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An Innovation and Design Process Perspective

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Toward Inclusive Pharmaceutical Packaging

An Innovation and Design Process Perspective

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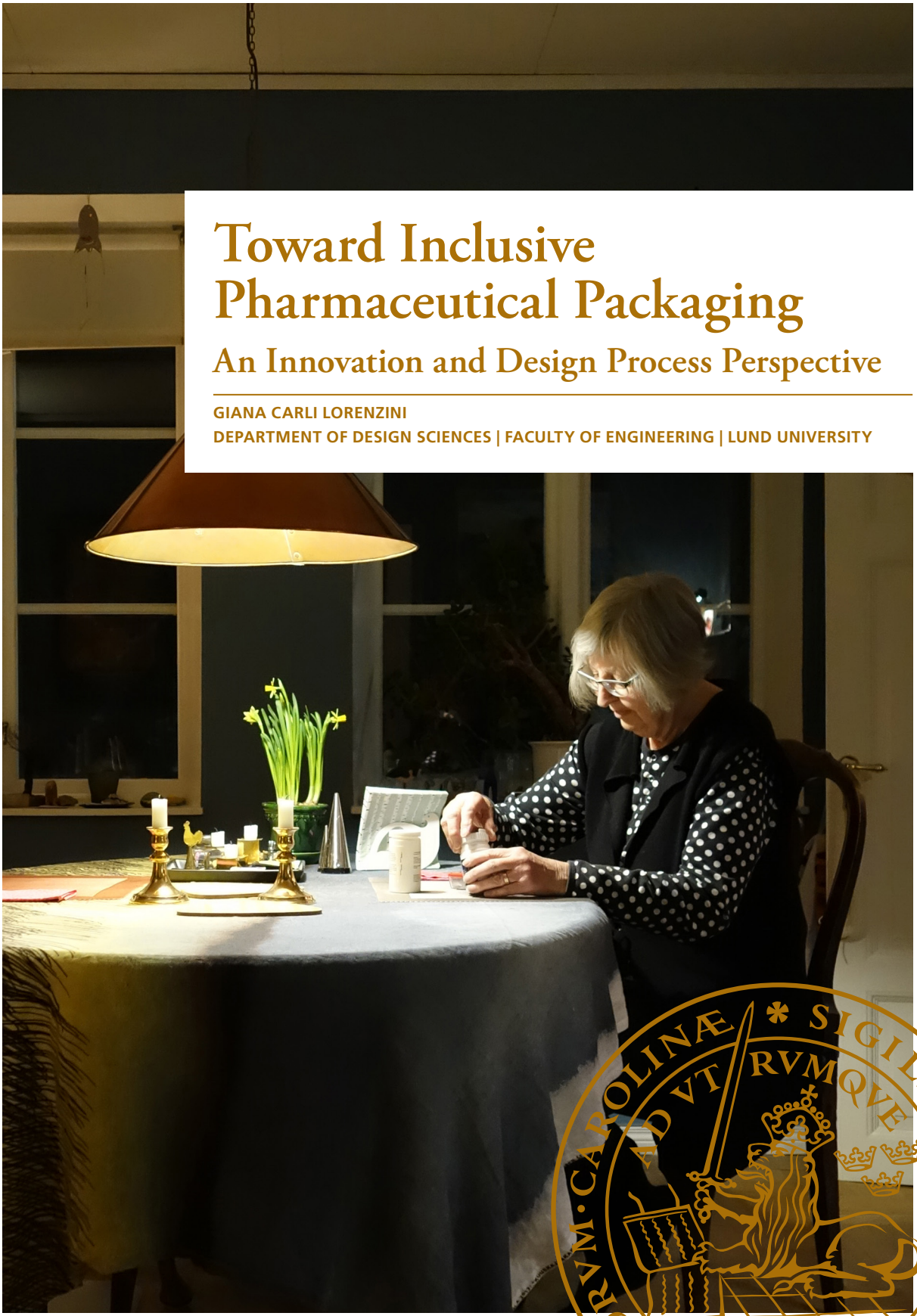

Toward Inclusive Pharmaceutical Packaging

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An Innovation and Design Process Perspective

Giana Carli Lorenzini

LUND UNIVERSITY

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Abstract

Pharmaceutical packaging has an increasing importance in aging societies, where people depend on medicines for their own care and well-being. Previous research shows that pharmaceutical packaging is a source of uncertainties, confusion, and daily struggles. The challenges experienced by users are extensive; the pharmaceutical industry needs to respond with packaging innovation. To address these complex challenges, more research is necessary on packaging that fulfills user needs and capabilities. This research purpose is to investigate innovation and design processes for pharmaceutical packaging, as well as to stimulate the uptake of inclusive design toward pharmaceutical packaging that meets society's needs.

The research is interdisciplinary with a qualitative, explorative approach based on three studies and five appended papers. The first study explored state-of-art pharmaceutical packaging use by older patients. Physical constraints regarding packaging design features and the need to support medication management were identified. Subsequent studies were based on empirical investigations. The second study investigated packaging innovation drivers based on a customer-supplier relationship case study of a brand-owner drug manufacturer, and a packaging supplier. The third study expanded those findings, through an interview study with stakeholders (top management, mid-management, and specialists) with experience in pharmaceutical packaging innovation and design processes.

As argued and shown in the empirical investigations, pharmaceutical packaging innovation is mainly driven by technology and legislation which reinforce standard and incremental packaging design. Furthermore, there are multiple stakeholders' needs to be balanced. Findings in this research suggest that if packaging design is to be user-centered and inclusive, stakeholders should be actively involved to broaden the spectrum of driving forces that lead packaging innovation and open up new business opportunities. The empirical studies also revealed different levels and modes of user involvement in pharmaceutical packaging design.

Overall, the research expands the rather technological focus of packaging toward the exploration of industry processes, opening the way for further studies on inclusive design and social aspects of pharmaceutical packaging innovation and design, being the collaboration and involvement of users in these processes also of great interest. Packaging practitioners can benefit from the results obtained to benchmark their own processes. Policy makers and health care providers can reflect about the dilemmas of innovating pharmaceutical packaging that is inclusive and user-centered, and can use the empirical evidence from this research to strengthen and pave the way for new regulations and guidelines. Future agendas may be leveraged from research to other spheres of society, increasing dialog about inclusively designed pharmaceutical packaging and better patient care.

Key words: Inclusive Design, Packaging Design, Packaging Innovation, Pharmaceutical Packaging

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An Innovation and Design Process Perspective

Giana Carli Lorenzini

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To the curious and restless minds.

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Abstract

Pharmaceutical packaging has an increasing importance in aging societies, where people depend on medicines for their own care and well-being. Previous research shows that pharmaceutical packaging is a source of uncertainties, confusion, and daily struggles. The challenges experienced by users are extensive; the pharmaceutical industry needs to respond with packaging innovation. To address these complex challenges, more research is necessary on packaging that fulfills user needs and capabilities. This research purpose is to investigate innovation and design processes for pharmaceutical packaging, as well as to stimulate the uptake of inclusive design toward pharmaceutical packaging that meets society's needs.

The research is interdisciplinary with a qualitative, explorative approach based on three studies and five appended papers. The first study explored state-of-art pharmaceutical packaging use by older patients. Physical constraints regarding packaging design features and the need to support medication management were identified. Subsequent studies were based on empirical investigations. The second study investigated packaging innovation drivers based on a customer-supplier relationship case study of a brand-owner drug manufacturer, and a packaging supplier. The third study expanded those findings, through an interview study with stakeholders (top management, mid-management, and specialists) with experience in pharmaceutical packaging innovation and design processes.

As argued and shown in the empirical investigations, pharmaceutical packaging innovation is mainly driven by technology and legislation which reinforce standard and incremental packaging design. Furthermore, there are multiple stakeholders' needs to be balanced. Findings in this research suggest that if packaging design is to be user-centered and inclusive, stakeholders should be actively involved to broaden the spectrum of driving forces that lead packaging innovation and open up new business opportunities. The empirical studies also revealed different levels and modes of user involvement in pharmaceutical packaging design.

Overall, the research expands the rather technological focus of packaging toward the exploration of industry processes, opening the way for further studies on inclusive design and social aspects of pharmaceutical packaging innovation and design, being the collaboration and involvement of users in these processes also of great interest. Packaging practitioners can benefit from the results obtained to benchmark their own processes. Policy makers and health care providers can reflect about the dilemmas of innovating pharmaceutical packaging that is inclusive and user-centered, and can use the empirical evidence from this research to strengthen and pave the way for new regulations and guidelines. Future agendas may be leveraged from research to other spheres of society, increasing dialog about inclusively designed pharmaceutical packaging and better patient care.

Popular science summary

Think about the moment when you are going to open a package. All you want is to reach the product inside. Suddenly, this is almost an impossible task. The packaging says ‘open here’, and it does not matter how hard you try, you cannot open it as instructed. At home, no one sees your struggle and no one can help you. It is only you and the packaging. Nevertheless, you feel angry and frustrated for not being able to perform a supposedly easy task. In a decisive act, you use a knife, scissors or even worse, your teeth to open the blamed packaging.

Now imagine yourself aged about 80, experiencing a similar situation every day when taking your medicines. How keen would you be to continue following your treatment? By analyzing findings of previous studies, this research found that difficulty opening is only one of the challenges older people commonly experience with pharmaceutical packaging. Many older people live alone and have chronic conditions (such as diabetes and arthritis), and are dependent on their daily medication to maintain or improve their health. Difficulties reading small text, differentiating medications, or recalling dosage routines are constant challenges. As a consequence of unfriendly packaging, older people have the anger and frustration mentioned above embedded in their routines; this affects their quality of life.

At this point, you might ask yourself why the problems persist and why pharmaceutical packaging is not user-friendly. This research presents results of hours of interviews with packaging designers, developers, and managers to understand their view of the patient and the packaging. Overall, the pharmaceutical industry has been driven by the development of very innovative drugs to cure or treat diseases. However, what this industry has not considered from the start is that packaging would become such a big challenge. Many technical aspects of packaging have been prioritized, such as high protection of the product, whereas patient needs and capabilities have been neglected.

As happens in many other industries, decisions about pharmaceutical packaging are like a seesaw: the more you do to improve one part, the less you get from the other. For instance, a drug product often travels on bumpy roads in the back of a truck until it reaches the pharmacy. So those packages need to be strong enough to resist to all the jolts along the way. This means that if packaging is designed to resist the shaking of a truck, it might be also harder for an older person to open it later. However, any changes in pharmaceutical packaging demand new rounds of testing and regulatory approval, which can be costly and time-consuming before a new drug is launched. Consequently, the pharmaceutical industry has been conservative in its packaging choices. Once a pharmaceutical package is released to the market, it is likely it will remain unchanged for years.

On the other hand, findings in this research also suggest there are opportunities when there is a new treatment that demands totally new packaging, or when

packaging is assessed as part of the outcome of the treatment. Listening to patients and involving them in cocreating packaging concepts together with packaging teams is a step toward packaging that can really be integrated in patients' lives. The fact that we have a society where people live longer, and want to live longer and more healthily, means we need packaging that is designed innovatively considering patient needs and capabilities. Finally, this research stimulates the debate that pharmaceutical packaging can be more than just a protective container, it is the ultimate resource we put in the hands of patients for them to care for themselves. Yet this mindset still needs support from the pharmaceutical industry, and from other parties such as regulatory bodies and health care providers.

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Doing a PhD is like being on a roller-coaster. There are many ups and downs that shake your body in unbelievable ways: the butterflies in your stomach when you present your research at a conference, the misery of getting a paper scrutinized in multiple rounds of review, the indescribable joy of having the same paper accepted for publication. Yet this is only a glimpse of all the learning, perseverance, and resilience that make you grow and become a researcher. Most importantly, what has made those years so memorable to me is the people that have supported me and cheered me up in my research endeavors. I am grateful to you all.

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It would not have been possible to conduct the empirical studies in this dissertation without the important participation of helpful people and organizations. I thank all the anonymous respondents who allocated time in their busy working lives to participate in the empirical studies within this dissertation, and for sharing with me their experience and the challenges they face in innovating and designing pharmaceutical packaging.

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Finally, I want to thank you, Francisco, for being my life partner, and for embracing the adventure of sitting in the front seat of the roller-coaster car with me. Your support and endless love always made me believe this was a possible journey. I admire you for your serenity and (almost) undisturbed peace of mind when you heard me talk about my research for, literally, hours. I bet you now know by heart some of the text I wrote in this dissertation. Well, people say there is a ‘normal life’ out there beyond the PhD. Let’s discover together whatever it means.

Contribution to appended papers

The research presented in this dissertation comprises five complete papers as listed below. A brief description of the contributions of the authors to each paper is included, and a more extensive summary of the results of each paper can be found in Chapter 5. The full version of each paper is appended at the end of the printed version of this dissertation.

Paper I

Lorenzini, G. C. and Hellström, D. (2017). Medication packaging and older patients: A systematic review. *Packaging Technology and Science,* 30(8), 525-558. Doi: 10.1002/pts.2241.

Paper I is a peer-reviewed journal paper. An earlier version of this paper was presented at the *20th IAPRI World Conference on Packaging*, Campinas, Brazil, in June 2016. As the leading author, Lorenzini collected and analyzed data. Hellström contributed with guidance in methodology. Both authors worked together to design the study. Lorenzini wrote most of the manuscript; it was then critically revised by Hellström.

Paper II

Lorenzini, G. C. and Olsson, A. (2015). Design towards better life experience: Closing the gap between pharmaceutical packaging design and elderly people. *In: Proceedings of the 20th International Conference on Engineering Design (ICED)*, 27-30 July 2015, Politecnico di Milano. Milan, Italy: Design Society, 9, 65-76.

Paper II is a blind peer-reviewed conference paper, presented at the *20th International Conference on Engineering Design (ICED)*, Milan, Italy, July 2015. Additionally, the paper was discussed in the *4th PUBLISH-ED Workshop to Foster Publication in Engineering Design 2016* – a post-event organized by the Design Society in Grenoble, France. Lorenzini performed the literature review and wrote the text. Olsson critically reviewed the text and provided experienced advice and suggestions. The propositions were developed in agreement by both authors.

Paper III

Lorenzini, G. C., Mostaghel, R., and Hellström, D. (2017). Drivers of pharmaceutical packaging innovation: A customer-supplier relationship case study. *Journal of Business Research*, accepted for publication, in press.
Doi: https://doi.org/10.1016/j.jbusres.2017.11.030

Paper III is a double-blind peer reviewed journal paper. An earlier version of this

paper was presented at the *7th Global Innovation and Knowledge Academy (GIKA) Conference*, Lisbon, Portugal, in June 2017. Lorenzini collected and analyzed the empirical data, and wrote the main parts of the manuscript. Lorenzini and Hellström worked together on the theoretical frame and methodological design of the study. Lorenzini and Mostaghel worked together on the presentation of results and discussion of main findings. Mostaghel and Hellström critically revised drafts of the manuscript by providing guidance and comments. Based on the initial analysis by Lorenzini, Hellström assisted in the refinement of the final propositions.

Paper IV

Lorenzini, G. C. and Olsson, A. (2018). Toward patient-centered packaging design: An industry perspective on processes, functions, and constraints. *Packaging Technology and Science* (under second review).

Paper IV is in the second round of review (minor review) at the *Packaging Technology and Science* journal. An earlier version of this paper has been accepted to be presented at the *21st IAPRI World Conference on Packaging*, Zhuhai, China, in June 2018. Lorenzini independently planned the study, collected and analyzed the data, and wrote most of the manuscript. Olsson provided guidance by structuring the final version of the paper. Olsson and Lorenzini worked together on discussing the results.

Paper V

Lorenzini, G. C., Olsson, A., and Larsson, A. (2018). Getting involved with patients: User involvement in pharmaceutical packaging design. *International Journal of Design* (under first review).

Paper V is in the first round of review at the *International Journal of Design*. Lorenzini independently planned the study, collected and coded data, and wrote the manuscript. Olsson and Larsson both provided valuable inputs on the structure and critically revised initial drafts of the manuscript.

Preface

Before you start reading this doctoral dissertation, I would like to introduce you to Jenny:

> Jenny has just turned 85. Like most of her friends, she is retired. She lives alone in a small town in Sweden. Her relatives visit several times a week, and twice a month she goes by herself to the health care facility nearby to see her family doctor. Even though she is a relatively healthy older woman, she takes five different medications every morning. At night, she takes four other medications. All the different types of plastic bottles and blister packs are displayed on her bedside table. Most of these medications have been part of her life for several years, prescribed for chronic diseases. Jenny understands how much of her well-being depends on taking her pills every day. What she doesn't understand, though, is why the task never becomes easier. She has trouble with her weak hands that causes her pain when she opens some of the push-and-turn bottles of pills. On days when she is not feeling well, she doesn't even try to open these bottles. To cope better with her regular treatment, she organizes the pills for the morning and for the night separately, and she uses a small, 7-day plastic multi-dose box to help her. When the doctor changes the dosage of her medication, however, she gets confused and prefers to throw away all the pills that are left; she then starts to refill the multi-dose box for the week. She has never managed to learn all the different names of her prescriptions by heart – in fact, she can barely read the instructions on the labels because the print is so small – so what she does is to write on the packaging what the pills are for. Jenny is glad she still can deal with the treatment by herself, but she wonders about her friend Ulla who has Parkinson's, or how about Agnate who has started to forget things – maybe an early sign of Alzheimer's? Or how about Maria, who has been taken to hospital at least twice because she took the wrong dosage of her prescribed pills? Jenny thinks a person aged 80+ would have experienced everything, but life always proves to be more challenging (adapted from Lorenzini, 2016) .

This description of Jenny's situation is the point of departure for understanding why the research presented in this dissertation and other similar research is relevant in a time of aging societies. Jenny is not a real person. In fact, she is a *persona* that I created about half-way through my doctoral journey. The description of Jenny provides a glimpse of what it means to be an older adult. Indeed, by elaborating on her description, it helped me to summarize what I had learned about older people as patients who need to deal with multiple daily medication packages.

This research has evolved over time, passing though many different forms of assessment that improved my search for knowledge along the way, from informal conversations with research peers to formal iterative review processes with many

feedback loops when submitting papers to scientific journals. One important assessment occurred in 2016 when I presented my licentiate thesis (Lorenzini, 2016) as a mid-point examination in my doctoral studies. From the licentiate thesis to this final doctoral dissertation, some of the foundational ideas, excerpts of texts, and figures have been kept as they form the basis of the overall doctoral research. Specifically, Study A and part of Study B from the licentiate thesis are included here in regard to the research questions, methodology, theoretical references, and discussions that relate to these studies. Paper I (an earlier version of which was included in the licentiate thesis) and Paper II (included in the licentiate thesis) are also included in this final doctoral dissertation.

1 Introduction

Chapter 1 starts by presenting packaging and its importance in our daily lives. Following this initial reflection, pharmaceutical packaging is introduced, with a description of the problems and challenges that gave rise to this research. Subsequently, the research gap, purpose, and research questions are presented, followed by the focus and demarcations, and the description of the main terminology adopted throughout the doctoral dissertation. The expected readership and overall outline for this dissertation are displayed at the end of the chapter.

1.1 Multifaceted role of packaging

In a globalized world of consumption, where international companies compete fiercely to sell their products and penetrate consumers' minds, packages travel long distances from their point of origin until their point of sale. Because of that, packaging has to fulfill different functions (Paine, 1981, Robertson, 1990, Livingstone and Sparks, 1994). Packaging has to accompany and protect the product along the whole journey. Once on the shelves, packaging works as the last resource in the chain for branding, recognition, and extra salesforce (Nickels and Jolson, 1976, Sara, 1990). In the consumer's hands, packaging will provide additional information such as expiry date, and product contents, and it will offer guidance on the usage of the product and post-use recycling (Hellström and Olsson, 2017).

As consumers, or users of products, we do not always critically reflect on the role of packaging, or on all the important functions a package realizes until it is used. In fact, it is not the case that people actively decide to go out to buy a package. People go out to buy products, such as milk, shampoo, tomato sauce contained in carton boxes, plastic bottles, and pouch sachets. Yet consumers come back home with plenty of packaging. In fact, we are surrounded by packaging. Estimations show that global retail demand for consumer packaging has reached 3.4 trillion packs (Euromonitor International, 2017). Research points out that our choices of products are influenced by packaging probably more than we perceive or would like to admit (Silayoi and Speece, 2004, Ampuero and Vila, 2006, Wells et al., 2007). Even in our imagination, packaging often represents the image of a product (Underwood, 2003). If we read 'Coca-Cola,' unsurprisingly, the image that first

comes to mind is a bottle or a can. Because of that, packaging also sets the experiences we have with products (Löfgren et al., 2008). A cold glass bottle that keeps the soft drink bubbly and tasty, and that makes a nice sound when the top is removed, is often considered a positive experience. Experiences with packages might be considered positive exactly because the packaging advances and fulfills user expectations transferred to the product, or because they evoke memory-like, nostalgic feelings of product use (Ryynänen et al., 2016). Even when not consciously noticed, packaging may represent a neutral experience, where the 'unnoticeable packages' probably fulfilled their functions quietly and peacefully: the top could be easily removed, the product is intact and fresh, etc. Contrariwise, packaging can be totally misleading in relation to the expectations initially created. Packaging can then cause frustration or infuriate consumers, because it does not work as intended, by leaking the contents, by being difficult to recycle, or even by being hard to open (Duizer et al., 2009, Joutsela and Korhonen, 2015, Ford et al., 2016).

Poorly designed packaging provides evidence that packaging is often regarded as a necessary evil or an unnecessary cost (Robertson, 1990). Companies, or producers, want to sell the products, but they need packaging to make products accessible to people. As emphasized by Hellström and Olsson (2017), designing packaging involves many professionals from multiple disciplines, as well as company functions and departments. However, packaging is not always at the core competence of those professionals, which leads to many misconceptions about what packaging may or can achieve. Consequently, by prioritizing cost-saving designs, companies end up by neglecting the final user experience and the packaging strategic role (Lockamy III, 1995, Simms and Trott, 2010).

1.2 Pharmaceutical packaging challenges

Pharmaceutical packaging contains drug products, which are typically taken when someone is ill, in pain, or needs to alleviate sickness symptoms. As a result, consumers of medication are patients who expect to improve their health. Even though all products have their particularities in relation to packaging, medication (i.e., drug products) requires great care. If the packaging of a medication fails, this could lead to failure to cure, and taken to the extreme, injuries and even death of patients (Lockhart and Paine, 1996).

Another intriguing fact is that pharmaceutical packaging, especially for prescribed medication, is designed to promote safe use by patients rather than to stimulate consumption (Cohen, 2007, NPSA, 2007). In line with that, the process of acquiring medication is extensively different than the act of buying ordinary goods in a supermarket. Even if some medication can nowadays be bought at grocery

stores, medication still needs to look like medication and not like candy (Morelli, 1993). The whole system that sustains and regulates the development of medication products also spills over to the way pharmaceutical packaging is planned, designed, and offered to people (EMA, 2011, FDA, 2013).

Previously, health care systems had to be responsive to acute diseases and emergency treatment. This is now shifting into an era of maintenance treatment, mostly due to the fact that people live longer with chronic conditions (WHO, 2002). To alleviate the pressure for long-term care in already hard-pressed social services, more sustainable scenarios of care need to be created (Metz and Underwood, 2005). As pointed out by Lloyd (2012), the role of medicine later in life has increased, giving rise to the debate about the pharmaceuticalization of old age and the importance of medicine in shaping experiences in older years. In the agenda of priorities in the Health 2020 (WHO, 2013), for instance, there is a growing interest in encouraging people to participate in better care of their own health. Among its priorities, Health 2020 emphasizes the empowerment of people. Empowering people triggers research about what kind of systems and tools have been provided (or can be provided) to support people in their need of treatment using medication. Patient-centered systems imply patients that are more informed about treatment options, and that share the power and responsibility to participate in their own care (Lloyd, 2012).

As discussed above, the role of pharmaceutical packaging is changing. Upcoming health policies and guidelines sum up the challenges of having an aging society that needs and deserves supportive and continued care in taking its medicines. The challenges experienced by people also challenge companies (e.g., pharmaceutical companies) that then have to create new or improved medication, their packages ending up in the hands of patients worldwide.

1.2.1 Pharmaceutical packaging use by older people

Estimations show that between 2015 and 2030 the number of people in the world aged 60 years or over will grow by 56 percent (from 901 million to 1.4 billion), whereas by 2050 the global population will reach nearly 2.1 billion older people (United Nations, 2015). Population aging is an ongoing phenomenon and a positive consequence of multiple advancements in education, improved lifestyle, and greater access to quality health services before and after people reach 65 years of age (OECD, 2014a).

On the other hand, population aging has its drawbacks. Previous research shows that the older we get, the more chances we have of living with one or more chronic diseases, such as arthritis, heart disease, cancer, and diabetes mellitus (Ward and Schiller, 2013). Consequently, it is almost certain that we will also become more dependent on the use of multiple daily medications (Hajjar et al., 2007, Eurostat,

2008). The aforementioned conditions make older patients more susceptible to experiencing significant errors or non-adherence in medication use in primary care (Gurwitz et al., 2003, Fialová et al., 2005, Olaniyana et al., 2015): This leads to rehospitalizations and increased health care costs (Cohen, 2000). Currently, "more than half of all medicines are prescribed, dispensed or sold inappropriately, and that half of all patients fail to take them correctly" (WHO, 2016). In that sense, "the overuse, underuse or misuse of medicines results in wastage of scarce resources and widespread health hazards" (ibid).

Like most of the products we have access to, medication comes packed, wrapped, contained in all sorts of packaging. The example of Jenny, reproduced in the Preface of this dissertation, gives us a picture of how challenging medication packaging has become. Cases including older people are the ones where stress and frustration seem to be more evident, but with the trend of aging, we are on target to have to manage our own care, and we may want to find help from the tools at our disposal. Medication packaging is a critical part of the use of medication products, with undesired consequences when it fails. Packaging may therefore be supportive enough to really achieve what is expected in terms of helping patients with their care, when other resources are scarce (Berman, 2004, Ward et al., 2010).

After all, we have created a society that lives longer, and that wants to live longer, but we have not yet designed all the systems and the support to sustain the longer life with full consideration of the functional and cognitive abilities of the user, and the way these abilities change over our lifespan (Haigh, 1993, Coleman, 1999, Huppert, 2003). Parker and Thorslund (2007, p. 151) explain that aging highlights an important issue about "whether the years added to life are characterized by good health and independence or by health problems and the need for care." The aspect of medicines that are not only developed to provide a final cure, but to maintain a better quality of life for patients is essential in the context of aging populations. It does not matter how efficient medical treatment is, as long as the patient is not able to perform the treatment correctly because of the packaging – either by not being able to open it or by not understanding how to take the medication.

1.2.2 Pharmaceutical packaging design

The pharmaceutical industry not only produces medication, but it also designs the modes of treatment, i.e., how people are given access to drug products and in each drug formulation (e.g., a tablet). For a long time, pharmaceutical packaging has been designed with a focus on innovation that protects the drug product (Lockhart and Paine, 1996). This need for protection of the medication remains as an important part of the packaging function, however pharmaceutical packaging has also to be considered as the means of patient access to daily treatment.

As for all packaging, pharmaceutical packaging is more complex than it looks at a first glance, as it involves systems of production, distribution, and delivery before it comes into the patients' hands. Contemporary societal demands may create new challenges, however, despite those challenges, this research also relates to the upcoming innovation opportunities the pharmaceutical industry can also benefit from (WHO, 2002). The pharmaceutical packaging is, as understood in this research, part of the treatment provided to patients. In the very near future, "advances in innovation, efforts to expand access and promote inclusiveness, and new approaches to ensuring the sustainability of health care systems will all have a bearing on the use of medicines" (Aitken et al., 2014, Introduction). Since the pharmaceutical industry has its core in research and development, innovation processes are an important part of the business within this industry. However, in this research, the focus is not on the development of new drug products, but on what goes together with the development of these new drug products, especially regarding packaging as a necessary and important tool for patient treatment.

