



Griffith College

**Evaluation of the impact of Quality management and  
Regulatory systems in the manufacturing processes of  
Albendazole in The Republic of Paraguay and The  
Republic of Ireland.**

Research Dissertation presented in partial fulfilment of  
the requirements for the degree of MSc in Pharmaceutical  
Business and Technology

Innopharma Faculty of Pharmaceutical Science

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May 2023

## **Candidate Declaration:**

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I certify that the dissertation entitled:

“Evaluation of the impact of Quality management and Regulatory systems in the manufacturing processes of Albendazole in The Republic of Paraguay and The Republic of Ireland.” submitted for MSc in Pharmaceutical business and technology is the product of my own research and references were made in areas where the work of others was utilized.

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## **Abstract**

The present dissertation aims to evaluate the impact of Quality management and Regulatory systems on the Albendazole manufacturing processes in the Republics of Paraguay and Ireland. The legal framework and quality managerial procedures of the business as well as its in both countries will be evaluated. When examining the impact of a company's quality system on its products, the opinion of pharmacists and other industry sectors regarding overseas and Paraguayan pharmaceutical industries products would also be considered. This objective would be accomplished through a quantitative questionnaire survey. The results of the survey with 54 participants, including pharmacists, quality officers, and other positions, and a literature review of the regulatory systems and quality management procedures of the pharmaceutical industry revealed that the regulatory framework in Paraguay needs to adjust in order to be able to manufacture Albendazole for exporting to Ireland and that the entire pharmaceutical industry has gaps that need to adjust the European union quality system. In addition, the research was able to recognize the variables that influence the quality and availability of Albendazole products manufactured in Paraguay that comply with Ireland pharmaceutical industries, such as regulations/guidelines for manufacturing of high-quality medicinal products, demand exceeding supply, and high prices for high-quality Albendazole products.

The study recommends that DINAVISA make the Paraguayan Pharmaceutical sector's activities more transparent and that additional resources be made available to Paraguayan pharmaceutical industries in order for them to comply with European Union regulations in order to manufacture Albendazole with the same quality.

**Key words:** Regulatory systems. Quality management practices, Albendazole, Good Manufacturing Practices, Paraguay, Ireland

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## **ABBREVIATIONS**

API – ACTIVE PHARMACEUTICAL INGREDIENTS

COMTRATE – UNITED NATIONS COMMODITY TRADE STATISTICS DATABASE

DINAVISA – DIRECCION NACIONAL DE VIGILANCIA SANITARIA (NATIONAL DIRECTORATE OF SANITARY SURVEILLANCE)

EU- EUROPEAN UNION

EC- EUROPEAN COMUNITY

EEA- EUROPEAN ECONOMIC AREA

GMP – GOOD MANUFACTURING PRACTICE

HPRA – THE HEALTH PRODUCTS REGULATORY AUTHORITY

ICH – INTERNATIONAL COUNCIL FOR HARMONISATION

# 1 CHAPTER 1

## INTRODUCTION

### 1.1. BACKGROUND OF THE STUDY

Pharmaceutical and biopharmaceutical manufacturing competence is a hallmark of Ireland's success in the business. This sector is a steady driver of growth, and Ireland has averaged €1 billion in annual capital expenditures over the last decade. There are approximately 85 pharmaceutical businesses in Ireland, including nine of the top ten pharmaceutical corporations in the world. Ireland is currently the greatest net exporter of medicines inside the EU, contributing for over fifty percent of the country's total exports.(TRUST, 2022)

The pharmaceutical industry in Paraguay has been around for over seven decades(Red, 2010) While the pharmaceutical industry's current share of national gross product and manufacturing output is relatively small, it has been growing in recent years, and this trend is expected to continue. Paraguay's pharmaceutical sector is dominated by large companies with roots in traditional medicine production; all of the sector's inputs come from abroad's pharmaceutical industry, making the country's drugmakers highly reliant on imports. Employment, exports, and value added are only few of the economic indicators that show that the pharmaceuticals sector is a vital part of Paraguay's manufacturing sector.(Servín, 2010)

More than 20 domestically funded research labs and two foreign-founded companies make up this sector; one of the foreign-founded firms is a subsidiary of a global holding company(News, 2022) Fourteen businesses out of a total of twenty-eight have Level 5 Good Manufacturing Practice and Control Certifications in Paraguay. There are also foreign-owned trading companies (branch offices, regional representatives, or subsidiaries) that sell finished goods to consumers. Paraguayan government export statistics indicate that these two medications are being manufactured and shipped to various locations throughout the world.(MRE, 2023)

Ireland Imports of Pharmaceutical products was US\$10.94 Billion during 2021, according to the United Nations COMTRATE database on international trade. Ireland Imports of Pharmaceutical products - data, historical chart and statistics - was last updated on January of 2023 and also the amount that Ireland imported of pharmaceutical products from Paraguay in 2021 was \$15,46 Thousand US Dollars. Pharmaceutical goods imported into Ireland from Paraguay are sourced from that country (COMTRATE, 2023)

An efficient regulatory environment that achieves high quality is merely a regulatory system which improves the capacity of individuals and organizations to ensure and address any potential safety and quality issues. This mechanism would involve both the institution or business as well as the national regulatory agency. For international corporations, the

controlling regulatory body may be the efficient policy institution in the nation where the firm is based, or it may be the regulatory body based at the company's headquarters.

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## **1.2 PROBLEM STATEMENT**

In Paraguay, the National Directorate for Sanitary Surveillance (Dirección Nacional de Vigilancia Sanitaria, DINAVISA) is responsible for approving biological medications. DINAVISA's mission is to ensure the execution of the functions of stewardship, management, financing, and provision of health services, with the goal of achieving universal coverage, under the social protection concept, within the framework of the National Health System.(GABI, 2022)

In Ireland The GMP inspectors of the HPRA conduct routine inspections of medicine manufacturers using a risk-based methodology to ensure that the manufacturers are in compliance with GMP regulations. Inspections to assess whether or not manufacturing operations are in line with the European Union Guide to Good Manufacturing Practice are the responsibility of the HPRA (GMP). In addition to routine inspections to assess continuing compliance, non-routine examinations may be done, for instance, in relation to a variation application or a major quality problem.(HPRA, 2023)

The International Council for Harmonization (ICH) is a global body established in the 1990s by the European community (EC), now known as the European Union (EU), with the goal of harmonizing the pharmaceutical market and improving public health through the standardization of technical guidelines, specifications, and requirements for the registration of new products. They expect that by generating this harmonization, resources would be used more efficiently, and unnecessary delays in the research and accessibility of new drugs will be eliminated.

Because pharmaceutical industries all over the world have become more competitive over the course of the years, governments in a variety of nations have realized that it is necessary to define regulatory bodies to monitor the actions of pharmaceutical industries. These authorities

are tasked with keeping an eye on the businesses' compliance with relevant laws. It is impossible to overstate the significance of the role that these regulatory systems play in the medication development process in a given nation; they are responsible for ensuring that all products comply with the standards that have been established for the industry there. Each nation that possesses pharmaceutical businesses that have been granted licenses has a regulatory authority that has been established and is in charge of enforcing guidelines and regulations to govern the manufacture of medicines. The table that follows contains a listing of several of the nations and the regulatory agencies that govern them.

*Table 1 Regulatory Authorities*

| <b>COUNTRY</b> | <b>TERM OF REGULATORY AUTHORITY</b>  |
|----------------|--|
| PARAGUAY       | THE NATIONAL DIRECTORATE FOR SANITARY SURVEILLANCE (DIRECCIÓN NACIONAL DE VIGILANCIA SANITARIA) DINAVISA |
| IRELAND        | HEALTH PRODUCTS REGULATORY AUTHORITY   |
| EUROPE         | EUROPEAN MEDICINES AGENCY (EMA)  |

Research in this area will center on the Good Manufacturing Practice (GMP) principles and Quality standards for producing APIs in accordance with an approved and effective quality management system. Up to ten national regulatory have implemented the ICH guidelines.(EMA, 2018b)

All active ingredients used in the production of albendazole are included in the scope of these guidelines, including those derived from chemical processing. It includes data on the following aspects for quality management systems

- Quality policy
- Quality manual
- Quality objectives
- Organizational structure and responsibilities
- Document and records control and management
- Processes and procedures
- Data management and analysis

- Continuous improvement
- Quality instruments (Stanton, 2022)

## **1.2. Research Objectives:**

- To evaluate, in terms of both quality and efficiency, the medicinal goods produced by the pharmaceutical firms of Paraguay in comparison to those produced by pharmaceutical corporations based in Ireland
- To determine the quality and availability of Albendazole manufacture in Paraguay in order to export to Ireland without disrupting the supply chain.
- To Identify the impact of the legal structure and regulatory system on the quality of pharmaceuticals manufactured by Paraguayan companies in Ireland
- To expand the size of the market for albenzadole manufacturing and stablish commercial alliance.

## **1.3. Research Questions:**

- What is the impact, in terms of both quality and efficacy, of Albendazole manufactured by Paraguayan pharmaceutical industries in comparison to those manufactured by Irish pharmaceutical industries?
- How can diverse regulatory systems impact the quality of Albendazole manufactured by different pharmaceutical industries in Paraguay and Ireland ?
- What impact does quality assurance have on the pharmaceutical manufacturing industry in Paraguay and Ireland?
- What is the market size for albenzadole production in Paraguay and Ireland?

## **1.4. Significance of the study**

Researching this topic is important because quality management systems enable businesses in strong regulated sectors to consistently apply quality processes, resulting in the distribution of products that fulfill both customers' expectations and regulatory standards. The International Council for Harmonization (ICH) provides a detailed guide for making medicines for people. These standards for pharmaceutical manufacturing have been implemented by a wide range of

nations. However, Paraguay, whose DINAVISA regulates medicines, has set its own criteria for acceptable manufacturing practices and has not adopted these. The HPRA's GMP inspectors conduct routine, risk-based inspections in Ireland to guarantee the country's adherence to GMP guidelines. This study will compare and contrast these two systems, as well as check for compliance.

The pharmaceutical industry as a whole, and specifically the companies present in Paraguay, will benefit practically from this research. The pharmaceutical ecosystem benefits from an understanding of the GMP standards and quality regulatory standards for exporting to Europe, specifically to Ireland, and from the implementation of some of the technology and tools that can be used to optimize manufacturing processes. The pharmaceutical industry as a whole, and specifically the companies present in Paraguay, will benefit practically from this research. The pharmaceutical ecosystem benefits from an understanding of the GMP standards and quality regulatory standards for exporting to Europe, specifically to Ireland, and from the implementation of some of the technology and tools that can be used to optimize manufacturing processes.

This research may also encourage a new generation of stockholders as well as workers to enter the Paraguayan pharmaceutical industry with the solitary intention of reshaping the production process to conform to global best practices. As Paraguay has an emerging pharmaceutical industry, these businesses will benefit from this research. And by utilizing the acquired knowledge and ideas, these businesses could introduce a great deal more change to the pharmaceuticals manufacturing industry, reaping numerous benefits for themselves and society.

### **1.5. Structure of the study:**

This research is divided into the following five chapters:

The first chapter of the dissertation is the introduction and objectives section. It establishes the research gap that motivated this study and identifies the literature gaps that led to the formulation of the study's purpose and objectives. Also included are the study's research concerns and significance.

The second chapter examines the significant preceding literature on the topic under investigation. In this research, secondary data sources such as books, academic journals with peer review also papers and publications will be utilized.

The third chapter describes the study's research methods, outlining the logical procedures followed for gathering and analyzing data.

The Fourth chapter it is going to present results and conclusions derived from the gathered and

analyzed primary data. Such findings are further addressed in the concluding and subsequent chapter.

The conclusion of the investigation presented in Chapter Five. This section gives an overview and analysis of the findings. It outlines the challenges facing the study, its potential for additional investigation, and the practical and theoretical effects of the result

## **2 CHAPTER 2**

### **2.1 LITERATURE REVIEW**

To apply this knowledge to the current investigation, Good Manufacturing Practice (GMP), GMP trends, and the pharmaceuticals business are the study's primary keywords. Paraguay and Ireland will be used to contextualize the discussions on GMP tendencies and their influence on the pharmaceutical sector. To avoid employing out-of-date information, this literature review will focus on evaluating recent published as well as unpublished works by researchers, relevant institutions, and practicing professionals. Overall, the process will be carried out with the section in accordance with the study objectives.

Paraguay is home to more than five pharmaceutical manufacturers that are European Union– and International Conference on Standardization. Some are domestic Paraguayan businesses, while others are branches of multinational pharmaceutical multinationals. When it comes to manufacturing quality goods, the overseas branches clearly dominate the market. Given the state of the country and the constraints they must work within, these businesses are thought to be doing the most they can.(GCP, 2023)

Manufacturers, importers, and distributors of active chemicals used in finished product manufacture are affected in a variety of ways by Directive 2011/62/EU, which updates Directive 2001/83/EC, the primary legislative instrument controlling pharmaceutical products for human and veterinary use. Importers, makers, and distributors of active substances based in the Union are required to register their operations with the appropriate authorities in the Member State in which they are located, per Article 52a, paragraph 1 of the FMD.(HPRA, 2023)

Manufacturers, importers, and distributors of active substances must now register with the HPRA through a system modeled after the EU's. Sites in Ireland engaging in any of these activities are required to report them to the Health Products Regulatory Authority (HPRA). The following terms have the following meanings within the context of this registration

system:(HPRA, 2023)

When utilized in the development of a medicinal product, an active ingredient is any substance or combination of substances that is intended to restore, correct, or modify physiological functions or to produce a medical diagnosis by exerting a pharmacological, immunological, or metabolic activity. Both the full and partial production of an active ingredient are included in the definition of "manufacture." The principles laid out in ICH Q7 are helpful in identifying the point at which production of the active substance can be considered to have begun thanks to the definition of an active ingredient (active pharmaceutical ingredient) beginning material included in the guidelines.(HPRA, 2023)

When we talk about "importation," we're referring to the practice of bringing in ingredients from outside the European Economic Area. The European Commission has compiled frequently asked questions and answers on the importing of active drugs on their website. It is necessary to register like an importer with the HPRA if the company want to procure (buy) active substances from sites in other countries for the purpose of importing them into the EEA, or if intend to be the site of direct importation of active ingredients from third countries.

