A Study on Interaction with Medication Package Inserts: Designing an Accessible System

Margarida Pereira Cordeiro, Lisbon School of Architecture, University of Lisbon

Ana Melo, CIAUD – Research Center for Architecture, Urbanism and Design,
Lisbon School of Architecture, University of Lisbon

Abstract
The article describes the process of an interaction design project, A BULA, which aims to address several usability and accessibility issues found in medication package inserts. These printed objects contain required legal information and are also the leading source of information for medication users about taking instructions, dosage, or side effects. The main goal of the project was redesigning a leaflet that facilitated access for users, since during an exploratory phase issues about readability, usability, and clarity were found.
Using a research through design methodology, we also created a design system that expands interaction with medication information, composed of printed and digital artifacts that complement and complete each other, not excluding the relevance that each one has individually. During the generative phase, we applied a set of methods, namely mind maps, information architecture, user journey maps, wireframes, and prototypes. An evaluation phase included performance tests and revealed positive results regarding the adopted design strategies, as well as valuable insights for further developments.

Keywords: Interaction design, Information design, research through design, medicine package inserts

1. Introduction

Package leaflets are a technical document containing all the information about the medicine that it accompanies. In accordance with Article 54 of Directive 2001/83/EC (European Commission, n.d.), a package leaflet must contain specific information about the medicine, respecting a logical organization and hierarchy of information. Article 61 states package leaflets must be written and designed to be clear and understandable, enabling users to act appropriately, when necessary with the help of health professionals.

Over the years more users have been seeking self-medication (Bennadi, 2013). This growing trend arises for a variety of reasons, such as the urge to self-care, lack of health services, financial constraint, and misbeliefs (Phalke et al, 2006). Users have more access to information and can play a more active role in their health care (Bennadi, 2013), but the associated potential risks include incorrect self-diagnosis and difficulty in recognizing warnings and precautions. Situations such as taking inappropriate medications due to quantity, durability, or even incompatibility with other medications or foods, stand out (Bennadi, 2013).

Self-medication can be considered adequate when medicines respect a set of rules, namely, the fact that they are accompanied by package leaflets with sufficiently clear and complete information, enabling the safe, effective, and rational use of the medicine (World Health Organization, 2000). It is therefore considered that package leaflets are essential artifacts for the health care system.

A BULA is an interaction design project with the purpose of addressing accessibility and usability issues detected in the most common medication leaflets. The paper describes a research through design process with three main steps: an exploratory phase applying various user-research methods, a generative phase with the development of an artifact system consisting of an alternative package leaflet template and a mobile application, and an evaluative phase of user testing.

During the first phase we collected data through performance tests and a questionnaire about whether package leaflets are used; how often, under what conditions, what information is most sought after. The majority of the sample indicated frequent difficulties regarding information comprehension.

Thus, the project's main goal was to conceive a format that would allow information to be read in an effective, and clear manner. It should also be able to adapt to any volume of information. To expand the possibilities of interaction a secondary goal was to create a digital artifact that could complement the package leaflet.

The project was also motivated by concerns of sustainability and accessibility. The design process made sure print and digital components were accessible to a wide audience, taking into account various aspects of legibility, readability, and intuitiveness of use. And considering each medication requires a printed medical leaflet, the use of recycled and recyclable paper was a priority. According to The World Counts (n.d.), it takes 324 liters of water to make 1 kilogram of paper, and about 10 liters of water are needed to make one sheet of A4 paper, so issues of paper production were taken into account.

The project fits into SDGs (Sustainable Development Goals) Goal 3 - "Ensure healthy lives and promote well-being for all at all ages" - as it intends to address issues of accessibility to medication information, impacting the overall health care system.

2 . Theoretical Background

2.1. Interaction design

Interaction design is an expanding discipline situated in increasingly complex scenarios, due to rapid technological innovations that encompass new interaction modalities and new hybrid interactive systems (Wiberg, 2018). Ubiquitous computing, Internet of Things, AI or virtual and mixed realities are some of the new contexts in which interaction design plays a defining role in shaping current human experience (Schwab, 2015).