As described, for those living in an aging society, the way packaging is designed might work as facilitator of, or obstacle to, taking medication. We are still demanding more inclusive, patient-centered perspectives to overcome this challenge (Stegemann, 2016). Rethinking packaging design and the social aspects of innovation are important when developing medication packages – something this dissertation wants to problematize.

1.3 Research problem and gap

From the previous sections, it is possible to visualize complementary challenges: we have patients facing difficulties with pharmaceutical packaging, but we also have a potent industry with a strong core of research and development, and plenty of product requirements to fulfill. The challenges identified are rather complex and multidimensional. To tackle the identified challenges, there is a need to build a cohesive body of knowledge on how user needs (essentially patient needs) could be considered in the innovation and design processes of pharmaceutical packaging.

Research within the field of pharmaceutical packaging has been so far multidisciplinary and diverse, drawing the attention of scholars from a myriad of research areas such as medicine, pharmacy, public health, as well as engineering and gerontology. Through the lenses of their own research areas, these researchers have contributed to building evidence about the functional problems users experience with pharmaceutical packaging. The difficulties of opening packaging have been of particular interest, for instance. One example is contrasting child-resistance features with senior-friendliness as a consequence of regulatory imposed design features on packaging (Robbins and Jahnigen, 1984, Thien and Rogmans,

1984, Bix et al., 2009a, de la Fuente and Bix, 2010, Rodriguez-Falcon and Yoxall, 2011). Other researchers have looked at how the continuity and recurrence of these functional problems affect end users more than just physically (Sudbury-Riley, 2014, Ford et al., 2016), with consequences relating to compliance and adherence of patients to their treatment (Murray et al., 1993, Gould et al., 2009, Lakey et al., 2009).

The research on pharmaceutical packaging innovation and design processes is limited. From a research point of view, packaging (including pharmaceutical packaging) is predominantly conceived as a technological object. Because of that, packaging has received abundant scholarly interest with focus on packaging processes from a product-centered design (PCD) orientation, where the technological development of packaging fulfills product and production requirements. Conversely, a user-centered design (UCD) orientation, where user needs are taken into consideration in packaging innovation and design processes, have been overlooked (Olsson, 2006, Bix et al., 2009b). Triggered by societal challenges such as aging, a growing body of research has started to pay attention to designing packaging inclusively for a broader spectrum of the population (Langley et al., 2005, Yoxall et al., 2006, Duizer et al., 2009, Chavalkul et al., 2011). Oygür (2018) argues that there is still further demand for research that advances knowledge about the integration of user information and user involvement methods when new products are being designed. Pharmaceutical packaging is certainly a domain of knowledge to benefit from research that looks more closely into inclusive design, to consider a broader spectrum of users such as older users, and their needs.

1.4 Research purpose and research questions

There is limited research on how user needs are acknowledged and taken into consideration in the innovation and design processes of pharmaceutical packaging. To fill the identified gap, this research adopts an integrative perspective, where knowledge from inclusive design and innovation is combined to contribute to the field of pharmaceutical packaging. Based on that, the overall purpose of this doctoral dissertation is:

> To investigate innovation and design processes for pharmaceutical packaging, as well as to stimulate the uptake of inclusive design toward pharmaceutical packaging that meets society's needs.

To achieve the overall purpose, five research questions (RQs) are proposed. The first two questions are related to the investigation of the field of knowledge of

pharmaceutical packaging design. Those questions lead the way toward the identification of saturated areas of debate, and point to novel areas of interest:

> RQ1: Overall, what are the characteristics of the current body of literature on pharmaceutical packaging design for older people?
>
> RQ2: What are the key scientific contributions of this body of literature to the field of pharmaceutical packaging design?

A third question is derived from the two initial questions. With knowledge of what has been researched, we can then look toward further development of pharmaceutical packaging design as a research field by asking:

> RQ3: What can be proposed to evolve the field of pharmaceutical packaging design?

The human-packaging interaction has been assessed in research through the use of standardized methods and tools, e.g., by having users open or close a package and perform specific tasks with it. Undoubtedly, the efforts made by researchers to increase knowledge on human-packaging interaction are invaluable; they support and inform designers and other professionals in the area about problems faced by users (Wever, 2016). Yet very little research has explored the extent of former investigation into industry practice, with rare contributions so far about the application of user data when new packaging is being designed (Carse et al., 2010). As addressed by Wever (2016, p. 605), it is striking that "although packaging is an applied field, and most researchers are close to industry practice, little is studied about the implementation of newly developed research and design methods. Or at least, very little is published about it. I see this as a missed opportunity." Such an opportunity is taken further in this research in connection with an inclusive design approach. Scholars have called for studies that not only investigate the problems experienced by users, but also consider the uptake of inclusive design by the industry to make products or packages more accessible to users (Goodman et al., 2006, Waller et al., 2015, Luck, 2018).

Pharmaceutical packaging is certainly a domain of knowledge that benefits from research that looks more closely at industry practices. The evidence from previous research suggests pharmaceutical packaging innovation has not been driven by user needs, resulting in consequent problems of use. By investigating the packaging innovation process, we can then identify and understand the primary forces in packaging innovation that really lead packaging design to changing or not changing. Based on that, the fourth research question is:

RQ4: What drives pharmaceutical packaging innovation in industry practice?

Importantly, by getting closer to industry practices, we may be aware that there are many stakeholders to influence design decisions; the user is only one of them (Lehoux et al., 2011). The domain of pharmaceutical packaging in particular is rather complex, with multiple stakeholders that act and 'speak' on behalf of users (i.e., patients). In spite of that, design scholars have advocated more user involvement in the design process, permitting these users to not only be 'observed testers' but also to become involved and to participate in designing products that are important in their lives (Luck, 2003, Wilkinson and De Angeli, 2014). Moreover, there is still further demand for studies that advance knowledge about the integration of user information and user involvement methods when new products are designed (Oygür, 2018). The last research questions in this dissertation therefore asks:

RQ5: How does industry incorporate user needs in the pharmaceutical packaging design process?

1.5 Focus and demarcations

This research project has been developed within the field of packaging, and specifically pharmaceutical packaging. The point of departure for this research is that pharmaceutical packaging has an overlooked strategic potential in terms of practice and research. As previously described, the challenges of pharmaceutical packaging serve as the foundation to explore and advance knowledge in the field, with the support of complementary theoretical perspectives such as design and innovation (see Chapter 3, Frame of reference). Before starting, it is important to clarify some of the thresholds in this dissertation.

First of all, this dissertation does not present an original empirical study conducted on older patients. A basic assumption was that there were sufficient empirical studies already conducted in this area, which have identified the main problems experienced by older patients. Instead, the problems previously identified were grouped, classified, and discussed through the review of studies on older patients and medication packaging (see Study A, Paper I).

Second, this research does not take on the challenge of proposing or prototyping any new packaging design. In the same way, this research does not assess whether certain packages are more or less innovative outcomes. Instead, the empirical investigation is focused on current innovation and design processes in the pharmaceutical industry. Changes in packaging happen through innovation processes that can then alter packaging design. Packages that are inclusively designed, considering user needs, may succeed more in facilitating and supporting

medication treatment. Innovation gives industry the opportunity to review and to propose completely new or improved packaging solutions. With the guidance of inclusive design, innovation processes can encompass social demands, such as aging and the needs of older patients.

Third, it is important to refer to what level of innovation was considered. The innovation process can be examined at different levels of analysis; in a firm's department, at an organizational level, or at an industry level, for instance (Gopalakrishnan and Damanpour, 1997). This research has prioritized the organizational level of analysis in empirical studies, with focus on technical innovations in the packaging domain. The argument for that is the same used by Crossan and Apaydin (2010, p. 1156), where they affirm that the organizational level is within the control of the firm. This means that, "by targeting the firm level, we can provide a practical basis on which managers can build structures and systems that would enable innovation within the firm."

Fourth, this research takes place in the Division of Packaging Logistics, in the Department of Design Sciences at Lund University, Sweden. As a direct consequence, it is important to mention how aspects of packaging logistics are considered in this research. So far, this dissertation focuses its analysis solely on medications that come directly into the hands of patients. However, there is no focus on any specific disease or treatment in the empirical investigations. For pharmaceutical packaging, the object of study is primary packaging, i.e., consumer packaging, as well secondary packaging as they are both handled by end users, e.g., patients. Primary packaging belongs to a larger and more complex packaging system, which also includes secondary packaging (packaging distribution), and tertiary (transport packaging) (Paine, 1990, Bramklev, 2007, The Consumer Goods Forum, 2011). Tertiary packaging might be mentioned in the studies, but its development process is not the focus of the dissertation.

Finally, environmental and economic aspects are only indirectly considered, and packaging in retail is not taken further into account, being out of the scope of this research. The original empirical investigations are not contextualized in any country in particular, as the companies and participants enrolled have an international profile, with worldwide knowledge of pharmaceutical packaging innovation and design processes.

1.6 Terminology

It is important to define terminology used in this dissertation and in the appended papers. The definition chosen for who is considered *older* is taken from the World Health Organization (2016), which explains that "most developed world countries have accepted the chronological age of 65 years as a definition of 'elderly' or older

person". Similarly, the United Nations (UN) "has not adopted a standard criterion, but generally use 60+ years to refer to the older population" (WHO, 2016). The definition of *older people* then refers to a heterogeneous group of individuals in developed countries, which are entitled to, or approaching the age to receive, pension benefits. *Patients* are the ones assigned medication therapy – and this can be done within different settings, such as at home, at health care facilities, in hospitals and so on. No previous specification of the context of medication being taken was chosen, even though I was aware of trends such as the prevalence of self-care in medication therapy for non-acute patients.

In design, for instance, *people* become *users* of industrial artifacts (Redström, 2006). In this dissertation, the group of interest is older people who use medication and medication packages; they are specifically defined as *older patients*, as well as *old patients*, *senior patients*, *elderly patients*, *elderly users,* or simply *the elderly*. I decided to use these terms interchangeably because no differentiation was found when the systematic review was conducted; these terms were used mostly as equivalents by scholars from distinct areas of research.

In relation to the terminology about packaging, Bramklev (2009) explains that *packaging* and *package* are often used as synonyms in relevant literature. However, according to the Bramklev (2009), there is a slight difference to be aware of: *package* refers to the physical artifact which contains a physical product. *Packaging* is a broader term which refers to physical objects as well as to the process of packing goods. This difference is not explored further in this dissertation, where *pharmaceutical packaging/package*, *medication packaging/package* and *medical/pharmaceutical container* are used indistinctively. For the appended papers, the preference for one or another term mainly led to previous terminology being used within the journal/conference to facilitate readability and a common understanding of the study across disciplines.

Regarding the empirical studies in this dissertation, some additional considerations about terminology must be added. Within the pharmaceutical industry, two stakeholders are then important. One stakeholder is the *packaging supplier*; a company that produces the packages to be used by the companies producing the drug product. The second stakeholder is the *brand-owner drug manufacturer*; the company that creates new drug products. Brand-owner drug manufacturers differ, for instance, from contract manufacturing organizations (CMOs), which can manufacture drugs, but they do not create those drugs. Brand-owner drug manufacturers also differ from generic companies that use the 'drug recipe' to produce drugs at a lower cost when drug patents have expired. This dissertation, even when referring only to *drug manufacturers*, means the brand-owners drug manufacturers as they are the companies with more interest in launching new totally new drugs onto the market, and they are also the companies with the greatest potential for innovation, which is of interest in this dissertation.

1.7 Readership

This dissertation is aimed at three different readerships. One readership is composed of academics. Since this is an interdisciplinary work, I can imagine that researchers interested in interdisciplinary scientific work in the fields of packaging and design would find this dissertation of interest. Additionally, any researcher that wants to do research with methods similar to a systematic literature review, case study, or an interview study could benefit from skimming through the pages of the methodology chapter or the methodology sections of the appended papers. I dare even to think that doctoral candidates in applied sciences (or perhaps any doctoral candidate) could benefit from examining the research process for this work. Of course, every research process is unique, but I learned a great deal just from reading the experiences described in colleagues' doctoral dissertations. I hope my research will also have a similar role in helping and inspiring others.

A second readership is composed of practitioners. Some chapters might be especially suitable for these readers. The introductory chapter, for example, provides a panorama of important challenges we face in relation to aging and medication treatment, mostly in developed and welfare countries. Later, the discussion chapter provides an overview of the most important findings and how they interrelate with knowledge from related fields of packaging, design, and innovation. In particular, I feel that those working with packaging design in general can benefit from reading this dissertation, particularly the parts that address the need for more user involvement and better understanding of patients' needs. Managers working with innovation in packaging, or even with innovation in new drug therapies, could also extract insights to guide their work within an inclusive and patient-centered approach. These professionals might want to read some of the interpretations of patients' problems faced when they used medication packaging (e.g., Paper I), or they might want to benchmark their own packaging innovation process and practices in design by reading about others' professional experiences (e.g., Paper III and Paper V).

A third readership is characterized by policy makers; those working in regulatory boards for medicines. The perspective brought by user-centricity and inclusive design into the development of packaging might provide them with insights about how to tackle the challenges of treatment and drug therapy in aging societies. The problems here discussed are the problems of everyone who cannot read the small letters on a bottle, everyone who cuts fingers and breaks nails trying to open an 'impossible cap.' Hopefully, in a dissertation like this one, policy makers find evidence to strengthen and stimulate the development of new and improved guidelines that are helpful for patients' genuine needs.

1.8 Dissertation outline

This dissertation is composed of seven chapters. Following this introduction, the next chapter discusses the research methodology, which includes the overall positioning and methodological approach. Chapter 2 also includes the description of the research design and applied methods for each study, as well as a reflection on the research process and quality. Chapter 3 presents the interdisciplinary frame of reference within the domains of innovation, design, and packaging. After that, Chapter 4 builds on secondary data to describe the empirical context of the pharmaceutical industry. Chapter 5 summarizes the main findings of the five papers which are appended to the dissertation. Subsequently, these findings are discussed in Chapter 6. Chapter 7 draws conclusions and highlights the theoretical and practical industry contribution to the research. The seventh and last chapter finalizes the dissertation by pointing to possible directions for further research.

2 Research methodology

This chapter comprises the research process followed since the beginning of my PhD studies up to the consolidation of this dissertation. I take the opportunity here to start by presenting the research approach taken. After, I reflect critically on the logical structure (research design) and the iterative process followed to gain knowledge and to transfer knowledge throughout the development of three studies and five scientific papers. The chapter ends with a reflection on the research quality in the studies and in the overall research in this dissertation.

2.1 Research approach

There are two possible worldviews that guide our understanding of reality and the search for knowledge: objectivist or subjectivist. From an ontological point of view, I see we live in a non-deterministic world, where facts cannot always be predicted and controlled. The real-life problems in this research relate to organizational systems where packaging is developed and delivered to users. However, I perceive packaging not only as a *developed* object, but as a *designed* object, where intentions of use (by designers) and actual use of the object (by end users) do not always correspond. This research therefore challenges the objective view of the 'perfect package,' created for optimal production lines, by contrasting it with the subjective view of packages that fail when humans (users) interact with them.

2.1.1 Epistemological approach

The epistemological approach in this research is multiple, extensive to different interpreters, and founded on social constructivism. I understand knowledge, as explained by Guba and Lincoln (1994, p. 113), as something where "multiple 'knowledges' can coexist, when equally competent (or trusted) interpreters disagree, and/or depending on social, political, cultural, economic, ethnic, and gender factors which differentiate the interpreters." The interpretation in science may be produced within a social scientific frame. The researcher's interpretations then "(…) have to

be further interpreted in terms of the concepts, theories, and literature of a discipline" (Bryman, 2012, p. 31).

As previously mentioned in this dissertation, the epistemological predominant view of packaging has been product-centered, where knowledge is gathered and applied to make the best use of technology to produce products and packages faster, more cheaply, or even more efficiently. On the other hand, a user-centered view might consider the production of knowledge about users, user needs, and the creation of meaning in how designed artifacts are used (Mao et al., 2005). Particularly important is the notion that design professionals adopt as to who the user of a product is, and how those professionals and users share knowledge about what meaningful design is (Krippendorff and Butter, 1984, Redström, 2006, Oygür, 2018). In that sense, I agree with Larsson (2005, p. 25) when he affirms: "technical artefacts are ultimately designed for human needs and purposes, with design activities involving intense communication and interaction between individuals and groups in complex social settings." The social view of design influences my role as a researcher of reality and gathering of knowledge. I see we need knowledge to improve organizational systems where packages can be produced, taking users and their needs into account. Ultimately, users have to be understood as diverse beings that can also have a role in designing objects (Waller et al., 2015), offering their perspectives and enriching the design process (Wilkinson and De Angeli, 2014).

Evidently, I cannot refute the fact that my educational and professional background has influenced my search for knowledge and the theoretical lenses I have used – see also item 2.4 and Chapter 3. I started my higher education at bachelor-degree level by learning about design as a powerful resource for innovation and the creation of products based on human needs and capabilities. The first job I had related to that my education, working in a creative agency. Later, I had the chance to do a master's course in industrial engineering. In the master's course, I decided to write my thesis about packaging, which also led me to obtain a job as a packaging specialist in a multinational organization. The creative, user-centered role I had in my former experience was suddenly transformed into a very technical role. I spent most of my days trying to improve packaging drawings to work better in existing machinery and to manage the demands of multiple stakeholders working in a packaging project.

As discussed in the literature by authors like Bix et al. (2009b), I have had the chance to experience the dichotomies that coexist between the two distinct views of product-centered and user-centered packaging, both in my higher education and professionally. Packaging has always been my greatest interest because it is indeed a very technical, product-centered artifact, but it has always had the potential to influence to large extent in the experience a user has with the product. After some years into practice, I have come to ask 'what led certain things to be done in a certain way?' leading my path back again to academia. Despite my know-how of packaging in general, I had no expertise in pharmaceutical packaging, yet a doctoral project

based on pharmaceutical packaging and older people matched with the questions and curiosity I had about the challenges packaging impose on both users and industry. Within the pharmaceutical context, research seemed even more challenging and in need of an integrative view to respond to real world challenges. As a researcher, I have learned (and I am still learning) to reflect on my role as an investigator. Importantly, I have learned to engage with the world of reality by being someone that asks questions to multiple stakeholders, and looks for answers by combining knowledge from different disciplines.

2.1.2 Methodological approach

The methodological view of a researcher is never free of ultimate presumptions that are there in the background. Yet there is no such thing as the 'best' methodological view as one methodological view needs to be reflectively considered in relation to other possible methodological views (Arbnor and Bjerke, 1997). In turn, this might also imply denying or not exploring other routes to access knowledge.

Arbnor and Bjerke (1997) describe three different methodological views or approaches a researcher can use: an analytical approach, a systems approach, and an actor's approach. In brief, the analytical approach is based on a positivistic paradigm, and focuses on facts that need to be described, explained, and prescribed with the support of theory. Within this approach, elaborating hypotheses and testing them against a theoretical framework is core. The system approach provides a holistic view of the phenomenon under study, where the whole becomes more important than its individual parts. From a systems approach, the researcher explores the system to understand complex phenomena with the final goal of improving that system (Gammelgaard, 2004). Finally, the actor's approach is closer to social sciences, and aims to "understand profoundly – and from the actor's point of view – the nature of the activities studied" (Pihlanto, 1994), where the researcher is not a mere observer but an action-oriented being that uses knowledge to understand and to emancipate (Arbnor and Bjerke, 1997). The real world is studied in terms of a few research objects, or in some instances only one such object, since the aim is not to generalize.

The systems approach seems to be the methodological approach which best aligns with the search for knowledge this research represents. I refute the analytical approach as it decomposes reality into smaller units, from where value-free, time-free, and context-independent causal-effect relations can be apprehended (Mentzer and Kahn, 1995). In contrast, my research is context-dependent, based on the peculiarities of the pharmaceutical industry. Specifically, pharmaceutical packaging innovation and design take place in connection to the general drug development process and other current boundaries set within the pharmaceutical industry (see also Chapter 4). Regulatory demands, among others, are very specific within this

context and also affect the way packages are designed. Moreover, and differently than the analytical approach, the systems approach permits the researcher "to come very close to the research objects and the concrete settings" and enables the formulation of recommendations (Gammelgaard, 2004, p. 487), all of which also aligns with the purpose of this research.

The actor's approach would be suitable if the focus was only on the individuals and if there were perhaps a project where I, as a researcher, was an active participant in discovering evidence of packaging problems, thereby supporting the claim for change and empowerment of patients in their treatments. However, the lack of previous research about industry practices in pharmaceutical packaging required me to take a step back, to first understand the processes in place. Importantly, this research focuses on the exploration of packaging innovation and design processes that go beyond merely human interaction. Those processes penetrate a technological field where industrial context, organizational structures, and the actions of multiple stakeholders need to be considered from a holistic view, which could be better explored through the systems approach. As a result, if packaging is meant to change, it might not be because of the action of one individual, but because the whole system supports change. In exploring significant relationships, a researcher can learn and grasp both the dominant forces in the system, as was done in the customer-supplier case study (Study B, Paper III), as well as current practices, as explored by interviewing multiple stakeholders (Study C, Paper IV and Paper V).

2.2 Research design and applied methods

Research design is what sustains the logical part of this research. Rather than merely being a plan of my work, research design is the invisible structure that frames the search for knowledge from the initial research questions to the development of particular studies and choice of methods (Yin, 2013). Overall, by defining the research design, a researcher is consciously deciding what will be observed and how, so that the research purpose is fulfilled and research questions are answered (Easterby-Smith et al., 2015).

Given the purpose and questions of this research, it is natural to follow an exploratory path, where qualitative research methods are prioritized in empirical studies. Due to my personal background, I also identify myself as a qualitative researcher, always eager to go out in the field and learn from it in the way Creswell (2013) describes. According to him, qualitative researchers collect data in its natural setting (i.e., not in a laboratory setting as in many experimental studies), and the researcher is quite active in interviewing and observing for data collection (Creswell, 2013). Rich data from multiple sources is gathered and analyzed iteratively through inductive-deductive reasoning to establish or identify patterns

and emergent themes. Importantly, Creswell (2013, p. 47) highlights the holistic account that qualitative research provides, which easily aligns with the systems approach previously described: "qualitative researchers try to develop a complex picture of the problem or issue under study. This involves reporting multiple perspectives, identifying the many factors involved in a situation, and generally sketching the large picture that emerges."

The overall research design unfolds into three studies in this dissertation, and each comprises one or two papers. The first study (Study A) was theoretically based, developed through investigations in the literature. The other two studies were empirically based, developed through a case study (Study B), and an interview study (Study C). Figure 1 presents the overall research design adopted in this dissertation.

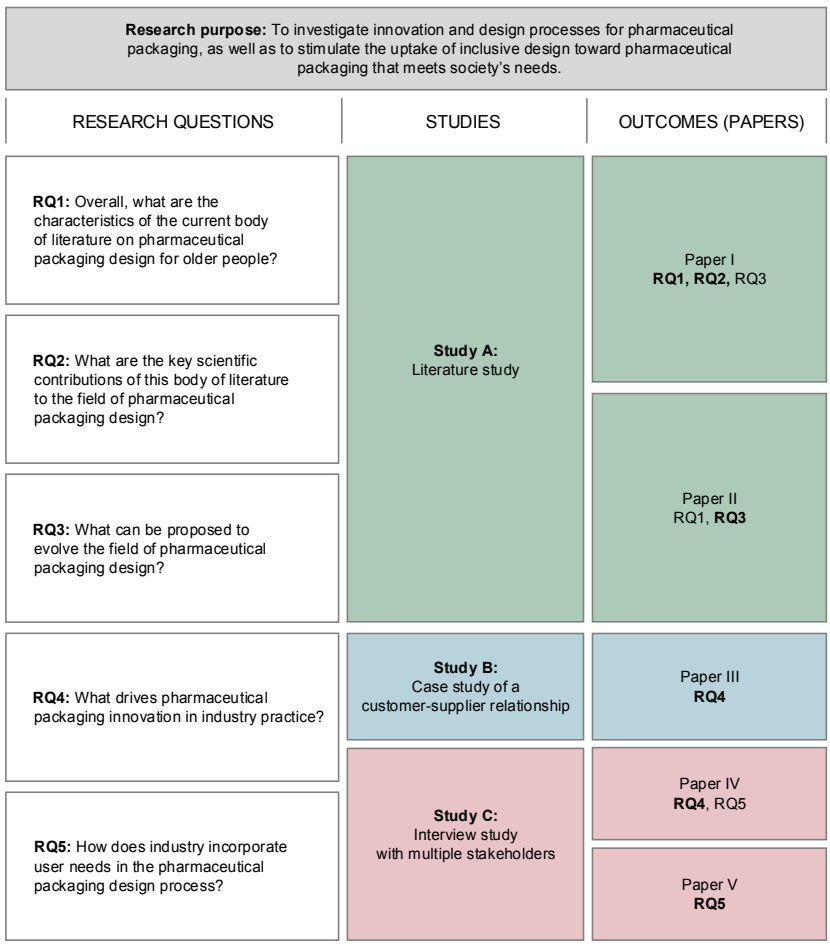

Figure 1 – Research design.

2.2.1 Study A – Literature review of pharmaceutical packaging

To master a field of research, or to establish a dialog among research peers, a researcher should be acquainted with existing relevant literature. As explained by Tranfield et al. (2003, p. 208), "the aim of conducting a literature review is often to enable the researcher both to map and to assess the existing intellectual territory, and to specify a research question to develop the existing body of knowledge further." Among other things, it helps the researcher to learn about a specific research topic. In particular, by reviewing the literature, we become aware of concepts, theories, and methods applied to this specific topic, we learn about controversies within different streams of research within the topic, and also find out who the main contributors (authors) are who have written or published on the topic (Bryman, 2012).

Starting with literature reviews is common and expected practice for a researcher stepping into a research field. Authors tend to rely on the work of others through critical reading. As affirmed by Bryman (2012, p. 102), "such literature reviews might occur as preludes to the presentation of some empirical findings or they might be works in their own right (for example, a dissertation or article based entirely on a review of the literature in an area)." Based on that, Study A was designed as a theoretically based study, based on the review of relevant literature, and aimed to answer the first three research questions in this dissertation. Evidently, there are different ways to design a literature review. In Study A, a systematic literature review and a narrative review were developed.

Systematic literature review

Early on in this research, the opportunity to provide an integrated view of the literature on medication packaging and older patients was identified. A systematic literature review seemed the most suitable choice, as this kind of review would help to identify gaps in research and guide further studies within this dissertation. It would respond to the two first research questions (RQ1; RQ2) and partly to the third research question (RQ3). A systematic review may be performed for the same reasons that any literature review is done, however, a systematic review outperforms other types of literature reviews because of its methodological strengths. In comparison with narrative reviews, a systematic review adopts a replicable, scientific, transparent process for identifying, selecting and appraising studies (Cook et al., 1997, Tranfield et al., 2003).

If the aim, scope, and questions to guide the search are well defined, this makes it possible to compile a set of key results to be analyzed; questions not covered in the key findings can direct others to future research topics within the field (Baines et al., 2009). Furthermore, a researcher performing a systematic review needs to explicitly report all the steps taken to select and evaluate the studies. It is crucial to have very clear inclusion and exclusion criteria about why certain studies became

part of the final selection or not. In that sense, a well-conducted systematic review gives other authors the chance to replicate the search strategy, taking the same steps with some room for slightly different interpretations (Booth et al., 2012). When it comes to examining advantages, Becheikh et al. (2006, p. 645) understand that the application of the principles of a systematic review can help "(…) to limit the bias (systematic errors), reduce chance effects, enhance the legitimacy and authority of the ensuing evidence and provide more reliable upon which to draw conclusions and make decisions."

Despite its originality and focus on medication packaging, it is important to comment that the systematic review in this dissertation find its place among other reviews. These reviews provided valuable insights during my task of reviewing systematically, for instance, the effect of interventions to reduce potentially inappropriate use of drugs in nursing homes (Forsetlund et al., 2011), the effects of reminder packaging on medication adherence (Boeni et al., 2014), the medication errors which happen in senior acute care (Metsälä and Vaherkoski, 2014), the adherence to electronic medical devices (Checchi et al., 2014), and the proposal of a universal design methodology for developing child-resistant drug packaging (de la Fuente, 2006).

