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Exploring The Effects Of Plastic-Free Packaging In The Pharmaceutical Industry

By Adela García González

Supervisor: Daniel Hellström
Examiner: Mats Johnsson

Department of Service Management, Logistics
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ABSTRACT

Today plastic packaging is used in a wide array of industries including the pharmaceutical industry. Nevertheless, the increasing amount of plastic waste from packaging is generating great amount of contaminants that do not only damage the environment, but as well the society and the economy as a whole.
Whilst industries of fast consumer goods, such as the food and fashion industry enjoy vast research in this respect, the pharmaceutical area is known for its lack of academic focus, perhaps due to the complexity, highly regulated and sensitive nature of this sector.

Motivated by the lack of research in this industry, this study is to support academic research within pharmaceutical packaging and explore how the services of sustainability, i.e. recycling, reducing and redesigning, affect the logistic operations and packaging design of pharmaceutical companies.
More specifically, through the collection and analysis of data in accordance to the Grounded Theory methodology, this study collects and analyses primary data in the form of semi-structured interviews and secondary data in the form of academic journals, newsletter, magazines and reports. The analysis evaluates how the latest regulations on plastic packaging, i.e. EU Directive on Single Use Plastic Packaging and EU Scheme on Producer Responsibility are perceived by the pharmaceutical industry and how these regulations could affect the packaging and logistic operations of pharmaceuticals.

The results of this study shows that all logistic areas will experience changes and risks caused by sustainable packaging designs, yet the procurement, production and shipping functions will experience a higher criticality and thus, prime focus and control must be allocated on these areas. The results of these inquiries are potential recommendations that pharmaceuticals are to implement for a successful journey towards sustainability in packaging.

Keywords: pharmaceutical packaging, packaging, sustainability, sustainability in packaging, sustainable packaging, sustainable pharmaceutical packaging,

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1. INTRODUCTION

This chapter will give the reader an introduction to the thesis.
It will first introduce the area of concern and the problem identified. Secondly, this chapter dives into the purpose of carrying out this study and the research questions to eventually answer. Consecutively, the reader is given a series of limitations that the author encountered.
Lastly, the disposition of the different chapters that configure this study is outlined.

1.1. Background

"By 2050 there will be more plastic than fish in the world's ocean unless people stop using single-use plastic", warned the United Nations (UN News, 2017).

It was in the beginning of the 70s when plastic production accelerated at sky rocketing numbers, leaving us what is reckoned today as the Plastic Waste Crisis (Parker, 2012).
In the beginning of the 20s, plastic waste increased more in a single decade that it had in the former 40 years. Today, 300 million tons of plastic waste is produced every year. That is nearly equivalent to the weight of the entire human population, declares the UN Environment Organization (UN Environment, u.d.).
The amount of plastic that our environment is swallowing is almost equal to damping one truck of plastic garbage per minute, that eventually ends up in the oceans in the form of eight million tons of plastic waste (UN News, Assembly President launches new initiative to purge plastics and purify oceans, 2018).

Plastic is nowadays a very common material used for the packaging of all sorts of goods. The long-lasting, easy to manage and proactive features make plastic a very good material to use for the safe transportation of all goods. However, these features make it also highly polluting before, during and after consumption.
Notoriously, plastic is often not recycled and half of all plastic product globally produced are designed to be used only once (UN Environment, u.d.). Today, 99% of plastics are produced from chemicals such us oil, natural gas and coal, which are dirty and non-renewable resources. If this tendency continues, the plastic industry will account for 20% of the world's total oil consumption. Conversely, only 9% of all plastic waste is recycled, 12% is incinerated and the remaining 79% is piled up in landfills, dumps or in the natural environment, such us rivers and canals.
If no global actions are taken, plastic production is expected to triple by 2050, corresponding to 13 per cent of our planet's total carbon budget, equally to the emission of 615 power stations (World Wildlife Fund , 2019).

Several sustainable global initiatives have been taken to mitigate plastic waste, such as the Global Plastic Action Partnership (GPAP) and the European Circular Economy Plan, among others.
In the event of the quantities of marine litter found in bays, the European Union has taken actions to tackle with this situation and it established in July of 2019 the EU Directive on Single-Use Plastics Packaging, which targets specific products whose producers are to replace plastic packaging with a more sustainable alternative by 2025. Otherwise financial bans will be applied.

1.2. Problem formulation

Evidence of great amount of plastic waste in the environment has motivated researchers to base their studies on plastic waste reduction and elimination at all stages of the Supply Chain.
While consumers actively demand plastic-free packaging to reduce the amount of plastic waste, the sustainable journey does not happen overnight as quick as a heartbeat, it requires careful planning and thorough implementation.
If plastic waste elimination has been the focus of a wide array of research papers since the beginning of last the century, why after two decades the business world is not yet plastic free?
Much focus has been given to the advantages and benefits of sustainability, and innovation has revolved greatly around this subject.
Nevertheless, less focus is given to the other side of the coin, to the downsides, logistic changes and risks that corporations counter fight when attempting to jump onto the sustainability cloud. This leads to question us: *What does really entail to become sustainable?*

While many industries such as the fast fashion and food industry enjoy of vast research into the subject, less research is given to the pharmaceutical industry. Maybe because of the significant ethical considerations that one might consider when altering the *status quo* of the medical sector.
Despite of the great efforts of the pharmaceutical industry to develop, market and sustain the life of every living being, the pharmaceutical industry relies heavily on plastic for the packaging of medicinal products.
Plastics are unbreakable, collapsible and light weight, making it a perfect material for pharmaceutical packaging.
However, research shows that great amounts of medicines, sometimes unused, are thrown away by all stakeholders in this industry, including patients.
In the view of the current Plastic Waste Crisis, the pharmaceutical industry is also to join the cause of plastic packaging reduction and eventual elimination.
In this area of concern, it is of interest to investigate how the demand of plastic elimination/reduction will shape the packaging ad logistic activities of pharmaceuticals, whilst still ensuring the safety and protection of medicines and patients..

Even tough packaging is studied in academia as a unique discipline, packaging is found in the area of Supply Chain and Logistics. Changing the packaging *modus operandi* does also affect the activities and services in the entire chain. This study is to investigate packaging from a holistic approach, considering the entire Supply Chain.

This report reflects on the novelty and the recent establishment of the EU Directive on Single Use Plastic Packaging. Considering that companies may have not yet implemented sustainable packaging, this research is to support pharmaceutical companies to comply with the Directive and other regulations of the same kind.

To sum up, this study puts together the concepts of logistics, service management and sustainability. Logistics is viewed in the functioning of pharmaceutical packaging across all the logistic functions. Service management can be found on how the sustainable services, i.e. recycling, reusing, redesigning, affect the logistic operations of pharmaceuticals.
The pharmaceutical industry not only offers medicinal products and healthcare services, pharmaceuticals are also the suppliers and buyers of many goods where products and services are exchanged. Following the newest view that services are both tangible and intangible goods (Bix et al., 2004) this study studies both tangible goods (medicinal packaging) and intangible goods (the services of sustainability) and how these two affect the logistics of pharmaceuticals.

1.3. Purpose & Research Questions

Motivated by the lack of research papers on the pharmaceutical industry, this study contributes to expand previous research on the subject matter and bring into academic research the latest sustainable demands addressing pharmaceutical packaging.

With the attempt to support pharma practitioners on the journey towards sustainable packaging, this exploratory paper is to investigate the potential changes and risks that sustainable packaging might cause on the packaging and logistic services of pharmaceuticals.
Even though sustainable packaging is been performed by other industries, such as the fast fashion and food industry, the pharmaceutical industry requires special attention due to its sensitive nature and regulated procedures.
The services of pharmaceutical packaging go beyond transportability; protection of all medical compounds and packaging usability is paramount to ensure patient's health.

In the event of these facts, if sustainability is to reach the pharmaceutical industry, careful implementation and prior research is needed to avoid tragic events.
Therefore, the research questions that this qualitative report will answer are the followings:

RQ1. How is the EU Directive on Single-Use Plastic Packaging (SUP) and the EU Scheme on Producer Responsibility perceived by pharmaceuticals?

In this question, the author seeks to (1) examine the level of stakeholder's awareness of the Directive and EU Scheme (2) Explore their perceptions of its effects and (3) investigate how they are working to comply with these regulations.

RQ2. What are the potential changes and risks that these regulations might cause in the packaging and logistics of pharmaceuticals?

Following up on RQ1, this question seeks to explore the operational changes and risks that these regulations will cause in the packaging and logistic activities of pharmaceuticals.

RQ3. Which logistic areas are more critical when implementing sustainability in pharmaceutical packaging?

This questions is to present the areas that pharmaceuticals should give higher priority to due to their likelihood of failure and critical outcomes if no primer attention is given.

The answer(s) to these questions is what pharma practitioners are suggested to consider when embarking themselves into sustainable packaging.

1.4. Limitations

There are a series of limitations that has restricted the author to conduct the study and that might, to a certain degree, diminish the reliability and validity of the findings.

This study is conducted during 16 weeks, from January until May of 2020, which unluckily coincided with the outbreak of the global pandemic Covid-19.

At the beginning of this study, the author made several arrangements with companies with whom conduct semi-structured interviews. Unfortunately, most of them got cancelled and the few remaining were changed to video-call or normal phone call.

The inability to meet the interviewees in person disabled the author to record non-verbal communication that might have indirectly provided additional insights. Additionally, due to the series of cancellations, the empirical findings became deteriorated due to the low participation level and due to the ungiven consent of some participants to record the interview. Therefore, this research is primarily supported on desk research, whilst interviews are used a secondary source of information of more detailed and company-specific knowledge.

Due to this unlucky event, the dimensionality that Grounded Theory requires (Randall & Mello, 2012) is not given. Interviewing stakeholders from different management levels would have provided richer data.

Furthermore, due to the time limitations of this study the theoretical saturation was rather difficult to determine, since it is very probable that the author would had needed significant additional time

to sample more organizations before no new theoretical concepts emerged from the research.

1.5. Chapter disposition

This study has been structured in five chapters to facilitate the comprehension for the reader.
First, the introductory chapter presents the founding reasons for the development of this study. This chapter also presents the research area where the author has identified a problem which is further studied. To ease the analytical journey, the problem is re-phrased into three research questions that articulate in a brief manner the focus and aim of this study. Lastly, delimitations, i.e. external and internal factors that restrict the scope of this study are outlined.
This chapter is followed by the methodology chapter where the author shows the procedures, methods and principles of Grounded Theory that govern the data collection & analysis and choice of academic theories.
The third chapter consists of the theoretical framework that presents the theoretical models that dominate the study and shows that the research problem under study exists.
Given the above, the study continues to the chapter of Empirical Data, of a more descriptive nature. In this chapter, the author presents the findings from Open Coding and Axial Coding following the Grounded Theory principles.
The fifth chapter is the Analysis where the Selective Coding step takes place. In this chapter, the issue of study is deeper explored and contrasted to the theoretical framework. The results of this analysis led to the development of a new theory that will answer the research questions.
Lastly, the Conclusion chapter provides the answers to the research questions, determines the implications and offers suggestions for future research.

2. METHODOLOGY

This chapter presents the work process and the methods to carry out the study.
This chapter is divided into four sub-topics following the order in which the study was conducted. First, the Theoretical Framework and the research process behind it are outlined; second, the use of Grounded Theory for the collection and analysis of data is presented; third, the codes and categories identified from the secondary data and interviews are explained; fourth, the identified codes and categories are analyzed according to Grounded Theory (GT) process of Open coding, Axial Coding and Selective Coding. Lastly data quality and ethical considerations are determined.

The aim of this study is two-fold: on one hand this paper attempts to describe the packaging and logistics of pharmaceuticals and on the other hand, this study is to explore the potential changes and risks that sustainable packaging could cause on the packaging logistics of pharmaceuticals. Since no similar studies have been developed in the field from this approach, there is no theoretical framework established. In this sense, GT is employed when the topic of interest has been either

ignored or has been given superficial attention. Consequently, the researcher must build a theory from the ground (Goulding, 2002).
Through coding processes, the author is able to find similarities and differences and develop categories among the different sets of data or codes, which eventually lead to the theory development.
Nevertheless, no one starts from scratch and a prior research in to the topic was needed to support the use of GT and confirm the research gap. Like that, the next sub-chapter explains in more detail the process undertaken to develop a theory of frame.