2.1 Manufacturing, importing, and dispensing of active drugs must be registered at any facility that has a Wholesale Dealers Authorization (WDA) for the distribution of human pharmaceutical products. Manufacturers, importers, and distributors of active substances must complete an application for registration. User may find this form on the website [www.hpra.ie](http://www.hpra.ie) in the 'Publications and Forms' area. Registration with the European Medicines Agency Organization is required before to submitting an application to the HPRA for active substance registration for human or veterinary use.(HPRA, 2023)

## **2.2 AVAILABILITY AND DISTRIBUTION OF ALBENDAZOLE PRODUCTS IN PARAGUAY.**

The pharmaceutical industry in Paraguay has been around for over seven decades. As there are no primary materials producers in Paraguay, especially for active ingredients, "similar" drug manufacturers control the country's pharmaceutical sector. There is a small handful of companies that make excipients. More than 20 domestically funded research labs and two foreign-founded companies make up this sector; one of the foreign-founded firms is a subsidiary of a global holding company. Albendazole's nomenclature is 3003.90.73 according the MERCOSUR/GMC/RES 31/04 export protocol. (MRE, 2023)

Albendazole is a drug licensed by the Food and Drug Administration (FDA) for the treatment of worm infections. Albendazole is an antihelminthic medicine used to treat a wide variety of

parasitic infections. It is most commonly prescribed for treating cystic hydatid illness, which is caused by the larval form of the canine tapeworm, *Echinococcus granulosus*. The parenchymal neurocysticercosis owing to active lesions brought on by infection with *Taenia solium* (pork tapeworm) larvae is another condition for which albendazole has been given the green light. It's also a potential asset for dealing with *Enterobius vermicularis*-related pinworm illness.(Malik and Dua, 2023)

## **2.3 REGULATION OF THE PHARMACEUTICAL INDUSTRY**

In Paraguay, the National Directorate for Sanitary Surveillance (Dirección Nacional de Vigilancia Sanitaria, DINAVISA) oversees the whole pharmaceutical industry. All pharmaceutical facilities are required by the act to be registered before beginning pharmaceutical operations. The Directorate is responsible for registering and conducting inspections of all pharmaceutical distribution and marketing facilities. DINAVISA's mission is to ensure the execution of the functions of stewardship, management, financing, and provision of health services, with the goal of achieving universal coverage, under the social protection concept, within the framework of the National Health System.(GABI, 2022)

## **2.4 GOOD MANUFACTURING PRACTICE (GMP)**

Services for obtaining GMP Certification in Paraguay, including but not limited to: implementation, documentation, audit, gap analysis, training, and registration. Producing, testing, and controlling the overall quality of food are the primary focuses of GMP certification in Paraguay. To ensure that products are regularly produced and controlled to the quality standards suitable for their intended purpose and as required by the marketing authorization, Good Manufacturing Practice (GMP) is the approach taken. The primary goal of Goods Manufacturing Practice is to lower the inherent dangers of making pharmaceutical products.(certvalue, 2023)

Paraguayan Good Manufacturing Practice (GMP) certification requires an assessment by a certification organization and proof of compliance with the applicable GMP criteria. Inspection of the manufacturing facility and assessment of the company's quality management system and documentation of its production processes are common components of the certification procedure. A GMP certificate will be issued to the business when the audit has been passed, and it will be valid for a set length of time, usually between one and three years.(B2BCERT, 2023)

Good Manufacturing Practice (GMP) audits are inspections of production facilities or companies by external or internal auditors to see how well they follow GMP regulations. The audit will check if the company's products are consistently high quality and compliant with all relevant regulations. During GMP inspections in Paraguay, auditors look at everything from the quality management system to the workers and machinery to the paperwork and final products. The audit will look into the company's GMP compliance processes in Paraguay to see if they are sufficient for preventing and dealing with problems.

In Paraguay, a GMP audit might be either internal or external. The difference between an internal audit and an external audit is that the latter is performed by an outside, objective party. Certification organisations approved to do GMP audits in Paraguay are the usual suspects for external GMP inspections. An external auditor will evaluate a business's compliance with Good Manufacturing Practices (GMP) rules and guidelines through a study of quality management system paperwork, a tour of the production plant, and interviews with company personnel. The auditor will submit a report outlining the audit's findings and any noncompliances they found after the audit is finished. The company will then have to fix the problems and make the changes needed to remain in compliance with GMP standards.(B2BCERT, 2023)

Getting a GMP certification in Paraguay is very comparable to getting it anywhere else in the world. Following are the broad outlines of how to get a GMP certification in Paraguay:

- Is the first step toward getting certified in Paraguay. This will be determined by the nature of the goods the company produce and the location of the factory.
- Develop a quality management system: The next step is to create a quality management system that complies with the applicable GMP standards. Every step of production, from raw materials to completed goods, should have its own set of procedures in this system.
- Implement the quality management system: The organization as a whole needs to adopt the quality management system after it has been created. Employees must be educated on the system's predetermined practices.
- Conduct internal audits: It is recommended that internal audits be performed to confirm GMP compliance prior to pursuing external certification. In preparation for the external audit.
- Choose a certification body: It must select a certification organization to carry out GMP audits in order to become GMP-certified.

- Schedule an external audit: When a certifying body is finally decided upon, it will need to arrange for an independent audit. In order to evaluate the compliance with Good Manufacturing Practice (GMP) standards and recommendations, an auditor will study the records of the quality management system, conduct a tour of company production facilities, and conduct interviews with key personnel.
- Address any non-compliances: Any issues that are found to be non-compliant during the audit must be fixed and improvements implemented to maintain GMP Certification in Paraguay.
- Receive GMP certification: If the company passes the external audit, it will be granted GMP certification in Paraguay for a set length of time (often between one and three years).(B2BCERT, 2023)

The quality control rules require manufacturers to maintain a fully operational quality control department that regularly communicates its findings to upper management. Also, this division must be managed exclusively by authorized and licensed individuals who possess the necessary expertise. Additionally, the department's management team needs access to a fully staffed and resourced control laboratory where tests can be conducted as needed. Before being released for sale or distribution, products must be inspected and approved by licensed management



Figure 1 Components of Good Manufacturing Practice (Vikash kumar ,2015)

## 2.5 REGULATIONS IN IRELAND

In Ireland The GMP inspectors of the HPRa conduct routine inspections of medicine manufacturers using a risk-based methodology to ensure that the manufacturers are in compliance with GMP regulations. Inspections to assess whether or not manufacturing operations are in line with the European Union Guide to Good Manufacturing Practice are the responsibility of the HPRa (GMP). In addition to routine inspections to assess continuing compliance, non-routine examinations may be done, for instance, in relation to a variation application or a major quality problem(HPRa, 2023)

The International Council for Harmonization (ICH) is a global body established in the 1990s by the European community (EC), now known as the European Union (EU), with the goal of harmonizing the pharmaceutical market and improving public health through the standardization of technical guidelines, specifications, and requirements for the registration of new products. They expect that by generating this harmonization, resources would be used more efficiently, and

unnecessary delays in the research and accessibility of new drugs will be eliminated.

Because pharmaceutical industries all over the world have become more competitive over the course of the years, governments in a variety of nations have realized that it is necessary to define regulatory authorities to monitor the activities of pharmaceutical industries. These authorities are tasked with keeping an eye on the businesses' compliance with relevant laws. It is impossible to overstate the significance of the role that these regulatory authorities play in the medication development process in a given nation; they are responsible for ensuring that all products comply with the standards that have been established for the industry there. Each nation that possesses pharmaceutical businesses that have been granted licenses has a regulatory authority that has been established and is in charge of enforcing guidelines and regulations to govern the manufacture of medicines. The table that follows contains a listing of several of the nations and the regulatory agencies that govern them.(EMA, 2018b)

Quality, safety, efficacy, and multidisciplinary recommendations are all included in the regulations. Pharmaceutical quality management is covered in "Q10" of the ICH guidelines, and "Good Manufacturing Practices" (GMP) for the manufacture of pharmaceutical medical products for human consumption are covered in "Q7."(EMA, 2000)

The ICH Q7 guidelines include quality assurance, with an emphasis on acceptable manufacturing procedures for human pharmaceutical active components. This document ensures that APIs are used in accordance with the appropriate quality management practices. The effort is also geared on ensuring that all APIs used are of adequate quality.

Preparation, review, approval, and distribution of all documents pertaining to the production of intermediates or APIs should follow established protocols. These records may be stored in hard copy or digital format. All papers should be managed, including their issuance, revision, superdense, and withdrawal, with revision histories kept. All relevant records (including reports on development history, scale-up, technological transfer, process validation, training, manufacturing, control, and distribution) should be archived according to a predetermined procedure. Timeframes for how long to keep these records should be laid out. For at least 1 year following the batch's expiration date, keep all manufacturing, control, and distribution records. For at least three years after a batch has been delivered in full, documentation should be kept for APIs with testing dates.(EMA, 2000)

Entries made in records should always be made permanently in the spaces allotted for that purpose, right after the corresponding actions have been taken, and the name of the person making the entry

should be included. Any changes made to an entry should indeed be dated and signed, and the entry should be left legible. Records, either the originals or copies, should be kept in the business where the events they document occurred throughout the retention term. It is appropriate to store records electronically or in some other manner from which they can be quickly retrieved. Photocopies, microfilm, microfiche, and other accurate reproductions of the original specifications, instructions, processes, and records can also be kept. Retrieval tools and a way to print out a hard copy should be easily accessible whenever space-saving techniques like microfilming or electronic data are employed. Raw ingredients, intermediates (if necessary), APIs, and labeling/packaging materials should all have defined and recorded specifications. Other materials utilized in the synthesis of intermediates or APIs, such as process assistance, gaskets, or other materials that could critically effect quality, may also require standards. In-process controls require the establishment and documentation of acceptance criteria.(EMA, 2000)

The fundamentals of quality management and the quality unit's specific responsibilities are discussed in length in the manual. Product quality assessments are geared on ensuring that all procedures and processes are uniform, and there is information regarding internal audits to ensure that they are. Consultants, employee credentials, and cleanliness are discussed further. Storage, packing, and labeling of finished pharmaceuticals, in addition to their documenting and record keeping operation. According to Directive 2001/83/EC, all medical goods imported into the EU must be provided with the necessary documentation, including a written statement from the manufacturer or importer detailing which the product conforms with EU specifications, as well as an analysis certificate or batch release license issued by a qualified person. Additionally, all pharmaceuticals exported from the European Union must meet the requirements and standards of the importing country and be accompanied by proper documentation, such as an official statement from the manufacturer or exporter that their item complies with the requirements of the EU. Furthermore to all of these requirements, Directive 2001/83/EC establishes guidelines for the preservation and distribution of pharmaceuticals, such as the requirement to ensure that products are shipped and kept under conditions that preserve their quality and safety.(European Commission, 2001)

Volume 4 of the EU GMP Guidelines provides guidance on good manufacturing practice for human and veterinary medicinal products. Chapter 2 of this volume addresses personnel and training in addition to equipment qualification. Personnel and Training: This chapter highlights the fact that every personnel involved in manufacturing operations must possess the appropriate

training, expertise, and education to perform their duties effectively. Regular training should be administered, and training records should be kept. The guidelines stipulate that personnel should be instructed on the principles of Good Manufacturing Practice (GMP) as well as the procedures and processes specific to their duties.(European Commission, 2013)

The chapter additionally offers guidelines on equipment qualification, which refers to the process of demonstrating that a piece of equipment is suitable for its intended use. The guidelines suggest that qualification of equipment should be risk-based, with an evaluation of the equipment's effects on product quality, safety, and efficacy. The qualification procedure for equipment should include the subsequent steps:

- Installation qualification (IQ): confirming that the equipment has been installed accurately and in accordance with the manufacturer's specifications.
- Operational qualification (OQ): ensuring the apparatus functions as designed under normal conditions.
- Performance qualification (PQ): ensuring that equipment performs as intended over an extended period of time.(European Commission, 2013)

The Paraguayan Pharmaceutical need to comply with the Directive 65/65/EEC in order to manufacture Albendazole per European Union Standards. This is a directive of the European Union that specifies the requirements for the marketing authorization of human medicinal products. The directive first took effect in 1965 and went through multiple revisions. Prior to being introduced to the market in the European Union, the directive stipulates that all human-use pharmaceuticals must be authorized. The authorization procedure entails submitting an authorization to market application to the appropriate regulatory body, which includes information on the product's quality, safety, and efficacy. In addition, the directive outlines specifications for the packaging and labeling of medicinal products, such as the incorporation of specific details including the product's name, active ingredients, and dosage form. The description must also include usage instructions and any necessary precautions or warnings.(European Commission, 1965)

In addition, the directive outlines specifications for the packaging and labeling of medicinal products, such as the incorporation of specific details including the product's name, active ingredients, and dosage form. The description must also include usage instructions and any

necessary precautions or warnings. The EU Good Manufacturing Practices (GMP) Guide stipulates that packaging operations must be conducted in an environment that is hygienic and clean with adequate safeguards established to avoid contamination or mix-ups. The packaging site must have adequate equipment to facilitate the storage and manipulation of packaging materials, as well as validated packaging processes, to guarantee that the products are packaged consistently based to the approved standards. The packaging site must endure a thorough examination by a regulatory body, including the European Medicines Agency (EMA) or a national regulatory authority, in order to be certified for EU GMP compliance. The inspection would evaluate the site's conformity to GMP standards, including its infrastructure, equipment, staff members, documentation, and quality management systems. If the facility is found to comply with GMP requirements, it will be granted a GMP certificate and will be permitted to manufacture and packaging pharmaceuticals for EU distribution. The site would be required to maintain GMP compliance through continuous surveillance and periodic inspections from regulatory bodies to ensure that it remains to meet the standards.(EMA, 2018a)

## **2.6 REGULATIONS IN PARAGUAY.**

In Paraguay, DINAVISA GMP inspectors execute routine inspections of pharmaceutical industries using a risk-based methodology to ensure manufacturers' compliance with GMP regulations.