Narrative review of the design research

Narrative reviews are broadly found in the field of design, where researchers usually discuss specific concepts or want to call attention to the need for more research within a specific topic. The narrative review in this dissertation follows this same reasoning, aiming to address RQ3, and partly RQ1.

A narrative review (Paper II), in comparison with a systematic review (Paper I), gives the researcher greater freedom to explore concepts, ideas, and insights from authors and published (scientific) material. It helps not only to understand, but also to connect, domains of knowledge. The narrative review in this dissertation therefore explores and reinforces the connections between pharmaceutical packaging, aging, and inclusive design approaches at a discursive level. Methods and research practices are reviewed, aiming to provide the researcher with knowledge about where the design field has its strengths and limitations in the research of pharmaceutical packaging. To some extent, this review complements the systematic review with some overlapping of literature, but also with the addition of the literature on aging and inclusivity. The narrative review explains the debate about different design approaches, and the older population, and uses some of the methodological freedom to select and discuss studies that could not be added in the systematic review. This study proposes empirical studies for further research.

2.2.2 Study B – Case study of a customer-supplier relationship

The third study in this dissertation responds to the fourth research question (RQ4). The nature of this research question called for an empirical investigation, here designed as a case study. Bolton (1985) recommends the use of case studies in new areas of research that require a more holistic view, or a systems thinking (i.e., a systems approach). Case studies are context-dependent, as they place the researcher close to real-life situations and allow data collection through different methods – such as interviews, observations, documents, and reports – that help an in-depth understanding of the case (Baxter and Jack, 2008, Creswell, 2013, Yin, 2013).

Case studies vary in their character and design. Yin (2013) suggests that a single-case study is suitable if the case is critical, unusual, typical or representative, revelatory, or longitudinal. Single-case design tends to prioritize the uniqueness and richness of the case, which can challenge or further develop existing theories. For instance, Siggelkow (2007) suggests three important uses for single-case design: motivation, inspiration, and illustration. First, a researcher uses the single-case study to motivate the investigation of a specific phenomenon (e.g., 'why A leads to B?'), using a real-life situation as the point of departure. Second, a researcher can use rich case data to be inspired or to inspire others wherever new ideas about a phenomenon or new themes inductively emerge. Third, the researcher uses the single-case study to illustrate theoretical constructs in a concrete example.

Conversely, multiple-case studies might fulfill a different intention, where the focus is on replication logic, where each case is then a stand-alone analytical unit, which can be contrasted with other units (Eisenhardt, 1989, Yin, 2013). Eisenhardt and Graebne (2007, p. 27) emphasize case-study research, and particularly multiple-case study, to build theory based on the theoretical sampling of cases that are "selected because they are particularly suitable for illuminating and extending relationships and logic among constructs." Even though no statistical validation is intended, the use of multiple cases can strengthen emergent theory.

After all, single- and multiple-case studies can be a part of a rather iterative process between theory and data, where emerging constructs and propositions enlightened by a single-case study can be further tested by being expanded into a multiple-case study (Eisenhardt and Graebne, 2007, Siggelkow, 2007). Either by designing a single- or a multiple-case study, a researcher needs to define the unit of analysis in the case, i.e., the subject (the who or what) that is investigated in particular and from where the researcher may generalize or draw relevant conclusions (Lewis-Beck et al., 2004). The unit of analysis can be holistic (one unit of analysis) or embedded (multiple units of analysis) (Yin, 2013).

Case study design and selection

Contextualized within the pharmaceutical industry, Study B is a single-case study of two companies – a global brand-owner drug manufacturer and a packaging

supplier – in a customer-supplier relationship, whereas the holistic unit of analysis is the packaging innovation process (Figure 2). The choice for a single-case study is justified given the fact that there is a lack of in-depth studies investigating industry practices of pharmaceutical packaging innovation. The theoretical point of departure for Study B is that innovation is a complex organizational process, where the actions of individuals and the organizational structure interact and determine the innovation outcomes (Slappendel, 1996). More precisely; packaging innovation is a complex organizational process, influenced by multiple driving forces.

According to Yin's (2013) definition, a single-case study can be considered as a typical or representative case, based on the type of companies selected and their presence within the pharmaceutical industry. As suggested by Siggelkow (2007), the study chosen then was designed with the intention to exemplify theoretical constructs in a concrete example. By considering the many problems experienced by users, as identified in Paper I, investigating a typical or representative case can lead to better understanding of common practices and the dominant processes that guide pharmaceutical packaging.

I should comment that, before starting the study, I was informed about the overall context of the pharmaceutical industry, as further described in Chapter 4. This previous knowledge was gathered by reading secondary data reports, which helped to decide about having a single-case study of these two organizations (brand-owner drug manufacturer; packaging supplier). Based on that, I knew from the start that the pharmaceutical industry is made up of large organizations (i.e., brand-owner drug manufacturers) that have most of the resources to invest in pharmaceutical innovation (Evaluate, 2016). Even though brand-owner drug manufacturers may outsource some of their R&D processes, they are still the ones responsible for applying for regulatory approval and answering for products launched in the market (IFPMA, 2017). On the other hand, these organizations do not have all the resources embedded in their processes to design and innovate in their packaging, which means they need to collaborate with packaging suppliers (i.e., organizations that manufacture and supply packaging to drug manufacturers). These packaging suppliers are rather specialized, since the pharmaceutical business has special regulations and standards that differ from those of other industries. This brief description elucidates that by investigating only one of these two stakeholders (brand-owner drug manufacturer; packaging supplier) only a partial or incomplete case about pharmaceutical packaging innovation process would be presented. The case study was therefore designed based on the focal relationship of a large brand-owner drug manufacturer and a packaging supplier specialized in pharmaceutical packaging.

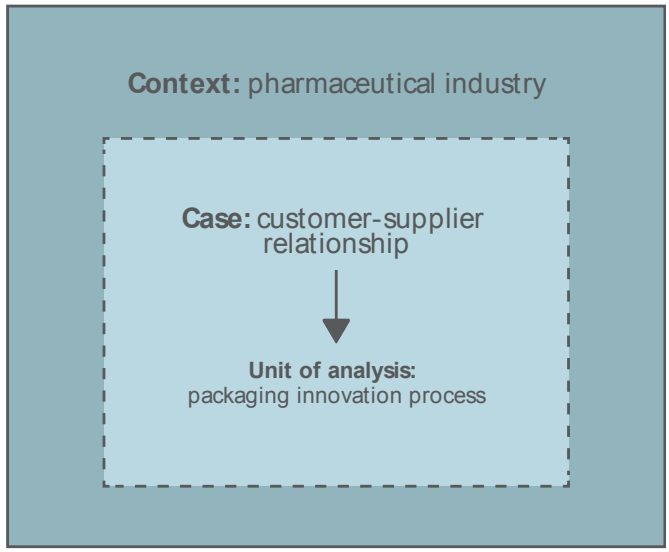

Figure 2 – Case study and unit of analysis.

2.2.3 Study C – Interview study with multiple stakeholders

The third study complements and expands Study B by empirically exploring the pharmaceutical packaging through the lenses of multiple stakeholders. Generally, this study presents the current practices, trade-offs and perspectives on pharmaceutical packaging innovation that impact packaging design (Paper IV). This study also considers how the pharmaceutical industry incorporates user needs in the pharmaceutical packaging design process. Study C addresses RQ4 and RQ5.

A common way to get to learn of experiences and practices is by interviewing people who have lived those experiences and have an in-depth expertise within a specific topic of interest. Based on that, the main advantage of the qualitative research interview as research method is "(…) the privileged access to people's basic experience of the lived world" (Brinkmann and Kvale, 2015, p. 32). However, differently than journalistic or therapeutic interviews, qualitative research interviews are indeed *inter-views* where interviewer and interviewee construct knowledge together (Brinkmann and Kvale, 2015). In research interviews a researcher is not only asking someone about an interesting topic, but rather, the researcher is also trying to understand the discourses, power relations, and ideologies that are embedded in a person's response, and "(…) that nonetheless affect and perhaps even constitute what they talk about and how" (Brinkmann and Kvale, 2015, p. 3).

Designed as a qualitative interview study, Study C is based on the epistemological view of having dialogs with stakeholders involved in

pharmaceutical packaging innovation, and considering their interpretations of their work and established processes.

In terms of methodological choices, an important aspect was to consider who to include or exclude. It was crucial to ensure that all respondents had sufficient experience of pharmaceutical packaging. In this study, only respondents that had experience of the innovation and/or design processes for pharmaceutical packaging were included, yet the respondents had varied educational and professional backgrounds. Regarding their education, most of them were not trained in packaging, but rather in engineering, marketing, and business administration; this is common in the packaging field where professionals often have hybrid educational backgrounds (Wever, 2009). For the respondents working at brand-owner drug manufacturers, it was common to have an educational background in life sciences or other scientific areas (e.g., chemistry and biology): They started their careers at the companies in these areas, evolving later for differing reasons to work with packaging. A limited number of respondents had no formal higher education or had a non-related educational background. Those respondents had gained all their expertise on packaging from their positions at the companies.

Regarding the professional experience of the respondents, most of them had built their careers in the same organization, where they evolved internally. The professionals were either top managers, mid-level managers, or specialists. Top managers have advanced their own careers vertically in the company, and had a micro as well as macro understanding of packaging processes. In their daily work, they were more involved in strategic decision-making and managing different teams, including packaging teams. Mid-level managers have also advanced their careers vertically, from specialist positions to management. In their daily work, they were directly involved in the specificities required for designing new packaging and managing parallel projects. They had smaller teams to manage, usually composed of designers and engineers. Specialists had senior positions and a high level of expertise about packaging and its requirements, achieved through horizontal career evolution.

Based on that, participants were drawn from fifteen different companies, described as drug and health care product manufacturers, medical equipment manufacturers, packaging suppliers, and non-profit organizations involved with packaging and patient care. The choice for including respondents from drug and health care product manufacturers and packaging suppliers was the same as in Study B. Respondents from medical equipment manufacturers had focus on self-care and chronic treatment, where packaging is essential for users to operate medical equipment and follow the treatment correctly. Patient and packaging organizations worked as a forum for discussion of user-centered packaging, with members directly involved with the pharmaceutical organizations. This also fitted with the purpose of this research.

2.3 Research process and phases

This final dissertation is composed of three main research studies, which led to five scientific papers – all conducted within one research project which was originally named *Pharmaceutical Packaging Design and Innovation for Older Patients*.

Importantly, the resources used to conduct this research came from the Brazilian scholarship program – *Science without Borders*. The program is a joint effort between the Ministry of Education (MEC) and the Ministry of Science and Technology (MCT) through their respective funding agencies – *Coordenação de Aperfeiçoamento de Pessoal de Nível Superior (CAPES)* and C*onselho Nacional de Desenvolvimento Científico e Tecnológico (CNPq)*. By supporting Brazilian students overseas, the program aims "(…) to promote the consolidation and expansion of science, technology and innovation in Brazil by means of international exchange and mobility" (CAPES and CNPq, 2016). Through this program, the Brazilian government fostered the network and partnerships between Brazilian researchers and research centers, and top universities abroad. Lund University was one of the partners. Additional resources and collaboration came from the Swedish National School of Aging (SWEAH), where I became a doctoral member of one of its first cohorts in January 2015. At SWEAH, I had the chance to mix with other doctoral students from different disciplines, such as medicine, law, and occupational health. These interactions were fruitful for me to identify and learn about theories of aging and other theoretical perspectives that were new to me.

Early in my studies I thought this research represented my work as a facilitator in the dialog between the needs of older people and the challenges within pharmaceutical packaging innovation and design. My initial interest has prevailed along the whole process, however, knowledge generation and methodological choices have evolved. Now at the end of this doctoral process, I can clearly see two successive phases which have developed naturally as the research has progressed. This clear view permits me to describe here Phase I, when I entered and came in contact with the field of pharmaceutical packaging; and Phase II, when I conducted the empirical investigation and enriched the field with new knowledge.

2.3.1 Phase I – Getting to know the research field

Phase I comprises the initial years of my doctoral studies, from January 2014 to August 2016, and was concluded when I submitted my licentiate thesis (Lorenzini, 2016). In the final doctoral dissertation, this first phase encompasses Study A and early stage of Study B.

For me personally, this was an important phase to discover the field of studies that I was going to enter for the subsequent four years. It was also an exciting period,

since I was open to new knowledge and I was not sure what I was going to discover. Despite that, the first study was a striking one, which consumed months and paved the way for the next studies. In particular, a systematic review can be strenuous. You could ingenuously think that accessibility to plenty of research makes it easier to do systematically reviews. This is not entirely true, as having about thousand articles at hand can make it a difficult task to establish the concise scope of a research field.

The iterative process of systematically searching the literature

The exploration of pharmaceutical packaging design started with the review of the literature; systematically and narratively. Study A began as a systematic investigation of the literature. The whole study took about eighteen months to complete, and it ran in parallel with Study B and other scholarly activities.

During the whole process and iterative cycles of search, I followed four steps adapted from Booth et al. (2012): (i) defining the strategy and meeting the criteria – study selection; (ii) conducting the search; (iii) selecting the studies – title and abstract review; (iv) verification and documenting the search. The procedures in each step are detailed in Paper I. My experience from doing a systematic review demonstrates that defining a search strategy requires many adjustments and iterations. By reading other systematic reviews and discussing them with colleagues, I understood that running a first pilot search would be helpful. Table 1 shows one of my initial attempts to define the strategy and search for the relevant literature. This initial period of searches lasted from March to May, 2014 and they were conducted through LUBSearch, a large database for scientific articles hosted by Lund University.

Table 1 – Conducting the search from March to May (2014) in LUBSearch.

Search terms combined with Boolean operators	No. of studies	Search area	Attributes /limitations	Practical screening
"packag* design" OR ”design for packag*”	570	title	English, peer-reviewed journals, available in the library collection	Deducting duplicates automatically (1,176)
(packag* design OR design for packag*) AND pharma*	4	title		
packag* design AND pharma*	404	abstract		
packag* design AND (pharma* OR drug* OR medic*)	501	title; abstract		
(packag* OR container* OR closure*) AND (pharma* OR drug* OR medic*) AND design	443	title; abstract; abstract		

As shown in Table 1, the searches were initially broad, aiming to retrieve as many published studies as possible. After some rounds of search, the focus was lost. I found it quite difficult to define what was, in fact, being searched for in relation to pharmaceutical packaging. I decided it would be important to use databases that were familiar to an international audience, which made me select Scopus, Web of Science, Medline, and Engineering Village. I also realized at a certain point that I would need to delimitate searches even more. From a design perspective, it is important to know 'the who', in this case, i.e., *who* was using the pharmaceutical packaging. I thus limited my searches to older people (as defined in Paper I). Studies that did not involve older people were excluded. Consequently, packaging was better defined, and the scope of search was also narrowed down, for instance, by excluding papers which only focused on labels. The systematic review also improved after been submitted to the scrutiny of reviewers, which suggested a final step where the methodological quality of the selected studies was analyzed based on a structured tool, i.e., the Mixed Methods Appraisal Tool (MMAT), developed by Pluye et al. (2011). The appraisal tool permitted me to assess the methodological quality of the papers included, reinforcing the fact that systematic review results are based on evidence from high-quality studies. The final selection comprised 34 studies that were included and analyzed. Early results of the systematic review were presented at a conference, and the final paper (Paper I) was improved, and then accepted and published in an international journal.

Setting the scene for the empirical studies

The narrative review was developed concomitantly with the systematic review. Within the context of this dissertation, the narrative review should be read as a very early discussion about inclusive design approaches, aging, and pharmaceutical packaging design. Despite being a design professional already, I was quite new as a pharmaceutical packaging design scholar, and some concepts and philosophies from inclusive design were also new to me at that time.

The narrative review was important to the general research process of this dissertation because of the four propositions elaborated in Paper II. These propositions can be considered as the 'first seeds' for the empirical studies conducted in Phase II. One of the propositions suggested "carrying out dialogs with the actors [stakeholders] along the supply chain, for better understanding of how user needs are planned for within packaging development" (Lorenzini and Olsson, 2015). With some slight adaptation, this proposition was the starting point for Study B, later expanded into Study C. Another proposition elaborates on "carrying out a joint dialog between industry and policy makers for an improved debate on inclusivity. This would impact the development of inclusive packaging and a revision of general protocols for pharmaceutical packaging" (ibid). This proposition was not fully carried out in this research, however the last two studies did indeed analyze current practices of medication packaging development and user

involvement in the design process, aiming for more debate about inclusivity. Paper II was presented at an international conference.

2.3.2 Phase II – Empirically investigating and enriching the field

Phase II comprises the final years of my doctoral studies, post-licentiate thesis, from September 2016 to March 2018. In this phase, the research has evolved and matured, supported by my previous literature studies. As a researcher, I had expanded my understanding of the pharmaceutical packaging as a research niche, and found myself able to continue toward empirical investigations.

Importantly, I found a place for this research to contribute. In Study A, a lack of studies within the industry was identified. The majority of papers prioritized human-packaging interaction, with emphasis on functional tasks performed by older people. Still, the perceptions of managers and packaging developers were not investigated, which opened up the opportunity to dig into this matter. I did not have access to all the data and all the respondents at once, and this is further described in the next subsections through the early days of the case study (Study B) until the interview study (Study C). Figure 3 illustrates the research process.

Piloting the empirical study

Based on the ideas that emerged from literature searches, and all my previous theoretical work, I had established myself as a researcher within the pharmaceutical packaging field, eager to explore empirical domains. Yet I faced the challenges that researchers normally face when collecting qualitative data. Multiple doubts emerged, such as who to talk to, how to get access to representative people, how to make these people interested in my research and so on. In addition to that, I had to deal with the challenges of penetrating the pharmaceutical industry where access to data is closed to the people that work within that pharmaceutical industry. Moreover, my personal background and the fact that pharmaceutical packaging was also a new field within the department where I work made me initiate all contacts with the pharmaceutical industry myself, from scratch.

The consciousness of these initial difficulties did not reduce my motivation to obtain empirical data, but they certainly reduced my initial ambitions with the empirical study. I therefore decided to focus on a small amount of initial data and work that as a pilot for a subsequent study. First, I purposefully selected one packaging supplier, specialized in manufacturing pharmaceutical packaging. There I had individual interviews with the Managing Director (as he gave his title) and then with the New Product Development (NPD) Manager. These two interviews were my first interaction with the 'real world of pharmaceutical packaging.' These two professionals were aware of all the processes in designing the packages, and they were the ones taking important packaging decisions in the company. During

the interviews, material from the company about flows, processes, and internal documents were made available to me for further analysis. Through the packaging supplier, I was given access to a customer company; a global brand-owner drug manufacturer. There I interviewed two managers and an associate scientist involved in packaging innovation. All the interviews followed an interview protocol, were fully recorded, and transcribed verbatim within days. Table 2 provides a description of the respondents.

For the analysis, for the first time in my doctoral career I could try out the skills I have learned from qualitative methods courses. Consequently, the transcription of the interviews was coded, inspired by Charmaz (2006). Charmaz (2006, p. 43) explains: "coding is the first step in moving beyond concrete statements in the data to making analytic interpretations." According to her, "qualitative codes take segments of data apart, name them in concise terms, and propose an analytic handle to develop abstract ideas for interpreting each segment of data" (Charmaz, 2006, p. 45). The process of coding is a suitable way of working comparatively with data and beyond the simple description of the phenomenon under study (Goulding, 2011). I manually coded the text and organized my codes in an Excel sheet. A case summary was sent, and revised by the respondents, followed by emails and phone calls for clarification. The first partial results of my pilot empirical investigation were presented in my licentiate thesis (Lorenzini, 2016). The case study is further detailed in Paper III, which was presented in a conference as an early draft, and further developed and published as a journal paper.

Table 2 – Description of case study interviewees of interviews. Adapted from (Lorenzini et al., 2017).

Participant pseudonym	Company	Position	Profile	Years with the company and main responsibilities	Interview time (h:m:s)
Anders	Packaging supplier	Head of Medical Pharmaceutical Packaging	51, male, MSc in Industrial Engineering and Organization	8 years with the company. Management of the business in the medical area.	02:17:22
Bernt	Packaging supplier	New Product Development (NPD) Manager	38, male, MSc in Polymer Engineering, MSc in Business Administration	13 years with the company. Responsible for the R&D, NPD, and management of the in-house tool shop.	00:42:13
Claus	Drug manufacturer	Team Manager of Primary Packaging	60, male, MSc in Chemical Engineering	34 years with the company. Leads primary packaging development for drug projects.	01:46:09
David	Drug manufacturer	Team Manager for Devices	50, male, MSc in Mechanical Engineering	20 years with the company. Leads device development projects.	01:09:06
Erik	Drug manufacturer	Associate Principal Scientist for Novel Packaging	46, male, PhD in Electronic Engineering	12 years with the company. Coordinates stakeholders for new technologies in packaging and devices.	00:40:46

Expanding the empirical study

After conducting the case study (Study B, Paper III), I had already understood the packaging innovation process within a pharmaceutical context. The experience I had at this point would prevent me asking only shallow questions. Instead, I felt more prepared to establish some sort of dialog with experts, and to penetrate the microcosm of the respondents' reality. Based on that, it was possible to better understand how the pharmaceutical market is run nowadays, what practices for designing pharmaceutical packages are, and what pushes innovation.

I had participants enroll in the study through direct communication and via chain referral. I did not only want to have access to people by convenience, rather I aimed for talking and getting access to respondents that were really representative to my research. To achieve that, I attended scientific and business conferences where professionals from the pharmaceutical and packaging industry mingled. I also attended lectures and small seminars organized at the university where I could network. On some occasions, I was also invited to present my research. Because of the huge structure of many pharmaceutical organizations, it was common that one

of the initial contacts made at those events led me through a chain of emails and calls until I could finally reach the right person to talk to.

The interviews from the case study were included in the interview study, and the interview protocol was kept the same with some slight difference on the questions. The reason for that is because the questions were proven to be relevant, encompassing a holistic view of packaging processes. The slight adaptations were mainly related to reaching a better flow of the interview, avoiding some repetitive parts, and improving the formulation of questions. After eight months of sparse interviews during 2016 and 2017, I stopped performing interviews as I had reached response saturation. As one could expect, I depended very much on the time and availability of the respondents to participate. A benefit of having the interview study spread along all these months was that I had time to reflect, and absorb all the information that was shared with me in each interview.

In total I collected data from twenty-five interviews, which resulted in many pages of transcripts. Based on discussions with coauthors, I adapted the general inductive approach by Thomas (2006) to analyze data, which has well-defined steps a researcher might follow: 1. preparation of raw data files, 2. close reading of texts, 3. creation of categories and refinement of category system, 4. overlapping coding and uncoded text, and 5. the assessment of trustworthiness. Initially, three interviews were coded entirely by hand, line by line, to let unstructured main themes emerge from the data, and so I could become acquainted with the interview data. After that, I imported all my transcripts into the qualitative data analysis software, QSR NVivo 11, which allowed me to access to the material altogether rather than in separate files. As suggested by Thomas (2006), I iteratively coded segments of the texts according to the main themes, where other emergent themes or subthemes appeared. I added then a deductive step, when I looked into related literature for concepts that could help me to refine and better frame my thematic coding. After all the interviews were coded, I then reviewed the themes to make sure they were still consistent with the research questions and that they did not overlap. I shared a report of the individual interview with each respondent to make sure I had not misinterpreted the findings (see also section 2.4). Due to the richness of data, I decided to present the findings in two separate papers which have different focuses: Paper IV, where attention is paid to the packaging innovation process, packaging functions, and constraints on packaging design; Paper V, where I present the multiple levels of user, and methods used for pharmaceutical packaging design.

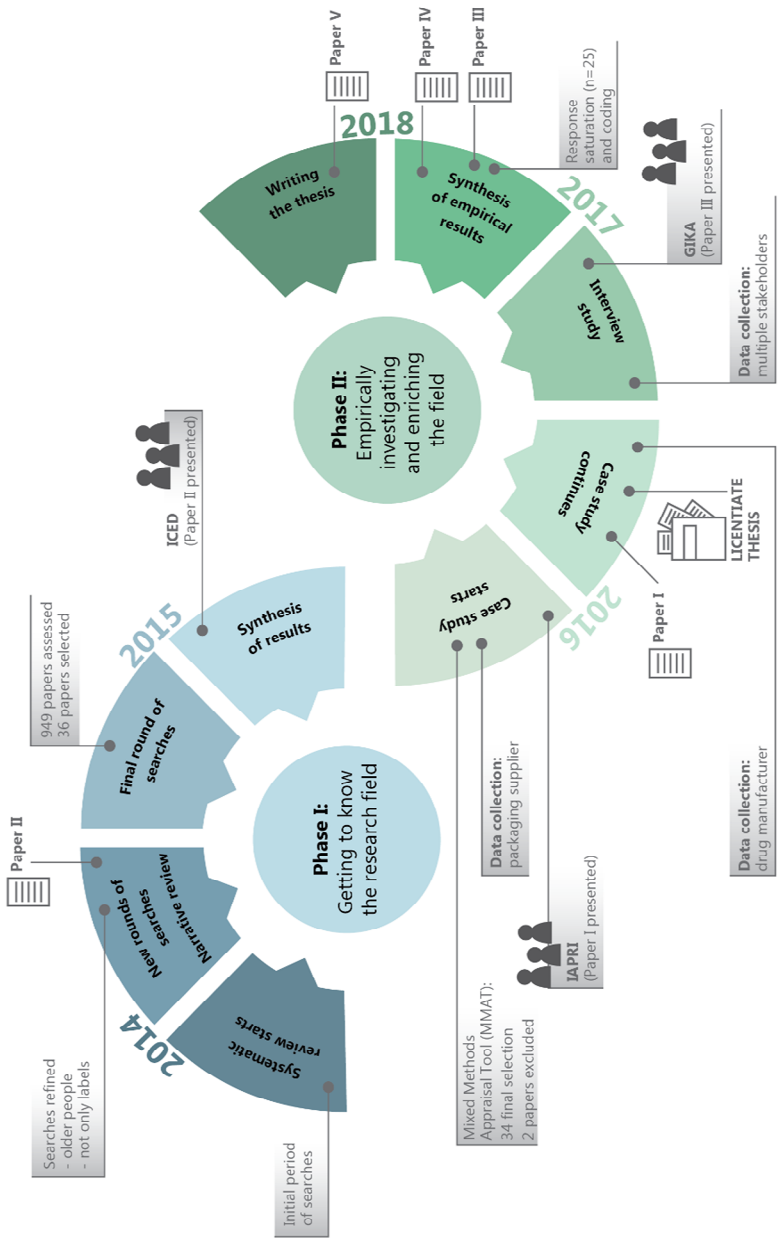

Figure 3: Research process.

2.3.3 Reflection about the process of knowledge generation

Deductive reasoning departs from a solid theoretical orientation. Based on that, the researcher usually creates hypotheses to be subjected to empirical scrutiny (Bryman, 2012). Research based on deductive reasoning is a theory-testing process (Hyde, 2000). Inductive reasoning starts on the opposite side. By that, the researcher has no theory at hand. The researcher goes to the field to collect empirical material, from which a theory will emerge. Research based on inductive reasoning is a theory-building process (Hyde, 2000).

Inductive and deductive reasoning lead to different directions. This, however, does not prevent the researcher from using both along the research process. Bryman (2012, p. 27) is critical of the sharp separation between deduction and induction. He explains that "to a large extent, deductive and inductive strategies are possibly better thought of as tendencies rather than as a hard-and-fast distinction." Similarly, Parkhe (1993) argues that deduction and induction may not always compete, since they are continuous and inseparable processes within theory development. In such way, deductive and inductive reasoning can take part in different moments of the research process (Hyde, 2000).

A third way of reasoning research relies on abduction. Abductive reasoning creates a process that goes back and forth between theory and empirical study (Dubois and Gadde, 2002, Kovács and Spens, 2005). Abductive reasoning is the one that best matches the overall scientific reasoning and the process of knowledge adopted in this research, due to the multiple iterative movements between theory and empirical data along the years.