2.1. Theoretical framework

Saunders, Lewis, & Thornhill (2015) explained that the concept "theory" is widely misused and misunderstood in education. Some think that "theory" is the material included in textbooks, whereas what is happening in the "real world" is practice.
Kelly (1995) argues that when individuals attempt to make sense of the different events of the daily life, we organize our results into a schemata and then into a broader system of schemata which are called theories. Likewise, she affirms that "we need such schemata and theories to make sense of the complexity of the world in which we live in. Without these organizing frameworks we would be overwhelmed by unconnected details that we would have to recall".
A Theoretical Frameworks delimits the concepts and theories that a research evolves around. In this respect, a research project either tests a theory or develops a new one.

The theoretical framework presented in this study is a description and critical analysis of what other authors have written in regards to packaging designs in sustainability. It is a way to discover research gaps and formulate research questions not previously investigated.
Whereas many industries are explored in this regard, the pharmaceutical industry is less common. Similarly, sustainability is very often explored as per its advantages and benefits in the business world. Yet, the disadvantages are not that emphasized in academic research.
In the view of these facts, the author decided to choose the perspective of pharmaceuticals and analyze the downsides of sustainability in pharmaceutical packaging.

2.1.1. The Research Process

As mentioned, to provide a solid foundation and understanding of the topic, the author did an initial extensive research. This was through academic journals within logistics. However, in the marketing field Packaging is considered one of the 7Ps of Marketing Mix, therefore the author very often analyzed journals within the marketing context. In like manner, pharmaceuticals are widely studied in more scientific contexts, therefore the author has also studied papers with a more scientific background, where the introduction was mainly reviewed instead of the results, as they were

unrelated to this study.
This review also adopts a critical viewpoint where the different authors' ideas and opinions are compared to form the researcher's opinions and base the conclusions on these.
From the above, the researcher was able to develop a theoretical framework with different theoretical models that served as focus lens to keep the study within the logistic context and to re-defined the research questions. As GT asserts, different theoretical models emerge as the research evolves and the research process changes at the same pace.
First, the author studied the concept of packaging, the materials, levels and functions.
Inspired by the global controversy of the function of sustainability in packaging, the author decided to dive deeper into the area and grant a single section to sustainability in packaging.
Aware of the latest regulations in plastic packaging, the third chapter consists of the definition and requirements of the EU Directive on Single-Use Plastic Packaging and EU Producer Responsibility Scheme.
To clarify the approach of this study, the last chapter explains the relationship between packaging and logistics; two areas studied in academia separately but that are both included under the umbrella of Supply Chain Management.

However no theories were taken from this initial research. Later on in the study, the collected data is analyzed following the principles of GT.

2.2. Grounded Theory

This study uses the method of Grounded Theory (GT) developed by Glaser & Straus (1967) to collect and analyze data.
GT was developed as a response to the "extreme positivism" of their time that was mainly used in natural sciences (Mello & Flint, 2009). Opposite to this trend, Glaser & Strauss asserted that social research should adopt an interpretivism approach where "reality is seen as socially constructed through the meanings that social actors ascribe to their experiences" (Saunders, Lewis, & Thornhill, 2015).
Therefore GT was developed to analyze, interpret and explain the different meanings that social actors create to make sense of their experiences in specific situations.
Like that, this study implements GT to analyze how pharmaceutical practitioners view and interpret the trend of sustainability in the pharmaceutical industry.
In the development of a theory, GT adopts an inductive approach where theory is grounded in the data collected. Therefore, theories arise from the data previously collected and analyzed. This data is constantly compared and tested, therefore, GT also adopts a deductive approach towards theory development.
As Goulding (2002) explain, the researcher in GT must build a theory from the ground with no pre-determined theoretical model, but built during the collection and analysis of data. Therefore GT

allows researchers the freedom to investigate the phenomena and adjust the RQs, procedures and analysis tools as the research evolves (Mello & Flint, A REFINED VIEW OF GROUNDED THEORY AND ITS APPLICATION TO LOGISTICS RESEARCH, 2009).

For this, GT uses codes to establish relationships among sets of data that produce categories that will further on develop a new theory.

Coding in Grounded theory is the process of constant comparison. Data is continuously compared with each other as well as against the codes. The aim is to find similarities and differences to promote consistency. As relationships among data items are established, interpretations and categories are created, which are further 'tested' by collecting new sets of data. Thus, moving between inductive and deductive reasoning, called as Abduction.

In like manner, both objectivity and subjectivity govern the research process and findings of this study.

The author subjectively interprets the interviews in order to understand pharmaceutical practitioners' viewpoints, state of mind and reactions regarding sustainable pharmaceutical packaging. Consequently, secondary data is objectively analyzed to study former literature without altering the arguments given by former researchers. As Goulding (2002) mention, reading before entering the field is not forbidden, it is a vital part of GT. However, the researcher should avoid pre-judgements and expectations based on the statements of other papers in order to strengthen the theoretical sensitivity

2.3. Data collection

Due to the external factors that occurred at the time of this study, primary data from the interview transcripts were not considered sufficient by the author. Following the GT approach, data sources can be from single or multiple-sources, therefore the author decided to implement additional data collection and analysis techniques to reinforce the findings.

These additional techniques were based on Secondary Data in the form of academic journals, online magazines, newsletters, companies sustainability reports and conference reports.

These additional sources of information where also used as means of triangulation. Through the use of different data sources and methods, the author attempts to seek convergence and corroboration to enhance credibility and reduce potential biases that can exist if findings are drawn from a single method.

The different data sources are further explained in the following sub-chapters:

2.3.1. Semi-structured Interviews

In GT the most common type of interviews are semi-structured interviews, open-ended, in-depth conversational interview (Goulding 2002). The author established a series of limitations and semi-structure interviews seem more appropriate.

Respondents were welcome to provide new aspects that could lead the discussion into new areas,

yet, the discussion were not touch upon unrelated issues.
The author met the interviewees with a pre-determined set of open-ended questions that could be elaborated further, but the author controlled the discussion flow to keep it always under the right scope.
In connection to GT, the questions varied slightly in each interview. After conducting an interview, the author immediately transcribed and analyzed it. This allowed the researchers to shape the next interview questions accordingly. In the consecutive interviews, the author could asked same or similar questions to corroborate or elaborate on the arguments from the former interviewees.
As seen in **Table I**, there are several weeks between interviews, this allowed the author to shape the questions in accordance to the former interview but as well in accordance to the collected secondary data.
Due to the external factors that occurred at the time the study was conducted (section 1.4) only 5 interviews could be performed, which had to be carried out through virtual platforms such as Skype and Jabber.

2.3.2. Sampling

Due to the concrete industry and RQs that this study deals with, probability sampling seemed more appropriate. This technique allowed the researcher to judge herself the respondents' profiles so the right information was extracted from the right people (Saunders, Lewis, & Thornhill, 2015). Only pharmaceutical practitioners working within pharmaceutical packaging were selected.
In probability techniques generalizations are made to the theory and not about the population. And the sample size is dependent on the research question (s) and aim (Patton, 2002).
Research literature suggests to collect as much qualitative data as possible until reaching theoretical saturation, this is, the moment in which additional data provide little, if any, new information or suggest new themes (Strauss & Corbin, 1998). However, due to the external factors, theoretical saturation from interviews could not be experienced in this study. The author decided to also collect secondary data that could fill in the data "gaps" from the interviews.

In connection to the sampling type, the author developed a profiling criteria to ensure the right sampling group was recruited: (a) Respondents who work in the pharmaceutical industry and (b) who handle in any way the packaging of pharmaceutical products..
This implies that the author used her judgements to delimit the respondents' profiles in accordance to the research question (s) and purpose of the study.
This is why purpose sampling is sometimes referred as judgement sampling or theoretical sampling in GT. The decision to choose purposive sampling is that the goal is to select information-rich cases over statistically representative cases (Patton, 2002).
In addition to this, the author implemented, although at a smaller scale, haphazard sampling, or convenience/availability sampling. This means, that the sample cases were chosen because they were easily available. In this study a couple of interviewees were selected through the authors'

network. As Bryman (2013) explain, it is always easier to gain access to data where you are able to use existing contacts, such as a friend, relative, co-worker and so.

Initial contact was done via email where the researcher presented herself, the aim of the study and the time-slots for the conduction of the interview. She also outlined some formalities such as confidentiality, anonymity and consent. Appendix A.
Most companies excused themselves under the justification that they were too busy and/had no time to participate due to the chaotic situation of Covid-19.
In other occasions the author was transferred to other departments that worked more closely with the issue of study.
Overall, the author contacted 45 pharmaceuticals and pharmaceutical packaging companies by email of which only 19 responded. Of this, 11 agreed to participate. Unfortunately, as the time passed, companies started to gradually withdraw their participation, which resulted in a total of 5 companies participating in the study.
Three of the interviews were conducted via Skype or Jabber call, which were recorded and later on transcribed. In only one of these calls, the researchers was not given the consent to record the interview but was given time during the interview to take notes. The remaining two interviews were conducted via video-call which allowed the researchers to note down non-verbal communication that provided additional insights.
Most of the interviews lasted approximately one hour.
Once interviews were transcribed, the researcher sent via email in word-format, the interview transcription and let respondents to review the collected answers to confirm, correct or withdraw their statements. Only confirmation with no data withdrawal was experienced. Appendix B.

Respondent	Company sector	Department	Job Position	Duration	Mode	Date
R1.	Food and Medical packaging	Medical & Healthcare	Segment Lead Medical	65’	Skype call	03/04/2020
R2.	Pharmaceutical	Global Procurement	Director Direct Procurement	55’ 48’’	Jabber video call	14/04/2020
R3.	Pharmaceutical	Global Supply Chain, Case Management	Pack & Text Design Engineer	46’ 23’’	Jabber call	24/04/2020
R4.	Pharmaceutical	Global Supply Chain Processes	SKU Lifecycle Manager	38’ 25’’	Jabber video call	04/05/2020
R5.	Packaging	Global Supplier Quality Assurance	Manager Global Supplier Quality Assurance	1’ 27’’	Skype call	14/05/2020

Table I. *Profile of Study Participants*

2.3.3. Secondary Data

As additional data source, secondary was collected to reinforce the findings. Secondary Data collection consisted of text documents such as sustainability reports, conference reports, journals, and books and e-sources such as pharmaceuticals websites.

The literature search strategy was based on a series of parameters that delimit the inclusion and exclusion of data.

The collection of secondary data for the literature review was performed through a thorough research on search engines and databases, such as, the LUB Search, Copenhagen Business School library access, Google Scholar and Emerald Insights.

Literature sources were usually constrained into academic journals and books, some obtained through digital means and others in paper-based form.

Other sources formats such as business websites, conferences reports and sustainability reports were also included as additional sources of data. Nevertheless, these are highly dependent on the time-specific audience and are given to change due to its online nature. The author considered these factors as potential biases and therefore, analyzed these sources with the highest level of objectivity.

Time of publication was also a constraining element. Only academic journals and books written and published from 2000 on-wards were selected. However, some sources from the 90s and 80s were used when the researcher needed to cite or describe an academic model or theory published in that time.

Despite of these outliers, literature before 2000 was usually discarded as the author considered that the field has developed greatly in the past two decades and literature from several decades ago would be outdated. To provide an updated view of the facts, 2005-onwards was the time constraint of secondary data collection.

The subject areas were mainly *pharmaceutical packaging, packaging, sustainability, sustainability in packaging, sustainable packaging, sustainable pharmaceutical packaging,* which also served as keywords used during the literature search. Additionally, the reference list of every document was reviewed in order to continue the research through a reverse search.

Language of publication was English and there were no limitation as of geographical area, since the aim was to investigate the pharmaceutical packaging industry in a general sense.

2.4. Data analysis

Similar to the data collection process, the author implemented the GT methodology in the process of data analysis.

In doing so, the author adopted the principles of both schools, the Glaserian from Barney G. Glaser and the Straussian from Anselm L. Strauss .

On one hand, the creativity and openness of the Glaserian approach was adopted to let concepts flow strictly from the data (Mello & Flint, 2009). On the other hand, the author took the guidance and data

analysis steps of the Straussian approach. Therefore this study uses a combination of both schools. In this regard, this study followed the three-steps coding method of Grounded Theory (See below **Figure I**).

Step 1: Open Coding

In accordance to the Glaserian approach, the author lets concepts to emerge organically from the interview transcript and secondary data. The interviews were analyzed line-by-line to become familiarized with the coding process and avoid missing out important information. As codes were emerging the author simultaneously searched for these codes in the Secondary Data to establish relationships. Additional codes also emerged from the analysis of Secondary Data. During this process 51 concepts emerged and a pattern began to develop. For instance on interviewee said that" *the industry is very conservative, so that means that they don't want to change if not needed"* another interviewee said that "*There is no customer request yet about sustainable packaging"* which is coded as *Reactive attitude.*

Step 2: Axial coding

The second step is to find and establish similarities and differences among the codes and group them into categories that explain the emerging patterns. As Goulding (2002) explain, through constant comparison, researchers can identify similarities and different between participants that increase the categories' explanatory power. In the previous example, the code *reactive attitude* and *rooted in tradition* are categorized as *Conservative Industry.*
Since the author is constantly going back and forth in the data analysis to find patterns and themes, the author is therefore following an abductive process for theory development.