Interaction design emerged as a practice informed by notions of HCI (Human-Computer Interaction), involving computing, psychology, cognitive and behavioral sciences, and human factors engineering (Carroll, n.d.; Blevis & Stolterman, 2009). In the late 1970s, with the development of personal computers and subsequent needs to adapt interfaces to make them accessible to users without technical computer knowledge, designers started to intervene in those systems, developing not only the graphical interface but also designing new models of interaction. (Moggridge, 2007; Zimmerman, Forlizzi & Evenson, 2007).

Due to such historical beginnings, the term interaction design has been associated as pertaining to the digital environment (Buchanan, 2001), and although the field encompasses areas dedicated to designing human interactions with digital artifacts, like ID (interface design) or UX (user experience), interaction design can be considered in a broader sense. Interaction design addresses four dimensions, taking into account space and time, and regarding elements that change and react to user inputs in a time frame (Cooper, Reimann & Cronin, 2007) and in this sense the scope of interaction includes the design of experiences mediated by various kinds of artifacts (Heeter, 2000).

Considering interaction design as "the creation of a dialog between a person and a product, service or system" (Kolko, 2010, p. 11), it regards the facilitation and mediation between human beings and physical objects, communication artifacts or immaterial touchpoints of a service, either in professional or personal realms (Rodgers, Sharp & Preece, 2011). Also, it shapes "how human beings relate to other human beings through the mediating influence of products" (Buchanan, 2001, p. 11). The material object of interaction can be digital, physical, or hybrid and its diversity shapes the whole socio-technical fabric, designing experience and meaning (Davis, 2008; Höök & Löwgren, 2021).

2.2. Design for communication and information

Communication design conveys messages and creates meaning by producing visual communication that combines textual and graphic elements in a structured and organized

way (Frascara, 2004). Its effectiveness is dependent on handling form, content, and context in a suitable way for users, also taking into account media, experience, and interaction (Grefé, 2011; Neves, 2020).

Although communication design is historically intertwined with more formal approaches that structure information visually, when graphic artists became graphic designers (Frascara, 1988; Hollis, 1997), it has evolved into a broader and more complex area as the design domain moves from the production of artifacts to the production of immaterial outcomes (Buchanan, 2001; Sanders & Stappers, 2008). Based on interdisciplinary cooperation, affected by rapid technological development and responding to increasingly complex problems (Icograda, 2011; Dur, 2014; Davis & Hunt, 2017), communication design has a role in the production and circulation of social meanings (Dorst, 2012).

Within communication design, information design is dedicated to organizing information in an easily accessible manner to users (Saffer, 2009), ensuring effective communication which facilitates perception, understanding, and memorization (Frascara, 2015). By processing and manipulating data, information design transforms and structures textual, numerical, and graphic elements (Wildbur & Burke, 1998), thus enabling knowledge, interpretation, and gaining of insights (Figueiras, 2016). Clarity, precision, legibility, readability, accessibility, and appropriateness are some of the principles that guide information design to help users attain their goals (Tufte, 1990; Horn, 2000; IIID, 2007).

The information design process is described by Frascara (2015) by a sequence of steps: identification of a need; collection of information; development of a design strategy; design development and production of prototypes; evaluation; redesign; production and implementation; and final evaluation followed by revision and adjustment.

2.3. Medicine information design

Medicine package inserts are print artifacts in which information design plays a particularly relevant role since correct comprehension of the content is crucial in preventing accidents or medicine misuse and enabling users to take appropriate action (Frascara, 2015; Waarde & Spinillo, 2015). A comparative study of package leaflets (Dickinson et al. 2010) points to recommendations for their redesign that contribute to enable more efficient interactions. Formats that allow smaller columns of text, while also providing white space between each block of information, offer different reading entry points, offer selective reading, and facilitate user interaction. Typographical hierarchy and highlighted sections that allow users to find the most frequently consulted information are relevant features in creating an organized document and may facilitate reading by a wide variety of users (Dickinson et al. 2010).

All these features allow the creation of an effective and clear object, increasing readers' confidence in the message's content. Visual presentation of information impacts legibility and readability, as well as the chances of the leaflet being read and its recommendations implemented (Frascara, 2015).

The positive impact of applying design guidelines is recognized by European regulatory authorities, which are responsible to check if visual information is suitable, correct, and accessible, thus enabling the use of information even among people with poor eyesight or literacy skills (European Commission, 2009; Waarde & Spinillo, 2015).