Looking back, I can see that abductive reasoning was not an upfront choice from the beginning of this research. The research started rather deductively, the material for investigation was based on previous research on medication packaging and older patients, as reported in Study A. In addition, the conceptualization of aging and inclusive design were essential for me to understand the need for developing user-friendly packaging, as explored in Study B. However, when the investigation of the context of production of medication packaging began, the reasoning shifted to induction. As a researcher, I went to the field with an open mind to listen to experts talking about their experiences and current practices for pharmaceutical packaging innovation. After listening to, and learning from, experts, I looked back on my data and reflected on it, trying to match it with theory. I then discovered that aspects that seemed new to me when I investigated pharmaceutical packaging innovation and design processes were not totally new in packaging research. For instance, I was faced with many trade-offs that impact decision-making in packaging design, as detailed in Paper IV. Additionally, in Paper III, I needed to expand the perspective of innovation process to organizational innovation process, which helps to understand the complexities that surround packaging in the enormous pharmaceutical industry. Further, it was also necessary to return to the user and to

understand their involvement in the process of designing and innovating in pharmaceutical packaging. This important step made me look back once more to concepts and frameworks that have been developed by other researchers. Learning from these concepts, I could 'put labels' on the different modes and levels of user involvement, which were finally examined in Paper V.

2.4 Research quality

An important step in research is to reflect on the researcher's own methodological choices and the consequences of these choices for the research. This type of reflection may be implicit in the papers as, from my understanding, reflecting on the quality of the research is not a final step, but rather a continuous process to be followed when the research is going on. Yet journals and other similar scientific publications often have limited space for the researcher's explicit writing about her reflexivity. The researcher may therefore adopt other means to reflect about personal influence in the way of shaping and interpreting the research findings.

First of all, it is important to clarify that reflexivity in the research process is independent of quantitative or qualitative approaches, as relevance and rigor are important in all research (Näslund, 2008). Nevertheless, the researcher needs to be aware that there are several terminologies available for judging research quality, and that quantitative and qualitative research may differ in their assessment methods. For instance, in quantitative research it is critical that: a) results are replicable; and b) that the means of measurement actually measures what was intended to be measured (Creswell and Clark, 2011). In their search to rebut criticism about rigor and quality, qualitative researchers have tried to redefine reliability and validity to judge qualitative research (LeCompte and Goetz, 1982, Golafshani, 2003).

Reliability and validity may not be applied to assess my overall research, but they were valuable criteria when I performed the systematic literature review (Paper I). Systematic reviews may follow very rigorous procedures, and I made sure that I had the procedures defined before starting my searches. For that, I read and learned from other systematic reviews, but I also perused methodological books, which were used almost as recipe books regarding the procedures. When conducting the searches, I filed every round of search in the databases. Furthermore, I personally performed the searches many times, in iterative cycles, to ensure the searches could be repeated and were reliable. I also discussed the inclusion and exclusion of studies with a coauthor.

A more detailed view of reliability and validity can be found in Yin's four criteria (construct validity, internal validity, external validity, reliability) for the assessment of case studies (Yin, 2013). I have seen many of my peers using Yin's (2013) four criteria to assess qualitative research developed through one or more case studies. I

agree that using these criteria can help to strengthen and defend the rigor through which a case study has been conducted. Yet I have become critical of to what extent I could apply those criteria to my research. Yin's criteria follow an objectivist worldview, which is not correspondent with the subjectivist (or interpretivist) worldview undertaken in this research. Thus, a challenge for me with conducting interdisciplinary research has always been to be consistent with my research's worldview but yet being able to navigate and show rigor to get published in journals with different disciplinary traditions.

Because of that, I would rather assess the quality of my research based on criteria of interpretative nature (Denzin and Lincoln, 2011). Consequently, "trustworthiness" is preferred when the quality of qualitative research in this dissertation is being discussed. According to Lincoln and Guba (1985), trustworthiness stands for "the truth" of the findings in qualitative research, which can be evaluated through credibility, transferability, dependability, and confirmability, as described next and summarized in Table 3.

Table 3 – Summary of research quality in this research.

Quality criteria	Overall approach	Data collection	Data analysis
Credibility	Trustworthiess of research findings based on participant's view	Triangulation of multiplie sources of evidence: interviews, revision of internal materials and protocols, observations *in loco* (case study)	Pattern matching of responses Member checks (reports with summary of interviews) Dialog with coauthors and pairs
Transferability	Detailing description of research methods and context of the study	Description of the sampling of respondents (stratified purposive sampling)	Coding scheme related back to theoretical concepts from literature
Dependability	Definition of steps for data collection and analysis	Case study/ Interview protocol Case study/ Interview database	Steps for data analysis (interview study) Coding scheme
Confirmability	Reflexivity about own epistemological and ontological view Chain of evidence	Chain referral through participants for variety Open-ended questions Data recorded digitally and physically	Interview files imported and coded in qualitative analysis software

Credibility

Credibility is the equivalent to internal validity, and refers to credible and truthful findings and interpretations (Lincoln and Guba, 1985, Creswell, 2013). To ensure credibility, a researcher will mitigate personal bias and preconceptions when interpreting findings.

In this research, a possible preconception claims that the pharmaceutical industry is not interested in innovation for patients and that all packages are designed to only protect the product or fulfill regulations. To avoid finding only facts that confirm

this preconception, I used and triangulated multiple sources of evidence: interviews, revision of internal materials and protocols, observations *in loco*. The preconception was partly confirmed, but not totally, since empirical evidence demonstrated that respondents were aware of the need to include users when designing new packaging (as presented in Paper V). The findings showed that many complexities bound a more user-centered perspective of packaging, as highlighted in Paper III and Paper IV.

Neither my case study nor my interview study had a longitudinal design, which limited the prolonged engagement *in loco* at the companies/with interviewees. However, I tried to maintain iterative and prolific discussions throughout member checks and I identified patterns in the interviews. As a result, I followed up questions to respondents, asking for feedback on my interpretations of the interview. I also interacted with colleagues and coauthors when I wrote the final results in the papers. Finally, I participated in, and had the chance to present findings of my empirical studies at industry meetings rather than only in academic conferences. By doing so, I was given feedback from other pairs not enrolled in my studies but belonging to the same industrial context.

Transferability

Transferability is the qualitative equivalent of external validity, or the generalizability of findings by other researchers in other contexts (Lincoln and Guba, 1985, Creswell, 2013). As earlier affirmed, qualitative research is context-dependent, which does not allow the simple transference of findings. Despite that, Lincoln and Guba (1985) argue that some transferability is possible when the researcher provides sufficient information about the context via thick descriptions, and tries to maximize the range of information collected (i.e., theoretical or purposive sampling). In all my empirical papers and in this dissertation, I provided additional information both about the respondents without disclosing their anonymity, and about the context of the companies. In the data analysis, the coding process began inductively, letting main themes emerge from the data. Yet I refined the final codes based on literature. In general, the findings from my empirical studies also point to the need for more inclusive packaging, which does not have to be limited to pharmaceutical packaging, but needs to incorporate packaging in general.

Regarding sampling, I purposefully selected participants and organizations (Miles and Huberman, 1994, Creswell and Clark, 2011). Reflecting on the quality of my empirical studies, I cannot ignore criticism about the possible bias of the researcher in choosing a case or respondents that only confirm the researcher's preconceived notions (Flyvbjerg, 2006). However, I tried to move out of my "comfort zone," or from my "backyard research" as Glesne (2011) call it – which means I avoided collecting data from people that I already knew or that were in my immediate work environment. I talked to people from different relevant organizations; people with a different professional and educational background than

my own, within the pharmaceutical industry context. I consider this an important step that enriched my data. On the other hand, I should say that selection of the case and respondents was supported by their representativeness (Gerring, 2004, Flyvbjerg, 2006). Critical for me was then to have clear criteria of who to involve in this research, and to ensure that I could have access to these respondents, and that all the respondents had a great range of experience and understanding of packaging innovation and design processes.

Dependability

Dependability concerns the matter of reliability, i.e., the stability of data, which means the reproduction of findings when other researchers perform research under the same circumstances but at another place and time (Lincoln and Guba, 1985). Particularly in relation to interviews, "this concerns whether the interview subjects will change their answers during an interview and whether they will give different replies to different interviewers" (Brinkmann and Kvale, 2015, p. 281). Obviously, there are many factors from the context and from the individuals that are unique and that change over time; they cannot therefore be controlled in the same manner as in a laboratory experiment. In addition to that, the researcher also changes and evolves when doing research. Despite the context-related aspects which were difficult to control, I had an interview protocol which I used to conduct all the interviews. Regarding my analysis, I also followed the same steps when coding the interviews. Even though subjectivity remains in the analysis, another researcher could use my study to understand how data was analyzed and to benchmark another similar study.

Confirmability

Confirmability addresses the matters of objectivity in qualitative research. According to Lincoln and Guba (1985), it is important to show the confirmability of data. This is not an easy task in qualitative research, as the researcher usually has more of an active role and interaction with the subjects of study than in quantitative research (Creswell, 2013). However, by practicing reflexivity, "researchers acknowledge and describe their entering beliefs and biases early in the research process" (Creswell and Miller, 2000). As stressed by Alvesson and Sköldberg (2009), it is important for the researcher to reflect about her own basis for interpretation, such as theoretical assumptions and preunderstanding. Moreover, these authors emphasize that a researcher needs to critically consider that there are numerous influences, such as belonging to a research community or general discourses in society, that can permeate the researcher's production of knowledge. I explicitly declared my epistemological and ontological views in this dissertation (Section 2.1 and 2.1.1), where I made clear my stance as a packaging design scholar and my intention to bring a user-centered perspective into a rather technological field. When conducting interviews, I followed the advice of Brinkmann and Kvale (2015), by letting my respondents speak and by letting the interview be a place

where (the researcher's) knowledge can be built up. Moreover, I focused on having interviews that "provide a coherent unity in themselves and present rich texts for further interpretation" (Brinkmann and Kvale, 2015, p. 192). This means the researcher (as an interviewer) verifies her interpretations and relevant aspects during the interview, which makes the interview able to sustain itself, without *a posteriori* explanations added to it. Moreover, all my data is recorded digitally and/or physically. All the interviews were audio recorded and transcribed verbatim. In the data analysis, I imported the interview files and coded them in qualitative analysis software, which also allowed to keep track of how this coding was done.

3 Frame of reference

This research has an interdisciplinary nature, which implies the interaction of distinct, but complementary domains of knowledge. Innovation, design, and packaging compose the three main domains of knowledge that ground this research. Since these three domains are rather extensive, I needed to look deeper to establish some boundaries for the frame of reference in the dissertation. As a result, in the intersection of each domain a sub-domain is presented. Figure 4 illustrates the three wide-ranging domains – innovation, design, and packaging, which in turn integrate three narrow domains; inclusive design, packaging innovation, and packaging design.

In fields where definitions are still immature, the absence of an indisputable definition is not always negative. In a peculiar way, this absence ends up contributing to activate debates that increase overall knowledge within a specific domain. The first section in this chapter examines innovation. Within this domain, I focus on innovation as a complex and large process carried out at organizations, where multiple stakeholders are involved. Second, I introduce the concept of design, here seen as a process encompassed by the innovation process, particularly important to the creation of new, designed outcomes such as new products or packages. In this design section, I framed design within a user-centered, inclusive perspective, to understand how to address user needs and how to avoid excluding people from using products. I also pay attention in describing the importance of involving users when designing, and the benefits and drawbacks that may result. Later, I address the fact that the design process may involve several stakeholders, not always trained as designers, with different interests and requirements as to the final outcome. The third section is about packaging, with focus on packaging design and packaging innovation processes.

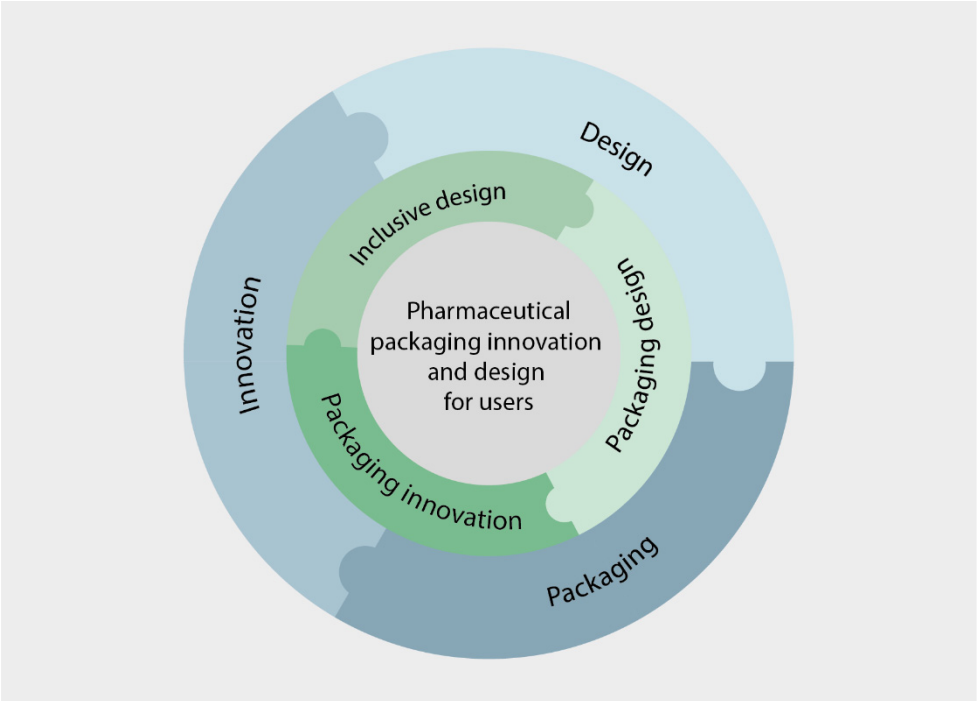

Figure 4 – Intersection of the domains of knowledge in this dissertation.
Adapted from Lorenzini (2016).

3.1 Innovation

Innovation is stunning. It removes the tediousness of ordinary days by adding to them new products, new concepts of consumption, new services that we always needed but have never been able to realize before. In daily life, innovation may be something that we all want. Consumers want to be surprised by novelties that improve our lives, and we are willing to pay for it. Citizens and policy makers want smarter cities, sustainable products, and effective solutions. Companies want to profit from the new generation of products.

Innovation is also frightening, as it implies new ways of thinking. Today's 'trendy' products were often viewed with suspicion by consumers when first launched. For instance, when the first smartphones came on the market, carrying out a cell phone with a flat screen and no physical keyboard was definitely not something people were used to. Within business, innovation implies taking actions that elicit efforts 'out of the comfort zone' and beyond standardized practices. Innovation is also very difficult to achieve. The uncertainties that surround

innovation make it challenging to understand and to reproduce, as there is no straightforward route to follow. This also means that by innovating one needs to embrace failure that might occur – something not everyone dares to do.

While in practice companies try to find their way to surpass competitors (Hamel, 2006), in research, scholars try to define innovation and to explain what it is and how it arises. A good point of departure is setting boundaries between innovation and invention. Fagerberg (2005, p. 4) posits that "invention is the first occurrence of an idea for a new product or process, while innovation is the first attempt to carry it out into practice." An innovation differs from a simple invention by the economic value it brings and by being diffused to parties other than its discoverers or developers (Garcia and Calantone, 2002). For an invention to exist, a new idea might be the trigger. This can then happen in basically any milieu, from university laboratories to the garage of the inventor's house. However, for an invention to become an innovation, the idea of the sole creator showing a 'flash of a genius' is old-fashioned (Drucker, 2002). Turning inventions into innovation implies exploiting the new idea commercially (Roberts, 1988). Innovation demands multiple resources as well as different types of knowledge, capabilities, and skills. Because of that, it is more likely that innovation will happen within and across organizations, such as private companies that can dedicate part of their time and budget to really invest in promising ideas (Tidd et al., 2005).

In its very basic understanding, innovation means something new (to the market, to the company, to the industry...) with a commercial value (Utterback and Abernathy, 1975, OECD, 2005). Drucker (2002, pp. 6-7) defines innovation as "(…) the effort to create purposeful, focused change in an enterprise's economic or social potential." Galanakis (2006, p. 1223) conceptualizes innovation as

> (…) the creation of new products, processes, knowledge or services by using new or existing scientific or technological knowledge, which provide a degree of novelty either to the developer, the industrial sector, the nation or the world and succeed in the marketplace.

In Galanakis' definition, we find the notion that innovation stems from some type of knowledge (scientific or technological). Innovation ranges from different degrees of novelty, from mere adaptations or improvements (usually known as incremental innovation), to radical innovations that "cause marketing and technological discontinuities," and really new innovations, which is a combination of these two extremes (Garcia and Calantone, 2002, p. 120).

A similar but more comprehensive definition is expressed by Crossan and Apaydin (2010, p. 1155), which aligns with my research:

> Innovation is: production or adoption, assimilation, and exploitation of a value-added novelty in economic and social spheres; renewal and enlargement of products, services, and markets; development of new methods of production; and establishment of new management systems. It is both a process and an outcome.

In general, I empathize with the efforts made by Crossan and Apaydin (2010) and others to scrutinize the vast literature available, in search of consolidating academic research within the innovation field. Indeed, it seems that innovation is 'out there,' seen in the marketplace and corporate business, but we still struggle to identify what it really means. However, since the purpose of this research is not to (re)define innovation, I relied on the work of others. I reviewed, framed, and cherry-picked the definitions that would best suit this research and help me to understand the innovation process related to pharmaceutical packaging. Consequently, in this dissertation I focus on the holistic view of innovation, with special attention to the innovation process at the organizational level.

3.1.1 Innovation as a process

As is evident from the preceding discussion, outcome and process are two facets of the innovation phenomenon. Nevertheless, innovation outcomes have gained much more attention from researchers than innovation as a process (Crossan and Apaydin, 2010). Fagerberg (2005) explains that traditionally, researchers have looked at innovation from an economic perspective, where the allocation of resources for innovation has been of greatest interest within the innovation field. This has left the notion of innovation process as a 'black box' to be further explored via other contemporaneous perspectives, coming from sociology, organizational science, management, and business studies. According to Slappendel (1996, pp. 107-108), "in its broadest conceptualization, the innovation process typically embraces periods of design and development, adoption, implementation, and diffusion." Likewise, Garud et al. (2013, p. 776) characterize the innovation process as "the sequence of events that unfold as ideas emerge, are developed, and are implemented within firms, across multi-party networks, and within communities."

In an organization, the innovation process is affected by different determinants, such as individuals (e.g., leaders, entrepreneurs), and/or structural characteristics (e.g., size of the company, formalization of processes) (Slappendel, 1996). Crossan and Apaydin (2010, p. 1177) explain the innovation process happens in the balance "between individual action and organizational determinants." According to them, the leadership on innovation will then spread and shape five managerial levers: organizational culture; organizational mission goals and strategy; creation of structure and systems; overall resource allocation; organizational learning and knowledge management tools. As highlighted by the authors, leadership will also

have an important role in creating an environment for experimentation, and trial-failure, where innovation can thrive better. These upper-management decisions will affect and enable the creation of core business processes, which will determine how the organization manages its projects and its portfolio of products (see Figure 5). The business processes will then be translated into the individual innovation processes, as the process of new product development, and translated into innovation outcomes.

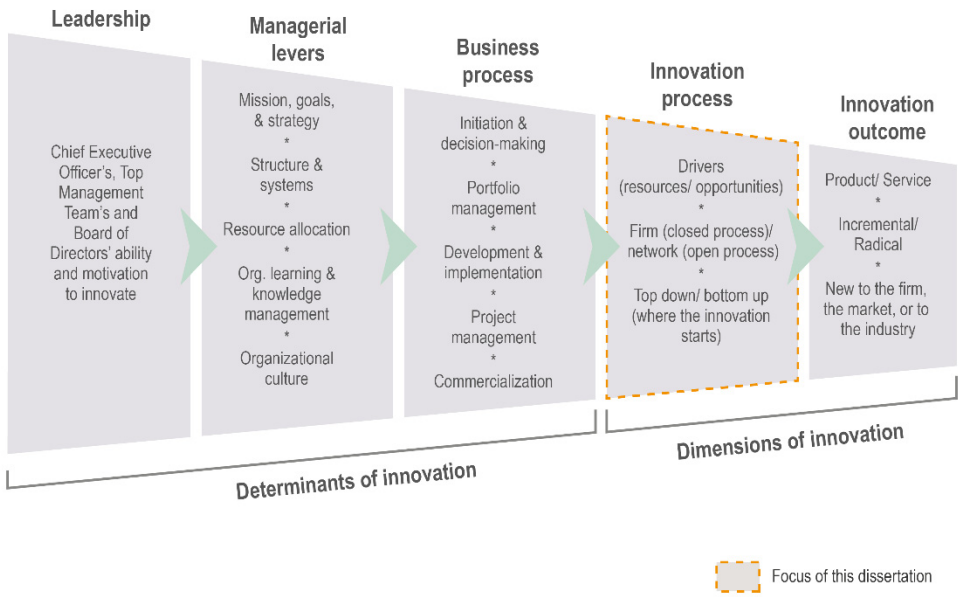

Figure 5 – Determinants and dimensions of organizational innovation.
Adapted from Crossan and Apaydin (2010).

In general, an innovation process will follow certain phases that lead to innovation outcomes. Tidd et al. (2005) maintain that, at its heart, the innovation process involves the following: *searching* for the internal and external environment to identify important threats and opportunities for change; *selecting* the ideas or signals to respond to; *implementing* the new ideas – which includes developing the trigger ideas into something new with a commercial value to be launched into the market, acquiring the resources (e.g., knowledge resources) to make the innovation possible to implement; executing the project under certain conditions; launching and sustaining the adoption of the innovation (and even reinnovating); and finally, *learning* from all the experiences through the innovation process (Figure 6).

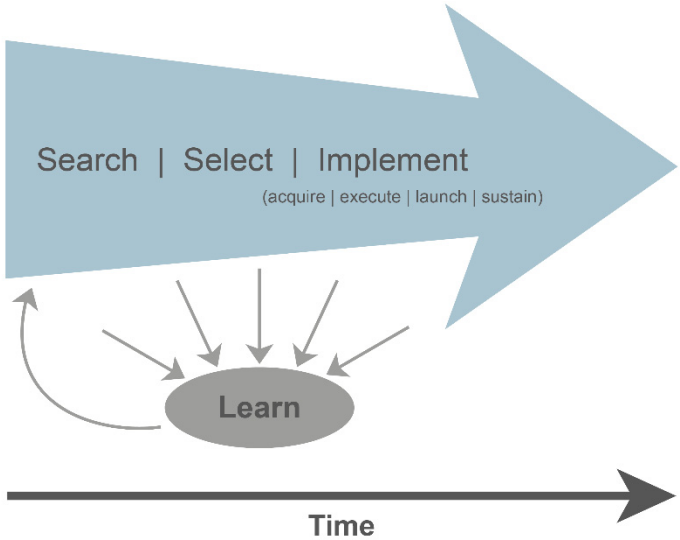

Figure 6 – The innovation process in a simplified version.
Adapted from Tidd et al. (2005).

Evidently, no organization will aim for innovation processes that favor new outcomes every time, aiming also to profit from outcomes that already exist and are successful. For instance, by looking into companies oriented to innovation, Nagji and Tuff (2012) found that many companies will follow the 70-20-10 principle for their portfolio of products. According to the authors, a company would dedicate 70% of its efforts to invest in optimizing existing products for existing customers; 20% of the resources would go to expanding into new business for the company; and 10% should then be committed to transformational, or breakthrough ideas, with the potential to create markets that do not exist yet. This is not an absolute principle to be followed by all companies, but it gives us some indication that balance is needed. No business can be sustainable by only looking for breakthrough innovation, as it would be very challenging and very expensive (Nagji and Tuff, 2012). Even in business where innovation is at its core, as happens with the pharmaceutical industry, innovation that revolutionizes the market is still supported by existing products that are already successful on the market. Companies will try to define complementary innovation processes, to improve successful ideas, but also to permit the development of totally new ideas into commercial solutions.

3.1.2 Innovation among stakeholders

Considering the complex scenarios for innovation nowadays, organizations establish themselves within intricate networks. van de Ven et al. (1999) explain that

the innovation journey is based on a "social system for innovation development", where multiple stakeholders from public and private sectors interact. In studying innovation processes, Garud et al. (2013, p. 777) have found that the innovation process "is characterized by a proliferation of paths as well as many setbacks," which demand the involvement of different stakeholders along the way. Innovation will lie within a "(…) multiplicity of heterogeneous and often confused decisions made by a large number of different and often conflicting groups" (Akrich et al., 2002, p. 91).

Authors have recommended companies to focus on their core business, and to rely on key partnerships in order to absorb knowledge and to learn (Barney, 1991, Tether, 2002). Moreover, sources of innovation, such as universities, research laboratories, suppliers, and customers, are external to the firm (Powell et al., 1996). Pittaway et al. (2004) found that the principal benefits for companies for networking include risk sharing, access to new markets and technology, speeding products to market, pooling complementary skills, safeguarding property rights, and obtaining access to knowledge.

By adding a system perspective to the study of innovation, Fagerberg (2005, p. 13) explains that "systems may – just as firms – be locked into a specific path of development that supports certain types of activities and constraints others." This can have advantages and disadvantages, as the whole system with its stakeholders will be locked into a certain type of development. Innovation systems will thus be open or closed. Firms may prefer a closed system with stakeholders from their network when the intention is continuous improvement. By sustaining and improving the same core processes with the same partners, the company will grow in its expertise and the expertise shared with its partners, but innovation can be limited or incremental. Granovetter (1973) characterizes the long-term relationship between stakeholders based on constant communication and confidence as strong ties. By keeping consistent relationships a company will also establish itself in steady networks of collaboration, where all the partners are aligned and know about each other and share practices (Fagerberg, 2005).

An open system occurs when the emphasis is on new knowledge. In early stages of the product life cycle, firms need to draw deeply from a small number of key sources of innovation, e.g., lead users, component suppliers, universities (Laursen and Salter, 2006, von Hippel, 2006, Tödtling et al., 2009). Firms therefore tend to seek suppliers from distant industries within domestic or neighboring markets, when trying to explore new ideas (Li and Vanhaverbeke, 2009). By looking for unexpected collaborations and by including partners from other industries, a company will establish 'weak ties' with its partners, but it can expect to achieve higher degrees of innovation (Granovetter, 1973). Open systems that permit new interactions with 'outsiders' have fewer chances of becoming locked within their own paths of development (Fagerberg, 2005). This is in line with the idea of open

innovation, which promotes external collaboration for innovation among organizations (Chesbrough, 2006).

It is difficult to know whether the stakeholders involved in the system will maintain the capacity to critically perceive how the system develops. Because of that, it is suggested that system managers (e.g., policy makers) observe the system, to avoid it becoming constrained by well-established practices and to permit new routes of exploration (Fagerberg, 2005).

3.2 Design

All products are designed; or, as expressed by Norman (2013, p. 4), "all artificial things are designed." Indeed, they have been designed since ancient times. The search for "better solutions to particular problems – a better stone axe, a better cooking pot, a better weapon, a better spinning wheel" has led to the development of artifacts, impacting the quality of our lives (Fiell and Fiell, 2013, p. 9).

As scholars, we may then ask about the definition of design. Design is known for its multiple roles, with no single definition that "adequately covers the diversity of ideas and methods gathered together under the label" (Buchanan, 1992, p. 5) and endless debate among practitioners and researchers about what design seems to be (Larsson, 2005). Consequently, it is difficult to escape looking back to etymology when a consensus of definition is lacking. In its origin, design comes from *designare* (Latin), which means to mark out, to devise, and to choose. In Margolin's (1997) definition, designing is both the activity of conception and planning. It can be a verb that specifies a process. Or it can be part of a definition of an object's form, as when we hear someone says 'this car is great design.' Associating something with design tends to be positive, but it does not clarify the importance of design or what design does, specifically, to objects and their use. For instance, Fiell and Fiell (2013, p. 10) conclude that "design is a slippery word, being both a verb and a noun – an action and its result."

