care" », *Oxford Economic Papers*, vol. 23, n° 2, 1971, pp. 191-193.

² AKERLOF, *op. cit.*, pp. 499-500.

³ James E. MILLER, "From bad pharma to good pharma: aligning market forces with good and trustworthy practices through accreditation, certification, and rating", *Journal of Law, Medicine & Ethics*, Vol. 41, No. 3, Autumn 2013, pp. 2, 3, 5, 6 and 8.

negative information—accurately and in a balanced manner, thereby establishing institutional honesty rather than superficial promotional communication.¹

- Activating "Self-Regulation": Certification acts as a defensive shield; it is a reassurance tool for regulators and the public, reducing the intensity of government interventions by proving the organization's commitment to strict self-imposed standards.
- Reliability through Independent Verification: The strength of certification lies in its departure from the realm of "organizational claims" into the realm of field verification by a third party, ensuring that the organization "actually does what it claims."
- Strategic Alignment: Certifications align market rewards with ethical practices, attracting conscious consumers and investors who find in the certification a guarantee of integrity values.

2. The relationship between legitimacy and trust: institutional credibility as a mediating variable:

2.1 Legitimacy Theory and Its Application to Pharmaceutical Trust:

Suchman is considered the primary theorist who linked "legitimacy" with "trust," defining it as: *"a general perception or assumption that the actions of an entity are desirable, proper, and congruent with the value and normative system of society."* From this perspective, legitimacy is not an intrinsic attribute of the regulatory institution, but rather a "social grant" whose strength derives from the public's ongoing evaluation of its behavior.²

To achieve this legitimacy in the pharmaceutical sector, regulatory agencies must simultaneously cultivate three interrelated dimensions:³

¹ Brad RAWLINS, « Give the Emperor a Mirror: Toward Developing a Stakeholder Measurement of Organizational Transparency », *Journal of Public Relations Research*, vol. 21, n° 1, 2008, p. 75.

² Mark C. SUCHMAN, « Managing Legitimacy: Strategic and Institutional Approaches », *Academy of Management Review*, vol. 20, n° 3, 1995, p. 574.

³ SUCHMAN, *op. cit.*, pp. 577-582.

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Tableau 8:Types of organizational legitimacy and their applications in the pharmaceutical sector

Form of Legitimacy	Theoretical Basis	Pharmaceutical Application	Regulatory
Pragmatic	Perceived benefit to affected stakeholders	Protecting consumer safety through the enforcement of effective quality standards.	
Moral	Commitment to normative expectations	Scientific integrity and working for the public good, free from commercial influences.	
Cognitive	Comprehensibility and intuitiveness	Operating according to stable, transparent, and clear rules that are understandable to the public.	

Source: *Elaborated by the author based on SUCHMAN.*

The critical theoretical insight lies in the "integration of these dimensions"; technical competence (pragmatic legitimacy) remains ineffective in the absence of integrity (moral legitimacy), as an agency perceived as being subject to commercial influence loses its ability to generate trust regardless of its technical precision.¹ In this context, regulatory institutions constitute a "cognitive shortcut" that spares the patient from direct technical verification; they provide him with "trust in expert systems" (Giddens, 1990) and "institution-based trust", offering a background of justified security.²

¹ SUCHMAN, *op. cit.*, p. 585.

² Anthony GIDDENS, *The Consequences of Modernity*, Stanford, CA, Stanford University Press, 1990, p. 34.

Thus, the institution acts as a bridge connecting the hidden technical quality of the drug with the patient's reassurance, where its social legitimacy transforms into a practical guarantee that obviates the need for personal knowledge of scientific complexities.

2.2 The Asymmetry Principle: Managing Trust Capital in the Pharmaceutical Sector:

The "asymmetry principle of trust" is one of the most well-established facts in the psychology of risk perception. Slovic states that: "Trust is relatively fragile, created slowly through consistent positive performance, but can be destroyed quickly — by a single dramatic event or a highly publicized failure; the process of destroying trust is faster, more complete, and harder to reverse than the process of building it."¹ This disparity is attributed to "negativity dominance" in human perception, where errors are more salient and influential in judging an institution's trustworthiness.²

This asymmetry gives trust the nature of "strategic capital"; Sztompka describes it as a cumulative resource that cannot be bought, but rather earned through proven performance, and its depletion occurs catastrophically when violations occur³. Accordingly, crisis management in the pharmaceutical sector is not a marginal procedure, but rather a central determinant of the sustainability of this "capital." According to Coombs, the sustainability of trust depends on the institution's level of response; transparent and proactive responses help preserve it, while defensive responses multiply the extent of damage⁴. To effectively

¹ Paul SLOVIC, « Perceived risk, trust, and democracy », *Risk Analysis*, vol. 13, n° 6, 1993, p. 677.

² Paul ROZIN et Edward B. ROYZMAN, « Negativity bias, negativity dominance, and contagion », *Personality and Social Psychology Review*, vol. 5, n° 4, 2001, p. 297.

³ Piotr SZTOMPKA, *Trust: A Sociological Theory*, Cambridge, UK, Cambridge University Press, 1999, pp. 76-77.

⁴ W. Timothy COOMBS, « Protecting Organization Reputations During a Crisis: The Development and Application of Situational Crisis Communication Theory », *Corporate Reputation Review*, vol. 10, n° 3, 2007, p. 165, 173 et 175.

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manage failures in a way that preserves the "legitimacy" the institution has built, Gillespie and Dietz (2009, p. 127) propose a three-stage framework:¹

Tableau 9:A framework for institutional crisis response in the pharmaceutical industry to reinforce legitimacy

Step	Institutional Action	Cumulative Impact (According to Suchman)
1. Acknowledgement	Immediate and transparent admission of failure, without downplaying or justifying.	Preservation of moral legitimacy.
2. Remediation	Taking visible and proportionate corrective action (recall, suspension, investigation).	Reinforcement of pragmatic legitimacy.
3. Prevention	Implementing systemic changes and communicating them to the public.	Demonstrating the capacity for learning and long-term commitment.

Source: Elaborated by the author based on Gillespie and Dietz (2009).

3.The Professional Mediation Model: Translating System Trust into Consumer Trust:

The success of generic medicine adoption depends on understanding how consumer trust is formed in an informationally complex environment. The Elaboration Likelihood

Model (ELM) by Petty and Cacioppo (1986) provides an analytical framework for this process, proposing two routes to persuasion: the central route, which requires technical analysis of quality (such as bioequivalence data), and the peripheral route, which relies on

¹ Nicole GILLESPIE et Graham DIETZ, « Trust Repair After an Organization Level Failure », *Academy of Management*

ent Review, vol. 34, n° 1, 2009, pp. 136-141.

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external cues (such as institutional credibility and pharmacist recommendation) to guide judgment in the absence of consumer cognitive capacity.¹

The variation in persuasive processing is clearly illustrated in the following table:²

Tableau 10:"ELM Pathways to Generic Medicine Trust: Determinants and

Processing Route	Consumer Characteristics	Primary Determinants of Trust	Attitude Change Impact
Central Route	Technical knowledge and high motivation for evaluation	Quality data, licensing, and efficacy	Strong, stable, and resistant to forgetting
Peripheral Route	Lack of technical knowledge or motivation	Source credibility, professional recommendation, and institutional reputation	Fragile, context-dependent, and susceptible to influence

Source: Elaborated by the author based on Petty and Cacioppo (1986).

Given that the majority of patients process quality information through the "peripheral route" as a cognitive shortcut to compensate for their technical knowledge gap, peripheral cues become the actual driver of trust. This psychological grounding supports the structural findings of Hassali et al. (2014), whose comparative studies demonstrated that successful generic medicine promotion policies do not rely solely on "technical quality" (processed

¹ Richard E. PETTY et John T. CACIOPPO, *Communication and Persuasion: Central and Peripheral Routes to Attitude Change*, New York, Springer-Verlag, 1986, pp. 3-4.

² *Ibid.*, p. 3, 4, 6, 7, 13 and 21.

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centrally), but rather require building a persuasive ecosystem (processed peripherally) grounded in four strategic pillars:¹

- Engaging health professionals: Transforming the pharmacist from a mere dispenser into an active "trust intermediary" who translates institutional assurances into personalized reassurance.
- Targeted communication: Adopting campaigns that address specific patient concerns rather than abstract promotion of scientific characteristics.
- Visible transparency: Making institutional quality assurance "visible and comprehensible" to enhance trust in the peripheral context.
- Systematic monitoring: Adopting consumer trust metrics as an explicit policy objective, rather than merely a secondary outcome of performance improvement.

¹ Mohamed Azmi Hassali *et al.*, « The experiences of implementing generic medicine policy in eight countries: A review and recommendations for a successful promotion of generic medicine use », *Saudi Pharmaceutical Journal*, vol. 22, n° 6, décembre 2014, pp. 498-499.

Conclusion:

This study concludes that consumer trust in generic medicines is not merely a technical evaluation, but rather a dynamic interaction between cognitive, affective, and behavioral dimensions shaped within a complex institutional context. In light of the patient's informational deficit, the latter resorts to "cognitive shortcuts" based on external cues (such as price and reputation) rather than scientific facts, thereby exacerbating the gap between technical reality and public perceptions due to psychological fears, demographic factors, and the influence of the media environment, which fuels hesitation regarding bioequivalence.

Conversely, the findings confirm that this trust is constructible and reinforceable through institutional mechanisms such as regulation and accreditation, which act as "reassurance signals," alongside the crucial role of professional mediation (physicians and pharmacists) in translating systemic trust into individual conviction for the patient. Thus, this chapter lays the methodological and analytical foundation that paves the way for moving from theoretical grounding to the empirical phase, in order to test these mechanisms and assess their effectiveness in the Algerian field reality.

CHAPTER III:

Empirical study

Introduction:

After presenting quality control systems in the first chapter and the concept of consumer trust in the second, this third chapter moves to the field application through a case study within the **SAIDAL Group (Dar El-Beida unit)**.

We will first present the institution, its organizational structure and quality control laboratories, then outline the methodology adopted for data collection through a questionnaire administered to a sample of consumers, complemented by direct observation within the laboratories.

This chapter aims to analyze how quality control systems contribute to strengthening consumer trust in generic medicines, and to test the formulated research hypotheses, in order to derive field results that enrich the theoretical framework and provide practical recommendations.

Section 01: Presentation of the Study Field – SAIDAL Group:

1. Presentation of the SAIDAL Group

SAIDAL Group is a joint-stock company (SPA) and an Algerian pharmaceutical entity established in 1982. Its share capital amounts to 2,500,000,000 Algerian Dinars. The State holds 80% of this capital, while the remaining 20% was floated on the stock exchange in 1999 to institutional investors and natural persons (other shareholders). The Group's mission is to develop, manufacture, and market pharmaceutical products for human and veterinary use. It is currently the national and regional leader in the production of generic drugs, holding a significant market share. Strategically, the Group aims to consolidate its leadership position and contribute to the implementation of the national drug policy established by the public authorities.



Figure 3:1.SAIDAL Group

2.Missions and Strategic Objectives of the SAIDAL Group:

The SAIDAL Group holds a pivotal role in the national health system, with its responsibilities divided between operational missions and strategic long-term goals:

a. Group Missions :

SAIDAL's missions span the entire pharmaceutical value chain, including manufacturing, production, and distribution, focusing on the following:

- Ensuring Quality and Availability: Providing a broad and diverse range of high-quality medicines to meet patient needs.
- Enhancing Therapeutic Accessibility: Implementing a pricing policy that facilitates access to treatments for the widest possible segment of society.
- Supporting Public Health Policy: Accompanying national health strategies by directing investments toward pharmaceutical industries that address essential population requirements.

b. Strategic Objectives :

Through its future vision, the Group aims to achieve several key objectives:

- Financial Sustainability: Improving financial profitability to ensure business continuity and fulfill commitments toward shareholders.
- Market Leadership: Strengthening its position as the leading player in the national pharmaceutical market.
- Corporate Culture and Human Capital: Building a unified corporate culture and developing human resources while retaining key talents.
- Innovation and Partnerships: Developing strategic partnerships to acquire new technologies and expand the product portfolio toward innovative medicines.
- Regulatory Instrument: Serving as a primary tool for public authorities to implement the national drug policy, effectively contributing to market regulation and the reduction of the pharmaceutical import bill.

3.Production Sites and Commercial Units:

- a. The SAIDAL Group relies on a diverse industrial base comprising 9 production units distributed according to pharmaceutical specialization:

- Dar El-Beida: A multi-form unit producing tablets, capsules, syrups, and topical forms.
 - Médéa: The main hub for antibiotic production (penicillin and derivatives), covering all pharmaceutical forms including injectables.
 - Constantine: Specialized in the production of liquid forms (syrups).
 - Constantine (Insulin Unit): A strategic unit exclusively dedicated to the production of human insulin (rapid-acting and long-acting).
 - Cherchell: Specialized in hemodialysis concentrates, in addition to dry forms and syrups.
 - Batna: A technical unit specialized in the production of suppositories.
 - Annaba: Specialized in the production of dry pharmaceutical forms.
 - El Harrach: Comprises 4 workshops for the production of syrups, solutions, and tablets (uncoated and coated).
 - Constantine (GDC): One of the most technologically advanced units, divided into two sections (non-sterile forms and sterile forms such as IV bags), with an on-site quality control laboratory.
- b. These units manage the marketing, storage, and distribution strategy to ensure national market coverage through three regional hubs:
- Central Commercial Unit (Algiers, 1996): The Group's first commercial branch, focusing on inventory management and distribution quality.
 - Eastern Commercial Unit (Batna, 1999): Responsible for supplying 18 provinces in the eastern region.
 - Western Commercial Unit (Oran, 2000): Manages distribution and balances supply and demand across 19 provinces in the western region.

4. Research and Innovation Infrastructure of the SAIDAL Group:

A. The Research and Development Center (CRD): The Research and Development Center has been the scientific cornerstone of the SAIDAL Group since 1977, responsible for pharmaceutical innovation and the development of new generic medicines. It provides technical support to production units to ensure the smooth transition from laboratory formulations to industrial manufacturing. The Center also plays a key role in scientific vigilance, diversifying the therapeutic portfolio and strengthening competitiveness.

B. The Bioequivalence Center: The Bioequivalence Center is the first strategic facility of its kind in Algeria, dedicated to demonstrating the conformity of generic medicines to their originator (reference) counterparts in terms of efficacy and safety, in accordance with precise international standards. Equipped with advanced clinical and laboratory facilities, the Center serves as the guarantor of national product quality and the cornerstone for building trust among physicians and consumers in the effectiveness of SAIDAL medicines and their ability to compete globally.

5.The Group's key partners are categorized as follows:

- Regional Arab Alliances (TAPHCO Project): Established in 1999 with ACDIMA (Arab League), SPIMACO (Saudi Arabia), and JPM (Jordan) for the manufacturing of solid dosage forms in Reghaia. Furthermore, SAIDAL collaborates with Julphar, a leading Emirati pharmaceutical group in the MENA region.
- Global Industry Leaders (Sanofi & Pfizer): Long-standing joint ventures with the French firm SANOFI and the American leader PFIZER (30% SAIDAL, 70% partner). These entities focus on the local formulation, manufacturing, and marketing of high-end pharmaceutical specialties.
- Strategic Investments and Biotechnology: This includes the 2012 partnership with the Kuwaiti North Africa Holding Company to establish SNM for oncology treatments, and the industrial agreement with NOVO NORDISK, the global leader in diabetes care, to produce insulin ranges at the Constantine facility.