According to Resolution No. 206/2002: establish that Good practices of clinical studies: standards meant to ensure the integrity of the clinical study of drugs.

- Good manufacturing and control practices are a set of rules that regulate the manufacturing and quality control procedures of pharmaceutical products in order to ensure their quality.
- Good laboratory practices are a set of rules and procedures that ensure that the data generated by a Quality Control laboratory are reproducible and representative, thereby ensuring the validity and dependability of the results.
- Quality: suitability of the drug for the intended use, which is determined by its efficacy in relation to its safety according to the labeled declaration or that promoted by the manufacturer, and its conformance to the specifications of identity, concentration, purity, and other chemical, physical, biological, or process characteristics and properties.
- Registration certificate: Numbering document issued by the national health authority that authorizes the commercialization of a pharmaceutical specialty.

- Fixed-dose combinations of medications: a pharmaceutical product with two or more active ingredients.
- Control during the process: system or specific set of activities planned and carried out in order to continuously ensure, throughout all of its processes, the preparation of batches of products in accordance with the specifications of identity, potency, purity, and efficacy and other requirements established in their respective monographs. Tests, inspections, and measurements conducted during the production of a product, including its packaging, to ensure that the final product conforms to the specifications.(MSPVS, 2011)

Article 6 The manufacture, importation, commercialization, and dispensing of pharmaceutical company specialties are subject to the prior authorization of the national health authority throughout the Republic. In accordance with the provisions of this law and its regulations, the pharmaceutical specialties authorized for sale on the national market will be those registered at the request of the manufacturers and representatives in a registry specified by the Ministry of Public Health and Social Welfare. On the entire national territory, the commercialization or unrestricted distribution of pharmaceutical specialties not registered with the sanitary authority is prohibited. Medications for personal use imported by their users or authorized third parties in quantities strictly necessary and reasonable will be exempt from the prior authorization process. Donations of medicines for charitable purposes or social action, as well as medicines required in cases of catastrophe, emergency, or exceptional public health needs, as determined by the competent authority, will not be subject to evaluation and registration, but must be authorized by the national health authority and communicated to the Associations of manufacturers and representatives of medicines.(MSPVS, 2011)

Article 7: Any modification, transfer, or cancellation of authorizations granted for pharmaceutical specialties shall be recorded in the registry referred to in Article 6. (MSPVS, 2011)

Article 8 The studies, data, and information submitted with the application for authorization to manufacture a pharmaceutical specialty must be prepared and signed by specialists with adequate technical and professional credentials. The studies and analyses of pharmaceutical specialties will be adapted to laboratory and clinical best practices The packaging, containers, and labeling of pharmaceutical specialties will ensure their prompt and unambiguous identification, their perfect conservation, and will foresee potential incidents in a reasonable manner.(MSPVS, 2011)

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Article 9 The national health authority will regulate the type of controls required of the manufacturer to guarantee the quality of raw materials, semi-finished products, the manufacturing process, and the final product, for the purposes of authorization and registration, maintaining said controls during the production and/or commercialization of the pharmaceutical specialty, without prejudice to changes or technological modifications that may occur as a result of the evolution of the pharmaceutical specialty. Such modifications or changes must be reported to the national health authority for sanction and file updating of the affected pharmaceutical specialty. For the controls referenced in this article, the monographs contained in the official codes or pharmacopoeias, as determined by the national health authority, constitute mandatory minimum requirements. If there are no references in official codes or pharmacopoeias, it may be necessary to rely on scientific papers or publications authored by organizations of recognized renown.(MSPVS, 2011)

Article 26 The national health authority is responsible for conducting the necessary inspections to assure compliance with this law. In order to accomplish this, it will regulate the good manufacturing practices and mandatory use control that apply to companies governed by this law. The national health authority will have inspectors with the training, knowledge, skills, and personal and specialized qualities required for the position. Inspections may be conducted in the following situations: when it is necessary to grant operating authorization to establishments engaging in any activity regulated by this law; and when the national health authority deems it necessary. The personnel at the service of the national health authority that develops inspection functions will be authorized to: control and inspect any establishment subject to this law, after proving his identity in the performance of his duties. if you had certain information regarding any significant abnormality in said establishments may be utilized by the search, which may involve obtaining a court order and, if necessary, the use of public force. Necessary; conduct the tests, investigations, or examinations required to verify compliance with this law and the standards derived from its corresponding regulation; and take the necessary actions in accordance with the procedure specified in the corresponding regulation.(MSPVS, 2011)

Article 27 The national health authority will have one or more analytical laboratories to carry out the required analyses, as outlined in the National Program of Control and Sanitary Surveillance, without prejudice to the fact that it may derive certain activities own quality control in authorized national, foreign or WHO laboratories and PAHO, with which it has entered into agreements for this purpose, or in specific cases for some determinations that by their naivety would be deemed unacceptable by international standards. Regulatory acceptable laboratory practices must be adhered to by the laboratories referred to in the preceding item.(MSPVS, 2011)

Article 28.- The national health authority will conduct periodic quality controls of the existing pharmaceutical specialties on the market, the raw materials and semi-finished products, as well as the packaging material and the conservation conditions, transport, and sale, in order to determine compliance with the conditions outlined in the authorization and registration of such products.(MSPVS, 2011)

Article 29.- The analyses referred to in the preceding section shall be conducted in accordance with the specifications established in the monograph adopted at the time of registration or its modifications.(MSPVS, 2011)

Article 31 - Permissions. A prior authorization from the Ministry of Public Health and Social Welfare is required for natural or legal persons to engage in any or some of the activities listed in Article 1 for purposes of this law. The national health authority will establish a specific authorization registry. This registration will include the initial authorization as well as any subsequent transfer, modification, or termination. Individuals or legal entities engaged in any of the activities listed in Article 1 must have the facilities, technical and control equipment required by the national health authority in order to function properly. Natural or legal persons engaged in one or more of the activities listed in Article 1 must obtain authorization from the national health authority before making modifications to their facilities that profoundly alter the terms of the initial authorization. The national health authority will publish all authorizations, modifications, and revocations in the Official Gazette for public knowledge. (MSPVS, 2011)

Article 32 of the quality assurance and guarantee. Whoever owns the Sanitary Registry within the national territory, whether the manufacturer or the manufacturer's legal representative, is responsible for ensuring the quality of the product that it manufactures, fractions, imports, distributes, or sells. To this end, the local manufacturer will implement a quality control system that certifies compliance with production, raw material, and final product specifications, as applicable. In the case of imported pharmaceuticals, the manufacturer's representative must present

a certificate issued by the exporting country's health authority attesting that the manufacturer has at least the same quality control system required for production in Paraguay. The quality control system may be developed in whole or in part by an organization's own quality control department or by authorized external laboratories for tests that, due to their complexity or nature, the organization is unable to conduct on its own. The aforementioned laboratories must adhere to the best practices of a regulated laboratory. Agreements with authorized external laboratories must be formalized by a written contract and declared in the paperwork to obtain the sanitary registry.(MSPVS, 2011)

Article 33 Concerning the Technical Director and Regent. Manufacturers, fractionators, representatives, importers, distributors, pharmacies, drug quality control laboratories, and cosmetic manufacturers are required to have a technical director and/or accountable regent on staff. The technical director and/or manager must hold a bachelor's degree in pharmaceutical chemistry, be a licensed doctor of pharmacy or pharmacist, and be enrolled with the Ministry of Health and Social Welfare. The technical director of a manufacturing establishment will ensure that each lot is manufactured, controlled, and preserved in accordance with the terms of the authorization or certificate of registration of the corresponding specialty, formalizing its guarantee through the appropriate documents and records, which must be continuously updated and accessible to accredited inspectors for at least two years after the product's expiration date. The technical director and/or regent of an establishment that possesses a health registration certificate is responsible for ensuring the timely and expeditious recovery of a batch of product corresponding to said certificate, when justifiable reasons necessitate it or the national health authority so determines. When the technical director and/or regent fails to comply with his obligations, he will be submitted by the authority national health authority to the corresponding summary, and in severe cases, he may be suspended from his functions, without prejudice to his other responsibilities. The technical director's and/or manager's responsibility does not preclude that of the company and/or its directors.(MSPVS, 2011)

## **2.7 Conceptual Framework**

The conceptual framework of this study, which aims to evaluate the impact of Quality management and Regulatory systems on the manufacturing processes of Albendazole in The Republic of Paraguay and The Republic of Ireland. These constructs comprise the trends that influence the

pharmaceutical industry's compliance with GMP regulations and Albendazole production. The likely outcomes would be increased compliance, quality and safe products that are ready for commercialization in Ireland, and an expansion of the market for albendazole in the pharmaceutical industry.

### 3 CHAPTER 3

#### 3.1 METHODOLOGY

This study's research philosophy is positivist, which differentiates among facts and values. Findings are considered as objective truth, whereas values are viewed as subjective, which is inherently deceptive and hinders the pursuit of truth. The study design is descriptive, and the research approach is quantitative. The selection of this study's research philosophy, research design, and methodology will be explained in the following sections. (Moroi, 2020) According to (Saunders *et al.*, 2019) through the research onion the author can visualize the different approach to the theory

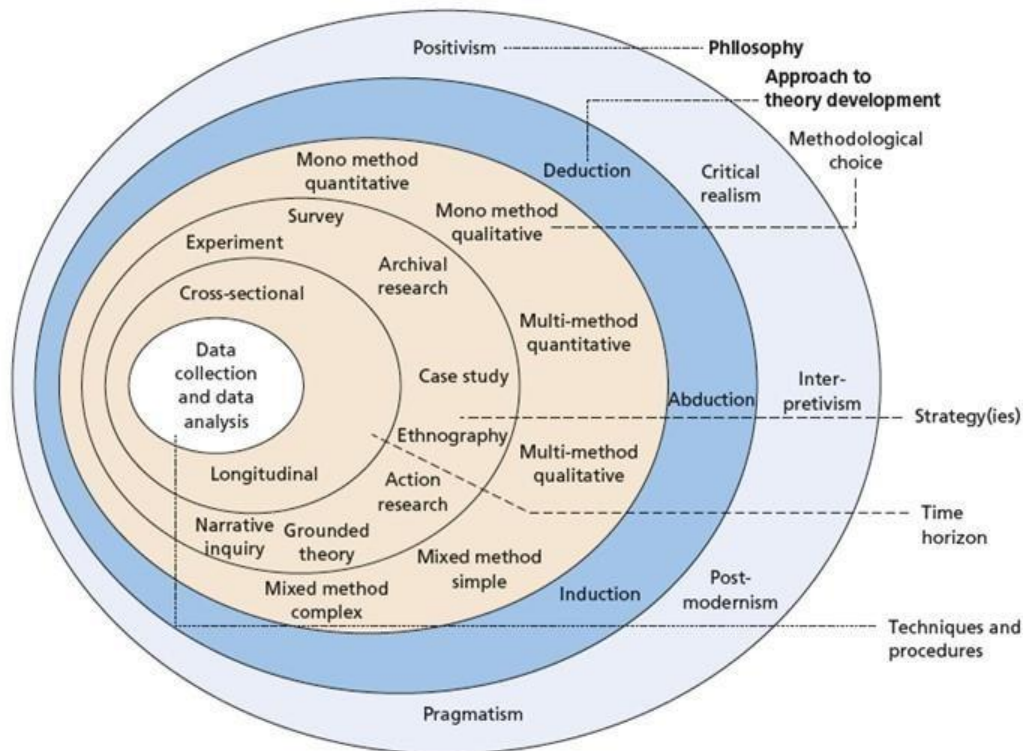


Figure 2 (Saunders et al, 2019)

### **3.2 Research Philosophy**

Positivism as a research philosophy this approach was applied to this investigation with the aim to guarantee a fair and critical examination of every information gathered, thereby avoiding bias and ethical issues. All information utilized in this instance will be fact-based and researched, with no regard to individual partiality. Is best adapted to the present research since the author intends to gather data from participants with relevant knowledge about GMP trends in pharmaceutical manufacturing in both countries. The participants, by virtue of their training and professional backgrounds, are familiar with these trends and will discuss how they have been implemented to improve the implementation of Good Manufacturing Practices in the pharmaceutical industries of Paraguay and Ireland. Consequently, by involving those taking part, the views and responses that they provide can be utilized to generate important concepts for analysis, thereby enhancing the researcher's understanding of the topic. In this study, the researcher will attend to the perspectives/perceptions of participants and interpret their shared experiences.

### **3.3 Research Approach**

Descriptive research is a method of inquiry used for identifying the characteristics of a population or specific phenomenon. Using descriptive research, someone can identify patterns in the characteristics of a group to establish everything one needs to know with the exception of the cause of an event.(Qualtrics, 2020) Positivists support quantitative methods such as social surveys, structured questionnaires, and official statistics due to their high reliability and replicability. Positivists believe that society shapes the individual and that social facts influence individual behavior. The positivist tradition emphasizes the significance of conducting quantitative research, such as large-scale surveys, to gain a comprehensive understanding of society and to reveal social patterns, such as the connection between educational achievement and social class. This subfield of sociology focuses more on trends and patterns than on individuals.(Surendranath College, 2020) There are Five core principles of positivism research philosophy. There are no distinctions between the sciences with regard to the logic of inquiry. The purpose of the study should be to clarify and predict. Research should be observable empirically by human senses. Inductive reasoning should be utilized to generate testable hypotheses (statements) for the research process. The scientific method is distinct from common sense. There should be no allowance for common sense to

influence research findings. Science must be value-free and evaluated solely on the basis of logic.(Surendranath College, 2020)

The participants were sent a well-designed survey through which data were collected, evaluated, and interpreted effectively. Due to the absence of personal connections with the participants, conflicts and bias are ruled out. The survey was created and distributed via electronic means. A method for quantitative study includes the evaluation of numerical data through questionnaires or surveys.