As described by Norman (2013, p. 5):

> Design is concerned with how things work, how they are controlled, and the nature of the interaction between people and technology. When well done, the results are brilliant, pleasurable products. When done badly, the products are unusable, leading to great frustration and irritation. Or they might be usable, but force use to behave the way the product wishes rather than as we wish.

In general, Norman's explanation gives a glimpse of the design process, but it also reminds us that designing means to create and deliver some sort of product to be used by someone. In their extended working definition of design, Gorb and Dumas (1987, p. 151) explain design as "a course of action for the development of an

artifact or a system of artifacts; including the series of organizational activities required to achieve that development." As a process, "design is the human power of conceiving, planning, and making products that serve human beings in the accomplishment of their individual and collective purposes" (Buchanan, 2001, p. 9). External appearance, style, color, and other aesthetic features are part of the decisions taken in the design process (Gorb and Dumas, 1987, Walsh, 1996).

According to Krippendorff (1989), design lives in the paradox of *innovating or developing new artifacts*, but also *in making sense of those artifacts*. Based on that, the Krippendorff (1989, p. 13) claims that artifacts are also designed for some imaginable contexts:

> What something is (the totality of what it means) to someone corresponds to the sum total of its imaginable contexts. A knife has all kinds of uses; cutting is merely the most prominent one. Prying open a box, tightening a screw, scraping paint from a surface, cleaning dirty fingernails are as imaginable as picking a pickle from a pickle jar. In the context of manufacturing, a knife is a cost. In the context of sales, a knife has an exchange value. In the context of a hold-up, a knife may constitute a significant threat. All possible contexts define what a knife is to people capable of using their imagination.

In this matter (and in this dissertation), design distinguishes itself from some of the artistic and stylish attributions to which it is ordinarily related. In line with Krippendorff (1989, p. 28), designers have two major kinds of activities when designing: one is "(…) to create highly individualized patterns in the form of drawings, sketches, models, descriptions of possible uses, specifications (of materials and production processes needed to enable others to realize their ideas as rendered), corporate strategies, and advertising campaigns." The second is to convince others to become involved with their creations. As a result, design runs in a circular flow from the development of drawings into production schedules, distribution plan, marketing strategies, etc. Finally, potential users become attracted to the use of the artifact. The whole circle is completed with research about "(…) patterns of interaction between products and users," which provides feedback to designers and producers (Krippendorff, 1989, p. 29).

In this dissertation, design is therefore investigated both as a process and as a solution. As a process, design is intrinsically connected to other fundamental processes in industry, such as the innovation process (Kumar, 2013). Walsh (1996) explains that whereas innovation may be broadly related to other technological aspects of new product development, design will connect closely to decisions taken about the use of the product, including ergonomics, ease of manufacture, efficient use of materials, user-friendliness, and even considerations of the incorporation of technological features into the products. Consequently, design has its own domain of practice, but it is interdependent on interactions with other broader processes.

As a solution, design relates to the *designed artifact*, the 'artificial object' created by humans and technology. This research has departed from the use of pharmaceutical packaging, where design becomes essential because it relates to human interaction with the package and has consequences for the medication treatment. Complementarily, this research looks closely at where development of packaging occurs and where design relates to the innovation process. Depending on efforts to improve packaging for the users, companies may dispose of more resources to design and develop design skills and capabilities.

3.2.1 A user-centered approach for design

Like other processes in industry, design has evolved. Parts of the most significant changes in design rely on the shift from designing objects to designing user experiences (Redström, 2006). Fiell and Fiell (2013) point to the changes which came after the readily mass-manufactured objects provided by the Industrial Revolution, when designers have started to shift attention from the material objects to the fit between people and their use of designed objects. According to Redström (2006, p. 135), this shift did not come without some confusion, since "(…) there is a fundamental difference between designing things to be used and trying to design use or the user experience." As a result, what often occurs is that designers 'over' determine use and users. Designers forget to acknowledge what they are, in fact, designing, and what is not included in their designs. As a consequence, Redström (2006, p. 135) points out that "(…) a plethora of objects try to make us do things in often incompatible ways – a situation requiring us to be creative in order to make everything work together." When user needs are not considered in product development, it is more likely that those products will exhibit poor performance, with consequent user abandonment (Phillips and Zhao, 1993).

To avoid designing artifacts that are difficult or impossible to use, users and their needs are brought first and put in the center of the design process (Marti and Bannon, 2009). A user-centered approach to design means designing is not only a matter of creating new products, but creating products that people want and can use. Importantly, we may consider that design needs to accommodate the "widest possible range of abilities, within the widest range of situations, reaching most, if not all, potential end users" (Wilkinson and De Angeli, 2014, p. 615). In light of that, this research focuses on inclusivity in relation to user-centered design.

Inclusive design

Different backgrounds, places of origin, and conceptualization gave rise to the idea of inclusivity in design as universal design, design for all, inclusive design (Heylighen and Bianchin, 2013, Clarkson and Coleman, 2015). Paper II and Paper V better illustrate the differences in the origins of these terms. Yet to avoid further

confusion with terminology, I have chosen to prioritize the expression *inclusive design* in this research, since it has its main background in product design (Waller et al., 2015). Inclusive design has been expanded by authors in relation to the development of products and packaging. In addition, inclusive design not only aims to extend "the reach of mainstream products," but it also "acknowledges the commercial constraints associated with satisfying the need of the target market" (Inclusive Design Toolkit, 2012).

According to the British Standards Institute (2005), inclusive design is defined as "the design of mainstream products and/or services that are accessible to, and usable by, as many people as reasonably possible (…) without the need for special adaptation or specialized design." Inclusive design implies "understanding diversity within the population" and "responding to this diversity with informed design decision" (Waller et al., 2015, p. 298). Inclusive design implies trying to design for the widest possible audience, through the combination of a technology push and demographic pull so that people are not excluded because of their age, disabilities, or changes in technology patterns (Coleman and Myerson, 2001).

Visualizing inclusivity in design

One way of visualizing this diversity and the need for an inclusive design approach is using a pyramid which displays the full range of ability variation within the population (see Figure 7). The different segments represent those with no difficulties (at the bottom) up to those with severe difficulties (at the top). The Population Pyramid model helps to visualize and plan how "(…) to extend the target market to include those who are less able, while accepting that specialist solutions may be required to satisfy the needs of those at the top of the pyramid" (Inclusive Design Toolkit, 2012). Building on the concept of the Population Pyramid, Keates and Clarkson (2003b) develop the Inclusive Design Cube. On the right, Figure 7 shows the Inclusive Design Cube, which presents the populations included or excluded by each design approach.

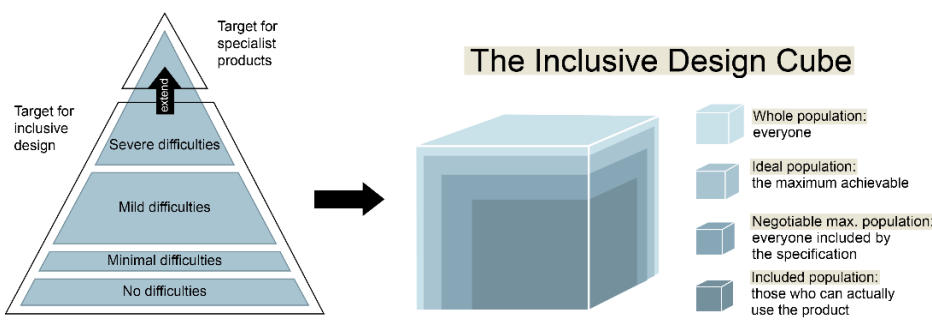

Figure 7 – Population Pyramid and the Inclusive Design Cube.
Adapted from Keates and Clarkson (2003), Inclusive Design Toolkit (2012), and Waller et al. (2015).
Used also in Lorenzini (2016).

Both the Population Pyramid and the Inclusive Design Cube help to understand and allocate designed products. More importantly, these are potent visualization tools which, aligned with a design methodology, can lead to more inclusive design practices (Keates and Clarkson, 2003b). Clarkson et al. (2015, p. 304) defend "the success of a product can also be measured in terms of its accessibility regardless of its market success." The authors explain that, despite their success in the market place, products often ignore or do not take into further consideration real challenges experienced by users when they use those products – something which demands attention and efforts when products are being designed.

3.2.2 From inclusion to participation in the design process

From the previous text, it is possible to understand that: a) designers or professionals responsible for design need to design not only for the sake of the product, but also for the sake of the user; b) a broader spectrum of users and their needs may be considered. The challenge then is how to make inclusive design possible, and how to bring it to the design process. Inclusivity, or user-centeredness, in design implies adopting new mindsets to identify and bring users into the design process.

Inclusivity may be lacking because designers often "(…) design for their own capabilities and skills" (Keates and Clarkson, 2003a, p. 224). Wilkinson and De Angeli (2014, p. 615) state that such situation is not a risk for alienation and exclusion of significant proportions of the population, but also poor business sense:

> Failing to engage with potential users or user groups that may form part of an increasingly influential market force potentially misses a commercial design opportunity. Developing products that cater more effectively for a larger demographic widens the commercial market, benefits a larger cross section of society, and makes both commercial and ethical sense. User involvement within the design process is seen as the key solution to affect such an outcome.

Margolin (1997, p. 228) states that professionals working with design need to understand the product milieu, i.e., where people use and experience products. As affirmed, these professionals "need to acknowledge its vastness, as well as the complexity of how products come to be and are then incorporated into users." According to the author, letting users participate in the design process enriches the product milieu with more meaningful products and better quality of life. Luck (2003) approximates inclusive design and user involvement, by affirming that through their involvement, users are given the chance to participate in design discussions and to influence design outcomes. This goes together with the idea that users "should be in an empowered consultative position in more aspects of their lives" (Luck, 2003, p. 524). Similarly, Damodaran (1996, p. 365) writes that "users should be able to influence design, not merely 'rubber stamp' it."

Heylighen and Bianchin (2013, p. 105) summarize the importance of the interaction between designers and users by reflecting on the impact it has on inclusive, good design. As they explain, it is almost impossible to separate one from another:

> Designers' competence is blank, if it is not informed by the aims to be pursued, and the users' inclusion will be worthless without being articulated in some kind of explicit knowledge. A designer will feel lost without some information about what the artefact to be designed is supposed to be used for. Correspondingly, people's needs will be nothing but subjective feelings without being interpreted in a way that makes them suitable to be responded to. So not only there is no conflict between inclusive design and good design: it may well be that one cannot have one without the other. You cannot have good design without it being inclusive and you cannot have inclusive design without it being good.

Based on the above, it is relevant to address the level to which users are involved in design, as well as the benefits and drawbacks user involvement brings to practice.

Levels and modes of user involvement

The ladder of citizen participation can be considered as a seminal work and point of departure to discuss user involvement in the design process. According to Arnstein (1969), citizen involvement ranges from non-involvement, to tokenism, and citizen power. Even though the ladder has been developed using a more social and political orientation, some of the ideas it showed were appropriated to user involvement within the design process due to the complex challenges of societal demands (Sanders and Stappers, 2008). For instance, Damodaran (1996) has distinguished three levels of user involvement: informative (users provide and receive information), consultative (users comment on predefined concepts), and participative (users influence decisions regarding the whole system). An equivalent has also been proposed by Kaulio (1998): design for users, design with users, and design by users.

Inputs from users may occur at different phases of the design process, with a strong focus on the early phases, when the deliverable of the design process is still uncertain and surrounded by open-ended questions such as "how can we improve the quality of life for people living with a chronic illness?" (Sanders and Stappers, 2008, p. 7). At later stages, users will play a more informative role, and at this point of the design process, it might be costly to make profound changes.

In line with that, Gould and Lewis (1985) have established three principles for user involvement: early focus on users and tasks, empirical measurement, and iterative design. The first principle relates to the involvement of users at early stages of the development process, when users also have the chance to "instill their knowledge and concern into the design process from the very beginning" (Gould

and Lewis, 1985, p. 302). The second principle relates to understanding potential users, instead of only identifying, describing, or stereotyping them. The authors recommend bringing the design team into direct contact with potential users, rather than using intermediary sources. The authors also recommend the design team, through direct contact, to talk to, and observe users and their interactions. Finally, the third principle relates to the back-and-forth process of acquiring information from iterations with users, and improving concepts along the design process.

The levels of user involvement also set the scene for the modes (i.e., design methods) used. In an informative or *design for users* approach, the user is like an object that provides data to designers in the design process. In a consultative or *design with users* approach, the user is involved in "defining, measuring, and thereby improving the usability of products" (Kaulio, 1998, p. 3). Task analysis, prototype tests, and other usability evaluations are common at this stage. On the other hand, a participatory or *design by users* approach implies having users to talk and elaborate actively on their experiences. The designer thus works as a facilitator to enhance and engage users in finding solutions to their own problems (Kaulio, 1998).

Benefits and drawbacks of user involvement

The involvement of users within the design process is critical not only to give voice to users and let them express their needs, but it also enables a better understanding of contexts where products are used. Users may have a high level of expertise, or tacit knowledge, but they can be also highly motivated to implement ideas that improve their situation of use (von Hippel, 2006, Lettl, 2007). As suggested by Luck (2003), user involvement elicits user needs that are critical to the development of a technical product. A company able to leverage the involvement of those users "can immediately improve the applicability, acceptance, and adoption of the end design, and consequently has the potential to reduce development risk" (Wilkinson and De Angeli, 2014, p. 617). By reviewing literature on the topic, Kujala (2003) found similar benefits, such as more accurate user requirements when users are involved, avoidance of resources spent on developing features that users do not want, and increased levels of user acceptance and user satisfaction.

Even though efforts have been made to engage users "as active actors and members of the design team," shifting users' roles from "simply being informants and testers to being co-designers," many drawbacks can limit user involvement (Marti and Bannon, 2009, p. 13). One drawback is related to the limitation of listening to users, as they may not always know what they want (Ulwick, 2002). Kujala (2003) explains that there might be also difficulties in communication, as users are experts in their context of use, but not experts in design. According to Lettl (2007), when aiming for higher degrees of innovation, it is challenging to identify users and it might demand other capabilities at the organizations than traditional market research.

Another drawback relates to the context of product development itself, where design teams often deal with limited time and budget (Goodman-Deane et al., 2010) as well as limited accessibility due to privacy and ethical considerations (Shah and Robinson, 2007). Design teams might end up not directly contacting users, or these teams might face long waits to obtain ethical approval for user involvement. Further drawbacks of user involvement encompass the large amount of raw data generated, which tends to be informal and descriptive, making it difficult for designers to select what is really relevant to attend users' needs (Kujala, 2003).

3.2.3 Non-designers in the design process

Since the design process may be an embedded part of the innovation process, it can also be expected that design activities will be conducted by professionals that have not been instructed in design, "but someone [that] makes a series of decisions that result in a product of a particular function, cost and appearance, any of which may contribute to its commercial success" (Walsh, 1996, p. 509). Moreover, design activities can be performed in-house or can be outsourced. The directives in an organization with regard to innovation may also delimitate who will be involved with design and how the design process will be conducted. This makes design teams become more and more diverse, with further collaboration among different stakeholders in the design process, inside and outside of the core organizations, and a myriad of professionals with hybrid design and research skills (Sanders and Stappers, 2008).

Lehoux et al. (2011, p. 316) have appropriated the concept of *design collective* from Bucciarelli (2002, p. 220), "to refer to the large set of individuals and groups who may have a legitimate say in the design process, either directly or indirectly." According to the authors, these collective design participants may not have been trained in industrial design or engineering design, although they are profoundly involved "in the design process of a given innovation" (Lehoux et al., 2011, p. 315). The authors have emphasized that those design participants use 'specific lenses' to look at the product to be designed, based on their knowledge and expertise, tasks and responsibilities, personal motivation, and interest in the project. Design participants also have their own 'world views' (for instance, the 'world of manufacturing') that frame how they envision an innovation. Importantly, Lehoux et al. (2011) show that design participants will be enrolled in a project because of their position in the company and/or their expertise. The design collective would then include potential users and a variety of stakeholders who either provide policy and/or financial support (e.g., policy makers, shareholders, capital investors) or who set specific constraints to development (e.g., regulators, third-party payers).

3.3 Packaging

Packaging has evolved from containers provided by nature to current complex industrial processes (Berger, 2005). In its original conception, a package would essentially protect and preserve a product. Along its development and extensive use in an industrialized society, other functions were attributed to packaging such as to store, to transport, and to promote product sales (Paine, 1981, Prendergast and Pitt, 1996, Hansen and Serin, 1999). Many aspects contribute to the extension of packaging functions. Increases in global trade, shifting lifestyles, discoveries of new materials, smaller households, people looking for convenience, etc. (Berger, 2005, Rundh, 2005). As a result, packaging has become pervasive and essential: "it surrounds, enhances and protects the goods we buy, from processing and manufacturing through handling and storage to the final consumer. Without packaging, materials handling would be a messy, inefficient and costly exercise" (Robertson, 1990, p. 37).

The development of packaging today is embedded in a multitude of complex decisions, which represent much more than just 'putting a box around a product.' (Oostendorp et al., 2006). Inspired by the well-established definition provided by Paine (1981) and the EU's definition (94/62/EC), Hellström and Olsson (2017) summarized:

(1) Packaging is a coordinated system made up of any materials of any nature, to be used for preparing goods for containment, protection, transport, handling, distribution, delivery and presentation.

(2) Packaging is the means of ensuring safe delivery from the producer to the ultimate consumer in sound and safe conditions.

(3) Packaging is the techno-economic function aimed at making delivery efficient while maximizing effectiveness.

This definition is considered adequate because it takes into consideration packaging functionalities or choices of materials, encompassing also the notion of packaging belonging to a system, where multiple stakeholders interact. In this research, I distinguish packaging as packaging design, in relation to what shapes and makes a package function; and packaging innovation, in relation to the extended process that influences the choices of the packaging design and that makes it possible to manufacture a package.

3.3.1 Packaging design

Packaging design has become a very specific area within the design domain, most commonly correlated with marketing, sales, and the commercial functions of the package (Young, 2002). Packaging design is planned to attract consumers' attention and to differentiate products. Furthermore, it introduces the experience of use of the product, by creating expectations about the product and by confirming/not confirming those created expectations (Löfgren et al., 2008). Wever (2009) states that packaging design relates to both sales and experience. From this viewpoint, packaging design will work to attract attention, communicate unique selling points, communicate brand image, create product appeal, demonstrate that the product has not been tampered with, and prevent theft.

Packaging design goes beyond the emphasis on marketing and sales. Klimchuk and Krasovec (2012) state that packaging design connects multiple elements such as form, structure, materials, color, images, typography, and regulatory information with design elements that facilitate marketing of the product. Packaging design is related to the functions of the package, as well as to the packaging system, the kind of products packed, the target market, and the social policy of the firm (ten Klooster, 2002).

In line with this, the global marketplace makes products to be produced, packed, distributed, and sold at different locations. Such a scenario further complicates design decisions as multiple stakeholders spread along the supply chain imply varying expectations that affect packaging design (Bix et al., 2009b). Furthermore, it is the way a package is designed that will ensure that it performs multiple functions along the supply chain or not, as explained by Olsson et al. (2011):

> A package adheres to the product throughout the entire value chain, which means that the package design will influence the efficiency of the entire chain in terms of functions, features, information and cost aspects. The efficiency of a product in these areas will depend on the package design, since a package has the potential to improve efficiency through optimum design.

Hellström and Olsson (2017, p. 35) stress that the appearance of multiple aspects of packaging design call for a new definition, which includes what packaging design is and what it does. As a result, they define packaging design "to be a set of choices regarding the form and the function of the packaging system, as well as the activities that underpin these choices." This definition encompasses the numerous needs, requirements, and constraints that affect packaging design. It also embraces the complexity designing a package entails. Design is powerful in making sense of objects, and this can also be attributed to packaging design. Packaging design may therefore not only be attractive in order to generate consumption, but it should benefit the use of product, without ignoring the need to create packages that can be optimally manufactured.

In past years, packaging design has advanced into other domains that do not only prioritize marketing aspects. For example, Azzi et al. (2012) identify and review 89 scientific articles published between 1990 and 2011, with contributions covering aspects of packaging design for safety, ergonomics, sustainability, logistics, marketing, and communication. According to them, these multiple aspects create many interdependences and trade-offs when decisions are made about packaging design. For example, by making a package more protective during distribution and transportation, more material will be added, which will entail additional cost, waste, and will affect recyclability. On the other hand, by making packages smaller and more compact, the ergonomics aspect might be affected, presenting the final user with more difficulties in handling.

According to ten Klooster (2002), packaging design has not yet reached maturity in terms of its economic and cultural values. In one example, the author refers to the use of materials. Due to lack of knowledge or excessive precaution of packaging teams, many designs use more material than necessary, exceeding the optimum amount. In many cases, the problems with packaging design occur because of its detachment from packaging engineering. Wever (2009, p. 37) calls attention to the fact that it is common practice to have different professionals with distinct expertise in design with diverse focuses that range from designing attractive packaging to developing packages for increased manufacturability. The lack of integration is evident, as "there are packaging designers and packaging engineers, but hardly any packaging design engineers." As a consequence, in many cases, packages either will be developed with a product orientation or they will be designed to a marketing (user) orientation, with a lack of holistic perspective (Bix et al., 2009b).

3.3.2 Packaging innovation

Packaging innovation is interpreted in this dissertation as a process. Importantly, the packaging innovation process directly affects packaging design, which means that some features and functions of the packaging will be altered and emphasized, whilst other features and functions will be considered not so relevant. As explained in the previous section, it is not always possible to emphasize or satisfy every aspect, so trade-offs will occur along the way.

One interesting point is how the packaging innovation process will be carried out. As defined by Crossan and Apaydin (2010), there are many determinants that set the scene for the innovation process in an organization. This also holds true for the packaging innovation process. For instance, the packaging innovation process will be affected by the positioning of packaging in the organization, and whether it is considered as a relevant process in relation to other core processes, such as product innovation. Overall, packaging and product processes will need to meet at certain points. One of the criticisms in the packaging literature is that the packaging

innovation process is not well established and not well integrated with the product innovation process. The packaging innovation process usually begins later so that opportunities for innovation are diminished (ten Klooster, 2002, Bramklev, 2009, Olander-Roese and Nilsson, 2009, Hellström and Olsson, 2017). Additionally, we may wonder to what extent packaging innovation happens within the organizational domain, with dedicated teams or not, or within a network of other organizations (Klevås, 2005).

Another point to consider is what will trigger packaging innovation. Coles and Beharrell (1990), for instance, defined packaging as being technology driven, consumer driven, and distribution driven. The authors emphasize the need for a balance between the three factors to gain competitive advantage. In general, packaging has a long history of technical innovation, where improvements were made primarily to optimize the processes of packing goods, but also to improve the features of the packaging. In terms of technology, Hellström and Nilsson (2011, p. 641) affirm that "in technological industries like the packaging manufacturing industry (e.g., packaging material producers and packaging converters), the development and innovation focus has traditionally been technology oriented." The growth of packaging relevance at the point of sale increases the need for brand reinforcement and sales (Sara, 1990, Vazquez et al., 2003, Rundh, 2005). Finally, distribution is a challenge for packaging innovation, especially when all the needs to be met along the value system of the distribution chain of consumer, retailers, distributors, and producers are considered (Bix et al., 2009b). The attention to packaging systems and the flow of goods and final products along the supply chain is also vital.

Similarly to Coles and Beharrell (1990), Sonneveld (2000) define four major areas which have influenced packaging innovation for food: business dynamics, distribution trends, trends in consumption, and legislative frames. Such areas can be interpreted in industry contexts other than the food industry. With regard to business dynamics, globalization has increased supply chain integration. Distribution trends are connected with internationalization, but also with market diversification and technologies of tracking and tracing. A third area relates to consumption and demographic development. As emphasized by Sonneveld (2000), demographic and social development impact changing habits, which also affects the demands on packaging, such as easy opening, reclosable packaging, single-portion packs and cluster packs, tamper-evident packaging, etc. Finally, the fourth area is about legislation, which is driven by laws, standards, and regulations on health and safety.

In relation to the fourth area pointed out by Sonneveld (2000), not only legislation is relevant, but also ethical aspects regarding packaging. In a more recent study, Vernuccio et al. (2010) consider ethics to be as important as marketing and logistics for packaging innovation. The authors explain that nowadays there is a strong appeal toward consumer consciousness and corporate responsibility. The impact of packaging in minimizing the environmental effects has been emphasized

by studies (Prendergast and Pitt, 1996, Verghese et al., 2015). Another ethical aspect claims that packaging should also be an important source of truthful information about the product and the company that produces it (Underwood, 1998). Moreover, Vernuccio et al. (2010, p. 340) suggest that a package has to have a societal orientation, which means the package is designed with consideration of user-friendliness toward potential user groups, such as:

- Children: designing a package that is either particularly easy for them to use, or has child-resistant closures if it is potentially harmful.
- Elderly people: taking into account age-related difficulties, for example, by handling the product or reading the label.
- Disabled people: diminishing obstacles to proper use of packaging, for example by ensuring that the package conveys information in Braille or by other suitable means in the case of potential users who are partially sighted.
- Other categories: such as immigrants or economically disadvantaged citizens.

The different studies here presented demonstrate that packaging innovation may be driven by different forces that influence the decision making and that determine the priorities in packaging design. The summary of the literature here presented allows us to extract five major drivers for packaging innovation: technology, legislation, marketing, logistics, and sustainability. Each of these drivers is further explained in Paper III.

4 Pharmaceutical industry context description

By investing in research and development of new medicines, the pharmaceutical industry helps alleviate the impact of illness in society and improve the well-being of individuals. This chapter presents important aspects of the pharmaceutical industry context that dominate most of the research in this dissertation and that could not be entirely addressed in the appended papers. The chapter also describes the general development of a new drug as well as providing a brief overview of relevant trends. The secondary data examined here comes from well-known consultancies and sectorial reports via public access. Overall, it is relevant to mention that there is a host of data available and to have a grasp of everything relating to the pharmaceutical industry is not work for one person alone. A realistic ambition for this chapter then is to concentrate on the data that connects with the purpose of this research.

4.1 The pharmaceutical industry

The pharmaceutical industry is a world-leading industry, which follows a technology-led business model based on the development of breakthrough drugs (Petrova, 2014). Notably, this is an industry of "billions of dollars and thousands of scientist-hours, it pushes the limits of science, fosters medical progress, and contributes to the prosperity of society" (IFPMA, 2017). Indeed, because of many of these advances, people can live longer. The longer citizens live, the longer they will need their medicines, which makes global spending on medicines vital in countries' health care agenda. On the other hand, citizens that have never had access to medication before are now becoming able to do so as emerging economies thrive (Aitken et al., 2016).

The pharmaceutical industry is generally dominated by large organizations, mostly global brand-owner drug manufacturers with an international profile, with operations distributed worldwide. R&D and manufacturing hubs of these organizations are located where it is politically, technically, and economically beneficial (Lockhart and Paine, 1996). The brand-owner drug manufacturer is a key

player in starting the development of a new drug and in profiting from its successful launch in the market. In the chain of development of a new drug, a brand-owner drug manufacturer usually establishes alliances outside the organization's boundaries to speed up the necessary testing for a new drug. Based on that, outsourced organizations, known as contract research organizations (CROs), are important partners that have been running clinical trials. Other important entities are the regulatory bodies such as the US Food and Drug Administration (FDA) and the European Medicines Agency that control the drugs on the market and also approve the new drugs to be launched.