6.Product Portfolio and Therapeutic Diversity of SAIDAL Group:

The SAIDAL Group is the national leader in generic medicines, aiming to support public health by providing high-quality treatments. Its portfolio includes 300 products, of which 215 are medicines covering 21 major therapeutic classes, including cardiology, neuropsychiatry, gastroenterology, pulmonology, and infectious diseases. The Group is also distinguished by its capacity to produce vital and complex medicines, most notably insulin for diabetes management, as well as anesthetics and analgesics, reinforcing its ability to meet the needs of the national market across the most sensitive medical specialties.

7.The Dar El-Beida unit:

7.1. General presentation and history

The Dar El-Beida unit is the oldest production unit of the SAIDAL Group and of the former PHARMAL subsidiary. It has existed since 1958, giving it more than six decades of experience in the Algerian pharmaceutical industry.

Originally owned by the French pharmaceutical laboratory LABAZ, the unit was gradually nationalized: 51% was attached to the Algerian State in 1970, then fully integrated (100%) in 1976 by the former Central Algerian Pharmacy (PCA). In 1982, when the SAIDAL Group was created through the restructuring of the PCA, the site was transferred to the new group and attached to the PHARMAL subsidiary — which was subsequently dissolved and absorbed directly by the General Management in January 2014

7.2. Activities and pharmaceutical forms produced:

The initial activity of the unit, which was once limited to a few medicines and cosmetic products, has undergone a significant transformation. Today, the site produces an extensive range of medications spanning more than 20 therapeutic classes, organized into three primary galenic families (workshops):



Atelier Formes Sèches

Comprimés : 74 000 u/j · Gélules : 50 000 u/j

- Comprimés (toutes classes thérapeutiques)
- Gélules
- Sels (formes solides)



Atelier Formes Pâteuses

Dentifrices : 50 000 u/j · Gels/Crèmes : 20 000–22 500 u/j

- Pommades ; Gels; Crèmes; Dentifrices.



Atelier Formes Liquides

Capacité : 40 000 unités/jour

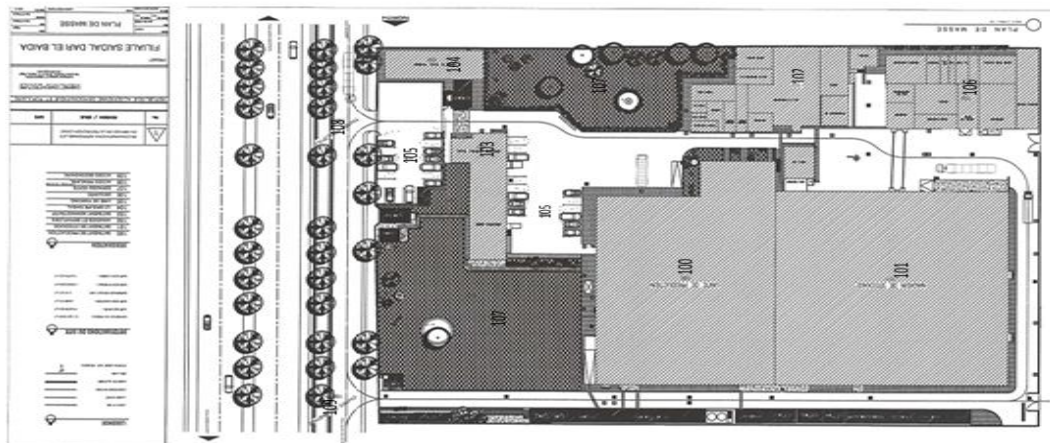
- Sirops (solutés buvables)
- Suspensions buvables
- Solutions dermiques

As of 2024, the unit's total production capacity is estimated at 55 million sales units per year, highlighting its strategic growth and high operational efficiency in meeting national market demands.

7.4. Site Structure and Activity Allocation:

The production site of the PHARMAL subsidiary in Dar El Beida is organized according to the established site layout plan. The Main Complex serves as the operational and administrative core of the unit, covering a total surface area of 9,609.30 m². This complex houses the site's most critical activities, including pharmaceutical production workshops, administrative offices, and the security department to ensure the facility's safety and integrity. Furthermore, the site features a specialized storage area of 6,600 m², with a capacity to accommodate up to 4,600 pallets of raw materials and finished products.

Figure 4:.. Site Structure



Source: Internal document of SAIDAL Group.

7.5. competitive Advantages and Strategic Pillars of the Dar El Beida Unit:

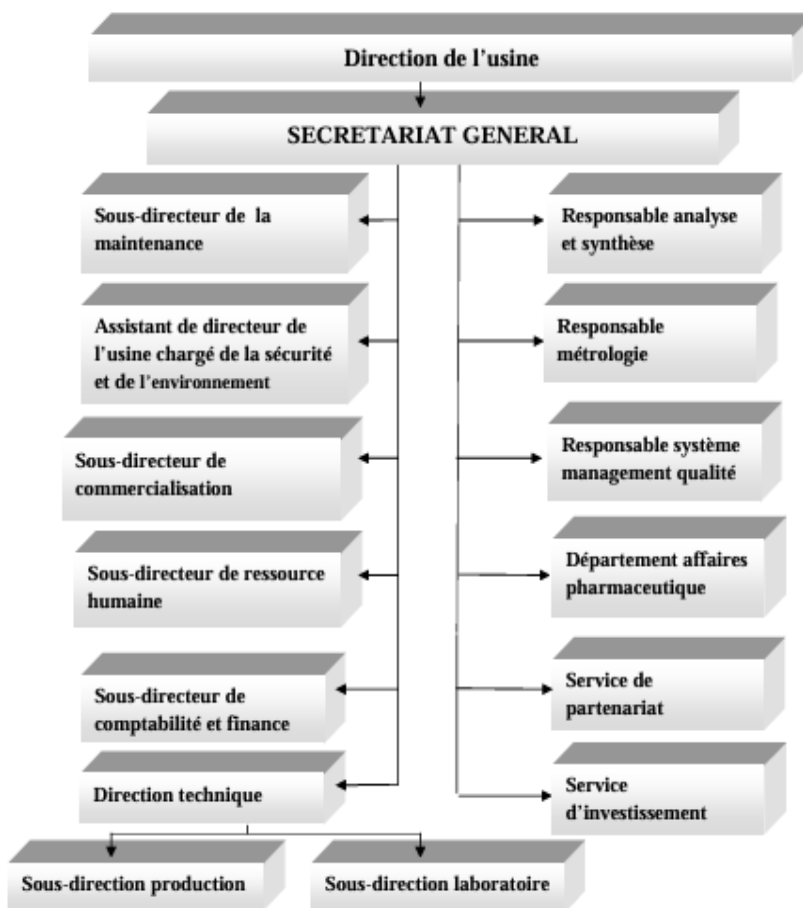
The Dar El Beida unit derives its excellence from a blend of technological heritage and logistical efficiency. It serves as the Group's industrial memory, with expertise dating back to 1958, making it a primary hub for transferring high-level technical Savoir-faire in production, quality control, and advanced laboratory analysis. The unit is uniquely characterized by its comprehensive production versatility, being the only site capable of

manufacturing all pharmaceutical forms (solid, liquid, and paste) simultaneously, providing the Group with exceptional flexibility to meet national market demands.

Technically and logistically, the unit features an advanced infrastructure, including a sophisticated water treatment plant (utilizing Reverse Osmosis and Ozone technologies). Its strategic location near the Blida distribution center ensures seamless supply chain flows. As a guardian of pharmaceutical security, with an annual output of 55 million units and massive storage capacity, the unit remains the cornerstone of national pharmaceutical sovereignty and a key driver of Innovation and R&D, bolstering the international competitiveness of the SAIDAL brand.

7.6. Organizational Structure:

Figure 5: Organizational Structure :

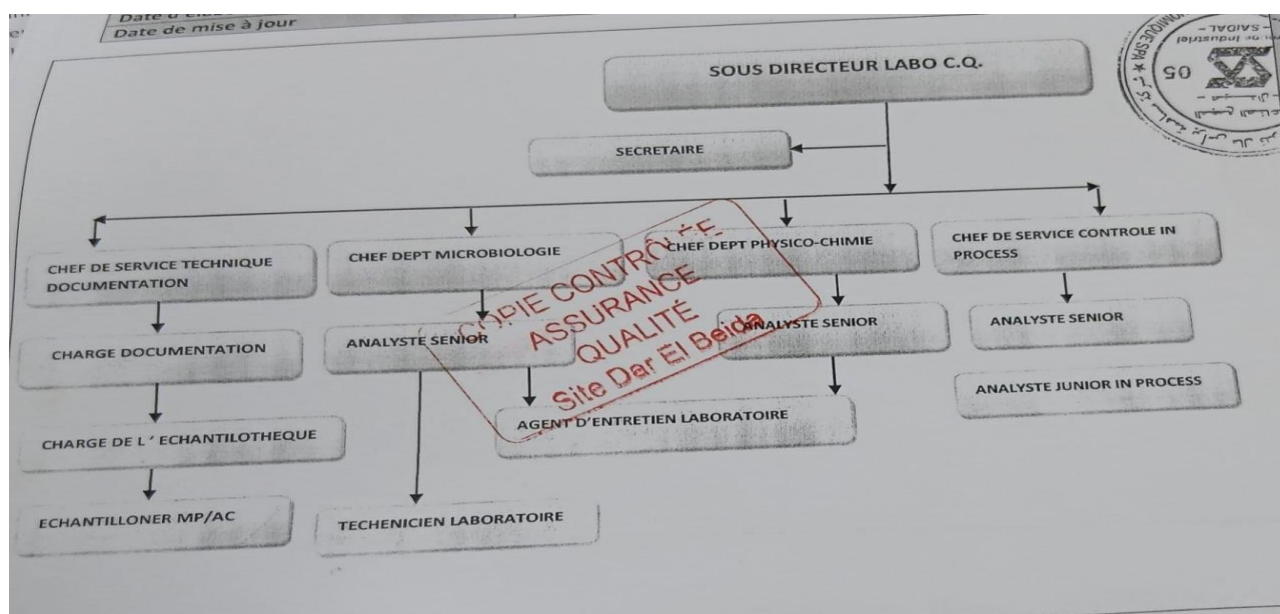


Source: Internal document of SAIDAL Group.

7.7. The Quality Control Directorate:

The Quality Control Directorate is considered a vital technical and administrative structure within the SAIDAL Group (specifically at the Dar El Beida unit). It is responsible for measuring and calibrating product characteristics—whether raw materials, semi-finished products, finished products, or packaging materials—and comparing them against the specifications defined in analytical protocols and official pharmacopoeias. The ultimate objective is to provide the consumer with a safe and effective medication that complies with the technical specifications and pharmaceutical regulations. Consequently, no pharmaceutical product can be released for consumption without obtaining a Certificate of Conformity (Certificat de Conformité) issued exclusively by this authority.

Figure 6: Organizational Structure of the Quality Control Directorate



Source: Internal document of SAIDAL Group.

a) Core Missions of the Quality Control Directorate (QCD):

1. Analysis and Testing:

Raw Material Control: Rigorous inspection of all incoming materials (Active Pharmaceutical Ingredients, excipients, and purified water) before their release for use, with a final decision of "Compliant" or "Non-Compliant."

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In-Process Control (IPC): A proactive role involving periodic checks within production workshops on intermediate and finished products to ensure early detection and immediate correction of any deviations.

Finished Product Control: The final and most critical stage, involving comprehensive physicochemical and microbiological tests to verify that the medicine meets specifications before being authorized for market release.

2. Environmental Monitoring:

Includes monitoring the manufacturing environment to ensure it is free from contamination, by testing the quality of pharmaceutical water, measuring air quality in cleanrooms, and verifying the cleanliness of surfaces and equipment to prevent cross-contamination.

3. Management of Reference Samples (Retention Samples):

Involves retaining "witness" samples from each production batch (Lot) and storing them under standardized conditions. These samples are kept for use when necessary, such as in the event of market complaints or to meet audit and inspection requirements from regulatory authorities such as the National Laboratory for the Control of Pharmaceutical Products (LNCPP).

b) Quality Control Directorate Departments:

Tableau 11:Quality Control Directorate Departments.

Comparison Criterion	Microbiology Laboratory	In-Process Control (IPC) Laboratory	Physicochemical Control Section
Primary Role	Ensuring the biological safety of products.	Proactive quality guardian during production.	Verifying the conformity of inputs to technical specifications.
Scope of Work	Comprehensive control from raw	Direct, real- time intervention in	Inspection of raw materials, packaging, and

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	materials to finished products.	manufacturing and packaging cycles.	the production environment.
Main Tasks	Testing non-sterile products, pathogen detection, and sterilization.	Periodic tests (hourly), adjustment of production parameters, and "line clearance."	Identification (HPLC), titration, purity tests, and water quality inspection.
Strategic Objective	Preventing microbial contamination and protecting patient health.	Ensuring product homogeneity and reducing waste and non-conforming results.	Full traceability and approval of batch conformity.
References and Standards	ISO 9001, GMP, GLP, European Pharmacopoeia.	GMP, GLP, Standard Operating Procedures (SOPs).	Approved technical specifications (IMP 01, Analytical Bulletin).

Source: Internal document of SAIDAL Group

Section 2: Questionnaire Study and Analysis:

1. Population and Sample of the Study:

1.1. Definition of the Study Population:

The study population consists of all pharmaceutical consumers in Algeria, that is, any individual residing within the national territory who purchases or uses pharmaceutical products, whether with or without a prescription. Consequently, they are potentially exposed, in one way or another, to the purchasing choice between the original (brand-name) drug and its generic equivalent. Given the impossibility of enumerating all members of this population within a unified national framework, and the lack of a comprehensive database listing all

pharmaceutical consumers in Algeria, it was not feasible to apply a probability (random) sampling method.

1.2. Sampling Method:

The study adopted a non-probability convenience (purposive) sampling method, for the following reasons:

- The absence of a comprehensive sampling frame that would allow for random selection.
- The exploratory nature of the study, which requires rapid access to respondents.
- The limited time and resources available to the researcher.

The questionnaire was distributed using two complementary methods:

- Online: using Google Forms, via social media platforms (Facebook, WhatsApp, Instagram, LinkedIn) to reach a wide segment of consumers.
- Paper-based: direct distribution in pharmacies and public places to reach groups less present on digital platforms (such as the elderly and people with limited income).

1.3. Sample Size:

The study sample consisted of 252 consumers-patients of various ages (over 18 years), after excluding incomplete or unusable questionnaires. This sample represents a response rate of 90% of the total distributed questionnaires (280 questionnaires). The survey was conducted between [April 1, 2026] and [April 30, 2026] (for data collection).

2. Study Tool:

The questionnaire was chosen as the primary research tool for collecting quantitative data, due to its suitability for the study's objectives and its ability to overcome the difficulties of field research. This tool was designed according to a rigorous methodology, based on reviewing previous studies to define the areas of investigation and formulate its items, while adhering to the criteria of clarity, simplicity, and comprehensiveness in question

formulation. The final draft was subjected to review and revision before being adopted in its final form¹.