The steps of Open coding and Constant Comparison correspond to Chapter 4: Empirical Finding. In this chapter, only the codes and categories are presented without analytic inputs.

Step 3: Selective Coding

Axial coding helps to get a more elaborated conceptualization analysis (Goulding, 2002). In this step, that correspond to Chapter 5: Analysis of Empirical Findings; the author establishes the relationship among concepts for the emerging of a new theory. It specifies the conditions and the context that gave rise to the categories.
For instance, in this study interviewees referred to sustainable packaging as not workable in the pharmaceutical industry; others said that recycling is very difficult with medicinal products. Thus, these comments were related as the perception that *sustainable packaging is not feasible in this industry.*

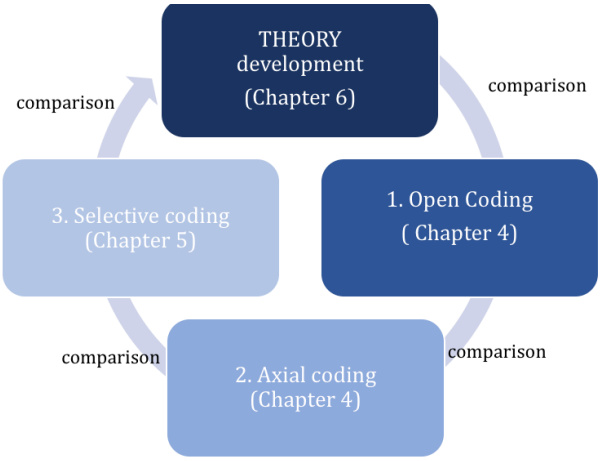

Figure I. Data Analysis Process Following Grounded Theory.

2.5. Data quality, credibility

Data quality can be assessed by simply answering a few questions developed by Raimond, T (1993): *How do I know? Will the evidence and my conclusions stand up to the closest scrutiny? How do I know that the results of my study have resulted in potential risks in the packaging logistics?*

Raimond, T (1993) explained that you cannot never know 100 percent, but you can reduce the possibility of getting the answers wrong. This is why good design is important.

Data quality and credibility is assessed in this study in terms of Reliability and Validity.

Reliability refers to the level of replication and consistency of the study. *If this design was to be replicated in X years' time, will the research design work? Will I get the same findings?*

This study follows a standard process of academic research, therefore it is considered highly reliable since future researchers will be able to copy this study research design while still getting the same findings.

Validity refers to how appropriate the measures used are, how accurate the analysis was and the level of generalizability of the findings., i.e. *Do the measures used to assess the phenomenon actually measure what they are intended to?*

Validity can be further assessed by the level of internal validity and external validity.

The former one refers when a research accurately demonstrates a causal relationship between two variables, e.g. plastic waste being the cause of wrong plastic disposal.

The latter one refers to the level of generalization, i.e. *Can I generalize my findings to other industries with the same research problem? For instance, can I apply my findings on the fashion, electronic or food industry?*

In this regard, this study is considered of a moderate validity. The pharmaceutical industry has certain features more "sensitive" than others, and these sensitives features prime over others in the results. For instance, cold-chain control is a feature rooted in pharmaceutical and not in fashion. Therefore, it is assumed that the findings of this study can be generalized to a moderate scale.

Additionally, the author validates the quality of primary data through triangulation and participant validation.
Triangulation consists of using more than once source of data and method. As explained above, this study performs a multi-method in the form of secondary data and semi-structured interviews.
The downside of member validation is that interviewees might withdraw certain answers as they become fearful or uncomfortable with the level of confidential information shared during the interview (Cayla & Arnould, 2013). Nevertheless, answer withdrawal was not experienced by any of the four respondents of this study.

2.6. Ethical considerations

Ethical concerns have been considered throughout the research process.
In the context of research, "ethics refer to the standards of behavior that guide your conduct in relation to the rights of those who become the subject of your work or are affected by it" This study considers a series of ethical principles developed by Saunders, Lewis, & Thornhill, 2015 (2015) for the research field.
The researcher has at all times held a high level of integrity and objectivity during data collection and analysis, this means that the author analyzes the data with no personal judgements nor preconceptions, so accuracy of the findings is preserved.
Similarly, interviewees have been treated with respect, and with no intention to cause any harm (non-maleficence). In this regard, interviewees' rights of privacy, anonymity and confidentiality are 100 percent assured.
Additionally, the researcher has always asked in a polite and respectful manner for the consent of the interviewers to conduct this study with an advance explanation of the study in matter. The follow-up questions that arose from the open-ended interview did not incite intrusive nor harassing comments.

3. THEORETICAL FRAMEWORK

Following the GT approach, the author firstly explored former research papers in the area of packaging and sustainability to confirm the research gap and shape the RQs. This theory of frame serves as a precedent for the present study.
Like that, this chapter presents what is understood for Packaging, its function, emphasizing on the function of Sustainability. Lastly, it presents the legislation regulating the sustainable demands of packaging designs.

3.1. Packaging

3.1.1. Definition

Packaging is defined as the "processes and materials (such as glass, metal, paper or paperboard) employed to contain, handle, protect, and/or transport an article" (Business Dictionary)..
Packaging is often perceived as an add-on cost to the product. On the contrary, Azzi et al., (2012) proposes to look at it not as a cost, but as value-added activity that can help companies to save on costs and improve business performance.
If no attention is given to packaging design, several problems can arise, such as failure to protect the product, over-packaging, loss of customers & sales and consumers dissatisfaction derived of unmet consumer's needs.
Some consider packaging as a socio-scientific endeavour with the potential to impact consumers purchasing decisions and everyone around them. Even tough functionality comes first during Packaging design, so does the influential role of Packaging in social contexts.
Likewise, packaging is defined by Bix et al., (2004) as one element of the promotion mix that influences consumer perceptions of tangible and intangible product characteristics and consumers buying behaviour.

3.1.2. Packaging levels and materials

Packaging is better understood if viewed as a system that compromises several levels or hierarchies. Primary packaging or consumer packaging is the container in contact with the actual product. This one is preserved or contained in a Secondary packaging (or transport packaging) which is in turn assembled with more of the same kind in the Tertiary packaging, such as a pallet or roll container. As Holmberg (2000) explain, these three levels or hierarchies are to be jointly and not separately assessed during the design of new packaging systems. Their suitability depends on each other. Additionally, the composition of the different packaging levels depend on the function they are designed to fulfil, i.e. the requirements of the filler and retailer as well as the distribution of the packaged product to the point of sale (Markwardt et al., 2017) .

Packaging can be manufactured using different materials, such as paper, metals glass and plastic, this one corresponding to the material with the highest likelihood of increased use.
To narrow down the scope of this study, plastic is the only packaging material under research in the current paper.
Particularly, plastic is the preferred material for almost all products due to the high level of protection and preservation, waste prevention, easy transportation and sustainable nature. Nevertheless, the sustainability feature of plastics is an area of high dispute. The sustainability aspect of plastics relies on the way it is handled, it can cause major polluting effects and damage not only the environment, but also the society and even the economy.

Packaging can be made of seven different types of plastic: polyethylene (PE), polypropylene (PP), polyvinyl chloride (PVC), polystyrene (PS), polyethylene terephthalate (PETE), polycarbonate (PC) and polyamide (PA) (Lockamy, 1995).

3.1.3. Functions of Packaging

In regard to the functions that Packaging designs must meet, several research papers mention different factors and others elaborate on previous research; Lockamy (1995), Azzi et al., (2012) and Lee & Lye (2002) include the functions of containment, protection, safety, convenience and communication/marketing. Lockamy (1995) and Lee & Lye (2002) elaborate further into the factor of unitization for transportation and storage capacity. Whereas Azzi et al., (2012) emphasize on the factor of Logistics and Sustainability.
In any case, all papers emphasize on the wide array of economic savings and business potential that companies can benefit from if packaging is designed at its fullest.

As any other packaging material, eight factors can define the functionality of plastic packaging. Plastic is a highly durable material, which in Packaging plays the role of a physical shield that protects the product from e.g. mechanical shock, vibration, compression, temperature etc. Likewise, it serves as a barrier protection against external factors such as oxygen, water vapor, dust etc.

These protective features of packaging are highly related to the need to ensure the security or safety of the product and mitigate potential risks during shipment, such as the risk of package pilferage, theft and resale of products. Anti-counterfeiting technologies can be used in the packaging such as authentication seals and security printing that indicate that the package and contents are not counterfeit. Dye-packs, RFID tags or electronic article surveillance tags are commonly used to prevent retail loss of sales or products (Lockamy III, , 1995).

Additionally, plastics are light weighted materials, which facilitate and speed up transit handling and lower the costs of manufacturing and shipping services. Plastic packaging allows small objects to be grouped together in one package instead of being separately packaged, which would take double of the space capacity than it would do in bundles. Therefore, plastic packaging allows containment or agglomeration for storage and handling efficiency.

Besides that, packaging has the role of communicating via labels how to use, transport, recycle or dispose of the package and product.
Similarly, P&L can be used as a marketing tool that displays marketing elements to enhance the product's image and visibility, attracts consumers to the product and eventually persuades them to purchase it (Prendergast & Pitt, 1996).

Equally important is the function of convenience. Packaging is to consider ergonomic features of human disposition *inter alia* usability for left-handed people, children, elderly people or people with disabilities (Langley et al., 2005). The versatility of plastics allow packaging formats to be shaped in different forms to ease its handling and usage.
In this sense, plastics facilitates products apportionment or portion control, since plastic packaging can be adjusted to the size of the product.

Furthermore, Azzi et al., (2012) adds on the packaging function of sustainability, a function that is nowadays highly contested in regard to plastic packaging.
Consequently, they explain that plastic is a sustainable material since it allows packaging to last longer, and it protects the packaging without the need of other reinforcing material.
On the contrary, plastics are considered unsustainable when they are wrongly disposed of after use.

Motivated by this global controversy, this study examines in more detail the sustainability and unsustainability features of plastic in packaging designs.

3.2.Sustainability in Packaging

The Sustainable Packaging Coalition or SPC (2011) defined sustainable packaging as packaging that is beneficial, safe and healthy for individuals and communities throughout its life cycle, as well as packaging that meets consumers perceptions, behaviors an habits (Nordin & Selke, 2010) and that it is sourced, manufactured, transported, and recycled using renewable energy.
Hanssen, et al., (2017) amplifies the scope of this definition by including the need to consider the size of the packaging in relation to the amount of product that it is actually consumed.
Furthermore, Kozik (2020) emphasizes in the new features of recyclability and waste avoidance of sustainable packaging.
Similarly, the European Organization for Packaging and Environment does not use the concept of "sustainable packaging" but "packaging design that contributes to sustainable development" (Europen, 2011).

To ease the implementation of Sustainability in business practices, the British consultant J. Elkington (1998) developed a framework, known in academia as the Triple Bottom Line (TBL), formed by the economic, social and environmental pillars of sustainability. Inspired by the TBL, Lee and Xu (2005) explain that the key to sustainable packaging is to adopt a more wide-ranging integrated approach where packaging is assessed throughout its lifecycle or Life Cycle Assessment (LCA) , whilst considering economic, social and environmental aspects.

According to this, sustainability can be compromised of a circular economy of closed loops where the three pillars of sustainability (economic, social and environmental) are constantly assessed throughout the stages of the product's life-time.
Plastics have a high recyclability potential. More preciously, the light weight nature, flexibility and durability of plastic, make it an effective material for packaging designs. That is why over one third of plastic material demand is used for plastic packaging designs (PlasticsEurope, 2016).

Plastic packaging, mostly Single-Use, has a short-life cycle that ends once the product is consumed. Therefore, plastics can be easily recycled after use, however, the reality is that only a small percentage of plastic packaging production, approx. 14% is recycled in a global scale (Ellen MacArthur Foundation, 2017).

In the packaging area, environmental footprints are by far the most discussed in academia.
As Lee & Xu (2005) explain, plastic is a sustainable material, what makes it unsustainable is the way it is treated after use. The main problem of plastic is that it does not degrade as fast as other materials and if it is not properly disposed of, it decomposes into tiny particles that pollute the eco-system.
Additionally, Plastic packaging is mostly designed for single-use which ends up either in landfilled, or incinerated, each of which produces vast amount of greenhouse gas emissions. Amongst the most polluting processes, landfilling is the method emitting the least greenhouse gasses, while incineration emits extremely high levels of greenhouse gases and it is, unfortunately, the method generally performed (CIEL, 2019).