Importantly, the pharmaceutical industry has built its business model on aggressive marketing to promote its products (Donohue et al., 2007, Gagnon and Lexchin, 2008). However, this is changing, and it will continue to change in the upcoming years. PricewaterhouseCoopers (PWC, 2009) points to seven major trends that can influence how pharmaceutical companies conduct their business:

- The prevalence of chronic diseases is growing, as a consequence of longevity, but also associated with some life, dietary, and sedentary habits. In Europe, for instance, the consumption of antihypertensive and antidiabetic medications has nearly doubled on average in EU countries between 2000 and 2012, while the consumption of cholesterol-lowering drugs has more than tripled in the same period (OECD, 2014).
- Health care policy makers and providers are becoming more influential on what physicians prescribe to patients, due to the shift from individual prescribing decisions to treatment protocols in a more systemic view.
- Pay-for-performance is rising, with a greater interest from health care providers about the outcome data of use of medicines and the effective performance of treatments. This means pharmaceutical companies only get paid when satisfactory outcomes of the treatment are reached, which means that better forms of intervention and patient adherence also become more important.
- Health care is migrating to other forms of care delivery, with an increase in self-care and the movement from hospitals to primary and ancillary care. With that, companies may review their provision of information and support tools to patients and professionals.
- Emerging economies (or pharmemerging markets) are demanding new medicines. Yet these markets are very heterogeneous, which demands different approaches from pharmaceutical companies.
- Many governments are putting efforts into preventive treatment as complements to care for chronic conditions.

- Regulatory bodies are becoming more risk averse, which may demand extra efforts from pharmaceutical companies to show the benefits of new treatments to be launched and to carefully select where to invest in innovation.

4.2 Innovation in the pharmaceutical industry

The success of the pharmaceutical industry leans "on continuous innovation – for the prevention and treatment of common, complex, and neglected diseases, and for improvements in existing treatments" (IFPMA, 2015, p. 7). In relation to innovation in the pharmaceutical industry, Petrova (2014, p. 23) affirms:

> No other industry is expected to affect how long people can live or how fast they can recover from an illness. No other industry is focused on relieving the physical pain and other discomforts everyone gets to experience in life. Consequently, no other industry is under such tremendous pressures to innovate. Still, no other industry can burn through billions of dollars and man-hours only to end up empty-handed, with not much to show for its vast expenditure, dedication, and effort.

According to PWC (2009, p. 11), innovative drug products are those which "cure a disease or condition; prevent a disease or condition; reduce mortality or morbidity; reduce the cost of care; improve the quality of life; are safer or easier to use; or improve patient compliance and persistence." As occurs with products in other industries, two types of new products can change the existing market: one is a superior product, an improved product with the same purpose; another is a differentiated product, which develops or creates a new market (Takayama and Watanabe, 2002). When a superior drug product enters the market, the tendency is that similar existing products will suffer a depreciation of their market share.

There are many challenges which surround and hamper innovation initiatives coming from the pharmaceutical industry. The higher costs of more complex clinical studies and costly technologies, and the expectations of a drop in revenues due to patent expiration of blockbuster medicines are among these challenges (EFPIA, 2015, Aitken et al., 2016). Consequently, as in many other industries with their core in R&D, the pharmaceutical industry also balances innovation processes that lead to radical and incremental innovation. An established practice is that after the first launch of a totally new successful drug, brand-owner drug manufacturers will continue to invest incrementally to improve this drug up to a third or fourth market entry into the market. Incremental innovation is essential to make the pharmaceutical business sustainable. Incremental innovation is then based on making existing medicines better or on expanding therapeutic classes of drugs

toward increased efficacy, safety, and quality, with fewer or less severe side effects (IFPMA, 2015; IFPMA, 2017). Improved versions of drugs may interfere with patients' routines and degree of ease with their medication, but incremental versions are also being developed in order to "(…) ensure cash-flow continuity, bring in additional streams of revenue for the firm, and increase shareholders' returns" (Petrova, 2014, p. 23).

4.2.1 R&D spending

In comparison with other high-technology industries, the annual spending of pharmaceutical industry is greater than that of industries such as defense, chemicals, and computer services (IFPMA, 2015). Over the years, the development of new medicines has become more expensive for pharmaceutical companies. In 1970, the cost of developing a successful medicine was about 179 million USD. In 2011, a new drug was estimated to cost an average of 1.5 billion USD (Mestre-Ferrandiz et al., 2012, IFPMA, 2015), whereas the latest estimate considers that developing a new drug can reach about USD 2.6 billion (DiMasi et al., 2016, IFPMA, 2017). Mestre-Ferrandiz et al. (2012) advise that the cost for developing a new drug demands caution, as costs vary depending on the therapeutic area: Neurology, respiratory and oncology have, for instance, lower success rates and longer development times in comparison with antiparasitic drugs and drugs to treat HIV/AIDS.

Mestre-Ferrandiz et al. (2012) explain that the reasoning to understand R&D costs is threefold. First, out-of-pocket development cost (i.e., expenses that are not reimbursed) has increased over the years due to increases in complexity of the clinical trials. A common practice to deal with this increasing cost is to outsource these clinical trials to CROs. Another practice is to conduct clinical trials in emerging markets (Africa, Asia, Eastern Europe, Latin America, and the Middle East), where companies pay less to perform tests and where patient recruitment may be faster. Second, there is an increase in failure rates over time and at different stages of development. Reasons for that could be the premature advance of tentative drugs that fail in final phases, when trials take place with a large amount of patients. Other reasons are that companies are now trying and learning new technologies (e.g. personalized medication), which are not always successful. Third, development times are sometimes extended. One reason is that for some drugs companies will extend their trials before proceeding with development. Another reason is the more risk-adverse behavior of regulatory bodies in approving new drugs, which makes these bodies prolong their reviews.

4.2.2 New product development

An overall understanding is that the pharmaceutical industry is not an industry that can come up with new solutions or a totally new drug from one year to another. In fact, from the outset until a new drug reaches the market, it can take more than a decade for patients to benefit from the solutions that originate within the pharmaceutical companies' laboratories. For the development of a completely new drug, the journey is strenuous and expensive, divided into three main phases: research, development, and approval. In the research phase, of about 5,000-10,000 compounds screened in laboratory, about 250 compounds will enter the preclinical (prehuman) testing. The chances of success in this phase are very low, and if one compound is promising in this phase, clinical trials are started. In 2015, for instance, 56 new medicines were approved for launch by the FDA (Evaluate, 2016), whereas more than 7,000 compounds are under development worldwide (PhRMA, 2016). The forecast is that a very limited amount of compounds will reach the market as drug products (IFPMA, 2017).

The clinical trials phase is the longest and most expensive phase, as it involves progressive testing with humans. The core of development is on three main clinical phases (I; II; III). In Phase I, only healthy volunteers are tested. In this initial clinical phase, it is important to check whether a new compound is tolerated, and what are the effects on the body. If successful, Phase II then starts. In this second phase, the potential new drug is tested with patients that have the targeted disease. At this point, the type of drug formulation is already decided, which will also determine the requirements for packaging of the drug. Next, Phase III expands the number of volunteers with the illness. Studies in the third phase are important to build up the evidence for patient use of the substance. Yet at this point, more than ten years will have elapsed, and major resources will have been already spent (IFPMA, 2017). If all clinical phases are successful, it is worth submitting an application to regulatory authorities to start the approval phase of the new drug development process. Importantly, the approval is based on the packaged drug. After approval, production of the drug can then be scaled up to manufacturing. Post-market surveillance is carried out on a regular basis when the drug is already on the market, which comprises Phase IV of the clinical trials. Figure 8 illustrates the new drug development process.

Takayama and Watanabe (2002) posit that one of the idiosyncrasies of the pharmaceutical industry is that professionals (e.g., physicians) are the main target rather than end users (patients). Many of the investments in new product development (NPD) are based on marketing and sales estimations. NPD can then be rejected if the market estimation is negative or small. In such contexts, pharmaceutical companies try to reduce time and cost to market, while they focus on addressing the widest patient populations and diseases with vast potentials in sales (Riboud, 2014). However, marketing knowledge may sometimes represent a

failure factor for successful NPD, as marketing cannot always forecast the creation of a new market (Takayama and Watanabe, 2002). In line with that, Petrova (2014, p. 23) explains that the creation of value for patients depends on this unpredictable path of scientific advance, and technological breakthroughs with largely erratic results and uneven timing.

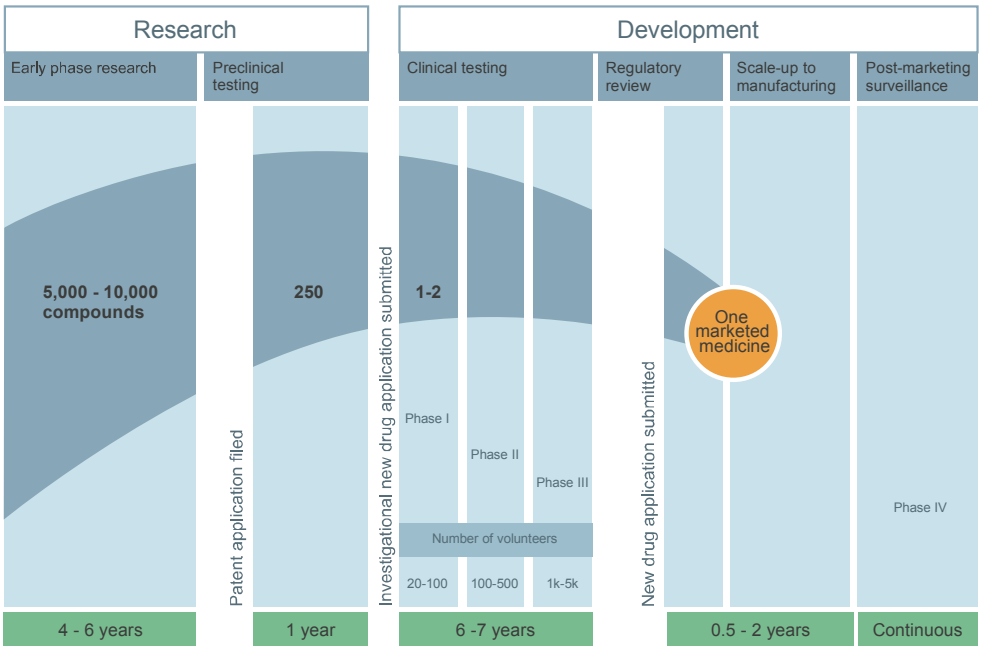

Figure 8 – Phases of the research and development process of a new drug.
Adapted from PhRMA (2012) .

4.3 The pharmaceutical packaging market

To support the distribution and access of medication around the globe, there is a growing pharmaceutical packaging market. The type of drug formulation has greatly influenced the type of packaging chosen (Zadbuke et al., 2013). Overall, the pharmaceutical packaging market was valued at 65.55 billion USD in 2015 and is projected to reach 94.93 billion USD by 2021 (Markets and Markets, 2017). More than half of the medicines on sale (51%) have been developed as tablets or capsules, usually packed in blister packs in (predominantly Europe in Asia) or in plastic pharmaceutical bottles (mainly USA). In addition, other types of drug formulation have been developed, also requiring different dosing regimens and different packaging. The market for other formulation is distributed among parenteral drugs (29%), inhalation/spray medication (17%), and transdermal drugs (3%) (Zadbuke et

al., 2013). In terms of materials, plastic is expected to continue with the highest market share among primary pharmaceutical containers.

The pharmaceutical packaging market has also been developing, pushed by upcoming trends. In particular, Zadbuke et al. (2013, p. 109) affirm that "the pharmaceutical packaging trends are on the verge of innovative rapid growth provided the needs of the product, its security, cost and patient convenience are taken into consideration to build brand identity." One important trend relates to the use of anti-counterfeiting technology implemented on packaging to make it easier for users to verify the authenticity of the drug product, and for stakeholders in the supply chain to track and trace the packed drugs. For the final user, design features are often applied in a way that makes it visible if the package has been tampered with. For instance, breakable caps and sealed tubes are common examples of such design. Zadbuke et al. (2013) have also pointed to the growing of self-administered drugs in connection with new drug formulation, and their impact on demand for packaging that provides a correct dosing system, prefilled syringes are one such example.

4.4 Global spending on pharmaceuticals

In 2016, the global pharmaceutical market was estimated at 1,100 billion USD. In 2021, the expectations are for a growth of around 350-380 USD, totaling 1,485 billion USD. The US market is by far the largest in the world with a spend of 461.7 billion USD in 2016, reaching 645-675 USD billion in 2021. The European share of the top five economies (Germany, the United Kingdom, Italy, France, and Spain) reached 151.8 billion USD in the same year, and 170-200 billion USD is expected to be spent in 2021. For the time being, pharmerging countries are expected to increase their spend from 242.9 USD in 2016 to 315-345 billion USD in 2021 (Aitken et al., 2016, IFPMA, 2017). According to Aitken et al. (2016, p. 1), "most global spending growth, particularly in developed markets, will be driven by oncology, autoimmune and diabetes treatments where significant innovations are expected."

Original branded products will account for over one half (56%) of global pharmaceutical market share in 2021, with global brand spending forecasted to increase to 815-832 billion USD (Aitken et al., 2016, IFPMA, 2017). Importantly, the last five years have been marked by a 'patent cliff', with the fall of patents for blockbuster branded products, increasing the market share for generics over time. In response to that, Aitken et al. (2016) points out that innovation will raise global spending for specialty medicines from 30% in 2016 to 35% in 2021. In developed markets (US and EU5), spending on specialty medicines will reach approximately half of the medicine sales. Figure 9 presents an infographic I designed based on the retrieved data about the pharmaceutical industry.

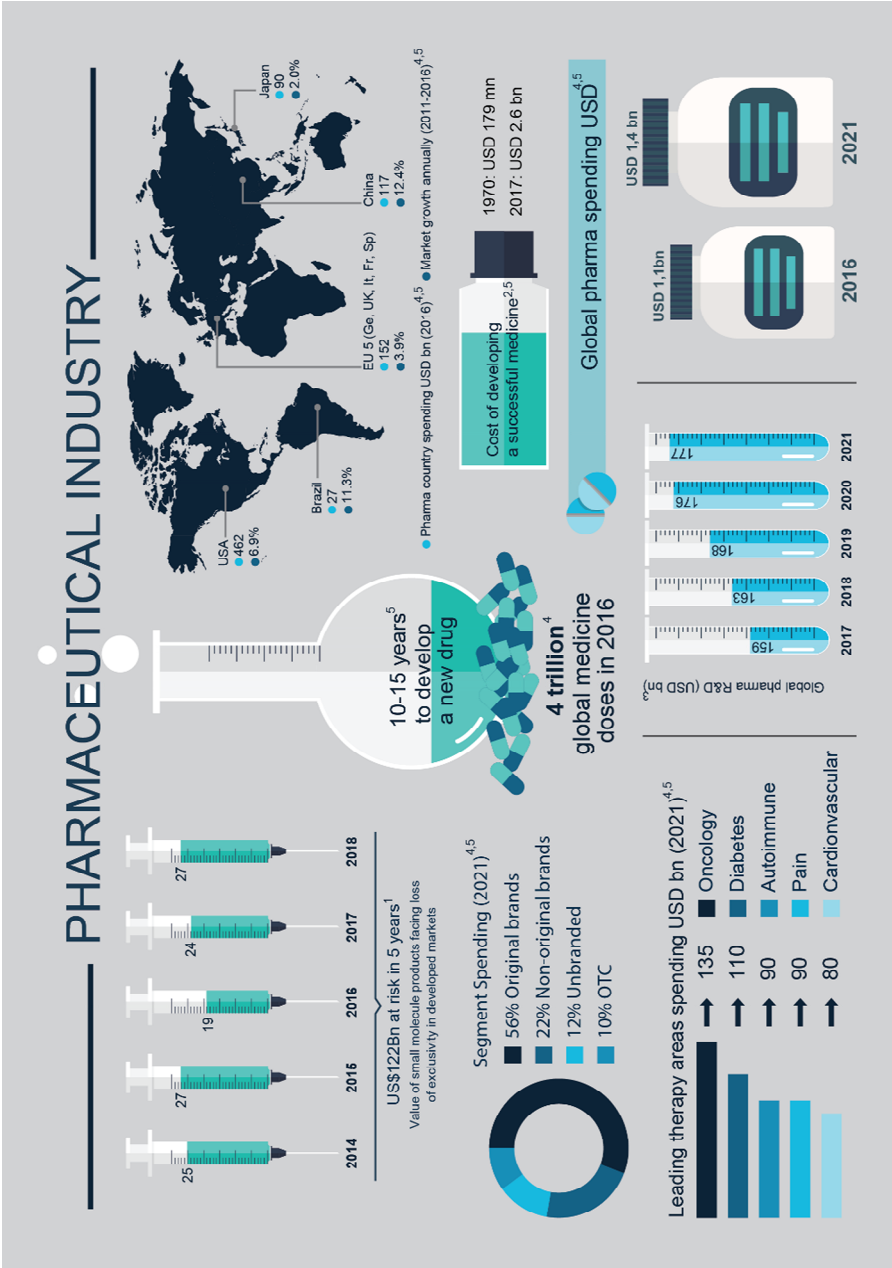

Figure 9 – Infographic of the pharmaceutical industry.
Sources: 1. Aitken et al. (2014), 2. DiMasi et al. (2016), 3. Evaluate (2016), 4. Aitken et al. (2016), 5. IFPMA (2017).

5 Summary of findings from appended papers

In this section, a summary of findings of each paper is presented. Each paper addresses one or more of the research questions posed in Chapter 1. The papers contribute individually to the overall purpose of the dissertation. The two initial papers examine the context of use of medication packaging based on the review of the literature. Paper I focuses on systematically reviewing former literature on the interaction of older patients with medication packaging, whereas Paper II focuses on narratively reviewing inclusive design literature and pharmaceutical packaging. Subsequent papers explore industry practice within the different organizations involved in pharmaceutical packaging innovation and design processes. Paper III presents a case study of a customer-supplier relationship, focusing on the main drivers in the packaging innovation process. Based on the interview study, Papers IV and Paper V resulted in the two final papers of this dissertation. Paper IV pays specific attention to packaging innovation that influences packaging design functions and features, and packaging design constraints. Paper V mainly explores user involvement in the pharmaceutical packaging design process. Table 4 summarizes the papers in relation to the research questions, aims/specific questions, methods, and key results.

Table 4 – Summary of appended papers.

Paper	RQs	Aims/ Specific questions	Methods	Key results
Paper I	**RQ1** **RQ2** RQ3	To present a comprehensive integrated view of the literature on medication packaging and older people through a multidisciplinary review of relevant original research. To synthetize published evidence and provide a basis for further study, practice and research.	Systematic literature review	Two major interconnected research streams (physical functionality and user capability; medication management) and orientations (packaging; user). Focus on physical and psychological characteristics which older patients exhibit when their functional use and management of packages is tested. Lack of original evidence-based research integrating perspectives from the pharmaceutical and packaging industries.
Paper II	RQ1 **RQ3**	To understand current practices in design research and to expand the perspectives of possible design approaches and opportunities to develop inclusive pharmaceutical packaging.	Narrative review	Three main challenges of pharmaceutical packaging design and inclusivity: the challenge of use, the challenge of packaging development and production, and the challenge of safety. Literature is extensively grounded on an 'aging-oriented approach', with the need for a more inclusive approach. Four propositions for future empirical studies to better explore contexts of use of medication packaging by older people, and to involve stakeholders responsible for pharmaceutical packaging design.
Paper III	**RQ4**	By considering innovation as a complex organizational process, the study aims to explore the specific drivers of pharmaceutical packaging innovation.	Case study	The key results are insights and a set of propositions. The narrow sprectrum of drivers is a barrier to pharmaceutical packaging innovation. Results show that technology and legislation strongly influence pharmaceutical packaging innovation, and outweigh other potential drivers such as logistics, marketing, and sustainability. The strategic dimension of packaging is determined by multiple stakeholders with influence on packaging innovation, who often have contradictory demands. The customer-supplier relationship sustains and reinforces product-centered packaging. This indicates that patient-centered innovation demands a more holistic view from external stakeholders to pull innovation.
Paper IV	**RQ4** RQ5	To increase knowledge about the medication packaging innovation process and its uptake toward patient-centered packaging design.	Interview study	Self-care and overall treatment outcomes are increasing areas of interest, yet are constrained by rigid incremental development processes, where compliance with regulations, extensive documentation, avoidance of manufacturing complexity, and additional cost prevail. Prioritized packaging design functions and features protect the drug product and ensure safety in drug usage. Non-standard packaging is a chosen option only when a new treatment demands new packaging design features due to different drug formulations or due to a higher complexity in the dosing regimen. Trade-offs that occur in packaging design often hinder patient-centered design (protection vs. openability, facilitated handling vs. cost, complexity of manufacturability vs. complexity of use). The main findings reveal patient-centered packaging is a societal challenge similar to other societal unsolved challenges, such as sustainable packaging.
Paper V	**RQ5**	To investigate user involvement in the pharmaceutical packaging design process. • How are users involved in the pharmaceutical packaging design process? • What are the perceived benefits or drawbacks of involving users in the pharmaceutical packaging design process? • What encourages or discourages user involvement in the pharmaceutical packaging design process?	Interview study	Packaging teams, especially at drug manufacturers, apply a wide spectrum of involvement modes, and consider different user expertise levels (pre-user, experienced user, and user advocate). Users' involvement fulfills different purposes, and ranges from informative (passive) to participative (active). Users are more actively and informally involved in early phases of new packaging design, helping to generate new packaging concepts, whereas in later or post phases users mainly act as informants or consultants to provide feedback or to ensure packaging guarantees safe drug usage and complies with legislation. User involvement is encouraged by understanding actual usage, creating empathy with users, and compliance with regulations, and discouraged by the challenges of identifying who to involve and when to involve them, the lack of resources, and the limitations imposed by legislation.

5.1 Paper I

Medication packaging and older patients: A systematic review

The purpose of this paper is to present a comprehensive, integrated view of the literature on medication packaging and older people through a multidisciplinary review of the relevant original research. In general, this paper follows the idea that it is fundamental to understand and review what other researchers have done in order to be up to date, and to propose new directions in a field of knowledge. Based on that, the systematic literature review synthetizes the published evidence and provides the basis for further research and practice.

A systematic review was conducted. Formal procedures to search, select, verify, and document the studies used were followed, using a transparent and reproducible methodology. Out of 949 abstracts, thirty-four papers were included in the final selection for analysis, after assessment for their methodological quality through a Mixed Method Appraisal Tool (MMAT). The final sample of thirty-four studies cannot be considered extensive, yet it is comprehensive since it includes relevant scientific works that report older people's problems in their use of medication packaging.

As for general characteristics of context, most of the studies retrieved were done in Europe (mainly the United Kingdom and Germany) and North America (the U.S. and Canada). The earliest study retrieved was published in 1980. Seven studies were published in the 1990s, and 20 articles were published from 2005 to 2014. The higher number of papers in later years points to an increasing research interest in investigating pharmaceutical packaging in use by senior patients. As for methodological choices, most of the authors opted to have a quantitative descriptive analysis (e.g., cross-sectional observational studies with test of packages). In terms of content, the synthesis of the original research indicates the literature is fragmented and diverse, spread among research fields like gerontology, psychology, and marketing (consumer behavior), multiple sources (25 journals), and different authors (113).

Despite the diversity of the field, it was possible to identify two major research streams (*physical functionality and user capability*; *medication management*), and two orientations (*packaging*; *user*) that summarize how/where researchers have put in their main efforts, as illustrated by Figure 10. Consequently, each stream is oriented either by packaging design features, which hinder or facilitate medication use, or by the user (older patient), who has certain characteristics and finds the packaging easy to use or not.

In the review, the first research stream represents the functional use of medication packages by patients. Most of the problems with packaging were found

in child-resistant containers (CRCs). Frequently, CRCs were compared to other types of packages to check their levels of difficulty, and patients' preferences. For users, CRCs compromise the ease of opening packages. Openability (or ease of opening a package) correlates to gender, cognitive functions, physical impairments, aging, living conditions, and experience of use. Importantly, females are found to be the patients most greatly affected by the lack of openability in medication packaging.

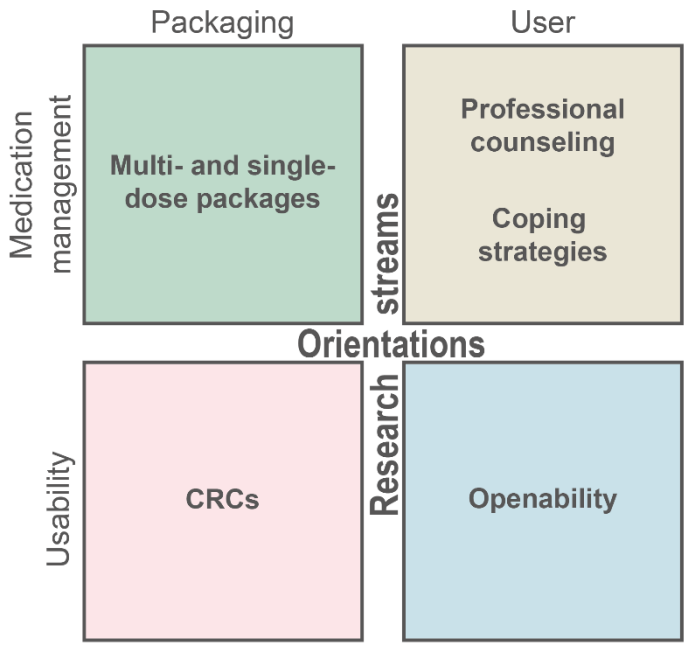

Figure 10 – Research streams and orientations.
Adapted from Lorenzini (2016).

The second research stream, *medication management*, relates to the management of medication by older people over time, including their compliance with, or adherence to treatment. In relation to the medication management research stream, packaging aids (i.e., multi-dose packaging or single-dose packaging) were often of interest to researchers. Packaging aids represent an alternative to ordinary packaging, and an attempt to provide a new source of assistance to patients through the container in use. In general, studies which focused on packaging aids were interested in the outcomes of use of such aids in comparison with conventional containers. Thus far, however, the results presented cannot be considered conclusive, and more research is necessary.

Regarding users, some studies presented older patients as being assessed by their coping strategies, e.g., patients' strategies to overcome difficulties caused by packaging features. Professional counseling for patients was also reported to be important. Patients usually seek counseling for their drug therapy in the pharmacy and with health care professionals. As reported, one-sided decisions taken by professionals, without discussion with patients, impact how patients feel and manage their treatments.

When critically analyzed, research streams and orientations point to some dilemmas (i.e., trade-offs) in pharmaceutical packaging design. CRCs and packaging aids relate to the dilemma of combining safety with 'senior friendliness.' Simple devices and counseling are also emblematic, since the literature does not point to 'one solution fits all.' The main findings of the paper show that authors have also put more effort into studying the physical and psychological impairments which older patients have, and that impact their use and management of packages. Other research streams might appear, for example, through further exploration of coping strategies, the patient's feelings when using the medication, and integration of the patient's view with the packaging developer's perspective.

By presenting a description and synthesis of the original research on medication packaging and older people, this paper strengthens the argument that packaging has a fundamental role in the intake of medication. Moreover, classification of literature according to research streams and orientations facilitates the understanding of this fragmented research field, and helps researchers to further explore other as yet underdeveloped research streams. For this dissertation, the findings from Paper I contribute to uncover the predominant topics and methodologies chosen by researchers within the medication packaging field. The paper also provides insights into the discussion on inclusivity elaborated in Paper II. Finally, the original findings provide valuable input to researchers and practitioners, and offer guidance on the further development of senior-friendly medication packaging.

5.2 Paper II

Design towards better life experience: Closing the gap between pharmaceutical packaging design and elderly people

Older patients often experience problems with medication packaging. From a design perspective, these practical problems offer the opportunity to advance the debate about inclusive design approaches in the emergent field of pharmaceutical packaging, with an emphasis on the process of aging. Relevant studies were purposefully selected to discuss the methods chosen by researchers in order to

understand and integrate the needs of older people in pharmaceutical packaging design.

Three main design approaches are reviewed: universal design, inclusive design, and design for all. These design approaches arose as new schools of thought to rethink design, in order to reduce the mismatch between products and people. Aging, and its conceptualization, is also reviewed in this paper. The trend of aging populations implies reflection on being old, on how old people want to be perceived, and how older people participate in society. Aging is complex as it encompasses multiple factors ranging from physical, psychological, and social aspects. For years, aging has been connected mainly to working life, retirement being the major threshold for becoming old. Illuminated by design approaches, aging can be perceived differently. Active seniors are in the limelight, claiming more inclusivity and attention. The paper stresses that aging and the interpretation of older patients' needs goes beyond impairment or compensation for reduced functions, which means older people can be more actively involved in the use and creation of new products.