The author will employ quantitative methodology to determine the difference between the quality management and regulatory systems used by pharmaceutical manufacturers in Paraguay and Ireland. A survey would be disseminated to healthcare providers and consumers as part of the quantitative research. The purpose of this survey is to determine whether the medicinal products manufactured in Paraguay by the Paraguayan pharmaceutical corporation and pharmaceutical industries in Ireland adhering to the same European standards are suitable for importation into Ireland. Healthcare providers, such as pharmacists working in large pharmacies in Paraguay, would be provided surveys. This is due to the fact that they can provide data regarding the quality of the pharmaceutical products supplied to them as well as the access of products from various pharmaceutical manufacturers and to ensure that they provide testimony to the efficacy and impact of the various pharmaceutical products they have utilized. The author could also collect data on their choices and the factors that influence them. All data gathered by the various groups will be compiled and thoroughly analyzed in order to formulate a conclusion.

### **3.4 Research Emphasis**

The primary goal of this research will be informative, conclusive, and descriptive.

The insightful investigation will provide sufficient knowledge and information on the topic. Research of a definitive nature will define the behaviors of participants under specific conditions. Descriptive research seeks to identify relationships between variables. The objective of descriptive research is to accurately characterize all evaluation factors.

### **3.5 Research Design**

Descriptive research design employs a variety of qualitative and quantitative data (although

quantitative research is the main study method) to collect information for the purpose of making precise projections about a particular problem or hypothesis. As a survey method, descriptive research designs will assist researchers in identifying market or population characteristics. These characteristics in the sample population can be identified, observed, and measured for decision-making purposes.(Qualtrics, 2020) Descriptive research has a number of predictable characteristics, despite the fact that it can employ a variety of methodologies for data collection. There are several factors to consider: Descriptive research is frequently used in survey research because it generates responses in a statistical format, making it simple for researchers to conduct a straightforward statistical analysis and interpret the data. Because descriptive research data collection produces statistical outcomes,it can also be used as secondary data for another study.(Qualtrics, 2020)

Additionally, descriptive research data can be subjected to additional forms of data analysis. This study's research design is therefore descriptive in nature. The decision to make use of this design is intended to aid the research in gaining a better understanding of GMP trends and their impact on the pharmaceutical industry in Paraguay.

### **3.6 Research Strategy**

This study's objective is to investigate and compare the various Albendazole-manufacturing pharmaceutical industries in Paraguay and Ireland. In both nations, regulatory systems and their influence on the quality and availability of Albendazole will be thoroughly evaluated.

The survey provides specific information about the investigation and its objective. It was also indicated that the research is an academic study, a dissertation written by the author as part of the master's degree requirements in pharmaceutical business and technology. The questionnaire is straightforward and direct to the point. It will be sent to approximately 50 participants from various backgrounds, but primarily pharmacists; the remaining participants are considered customers.

### **3.7 Primary Data Collection**

The survey was developed using Google forms. It consisted of 18 questions that aligned with the research's objectives and inquiries. The survey was distributed electronically to those who

participated. All respondents were given instructions to respond to the highest standard of their knowledge, and the author had no influence over their responses.

In the first query of the survey, all respondents were properly asked for their permission to participate. It was a mandatory query, so the survey could not proceed until it was completed. All of them were informed that participation in the survey posed no risk as the answers they provided would be kept confidential. In addition, no personally identifiable data that includes name or e-mail address was collected in order to safeguard their privacy.

The primary data was gathered using a questionnaire. The survey was distributed to health care professionals, primarily pharmacists. The survey questions were designed to assess respondents' general understanding of and experience with Albendazole produced by various pharmaceutical industries in Paraguay and Ireland. The queries in the survey compared the quality of albendazole produced by Paraguayan and Irish pharmaceutical industries.

### **3.8 Inclusion and Exclusion Criteria**

This study's survey was completed by healthcare workers, primarily pharmacists, who have personal knowledge with the administration of medicinal products and their outcomes. The survey was also completed by consumers who provide testimony to the efficacy as well as accessibility of the medicine known as Albendazole. In accordance with the first query of the survey, research participants who did not provide informed consent were excluded.

### **3.9 Ethical Considerations**

Before the research was conducted, an Ethics application form was given to Griffith college to address all ethical concerns. In addition, all participants were given a participant consent form and a participant data form that described the study, the reason they had been communicated, and how to complete the survey questionnaire. The consent form also included information regarding the potential risks associated with participating in the research and the fact that every one of the participants possessed the right to disengage from the study without repercussions. On the initial page of the web-based survey, the researcher provided a clear explanation of the research topic. All survey questions were designed to ensure that no identifiable personal data was collected from respondents.

The supervisor of the present investigation confirmed the validity of the research implement by

assuring that it was adequate for addressing the research goals of this study. Before participants were recruited for the survey, they voluntarily provided informed consent and were briefed on the purpose of the study and their role, which was limited to providing answers to the survey. Contributors were also informed that they could discontinue the survey at any time without suffering any negative consequences. They were additionally reassured that they could choose not to answer any question that made them feel uneasy. They were assured that every data they provided to the researcher was going to be treated anonymously and would be used solely for the objectives of this study.

### **3.10 Conclusion**

This study's primary research involved a survey given to pharmacists, production personnel, and quality-related staff. The survey contained 18 questions. In the present case, the research philosophy was positivism. A type selected to demonstrate that conclusions from all survey as well as literature review data were objectively analyzed.

In order to determine the impact of Quality management and Regulatory systems on the manufacturing processes of Albendazole in The Republic of Paraguay and The Republic of Ireland, all of the information from chapter 2 (literature review) of the study and data from the survey were properly examined and compiled. A comprehensive review of the survey results will be presented in the following chapter.

## **4 CHAPTER 4**

### **4.1 ANALYSIS AND FINDINGS**

In the following section, an extensive evaluation of all the survey questionnaire data will be presented. The information collected from the survey will assist in determining the respondents' general knowledge and experience with the pharmaceutical products manufactured by various Paraguayan and Irish pharmaceutical industries. In addition to periodic reminders, questionnaires were sent via email, text message, and other social media networks (WhatsApp, LinkedIn) to various groups of participants, that raised the participation rate. Participants from diverse healthcare areas for 54 of the respondents.

## 4.2 PARTICIPANTS' DEMOGRAPHIC REPRESENTATION

### 4.2.1 The categories of participants

Breakdown of Participants based in Ireland divided on the Segments

Table 2 BREAKDOWN OF PARTICIPANTS

| Respondents        | Frequency<br>(Number) | Frequency (%) |
|--------------------|-----------------------|---------------|
| Pharmacists        | 13                    | 48,1%         |
| Quality control    | 6                     | 22,2%         |
| Production         | 4                     | 14,8%         |
| Quality Assurance  | 2                     | 7,4%          |
| Others (consumers) | 2                     | 7,4%          |
| Total              | 28                    | 100%          |

A pie chart illustration of the participants' respective segments in percentage

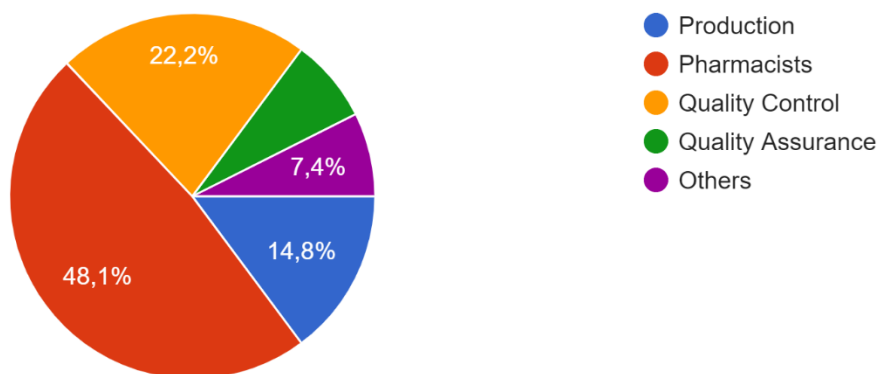


Figure 3 Participants in Ireland

Table 2 and Figure 3 illustrate the proportions of the various sectors that filled out to this survey. In Ireland, 28 individuals participated in the survey. 13 (48.1%) of the participants were pharmacists, 6 (22.2%) were Quality control, Production 4 (14.8%), and Quality Assurance 2 (7.4%), and 2 (7.4%) were Others (consumers).

Breakdown of Participants based in Paraguay divided on the Segments

Table 3 Breakdown of Participants

| Respondents        | Frequency<br>(Number) | Frequency (%) |
|--------------------|-----------------------|---------------|
| Pharmacists        | 14                    | 53,8%         |
| Quality control    | 5                     | 19,2%         |
| Production         | 2                     | 7,7%          |
| Quality Assurance  | 3                     | 11,5%         |
| Others (consumers) | 2                     | 7,7%          |
| Total              | 26                    | 100%          |

A pie chart illustration of the participants' respective segments in percentage

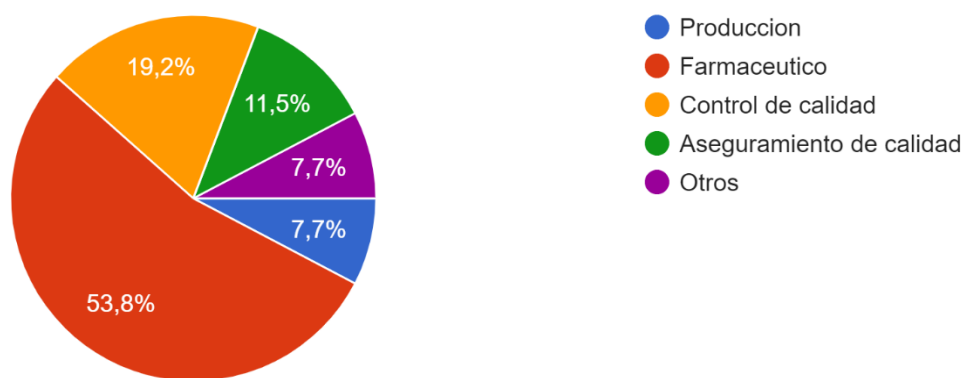


Figure 4 Participants in Paraguay

Table 3 and Figure 4 illustrate the proportions of the various sectors that filled out to this survey. In Paraguay, 26 individuals participated in the survey. 14 (53,8%) of the participants were pharmacists, 5 (19,2%) were Quality control, Production 2 (7.7%), and Quality Assurance 3 (11.5%), and 2 (7.7%) were Others (consumers).

#### 4.2.2. Distribution of years' worth of employment experience

Work knowledge of the respondents from Ireland

Table 4 Work knowledge Ireland

| Work experience by year | Respondents (%) |
|-------------------------|-----------------|
| <1 year                 | 14,8%           |
| 1-2 years               | 51,9%           |
| 3- 4years               | 14,8%           |
| 5+ years                | 18,5%           |
| Total                   | 100%            |

Pie chart representation of work knowledge of participants

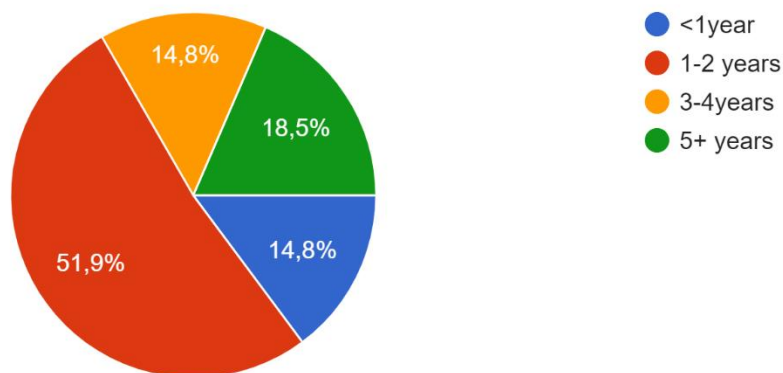


Figure 5 Work experience Ireland

Among the 28 participants in Ireland, 4 (14,8%) have work knowledge of less than a year, 14 (51,9%) have work knowledge of 1-2, (14,8%) 4 have work knowledge of 3-4 years and 5 (18,5%) more than 5 years.

## Work experience of the respondents from Paraguay

Table 5 Work experience Paraguay

| Year of work experience | Respondents (%) |
|-------------------------|-----------------|
| <1 year                 | 15,4%           |
| 1-2 years               | 65,4%           |
| 3- 4years               | 11,5%           |
| 5+ years                | 7,7%            |
| Total                   | 100%            |

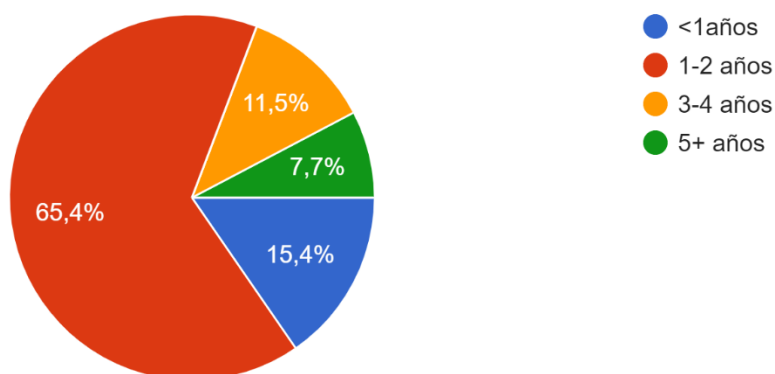


Figure 6 Work Experience Paraguay

Pie chart representation of work experience of participants

Among the 26 participants in Paraguay, 4 (11,5%) have work knowledge of less than a year, 17 (65,94%) have work industries of 1-2, (11,5%) 3 have work knowledge of 3-4 years and 2 (7,7%) more than 5 years.

### 4.3 ANALYSIS OF OBJECTIVES:

#### 4.3.1 To evaluate, in terms of both quality and efficiency, of Albendazole produced by the pharmaceutical firms of Paraguay in comparison to those produced by pharmaceutical corporations based in Ireland.

To evaluate the quality and efficacy, it is necessary to consider a number of factors.