Researchers propose to tackle plastic pollution by handling plastic packaging in a more sustainable manner and/or replacing plastic for a more sustainable material.

In this regard, the authors Garcia-Arca & Prado Prado (2008) propose to reuse, recycle and recover plastic components at the end of their life span (reverse logistics). However, this is a reactive attitude towards pollution. On the contrary, Dickner (2012) proposes a more proactive attitude that goes beyond reverse logistics. He appeals to reduce the environmental effects of direct logistics, i.e. the renewable and non-renewable resources, waste, emissions and pollution created (Verghese & Lewis , 2007) during the production, distribution and commercialization of packaging.

In regard to a more sustainable material, manufacturers are looking for new packaging solutions made of, e.g. biodegradable or renewable materials (Kozik, 2020). However, Almeida et al., (2017) agrees with Lee and Xu (2005) on LCA and argue that the solution is not to merely replace these materials with more eco-friendly ones. The key is to assess these components' life cycle and improve those areas that do not meet the sustainable requirements (Kozik, 2020).

In this sense, LCA can be used to study which materials are least harmful to the environment and compare the environmental impacts of different disposal methods (Almeida et al., 2017).

In regard to the economic pillar, economic sustainability is defined as "practices that support long-term economic growth without negatively impacting social, environmental and cultural aspects of the community".

In this regard, researchers explain that sustainable packaging designs allows businesses to save on costs and increase profits (Tolinski, 2009).
As mentioned, Single- Use Plastic Packaging is meant to be used only once, which means that SUP packaging has a lineal and short life cycle. In this lineal economy, single use plastic packaging are consecutively produced one after another, while utilizing new amounts of energy, power, capital and time.
Nevertheless, these resources could be used at half rate, whilst saving money, if companies where to extend the plastic's life span through a circular flow (or circular economy) of closed loops in which plastic production is reduced, continuously reused and recycled.

Similar to the environmental pillar, Life Cycle Analysis can be also used to assess and prevent the economic losses that packaging generates throughout its life-span. These losses are of a more indirect nature and are usually overseen. Through careful LCA, companies can identify losses generated from complaints or poor handling, warehousing and transportation malfunctions and then, design the packaging system accordingly.

In regard to the last pillar, Azzi et al., (2012) explain that the social aspect is the least developed of the three pillars of sustainability in the packaging area, yet its application is equally important. Social Sustainability is defined by the UN as " identifying and managing business impacts, both positive and negative, on people. The quality of a company's relationships and engagement with its stakeholders is critical. Directly or indirectly, companies affect what happens to employees, workers in the value chain, customers and local communities, and it is important to manage impacts proactively",

The social aspect of sustainable packaging can facilitate recycling, it provides honest, clear and true information, it adapt product use to the needs of specific customers, and it also guarantees safety in product consumption (Vernuccio et al., 2010; Azzi et al., 2012).

Despite of the multiple research papers dealing with sustainability in packaging, Tidy, Wang, & Hall (2016) argued that the packaging industry lacks of adequate training and progress monitoring and suffers from poor consumer awareness and lack of global pressure to adapt green supply chains.

However, it seems that this tendency is slightly changing and what used to be a global advise has now become (in some countries), as a requirement demanded by national law.
The next sub-chapter explains in more detail the most recent regulations pertaining minimization of plastic packaging in the European Union.

3.3. Packaging legislation

The European Commission has classified plastics amongst the five priority areas where progress needs to be made towards a circular economy (EC, 2018).
In the view of the high rates of plastic waste in the eco-system, several authorities have established corporate measures that companies are to obey in time with the attempt to slow down climate change and reduce environmental pollution.
The European Circular Economy Action Plan, the European Directive on Single-Use Plastic Directive and the Extended Producer Responsibility are examples of these corporate measures.

3.3.1. The European Directive on Single-Use Plastic Packaging (SUP)

The EU has taken further steps with the establishment of the Single-Use Plastic Directive (SUP Directive).
An European Directive is a statutory instrument that require all member states to transpose the new legislation into their national legislation in order to achieve a certain legal standard in the Union.

The SUP Directive aims to retain the value of plastic products as much as possible and generate less plastic waste. This Directive will help to achieve the United Nations (UN) Sustainable Development Goal 12 to ensure sustainable consumption and production pattern.
The goal is that by 2030 all plastic packaging placed on the EU market is re-usable or easily recycled.

The Single-Use Plastic Directive contains a thorough list of products mostly found at sea bays and whose producers are to establish a new strategy for alternative plastic packaging by 2024.
For plastic manufactures, the most important issues to bear in mind are:

- European Member States must take the necessary measures to reduce and prevent the consumption of single use plastic products (Art 4).
- Article 5 states that member states must prohibit the placing in the market of products made from oxo-degradable plastic (conventional plastic materials with artificial additivities that do not biodegrade but fragmented into small pieces)
- Article 7 states that certain sanitary products communicated in its labeling the presence of plastics and the negative impact of littering or wrongful disposal.
- Article 8 oblige member states to develop and establish the extension of producer responsibility schemes for certain single-use plastic products.

The above obligations will be binding two years after the ratification of the Directive, this means that European Member States have four years to review their activities and establish a path to compliance with the new single use plastic regime. Violations of this regime will result in significant administrative fines.

3.3.2. The European Scheme on Extended Producer Responsibility

Furthermore, the SUP Directive contains the "The extended producer responsibility" scheme defined as "an environmental policy approach in which a producer's responsibility for a product is extended to the post-consumer stage of a product's life cycle", this means that the EPR follows the "polluter pays" principle.

This regime seeks to shift the responsibility from governments or municipalities to the producers of packaging products and encourage them to consider the environment during product development. The aim is to reduce the environmental impact of products throughout their life cycle.

The EPR scheme has four main statements:

- EPR blames producers of plastic packaging waste and make them to change packaging design that allows recyclability and/or less use of packaging.
- EPR improves the efficiency of recycling programs, which translates into less cost and thus, a benefit to society.
- EPR implements a fairer system of waste management in which individual consumers pay the cost of their own consumption rather than general taxpayers (Reid, Atalay, & Naoko, 2013).

It is worth mentioning that the scope of the above regulations do not directly mention nor exclude certain industries, therefore it is assumed that companies regardless of industrial sector, will have to change their packaging and logistic operations to comply with the above-mentioned requirements. To clarify this aspect, the next chapter presents in more detail the reciprocal relationship between packaging and logistics.

3.4. Packaging in Logistics

Packaging is sometimes studied in academia as a separate disciple either in the area of Marketing Management and/or in the area of Supply Chain.

Nonetheless, packaging is part of a Supply Chain and must be understood as a discipline within logistics. Packaging relevance within logistics is sometimes shadowed.

Garcia-Arca & Prado Prado (2008) recognizes that efforts have been taken to acknowledge the role of packaging in improving the operations of businesses, yet packaging is mostly related to the protection function, whilst omitting its influence outside of this traditional view.

In this context, Lockamy (1995) explains that even tough packaging is sometimes regarded as a non-strategic value discipline, it actually influences the efficiency of the entire supply chain operations and it can influence the level of competitiveness of any business.
Packaging, whether if it is the primary, secondary and/or tertiary, follows the product from the moment it is manufactured until it reaches the consumers hands. Without packaging, there is no product. Therefore, packaging is a central resource in logistics (Jahre & Hatteland, 2004).
During its journey from upstream to downstream logistics, and sometimes, reversely, packaging interacts with other resources, such as equipment, vehicles, warehouses, information systems, products and customers. A change in the packaging design triggers changes in all the resources that it passes through (Twede, 1991).
In the view of the natural link between packaging and logistic operations, Dominic, et al., (2000) developed the concept of "Packaging Logistics", defined as "An approach which aims at developing packages and packaging systems in order to support the logistical process and to meet customers' demands".
Bjarnemo, et al., (2000) re-defined the concept of "Packaging Logistics" to include the added-value feature of packaging in the logistic system. Thereafter, Saghir (2002) proposed a more detailed definition for Packaging Logistics, as " The process of planning, implementing and controlling the coordinated Packaging system of preparing goods for safe, secure, efficient and effective handling, transport, distribution, storage, retailing, consumption and recovery, reuse or disposal and related information combined with maximising consumer value, sales and hence profit".
Therefore, Packaging Logistics is to be understood from a commercial, logistical and environmental approach with the ability to increase business competitiveness.

This thorough definition of packaging logistics is important in this study to clarify that changing conventional packaging for sustainable materials, will not only change the packaging design, but all the logistic processes.

4. EMPIRICAL FINDINGS (Open coding and Axial Coding)

Following with the GT procedure of data collection and analysis, this chapter presents the codes and categories developed from the results of the empirical findings.
Therefore, the chapter presents pharmaceutical packaging design, its different functions, its role in sustainability and lastly, how the EU Directive and EU Scheme is perceived by the industry.

It is important to keep in mind that the results and analysis are presented from the perspective of pharmaceuticals. Therefore, statements and direct quotes from the interviewees and secondary data are included for the reader's reference.

Supporting the Glaser's approach, for the development of theory this chapter focuses greatly on the data and less on external factors. Therefore, the interpretation of the results and emerging theory are developed completely from the analysis of the data collected. Like that, all concepts and findings of this study are grounded on the data obtained from the interviews and secondary sources. Hence, they are not to prove a theory nor to be generalized to a greater theory. Instead the results are to support a substantive theory.

4.1. Pharmaceutical Packaging

The packaging design of pharmaceuticals can be made of different materials depending on the function the packaging is to fulfill. Findings show that pharmaceutical have a general attitude towards changing the material or design of drug packaging. Results also show that in the event of change, the packaging would be exposed to different barriers.

4.1.1. Pharmaceutical Packaging Design

Findings show that pharmaceuticals attitude towards changing packaging designs can be summarized as "Conservative industry", "Change reluctancy", and "Profitability"

Table II presents these categories with their different codes and provides examples of quotes that emerged through de data analysis process.

These categories and their different codes are here-in explore:

Categories	Codes	Quotes *(from interviews and secondary data)*
Conservative Industry	• rooted in tradition • change reluctancy	○ *it has always been like that* ○ *not too much has changed* ○ *the machines are specific for plastic packaging* ○ *I don't think production colleagues will be happy to work with less thicker materials (…)*
Customer centric Approach	• Reactive attitude	○ *we don't want to change if not needed* ○ *our customers need to deal with it*
Proftability	• Forecasting activities • Long bureacratic procedures • Costly operations	○ *lets say we have a number of years data, that helps to secure how to launch a new product* ○ *we need to do a lot of clinical studies* ○ *we need to reguster the new design in every country, separate.y, and that costs a lot of money*
Sustainability in 1 and 2 packaging		○ primary packaging (…) it is never going to be recycled, it's going to be burnt, in the ground ○ if primary packaging is in direct contact with the drug then it cannot be sustainable, and there are rules about how to destroy it

Table II. *Results from the Grounded Theory Data Analysis in regard to pharmaceuticals attitude towards changing pharmaceutical packaging design.*

Pharmaceutical packaging is composed of different levels and materials.
Primary packaging is the material that holds the medicinal item and has a direct effect on the medicines shelf-life. Primary packaging can be seen in the form of vials, prefilled syringes, IV containers, powders, pastilles and liquids, all of them made of plastic except ampoules, which are contained in glass containers (Nityanand et al., 2013).
This is further assembled in the secondary packaging, which is the outer packaging used to assemble primary packaging in e.g. cartons, boxes, shipping containers or injection trays.
Lastly, the tertiary packaging system in the form of barrels, containers or shipping cases are used for bulk handling and shipping.

- *Conservative industry*

  In this regard, the interviewees explained that the reason to use these materials for pharmaceutical packaging resides in the tradition and standardized *modus operandi*. An Interviewee defined the pharmaceutical industry as conservative, which does not implement changes unless required in solid grounds.
  Another reason to avoid changing packaging materials is that production sites have to be changed accordingly to the new materials specification, something that manufacturers are not especially keen on doing.

- *Customer-Centre Approach*

  It also seems that the industry is in this respect slightly reactive to customer needs. Interviewees recognized that changes can be done only if customers request them upfront, but no proactive changes seem to take place due to the complexity of operations.