2.1 Types of Questions Used:

In response to the specific needs of our study, several types of questions were combined within a single instrument:

- Single-choice or multiple-choice questions were used for collecting sociodemographic data (gender, age, education level, profession), as well as for filter questions related to consumption habits (source of medication information, prior experience with generic medicines, awareness of the difference between original and generic drugs, main concerns regarding generic medicines).
- The five-point Likert scale, ranging from "Strongly Disagree" to "Strongly Agree", was adopted to measure attitudinal and perceptual variables. This type of scale is particularly suitable for research in management sciences as it is compatible with standard statistical treatments (mean, standard deviation, t-test, regression), thus facilitating the quantitative analysis of the collected data.²

Response	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
Score	1	2	3	4	5

Figure 7: Five-Point Likert Scale Used in the Study

2.2 Questionnaire Structure:

To maximize the effectiveness of the questionnaire, we diversified the question types, including closed, open, dichotomous, single-choice, and multiple-choice questions, in

¹ S. CHABANI and H. OUACHERINE, Guide to Research Methodology in Social Sciences, 1st ed., Taleb impression, 2013, p. 77.

² R. LIKERT, « A Technique for the Measurement of Attitudes », Archives of Psychology, n° 140, New York, 1932, p. 15.

addition to using the Likert scale. The final version of the questionnaire comprises **19 items** distributed across three main sections:

- Section 1: Personal Information – This section collects: gender, age, education level, profession, the usual source of medication information, experience with generic medicines, awareness of the difference between original and generic drugs, and main concerns regarding generic medicines.
- Section 2: Independent Variables – Quality Control Systems – This section measures consumer perceptions regarding the three dimensions of quality control systems, using a 5-point Likert scale:

Dimension	Number of Items	Content
Perceived Quality	5 items (Q1–Q5)	Assessment of efficacy, safety, therapeutic equivalence, and past experiences.
Recommendations of Health Professionals	5 items (Q6–Q10)	Perception of the pharmacist's and physician's role in explaining equivalence and recommending generics.
Knowledge and Perception of Institutional Control	6 items (Q11–Q16)	Awareness of the ANPP's existence, perception of controls, inspections, and transparency.

- Section 3: Dependent Variable – Consumer Trust – This section measures consumer trust in generic medicines through 3 items (Q17, Q18, Q19) using a 5-point Likert scale.

This three-axis structuring of the independent variable directly corresponds to the three sub-hypotheses of the research (H1, H2, H3), ensuring coherence between the measurement instrument and the conceptual model being tested. The internal consistency of the instrument was verified using Cronbach's Alpha coefficient, the results of which are presented in detail in the empirical chapter.

3. Data Processing Tools and Software:

Responses collected via Google Forms were automatically synchronized into a data spreadsheet, while responses collected on paper were manually entered using the same

coding system to ensure the homogeneity of the final database. All 252 valid responses were then imported into IBM SPSS Statistics, a widely recognized tool for processing and statistically analyzing data in the social and management sciences.

Several types of analyses were used to process the collected data:

- Reliability analysis, using Cronbach's Alpha coefficient, to verify the internal consistency of the measurement instrument, both for the questionnaire as a whole and for each of its axes.
- Frequency distributions (descriptive statistics), which allow the calculation of frequencies and percentages, used to describe the sociodemographic profile of the sample as well as the distribution of responses to each item.
- One-sample t-test, to verify the statistical significance of the means obtained for each item and each axis compared to the central value of the Likert scale.
- Simple linear regression, complemented by analysis of variance (ANOVA), to determine the nature and strength of the relationship between the independent variable (and its three axes) and the dependent variable, allowing the acceptance or rejection of the general hypothesis (H) and the three sub-hypotheses (H1, H2, H3), the results of which are presented in the following chapter.
- Pearson correlation analysis, to measure the strength and direction of relationships between variables.

4. Validity and Reliability of the Study Instrument (Questionnaire):

Before administering the questionnaire to the study sample, its validity and reliability were verified to ensure its ability to accurately and objectively measure what it was designed to measure, as follows:

4.1. Content Validity (Face Validity):

The content validity of the questionnaire was verified by submitting it to a panel of experts and academics specialized in health services management, business administration, and behavioral sciences, to assess:

- The relevance of each item to the dimension to which it belongs.

- The clarity of language and ease of understanding.
- The absence of ambiguity, repetition, or bias.
- Its comprehensive representation of the components of the studied variables (quality control systems with its three dimensions, and consumer trust).

Based on their observations and recommendations, some items were modified and others rephrased. The final version of the questionnaire was then adopted, giving it an acceptable degree of face and logical validity.

4.2. Internal Consistency Reliability (Cronbach's Alpha Coefficient):

The reliability (internal consistency) of the study instrument was measured using Cronbach's Alpha coefficient, the most commonly used measure to assess the homogeneity of items within each axis and the scale as a whole. The coefficient was calculated based on the responses of the study sample of 252 respondents.

The results showed high values supporting the reliability of the instrument and its suitability for statistical analysis, as shown in the following table:

Tableau 12: Internal Consistency Reliability.

Axis / Variable	Number of Items	Cronbach's Alpha	Reliability Level
Perceived Quality (Axis 1)	5	0.869	Very High
Recommendations of Health Professionals (Axis 2)	5	0.889	Very High
Knowledge and Perception of Institutional Control (Axis 3)	6	0.892	Very High
Independent Variable – Quality Control Systems (Total Axes)	16	0.927	Very High
Dependent Variable – Consumer Trust in Generic Medicines	3	0.610	Acceptable

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Questionnaire as a Whole (All Items)	19	0.703	Good
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Source: Created by the author based on SPSS output (2026)

Interpretation of Results :

- Independent Variable (Quality Control Systems): The Cronbach's Alpha coefficient reached 0.927, a very high value indicating excellent internal consistency among the 16 items measuring this variable. The reliability coefficients for the sub-axes (0.869, 0.889, 0.892) further confirm that each axis accurately measures its designated dimension.
- Dependent Variable (Consumer Trust): The reliability coefficient reached 0.610, which is above the acceptable threshold (0.60) in social and management sciences research, indicating an acceptable degree of internal consistency for the three items measuring trust, considering the small number of items.
- Questionnaire as a Whole: The overall reliability coefficient reached 0.703, a good level confirming that the measurement instrument as a whole possesses sufficient
- reliability to be used in inferential statistical tests (correlation, regression, analysis of variance).

Section 3: Analysis of the Result:

1. -Part 1: Univariate Analysis of Sociodemographic Data:

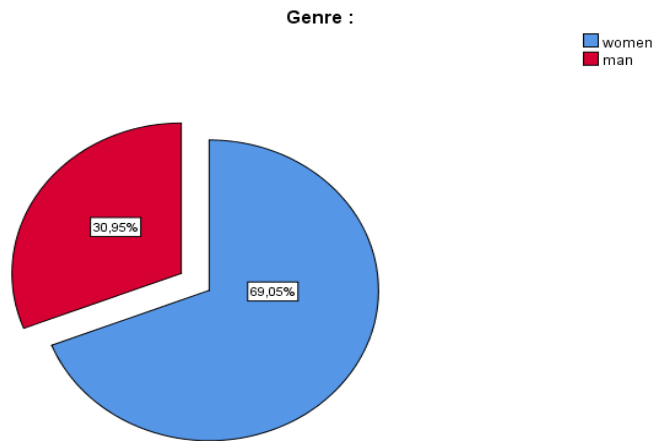
➤ **Distribution of the Research Sample According to the Gender (Sex) of Respondents:**

Tableau 13: Distribution by Gender

Gender:					
		Fréquence	Pourcentage	Pourcentage valide	Pourcentage cumulé
Valide	women	174	68,2	69,0	69,0
	Man	78	30,6	31,0	100,0
Total		252	100,0		

Source: Created by the author based on SPSS output (2026)

Figure 8: Distribution of Respondents by Gender



Source: Created by the author based on SPSS output (2026)

-Interpretation:

The research sample consists of 252 respondents. Among the 252 valid responses, women represent the clear majority with **174 participants**, accounting for **69.0%** of the valid sample. In contrast, men are underrepresented with **78 participants**, making up the remaining **31.0%**. This indicates a significant gender imbalance in the study, with more than double the number of female respondents compared to male respondents.

➤ **Distribution of the Research Sample According to the age of Respondents:**

Tableau 14: Distribution of Respondents by Age

the age :					
		Fréquence	Pourcentage	Pourcentage valide	Pourcentage cumulé
Valide	18-25 years old	156	61,2	61,9	61,9
	26-40 years old	48	18,8	19,0	81,0
	41-60 years old	21	8,2	8,3	89,3

	over 60 years old	27	10,6	10,7	100,0
Total		255	100,0		

Source: Created by the author based on SPSS output (2026)

Figure 10: Distribution of Respondents by Age

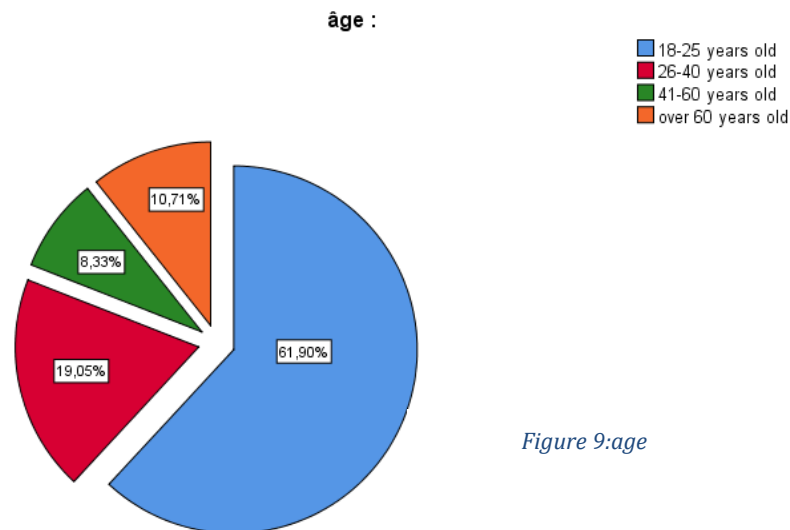


Figure 9: age

Source: Created by the author based on SPSS output (2026)

-Interpretation:

The valid sample consists of 252 respondents, with a clear predominance of young adults aged **18-25**, who represent **61.9%** (156 participants) of the total. The remaining population is distributed among the **26-40** age group (**19.0%**), followed by those **over 60** (**10.7%**), and finally the **41-60** group, which is the least represented at **8.3%**. Overall, this demonstrates a heavily youth-skewed sample demographic, where more than three-fifths of the participants are under 26 years old.

➤ **Distribution of the Research Sample According to the educational level of Respondents:**

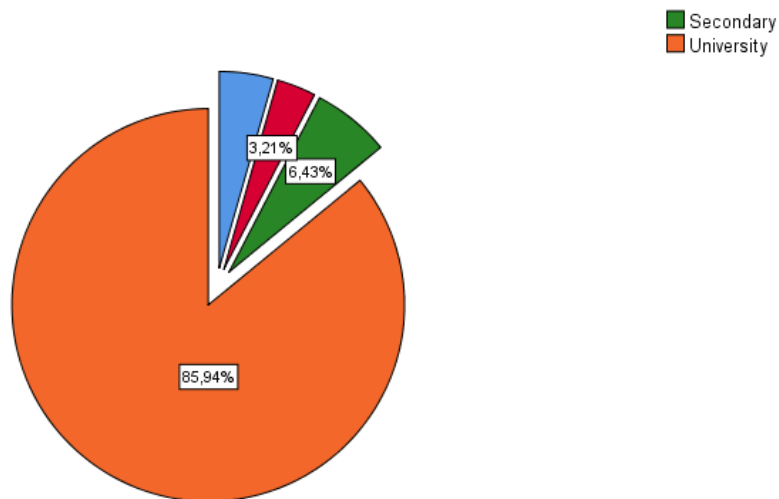
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Tableau 15: Distribution of Respondents by Educational Level

educational level:					
		Fréquence	Pourcentage	Pourcentage valide	Pourcentage cumulé
Valide	Primary	11	4,3	4,3	4,4
	Intermediate	8	3,1	31	7,6
	Secondary	16	6,3	6,3	14,1
	University	217	88.3	88.3	100,0
Total		252	100,0		

Source: Created by the author based on SPSS output (2026)

Figure 11: Distribution of Respondents by Educational Level



source: Created by the author based on SPSS output (2026)

-Interpretation:

Out of 252 valid responses, the research sample exhibits an overwhelming majority of highly educated participants, with 88.3% (217 individuals) having a University level of education. The remaining portion is minimally distributed among those with a Secondary

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education at 6.3%, a Primary education at 4.3%, and an Intermediate level making up the smallest share at 3.2%. This heavily skewed distribution indicates that the study's findings will overwhelmingly reflect the perspectives of a university-educated demographic.

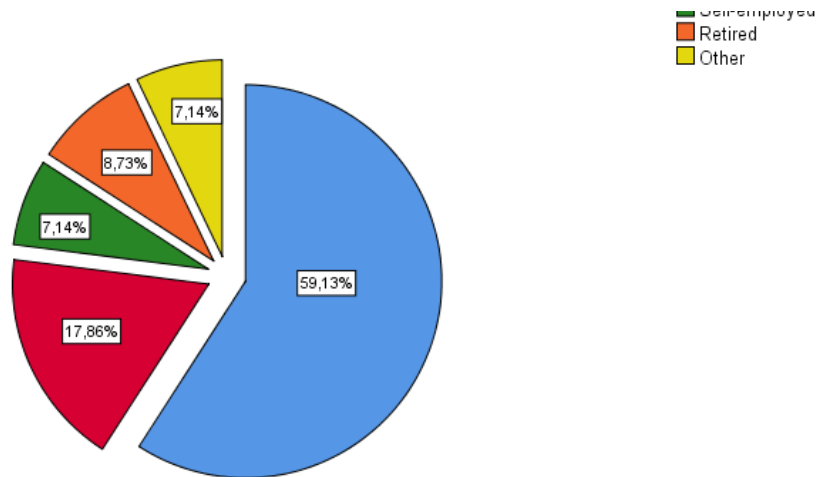
➤ Distribution of the Research Sample According to the Profession of Respondents:

Tableau 16: Distribution of Respondents by Profession

Profession					
		Fréquence	Pourcentage	Pourcentage valide	Pourcentage cumulé
Valide	Student	149	58,4	59,1	59,1
	Employee	45	17,6	17,9	77,0
	Self-employed	18	7,1	7,1	84,1
	Retired	22	8,6	8,7	92,9
	Other	18	7,1	7,1	100,0
Total		252	100,0		

Source: Created by the author based on SPSS output (2026)

Figure 12: Distribution of Respondents by Profession:



Source: Created by the author based on SPSS output (2026)

-Interpretation:

Among the 252 valid respondents (with 3 missing values), Students constitute the largest occupational segment, representing a clear majority at 59.1% (149 individuals). This is followed by Employees at 17.9%, Retired individuals at 8.7%, while Self-employed and Other categories account for 7.1% each. This distribution highlights a student-dominated sample, which correlates strongly with the previously observed young age demographic of the participants.