- Quality Control: Whenever evaluating the quality of Albendazole produced by pharmaceutical industries in Paraguay and Ireland, one of the most important factors to consider is the

manufacturers' quality control procedures. Both Paraguayan and Irish businesses will be required to conform to rigorous quality control regulations, although the efficiency of their processes may vary. Each manufacturer's quality control procedures must be evaluated to ensure that their products comply with regulatory requirements and are safe for human and animal consumption.

- **Cost:** The financial implications of the product can also be considered when assessing the product's efficiency. It will need to evaluate the prices of Albendazole produced by pharmaceutical industries in Paraguay and Ireland in order to determine which is more cost-effective. This would necessitate analyzing each company's production, distribution, and marketing costs, as well as other associated expenses.
- **Manufacturing Standards:** The pharmaceutical industries in Paraguay and Ireland may use different manufacturing standards. Each manufacturer's manufacturing processes must be evaluated in order to guarantee that they are effective and efficient. This would involve examining the basic components used, all the equipment and infrastructure utilized, and the manufacturing processes utilized by each company.

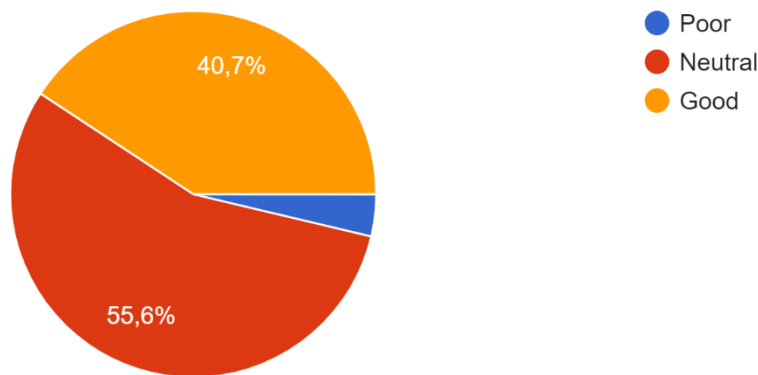


Figure 7 Opinion standards of Albendazole Ireland

Pie chart representation of the opinion regarding the standard of Albendazole products in Ireland

Among the 28 participants in Ireland, 15 (55,6%) establish a neutral opinion regarding the quality of Albendazole produced in Ireland, 12 (40,7%) consider that Albendazole produce in Ireland it is Good quality and 1 (3,7%) % consider that Albendazole produce in Ireland it is Poor quality

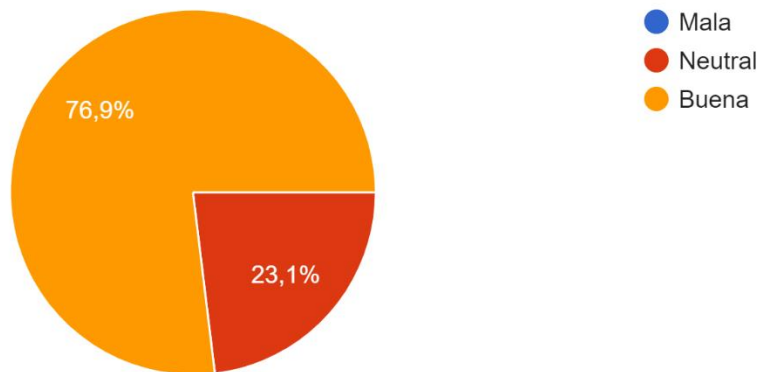


Figure 8 Opinion standards of Albendazole Paraguay

Pie chart representation of the opinion regarding the standard of Albendazole products in Paraguay. Among the 26 participants in Paraguay, 6 (23,1%) establish a neutral opinion regarding the quality of Albendazole produced in Ireland, 20 (76,9%) consider that Albendazole produce in Ireland it is Good quality.

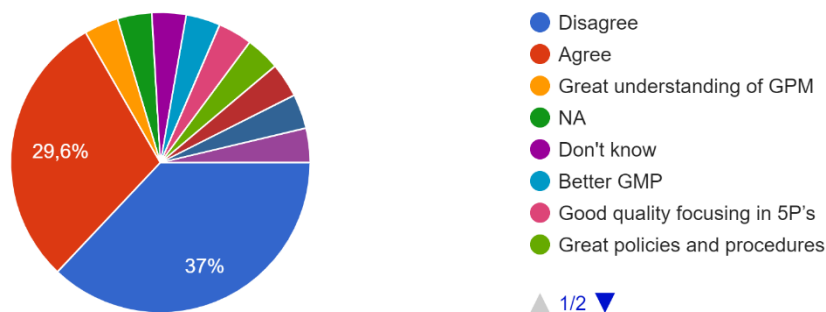


Figure 9 Opinion Albendazole Ireland

Pie chart representation of the opinion regarding Albendazole products produced by Irish pharmaceutical industries are of superior quality than those produced by international pharmaceutical industries.

Among the 28 participants in Ireland, (29,6%)Agrees with no comments the statement that Albendazole products produced by Irish pharmaceutical industries are of superior quality than those produced by international pharmaceutical industries,(33.,4%) Agrees with comments the statement that Albendazole products produced by Irish pharmaceutical industries are of superior quality than those produced by international pharmaceutical industries, (37%) Disagrees with no comments the statement that Albendazole products produced by Irish pharmaceutical industries are of superior quality than those produced by international pharmaceutical industries

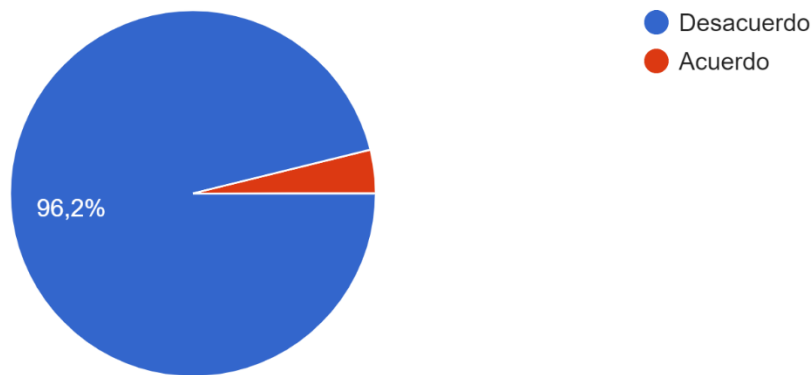


Figure 10 Opinion Albendazole Paraguay

Pie chart representation of the opinion regarding Albendazole products produced by Paraguayan pharmaceutical industries are of superior quality than those produced by international pharmaceutical industries.

Among the 26 participants in Ireland, (96,2%) Disagrees with no comments the statement that Albendazole products produced by Paraguayan pharmaceutical industries are of superior quality than those produced by international pharmaceutical industries, (3,8%) Disagrees with no comments the statement that Albendazole products produced by Paraguayan pharmaceutical industries are of superior quality than those produced by international pharmaceutical industries

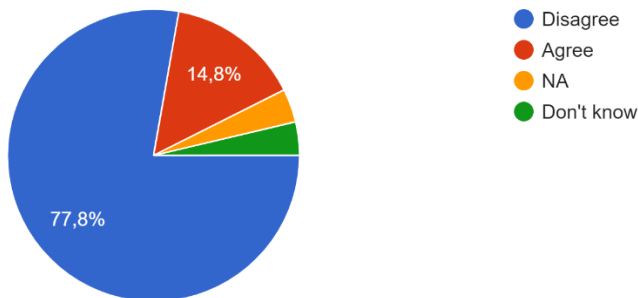


Figure 11 Albendazole High quality Ireland

Pie chart representation of the opinion regarding statement that Albendazole produced by imported pharmaceutical businesses are of higher quality than those produced by domestic Irish pharmaceutical industries

Among the 28 participants in Ireland, (14,8%)Agrees with no comments the statement that Albendazole goods produced by imported pharmaceutical businesses are of higher quality than those produced by domestic Irish pharmaceutical industries,(7,4%) Agrees with comments the statement that Albendazole goods produced by imported pharmaceutical businesses are of higher quality than those produced by domestic Irish pharmaceutical industries, (77,8%) Disagrees with no comments the statement that Albendazole goods produced by imported pharmaceutical businesses are of higher quality than those produced by domestic Irish pharmaceutical industries.

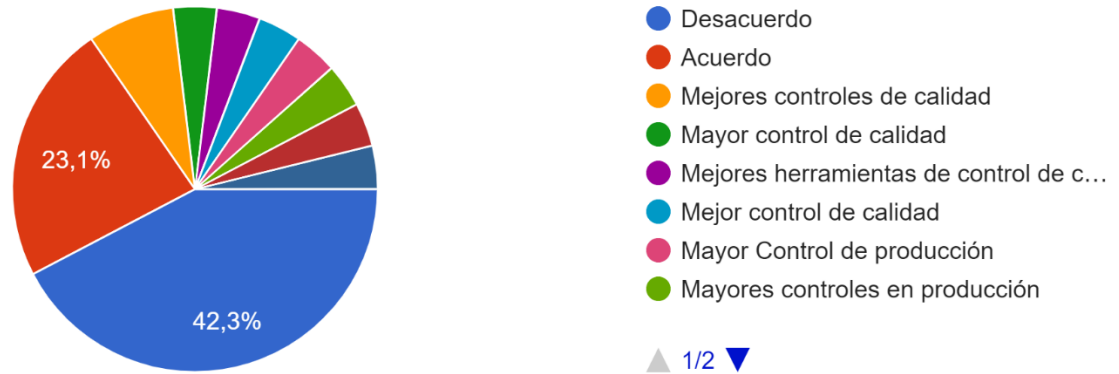


Figure 12 Opinion Albendazole Quality Paraguay

Pie chart representation of the opinion regarding statement that Albendazole goods produced by imported pharmaceutical businesses are of higher quality than those produced by domestic Paraguayan pharmaceutical industries

Among the 26 participants in Paraguay, (23,1%)Agrees with no comments the statement that Albendazole goods produced by imported pharmaceutical businesses are of higher quality than those produced by domestic Paraguayan pharmaceutical industries,(34,6%) Agrees with comments the statement that Albendazole goods produced by imported pharmaceutical businesses are of higher quality than those produced by domestic Irish pharmaceutical industries, (42,3%) Disagrees with no comments the statement that Albendazole goods produced by imported pharmaceutical businesses are of higher quality than those produced by domestic Paraguayan pharmaceutical industries.

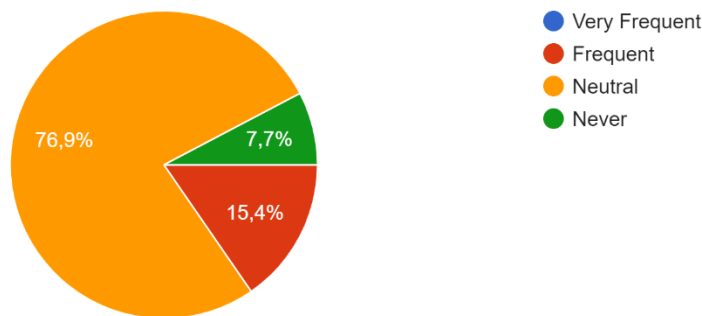


Figure 13 Albendazole from Ireland

Pie chart representation of the opinion regarding How frequently do Albendazole products from irish pharmaceutical manufacturers have production faults, such as low-quality medications, bad/incorrect packaging, inaccurate labeling, faulty seal, smudges, scratches, and ink splatters on the medicinal product booklet, or other problems.

Among the 28 participants in Ireland, (76,9%) Responded neutral opinions regarding this question, (7,7%) Responded that they had never experienced this issue. (15,5%) Responded that this issue happened frequently.

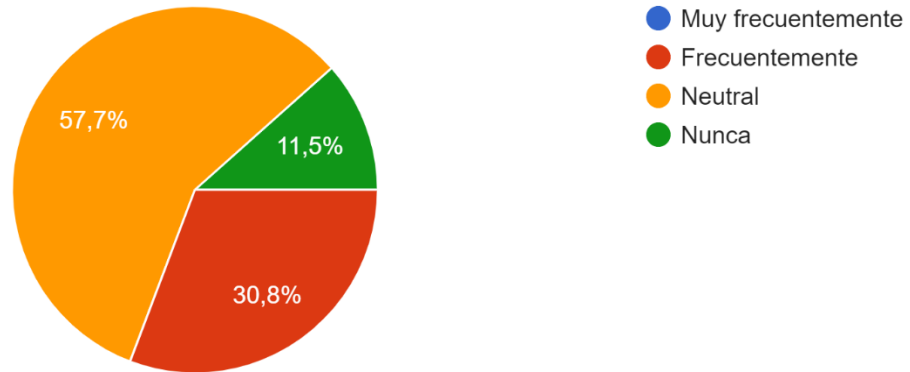


Figure 14 Albendazole from Paraguay

Pie chart representation of the opinion regarding How frequently do Albendazole products from Paraguayan pharmaceutical manufacturers have production faults, such as low quality medications, bad/incorrect packaging, inaccurate labeling, faulty seal, smudges, scratches, and ink splatters on the medicinal product booklet, or other problems.

Among the 26 participants in Paraguayan, (57,7%) Responded neutral opinions regarding this question, (11,5%) Responded that they had never experienced this issue. (30,8%) Responded that this issue happened frequently.

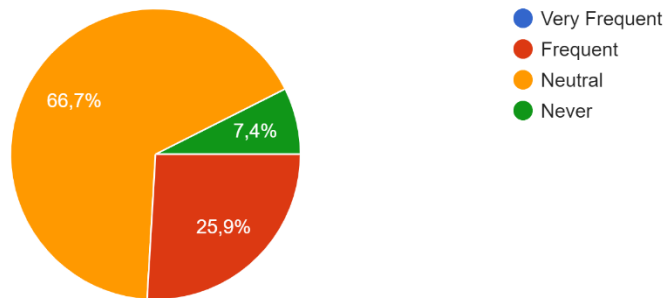


Figure 15 Albendazole Ireland faults

Pie chart representation of the opinion regarding How frequently do Albendazole products from foreign pharmaceutical businesses have production faults such as incomplete medications, bad/incorrect packing, inaccurate labeling, faulty seal, smudges, scratches, and ink splatters on the medicinal product leaflet, or other problems.