- *Profitability*

  Changing materials will demand a great number of clinical and stability studies to test the adequacy of the new materials. Similarly, Johnson & Johnson explained that packaging regulations are different in every market and these different designs considerations may involve trade-offs, such as fear of damaging the product or breaking regulations.
  Additionally, the design of a new packaging system entails a long bureaucratic procedure where the packaging container, closure and labeling must be registered at the expense and inconvenience of some manufacturers (Blatha, 2018).
  Once the packaging design is market authorized, patent protection applies. However, a patent is obtained at the early stage of R&D, which means that once market authorization is given, a short time remains before the patent expires. Once this happens, competition launches generic drugs whilst dragging prices down, resulting in less profit for the drug founder. Hereby pharmaceuticals are greatly focus on reducing the Time-To-Market (TTM) to prolong profits under patent protection (Reinholdt, Hansen, & Grunow, 2015). Using past data from the existing procedures for forecasting is another reason identified by the interviewees.

- *Sustainability in Secondary and Tertiary Packaging*

Nevertheless in an interview made by the magazine NS-Healthcare to Johnson and Johnson, the US multinational explained that "In the pharmaceutical sector we can do more with secondary and tertiary packaging because it is less tightly regulated than primary packaging" (NS Healthcare, 2014).

Respectively, half of the interviewees emphasized that sustainable packaging in primary packaging will never happen, since primary packaging is in direct contact with the medicine itself and a sustainable material might jeopardize the drug effectiveness.

4.1.2. Functions of Pharmaceutical Packaging

Pharmaceutical packaging as any other product design, is to comply the functions outlined in section 3.1.3. All these functions have to be particularly considered when dealing with pharmaceutical products. However, findings show that pharmaceutical prioritize certain functions over others during packaging design. Their choices are grounded in the challenges regularly faced by the industry. As illustrated in **Table II**, the main function that pharmaceutical consider can be summarized as "long-shelf life and multiple handling" , "patients priority", "convenience & ergonomics". The challenges faced by the industry can be named "Drug recalls" and "counterfeiting".

Categories	Codes	Quotes *(from interviews and secondary data)*
Long-shelf life & multiple handling	• Containment • Long storage handling	○ *The containment function is responsible for restraining the contents of a package (Lockamy, 1995)* ○ *30-80 % of stock is for annual demand* ○ *4-24 weeks stock shelf life.* ○ *multiple stock turns (Shah, 2004)*
Patients priority	• Protection • Safety	○ *For (company) is that the patient gets better with the medicine and if we have to use plastic for that, then we don't think it twice.*
Drug recalls	• Dedicated R&D personnel • Multiple of quality checks during the supply chain • Sample inspection	○ we use dedicated R&D people for pharmaceuticals, who run in different machines different tests. ○ *we run Q&A inspection at every stage*
Convenience and ergonomics	• child – senior friendly • multiple handling	○ *patients killed ue to poor diligence on P&L (Kenagy & Stein, 2001)*
Counterfeiting	• Long pharmaceutical Supply Chains • Low visibility of operations	○ The extensive Pharmaceutical Supply Chain circle the globe multiple times, offering several points of leakage into the legitimate drug Supply Chain (Kapoor, Vyas, & Dadarwal, 2018).

Table II. *Results from the Grounded Theory Data Analysis presenting the most important factors of pharma. Packaging design.*

- *Long shelf-life & multiple handling*

The containment of the product is the most essential function of pharmaceutical packaging. The packaging must not leak, nor allows the diffusion and permeation of the product (Lockamy, 1995).

Consequently, pharmaceutical packaging is to protect the medicine against external factors such as light, moisture, oxygen, biological contamination, mechanical damage and counterfeiting.

This is highly important during the storage and shipping of pharmaceuticals.

Shah's study (2004) explains that the stock level of medicines amount to 30-90 percent of annual demand and finished goods are in stock for around 4-24 weeks.

Additionally, stock turns are usually between 1 to 8 and supply chain cycle times between 1000 and 8000 hours. This means that packaging must support the medicine to last a long shelf-life and storage handling. An interviewee mentioned that shelf-life is paramount during packaging design. Medicines are not consumed right away, some are to last minimum 5 years.

- *Patients priority*

Moreover, pharmaceutical packaging is to ensure and protect the safety of patients by containing the right labelling. Therefore, the communication function (labeling) in packaging plays a crucial role in ensuring the safety of patients. Labelling gives identity to the medicine and provides patients with the medicine strength, dose, route and contraindications (Chirag et al., 2012).

The consumers of this industry are patients with some sort of sickness which can consequently hinder them to properly read or identify their medication. This is why labelling and packaging of medicinal products require special attention to help patients to intake their medication.

Wrong labelling or packaging can hinder difficulties in e.g. opening containers, mix-ups between medicines due to similar appearance and unclear wording (Ward et al. 2010).

- *Drug recalls*

To avoid drug recalls, pharmaceuticals implement laboratory simulation to test the adequacy of packaging systems (Xiang & Eschke , 2004). Interviewees mention the technique of sampling as another method to ensure high quality packaging systems. Sampling is used to check that the label, packaging material or container reference are correct as well as to detect adulteration of the medicinal products.

Despite of the quality assurance techniques, local authorities have the right to force pharmaceutical companies to change the labels or leaflets if they are considered misleading and wrong wording. If changes on already packaged medicines are needed, firms are to

scrap all the packages and start the process again, since the industry does not allow re-packaging.

Nevertheless, the interviewees affirmed that this seldom happens, since the industry uses well-developed techniques and strict procedures to prevent these sort of errors.

- *Convenience and Ergonomics*

Moreover both physical and cognitive ability of patients are to be equally considered during pharmaceutical packaging design (DTI, 1999).

The Institute for Safe Medication Practices (ISMP) estimated that around 10.000 patients are injured or killed every year due to poor diligence on labelling and packaging (Kenagy & Stein, 2001).

Pharmaceutical packaging must be designed in a way that facilitates the use or administration of the product. For instance, a unit dose of eye drops is to administer only a single dose at a time in order to eliminate the need for preservative and reduce the risk of cross infection.

- *Counterfeiting*

Furthermore, special attention during pharmaceutical packaging design must be given to the threat of counterfeiting.

Packaging counterfeiting consists of producing pharmaceuticals packaging similar to the original and selling the fake one as authentic products. Counterfeiting can be experienced as duplicates of labels, packaging, products or instructions, substitution of the authentic product for invalid or reused packaging (Nityanand et al., 2013).

The researchers Degardin & Roggo (2015) explain that "In case a bulk of medicine has been stolen and repacked or reused after expiration, the careful analysis of its packaging is almost the only indication of manipulation and/or counterfeiting".

Unfortunately, the nature of pharmaceutical industry is a favourable market for counterfeiting. The extensive Pharmaceutical Supply Chain circle the globe multiple times, offering several points of leakage into the legitimate drug Supply Chain. Moreover, there is limited visibility of movement of inventory and stocks, which make it all an incentive for criminal activities (Kapoor, Vyas, & Dadarwal, 2018).

As seen in sub-chapter 3.2. sustainability is another function of pharmaceutical packaging. Likewise, sustainability in pharmaceutical packaging is here-by explored deeper in the next sub-chapter.

4.2. Sustainability in Pharmaceutical Packaging

As previously seen in chapter 3, packaging can be also sustainable if correctly treated, what makes it unsustainable is how plastic packaging is handled after consumption. In this regard, the author investigated the unsustainable practices of the pharmaceutical packaging with the use of the three pillars of sustainability.

The different pillars serve as core categories which contain more specific categories and codes explaining the unsustainable and sustainable practices of pharmaceutical packaging.

4.2.1. Environmental Pillar

As **Table III** presents, pharmaceutical packaging waste come from "Wrongul Storage" and "Wrongul disposal".

In an attempt to mitigate this waste, results show pharmaceutical greatly focus on the environmental side of sustainability and less on other areas. Their environmental sustainable initiatives are based on "circular economies" and "across-department collaboration". However, these activities entail several threats such as "lack of coordination with the legislation", "temperature variation", "dependency on other countries' infrastructures", "lead time" and the use of "counterproductive materials"

Core categories	Categories	Codes	Quotes *(from interviews and secondary data)*
Unsustainable practices	**Wrongful storage**	• dust and within reach of children	○ Martins et al., 2017
	Wronful disposal	• sewage syste • incineration • landfill	○ Jaseen, Kumar, & John, 2017
Sustainable practices	**Circular economies**	• close loops: reuse, redesign, reduce	○ *Obtained from company website analysis* ○ *we try to re-walk the materials back to the line*
	Across-department collaboration	• merge food and pharmaceutical sectors	○ *I can say that most development in the food will slowly move to the pharmaceutical*
Challenges	**lack of coordination with the legislation**	• PVC blisters	○ We are also looking for the holy grail of pharmaceutical packaging, which is the replacement of PVC blister packs for tablets – by J&J
	temperature variation	• multiple hand-offs • long custom procedures	○ *temperature excursions, customs delays, packaging breakdowns, incorrect shipping, and packing choise are all risks inherent in todayøs globa logistic markets* (Markarian, 2015)
	Dependency on countries infrastructure		○ "methods used for controlling the temperature cannot always be viable at the destination due to lack of infrastructure, the producers need to invest in packaging that is independent of the physical facilities (Lee & Xu, 2005)
	Lead time		○ yes, we are re-shuffling, we are looking to not only buy local for local, but sell local for local. This is to reduce the footprint the transport and time. That's why we have three main plants is in EU, US and India.
	Counterproductve materials		○ use more plastics to packaging the pallets, so that's counterproductive

Table III. *Results from the Grounded Theory Data Analysis illustrating the current (un) sustainable practices of pharmaceutical and their challenges from an environmental approach.*

- *Wrongful Storage*

Despite of the different measures that pharmaceuticals undertake to preserve the packaging and medicines in good condition, it has been evidenced that these measures are not that strictly taken by consumers.

A study made by Martins et al., (2017) shows that 76 per cent of medicines are inadequately stored at the consumers households. More preciously, 10 per cent of medicines are also

exposed to sunlight, 23.6 percent is in the presence of dust and stored within reach of children.

- *Wrongful disposal*

It has been estimated that when patients get rid of unused medication, 91 percent disposes them of into the environment through the sewage system.

In addition to this, polluting pharma packaging is also that unused packaging that is never consumed and then scrapped. Unused medication indicates that some time, money and human resources have been wasted during the production and distribution of these unused medicines.

All the above is known as pharmaceutical waste since resources have been utilized at zero value.

Pharmaceutical waste is defined as the "unwated materials which can no longer be used in the manufacturing processes that can eventually turn into hazardous or non-hazardous material, to humans/environment". It can be i.e. expired medicines, discarded medication, contaminated garments or open containers of drugs that cannot be used (Jaseen, Kumar, & John, 2017).

Even when pharma packaging items are properly discarded, they continue to pollute.

Most of medical packaging items are disposed of by landfill, partly because the contaminants are difficult to separate and they create complications in recycling.

Furthermore the incineration of pharmaceutical packaging requires high temperature incineration levels to minimize the risk of pharmaceuticals entering the environment (Kale, et al., 2007).

- *Circular economies*

In the view of these facts, Leaver (2008) explain that the pharmaceutical industry is highly pressured by stakeholders to become more environmental friendly.

Companies such as Swiftpak (2019) and MedicoPack explain that plastics can be sustainable through recycling processes. Other companies opt to replace plastic for more sustainable materials.

Older plastics such as PVC are being replaced with newer and more efficient materials such as crystalline and biologically derived plastics (Bauer, 2009).

A thorough review of 5 different packaging pharmaceutical companies reveal that the UN Sustainable Goals are present in their cultures. It seems that circular economies where resources are constantly reused and reduced to mitigate CO2 emissions are the main sustainable initiatives undertaken by companies.

In this respect, one of the interviewees confirmed that his company has implemented close loops operations in order to avoid the creation of plastic waste. In these close loops, materials are constantly reduced, reused and recycled. Similarly, another interviewee

explained that his company's sustainability strategy is based on returning the waste to the production line for further process, working with recycling companies to whom delivery waste for further recycling into low quality products and in a very small percentage, disposal of waste into in landfills or incineration.

On the other hand, half of the interviewees did not know where their company stands in regard to plastic waste.

Other pharmaceuticals such as AstraZeneca has launched a blister laminate that reduces waste, a mail-back pilot program to collect used inhalers, and initiatives to prevent pharmaceuticals from contaminating the environment (Forcinio, 2020).

In like manner, Johnson & Johnson (J&) has designed its sustainability strategy in five pillars that involve reducing material use by decreasing packaging size and packaging thickness, using packaging materials with more recycled content, selecting materials that have already been recycled, purchasing responsibly sourced packaging materials and increasing consumer awareness.

Equally, in an interview with NS Healthcare (2014) J&J explained that sustainability in pharmaceutical packaging is all about two main questions: (1) how to use less packaging while ensuring product integrity, and (2) how to use more sustainable materials in packaging. Given that patients safety and medicine integrity are always number one priority.