Based on a narrative review of the relevant literature, the paper then explores the different methods chosen by researchers in relation to design research and pharmaceutical packaging. The choices of methods and common practices in research are grouped and presented as three different challenges for pharmaceutical packaging: *challenge of use*; *challenge of packaging development and production*; *challenge of safety*. In the *challenge of use*, observations and interviews are common methodological choices for assessing the needs of older people in relation to medication packages. Tasks are performed to assess how people use packages, with great focus on an aging orientation. In the *challenge of packaging development and production*, researchers highlight packaging as a means to safety in distribution of the medical product, and the extension of product shelf life. Mathematical models, laboratory tests, and prototyping are the principal choices for simulating adverse conditions for taking medication. In the *challenge of safety*, the emphasis is on the dilemma of child resistance and senior friendliness. Reports and analyses of population statistics are on the spot. Ethical aspects and the testing of usability protocols are given special attention.

From the review of literature on design approaches, aging, and the compilation of the general challenges highlighted by studies, four propositions were presented. The propositions were developed considering the need to explore other challenges in the use and development of pharmaceutical packages. As discussed, the literature shows a repetition of choices of methods, where aging is mainly associated with multiple problems in using medication packages. Older patients could be more actively engaged in the packaging innovation process and in sharing their experiences. Researchers could then be inspired to study medication packaging in other contexts that are more familiar to older users, rather than in laboratory settings. Older users can not only test packages, but also report their experiences and frustrations in full in different types of qualitative studies. Furthermore, inclusive

design approaches could be explored with stakeholders from the pharmaceutical industry, to better understand their view of medication packaging and older patients.

In general, this paper contributes to the literature by presenting propositions that can form the basis for future empirical studies on senior users, as well as the regulations for, and the processes of, developing pharmaceutical packaging. For this dissertation, Paper II brings an inclusive design perspective to pharmaceutical packaging, opening up for further investigations on how user needs (i.e., patient needs) are considered within pharmaceutical industry practices when innovating in pharmaceutical packaging.

5.3 Paper III

Drivers of pharmaceutical packaging innovation: A customer-supplier relationship case study

Pharmaceutical packaging can be an important facilitator in the treatment carried out by patients, especially older patients. However, previous studies also reports many problems experienced by those patients. From a research point of view, it is intriguing why certain problems that users experience with pharmaceutical packaging remain. It leads to the question of what really drives innovation in this area. As a result, this paper aims to explore the drivers of pharmaceutical packaging innovation.

The paper presents a framework of innovation as a complex organizational process, where major structural influences and the action of stakeholders take place. Turning to packaging, the paper focuses on what stimulates packaging innovation. With support from previous literature, five contemporary drivers of packaging innovation are presented: technology, legislation, marketing, logistics, and sustainability.

Technology-driven packaging innovation is prominent in packaging literature, with highlights on better product performance and features that optimize the tracking of goods along supply chains. Legislation-driven packaging innovation relates to the stringent and non-stringent regulations that impose changes on packaging. Market-driven innovation relates to insights that originate in, and affect the market place, especially regarding branding, boosting sales, and identification of clutter-breaking opportunities. Logistic-driven packaging innovation relates to changes in the packaging system with effects that span the whole supply chain. Finally, sustainability-driven packaging innovation relates to environmental aspects which spread along supply chains, commonly studied via life-cycle analysis, or via consumer input.

These drivers were investigated in pharmaceutical packaging following an abductive process and qualitative research approach, based on one in-depth case

study of two companies in a customer-supplier relationship. From the data, it was possible to gain knowledge about the overall network that is relevant in pharmaceutical packaging innovation.

One major finding shows that two drivers – technology and legislation – are strongly present in the development of pharmaceutical packaging. Technology drives optimization in manufacturability and makes it possible to deliver new treatment systems. For instance, existing technology (e.g., sensors or applications for smartphones) can be combined with medication packaging to reinforce patients' compliance with treatment. Legislation is stringent in the pharmaceutical domain, with a focus on safety and quality. Nevertheless, legislation was also found to have the downside of a long process of approval of packaging changes. Market, logistics, and sustainability were identified as potential drivers yet to be realized into business, but outweighed by technology and legislation.

A second finding relates to the necessary movement from product-centered to patient-centered innovation. In its current practices, pharmaceutical packaging design is focused on drug product protection, however, there are possibilities for the pharmaceutical business to evolve toward a more holistic improvement of treatment. Patient-centered innovation could happen if demanded by external stakeholders beyond the customer-supplier relationship. For instance, regulatory bodies or insurance providers might require certain packaging features or may demand better treatment outcomes, which would influence packaging innovation and benefit patients. Another finding reflects on the complexity of pharmaceutical packaging innovation, where multiple and contradictory needs from multiple stakeholders may be addressed. Because of that, patients' needs compete with other needs, such as the need for protective packaging that reduces openability or the need to reduce packaging costs; these factors preclude the investment in patient-centered features. The balance is resolved, based on the strategic level of the packaging and its unexplored business potential.

These main empirical findings are discussed in the paper, culminating in seven propositions that can guide further research in pharmaceutical packaging or related fields of packaging innovation. The propositions could also further develop into hypotheses for quantitative investigations. The paper contributes to the scarce literature on packaging innovation, and sheds light on a patient-centered approach, which is still immature in pharmaceutical packaging research and practice. For this dissertation, the investigation of a customer-supplier relationship created the base for understanding packaging innovation within the pharmaceutical industry. It also opened the way to a more extensive empirical investigation presented in Paper IV and Paper V.

5.4 Paper IV

Toward patient-centered packaging design: An industry perspective on processes, functions, and constraints

Paper IV aims to increase the knowledge about medication packaging innovation processes and its uptake toward patient-centered design. The point of departure is that decisions made to change or adapt packaging will impact packaging design outcomes; the functions and features of the packaging, for instance. Medication packaging is part of the problem, but also part of the solution regarding aging societies and the increasing demand on self-care. In its current form, medication packaging does not seem to consider patient's needs, especially in regards to openability and medication adherence. Acknowledging the problems of medication packaging use is half the challenge, whereas the other half remains in exploring the process and practices established for medication packaging.

The paper uses interview data from twenty-five interviews, where different stakeholders from drug manufacturers, packaging suppliers, and packaging and patient associations were involved. The findings are then presented according to four main themes that inductively emerged from the interview data: medication packaging innovation process, medication packaging functions and features, medication packaging design constraints, and patient-centered medication packaging design. Table 5 presents the summary of these main themes, their overall description, and key aspects.

Table 5 – Summary of main themes, description, and key aspects.

Main themes	Description	Key aspects
Medication packaging innovation processes	Packaging innovation is implemented at a low pace and fixed by well-structured and established processes. Packaging innovation is dependent on the drug discovery process.	Stage-gate processes Product-packaging integration Customer-supplier relationship
Medication packaging design functions and features	The packaging protects the drug product (medication) along the whole supply chain journey and also during use The packaging leads to easy, correct use and dosage of the drug product.	Protection and safety (robustness, thickness and stability, extended shelf-life, anti-counterfeiting, child-resistance). Facilitate handling (correct use, openability, portability, apportionment). Communication (identification, instruction).
Medication packaging design constraints	The packaging needs to comply with regulations. The packaging needs to avoid unnecessary complexity or cost.	Standardization Manufacturability (cost of change) Stringent regulations and extended documentation Reduction of complexities
Patient-centered medication packaging design	Expensive solutions are not affordable for the health care system or by the patient. Packaging is becoming more important in supporting patients in their own care.	Self-care Overall cost of treatment

The findings support and make the previous findings from Paper III bolder, by showing that drug manufacturers and packaging suppliers play major roles in negotiating packaging design functions and features, constraints, and decision-making processes. In response to the research question, medication packaging innovation is based on well-structured, low-pace processes. Interestingly, problems that arise from the use of medication packaging are commonly known by companies producing those packages. However, user needs (i.e., patient needs) cannot be fully addressed and transferred to packaging design due to the rigidity of internal and external processes and multiple trade-offs.

Three specific trade-offs were found to be very salient yet not exclusive of medication packaging design: protection versus openability, where highly protective packaging makes packaging very difficult to open; facilitated handling versus cost, where convenient features may add cost to production; complexity of manufacturability versus complexity of use, where new complex treatments might demand packages that are more complex to produce but easier to use. So far, the trade-offs often are resolved to the detriment of patients. In spite of that, findings in the paper highlight some coming trends that might impact more patient-centered packaging design. For instance, companies know that patients are becoming more responsible for their own care and are more active in seeking information about their diseases and treatment. Because of that, companies (and particularly drug manufacturers) are more interested in understanding patients' needs. Another finding shows that, unlike the costs that directly apply to packaging, health care providers are becoming more interested in the overall cost of treatment and patient outcomes. Ultimately, the findings in this paper reflect similar complex societal challenges that have not yet been fully addressed in packaging; sustainable development is a remarkable example.

The paper contributes by bringing empirical industry-based evidence to the fragmented field of medication packaging research, which is closely related to the main purpose in this dissertation. Based on that, the paper complements previous research identified in Paper I, which has mainly focused on testing and identifying problems with packaging use. This empirical evidence might instigate other researchers to not only investigate existing problems with medication packaging, but also to embrace and understand the complexities that surround packaging innovation processes and that result in a lack of patient-centered design. For practitioners, the paper might stimulate critical thinking about medication packaging and its potentialities to respond to the needs of patients.

5.5 Paper V

Getting involved with patients: User involvement in pharmaceutical packaging design

Paper V explores user involvement in the pharmaceutical packaging design process. It narrows down the main research question into three specific questions: 'How are users involved in the pharmaceutical packaging design process?'; 'what are the perceived benefits or drawbacks of involving users in the pharmaceutical packaging design process?'; 'what encourages or discourages user involvement in the pharmaceutical packaging design process?'. This paper focuses on design as a process, which tries to integrate user needs when new packaging is being developed. This paper therefore reinstates some of the notions of inclusivity and design approaches from Paper II. Primordial considerations here are that user involvement demands a systematic identification of users, the acknowledgement of the level of user involvement, and whether traditions in the specific industry are design-oriented or not.

The results presented in the paper come from the interview study (Study C). In user involvement for pharmaceutical packaging design, three constructs of users were identified: pre-user, who has no experience of a certain treatment, disease, or packaging; experienced user, who has experience of treating a disease and dealing with specific medication; user advocate, who is a member of patient associations and who is not only experienced but engaged in creating better situations for patients in a similar health situation. Patient associations are revealed to be extreme important in highlighting patients' needs and creating a bridge between patients and industry.

This paper also identifies and describes the levels of user involvement, which range from active to passive involvement. In early phases of packaging design, drug manufacturers use ethnography, encounters with patients, and cocreation workshops to become inspired, to develop initial concepts, or to learn from patients' lives and routines. In validation phases, rapid prototyping workshops, followed by usability studies often take place in a laboratory setting. In later or post-development phases, companies also meet with patients again to hear their experiences of the medication and to formally assess patients' complaints. The findings indicate that the level of user involvement fulfills different purposes and is dependent on the type of packaging project. For platform or standard packaging design, for instance, only regulatory-body required human factors studies (like usability tests) will be carried out, whereas for new treatments with different drug formulation, more modes of user involvement can be applied. Packaging suppliers often tend to learn about patient needs from drug manufacturers, which means they rarely involve users in their design process.

Findings also reveal that there are different encouraging and discouraging factors for user involvement. Among the encouraging factors, user involvement provides a better understanding of the experiences users have with their diseases. In addition, user involvement creates packaging teams' empathy with users (patients). This is particularly important when new treatment or new drugs are planned to be launched. The discouraging factors are the difficulty of identifying the correct patient group and the point of user involvement that can really provide valuable insights. In addition to that, limited resources, such as budget and time, can hinder user involvement. Finally, regulations are found to be both encouraging and discouraging, as they might require extensive documentation and might necessitate hiring external professionals. Yet stringent regulations may impose the need for some user involvement to ensure packaging can be managed along the entire treatment.

The paper contributes to the literature by exploring user involvement, and particularly patient involvement. So far, active user involvement has been stressed by authors, but few studies have dedicated efforts to investigate user involvement within contexts that are not acknowledged as design-driven. For this dissertation, Paper V presents evidence from industry practice and deepens the discussion started in Paper I and Paper II about more inclusive medication packaging, and the participation of users in the design process.

6 Discussion

Research within the field of pharmaceutical packaging benefits from a complementary view of user-centered orientation regarding the predominant view of product-centered orientation. To stimulate the uptake of inclusive design, this research has explored industry processes and practices in regard of pharmaceutical packaging innovation and user involvement in pharmaceutical packaging design. As a result, the discussion in this chapter complements and enlarges those individual discussions that took place in each appended paper which together compose the overall dissertation. I highlight some of the interesting findings that emerged from the research in this dissertation. Altogether, the studies and papers permit further insights which can be analyzed in the light of the interdisciplinary literature to provide a more cohesive picture of pharmaceutical packaging innovation and design.

6.1 Packaging innovation process and practices

Studies in the field of pharmaceutical packaging design have identified similar problems experienced by older people. The persistence of analogous problems spread over decades, such as difficulties opening child-resistant caps, suggests pharmaceutical packaging design has also persisted in an equivalent way. From the studies retrieved in Paper I (Study A), it was not possible to apprehend whether the pharmaceutical industry knows about those problems, or whether some sort of inclusive design principles are considered when pharmaceutical packaging is being designed. The findings from the empirical investigation have added to this gap in knowledge. Additionally, these findings have helped to better understand the challenges that exist in innovating in pharmaceutical packaging design, and that explain why certain problems of use persist. Conversely, opportunities were also found.

6.1.1 Challenges in packaging innovation and design

This research found that technology and legislation are the dominant drivers of medication packaging innovation (Paper III). The fact that technology and legislation drive the pharmaceutical packaging innovation process helps to understand why it is so difficult to change packaging design that already exists. The pharmaceutical industry is founded on a decade-long drug development process. The drug development process is open to the main opportunities for innovation and resources, and also determines the type of packaging used. Until a drug formulation is known, packaging teams are left on hold. This is supported by the fact that the costs of drug innovation have been rising, together with the fact that many drug candidates will fail in early phases of clinical trials (DiMasi et al., 2016). No investments will therefore be made or additional risks taken on packaging for an uncertain drug candidate.

Once a drug formulation is known, there are two alternative routes for packaging design: a standard package or a totally new package design. The empirical investigations in this dissertation have shown that the pharmaceutical industry is a very innovative industry, yet quite conservative in relation to packaging innovation. Because of that, in many drug projects managers and packaging teams will concentrate their efforts on avoiding risks with packaging, adopting standard packaging design whenever possible. As a result, a traditional drug formulation, e.g., a tablet, is rarely a motivation for changes in packaging design. The reason is that a traditional drug formulation can be packed in a standard package design that has already been tested and approved as regards relevant legislation. It has also been tested and approved to be produced in the existing machinery of packaging suppliers, without the need for further investments.

Legislation specifically acts as a major force in the pharmaceutical industry to guarantee that medication is provided and used in a safe manner. Despite the common notion that legislation can only hinder innovation, literature has shown that stringent regulation has fostered innovation and competition in the development of new medicines (Munos, 2009). The possible reasoning behind this phenomenon is that companies are more selective with the investments they aim to bring to the market. In relation to pharmaceutical packaging, discussions about regulations are highly important in the pharmaceutical field as they may imply innovation from the time they are established, as companies need to perform changes to adapt. Yet in the long term, legislation also sets many boundaries for the establishment of standard packaging design for years afterward.

For instance, Bix et al. (2009a, p. 431) have discussed the impact of long-standing regulations that have affected a generation of new medication packaging designs. The authors use the example of the Poison Prevention Packaging Act (PPPA) established in 1970 in the US. As they emphasize, “because the US protocol was the first of its kind, it has served as the basis for numerous other protocols”

(ibid). From the establishment of PPPA, packaging designers have put their efforts into creating designs that would protect children from being poisoned. As we have seen in Paper I, older people have also been affected. Aligned with that, results from the empirical studies (Paper III, Paper IV) show that packaging teams at drug manufacturers have always prioritized the most stringent legislation to follow in packaging design. Less stringent regulation, which is not compulsory, is followed when the teams can envision other opportunities, such as a market opportunity to gain competitive advantage (Ashford et al., 1985). This explains why many child-resistant packages have been designed, whereas packaging with design features that facilitate use by older people is still underdeveloped or left to drug projects where there is a greater consumer appeal, such as over-the-counter medication (OTC). Based on that, previous literature and findings from this research indicate that legislation helps to create new standard packaging, setting the boundaries for minimum quality and features a packaging design is expected to have. Yet legislation can also stress the lack of inclusivity in pharmaceutical packaging, when standard packaging is designed without considering user needs or without the awareness of evidence of multiple problems (as reported in Paper I).

Regarding technology, results from the empirical investigations have shown that the packaging innovation process may not delay the launch of a drug onto the market, and that is why it is not always possible or desirable to have new packaging for every new drug project. Entirely new packaging might require new machinery or new tests on production, whereas standardized packaging avoids new tests or investments. This finding also relates to previous research on the field of packaging and product integration, where authors have stressed that packaging often comes late in the product innovation process (ten Klooster, 2002, Bramklev, 2009, Olander-Roese and Nilsson, 2009). In that sense, as for packaging in general, pharmaceutical packaging is not always given the time and resources to develop its strategic role in a project (Lockamy III, 1995). Limitations in technology combined with a lack of view of the strategic potential of packaging also explain why certain design features that would be preferred by users cannot be easily implemented.

6.1.2 Opportunities in packaging innovation and design

Findings from this research have highlighted that pharmaceutical packaging has been a ‘dormant’ area of innovation within the pharmaceutical industry, where standards are kept and improved for years, oiled by well-defined and rigid processes (especially as presented in Paper IV). However, new opportunities are also foreseen. As presented in Chapter 3 (empirical context), the difficulties of launching new breakthrough drugs, and the loss of drug patents are among the relevant facts that might lead the pharmaceutical business into new directions (Munos, 2009). In combination, governments are demanding better outcomes for treatment – their

demands go beyond proven clinical trials, as many packaging-related mistakes or unexpected outcomes can also come from people's behavior when they take their medicine.

As found in the empirical studies, having a new drug formulation that could not be packed in standard packaging creates the demand for new packaging. Additional secondary data shows that plenty of new types of treatment are under investigation, which seems promising for pharmaceutical packaging innovation (Aitken et al., 2014; IFPMA, 2017). Despite being a challenge, legislation can also stimulate change in packaging design. Findings in Study B and Study C stressed that for treatment with complex drug regimens, new packaging may be necessary when standard packaging is considered by drug manufacturers as insufficient to guarantee patient safety, which is a requisite from regulatory bodies such as US FDA and EMA.

So far, partnerships in medication packaging innovation have been based on strong ties, where optimizations of routines and trustfulness are important (Granovetter, 1973). The close relationship between drug manufacturers and packaging suppliers has had a focus on product-centered packaging, based on continuous improvements and reshaping of designs, rather than on completely new designs (Paper III, Paper IV). In new scenarios where medication packaging has a greater importance in relation to treatment outcomes, technology would probably still be a driver for innovation. The focus, however, would possibly expand from only optimization of materials and manufacturability, toward the implementation of new tools and systems to support patients (Zadbuke et al., 2013). Despite the fact that many respondents in Study B and Study C could not disclose details of ongoing projects, they revealed their interest in technological systems that surround packaging use. This would imply that the focal relationship of drug manufacturer-packaging supplier would need to be expanded and become more open to other partnerships.

As suggested by relevant literature, companies need to engage in routines of networking opportunities to identify other partners for their innovation processes (Kazadi et al., 2016). Findings in this research have shown that drug manufacturers and packaging suppliers have made some efforts to expand their networks for packaging innovation, with patient and packaging associations, for instance, where they could establish a forum for the exchange of ideas. Other companies have invested in innovation laboratories to work with online communities of users, exploring the context that surrounds medicine and its packaging. Further, packaging teams have looked to innovation in other industries such as food packaging, to find inspiration. A suggestion is that efforts like that need to be continually supported at the strategic level within organizations involved in designing new packaging, as such efforts could increase the strategic potential of packaging, as well as give rise to potential drivers of innovation becoming more evident and powerful.

Finally, an important finding is that when an opportunity for creating a new packaging design exists, it should be taken as a market opportunity for designing inclusive packaging. Designing inclusive packaging from scratch is therefore essential to avoid non-inclusive standard packaging. It may take decades to change the current standards that exist in the market. However, new packaging designed inclusively may slowly replace non-inclusive packaging.

6.2 Patient-centered design in medication packaging

The phenomenon of aging in combination with the multiple use of medication has put many new demands on older patients, especially in relation to self-care (Sino et al., 2014). The recommendations of health policy makers encourage older people to live independently in their homes (WHO, 2015). In this research, the notion of user-centered design originates from the notion that user needs may be considered when products are designed (Sanders and Stappers, 2008). Patient-centered design works as a common thread in this dissertation as the multiple studies herein have paid attention to the considerations of users' needs either in literature or in pharmaceutical industry practice. A significant part of this dissertation has been dedicated to investigating how user needs are taken into the process of designing pharmaceutical packaging. In the compound of studies, the notion of inclusivity has evolved from simply considering user needs to more user involvement in the design process.

Regarding the previous session (6.1.2), patient-centered design in pharmaceutical packaging can also be seen as an opportunity to address society's needs and for innovation of pharmaceutical packaging design. In consideration of this opportunity, I reflect here on the potential of inclusivity in medication packaging based on the problems identified in the relevant literature (Paper I), and the levels of user involvement.

6.2.1 The potential of inclusive design in packaging

Since its early stages, the lack of inclusive approaches has been problematized in this research. The idea that it is important to consider user needs broadly, and beyond the mainstream population, were identified in the literature. Inclusive design, design for all, and universal design were presented in Paper II and Paper V as design approaches or design philosophies that help to elaborate on the argument about design that considers people's capabilities (Clarkson and Coleman, 2015).

If we take inclusive design as a lens to look through at the problems faced by users, we can see that the lack of inclusivity in pharmaceutical packaging design

was reported by many of the studies retrieved in Paper I. Repeatedly, constraints imposed by packaging design appeared in the studies, difficulties to open packaging being of greatest interest to researchers. Findings from those studies also indicated that difficulties with packaging may be analyzed within a broader scope, as those difficulties can lead to non-adherent (Nikolaus et al., 1995) or even unsafe behaviors toward treatment (Gould et al., 2009, Notenboom et al., 2014). Due to the lack of inclusivity, many users of medication will need additional tools to handle their medication packaging (Dong and Vanns, 2008). As addressed by some studies in Paper I, patients often use aid tools as substitutes for packaging to help them manage their medication. Yet by changing their medication to other containers, patients also lose some of the protection and information intended by the original packaging. Overall, research on human-packaging interaction suggests that pharmaceutical packaging has consequences on how patients perform their treatment, often related to poor adherence and to negative outcomes.

The problems stressed by former research become even more critical when we consider that we live a phenomenon of medicalization of society, especially in later life (Paper V). The design of packaging that ignores or does not fully consider users' capabilities and their needs stresses the fact that future generations of older people will continuously face similar constraints in their treatment. However, in contrast to former generations of older adults, the now aging baby-boomer generation is less likely to tolerate products that are impossible or very difficult to use (Inclusive Design Toolkit, 2012). The Inclusive Design Toolkit (2012) has pinpointed the following risks of ignoring users' diversity or postponing inclusive design in product development: excessive customer support costs, a large proportion of no-fault warranty returns, lawsuits, costly rectification work required close to or after launch, customer dissatisfaction, and brand degradation. In the case of pharmaceutical packaging, even with certain limitations in their choices of drug product, users are trying to have some influence by becoming informed and by articulating their needs. This finding was reported in some of the interviews (Study C), but also in the literature. As reported by Weiner and Will (2016), in many situations patients are resistant to treatment and they also try to negotiate the choice of treatment with physicians.

Inclusive design helps in responding to major challenges in society. At an individual level, it means providing users or patients with appropriate tools so that they can own their treatment and feel empowered to care for their own health. A disease can be a burden that has physical and psychological effects on health, however, having control of treatment, by being able to establish and perform daily routines correctly, allows patients alleviate some of the burden. Findings in research support this idea, since when patients were given packages with appropriate design features, they could also better follow their dosing regimen, as found by Ware et al. (1991). Wong and Norman (1987) found better medication compliance with patients that used calendar blister pack. Murray et al. (1993) found that unit-of-use

packaging and twice-daily dosing improved medication compliance when compared with conventional packaging. Ringe et al. (2006) identified that for drug regimens that demand a combination of drugs, providing a combined packaging is better than patients handling the medication separately.

As suggested by the authors, "an alternative agenda would not rely on initiatives to encourage people to use medicines as directed, but focus on improving safety of medicines and on identifying and evaluating patients' preferred treatments" (Weiner and Will, 2016, pp. 273-274). This understanding stresses that pharmacy and health care professionals also have a role in establishing dialog with patients and in identifying the main problems experienced by those patients with their treatment. Despite their limited choices, patients could be allowed to choose medication with different packaging or dosing systems (Philbert et al., 2014). Even paid-by-the-pocket alternatives could be better explored and further considered.

Furthermore, inclusive design offers the chance to think about packaging as a resource for better treatment outcomes, rather than only as a cost to treatment. When patients adopt unsafe behaviors to take their medication, or when they simply do not take the treatment, it costs. For instance, it costs in quality of life, as people might not benefit from treatment as they could; it costs the health care system, as people might remain ill or might need assistance at health care facilities that could be avoided with the correct use of medication. However, packaging also costs, and it is generally the mindset that packaging is only a cost that has impeded packaging becoming more than a commodity. There is a need to balance what those costs really mean in relation to treatment outcomes. As presented in Study C, it is nowadays sufficient to prove that a drug has positive outcomes in clinical trials and that the packaging offered is safe for use. Consequently, drug manufacturers are then reimbursed through the drugs sold. Yet reality is much more complex when it comes to treatment outcomes in the real lives of patients, as many obstacles appear, packaging being one of those. Successful outcomes of treatment could potentially dictate reimbursement for drugs sold, adding a new dimension to packaging, as pharmaceutical companies would need to think more systemically about overall treatment and about the whole process of patients taking the medication as instructed. Such discussion has already started in public agendas, and it is expected to grow in the coming years, opening up the way for inclusive design in pharmaceutical packaging.

6.2.2 Toward user involvement in packaging design

In the design field, researchers have argued for a shift from user-centered design to participatory design. Damodaran (1996) has written that users should participate in the design process and not just 'rubber stamp it.' Heylighen and Bianchin (2013, p. 97) reinforce this idea, affirming that "inclusion requires not just to converge *ex post*

on perceiving and judging design quality, but to cooperate in the production of it." From a design perspective, this translates into users not only being consulted in relation to final designed artifacts, but also being involved in designing the artifacts to best fit their needs. Design research emphasizes that users should be involved early on in the design process, when they can have roles as sources of new ideas, and to promote exploration of those ideas (Kaulio, 1998).

In spite of that, both research and industry practice still include users mainly as 'testers' of packaging concepts. As presented in Study A, testing physical aspects of the packaging with users seems to be quite common in research. Most of the studies retrieved in Paper I tested packages that were already on the market, trying to identify the ones most or least preferred by users. A missed opportunity was to further explore any possible ideas or suggestions these users had about other design features in the packaging. Similarly, in industry practice, the most common assessment of packaging with users was focused on giving users packaging prototypes to test, while packaging teams observed and drew conclusions. In practice, a passive view of users of medication packaging is still predominant due to regulatory and also organizational constraints.