Among the 28 participants in Ireland, (66,7%) Responded neutral opinions regarding this question, (7,4%) Responded that they had never experienced this issue. (25,9%) Responded that this issue happened frequently.

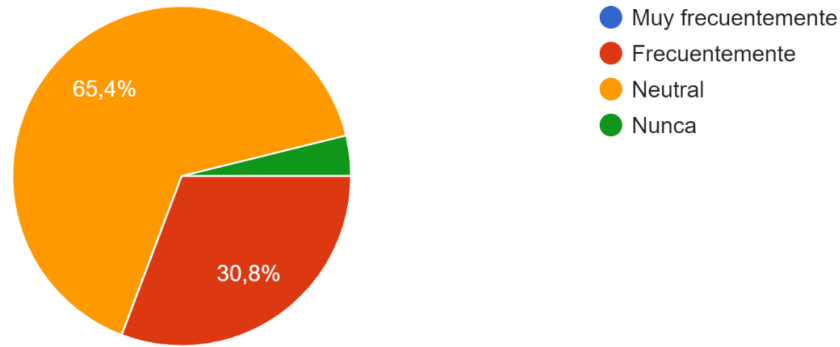


Figure 16 Albendazole Paraguay Faults

Pie chart representation of the opinion regarding How frequently do Albendazole products from foreign pharmaceutical businesses have production faults such as incomplete medications, bad/incorrect packing, inaccurate labeling, faulty seal, smudges, scratches, and ink splatters on the medicinal product leaflet, or other problems.

Among the 26 participants in Paraguay, (65,4%) Responded neutral opinions regarding this question, (3,8%) Responded that they had never experienced this issue. (30,8%) Responded that this issue happened frequently.

#### 4.3.2 To determine the quality and availability of Albendazole manufacture in Paraguay in order to export to Ireland without disrupting the supply chain.

Several steps are required to determine the quality and availability of Albendazole produced in Paraguay for export to Ireland.

Studies conducted Albendazole Manufacturing in Paraguay Researching Albendazole manufacturing in Paraguay is the first step. This involves determining the pharmaceutical manufacturers of Albendazole in Paraguay, as well as their capacity for manufacturing, quality control standards, and regulatory compliance. Once the Paraguayan Albendazole manufacturers have been established, their quality control standards must be assessed. This includes examining their manufacturing processes, quality control measures, and regulatory compliance. This can be accomplished by examining the manufacturer's website, quality control certifications, and records of regulatory conformance.

Request Testing Samples To assure the quality of the Albendazole manufactured in Paraguay, it is recommended to request testing samples. The following can be accomplished by contacting the manufacturer of the product and requesting that samples be sent to an independent laboratory for analysis. The laboratory must be accredited and have testing experience with pharmaceutical products. The testing process should be exhaustive and should include purity, potency, and impurity tests.

Verify Regulatory Conformity: Prior to sending Albendazole from Paraguay to Ireland, it is essential to confirm that the product complies with all applicable regulations in both countries. This involves confirming that the manufacturer has a license and a registration with the regulatory organizations in both countries, and that the product satisfies the required purity, potency, and labeling standards.

Determine Supply and Efficiency: Lastly, it is essential to ascertain the availability as well as the capacity of the Albendazole producer in Paraguay. This includes assessing the company's

manufacturing capacity, lead periods, and on-time delivery capabilities. This can be accomplished by directly contacting the manufacturer and requesting information regarding their ability, production schedules, and hold periods.

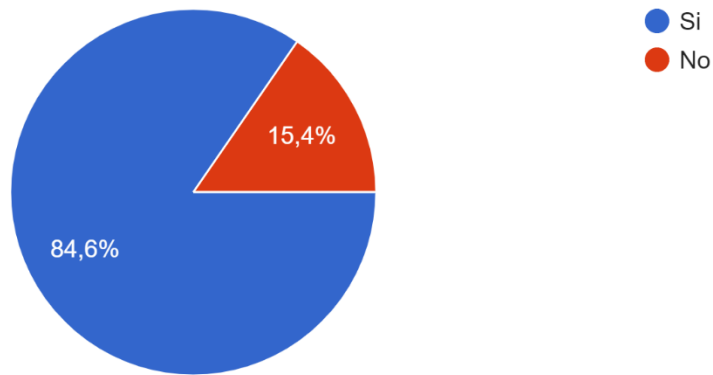


Figure 17 Albendazole errors Paraguay

Pie chart representation of the opinion if you ever had to send Albendazole items back to the pharmaceutical business where they were created due to production errors in Paraguay.

Among the 26 participants in Paraguay, (84,6%) Responded yes regarding this question, (15,4%) Responded no regarding this question

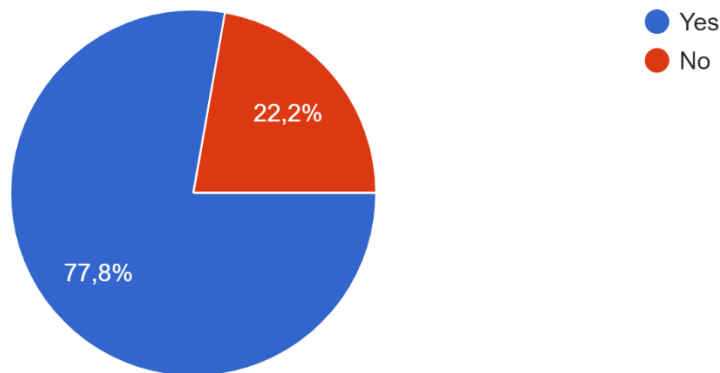


Figure 18 Albendazole errors Ireland

Pie chart representation of the opinion if you ever had to send Albendazole items back to the pharmaceutical business where they were created due to production errors in Ireland.

Among the 28 participants in Ireland, (77,8%) Responded yes regarding this question, (22,2%) Responded no regarding this question

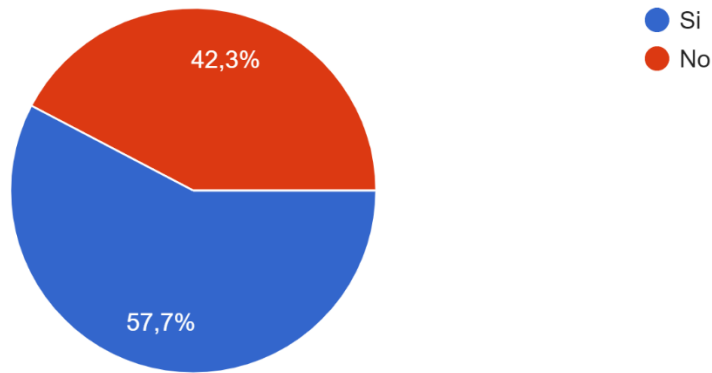


Figure 19 Albendazole unavailable Paraguay

Pie chart representation of the opinion if in the past few months, have you encountered situations in which the Albendazole you required was unavailable in Paraguay.

Among the 26 participants in Paraguay, (57,7%) Responded yes regarding this question, (42,3%) Responded no regarding this question

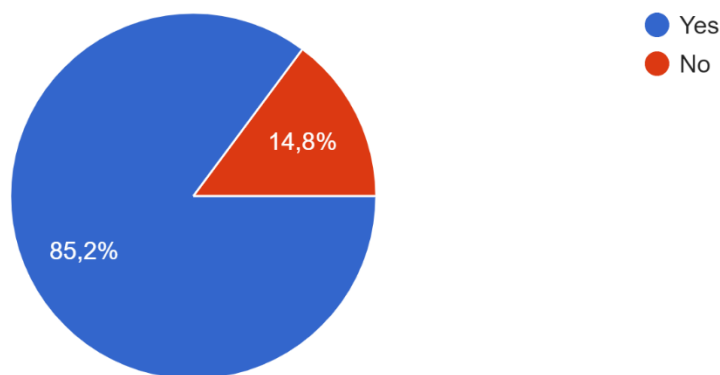


Figure 20 Albendazole unavailable Ireland

Pie chart representation of the opinion if In the past few months, have you encountered situations in which the Albendazole you required was unavailable in Ireland.

Among the 28 participants in Ireland, (85,2%) Responded yes regarding this question, (14,8%) Responded no regarding this question

#### 4.3.3. To Identify the impact of the legal structure and regulatory system on the quality of pharmaceuticals manufactured by Paraguayan companies in Ireland

The legal framework and regulatory structure can have a substantial effect on the overall quality of products manufactured in Ireland by Paraguayan companies. The regulatory and legal framework can impact the overall quality of pharmaceuticals in a number of ways. Being compliant alongside Regulation Specifications: The regulatory and legal structure in Ireland is intended to guarantee that pharmaceuticals meet rigorous safety, efficacy, and quality standards. Companies from Paraguay that manufacture pharmaceuticals with Ireland must adhere to such requirements in order to guarantee that their products satisfy the necessary criteria. Noncompliance with rules

and regulations can result in fines, product recalls, and reputational harm to the company.

**Access to High-Quality Raw Materials** The legal and regulatory system can also impact the accessibility as well as the quality of raw materials used in the pharmaceutical manufacturing process. Companies from Paraguay that manufacture products with Ireland must adhere to regulations governing the source and purity of raw materials. This may involve verifying the raw materials are obtained from reputable vendors and satisfy the necessary quality standards.

**Quality Control** The regulatory and legal framework can also influence the quality control procedures utilized by Paraguayan pharmaceutical manufacturers in Ireland. Pharmaceutical manufacturers are required to implement rigorous quality control procedures to guarantee that their products satisfy the required quality, safety, and effectiveness standards. Companies in Paraguay must adhere to these regulations to guarantee that the Albendazole their offering correspond to the highest possible standard.

Pharmaceutical products must be analyzed to guarantee their compliance with comply with the necessary standards for quality, safety, and efficacy, per the regulations. Before releasing their products for sale, Paraguayan companies that manufacture medicinal products with Ireland have to comply alongside these regulations and guarantee that their products endure the necessary testing.

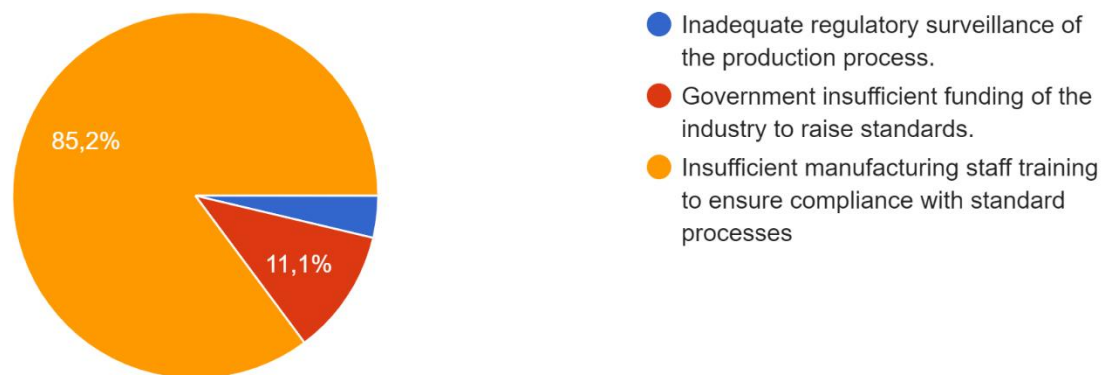


Figure 21 Quality Manufacturing Albendazole Ireland

Pie chart representation of the opinion regarding the difficulties that the participants believe affect the product quality of locally manufactured albendazole.

Among the 28 participants in Ireland, (85,2%) Responded that Insufficient manufacturing staff training to ensure compliance with standard processes, (11,1%) Government insufficient funding of the industry to raise standards, and (3,7%) Inadequate regulatory surveillance of the production process



Figure 22 Quality Manufacturing Albendazole Paraguay

Pie chart representation of the opinion regarding the difficulties that the participants believe affect the product quality of locally manufactured albendazole.

Among the 26 participants in Paraguay, (46,2%) Responded that Insufficient manufacturing staff training to ensure compliance with standard processes, (34,6%) Government insufficient funding of the industry to raise standards, and (19,2%) Inadequate regulatory surveillance of the production process.

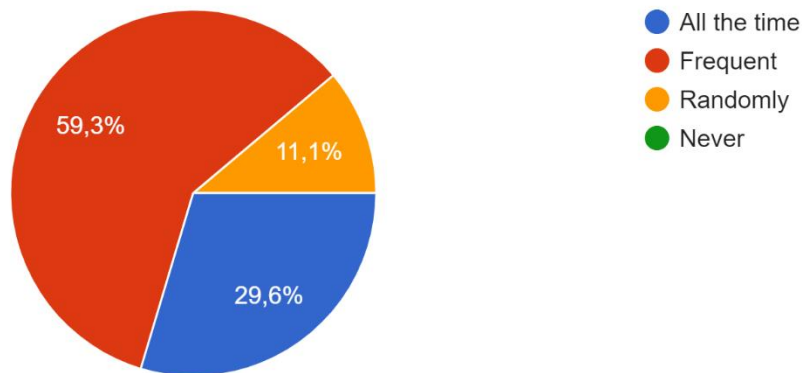


Figure 23 Quality albendazole Ireland

Pie chart representation of the opinion regarding the frequency that the HPRAs conduct regulatory checks on domestically manufactured products.

Among the 28 participants in Ireland, (59,3%) Responded Frequently, (29,6%) All the time and (11,1%) responded randomly.

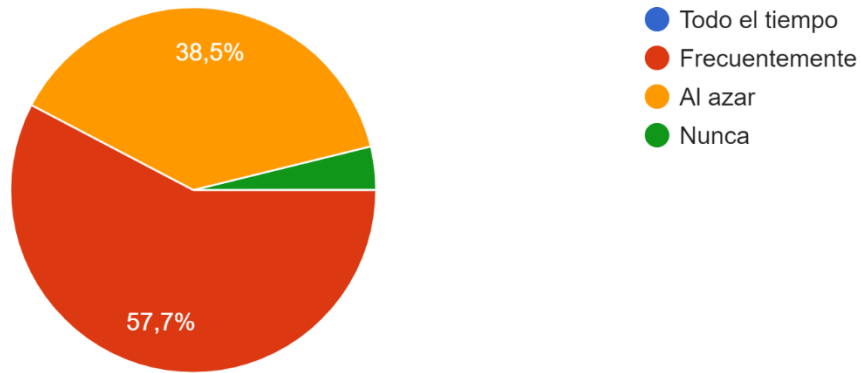


Figure 24 Quality Albendazole Paraguay

Pie chart representation of the opinion regarding the frequency that the DINAVISA conduct regulatory checks on domestically manufactured products.