- *Across-department collaboration*

To solve the above inquiries, the company mirrors the innovations from the consumer good market and evaluates their feasibility for the pharmaceutical sector. Like that, J&J has already minimized space, improved packaging efficiency and maximized the use of recycled materials while still considering the ergonomics with "easy-to-use" packaging designs.

Further, J&J explained that any sort of innovation takes time and money in the pharmaceutical space. Looking into consumer good markets is a good path to speed up the process.

Comparably, one of the interviewees explained that his company has prospects to merge the food sector with healthcare and work together to develop feasible sustainable packaging.

Opposite to this, some interviewees argued that plastics used in the supermarkets cannot be compared with healthcare, since both sectors have different regulations and requirements.

- *Lack of coordination with the legislation*

Nevertheless, the company argues that in this free space of innovation, there is still one enigma to be cracked: to replace PVC blister packs for tablets.

Europe is a market promoting sustainable packaging initiatives, yet, EU regulations demand unit-dose packaging, which drives greater use of blister packs. Blister packs are not only more expensive than bottle packaging, they are also not recyclable.

- *Temperature Variation & complex operations*

Despite of all the above improvements, companies also shared the downsides of sustainability in packaging.

In regard to the need to preserve temperature levels, the global pharmaceutical network PharmaTech (Markarian, 2015) explained that the shipping of pharmaceutical products involves long, complex routes and demand temperature-controlled environments to ensure the continuity of the cold-chain. At present, temperature control is challenged by customs delays, packaging breakdowns, incorrect shipping and wrong choice of packaging. Besides this, from point A to point Z, the medicinal cargo and the cargo custody is handed over to many parties, which increases the likelihood of temperature deviation. Consequently, the global supply chain is to comply with the custody procedures of each country the cargo is shipped through, some procedures are slower than others, such as those outside of North America and Europe.

Furthermore, unexpected events like mechanical issues, labor strikes, or extreme weather might hinder the smooth transit of medicines across countries.

- *Dependency on countries infrastructure*

In the same fashion, an interviewee explained that there are some countries who do not have the facilities to preserve the right temperature control nor have any sort of recycling processes in place.

Besides that, when shipments are executed in countries where it cannot be guaranteed the integrity of cold-chains, shipping methods such thermal blankets for pallets are used against sunlight, humidity and tarmac heat. But these alternative methods cannot always be guaranteed. Lee & Xu (2005) explain that "methods used for controlling the temperature cannot always be viable at the destination due to lack of infrastructure, the producers need to invest in packaging that is independent of the physical facilities".

- *Lead time*

One of the interviewee also mentioned that they are thinking of shipping through sea or road instead of air freight, to become more environmentally friendly. Yet lead time is a challenge as air freight allows to delivery at a higher speed. In like manner, another interviewee explained that his company is working on buying more local and selling more local to shorten lead times and thus, decrease time & costs and mitigate environmental pollution.

- *Counterproductive sustainable materials*

Another downside identified by one of the interviewees is that with a more biodegradable packaging during long ocean transit with a lot of moisture, packaging would degrade faster as with ordinary packaging. To prevent this, they would need additional materials, most likely, plastic, to avoid damaged goods. Another interviewee revealed that virgin materials tend to be stronger than recycling materials and the company cannot risk damaged

medicines simply to become more environmental friendly during transit.

4.2.2. Economic Pillar

In a second phase, findings show that pharmaceutical attempt to focus on the economic aspect of sustainability, yet the economic focus is much lower than the environmental pillar.

As presented below in **Table IV**, in order to act more economically friendly, pharmaceuticals employ the use of technology. But, findings identified several economic challenges derived of sustainable pharmaceutical packaging. These challenges are "low efficiency", "single-sourcing", and "local sourcing"

Core categories	Categories	Quotes *(from interviews and secondary data)*
Unsustainable practices	**Low economic focus**	*obtained from companies websites*
Sustainable practices	**Use of technology**	*the leaflet inside each packaging, people can find everything online.*
Challenges	**Low efficiency**	*the OE overall would be lower with green materials.*
	Single-Sourcing	*nowadays sustainable materials are less available, which means that there are limited sources, so prices will likely be higher and it will also be complicated to obtain them.*
	Local Sourcing	*yes, we are re-shuffling, we are looking to not only buy local for local,but sell local for local. This is to reduce the footprint the transport. That's why we have three main plants is in EU, US and India.*

Table IV. Results from the Grounded Theory Data Analysis illustrating the current (un) sustainable practices of pharmaceutical and their challenges from an economic approach.

- *Low economic focus*

Only one of the interviewees seemed to have a slight economic approach towards sustainability, whilst sharing that "we are trying to become more green, to get a green mindset, something more economic, maybe less sophisticated" .

Pharmaceutical waste has financial consequences, in 2011 it was estimated that 42 percent of prescribed medication in the USA was never used, which resulted into 117 billions of US dollars wasted (Law et al., 2015). In the same fashion, 250 GBP were wasted in England in 2008 from scrapped unused medicines (Health, 2010).

- *Use of technology*

One technique discovered in one company's sustainability report was the term Industry 4.0, this means the use of digital processes to optimize all sort of areas. In an interview made by the magazine NS Healthcare (Blatha, 2018) to Abbot Laboratories, the company explained that it uses software programs and 3D printers that analyze smarter design and manufacturer processes. Like that, the company acts sustainably by re-designing packaging to weigh less, whilst requiring less storage and thus, maximizing profits. In like manner, one interviewee mentioned that sustainability requires freeing storage space and capacity. Besides having space for stock, the company has extra space for the recycling materials that

recycling companies pick up once a week for further processing. The challenge is this case is to have enough space for the stock and recycling materials. Still the company confirms to manage well both by establishing different frequencies for the pick-up of recycling materials.

- *Low efficiecy*

Conversely, one of the interviewee explained that due to the low familiarity with sustainable materials, in the beginning the production function would experience a low Operational Efficiency (OE). Further, he explained that his company should change their mindset and think more of the Total Cost of Ownership. Sustainable material are longer lasting than plastic components and easier to recycle, but with higher purchasing costs. Therefore companies should not only to think of the initial costs but the savings generated in the long run.

Another interviewee revealed that lead time is not an area of concern during production, but product availability. In the event of e.g. an hurricane, "for us it is more important to have the product available, the term of lead time is not important [...] we prefer supply safety and make sure production is not interrupted"

- *Single-sourcing*

Another economic downside identified by one interviewee is that there are not many suppliers that procure sustainable materials, therefore they will have to rely on a few players, who would most likely increase raw materials prices due to the low market availability. It will also be difficult for the procurement functions to make sure that those suppliers are 100 percent sustainable, since the concept of "sustainability" is new in pharma.

- *Local-sourcing*

On top of this, he elaborated that his company will most likely change to suppliers based in EU instead of suppliers from e.g. India or China. Despite of the potential increase on raw material prices, the company will be sure that the materials have been produced according to the Good Manufacturing Practices, whereas suppliers from outside Europe might not have taken any sort of Waste Management processes.

4.2.3. Social Pillar

As the least developed, pharmaceuticals barely focus on the social responsibility side of sustainability. Still, patients safety and protection is one number one priority. **Table V.**

Core categories	Categories	Quotes *(from interviews and secondary data)*
Unsustainable practices	**Low focus on social responsibility**	*Obtained from companies website analysis*
Challenges	**Patients priority**	For (Company) is that the patient gets better with the medicine and if we have to use plastic for that, then we don't think it twice.

Table V. Results from the Grounded Theory Data Analysis illustrating the current (un) sustainable practices of pharmaceutical and their challenges from an social approach.

- *Low focus on social responsibility*

Azzi et al., (2012) explain that pharmaceutical packaging is to consider the different ergonomic features of everyone involve in the value chain, including healthcare practitioners. Packaging design improves workers' productivity as well as to protect patients health. On the contrary, serious consequences can occur.

- *Patients priority*

The interviewees explained that the risk of substance migration and Product Integrity were the most challenging factors in sustainable packaging. The safety of patients has to always be number one priority, despite of the packaging material used.

As presented, sustainability in packaging not only brings advantages to the environment economy and society but it also generates several pitfalls that have to be overcome by pharmaceuticals.
Yet the advantages weight more and, as seen in chapter 3.3. and 3.4, what it was a mere recommendation has become a requirement at the Union Level.
The next sub-chapter presents how pharmaceuticals foresee that the Single-Use Plastic Directive and EU Scheme on Producer Responsibility will influence their operations in the European market.

4.3. Packaging Legislation

Knowing that pharmaceuticals were already implementing sustainability in their packaging design and processes, the researcher was interested to investigate how much they knew in regard to the latest regulations targeting packaging designs made of plastic.
In this respect, two categories were identified from the respondents arguments: "Low Awareness" and "Low Feasibility".

Categories	Quotes *(from interviews and secondary data)*
Low awareness	*You are the 1st one really mentioning it* *I don't know* *I have not heard of it*
Low feasibility	*Not workable* *Difficult in the pharmaceutical industry* *Complicated for materials where EU need some barriers*

Table VI. Results from the Grounded Theory Data Analysis illustrating pharmaceuticals attitude towards legislation regulating plastic materials during packaging designs.

- *Low awareness*

Less than half of the interviewees had heard about the Single Use Plastic Directive. One did not really know what it consisted of unlike the two others, who were fully aware of its demands. The other three interviewees had never heard of it. This is the same in regard to the EU Scheme on Producer Responsibility. The author had to explain briefly these two regulations which triggered further elaboration.

The interviewees replied that these two regulations were not in the pipeline of their departments, except for one whose R&D department is working on it.

- *Low Feasibility*
  Still, all interviewees explained that these regulations are not workable in the pharmaceutical industry as the components in the packaging design are very difficult to recycle and it will compromise the safety of the medicines. Additionally, they emphasize that plastic is a very good isolator material for medicines and it really helps to protect the medicinal item. For their companies, patients come first and there are some countries that need their medicines in whatever format, in those cases companies do not think of sustainability but on shipping the right medicines in due time and in the right condition, even if that requires unsustainable practices.

In this chapter the author has synthesized the empirical findings and presented hypotheses that would inform the current sustainable state of the industry and that the challenges that sustainability brings along. In the next chapter the author presents an analysis of the results in which the findings from chapter 3 and 4 are constantly compared for the emerging of a theory.

5. ANALYSIS OF EMPIRICAL FINDINGS (Axial Coding)

This section consists of the Axial coding step of Grounded Theory, whereby the codes and categories presented in the former chapter are here-in analyzed to find similarities and differences. The patterns emerging from this analysis will give rise to an emerging theory.
For easier readability, the chapter is divided into two sub-chapters. First, sustainability in pharmaceutical packaging where the author analyzes how sustainability is viewed by pharmaceuticals (RQ 1) and second, the identified Changes and Risks (RQ 2 and RQ 3).
Given the time-constraints, limitations and research experience of the author, it would be unrealistic to attempt to build a general theory from a small-scale study like this one. Thus, the researcher critiques the results in relation to their use and potential implication for the development of a more general theory in future studies.

5.1. Analysis of Sustainable Packaging in the Pharmaceutical Industry

Following the GT methodology, several codes have been identified and further grouped up into different categories. These findings include the following:

5.1.1. As seen in sub-chapter 3.1.5 packaging is to perform different functions. Findings show that pharmaceuticals are specially interested on the functions of safety of patients, protection of

medicinal compound and shelf-life during storage. However, companies give less focus on the function of sustainability as widely presented by Azzi et al., (2012).

5.1.2. In regard to the former point, pharmaceuticals are aware of the need to implement sustainable initiatives to reduce the amount of plastic pollution in their Supply Chains. Respondents seem to be in line with the literature regarding environmental sustainability, where circular economies of close loop operations seem to be the general sustainable strategies. Additionally, respondents confirm the use of IT to drive sustainability forward. However, as seen in chapter 3.2, sustainability is composed of three pillars. Findings show that pharmaceuticals focus greater on environment sustainability while leaving aside the economic and social aspects. Yet, the economy side is present in some pharmaceuticals with the main objective to decrease costs, in line with the researcher Tolinski (2009). Similarly, pharmaceuticals seem to be in line with literature where Life Cycle Analysis are proposed to assess and prevent economic losses during the packaging life-span.

Conversely, as literature explains, the social side of sustainability is completely shadowed which can be due to the low relevance given to this pillar or the lack of awareness of the term sustainability in its full sense. This is in line with chapter 3.1. where different authors provide different and overlapping definitions of the term Sustainability with no common and generalized definition.

The same is experienced in regard to plastic waste. Pharmaceuticals seem to not be fully aware of the amount and type of waste produced in their operations, which shows either the lack of interested or focus of the company.