Surprising results originated from the interview study (Study C, Paper V) indicating that drug manufacturers have put efforts into trying to expand their perception about patients, and to gain more in-depth knowledge about patients' use of medication. Drug manufacturers are trying to get closer to the user/patient to build a more holistic perspective about patients' experiences of their disease. For drug manufacturers, the idea of a user, or patient, is framed around the disease and a person's experience of the treatment. In that sense, what respondents reported was their core expertise in targeting patient groups with a specific illness and the consequences of that. Notably, respondents working at drug manufacturers revealed their interest in testing packaging with users with different levels of expertise and engagement in their treatment. Experienced users were therefore included together with non-experienced users (pre-users) as well as user advocates enrolled in patient associations (Paper V). Respondents reported using methodologies coming from fields such as anthropology, design, or sociology to conduct ethnographic studies with patients, or to perform workshops where patients could create and elaborate on new packaging concepts together with packaging teams. Parts of the users' needs identified on those occasions were then spread among other organizations, such as packaging suppliers, as the latter usually only have indirect data about the patient.

Such results should be taken carefully, as they may not represent the overall practice of designing medication packages. In addition to that, the organizations studied were large enough to have the resources to spend on methodologies beyond the ones demanded by regulation. The innumerable problems faced by patients (Paper I) prove that overall medication packaging design does not consider user needs fully. In addition, it is evident that packaging teams and professionals responsible for packaging innovation are often hindered by their context of

development and the drawbacks of user involvement often surpass the possible foreseen benefits, limiting user involvement to a few selected projects as detailed in Paper V.

6.3 Bridging research and practice

Departing from a comprehensive literature review (Study A), from the start this research has identified some of the common avenues of former investigation (Paper I), and the uncommon pathways to be further explored (Paper II). As shown in Paper I, many scholars from different disciplines have reported a myriad of experiences of older people with pharmaceutical packaging design. Findings serve as a basis for fundamental knowledge about the use of pharmaceutical packaging design by older people. Further, these findings point to the main consequences of packaging design choices made by the many stakeholders, such as industry and regulatory bodies.

6.3.1 Going beyond stereotypes

Importantly, for the field of pharmaceutical packaging design to evolve toward inclusivity, aging and the concept of older person must become broader, beyond impairment. The systematic review in Paper I and the narrative review in Paper II show there is still a reductionist approach to older people, where those people were mainly assessed in regard to their impairments, created by biological age. Older patients are a group of extreme users of medication and, consequently, of medication packaging. This immediately justifies the interest of researchers in searching for problems these users have with packaging. The greatest attention to physical impairments reinforces the stereotype of older people as weak and limited. This finding is similar to what other researchers have found regarding the predominant stereotypes that exist about older people and their interaction with designed technological artifacts (Essén and Östlund, 2011).

Challenging the predominant view of aging as a burden, few studies retrieved in Paper I showed that some seniors are very keen to search for their own design alternatives. For instance, as identified by Notenboom et al. (2014), out of 211 problems reported with medication and medication packages, 184 correspondent coping strategies were found. As found by Nunney et al. (2011), older patients may want helpful packaging, but they do not want ‘childlike’ solutions. These findings connect with the concept of active seniors, in which older people act and react promptly in their everyday life practices (Botero and Hyysalo, 2013). The findings presented in the literature also reinforce the principle of not having adapted designs, but rather inclusive designs. The stereotypes of age stretch the distance between ‘the

average user' and 'the rest of the population' (Huppert, 2003). The most important is not to create two separate populations, but rather to include a population that has shown difficulties as the foundation to design (Keates and Clarkson, 2003a). From the inclusive perspective in this dissertation, as stressed by Paper II, older people should not be considered only in the matters or their 'loss of capability', but in regard to what they are still capable to do in their own terms.

6.3.2 From multidisciplinarity to inter and transdisciplinarity

Another area for research to evolve is to broaden the scope and methods used in the studies within the field of pharmaceutical packaging. According to Lawrence (2010, p. 126), the complexity of real-world problems makes it impossible to "one discipline or profession to deal with them effectively." By affirming that, the author suggests that there is a necessary movement that permits going from multidisciplinary to interdisciplinary research. In his understanding, "multi-disciplinary refers to an additive research agenda in which each researcher remains within his or her discipline and applies its concepts and methods without necessarily sharing a common goal with other researchers." Interdisciplinary research expands multidisciplinarity by integrating "concepts, methods, and principles from different disciplines" toward a common goal (Lawrence, 2010, p. 127).

Interestingly, the studies retrieved in the systematic review (Paper I) did not come from the design field, but they supported the argument of a need for inclusive design. Yet many studies still used the viewpoints from their own disciplines to study user experiences of pharmaceutical packaging. The focus on objective measurement, mostly through physical tasks, has overshadowed other important subjective aspects that frame the use of packaging in real life. Studies on packaging have already started to grow interest on the experiences created through interaction with packaging that are not only based on physical constraints, but also on psychological and emotional aspects (Sudbury-Riley, 2014, de la Fuente et al., 2015, Ford et al., 2016). As already started by this research, interdisciplinary research could then be stimulated to combine and evolve knowledge generated and performed in the silos of individual disciplines into knowledge that is created by intertwined methods and concepts.

There is also an upper level which is transdisciplinary, where research moves beyond academia to instigate action and dialog in other spheres of society. Transdisciplinarity has barely any accepted definition, however, it can be understood as contributions that "incorporate a combination of concepts and knowledge not only used by academics and researchers but also other actors in civic society, including representatives of the private sector, public administrators, and the public" (Lawrence, 2010, p. 126). Transdisciplinarity can happen in areas where discussion has already evolved, and is also supported by comprehensive research.

An example of transdisciplinarity is the impact of inclusive/universal design in public environments. Started and supported through research, the disability movement has created dialog with many instances in society, from architects and designers to policy makers; changing buildings to become more accessible (Mace et al., 1997, Clarkson and Coleman, 2015). As I identified when starting this research, and particularly in the systematic review (Paper I), discussions about user-centered approaches to pharmaceutical packaging design are becoming more important, yet still need to reach broader instances outside academia. This research has given the first step from multidisciplinarity to interdisciplinarity, by using and combining concepts from design and innovation domains into a rather technical topic of pharmaceutical packaging. Nevertheless, to reach transdisciplinarity endeavors, more efforts will be necessary, especially through the creation of common agenda and more collaborative projects that really involve stakeholders so that they can take action to ensure inclusive pharmaceutical packaging.

7 Conclusion

Pharmaceutical packaging is challenging for those using it and those designing it. To address the challenges of use and design of packaging, this research has called for packaging that is more inclusive from the time it is designed to the time it reaches the lives of users. This research has called attention to the opportunities of understanding medication packaging as more than a necessary cost and a protective barrier by proposing *to investigate innovation and design processes for pharmaceutical packaging, as well as to stimulate the uptake of inclusive design toward pharmaceutical packaging that meets society's needs.* It is possible to conclude that:

In order to explore complex challenges such as those faced by pharmaceutical packaging, a researcher also needs to extend her search for knowledge, by using and establishing links among different domains of knowledge. This research has been based on the complementarities of design, innovation, and packaging; all connected through the perspective on inclusivity.

Another conclusion is that decisions on packaging are made by many stakeholders that influence innovation and design processes. It is a difficult task to listen and incorporate all the different stakeholders' demands without having some trade-offs along the way. These stakeholders need to become aware of users' needs and capabilities, and trade-offs that favor users should also be considered. Understanding users' experiences with pharmaceutical packaging is a first step to be taken by stakeholders. Another step is to let users to 'talk' themselves, by involving and collaborating with them when innovating and designing pharmaceutical packaging in industry practice.

Pharmaceutical packaging has the vital role of keeping medicines safe, but also keeping patients safe when they follow their treatment. The focus on safety has been driven by legislation and technological advancements that, for decades, have helped to create and optimize packaging design standards and stable manufacturing systems. Once established, design standards are difficult and intricate to change. Nevertheless, new drug formulations or new treatments often create an opportunity for new pharmaceutical packaging. When such an opportunity exists, inclusive packaging solutions should be considered from the early phases. In addition, the greatest attention to treatment outcomes can stimulate and potentialize the strategic role of packaging from being a mere technological object to becoming an object that empowers patients in their own care.

Users of pharmaceutical packaging differ in their expertise with their treatment and in their responses to it. Some users may avoid treatment because of difficulties or stigma reinforced by packaging, while others may become highly expert in their treatment, and active in developing their own strategies to follow the treatment and circumvent difficulties created by packaging. Understanding and empathizing with users is then highly recommended as this means greater user involvement, where users are not merely testers and/or validation subjects of packaging concepts. By including users, packaging professionals can better understand them and gain insights, as well as avoiding creating and maintaining stereotypes of users 'being a patient' or an 'older person'.

7.1 Contributions to theory

One contribution of this research is to provide a cohesive framework for research streams and orientations (Paper 1). Being the field of pharmaceutical packaging still immature, knowledge that connects studies and their overall contributions is required. Thus, the systematic literature review has particularly contributed by presenting the landscape of the research within the field of pharmaceutical packaging design and use by older people. Researchers within the field of packaging may benefit from this exploration by placing future research and problematizing underdeveloped aspects of pharmaceutical packaging design.

Another contribution relies on the interdisciplinary view of packaging adopted in this research. Integrating different domains of knowledge is per se a relevant contribution as it adds new lenses to existing research problems (Lawrence, 2010). From the theoretical perspective adopted, packaging innovation is a process connected with other organizational processes and driven by multiple forces. Innovation as a process is nascent in research, as innovation outcomes are often prioritized (Crossan and Apaydin, 2010). Yet to understand *how* and *why* outcomes are reached, a researcher may also look to the processes that have led to those outcomes. This research has specifically looked at the process of pharmaceutical packaging innovation by exploring a customer-supplier relationship (Study B). Key results in this research show that dominant driving forces for packaging innovation do not always accommodate the integration of user needs, resulting in multiple trade-offs in packaging design (Paper IV and Paper V). Because of that, design functions and features culminate in emphasizing protective packaging rather than user-centered packaging. The theoretical framework of packaging innovation drivers adds to the literature on the processes of packaging innovation. Researchers interested in studying packaging innovation can use this framework to investigate dominant forces in other industries or within other contexts of packaging.

Another theoretical contribution relates to aspects of inclusivity and user-centered design, with especial attention to the involvement of patients. From a theoretical point of view, inclusive packaging depends on the understanding of *who* the users are, as well as *how* and *when* to involve those users in the design process. User involvement has been explored in other areas of design research, but investigation of industry practices of involving users in the packaging design process is still lacking. This research has added to scientific knowledge by investigating the different methodologies implemented by companies wanting to involve users. As suggested by scholars, users can have extended involvement that goes beyond mere consultation toward participation (Damodaran, 1996, Kaulio, 1998). Such a view expands the notion of packaging as a mere artifact for drug protection to a designed artifact placed in patients' lives. Yet having users involved does not happen without drawback such as the difficulties in identifying who the user really is, when to involve this user, and the limitations of resources and contextual industry boundaries. The findings from this research add to the discussion on the benefits and drawbacks of user involvement (Kujala, 2003).

Product- and user-centered approaches to packaging may coexist, but are seldom integrated. This research also contributes with a set of propositions that have been elaborated in the studies, especially in Paper II and Paper III. Pharmaceutical packaging is still in its infancy as regards responses to societal challenges. Researchers can benefit by gaining inspiration from those propositions to conduct research that challenges and adds to existing scientific knowledge.

7.2 Contributions to industry

As affirmed by Crossan and Apaydin (2010, p. 1179), "many of the 'how to' books focus on managing the innovative process, with little regard for business practices that support innovation." This research has empirically investigated industry practice in regard to the uptake of user needs in the processes of innovating and designing new pharmaceutical packaging. By looking at the findings reported in this dissertation and its appended papers, managers can learn a number of lessons when conducting innovation activities that affect pharmaceutical packaging design.

This research has particularly contributed by identifying and analyzing the drivers in place in the packaging innovation process. Key findings showed that the limited number of drivers in the practice of pharmaceutical packaging innovation (essentially technology and legislation) have constrained key strategic opportunities for user-centered packaging. Importantly, to introduce new driving forces able to meet society's demands on pharmaceutical packaging, findings in this research suggest that organizations may also need to balance stakeholders' needs. The identified drivers can be used by managers as a framework for their packaging

practice, where they could look to the dominant forces that have led them to packaging innovation.

Another important aspect found relates to the network established for packaging innovation. As shown, the solid and long-term relationships established between drug manufacturers and packaging suppliers continually emphasizes the optimization of packaging design. Main findings in this research suggest that more inclusive packaging would require other external stakeholders to be involved in innovation to change packaging design. This understanding may be useful to managers to build other relationships with stakeholders for inclusive packaging. For stakeholders not directly involved in designing packaging but with influence on packaging, such as regulatory bodies and policy makers, this research provides a broad view of how their decisions impact industry practices.

Design is recurrently applied in business with a limited view of its potential. In this research, design is viewed from a deeper level with emphasis on the process that leads to capturing and integrating user needs and on the resulting outcome that frames human-packaging interaction. The pharmaceutical context is particularly challenging for design as the design process can be drowned by other processes where user needs and user involvement are not prioritized. As a result, designing inclusive packaging is embedded in a complex organizational innovation process, where opportunities may be created to support the uptake of user needs.

In spite of that, this research identified industry practices for user involvement when new packaging is designed. As found, drug manufacturers have had a key role in involving users with different expertise and at different levels in the design process. Their proximity with users, even though still bound by ethical and regulatory approvals, has permitted them to enrich their knowledge about users as patients and how they live with their disease. The benefits and drawbacks reported may be useful for other managers to mirror their own modes of user involvement. Usability tests are still a predominant way of assessing packaging in practice and in research, however, new methodologies have proven to be useful to uncover user needs that go beyond physical assessment. Medication management and adherence are complex for companies to understand, as they are also complex for patients (especially older patients using multiple medicines).

Evidently, this contribution is not only limited to pharmaceutical packaging, but to other types of packaging where inclusivity is lacking in general. Packaging suppliers have had more limited access to users than brand-owner drug manufacturers, but they have also demonstrated an increasing interest in consumer trends and the overall use of packaging by end users. Managers working with packaging innovation and design can then critically reflect on their own practices. For instance, those managers could look at methods of user involvement here described to mirror the methods in place at their organizations. Furthermore, policy makers and health care associations can use this research as a source of evidence to

build arguments for more patient-centered and inclusive approaches when developing or advocating new regulations and guidelines.

7.3 Further research

In the final section of this dissertation, it is possible now to suggest that there is still a long way to go toward inclusive pharmaceutical packaging. The creation of breakthrough drugs is, and may remain as, the core of the pharmaceutical industry, especially for drug manufacturers. However, there is a way forward through more interest from multiple stakeholders involved and affecting this complex business. Furthermore, user involvement also encompasses treatment from a holistic perspective, where users of medication are given supportive tools for their care, packaging being the main focus. On the basis of what has been presented in this dissertation, I highlight three main areas that are also related to further exploration of innovation and design processes.

First, researchers could expand the study of industry practice by looking into real cases of successfully designed pharmaceutical packaging. Buckle et al. (2006, p. 498) affirm that "industry is unlikely to respond to abstract directives or inducements. What is needed, therefore, is a body of exemplar case studies and demonstration projects that show how such an approach can lead to better and more competitive products." As identified in this research, there are some emergent drivers that could increase the potential of packaging innovation toward a more user-centered orientation. Inspired by that, further research can build on finding and reporting best practices and/or best examples of pharmaceutical packaging where users were involved and where the outcomes of the process led to inclusively designed packaging. The perspective on best practices can help organizations in benchmarking processes to involve more users. It can also provide insights for other stakeholders so that they could see what industry has done. Based on that, they could gain insights into how to support more inclusive packaging design.

Second, researchers could decide to adopt an actors' approach to reinforce the need for empowerment of patients in their treatments. This research has so far used a systems approach, with greatest focus on packaging innovation and design processes. By adopting an actors' approach, a researcher could investigate and also strengthen the dialog in conjoint projects, aiming for more inclusive packaging. Other stakeholders could be involved, such as policy makers and organizations providing the treatment. So far, there is a need to create a forum for further discussion where different views about the role of packaging are expressed, and where a common platform for action could be created. As discussed earlier, this research has an interdisciplinary contribution but not a transdisciplinary contribution. The actors' approach helps to pave the way toward transdisciplinary

action, where there is a need for greater involvement and conjoint effort that goes beyond academia (Lawrence, 2010). As has happened in the past as regards other matters of inclusive design, pharmaceutical packaging is a potential area for a future agenda that considers and responds to complex societal challenges.

Third, Paper V has opened a trail of discussion about the level of user involvement in pharmaceutical packaging design based on the concepts of designing *for, with*, or *by* users. So far, 'designing by users' is still a very premature topic in the field of pharmaceutical packaging. Evidence from the relevant literature and some of the comments from the interviews (Study C) suggest users are active in finding their way out of, or around, difficult packaging. Researchers could be inspired to better explore contexts of medication packaging use through more creative or diversified methodologies borrowed from other domains of knowledge. The investigation of patients' narratives about the continuous use of medication packages and package aids, the development of routines in taking medication, and coping behavior in connection to self-care are recent and still underexplored. Furthermore, research could take an open innovation perspective to understand how users/patients solve their problems, how they report those issues in their communities, and finally, how industry can also learn from 'user innovation.'

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Appendix A

Interview protocol for Study B and Study C

Summary of the doctoral project

A PhD research project on pharmaceutical packaging design and innovation for users started in 2014, conducted at the Division of Packaging Logistics, Design Sciences, at Lund University, Sweden. In the first two years of the doctoral project, major revisions of previous research and theory in the area of pharmaceutical packaging design were made.

Design has an important role in capturing main users' needs within the broad context of society. Very limited research, however, turns to the other side to investigate how stakeholders within the pharmaceutical industry incorporate user needs when they develop medication packages.

More than an assessment of the final package, the interest here is to understand how the process of developing pharmaceutical packaging occurs, how the innovation process for the pharmaceutical packages starts and who is included, and where is the user (patient) placed in this process.

Study aim

To explore the design process of developing and innovating in pharmaceutical packaging.

Study description

This study involves a series of interviews and data collection with different stakeholders involved in pharmaceutical packaging development; mainly drug manufacturers and packaging suppliers. As usual in doctoral research, the interviews conducted will be part of a final doctoral dissertation. Relevant results of the study will be added and discussed in academic papers to be published in scientific journals. The names of the interviewees and the companies will remain anonymous.

1 Introduction and background

A brief introduction of the interviewee, background, responsibilities, and expertise within the company.

Can you please provide:

- Name:
- Age:
- Your current position:
- What is your educational and professional background? Previous experience?
- How did you end up working here?
- How long have you been working with packaging?
- How long have you been working in this position?
- What are your responsibilities? / What do you do in your everyday job (your active role, main responsibilities and tasks, etc.)?

2 General information about the company

Overview of the company, its business, and position in relation to stakeholders.

2.1 Can you please tell me a bit about the company? Mission, values, and position in the market?

2.2 What is the company's position in relation to the pharmaceutical industry:

- Who are the main customers/ stakeholders?
- How is the company connected with health care? What is the company's position within the health care chain?
- How is the company connected with the pharmaceutical industry?

3 Activities and processes

I would like to know more about the overall process of developing a pharmaceutical package, from the beginning until the end.

3.1 How is the packaging development process organized within the company and with the stakeholders?

3.2 When a new project or packaging development is started, what is the interaction within the company (departments and professionals) like?

- How is the process started and by whom?
- Who are the key people in the design of new packaging?
- Who approves?

3.3 Describe the process with external partners/ stakeholders?

- Who is involved?
- Who are the key external persons involved?

3.4 How long does it take to develop a new pharmaceutical package?

- How is the process structured?

3.5 How is the process concluded?

- Is there any formal post-evaluation about the project/ the package?

4 Pharmaceutical packaging

I would like you to tell me about the types of packages/smart packaging/devices developed.

4.1 Any examples of packages that you consider interesting to mention to me? And why have you chosen these examples?

4.2 What do you consider to be critical when designing pharmaceutical packaging?

- Which are the aspects/features of the packaging that are prioritized? Why?

5 Packaging innovation

I would like you to tell me about pharmaceutical packaging innovation.

5.1 How do you see innovation in pharmaceutical packaging?

- Drivers and barriers?
- Radical vs. incremental innovation?

5.2 Which trends do you foresee as important in packaging/pharmaceutical packaging development?

- Do you see any of those trends already affecting the development of pharmaceutical packaging? How?

5.3 Who do you think pushes innovation in packaging?

5.4 Do you see any changes in role of the pharmaceutical packaging in innovation in health care?

6 User of medication (patient)

I would like to know more about your view of the user (i.e., patient) and user needs in pharmaceutical packaging development.

6.1 What is the knowledge of the company about the final user of medication (patient)?

- Where does the person responsible for packaging get access to knowledge about the patient?

- Does the company/team work together with patients when designing the packages?

6.2 Do you see the patient influences in the innovation of packaging within the pharmaceutical industry and within the company/team?

6.3 Child-resistant packages and senior patients:

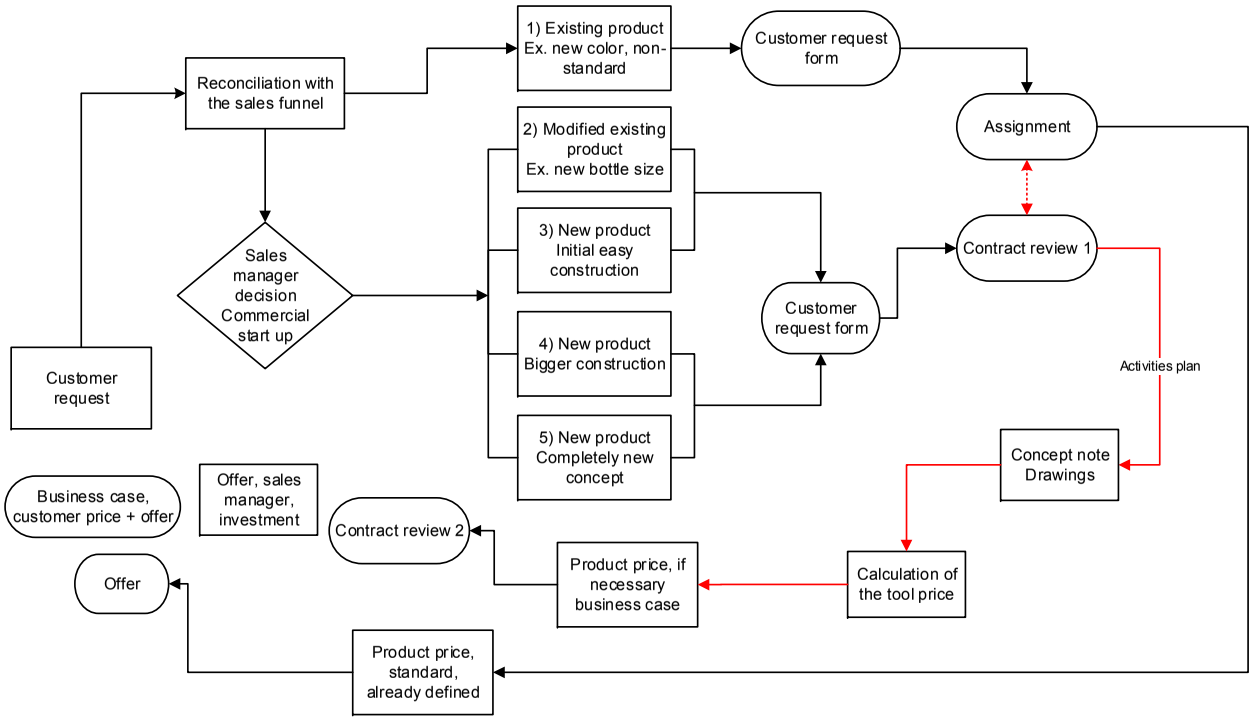
- How is that considered by the company?
- Anything that hinders innovation?

7 Further contacts

Any person I could further contact for the study (internal or external to the company)?

Appendix B

Flow chart of customer request for a new pharmaceutical packaging. Source: Packaging supplier (Study B).



Appendix C

Respondents interviewed (Study C).

Respondent	Company	Company type	Gender	Position	Education	Years of experience	Main responsibilities in the current role	Interview time (hh:mm:ss)
P1	1	PS	M	Managing Director	MSc	45-50	Main executive at the company	00:25:02
P2	2	PS	M	Marketing and Strategy Director	MBA	15-20	Coordination of packaging teams, product and market strategies	01:25:49
D2			M	Devices Manager	MSc	15-20	Management of device development projects	01:09:06
D7	3	DM	M	Senior Scientist	PhD	10-15	Coordination of stakeholders for new technologies in packaging and devices	00:40:46
D8			M	Packaging Manager	MSc	30-35	Management of packaging development	01:46:09
D10			M	Global Packaging Manager	BSc	30-35	Management of packaging teams and packaging processes	01:19:47
M1	4	ME	M	Technical Director	PhD	30-35	Responsible for development of new products and improvements in machinery, and patenting	01:06:28

Respondents interviewed (continued).

Respondents	Company	Company type	Gender	Position	Education	Years of experience	Main responsibilities in the current role	Interview time (hh:mm:ss)
M2	4	ME	F	Human Factors Manager	MSc	10-15	Management of packaging usability and user experience	01:35:30
D3	5	DM	M	Packaging Director	Technical background	30-35	Management of packaging and process technology innovation	00:57:45
P5	6	PS	M	Packaging Manager	BSc	5-10	Coordination of packaging development	01:13:33
P6	7	PS	F	Product and Marketing Manager	MSc	5-10	Portfolio management and market research	01:05:52
A1	8	PA	M	Executive Board	MSc	5-10	Corporate partnerships, information and education services	00:48:08
A2			M	Executive Board	PhD	25-30	Corporate partnerships, information and education services	01:15:25
D9			M	Chief Growth Officer	MSc	10-15	Growth hacking activities and communication	00:51:09
D5	9	DM	F	Senior Scientist	Technical background	30-35	Packaging development and packaging strategy	01:58:28
D1			F	R&D Director	PhD	20-25	Sourcing of new drug projects and alliance management	00:56:01
P7	10	PS	M	Managing Director	PhD	25-30	Opening new markets for the company	00:45:39

Respondents interviewed (continued).

Respondents	Company	Company type	Gender	Position	Education	Years of experience	Main responsibilities in the current role	Interview time (hh:mm:ss)
P3	11	PS	M	NPD Manager	MSc	20-25	R&D, NPD, and management of the in-house tool shop	00:42:13
P4			M	Managing Director	MSc	25-30	Management and development of the medical business area	02:17:22
D12	12	DM	M	Usability Manager	PhD	10-15	Management of packaging usability and user experience	01:35:37
D11			M	Packaging Manager	MSc	10-15	Management of packaging development	02:01:50
D6			M	Packaging Director	PhD	15-20	Management of packaging teams and packaging processes	01:28:07
D4	13	CG	F	Senior Packaging Developer	MSc	15-20	Packaging development and packaging strategy	01:15:27
A3	14	PA	M	Project Leader	BSc	5-10	Internationalization, corporate collaboration and education services	00:42:18
P8	15	PS	M	Marketing Director	Technical background	45-50	Knowledge transfer and business development with customers	01:20:18

CM= brand-owner consumer health care goods; DM= brand-owner drug manufacturer; ME= medical equipaments; PS= packaging supplier; PA= packaging/ patient association

Have you ever experienced the frustration of not being able to open packaging as instructed? This is only one of the challenges experienced by people taking their medication. When considering aging societies, it is of utmost importance to provide people with pharmaceutical packaging that enables the user to correctly administer their treatment. This doctoral dissertation investigates the complexities that surround the industry processes of innovating and designing inclusive pharmaceutical packaging to meet society's needs.

GIANA CARLI LORENZINI studied Visual Design and Communication, followed by a master's degree in Industrial Engineering at the Federal University of Rio Grande do Sul, in Brazil. She has always been curious about how design can facilitate or hinder the use of everyday products. In 2014, Giana moved from Brazil to Sweden to do her doctoral research on pharmaceutical packaging. By entering this research field, she has been able to explore the need to consider an inclusive approach to design packaging, packaging that people can really use.

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