Among the 26 participants in Paraguay, (57,7%) Responded Frequently, (29,6%) Randomly and (3,8%) and responded never.

#### 4.3.4. To expand the size of the market for Albendazole manufacturing and stablish commercial alliance

A strategic approach is necessary for expanding the scale of the market for Albendazole production in Paraguay and forming a commercial alliance with Ireland. The following measures can be implemented to reach this objective:

The first stage is to conduct market research to determine the need for Albendazole in Ireland as well as to identify prospective consumers. This can be accomplished through analyzing market data, detecting the industry's main competitors, and comprehending the regulatory landscape in Ireland. Once market research has been completed, it is essential to conduct a competitive analysis. This includes identifying other manufacturers of Albendazole in Ireland and comprehending their costs, product quality, and transportation channels. Establish a Marketing Strategy in accordance with the market research and competitive assessment, a marketing strategy must be created. This involves determining the distinct selling proposal of Albendazole produced in Paraguayan and developing promotional materials that emphasize its benefits. Develop a Commercial Alliance It is necessary to identify potential partners for the purpose to establish a business alliance with Ireland. Develop a Distribution Strategy by following the formation of a commercial alliance, it is crucial to establish a method of distribution that meets the requirements of customers in Ireland. This may involve establishing partnerships with local distributors or a channel of direct distribution. Ensure Compliance with Regulations: Lastly, it is essential to ensure that the Albendazole produced in Paraguay complies with every regulation that applies in Ireland. This includes acquiring the necessary permits and certifications and guaranteeing the product complies with all labeling

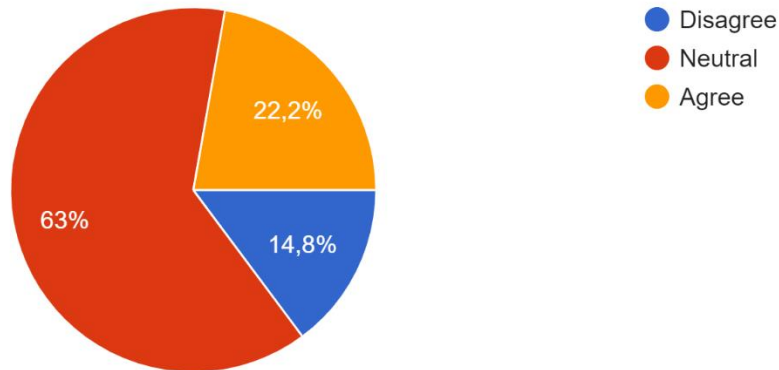


Figure 25 Government policies Ireland

Pie chart representation of the opinion regarding if these factors can affect the quality and availability of pharmaceuticals in Ireland. (Government policies)

Among the 28 participants in Ireland, (22,2%) Agrees, (63%) had a neutral opinion (14,8%) and Disagree.

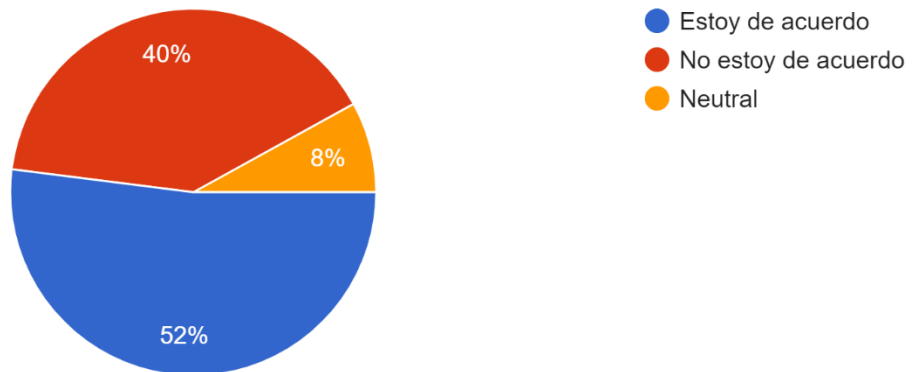


Figure 26 Government Policies Paraguay

Pie chart representation of the opinion regarding if these factors can affect the quality and availability of pharmaceuticals in Paraguay. (Government policies)

Among the 26 participants in Paraguay, (52%) Agrees, (8%) had a neutral opinion (40%) and Disagree.

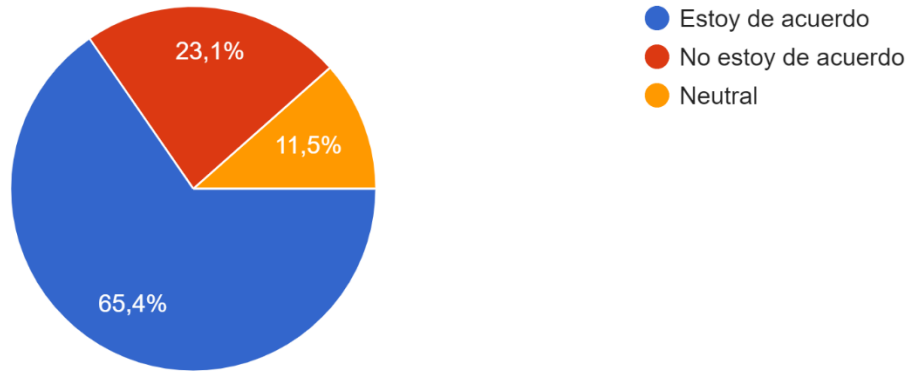


Figure 27 laws and enforcement Paraguay

Pie chart representation of the opinion regarding if these factors can affect the quality and availability of pharmaceuticals in Paraguay. (Insufficient laws or ineffective enforcement of existing regulations/guidelines for the manufacture of high-quality pharmaceuticals)

Among the 26 participants in Paraguay, (65,4%) Agrees, (11,5%) had a neutral opinion (23,1%) and Disagree.

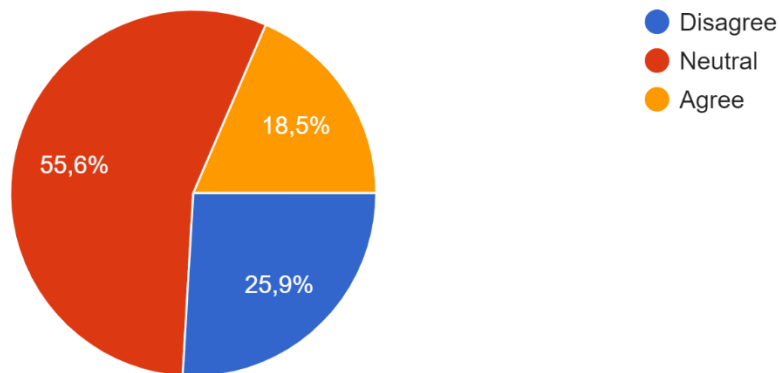


Figure 28 laws and enforcement Ireland

Pie chart representation of the opinion regarding if these factors can affect the quality and availability of pharmaceuticals in Ireland. (Insufficient laws or ineffective enforcement of existing regulations/guidelines for the manufacture of high-quality pharmaceuticals)

Among the 28 participants in Ireland, (18,5%) Agrees, (55,6%) had a neutral opinion (25,9%) and Disagree.

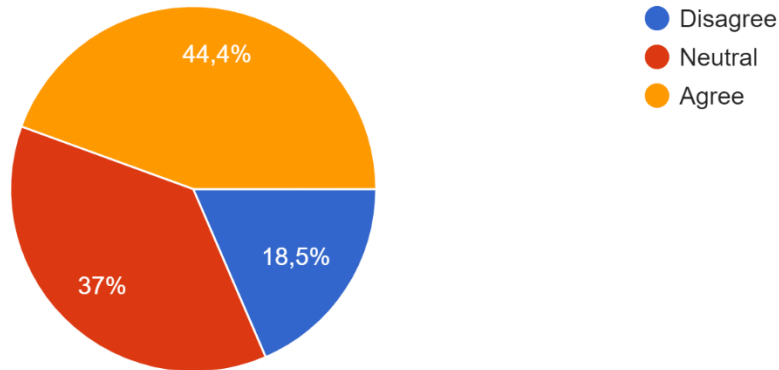


Figure 29 Supply Ireland

Pie chart representation of the opinion regarding if these factors can affect the quality and availability of pharmaceuticals in Ireland. (Supply exceeds demand)

Among the 26 participants in Ireland, (44,4%) Agrees, (37%) had a neutral opinion (18,5%) and Disagree.

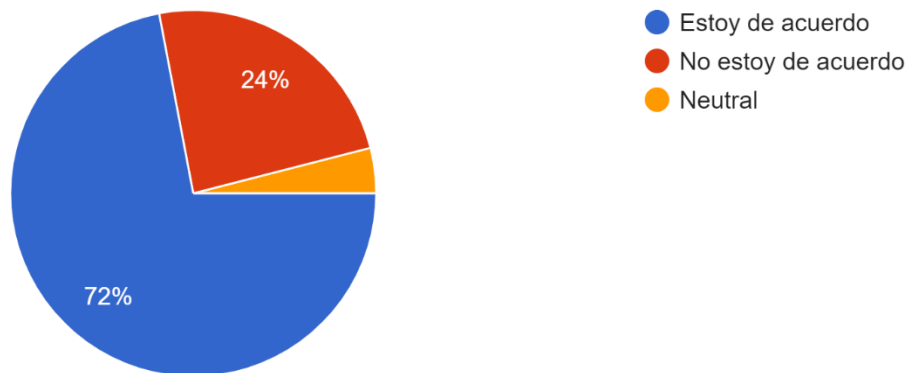


Figure 30 Supply Paraguay

Pie chart representation of the opinion regarding if these factors can affect the quality and availability of pharmaceuticals in Paraguay. (Supply exceeds demand)

Among the 26 participants in Ireland, (72%) Agrees, (4%) had a neutral opinion (24%) and Disagree.

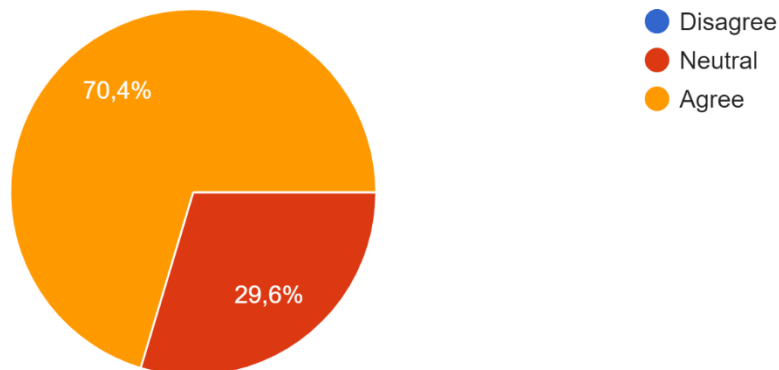


Figure 31 Expensiveness quality

Pie chart representation of the opinion regarding if these factors can affect the quality and

availability of pharmaceuticals in Paraguay. (Expensiveness of high-quality medications)  
 Among the 26 participants in Ireland, (70,4%) Agrees, (29,6%) and disagree.

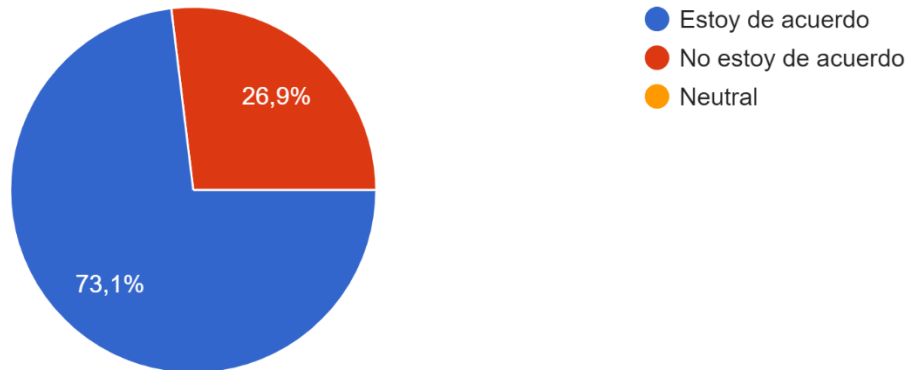


Figure 32 Expensiveness quality

Figure 4.7 Pie chart representation of the opinion regarding if these factors can affect the quality and availability of pharmaceuticals in Paraguay. (Expensiveness of high-quality medications)  
 Among the 26 participants in Paraguay, (73,1%) Agrees, (26,9%) and disagree.

## 5 CHAPTER 5

### 5.1 CONCLUSION AND RECOMMENDATIONS

#### 5.1.1 CONCLUSION

Five of the world's leading manufacturers of pharmaceuticals are commercializing in Ireland. Ancare, Chanelle Pharma, J&M Veterinary, Bimeda Animal Health, and Univet are among the companies listed. This business is regulated by the HPRA and adheres to the GMP and other ICH guidelines (animalhealthireland, 2021). Guayaki, Galmedic, Eticos, Indufar, Lasca, and Quimfa are the pharmaceutical industries in Paraguay that produce and market Albenzadole. Antibiotics, antihistamines, and other types of medication are produced by the company. These companies are regulated by DINAVISA and comply to GMP guidelines for the production of human and animal pharmaceuticals. (MRE, 2023).