5.1.3. In this context, when interviewees were asked about the SUP Directive and EPR Scheme, most of them did not know about nor have heard of them.

When further explanation was given, there was a common understanding among the five respondents. It was agreed that pharmaceutical sustainability can never occur in primary packaging due to the high risks of cross-contamination with the packaging and the drug component. Secondary and Tertiary sustainability can be achieved, yet, the complex operations of the industry, and established processes together with the increased costs and time, show how *conservative, reactive* and *rooted in tradition* the pharmaceutical industry is. This system is equal to the system proposed by Garcia-Arca & Prado Prado (2008), but still opposite to Dickner (2012) who opts for adopting a more proactive attitude beyond reverse logistics and instead, tackle plastic waste of direct logistics.

5.1.4. However, it seems that pharmaceuticals are not interested on Dickner's approach. Pharmaceuticals are ready to act more sustainably by reusing and reducing the amount of plastic. Still, the use of plastic will not be 100% eliminated. The high flexibility and protection features of plastic seem to be the preferred material for pharmaceutical packaging.

Respondents confirmed that sustainability can be only achieved in the secondary and tertiary packaging. But, as seen in chapter 3.1. by Holmberg (2000), the three levels of packaging design has to be jointly considered, as their suitability depends on each other.

5.1.5. Findings also identified that there might exist several *paradoxes in the current sustainability legislation*. Whereas the EU Directive and Scheme opt for sustainable packaging, yet there are simultaneous regulations that hinder sustainability. J&J exemplified that EU regulations demand unit dose packaging, e.g. through blister packs, yet blister packs are made of a type of plastic that the Directive targets to eliminate.

5.1.6. The findings also show that the industry has different techniques to implement sustainable packaging. A few respondents and J&J would opt to mirror the food sector, whereas other respondents disagreed on departmental cross-collaboration since the industry is characterized by specific and robust regulation and requirements, which are incomparable to other industries.

In addition to this, it is unanimously agreed that ensuring the safety of patients through high protective packaging is number one priority even if that entails the use of unsustainable practices. Moreover, product integrity, product availability and product shelf-life are also among the most important factors to consider during packaging design. This shows that sustainability is in a second place, with prospects to develop but in a slow pace.

5.1.7. Despite of the above arguments, pharmaceutical packaging is made of PP and PET, which are chemically based polymeric substances. Therefore, pharmaceutical packaging made of PP and PET are within the scope of the EU Directive on Single-Use Plastic Packaging. Similarly, the Extended Producer Responsibility Scheme (EPR) includes all producers of plastic packaging regardless of industry type.

Therefore, it is to positively assume that the pharmaceutical industry will have to eventually re-design its packaging to commit to the directive's goals, replace plastic packaging for more sustainable alternatives, as well as, bear the responsibility and costs associated with the instruction of packaging consumption and disposal.

5.2. Changes and risk caused by Sustainable Pharmaceutical Packaging

From the previous sub-chapter, the author identified several changes and risks whose criticality is here-in assessed through the tool FMECA.

The FMECA allows to (1) easily visualize the potential changes of sustainable packaging in Supply Chain operations (2) to assess the potential risks, probability and criticality. See table II below.
The potential changes and risks correspond to the categories identified through the GT data analysis process.
Each category is assessed according to the level of severity, occurrence, detectability, probability of occurrence and criticality.

The number resulted from this quantification allows to identify the key areas that are more likely to fail if they are not prioritized.
Since the study focuses on changes and risks in the entire Supply Chain, the FMEA presents the categories divided into five, these being the areas of: procurement, production, shipping, storage and consumer consumption.

Besides this, there is the need to make a distinction between the potential changes and risks that sustainable packaging will generate and the risks that that pharmaceuticals face in a regular basis. Therefore this analysis also considers the risks given by the industry that are assumed to still happen regardless of the packaging design.

5.2.1. Changes and Risk in Procurement

The procurement department of pharmaceutical packaging firms will have to source new packaging materials from new suppliers. This will have two different effects with different ratings in their criticality levels.
On one hand, the need to find new suppliers will require to develop a new supplier selection criteria to ensure that materials are manufactured within sustainable standards. However, sustainability is considered by the interviewees as a niche market, which will make pharmaceuticals highly reliant on one or a few suppliers of sustainable packaging materials. These single-sourcing relationships are likely to create an imbalance power-dominance relationship where suppliers are the dominant players and pharmaceuticals the weaken parties. Single-sourcing might also jeopardize the supply-demand levels, since the suppliers' capacity might not be enough to supply the requested sustainable material.
The risk of unbalance power relationship, low availability and increased costs and time is of high severity for the procurement function.
Single-sourcing has a high degree of occurrence because it is certain that every time that new sustainable materials needs to be supplied, pharmaceuticals will have to seek new suppliers. However occurrence is moderate since it is not certainly given that suppliers will take advantage and crown themselves as the dominant players. Similarly, supply shortcuts is of high severity in an industry where supplying medicines in the right time and quantity is paramount to ensure patients health. As a niche market with scarce resources, low availability is likely to occur. But, it can be detected in advance and forecast accordingly.
On the other hand, firms will have to break the existing contractual agreements with plastic suppliers and build new ones with new suppliers, which requires time and generate additional costs. Higher costs will be also experienced due to the need to find suppliers according to close proximity. An interviewee explained that EU market ensures supplies are produced within Good Practices, which might not be the case of outside-EU suppliers. This is a tradeoff where Good Practices entail higher prices but higher sustainable practices.

The severity of this risk is rated slightly moderate, since the industry is known for its complex process and long lead time. Therefore, these risks are already experienced by the industry and they will only be detected when they take place.

5.2.2. Changes and Risk in Production

As of present, batches of packaged medicines with the wrong labelling must be scrapped and packaging from start as the industry does not allow re-packaging of already packaged medicines. If this happens, firms would be creating extra packaging and deploying time and money at zero value.

Nevertheless, this situation rarely happens since pharmaceuticals use advanced technology and dedicated personnel to prevent these type of failures. Therefore, occurrence is rated low and detectability high.

Additionally, the production of sustainable packaging will require a new production system with new processes. This might slow down the production and create longer lead times. In this regard, one of the interviewees recognized that it is likely that production workers will not be especially happy to change the existing layout to a new one and learn new production procedures.

An interviewee shared that due to the lack of expertise and familiarity with the new specifications of sustainable packaging, pharmaceuticals might outsource their production, which would result in longer lead times.

This is highly severe since the industry is timely organized and medicines are to get to the consumers as fast as possible as well as to enjoy the patent protection at its full potential. If lead time becomes longer, there is less time to exploit profits from patent protection.

Unfortunately, due to the lack of expertise on sustainability, it is very likely that companies will experience long-lead times until becoming more familiarized with the new processes.

Similarly, pharmaceutical will have to invest in new machinery and change the production processes to adapt to the specification of sustainable materials, which might result in higher costs, time-consuming and slow down on productivity.

This is of severe consequences, since it will mean that less medicines are shipped and therefore, less profit generated. However, firms can forecast the occurrence and plan production accordingly.

5.2.3. Changes and Risk in Shipping

The Vicepresident at FedEx recognizes that the shipping process in pharma is crucial, since "Lives may depend on a drug making it safely from origin to destination, within temperature range, and on-time" (Markarian, 2015).

During transit, medicines are the target of several factors that eventually damage the quality of the drug. The different hand-offs, custody transfer, long and time-consuming custom

procedures and unexpected events are potential risk factors that medicine are continuously exposed to.

When a product is transported from origin to destination, the chain of custody can become complicated and long as the product passes among the shipper, the airline, the forwarder, and eventually to the end customer. All of these changes in custody are potential areas for counterfeiting.
However, falsified medicines do not happen that often, since the industry uses advanced technology to identify right away falsified medicines. Still, sustainable packaging needs to be designed in such a way so counterfeiting does not occur.
All of these changes in custody are also potential areas of concern as the risk for temperature deviation increases.
As of now, shipping companies use shipping techniques to preserve the temperature level and to protect the medicine e.g. through thermo blankets.
As explained above by Lee & Xu (2005), the new sustainable packaging will require new shipping techniques to protect the medicine.
In this regard, one of the interviewee mentioned that during ocean transit, medicines are exposed to high levels of moisture and plastics are used as isolator. With sustainable packaging, the interviewee explained that even more plastic will be used to protect the medicines during transit. Therefore, sustainability in shipping would be counterproductive; on one hand secondary packaging will be sustainable but the tertiary packaging will be even more unsustainable, whilst creating the need to use more wrapping plastic to isolate the sustainable packaging. This is of high criticality, due to high likelihood of severity and occurrence. However, it can be detected in advance through quality assurance techniques.

Besides this, there are certain geographical areas where temperature controls are even more difficult to maintain. E.g. respondents explain that countries like China and/or South Corea do not have the infrastructure needed to preserve the quality of the medicines. The lack of correct infrastructure also hinders pharmaceutical from developing sustainable packaging.
In an industry where patients health primes over the environment well-being, unsustainable packaging is chosen over sustainable packaging, as long as patients get their medicines. The lack of correct infrastructure also hinders pharmaceuticals from developing sustainable packaging.

To avoid external factors such as humidity, moisture, light and movement affecting the quality of the drugs, pharmaceuticals carry out several tests either through simulation or sampling. Therefore the probability of occurrence is low.

In addition to the above, another change identified is the use of sea and/or road transport instead of the commonly used air-freight.
Sea and road freight is considered more environmentally friendly than air-freight, but lead times becomes longer. Interviewees revealed this change but did not explain how feasible it will be nor if they will be able to trade off speed for sustainability. The risk associated with this change is medicines and packaging in longer transit with the associated risks explained above. Thus, severity is also rated as high, as well as criticality and detectability.

5.2.4. Changes and Risk in Storage

The risks identified for the storing activities are no other that the regular difficulties encounter on a regular basis. Past data shows that packaging faces the risks of improper storage where the cold-chain is broken and/or it occurs substance adherence, cross-contamination which all result in damaged medicines.
As one of the interviewee explained, improper storage can occur due to lack of space in the warehouse.
This situation is rated as moderate. Improper storage can cause serious effects like damaged medicine, however storage facilities can be optimized in advance to secure a well storing condition of sustainable packaging.

5.2.5. Changes and Risk in consumer consumption

As evidenced by the researchers R. Martins et al., (2017) consumers do not usually care of where to store the medicines and this can have consequences on the level of effectiveness of the medicine against sickness. Thus, this risk is of high severity.
The Extended Producer Responsibility (EPR) asserts producers to bear all the costs and liability of the medicine during its entire life-cycle, this includes even when the medicine are under the consumers custody.
Since it is apparent that consumers are nowadays not taking care of the medicines quality, this is very likely to occur but not that easy to detect.

	CHANGES	NEW & EXISTING RISKS	Severity	Ocurrence	Detectability	Risk Probability	Criticality
Procurement	Single sourcing	Inbalance power-dominance relationship	9	5	5	225	45
		Low availability	10	7	7	490	70
	New supplier negotiations	Local sourcing	5	6	3	90	30
		High costs & time					
Production	-	Waste from wrong P&L	10	2	10	200	20
	New production lines	Longer lead times, unhappy workforce	8	9	5	360	72
		Low OE	10	9	5	450	90
		Less time to exploit patent protection					
		High costs & time	7	9	9	567	63
Shipping	multiple hand-offs, long custom procedures, longer lead time, lack of infrastructure	Temperature variation	10	7	5	350	70
	techniques	High costs & time	7	7	8	392	49
		Counter productive techniques	10	7	8	560	70
	Sea and road transport	Longer lead times	10	9	8	720	90
		Counterfeting	10	3	10	300	30
Storage	Damaged medicines	Improper storage, substance adherence, cross-contamination	10	6	9	540	60
Consumer consumption	Damaged medicines	Improper storage	10	8	5	400	80

Table II. *Adapted Failure Mode, Effect and Criticality Analysis.*

In this analysis, the author has expanded on the similarities and differences of this study and previous research papers. As a result, deeper meanings have emerged that reflect the complexities of pharmaceutical packaging design.

The next chapter offers a concluding discussion about the results of this study and several reflections of the author about the conducted work and finalized study.

6. CONCLUSION

This final chapter provides the answers to the Research Questions presented in the Introduction chapter. It also explains the accomplished purpose with a brief description of the completed research. Lastly, future research directions are proposed.

6.1.Answering the Research Questions

First , addressing **RQ1. How is the EU Directive on Single-Use Plastic Packaging (SUP) and the EU Scheme on Producer Responsibility perceived by pharmaceuticals?**

This study shows that the SUP regulation and the EU Scheme are not that well known by pharmaceuticals, as it might be for food producers. Even though pharmaceutical packaging is not directly excluded from the scope of these regulations, pharmaceuticals seem to not be compromised and do not have any initiatives in the pipeline to meet with these regulations.
Despite of the lack of awareness of these regulations, it seems that pharmaceuticals are slowly adopting more sustainable initiatives where environmental activities primer over other areas, leaving the social pillar highly shadowed.