Although package inserts remain the primary source of regulated medicine information for a majority of users (Dickinson et al. 2010), more and more request and utilize health-related services on digital platforms, so health providers are increasingly present in digital systems. According to European Commission Eurostat "In the last three months prior to the 2019 survey on the use of ICT in households and by individuals, one in two EU citizens (53%) aged 16-74 reported that they sought online health information related to injury, disease, nutrition, improving health or similar. This was two percentage points (pp) higher than the previous year (53% compared with 51%) and up by 19 pp from 2009 (32%)." (Eurostat 2020).

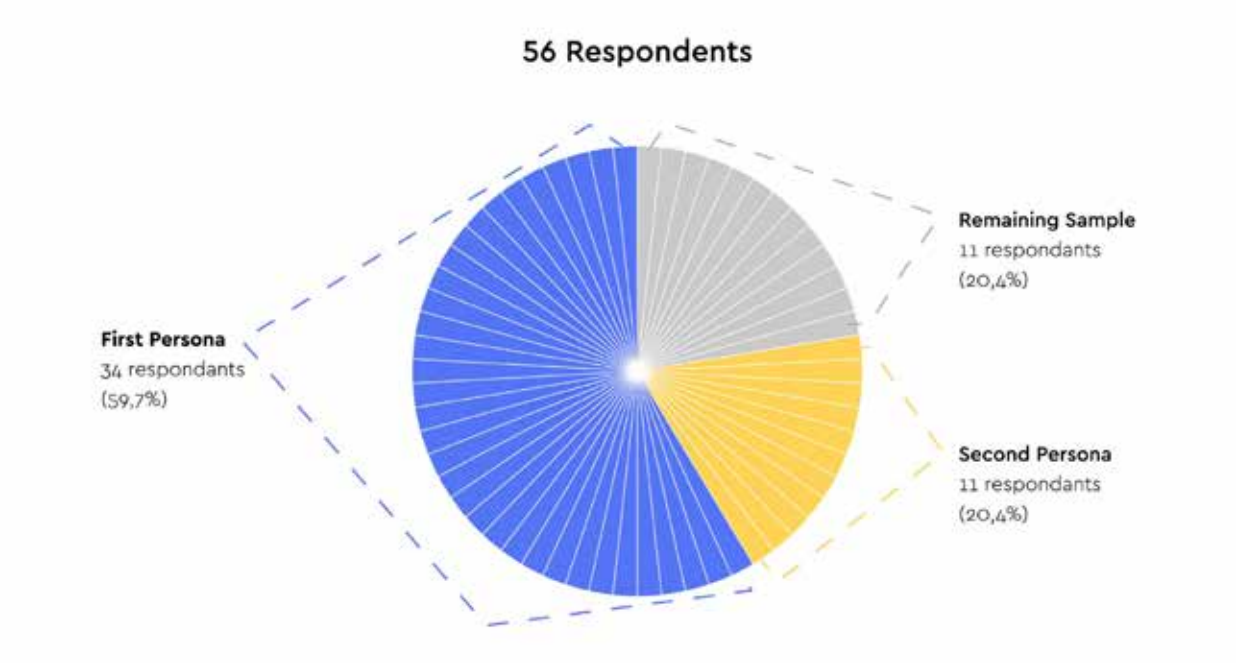

Figure 1. Graphic representation of the questionnaire's full sample divided in the developed personas.

3. A BULA - a design process to improve usability and accessibility

The project had as its initial objective facilitating user interaction with medicinal leaflets. We adopted a methodology divided into three phases, each one applying a set of methods. An exploratory phase had as its main goal gathering information about medication leaflets user's and consisted of a questionnaire, a performance test, and the creation of personas. A generative phase sought the creation of innovative medicinal leaflet systems using a research through design process and applied methods such as mind maps, information architecture, wireframes, visual identity development, user journey maps, and prototypes. In the last phase, we conducted an evaluation with potential users.

3.1. Exploratory phase

The gathering of information started with a questionnaire structured on Google Forms and disseminated through digital platforms. The main objectives were to understand the current existing interaction that the sample has with package leaflets, namely circumstances that make them consult package leaflets, regularity of use and what other means are used to gather information about medicines. It was also intended to collect positive and negative characteristics of package leaflets and to find out about the acceptance of a proposal that could improve the information search experience. Fifty-six participants answered the questionnaire. Data processing gave us decisive information for the project, since regarding the question "Do you use Medicinal Leaflets?", 80.7% of the sample said yes. Relating to the frequency of use, on a scale where 1 corresponds to infrequent and 10 to very frequent, 70.2% of the sample answered between 6 and 10. This made clear that the redesign of the package leaflet was a priority over a digital solution.