Upon an extensive review of the quality systems employed by these companies, as detailed on their websites, there was a clear distinction between the systems in place. The quality management systems of Paraguayan pharmaceutical industries are inadequately represented on their websites. The information presented was in no way exhaustive, and a number of crucial issues were neither mentioned nor addressed. Compared to the quality system of Irish companies, theirs was reliable and covered all essential aspects in depth. They must improve the public display of information so that it is simple to resolve the quality systems utilized by such companies. The fact that the quality system in the Paraguayan company was not comprehensive could create gaps in their quality assurance program, which would have a negative impact on the pharmaceuticals they manufacture. Pharmaceutical manufacturing regulations have been established to detect these issues and prevent the distribution of products that have failed the quality assurance test; however, the authorities in

charge and the regulatory system are not trusted by the Paraguayans, resulting in a lack of confidence in Paraguayan production. Thus, the lack of a comprehensive quality system in Paraguayan companies will inevitably result in the production of low-quality pharmaceuticals, whereas the comprehensive quality systems outlined by the Irish pharmaceutical company will result in the production of pharmaceuticals of the highest quality.

The pharmaceutical industry's activities are viewed as being extremely private. Numerous products are registered on the DINAVISA website, particularly Guayakil's export of Albendazole to other South American countries. However, not much data is provided about the products, making it difficult to assess the impact of the company's quality management systems on the products that they manufacturing. In addition, the employees of pharmaceutical industries in Paraguay and Ireland were asked a number of questions about the medicinal products manufactured in their respective countries. A greater proportion of Paraguayan respondents believed that the foreign pharmaceutical industries medical products were of higher quality than those of the domestic pharmaceutical industries. A larger percentage of respondents added that they believed that medicines from foreign pharmaceutical industries were more effective due to the assurance of quality control from their governments and GMP certification, and the pharmacists stated that the consumers are more likely to purchase medicinal products manufactured by foreign pharmaceutical industries as opposed to those manufactured by Paraguayan pharmaceutical industries.

This study was also able to identify the other variables that influence the quality and availability of Albendazole products in Paraguay. The survey provides evidence for the following factors: Due to the fact that the majority of them are manufactured by foreign pharmaceutical manufacturers or imported from countries other than Paraguay, as well as the fact that Paraguayans prefer foreign products because to a lack of information and marketing about domestic products, the high cost of medicinal products of good quality is not indicative of poor quality. Due to the condition of the country and considering that Paraguay is a well-known producer of agriculture and livestock, they need to include albendazole in their parasite control calendar because demand for medicinal products exceeds supply. The research conducted makes important additions to the literature on GMP and the current developments that facilitate its implementation in Paraguay's pharmaceutical industry. GMP developments within the pharmaceutical sector have benefited the industry, however there is still opportunity for expansion and growth if the pharmaceutical business is to compete with similar industries in the remainder of the industrialized world, particularly in the areas of higher adoption of technology and improving of the legal framework governing the industry.

Prospective studies may expand on the findings or results of this study by employing alternative research methodologies to overcome the limitations of quantitative research or by examining the same topic in an alternate research setting. Overall, researchers from universities, authorities, pharmaceutical product manufacturers, consumers as well, and government officials will find this study useful for promoting good manufacturing practices and quality control in the Paraguayan pharmaceutical industry so that it can become a potential ally of Irish pharmaceutical industries.

### **5.1.2 RECOMMENDATIONS:**

DINAVISA should make every inspection (internal and external) conducted in pharmaceutical industries by DINAVISA regulators and auditors accessible to the public and be able to compare or even allow pharmaceutical industries to follow the different regulations from other countries, the FDA, or the EU, so that it is simple for companies to prepare for future collaborations with foreign companies. This is recommended because scrutiny from the public may act as an incentive

for authorities to do a more effective job of ensuring compliance in industries such as manufacturing and a motivation for the company to establish an improved quality system to prevent negative feedback from reaching the publi

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## 7 APPENDIX: SURVEY QUESTIONNAIRE



### **Evaluation of the impact of Quality management and Regulatory systems in the manufacturing processes of Albendazole in The Republic of Paraguay and The Republic of Ireland.**

My name is Maria Lujan Ferreira, and I am pursuing a Master of Science in Pharmaceutical Business and Technology at Griffith College. You are being invited to participate in this research study named Evaluation of the impact of Quality management and Regulatory systems on the Albendazole manufacturing processes in the Republic of Paraguay and the Republic of Ireland. I am interested in finding out about the impact of the legal structure and regulatory system on the quality of Albendazole produced by Paraguayan companies and Irish companies, as well as the possibility of future commercial cooperation between the two countries. Participation in the study requires completion of the online survey, which should take approximately 10 minutes. The information you provide will be entirely anonymous, and after the study you will not be contacted again. All of your responses will be held strictly confidential. There is no incentive for your participation; however, the results of the study may encourage a new generation of stockholders as well as workers to enter the Paraguayan pharmaceutical industry with the solitary intention of reshaping the production process to conform to global best practices. Please note that participation in this study is entirely voluntary, and I am glad to answer any questions you may have. For any questions, you may contact me at [marialujan.ferreiraayala@student.griffith.ie](mailto:marialujan.ferreiraayala@student.griffith.ie),

## Participant Information Letter

A comparative Evaluation of Quality management and Regulatory systems in the manufacturing processes of Albendazole in The Republic of Paraguay and The Republic of Ireland

I would like to invite you to take part in a research study. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Ask questions if anything you read is not clear or if you would like more information. Take time to decide whether or not to take part.

### WHO I AM AND WHAT THIS STUDY IS ABOUT

My name is Maria Lujan Ferreira. I am conducting this research as part of my dissertation for my master's degree in pharmaceutical business and technology at Griffith College, Dublin. This study's goal is to compare and contrast pharmaceutical manufacturing companies in Paraguay and Ireland. The regulatory procedures and their impact on the quality of Albendazole production in Paraguay, as well as the product's suitability for export to Ireland, will be thoroughly evaluated.

### WHAT WOULD TAKING PART INVOLVE?

We will request your permission (signed consent) to include questionnaire responses in our research. It will not require the collection of any sensitive data regarding your work.

### WHY HAVE YOU BEEN INVITED TO TAKE PART?

Large pharmacy pharmacists in Paraguay and Ireland will be provided with questionnaires. This is due to the fact that they can supply information regarding the quality of Albendazole goods supplied by pharmaceutical firms as well as the availability of items from various pharmaceutical industries.

### DO YOU HAVE TO TAKE PART?

The participants' anonymity and confidentiality will be respected and the participation is voluntary; that consent can be withdrawn at any time. No risk is involved in completing the survey, If you need to withdraw, please contact, the author Maria Ferreira on 0864562022 or via email [marialujan.ferreiraayala@student.griffith.ie](mailto:marialujan.ferreiraayala@student.griffith.ie)

### WHAT ARE THE POSSIBLE RISKS AND BENEFITS OF TAKING PART?

There are no disadvantages or risks to taking part. There are no direct benefits to you, however the outcomes of investigations utilizing this data will aid future commercial connections between Paraguay and Ireland.

### WILL TAKING PART BE CONFIDENTIAL?

The participants' anonymity and confidentiality will be respected and the participation is voluntary; that consent can be withdrawn at any time. No risk is involved in completing the survey, as identifiable information such as your name or email address will not be gathered. In order to safeguard your privacy, the questionnaire will not contain any information that may be used to identify you. The findings of this study will only be utilized for academic purposes.

#### HOW WILL INFORMATION YOU PROVIDE BE STORED AND PROTECTED?

The author will save signed consent forms and original audio recordings in a password-protected, secure file to which only the author will have access. All files and documents containing personal information are protected by a password. Until the Griffith College examination board has confirmed the outcome of this dissertation.

A transcript of interviews from which all identifying information has been deleted will be kept for an additional two years. Under the legalization of freedom of information, participants may view the information you have submitted at any moment.

#### WHAT WILL HAPPEN TO THE RESULTS OF THE STUDY?

The results will appear in my master's dissertation in pharmaceutical business and technology at Griffith College, Dublin, but you will not be revealed in any report or publication. And all dissertation research projects and their content will be made accessible in the college library.

#### WHO SHOULD YOU CONTACT FOR FURTHER INFORMATION?

Author Maria Ferreira on 0864562022 or via email  
marialujan.ferreiraayala@student.griffith.ie

[THANK YOU]

## QUESTIONNAIRE

### Paraguay

1. What is your role in the industry?

- Production
- Pharmacists
- Quality Control
- Quality Assurance
- Others

2. How significant is your professional experience?

- <1 year
- 1-2 years
- 3-4 years
- 5+ years

3. How Good is your knowledge about the medication Albendazole

- Poor
- Neutral
- Good

4. What is your opinion about the quality of Albendazole products in Paraguay?

- Poor
- Neutral
- Good

5. Do you agree or disagree with the statement that Albendazole products manufactured by Paraguayan pharmaceutical firms are of higher quality than those manufactured by international pharmaceutical firms? If agree explain why and if disagree explain reasons.

- Disagree
- Neutral
- Agree

6. Do you have any agreement or disagreement with the statement that Albendazole goods produced by imported pharmaceutical businesses are of higher quality than those produced by domestic Paraguayan pharmaceutical companies? If agree explain why and if disagree explain reasons.

7.

- Disagree
- Neutral
- Agree

8. Do you believe that these factors can affect the quality and availability of pharmaceuticals in Paraguay?

Please check the applicable box

I. Government policies

- Disagree
- Neutral
- Agree

II. Insufficient laws or ineffective enforcement of existing regulations/guidelines for the manufacture of high-quality pharmaceuticals

- Disagree
- Neutral
- Agree

III. Supply exceeds demand

Disagree                       Neutral                       Agree

IV.    Expensiveness of high-quality medications

Disagree                       Neutral                       Agree

9. Where do you obtain the majority of your Albendazole products?

- Foreign Pharmaceutical companies
- Paraguayan pharmaceutical companies

10. How frequently do Albendazole products from Paraguayan pharmaceutical manufacturers have production faults, such as low quality medications, bad/incorrect packaging, inaccurate labeling, faulty seal, smudges, scratches, and ink splatters on the medicinal product booklet, or other problems?

Very Frequent    Frequent                       Neutral                       Never

11. How frequently do Albendazole products from foreign pharmaceutical businesses have production faults such as incomplete medications, bad/incorrect packing, inaccurate labeling, faulty seal, smudges, scratches, and ink splatters on the medicinal product leaflet, or other problems?

Very Frequent    Frequent                       Neutral                       Never

12. Have you ever had to send Albendazole items back to the pharmaceutical business where they were created due to production errors?

Yes                       No

13. In your experience, which Albendazole product is most likely to be purchased by consumers?

- Foreign Albendazole manufacturers    Local Albendazole manufacturers

14. Which of the following Albendazole options is the most cost-effective for your pharmacy:

- Foreign Albendazole manufacturers    Local Albendazole manufacturers

15. How would you rate the quality of Albendazole products in Paraguay?

Poor                       Neutral                       Good

16. What difficulties do you believe affect the product quality of locally manufactured albendazole?

- Inadequate regulatory surveillance of the production process
- Government insufficient funding of the industry to raise standards.
- Insufficient manufacturing staff training to ensure compliance with standard processes

17. How frequently does the MSPBS conduct regulatory checks on domestically manufactured products?

- All the time       Frequent       Randomly       Never
18. In the past few months, have you encountered situations in which the Albendazole you required was unavailable?
- Yes       No

## Ireland

1. What is your role in the industry?

- Production  
 Pharmacists  
 Quality Control  
 Quality Assurance  
 Others

2. How significant is your professional experience?

- <1year       1-2 years       3-4years       5+ years

3. How Good is your knowledge about the medication Albendazole

- Poor       Neutral       Good

4. What is your opinion about the quality of Albendazole products in Ireland?

- Poor       Neutral       Good

5. Do you agree or disagree with the statement that Albendazole products manufactured by the Irish pharmaceutical firms are of higher quality than those manufactured by international pharmaceutical firms? If agree explain why and if disagree explain reasons.

- Disagree       Neutral       Agree

6. Do you have any agreement or disagreement with the statement that Albendazole goods produced by imported pharmaceutical businesses are of higher quality than those produced by domestic Irish pharmaceutical companies? If agree explain why and if disagree explain reasons.

7.

- Disagree       Neutral       Agree

8. Do you believe that these factors can affect the quality and availability of pharmaceuticals in Ireland?

Please check the applicable box

V. Government policies

- Disagree       Neutral       Agree

VI. Insufficient laws or ineffective enforcement of existing regulations/guidelines for the manufacture of high-quality pharmaceuticals

Disagree       Neutral       Agree

VII. Supply exceeds demand

Disagree       Neutral       Agree

VIII. Expensiveness of high-quality medications

Disagree       Neutral       Agree

9. Where do you obtain the majority of your Albendazole products?

- Foreign Pharmaceutical companies
- Irish pharmaceutical companies

10. How frequently do Albendazole products from Irish pharmaceutical manufacturers have production faults, such as low quality medications, bad/incorrect packaging, inaccurate labeling, faulty seal, smudges, scratches, and ink splatters on the medicinal product booklet, or other problems?

Very Frequent       Frequent       Neutral       Never

11. How frequently do Albendazole products from foreign pharmaceutical businesses have production faults such as incomplete medications, bad/incorrect packing, inaccurate labeling, faulty seal, smudges, scratches, and ink splatters on the medicinal product leaflet, or other problems?

Very Frequent       Frequent       Neutral       Never

12. Have you ever had to send Albendazole items back to the pharmaceutical business where they were created due to production errors?

Yes       No

13. In your experience, which Albendazole product is most likely to be purchased by consumers?

Foreign Albendazole manufacturers       Local Albendazole manufacturers

14. Which of the following Albendazole options is the most cost-effective for your pharmacy:

Foreign Albendazole manufacturers       Local Albendazole manufacturers

15. How would you rate the quality of Albendazole products in Ireland?

Poor       Neutral       Good

16. What difficulties do you believe affect the product quality of locally manufactured albendazole?

- Inadequate regulatory surveillance of the production process
- Government insufficient funding of the industry to raise standards.

Insufficient manufacturing staff training to ensure compliance with standard processes

17. How frequently does the HPRA conduct regulatory checks on domestically manufactured products?

All the time

Frequent

Randomly

Never

18. In the past few months, have you encountered situations in which the Albendazole you required was unavailable?

Yes

No