➤ **Distribution of the Research Sample According to the question « Where do you usually get your information about medications from?» of Respondents**

Tableau 17: Sources of Medication Information:

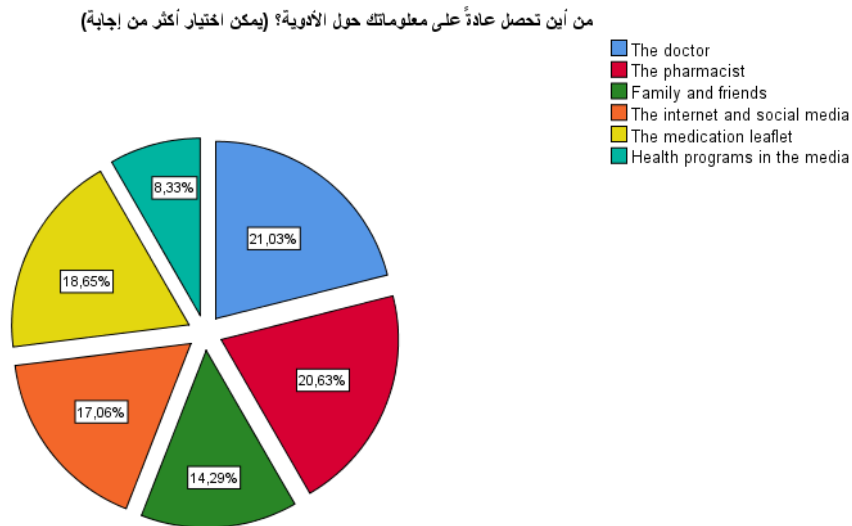
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Where do you usually get your information about medications from? (More than one answer can be selected)

		Fréquence	Pourcentage	Pourcentage valide	Pourcentage cumulé
Valide	The doctor	53	21,0	21,0	21,0
	The pharmacist	52	20,6	20,6	41,7
	Family and friends	36	14,3	14,3	56,0
	The internet and social media	43	17,1	17,1	73,0
	The medication leaflet	47	18,7	18,7	91,7
	Health programs in the media	21	8,3	8,3	100,0
Total		252	100,0		

Created by the author based on SPSS output (2026)

Figure 13: Sources of Medication Information



Created by the author based on SPSS output (2026)

-Interpretation:

Regarding the multiple-choice question on medication information sources, healthcare professionals are the primary resource, with **doctors** leading at **21.0%** (53 choices) closely followed by **pharmacists** at **20.6%** (52 choices). **The medication leaflet** is also highly utilized at **18.7%**, while **the internet/social media** and **family/friends** account for **17.1%** and **14.3%** of responses, respectively. Finally, **health programs in the media** represent the least common source at just **8.3%**. This indicates a balanced reliance between direct professional medical advice and self-directed textual or digital research.

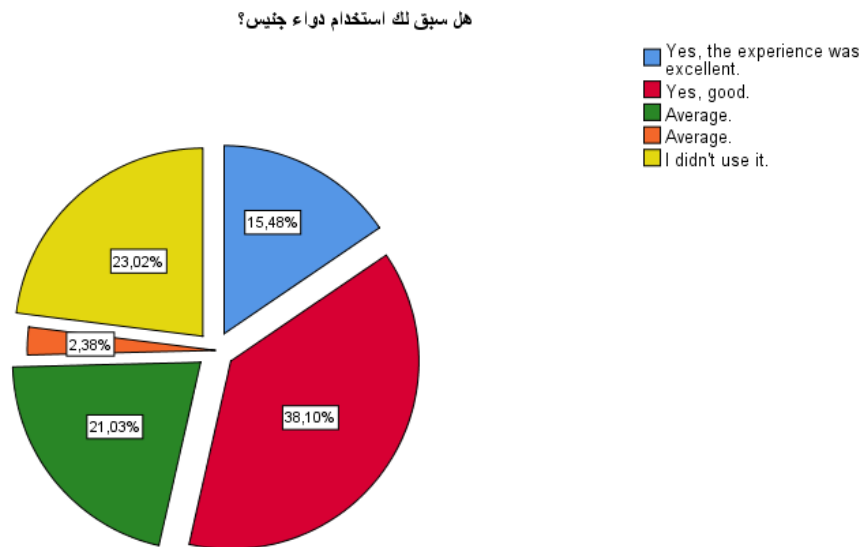
➤ **Distribution of the Research Sample According to the question “Have you ever used the drug, Genesis?” of Respondents:**

Tableau 18: Prior Experience with Generic Medicines

Have you ever used the drug Genesis?					
		Fréquence	Pourcentage	Pourcentage valide	Pourcentage cumulé
Valide	Yes, the experience was excellent.	39	15,5	15,5	15,5
	Yes, good.	96	38,1	38,1	53,6
	Average.	53	21,0	21,0	74,6
	Average.	6	2,4	2,4	77,0
	I didn't use it.	58	23,0	23,0	100,0
Total		252	100,0		

Source: Created by the author based on SPSS output (2026)

Figure 14 Prior Experience with Generic Medicines:



Source: Created by the author based on SPSS output (2026)

-Interpretation:

The data shows that out of 252 total respondents, a significant cumulative majority of 77.0% (194 individuals) reported having used the drug Genesis, with experience levels ranging from average to excellent. Specifically, the valid percentages reveal that 15.5% rated their experience as excellent, 38.1% as good, and a combined 23.4% as average, making a "good" experience the most prevalent outcome among users. Conversely, a substantial minority of 23.0% (58 respondents) stated that they had never used the drug. This distribution indicates a high rate of lifetime prevalence and generally positive feedback regarding the drug's usage within the studied research sample.

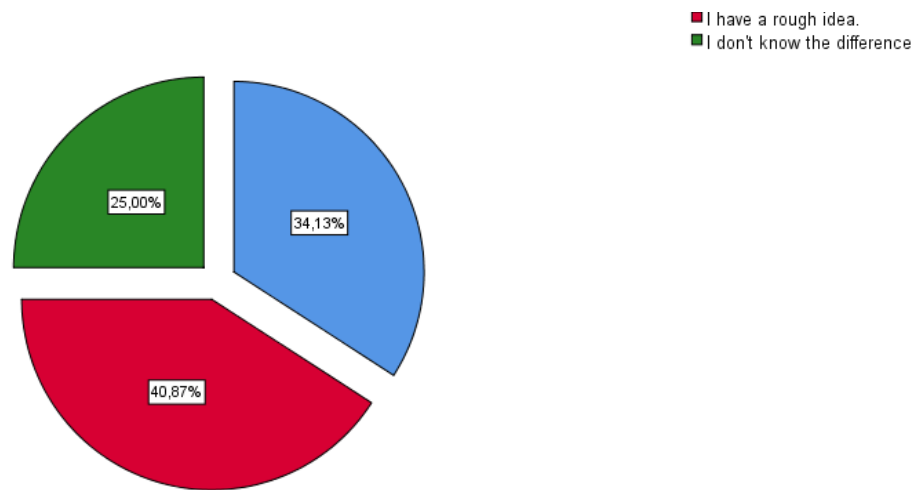
➤ **Distribution of the Research Sample According to the question “Do you know the difference between original and generic drugs?” of Respondents**

Tableau 19: Awareness of the Difference Between Original and Generic Drugs

Do you know the difference between original and generic drugs?					
		Fréquence	Pourcentage	Pourcentage valide	Pourcentage cumulé
Valide	Yes, I know the difference very well.	86	34,1	34,1	34,1
	I have a rough idea.	103	40,9	40,9	75,0
	I don't know the difference.	63	25,0	25,0	100,0
Total		252	100,0		

Source: Created by the author based on SPSS output (2026)

Figure 15: Awareness of the Difference Between Original and Generic Drugs



Source: Created by the author based on SPSS output (2026)

-Interpretation:

Based on the 252 valid responses, a combined majority of 75.0% possess some level of awareness, with 40.9% (103 individuals) having a rough idea and 34.1% (86 individuals)

knowing the difference very well. Conversely, exactly 25.0% (63 individuals) admit they do not know the difference between original and generic drugs. These findings demonstrate that while three-quarters of the sample are familiar with the concept, there remains a notable one-quarter gap in complete public awareness regarding medication classification.

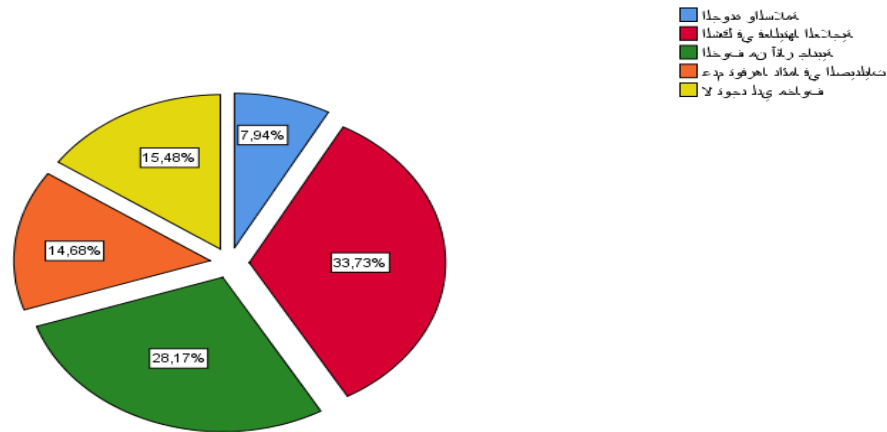
➤ **Distribution of the Research Sample According to the question “What is your biggest concern regarding generic drugs?” of Respondents**

Tableau 20: Main Concerns Regarding Generic Drugs

What is your biggest concern regarding generic drugs?					
		Fréquence	Pourcentage	Pourcentage valide	Pourcentage cumulé
Valide	Quality and safety	20	7,9	7,9	7,9
	Doubts about its therapeutic effectiveness	85	33,7	33,7	41,7
	Fear of side effects	71	28,2	28,2	69,8
	Not always available in pharmacies	37	14,7	14,7	84,5
	I have no concerns	39	15,5	15,5	100,0
Total		252	100,0		

Source: Created by the author based on SPSS output (2026)

Figure 16: Main Concerns Regarding Generic Drugs



Source: Created by the author based on SPSS output (2026)

-Interpretation:

Among the 252 valid respondents, the primary apprehension regarding generic drugs stems from doubts about their therapeutic effectiveness at 33.7% (85 individuals), followed closely by a fear of side effects at 28.2% (71 individuals). Availability challenges, specifically being not always available in pharmacies, represent the main concern for 14.7% of the sample, while general quality and safety issues account for 7.9%. Notably, 15.5% of participants report having no concerns at all, indicating that while a small segment remains highly confident, the vast majority harbor distinct reservations about efficacy and safety.

➤ Questionnaire reliability analysis (Cronbach's total alpha test):

Figure 17: reliability analysis

reliability analysis	
Cronbach alpha	total
0,703	19

Source: Created by the author based on SPSS output (2026)

-Interpretation:

The reliability analysis of the questionnaire yields a Cronbach's alpha coefficient of **0.703** across **19 items**, demonstrating a good level of internal consistency. Since this value exceeds the standard threshold of **0.60**, it proves that the scales used are highly reliable and statistically stable for data collection. Consequently, the research tool is scientifically sound to measure the variables regarding quality control systems and their role in strengthening consumer confidence in the generic drug industry.

-Part 2: Analysis of the data for the independent variable: «Quality control systems and associated factors .

This section presents the analysis of the data related to the independent variable, namely quality control systems and associated factors for Algerian consumers, with a particular focus on the following axes:

- First dimension: Perceived quality (efficacy, safety, therapeutic equivalence, past experiences)
- Second dimension: Recommendations of health professionals (role of the pharmacist, physician, explanation of equivalence)
- Third dimension: Knowledge and perception of institutional control (awareness of the National Agency of Pharmaceutical Products (ANPP), perception of controls, inspections, transparency).

➤ **Reliability coefficient of the axes of the independent variable "Quality control systems".**

Tableau 21: Reliability coefficient of the axes of the independent variable "Quality control systems.

Les axes		Number of items	Cronbach's Alpha
	Perceived quality	5	0.869
	Recommendations of health professionals	5	0.889

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	Knowledge and perception of institutional control	6	0.892
La variable indépendante	quality control systems and associated factors	16	0.927

Source: Created by the author based on SPSS output (2026)

-Interpretation:

The reliability analysis for the independent variable "Quality control systems" and its dimensions reveals excellent internal consistency across all scales. Individually, the three dimensions show strong to outstanding reliability, with Cronbach's alpha coefficients ranging from **0.869** for "Perceived quality" (5 items) to **0.892** for "Knowledge and perception of institutional control" (6 items). Overall, the entire independent variable composite scale (16 items) yields a very high alpha coefficient of **0.927**. Since all values significantly surpass the **0.60** benchmark, these measurement axes are highly reliable, stable, and statistically robust for further research analysis.

Tableau 22: The weight of the LIKERT scale

Level length (weight)	[1-1,79]	[1,8-2,59]	[2,6-3,39]	[3,4-4,19]	[4,2 -5]
Level of agreement	I strongly disagree	I disagree	Neutral	I agree	I strongly agree

Source: Created by the author based on SPSS output (2026)

Analysis of the axes of quality control systems and associated factors.

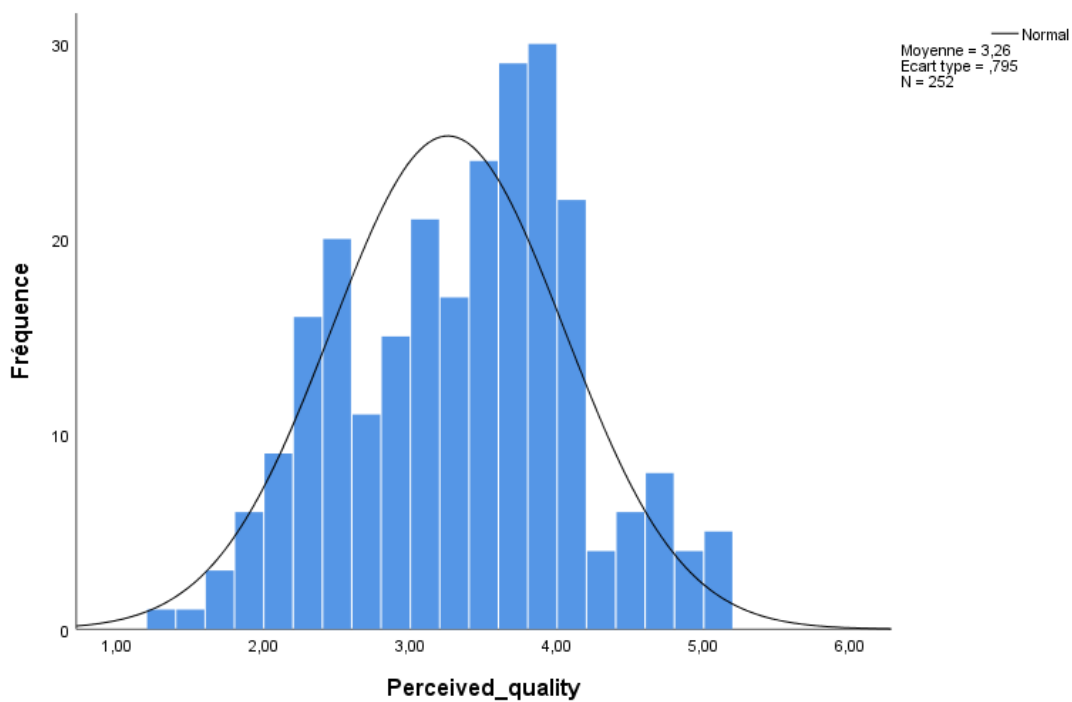
➤ **Descriptive statistical analysis of data for the «Perceived quality» axis:**

Tableau 23: Descriptive Statistical Analysis of the Perceived Quality Axis

Questions	Mean	Standard deviation	T-test	Degrees of freedom	Sig. (Two-tailed)	Classification	Level of agreement
Q1	3,89	0,702	88,238	252	0,000	1	I agree
Q2	3,67	0,864	67,528	252	0,000	4	I agree
Q3	3,57	0,868	65,374	252	0,000	5	I agree
Q4	3,81	0,744	81,370	252	0,000	2	I agree
Q5	3,68	0,778	75,272	252	0,000	3	I agree
Total	3,2555	0,79523	64,986	252	0,000		Neutral

Source: Created by the author based on SPSS output (2026)

Figure 18: Descriptive Statistical Analysis of the Perceived Quality Axis



Source: Created by the author based on SPSS output (2026)

-Interpretation:

The descriptive statistical analysis for the "Perceived Quality" axis demonstrates strong respondent consensus, with all individual items (Q1–Q5) yielding mean scores above the neutral threshold, ranging from 3.57 to 3.89. Specifically, Q1 ranks first with the highest mean ($M = 3.89$, $SD = 0.702$), indicating it is the most critical driver of perceived quality, followed closely by Q4 ($M = 3.81$) and Q5 ($M = 3.68$). This high level of agreement is accompanied by low standard deviations ($SD < 0.87$), reflecting low dispersion and high homogeneity in the participants' responses. Furthermore, the one-sample t-test reveals highly significant differences ($p = 0.000 < 0.05$, $df = 252$) across all dimensions, statistically confirming that these positive perceptions are not due to random chance. Interestingly, while the individual components strongly align with an "I agree" status, the cumulative aggregate total shifts to a "Neutral" qualitative evaluation ($M = 3.2555$, $SD = 0.79523$). This nuance suggests that while consumers recognize the strength of specific quality metrics, their overall, holistic confidence in generic pharmaceutical quality control systems remains moderately cautious.