Data presents that sustainability is a highly contested concept within packaging, more in the research area than in practical implications.
The complexity of the pharmaceutical logistic operations, long, country-based and time-consuming procedures and lack of standard sustainable practices around the globe seem to hinder pharmaceuticals to become fully sustainable in their packaging, together with the prime aim of ensuring patient's health.
Besides this, the industry is highly conservative that unless customer request it otherwise, the industry will continue with the existing *modus operandi*.
Nevertheless, pharmaceuticals seem to be well aware of the areas that lack of sustainable attention. They have a good understanding of what sustainability is, yet sustainable packaging is not a priority and delivering medicines to patients will always be number one priority at any cost, even if unsustainable practices need to be performed.

RQ2. What are the potential changes and risks that these regulations might cause in the packaging and logistics of pharmaceuticals?

Sustainable packaging will affect directly all logistic areas of pharmaceuticals, some with more critical effects than others.
Procurement will experience a single-sourcing relationship where only a few suppliers are able to supply sustainable materials for pharmaceutical packaging design. These few suppliers would be well aware of their dominant position which will most likely exploit to increase prices. This will mean that pharmaceuticals will have to enter into new contractual agreements with new suppliers and bear the cost associated with it. Additionally, in order to ensure sustainable sourced materials, companies will have to opt for local sourcing in the EU, which supposes a trade off between low prices and short lead time.

The production function will experience the usual risk of scrapping already packaged medicines if wrong or misleading labels are identified. Sustainable packaging will also generate higher investment costs in new machinery. Similarly, production workers will feel reluctant to change since new procedures need to be established.
The lack of familiarity with the new procedures might slow down production and create longer lead times. This is of high relevance since the industry aims to exploit patent protection as early as possible, which might not happen if lead times becomes longer.
During shipping, temperature level will continue to be a factor prompted to change due to several factors such as long custom procedures, changes on custody, multiple hand-offs and unexpected events. Counterfeiting is another threat that sustainable packaging must be designed in a way to avoid medicine falsification.
Lastly, improper storage will continue to be an issue at warehouses and at consumers households. Wrongful storage affects the quality and strength of the packaging and therefore, the medicines.

RQ3. Which logistic areas are more critical when implementing sustainability in pharmaceutical packaging?

Among of all the affected areas, production and shipping are the activities that will be mostly affected by sustainable packaging designs but also procurement in a second stage.
Pharmaceuticals are suggested to carefully consider the following operational changes and risks:
Low availability due to single-sourcing is the most critical risk in the procurement function. If pharmaceutical do not forecast and schedule correctly they will risk supply shortcuts and unmet demand that will result in sick patients with no medicines.

In the same fashion, the need to establish new production systems, invest in new machinery, joined with the low familiarity of sustainability, will slow down production, whilst enlarging lead times and generating less profit that endanger profit maximization during patent protection.

When it comes to shipping, there is a high risk of attempting to become sustainable in the secondary packaging but failing in the tertiary packaging where extra plastic might be used to ensure protection of the medicine.
Similar to production, longer lead times will be experienced when attempting to become more environmentally friendly by switching to road and sea freight, where the above counterproductive risk is very likely to occur.

6.2. Managerial implications

In a practical level, this study presents the different changes that pharmaceuticals will experience when re-designing their packaging to contain less or zero plastic components .
Consequently change can turn into failure or success that depends on how carefully the processes have been evaluated. Given this fact, this study also presents the different risks associated to the operational changes.
Lastly, the study suggests the different changes and risks that should be prioritized depending on their criticality and probability of occurrence.

In this regard, the EU Commission demands companies to replace plastic from their packaging by 2030.
Pharmaceuticals already implementing sustainable initiatives where environmental initiatives private over the economic and social areas.
Findings show that pharmaceutical are not specially aware of the latest regulation on plastic elimination and excuse themselves due to the long and complex process that characterizes the pharmaceutical industry. Nevertheless, the European Directive on Single Use Plastic Packaging nor the European Scheme on Producer Responsibility exclude pharmaceutical from their scope.
Therefore it is matter of time that pharmaceutical will have to commit to these demands.

6.3. Theoretical implications

This study contributes to academia by investigating an unexplored area with the use of empirical data.
Unlike other papers where service management is viewed by adopting the approach of service providers, this study adopts the approach of pharmaceutical companies where both tangible goods and intangible services are part of their business.
Pharmaceuticals are the producers of tangible medicines but as well, the service providers of intangible goods such as the sustainable services of redesigning, reducing and reusing of pharmaceutical packaging. Therefore, this study attempt to conceal the new view that products are both services and physical goods and how both can become more sustainable.
Furthermore, unlike many researchers in similar areas, this study attempts to put into discussion the disadvantages of sustainability, a term that is widely discussed in academia by its positive outcomes. This is the gap discovered between theory and practice. In this regard, in a smaller scale, this study has developed a substantive theory that sets the foundations for the development of a more general theory evolving sustainability in pharmaceutical packaging. Likewise, this study can be replicated in different industries and contexts to compare and support or criticize the generalizability of this study.
In this regard, the next sub-chapters presents several reflections that the author made in regard to the limitations encountered during this research and proposes future research directions.

6.4. Limitations and Further research

This study is an initial step in the understanding of potential changes and risks of sustainable packaging designs in the pharmaceutical industry. It provided valuable insights for both academia and industry; nonetheless, there are several limitations that must be outlined.

First, this study has examined sustainable packaging in a small group of packaging firms and pharmaceuticals. This was due to the inability to recruit more companies due to the hectic situation of the global pandemic Covid-19 that occurred at the time of this study.
After evidencing the low participation level, the author decided to reinforce data collection by collecting extra secondary data, such as academic reports, journals, newsletters and magazines. Thus, the findings of this study are not definite, the results of this study should be seen as indicators of what further researchers may want to study in order to complete them. Further research with a bigger sample size would provide more detailed insights of sustainability in the pharmaceutical industry.

The above limitation could have been mitigated if the author had changed the research area at the early start of the pandemic and if she had re-designed the study to recruit samples more accessible and not dependent on external factors. Nonetheless, the author excuses herself that no reference about the scale of this pandemic was provided. The magnitude of this pandemic became larger than the initial expectation and when the situation worsened, the time remaining to conduct this study played against.
If this situation had not happened, the author would have conducted sufficient number of interviews to fully complete the study from first-hand empirical data.

Another limitation is the choice of industry.
This study focuses on the pharmaceutical industry where sustainability is not yet fully applied. Carrying out the same study but on other industries with higher sustainability efforts, such as the food or fashion industry would provide richer and more detailed knowledge, with a higher potential for generalizing the findings to all industries. Nevertheless, this study aimed to contribute to amplify research on pharmaceutical packaging.

Thirdly, researchers could use different approaches to achieve new levels of knowledge. For instance, researches could adopt a quantitative approach contrary to the qualitative nature of this study. Or even mix both approaches, qualitative and quantitative which could reaffirm results obtained in both cases.

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7. Appendix

Appendix A. Interview guideline:

Hello [name]
Let me thank you first of all for your collaboration to this study. I know that things are not easy due to the situation with Covid-19, so I highly appreciate that you could find time and support me on collection some data for my study.

The interview will take approximately one hour and I will ask open-ended questions, which means that you are welcome to elaborate as much as you want and mention new ideas, concepts or anything that comes to mind. I might also ask follow-up questions depending on your answers.

I will first introduce briefly what the interview will be about, and then I will move to the questions.

Introduction

The aim of this study is to study the potential effects, risks and changes that sustainable packaging generate in the packaging logistics of pharmaceutical. This is based on the recent European Directive on Single-Use Plastic Packaging.
In regard to the formalities:
Your company name, [company name], will be kept anonymously as well as your name and title. The results will not be published in public databases, so myself and the examinations will be the only ones reading this study. And after that it will be kept temporarily in my University's private database.
Please note:
The list of interview question was designed for a semi-structure interview for a qualitative study. Due to the current circumstances of Covid-19, interviews cannot longer take place.
The interviewer kindly ask to reply the questions as if it was an interview. Kindly answer the questions as thorough as possible and feel welcome to include new concepts, ideas or approaches not directly addressed.

Interview Questions

Background

1. What type of materials does [company] use for the primary packaging of its medicines?

1.1. Why does [company] use these materials for the packaging?

Plastic Waste

Waste is defined in this study as all medicinal packaging containing plastic components that have to be scrapped, and thus can no longer be used in the manufacturing processes and that can eventually turn

into hazardous or non-hazardous materials to humans and the environment if not been correctly disposed of.

2. Does [company] ever generate any sort of plastic waste during the production of pharmaceutical packaging?

If Yes.

3.1. Why does [company] sometimes generate plastic Waste? *(e.g. mistakes, wrong handling, wrong instructions…)*

If No.

3.2. How does [company] avoid the generation of plastic Waste during the production of pharmaceutical packaging?

3. Imagine that when [company] has already packaged and labeled a batch of medicines, [company] is informed that the wording is incorrect and therefore the whole batch cannot be processed further. What does [company] do with the batch of medicines?

Regulations

4. Have you heard of the EU Directive on Single-Use Plastic Packaging?

If Yes.

5.1. What do you know about it?

5.2. What is your view on it? How do you think it will help to mitigate plastic waste?

5.3. How do you feel about this Directive on pharmaceutical packaging?

5.4. Is the Directive within [company] pipeline?

If No.

The Single-Use Plastic Packaging Directive aims that by 2030 all plastic packaging placed in the EU is re-usable or easily recycled. The Directive demands companies to establish sustainable packaging designs by 2024, otherwise fines will be applicable.

5.5. What is your view on it? How do you think it will help to mitigate plastic waste?

5.6. How do you feel about this Directive on pharmaceutical packaging?

5.7. Will [company] include this Directive within its pipeline?

If Yes.

5.8. How? What are the actions to take?

If No.

5.9. Why not?

5. Have you also heard about the EU Scheme on Extended Producer Responsibility?

If Yes.

5.1. What do you know about it?

5.2. What is your view on it? How do you think it will help to mitigate plastic waste?

5.3. How do you feel about this Scheme on pharmaceutical packaging?

If No.

The Scheme is a an environmental policy approach in which producer's responsibility for a product

is extended to the post-consumer stage of a product's life cycle. It follows the principle "the polluter pays".

The scheme aims to shift the responsibility of pollution to manufacturers and demand them to take actions to prevent pollution at the consumption stage.

6.1. What is your view on it? How do you think it will help to mitigate plastic waste?

6.2. How do you feel about this Scheme on pharmaceutical packaging?

6.3. Will [company] include this Scheme within its pipeline?

If Yes. How? What are the actions to take?

If No. Why not?

Sustainable Packaging Logistics

6. What is for you sustainability? And sustainable packaging?

7. Does [company] implement any sort of sustainable practices?

If Yes.

7.1. What sort of sustainable practices? Please, elaborate.

If Now.

7.2. Why not?

8. In your view, what are the most challenging factors in the design of sustainable packaging for pharmaceuticals?

9. Has [company] thought of replacing plastic with a more sustainable material?

If Yes.

7.1. Why?

7.2. What type of sustainable material? And why that material?

7.3. How does [company] assess the sustainability level of the packaging?

If No.

7.4. Why not?

10. How does [company] ensure the packaging will protect the medicine from externals? What techniques?

11. If you are/if you were to eliminate plastic from your packaging logistics and replace it with sustainable materials, what are the logistics areas mostly affected of this change?
Please mention those areas that come first to mind, and please elaborate.

12. Please explain the changes that, in your view, sustainable packaging will demand in the following areas:

16.1. Procurement *(e.g. new supplier selection?)*

16.2. Production *(e.g. longer lead time, in-house/outsourcing?)*

16.3. Shipping

16.4. Storage

13. And What possible effects will these changes cause in the following areas?

11.1. Procurement

11.2. Production

11.3. Shipping

11.4. Storage

12. And What possible risks will these effects cause in the following areas?

12.1. Procurement

12.2. Production

12.3. Shipping

12.4. Storage

13. How will [company] tackle with these potential effects and risks?

13.1. Procurement

13.2. Production

13.3. Shipping

13.4. Storage

Appendix B. Participant validation email

Dear [name],

Thank you for your collaboration on the University study regarding sustainability pharmaceutical packaging.

I here-in attached the interview transcription and I kindly ask you to review it and revert if transcriptions contained the wrong statements.

Best regards,
Adela García