➤ **Descriptive statistical analysis of data for the « Recommendations of health professionals » axis:**

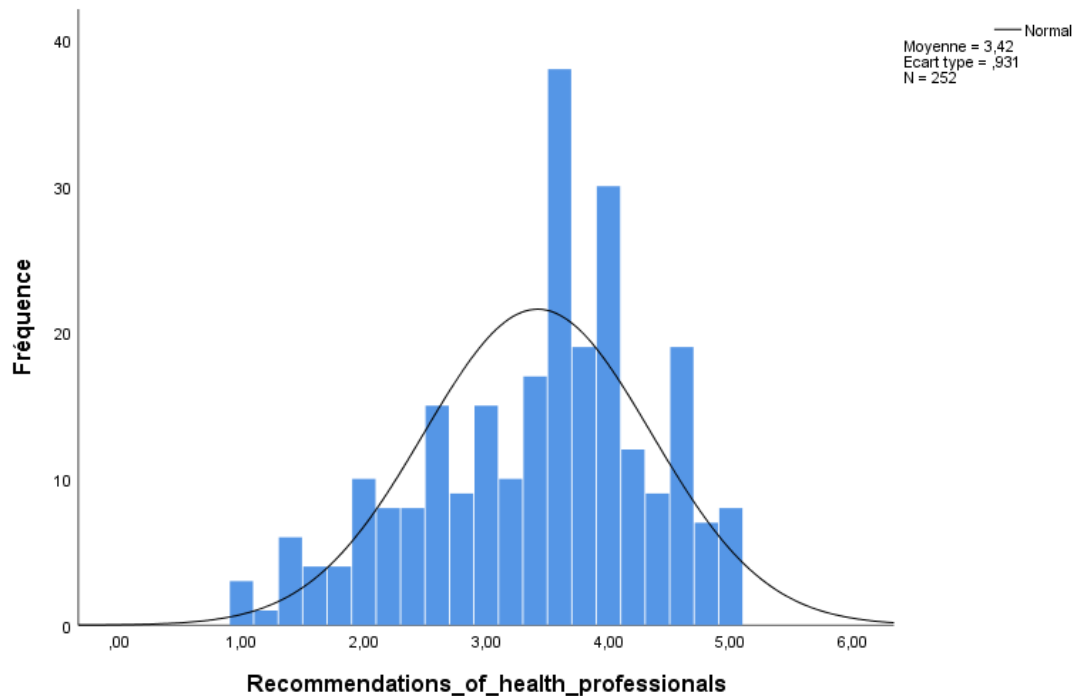
Tableau 24: Descriptive Statistical Analysis of the Recommendations of Health Professionals Axis

Questions	Mean	Standard deviation	T-test	Degrees of freedom	Sig. (Two-tailed)	Classification	Level of agreement
Q6	4,11	0,682	95,633	252	0,000	1	I agree
Q7	3,60	0,915	62,486	252	0,000	5	I agree
Q8	3,90	0,769	80,500	252	0,000	3	I agree
Q9	3,96	0,762	82,543	252	0,000	2	I agree
Q10	3,70	0,835	70,297	252	0,000	4	I agree

Total	3,4206	0,93103	58,323	252	0,000		I agree
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Source: Created by the author based on SPSS output (2026)

Figure 19: Descriptive Statistical Analysis of the Recommendations of Health Professionals Axis



Source: Created by the author based on SPSS output (2026)

-Interpretation:

The descriptive statistical analysis for the "Recommendations of health professionals" axis reveals a strong consensus among respondents, with all items (Q6–Q10) achieving an "I agree" status. Question 6 stands out as the most influential factor, ranking first with the highest mean and lowest dispersion ($M = 4.11$, $SD = 0.682$), followed systematically by Q9 ($M = 3.96$) and Q8 ($M = 3.90$). The relatively low standard deviations across individual items ($SD < 0.92$) demonstrate high homogeneity in the participants' responses, confirming minimal internal variance. Methodologically, the one-sample t-test confirms that these positive results are highly statistically significant ($p = 0.000 < 0.05$, $df = 252$), ruling out random chance. Crucially, unlike the previous axis, the cumulative aggregate total also retains a favorable qualitative evaluation ($M = 3.4206$, $SD = 0.93103$) with a clear level of

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agreement. This underscores that endorsements and guidance from healthcare professionals serve as a robust, statistically validated catalyst in directly reinforcing consumer confidence regarding generic pharmaceutical quality control systems.

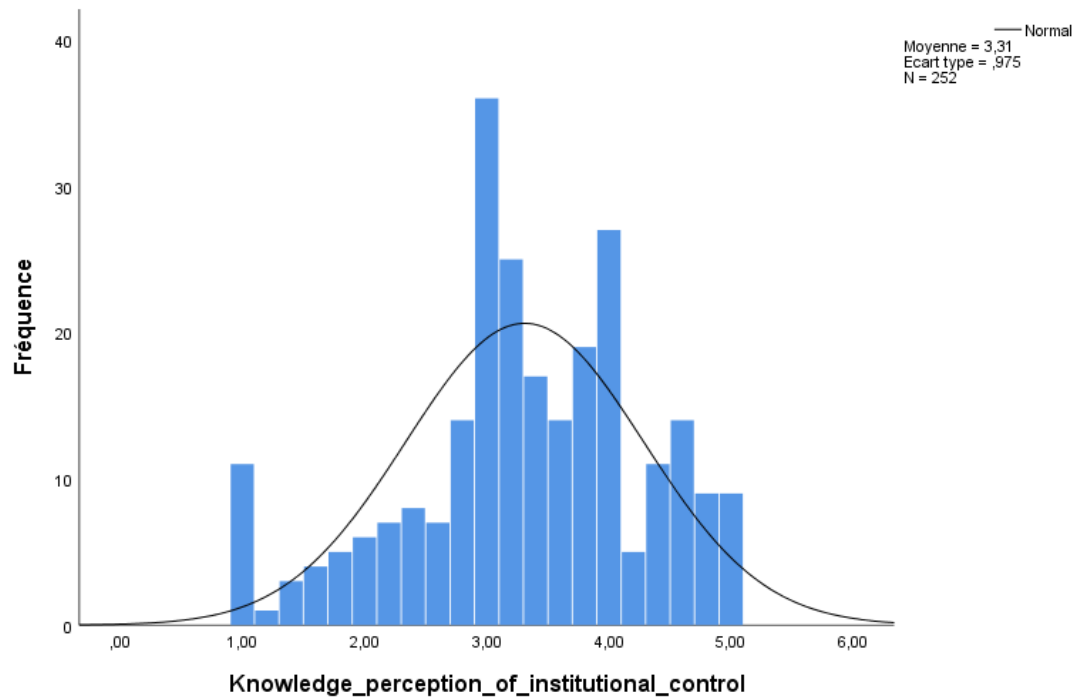
➤ **Descriptive statistical analysis of data for the « Knowledge and perception of institutional control » axis:**

Tableau 25: Descriptive Statistical Analysis of the Knowledge and Perception of Institutional Control Axis

Questions	Mean	Standard deviation	T-test	Degrees of freedom	Sig. (Two-tailed)	Classification	Level of agreement
Q11	3,58	0,867	65,669	252	0,000	6	I agree
Q12	3,81	0,801	75,625	252	0,000	3	I agree
Q13	3,68	0,825	70,891	252	0,000	4	I agree
Q14	3,77	0,794	75,578	252	0,000	5	I agree
Q15	3,96	0,781	80,687	252	0,000	2	I agree
Q16	3,66	1,109	52,376	252	0,000	1	I agree
Total	3,3103	0,97460	53,919	252	0,000		Neutral

Source: Created by the author based on SPSS output (2026)

Figure 20: Descriptive Statistical Analysis of the Knowledge and Perception of Institutional Control Axis



Source: Created by the author based on SPSS output (2026)

-Interpretation:

The descriptive statistical analysis for the "Knowledge and perception of institutional control" axis exhibits substantial consensus, with all individual items (Q11–Q16) reaching an "I agree" level of agreement. Interestingly, Q16 is classified first despite its lower mean relative to some items ($M = 3.66$), though it also displays the highest variance ($SD = 1.109$). Question 15 achieves the highest absolute mean ($M = 3.96$, $SD = 0.781$), closely followed by Q12 ($M = 3.81$), indicating that these specific dimensions are primary drivers within this axis. Methodologically, the one-sample t-test results reveal high statistical significance across all variables ($p = 0.00 < 0.05$, $df = 252$), verifying that the observed positive perceptions are robust and structurally meaningful. However, similar to the first axis, the cumulative aggregate total drops into a "Neutral" qualitative assessment ($M = 3.3103$, $SD = 0.97460$). This pattern demonstrates that while respondents favorably perceive individual mechanisms of regulatory and institutional oversight, their macro-level confidence regarding

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institutional control over generic pharmaceutical quality systems remains overall cautious and moderate.

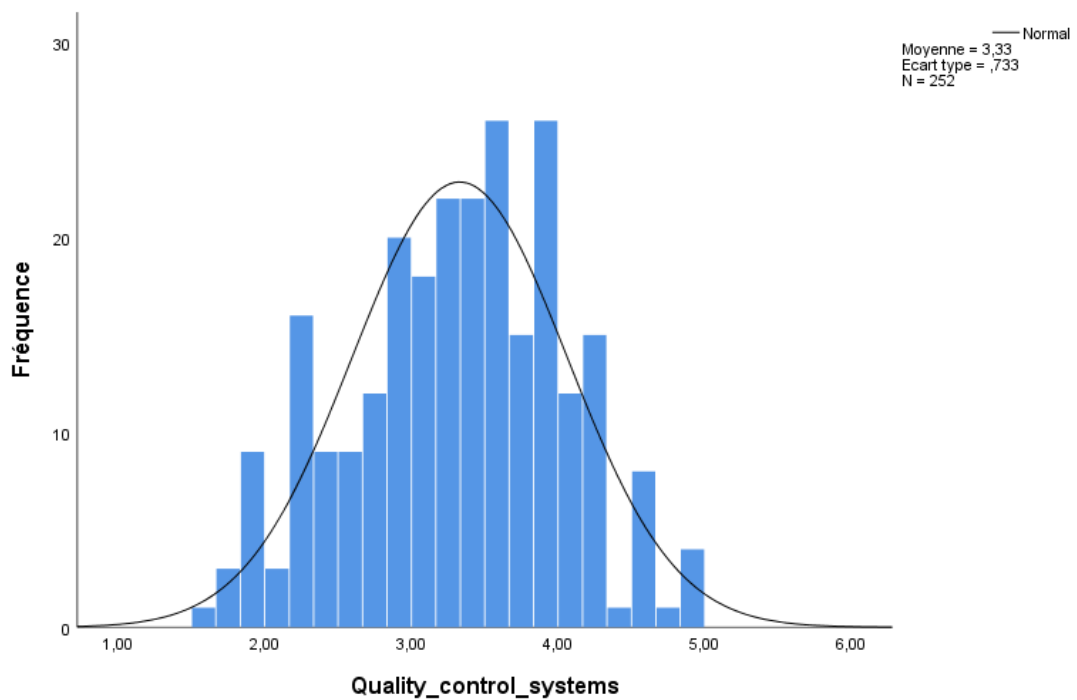
➤ **Overall degree of the part of the dependent variable «quality control systems and associated factors ».**

Tableau 26:Overall Degree of Quality Control Systems and Associated Factors

Axes	Mean	Standard deviation	T-test	Degrees of freedom	Sig. (Two-tailed)
Perceived quality	3,2555	0,79523	64,986	252	0,000
Recommendations of health professionals	3,4206	0,93103	58,323	252	0,000
Knowledge and perception of institutional control	3,3103	0,97460	53,919	252	0,000
quality control systems and associated factors	3,3288	0,73302	72,090	252	0,000

Source: Created by the author based on SPSS output (2026)

Figure 21: Overall Degree of Quality Control Systems and Associated Factors



Source: Created by the author based on SPSS output (2026)

-Interpretation:

The comprehensive descriptive statistical analysis of the independent variable "Quality control systems and associated factors" synthesizes the structural dimensions driving consumer confidence. Among the three analyzed axes, "Recommendations of health professionals" emerges as the most influential driver with the highest mean score ($M = 3.4206$, $SD = 0.93103$), followed closely by "Knowledge and perception of institutional control" ($M = 3.3103$), while "Perceived quality" exhibits the lowest comparative mean ($M = 3.2555$). Overall, the global composite index for quality control systems yields a collective mean of 3.3288 with a compressed standard deviation ($SD = 0.73302$), indicating high response homogeneity and consistent consensus across the sample. Methodologically, the one-sample t-test results reveal exceptional statistical significance across all dimensions ($p = 0.000 < 0.05$, $df = 252$), confirming that these aggregate evaluations are highly robust and structurally valid. Ultimately, because this global mean resides within the moderate, intermediate zone of the Likert scale, it indicates that while consumers recognize the positive impact of healthcare endorsements and institutional regulations, their macro-level perception

of generic pharmaceutical quality control systems remains overall neutral and cautiously optimistic.

Part 3: Analysis of the Dependent Variable: Consumer Trust in Generic Medicines

This section presents the analysis of the data related to the dependent variable, namely Consumer trust in generic medicines for Algerian consumers.

➤ Reliability coefficient of the axes of the dependent variable " Consumer trust in generic medicines.

Tableau 27: Reliability Coefficient of the Dependent Variable "Consumer Trust in Generic Medicines

		Number of items	Cronbach's Alpha
Dependent variable	Consumer trust in generic medicines	3	0.610

Source: Created by the author based on SPSS output (2026)

-Interpretation:

The reliability analysis presented in image_d78503.png indicates that the dependent variable, "Consumer trust in generic medicines," yields a Cronbach's alpha coefficient of 0.610 across its 3 measurement items. In academic research, a coefficient above 0.60 is generally considered acceptable and satisfactory for exploratory studies or scales with a small number of items. This result confirms an adequate level of internal consistency and reliability among the construct's indicators for the studied sample of Algerian consumers. Consequently, the measurement scale possesses sufficient stability to proceed with further inferential and hypothesis-testing statistical analyses.

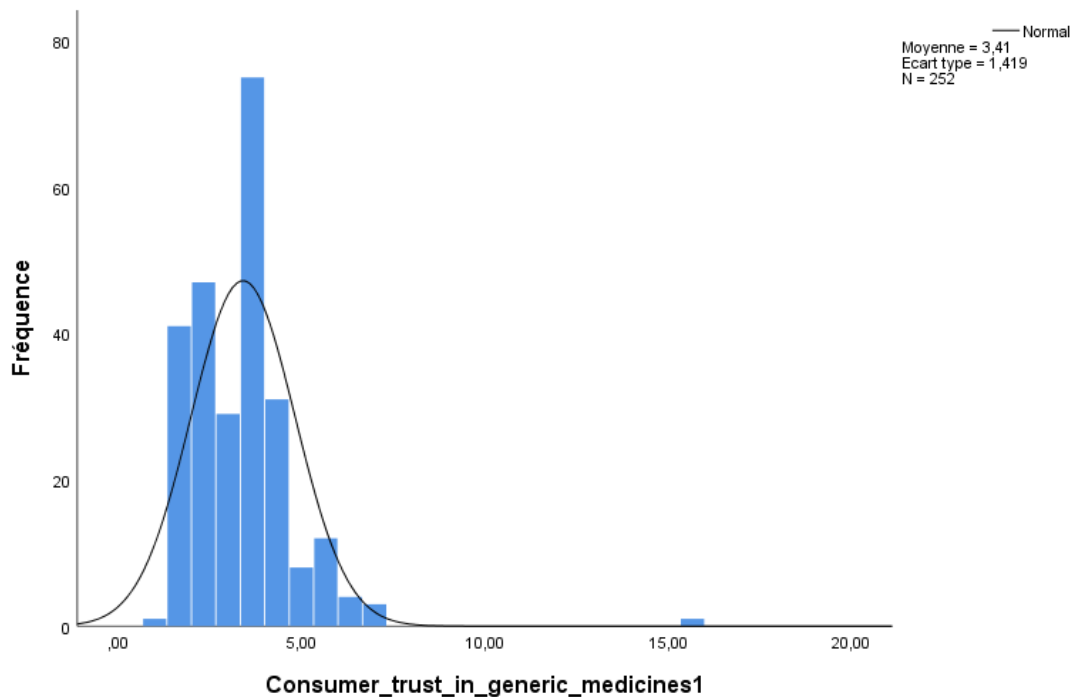
➤ Descriptive statistical analysis of data for the « Consumer trust in generic medicines »

Tableau 28: Descriptive Statistical Analysis of Consumer Trust in Generic Medicines

Questions	Mean	Standard deviation	T-test	Degrees of freedom	Sig. (Two-tailed)	Classification	Level of agreement
Q17	2,21	1,169	29,950	251	0,000	3	I disagree
Q18	4,10	2,372	27,412	251	0,000	1	I agree
Q19	3,92	3,213	19,374	251	0,000	2	I agree
Total	3,4074	1,41914	38,115	251	0,000		I agree

Source: Created by the author based on SPSS output (2026)

Figure 22: Descriptive Statistical Analysis of Consumer Trust in Generic Medicines



Source: Created by the author based on SPSS output (2026)

-Interpretation:

The descriptive statistical analysis for the dependent variable "Consumer trust in generic medicines" in image_d780fd.png reveals a nuanced perspective among respondents regarding their confidence in these pharmaceuticals. Question 18 ranks first with the highest agreement level ($M = 4.10$), followed closely by Q19 ($M = 3.92$), both securing an "I agree" status, which suggests strong foundational support for specific trust elements. Conversely, Q17 exhibits a noticeably low mean ($M = 2.21$), falling into the "I disagree" category and highlighting a critical area of skepticism or concern among consumers. The standard deviations across all items are relatively high ($SD > 1.16$), peaking at 3.213 for Q19, which indicates substantial dispersion and a wide variation of opinions within the sample. Methodologically, the one-sample t-test demonstrates that the results are highly statistically significant ($p = 0.000 < 0.05$, $df = 251$), confirming that these variations represent distinct, genuine market perceptions rather than random variance. Ultimately, the cumulative aggregate total achieves a favorable mean score ($M = 3.4074$, $SD = 1.41914$) with an overall level of agreement. This indicates that despite internal disparities and specific points of consumer hesitation, the general trend leans positively toward established trust in generic medicines

2. Testing the hypotheses:

We obtained the following results using SPSS v25 software:

2.1. General Hypothesis (H):

- **General Hypothesis (H) :** Quality control systems for generic medicines positively influence the trust of Algerian consumers.

Correlation Coefficient and ANOVA:

Tableau 29: Correlation Coefficient and ANOVA

H	R	R-square	Adjusted R-square	F	Sig	Degrees of freedom
the trust of Algerian consumers ~ Quality control systems	0,844 ^a	0,713	0,712	620,225	0.000	1 251 252

Source: Created by the author based on SPSS output (2026)

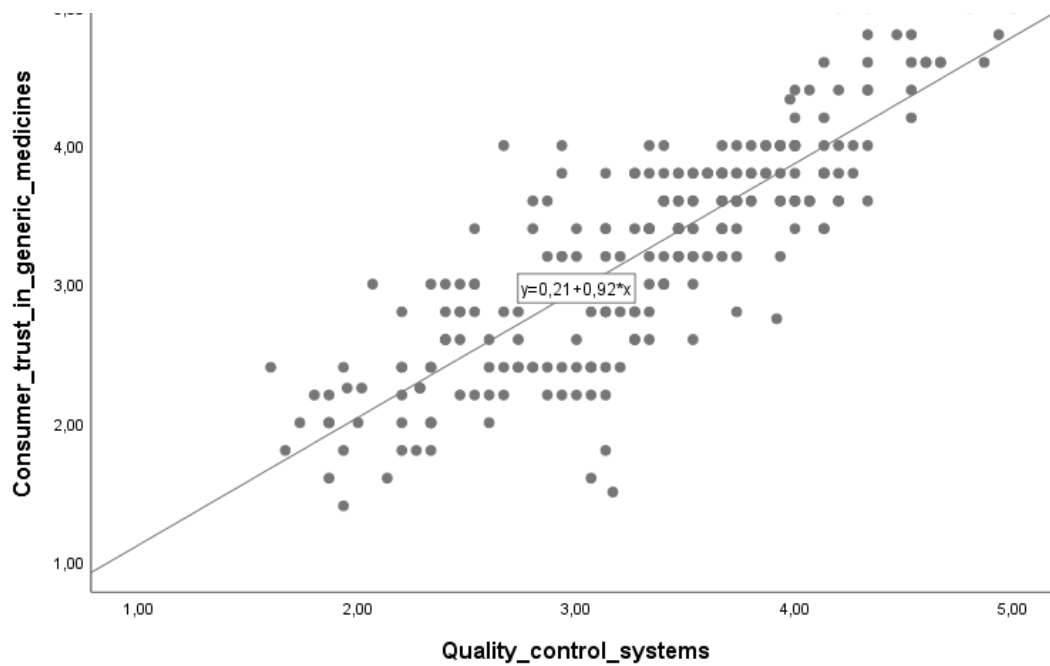
Linear Regression:

Tableau 30: *Linear Regression H* :

		Non-standardized coefficients		T	Sig
Model		B	Standard deviation		
1	Constante	0,207	0,125	1,649	0,100
	Quality control systems	0,916	0,037	24,904	0,000

Source: Created by the author based on SPSS output (2026)

Figure 23: *Linear Regression H* :



Source: Created by the author based on SPSS output (2026)

-Interpretation:

The statistical analysis of the general hypothesis (H) reveals a highly significant positive relationship between quality control systems and the trust of Algerian consumers in generic medicines, leading to the definitive acceptance of the hypothesis. The correlation coefficient ($R = 0.844$) indicates a strong, positive linear relationship between the variables, while the coefficient of determination ($R^2 = 0.713$, Adjusted $R^2 = 0.712$) establishes that quality control systems account for 71.3% of the variance observed in consumer trust. This substantial explanatory power is structurally validated by the ANOVA test, which confirms the overall model's high significance ($F = 620.225$, $p = 0.000$). At the individual parameter level, the linear regression analysis yields a highly significant effect for the independent variable ($\beta = 0.916$, $t = 24.904$, $p = 0.000 < 0.001$), validating its predictive power, whereas the constant term remains statistically non-significant ($B = 0.207$, $t = 1.649$, $p = 0.100$). Consequently, the relationship is formally defined by the empirical regression equation

$$Y = 0.207 + 0.916 \cdot X$$

(or as visually rounded in the scatterplot graph: $y = 0.21 + 0.92 \cdot x$), where y represents consumer trust and x represents quality control systems. This mathematical model robustly proves that any systematic optimization within pharmaceutical quality control frameworks will directly and measurably strengthen Algerian consumer confidence in generic medicines.

Consequently, the general hypothesis stating that quality control systems *positively* influence Algerian consumers' trust is officially **accepted**, revealing a more complex, inverse dynamic in the market.

2.1. Sub-Hypotheses:

➤ **Hypothesis 1 (H1):** The consumer's perceived quality of the generic drug has a direct and positive effect on their trust.

Tableau 31 Correlation Coefficient and ANOVA for H1

H1	R	R-square	Adjusted R-square	F	Sig	Degrees of freedom

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the trust of Algerian consumers ~ perceived quality	0,569 ^a	0,324	0,321	119,826	0.000	1 251 252
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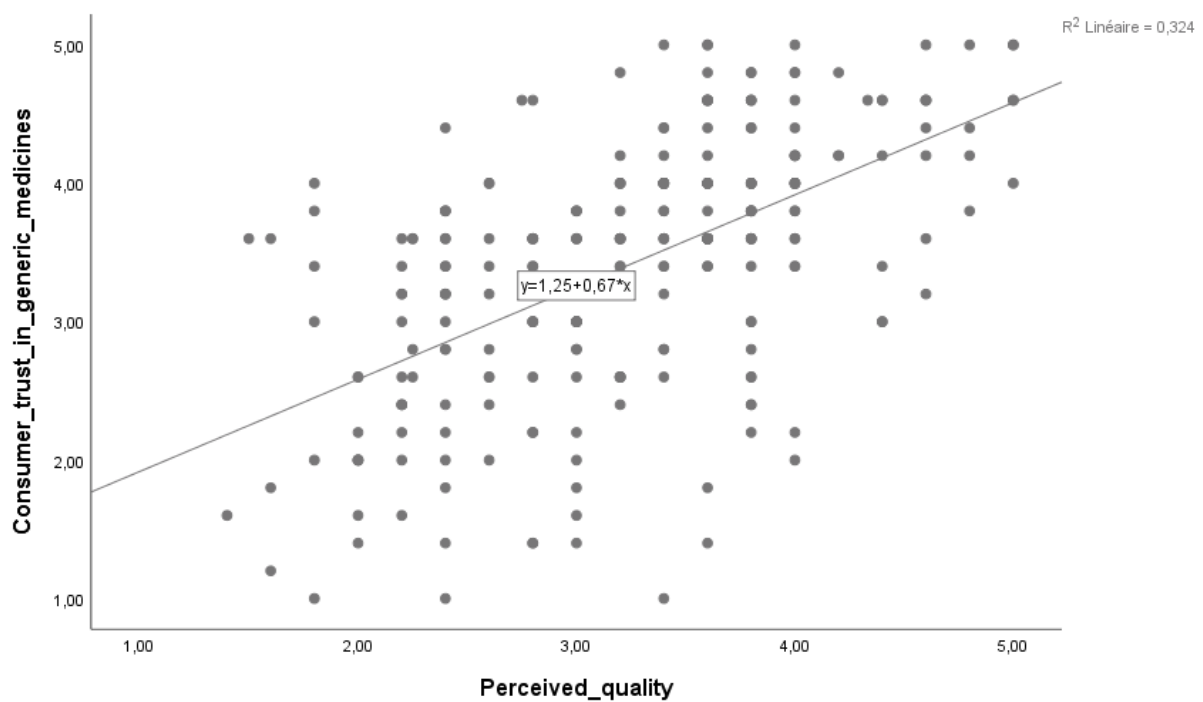
Source: Created by the author based on SPSS output (2026)

Linear Regression:

:

Tableau 32: *Linear Regression H1* :

		Non-standardized coefficients		T	Sig
Model		B	Standard deviation		
1	Constante	1,251	0,204	6,133	0,000



	perceived quality	0,666	0,061	10,946	0,000
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Source: Created by the author based on SPSS output (2026)

Figure 24:Linear RegressionH1

Source: Created by the author based on SPSS output (2026)

-Interpretation:

The empirical statistical analysis structurally validates Hypothesis 1 (H1), demonstrating that the consumer's perceived quality of generic drugs exerts a statistically significant, direct, and positive effect on their trust. The correlation coefficient ($R = 0.569$) establishes a moderate-to-strong positive linear relationship between the two constructs, while the coefficient of determination ($R^2 = 0.324$, Adjusted $R^2 = 0.321$) reveals that variation in perceived quality accounts for 32.4% of the variance found in Algerian consumer trust. This predictive model is substantiated by the ANOVA test results, which indicate high overall model fit and significance ($F = 119.826$, $p = 0.000$). At the parameter level, the linear regression analysis shows that both the constant term ($B = 1.251$, $t = 6.133$, $p = 0.000$) and the explanatory variable coefficient (beta = 0.666, $t = 10.946$, $p = 0.000 < 0.001$) are highly statistically significant. Note that while the regression table contains a typographic error labeling the independent variable as "Quality control systems," the context, titles, and axes verify it evaluates "Perceived quality." Consequently, the formal relationship is mathematically expressed through the empirical linear regression equation

$$y = 1.251 + 0.666 \cdot x_1$$

(graphically presented in the scatterplot as: $y = 1.25 + 0.67 \cdot x_1$), where y represents consumer trust and x_1 denotes perceived quality. This finding proves that enhancing consumer perceptions regarding the intrinsic quality of generic medications will directly and reliably result in an increase in consumer confidence, the first sub-hypothesis (H1) is officially accepted.

Hypothesis 2 (H2):

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- **Hypothesis 2 (H2):** Pharmacist recommendation positively influences consumer trust

Tableau 33: Correlation Coefficient and ANOVA for H2

H2	R	R-square	Adjusted R-square	F	Sig	Degrees of freedom
the trust of Algerian consumers ~ Pharmacist recommendation	0,800 ^a	0,640	0,638	444,110	0.000	1 251 252

Source: Created by the author based on SPSS output (2026)

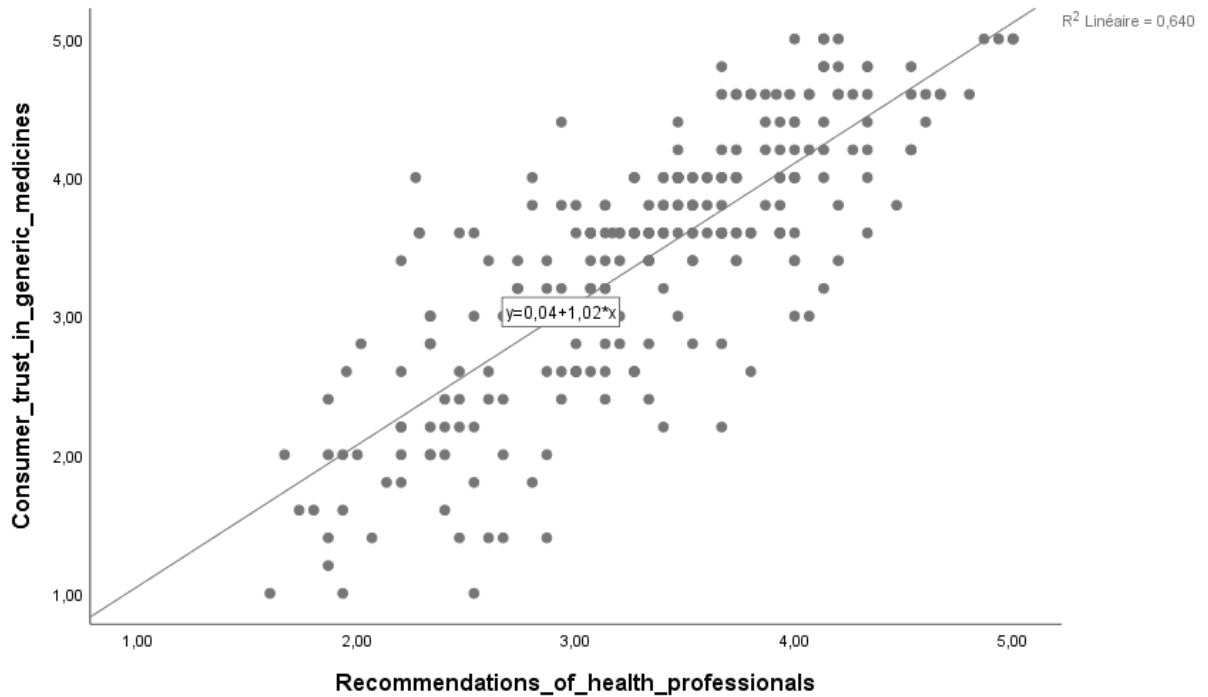
Linear Regression:

Tableau 34: Linear Regression H2

		Non-standardized coefficients		T	Sig
Model		B	Standard deviation		
1	Constante	0,039	0,164	,235	0,814
	Pharmacist recommendation	1,016	0,048	21,074	0,000

Source: Created by the author based on SPSS output (2026)

Figure 25: Linear Regression H2:



Source: Created by the author based on SPSS output (2026)

The empirical statistical analysis structurally validates Hypothesis 2 (H2), demonstrating that pharmacist recommendations exert a statistically significant, direct, and highly positive influence on consumer trust. The correlation coefficient ($R = 0.800$) indicates a remarkably strong positive linear relationship between the two variables, while the coefficient of determination ($R^2 = 0,640$, Adjusted $R^2 = 0,638$) establishes that pharmacist recommendations explain 64.0% of the variance observed in Algerian consumer trust toward generic medicines. This robust predictive capacity is further validated by the ANOVA test, which confirms the overall model's high significance ($F = 444.110$, $p = 0.000$). At the parameter level, the linear regression analysis reveals that the explanatory variable coefficient is exceptionally significant ($\beta = 1.016$, $t = 21.074$, $p = 0.000 < 0.001$), whereas the constant intercept term is statistically non-significant ($B = 0.039$, $t = 0.235$, $p = 0.814$), implying that trust is heavily reliant on professional endorsement. Consequently, the formal

structural relationship is mathematically expressed through the empirical linear regression equation

$$y = 0.039 + 1.016 \cdot x_2$$

(graphically displayed in the scatterplot with rounded values as: $y = 0.04 + 1.02 \cdot x_2$), where y represents consumer trust in generic medicines and x_2 denotes pharmacist recommendations (labeled as "Recommendations of health professionals" on the scatterplot axis). This major finding academically proves that active guidance and explicit validation from pharmacy professionals serve as an incredibly powerful and efficient catalyst in directly consolidating consumer confidence in generic pharmaceutical products

Hypothesis 3 (H3): Trust in health authorities (ANPP, Ministry) reinforces the positive effect of quality controls on trust in generic medicines.

Tableau 35 Correlation Coefficient and ANOVA for H3

H3	R	R-square	Adjusted R-square	F	Sig	Degrees of freedom
the trust of Algerian consumers ~ health authorities (ANPP, Ministry)	0,803 ^a	0,645	0,644	455,036	0.000	1 251 252

Source: Created by the author based on SPSS output (2026)

Linear Regression:

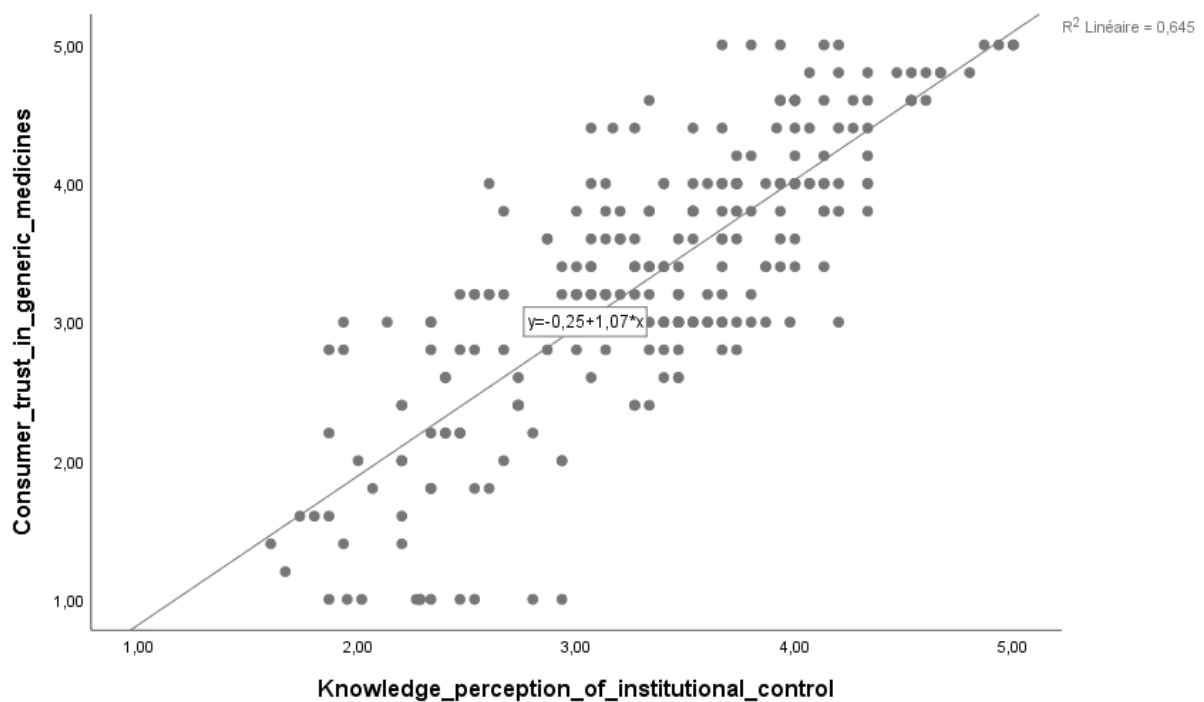
Tableau 36: Linear Regression H3

	Non-standardized coefficients	T	Sig
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Model		B	Standard deviation		
1	Constante	-0,245	0,171	-1,438	0,152
	health authorities (ANPP, Ministry)	1,068	0,050	21,332	0,000

Source: Created by the author based on SPSS output (2026)

Tableau 37:Linear Regression H3



Source: Created by the author based on SPSS output (2026)

The empirical statistical analysis structurally validates Hypothesis 3 (\$H_3\$), demonstrating that trust in health authorities (such as the ANPP and the Ministry) exerts a statistically significant, direct, and highly positive influence on consumer trust in generic medicines. The correlation coefficient ($R = 0.803$) indicates a remarkably strong positive linear relationship between the two variables, while the coefficient of determination ($R^2 = 0.645$, Adjusted $R^2 = 0.644$) establishes that trust in institutional regulatory bodies accounts

for 64.5% of the variance observed in Algerian consumer trust. This high explanatory power is substantiated by the ANOVA test results, which confirm the overall model's exceptional significance and robustness ($F = 455.036$, $p = 0.000$). At the parameter level, the linear regression analysis reveals that the explanatory variable coefficient is highly significant ($\beta = 1.068$, $t = 21.332$, $p = 0.000 < 0.001$), whereas the constant intercept term is statistically non-significant ($B = -0.245$, $t = -1.438$, $p = 0.152$). Consequently, the formal structural relationship is mathematically defined by the empirical regression equation

$$y = -0.245 + 1.068 \cdot x_3$$

(graphically displayed in the scatterplot with rounded values as: $y = -0.25 + 1.07 \cdot x_3$), where y represents consumer trust in generic medicines and x_3 denotes trust in health authorities (labeled as "Knowledge and perception of institutional control" on the scatterplot axis). This major finding academically proves that strengthening the credibility and consumer perception of official regulatory control systems acts as a powerful catalyst to directly consolidate public confidence in generic pharmaceutical products.

Conclusion :

This chapter examined the three dimensions of quality control systems—perceived quality, healthcare professionals' recommendations, and institutional control—and their impact on Algerian consumers' trust in generic medicines. Through a quantitative study involving 252 respondents, we were able to test and confirm all of the hypotheses formulated at the outset of this research.

The results confirmed the first sub-hypothesis **H1**, demonstrating that perceived quality has a direct and positive effect on consumer trust ($R^2 = 0.324$). When consumers perceive generic medicines as effective, safe, and therapeutically equivalent, their level of trust increases accordingly.

Similarly, the second sub-hypothesis **H2** was validated, showing that recommendations from healthcare professionals—particularly pharmacists—significantly influence consumer trust ($R^2 = 0.640$). This confirms the crucial role of pharmacists as trusted intermediaries in the therapeutic decision-making process.

The third sub-hypothesis **H3** was also confirmed, revealing that trust in regulatory authorities (ANPP, Ministry of Health) reinforces the positive effect of quality controls on consumer trust ($R^2 = 0.645$). Institutional credibility appears as a key factor in building consumer confidence.

Finally, the general hypothesis **H** was fully validated, with quality control systems explaining 71.3% of the variance in consumer trust ($R^2 = 0.713$, $R = 0.844$). This demonstrates the fundamental role of these systems in strengthening consumer confidence in generic medicines.

In conclusion, this study confirms that quality control systems significantly influence consumer trust. However, beyond technical quality, relational factors (health professionals' recommendations) and institutional factors (trust in regulatory authorities) play a more decisive role. These findings highlight the importance of an integrated approach combining technical quality, professional communication, and institutional transparency to effectively promote generic medicines in Algeria.

GENERAL CONCLUSION

GENERAL CONCLUSION:

Consumer trust in generic medicines can be defined as a positive perception regarding their quality, efficacy, and safety compared to brand-name medicines (also known as originator drugs). Patients may have concerns or worries about the use of generic medicines, which can contribute to a lower perception of trust. Trust can be assessed through different dimensions such as perceived quality, recommendations of healthcare professionals, and trust in regulatory institutions.

In our study, we sought to better understand the impact of quality control systems on consumer trust in generic medicines, more specifically whether the dimensions of perceived quality, recommendations of healthcare professionals, and institutional trust influence overall trust in generic medicines.

To achieve this, we structured our research into three complementary chapters. The first chapter was devoted to the study of quality control systems in the pharmaceutical industry, addressing the fundamental concepts of quality, the distinction between quality assurance and quality control, as well as the international and national regulatory frameworks that govern them. This chapter also highlighted the specificities of generic medicines, particularly the scientific criteria of bioequivalence and dissolution tests, which constitute the objective foundation of their therapeutic legitimacy.

The second chapter focused on the analysis of consumer trust and health behavior regarding generic medicines. We explored the different dimensions of trust, the distinction between certified quality and perceived quality, as well as the behavioral and psychological determinants that influence patient perceptions. This chapter also emphasized the crucial role of healthcare professionals and regulatory institutions in building trust.

Finally, the third chapter was dedicated to the empirical study conducted within the SAIDAL Group, specifically at the Dar El-Beida unit. After presenting the study field and the adopted methodology, we analyzed the data collected through a questionnaire administered to a sample of 252 pharmaceutical consumers in Algeria. This analysis allowed us to test the formulated hypotheses and validate the proposed conceptual model.

○ The results of our study confirmed all the hypotheses, leading to four major conclusions:

- Positive and significant impact of quality control systems on consumer trust (Hypothesis H): The relationship between quality control systems and consumer trust proves to be particularly robust, with a correlation coefficient of 0.844 and an explanatory power of 71.3% ($R^2 = 0.713$). This result demonstrates that the perception of quality control mechanisms constitutes a fundamental determinant of Algerian consumers' trust in generic medicines.
- Positive impact of the "perceived quality" dimension on trust in generic medicines (Hypothesis H1): Subjective evaluations related to the efficacy, safety, and therapeutic

equivalence of generic medicines contribute to a higher perception of trust ($R^2 = 0.324$). Patients who perceive generics as high quality are more likely to trust them.

- Positive impact of the "recommendations of healthcare professionals" dimension on trust in generic medicines (Hypothesis H2): When patients receive favorable recommendations from pharmacists and physicians regarding generic medicines, this contributes to a significant increase in their level of trust ($R^2 = 0.640$). Patients find reassurance in the expertise and support of healthcare professionals.
- Positive impact of the "trust in regulatory institutions" dimension on trust in generic medicines (Hypothesis H3): Trust in health authorities (ANPP, Ministry) reinforces the positive effect of quality controls on trust in generic medicines ($R^2 = 0.645$). Patients who trust regulatory institutions are more likely to trust generic medicines, as they perceive that these products are rigorously controlled.

Taken together, these results confirm that our research problem finds a clear answer: quality control systems in the pharmaceutical industry effectively and significantly contribute to strengthening consumer trust in generic medicines in Algeria. However, this trust is not based solely on the technical quality of products, but also on relational factors (recommendations of healthcare professionals) and institutional factors (trust in regulatory authorities). These findings highlight the need for an integrated approach combining technical quality, professional communication, and institutional transparency to effectively promote generic medicines.

- Recommendations:

Based on the findings of this study, the following recommendations can be formulated:

- a) For regulatory institutions (ANPP, Ministry of Health, Ministry of Pharmaceutical Industry):
 - Strengthen institutional transparency by regularly publishing quality control results in clear and accessible language for the public, in order to consolidate the credibility of the ANPP as a guarantor of medicine safety.
 - Intensify awareness and health education campaigns for consumers, explaining the benefits of generic medicines, the criteria for their approval, and the role of regulatory institutions in ensuring their quality and safety.

- Develop continuing education programs for pharmacists and physicians, to enhance their knowledge of generic medicines and bioequivalence, and to equip them to provide accurate and reliable recommendations to patients.
 - b) For pharmaceutical laboratories (particularly the SAIDAL Group):
 - Improve the perceived quality of generic medicines by paying attention to external aspects (packaging, shape, color) while maintaining technical excellence, in order to reduce consumer reservations.
 - Highlight quality certifications and accreditations on packaging as trust signals for consumers.
 - Invest in research and development to strengthen the competitiveness of national products and improve their image among healthcare professionals and patients.
 - Develop targeted communication strategies emphasizing the rigorous quality control processes to which generic medicines are subjected.
 - c) For healthcare professionals:
 - Strengthen the pharmacist's advisory role as a trusted intermediary, by explaining bioequivalence criteria to patients and addressing their concerns.
 - Improve communication with patients by using simple and accessible language to explain the benefits of generic medicines.
 - Actively participate in continuing education programs to stay informed about scientific and regulatory developments concerning generic medicines.
 - d) For researchers and academics:
 - Expand the geographical scope of the study to other regions of Algeria to obtain more representative and generalizable results.
 - Explore other dimensions of trust, such as the influence of cultural factors, past experiences, and personal beliefs on the perception of generic medicines.
 - Conduct longitudinal studies to track the evolution of consumer trust over time and measure the impact of generic promotion policies.
 - Study the impact of digitalization and new technologies on the formation of trust, particularly through mobile applications and online information platforms.
- Limitations of the Study:

In conducting this research, we encountered a number of difficulties and obstacles, including:

- Non-probability and biased sample: The use of a convenience sample, although common in exploratory research, limits the generalizability of the results. The predominance of young people, women, and university-educated individuals does not perfectly reflect the diversity of the Algerian population.
- Geographical limitations: The study focused on the region of Algiers and its surroundings. An extension to other regions of the country would have allowed for more representative results.
- Absence of qualitative data: Although the quantitative approach allowed for statistical testing of the hypotheses, the absence of in-depth interviews limits the understanding of consumers' deeper motivations and subjective experiences.
- Reliance on declarative data: Responses to the questionnaire are based on subjective statements from participants, which may be influenced by memory bias or social desirability bias.
- Limited access to certain information: Access to some internal data from SAIDAL was partial, which limited the in-depth analysis of certain aspects of quality management.
- Time constraints: The time allocated for this study did not allow for the exploration of all relevant dimensions of the subject.
 - Future Research Perspectives:
- Based on what has been discussed in this study, a number of suggestions can be made for future research:
- Comparative study between different MENA region countries on consumer trust in generic medicines.
- Analysis of the impact of communication campaigns on the evolution of consumer trust in generic medicines.
- Study of trust determinants among vulnerable populations (elderly, rural populations, low-income individuals).
- Research on the influence of social media and influencers in shaping perceptions of generic medicines.
- Study of the impact of pharmacist substitution policies on patient trust and adherence.

GENERAL CONCLUSION

- Analysis of the relationship between trust in generic medicines and therapeutic adherence among patients with chronic diseases.

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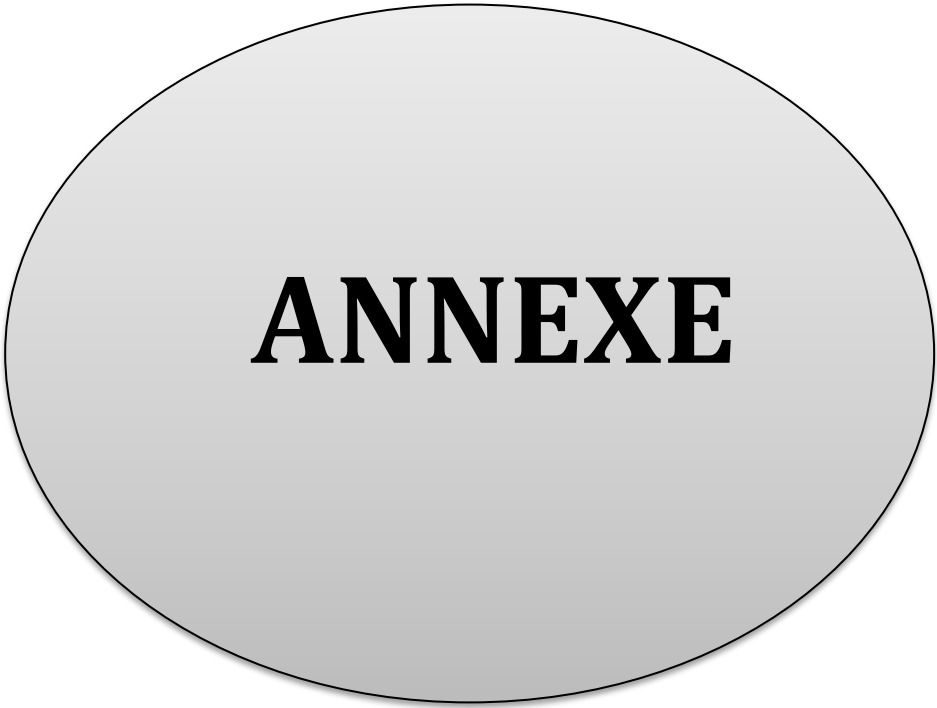
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ANNEXE

استبيان حول ثقة المستهلك في الأدوية الجنيسة وأنظمة مراقبة الجودة في الجزائر:

مقدمة:

في إطار إعداد مذكرة ماستر بعنوان:

أنظمة مراقبة الجودة في صناعة الأدوية الجنيسة ودورها في تعزيز ثقة المستهلك في الجزائر "

نضع بين أيديكم هذا الاستبيان بهدف دراسة آراء المستهلكين حول الأدوية الجنيسة ومدى ثقتهم بها، والعوامل المؤثرة في ذلك.

جميع الإجابات سرية وتستخدم لأغراض البحث العلمي فقط.

مدة الإجابة: حوالي 5 دقائق.

شكراً على تعاونكم.

القسم الأول: المعلومات الشخصية

الجنس: إجابة واحدة

- أنثى
- ذكر

العمر:

- 18–25
- 26–40
- 41–60
- أكثر من 60

المستوى التعليمي:

- ابتدائي
- متوسط
- ثانوي

- جامعي

المهنة:

- طالب
- موظف
- أعمال حرة
- متقاعد
- أخرى :

القسم الثاني: التجربة والمعرفة

هل سبق لك استخدام دواء جنيس؟

- نعم، وكانت التجربة ممتازة
- نعم، جيدة
- متوسطة
- سيئة
- لم أستخدم

هل تعرف الفرق بين الدواء الأصلي والدواء الجنيس؟

- نعم، أعرف جيدًا
- لدي فكرة
- لا أعرف

من أين تحصل عادةً على معلوماتك حول الأدوية؟ (يمكن اختيار أكثر من إجابة)

- الطبيب
- الصيدلي
- الأهل والمعارف
- الإنترنت ووسائل التواصل الاجتماعي
- نشرة الدواء المرفقة

- البرامج الصحية في الإعلام

ملاحظة :

الدواء الجنييس: médicament génériques

هو دواء يحتوي على نفس المادة الفعالة الموجودة في الدواء الأصلي، وله نفس الفعالية ونفس الأمان، لكن سعره أقل لأنه يُصنع بعد انتهاء صلاحية براءة اختراع الدواء الأصلي.

القسم الثالث: الثقة و الجودة المدركة في الأدوية الجنييسة (الفرضية 1)

مقياس ليكرت 1 → 5

1 لا أوافق إطلاقاً | 5 أوافق تماماً

الرقم	العبرة	1	2	3	4	5
	أعتقد أن الأدوية الجنييسة آمنة عند استخدامها بشكل صحيح	☐	☐	☐	☐	☐
	أعتقد أن الأدوية الجنييسة لها نفس الفعالية العلاجية للأدوية الأصلية	☐	☐	☐	☐	☐
	أعتقد أن الأدوية الجنييسة تخضع لنفس معايير الإنتاج الصارمة كالأدوية الأصلية.	☐	☐	☐	☐	☐
	لو وصف لي طبيب دواء جنييس، أثق في أنه سيعالجني مثلما يفعل الدواء الأصلي	☐	☐	☐	☐	☐
	أثق في الأدوية الجنييسة المنتجة في الجزائر (مثل صيدال) بقدر ثقتي في الأدوية الجنييسة المستوردة.	☐	☐	☐	☐	☐

ما أكبر قلق لديك تجاه الأدوية الجنييسة؟

☐ الجودة والسلامة

☐ الشك في فعاليتها العلاجية

☐ الخوف من آثار جانبية

☐ عدم توفرها دائما في الصيدليات

☐ لا توجد لدي مخاوف

القسم الرابع: دور الطبيب والصيدلي (الفرضية 2)

الرقم	العبارة	1	2	3	4	5
	شرح الصيدلي للفروق بين الدواء الأصلي والجنيس، أو توصيته الصريحة به، يزيد من ثقتي بشكل كبير	☐	☐	☐	☐	☐
	إذا اقترح الصيدلي دواء جنيساً بدلاً من الأصلي الموصوف لي، أقبل الاقتراح مباشرة دون تردد	☐	☐	☐	☐	☐
	الصيدلي هو المرجع الأول الذي ألجأ إليه عند الشك في جودة دواء جنيس	☐	☐	☐	☐	☐
	تجربة الصيدلي ومعرفته بالأدوية الجنيسة تجعل توصياته موثوقة في نظري	☐	☐	☐	☐	☐
	عند قراري بقبول دواء جنيس، فإن شرح الصيدلي له وزن أكبر عندي من مجرد وصف الطبيب	☐	☐	☐	☐	☐

ما هي المعلومة التي تتوقع أن يقدمها لك الصيدلي والتي من شأنها أن تزيد ثقتك بالدواء الجنيس بشكل أكبر؟

(médicament génériques دواءً جنيساً) :

☐ ذكر اسم الشركة المصنعة للدواء وسمعتها.

- ☐ شرح أن الدواء يخضع لنفس معايير الجودة والتصنيع الصارمة كالدواء الأصلي.
- ☐ شرح معنى "التكافؤ الحيوي" بأسلوب مبسط (مثل: أن الجنيس يُمتص في الدم، ويؤثر، ويبقى في الجسم بنفس طريقة الدواء الأصلي)
- ☐ لست بحاجة لأي شرح، الثقة تأتي من تجربتي الشخصية.

● القسم الخامس: الهيئات الرقابية (الفرضية 3)

1. هل سمعت من قبل عن الوكالة الوطنية للمنتجات الصيدلانية (ANPP) ؟

- نعم، وأعرف دورها جيداً في مراقبة الأدوية
- سمعت الاسم فقط دون معرفة دورها
- لم أسمع عنها من قبل

هل تعلم أنه لا يمكن لأي دواء جنيس أن يباع في الصيدليات الجزائرية إلا بعد حصوله على ترخيص من ANPP؟

- نعم، كنت أعلم ذلك
- سمعت لكن لا أعرف التفاصيل
- لم أكن أعلم

الرقم	العبارة	1	2	3	4	5
	أثقت في قدرة ANPP على اكتشاف الأدوية منخفضة الجودة قبل وصولها للأسواق	☐	☐	☐	☐	☐
	تُسهم معرفتي بقيام الوكالة الوطنية للمنتجات الصيدلانية (ANPP) بإجراء فحوصات مفاجئة على الأدوية الجنيسة في تعزيز ثقتي بها .	☐	☐	☐	☐	☐
	وجود ANPP يجعلني أثق أكثر في الأدوية الجنيسة	☐	☐	☐	☐	☐
	أعتقد أن الاختبارات التي تجريها ANPP قبل التسويق كافية لضمان جودة الجنييس	☐	☐	☐	☐	☐
	أشعر بالاطمئنان لأن مصانع الأدوية الجزائرية تخضع لتفتيش دوري من ANPP	☐	☐	☐	☐	☐
	نشر نتائج مراقبة الجودة للجمهور يقوي ثقتي في الأدوية الجنيسة	☐	☐	☐	☐	☐

القسم السادس: سلوك المستهلك

- كيف تغيرت ثقتك في الأدوية الجنيسة بعد تجربتك الشخصية أو الحصول على معلومات أكثر؟

- ☐ أصبحت أكثر ثقة
- ☐ أصبحت أقل ثقة
- ☐ لم تتغير
- ☐ لا توجد لدي تجربة سابقة

ما هي العوامل التي تؤثر على قرارك عند شراء دواء جنيس؟ (يمكن اختيار أكثر من إجابة)

- اسم المختبر الصيدلاني (مثل: صيدال، سانوفي، حكمة)
- بلد تصنيع الدواء (محلي vs مستورد)
- سعر الدواء
- توصية الطبيب
- توصية الصيدلي
- تجربتي السابقة مع الدواء

- ☐ توفر الدواء في الصيدلية
- ☐ شكل الدواء وتغليفه
- ☐ لا يوجد عامل محدد يؤثر في قراره
- ☐ أخرى..... :

. ما هي الإجراءات التي تراها أكثر فعالية لتعزيز ثقة المستهلك في الأدوية الجنيسة في الجزائر؟

(يمكن اختيار أكثر من إجابة)

- تعزيز دور الصيدلي في الشرح والتوعية
- تعزيز مصداقية الهيئات الرقابية مثل ANPP
- تعزيز دور الطبيب في توعية المرضى بالأدوية الجنيسة
- نشر نتائج اختبارات الجودة والرقابة للعموم بشفافية
- تنظيم حملات إعلامية وتوعوية وطنية حول الأدوية الجنيسة و التكافؤ الحيوي
- ضمان توفر الأدوية الجنيسة بشكل دائم في الصيدليات
- تقديم معلومات واضحة داخل النشرة (bioéquivalence ،sécurité ،efficacité)
- وضع علامات جودة مثل "دواء جنيس مراقب" على علب الأدوية
- أخرى:

هل لديك أي تعليقات أو اقتراحات إضافية بخصوص الأدوية الجنيسة أو هذا الاستبيان؟

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الملخص:

تدرس هذه الدراسة دور أنظمة مراقبة الجودة في تعزيز ثقة المستهلكين في الأدوية الجينية بالجزائر، عبر تحليل أثر ثلاثة أبعاد: الجودة المدركة، توصيات المهنيين الصحيين، والثقة في المؤسسات التنظيمية. تندرج الدراسة في سياق السياسة الوطنية الرامية إلى تعزيز الجينيس لخفض الاستيراد وتحقيق السيادة الدوائية. اعتمدت المنهج الكمي بناءً على إطار نظري حول الثقة والجودة المدركة. أظهرت النتائج أن أنظمة مراقبة الجودة تؤثر إيجاباً في ثقة المستهلكين، وأن هذه الثقة لا ترتبط فقط بالجودة التقنية، بل تتأثر أيضاً بعوامل علائقية (توصيات المهنيين) ومؤسسية (مصادقية الهيئات الرقابية). مما يستدعي نهجاً متكاملًا يجمع بين الجودة، والتواصل، والشفافية. وتختتم الدراسة بتوصيات للجهات التنظيمية والمخابر والمهنيين لتعزيز الثقة والترويج للجينيس في الجزائر.

الكلمات المفتاحية: مراقبة الجودة، أدوية جينية، ثقة المستهلك، الجزائر.

Abstract:

This study examines the role of quality control systems in enhancing consumer trust in generic medicines in Algeria, by analyzing the impact of three dimensions: perceived quality, healthcare professionals' recommendations, and trust in regulatory institutions. The research is situated within the context of national policy aimed at promoting generic medicines to reduce imports and achieve pharmaceutical sovereignty. A quantitative approach was adopted, based on a theoretical framework of trust and perceived quality. The findings indicate that quality control systems positively influence consumer trust, and that this trust is not only linked to technical quality, but is also shaped by relational factors (professional recommendations) and institutional factors (credibility of regulatory bodies). This highlights the need for an integrated approach combining quality, communication, and transparency. The study concludes with recommendations for regulatory authorities, pharmaceutical laboratories, and healthcare professionals to strengthen trust and promote the use of generic medicines in Algeria.

Keywords: Quality Control, Generic Medicines, Consumer Trust, Algeria.