Through this data, it was possible to collect information that facilitated the creation of personas. This method originates archetypal profiles of the target audience, based on data collected with users and synthesizing behavior patterns, needs, motivations, and common characteristics, facilitating a human-centered approach to the design process (Martin & Hanington, 2012; Stickdorn, Hormess, Lawrence & Schneider, 2017). From data processing, it was possible to divide the total sample into groups that are characterized by the similarity and closeness of the answers given to each question of the questionnaire (figure 1).

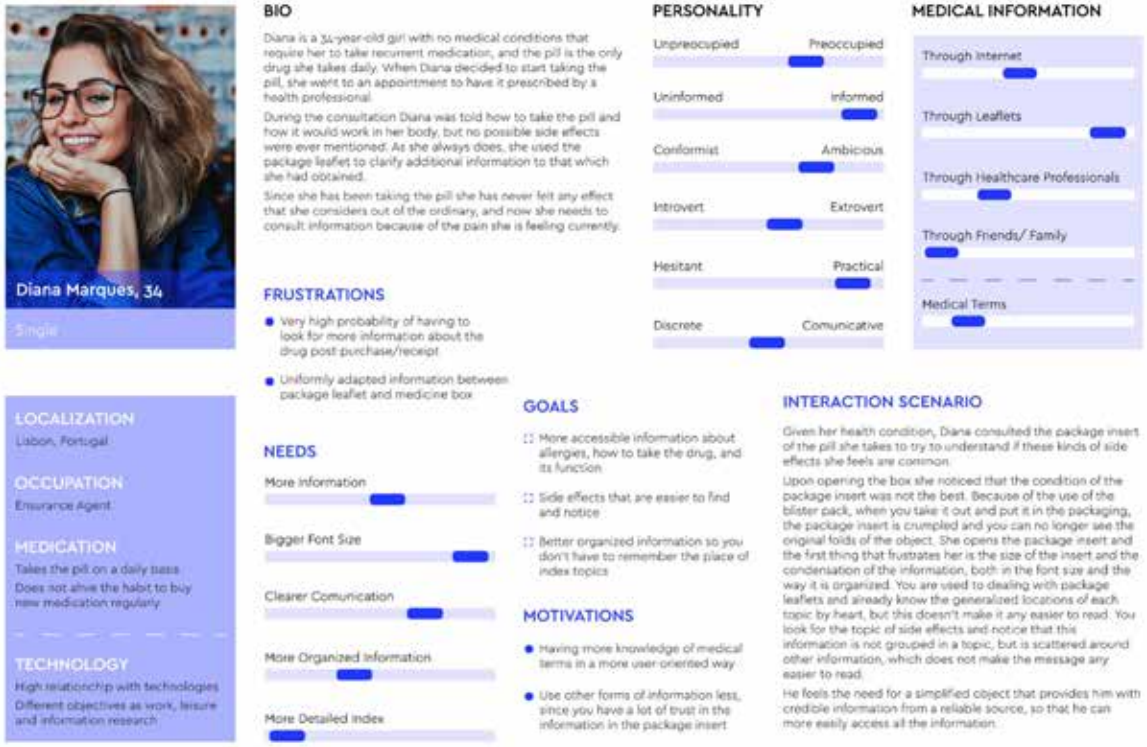

Figure 2. Persona 1.

Figure 3. Persona 2.

Positive Aspects	
Grid Organization (100%)	Colored Highlighted Topics (50%)
Illustrations (75%)	Font Size (50%) Bigger that usual
Topic Spacing (75%)	Higher paper gram (25%)
Format (75%) Booklet	Text Color (25%) Blue
Font (75%) Non-Serif	

Table 1. Positive characteristics indicated by the sample.

Negative Aspects	
Info. Organization (100%)	Bad Index (50%)
Folds (100%)	Text Volume (25%)
Font Size (100%) Usual	Text Color (50%)
Topic Spacement (75%)	Font (25%) Serif
Format (75%) Unusual	

Table 2. Negative characteristics indicated by the sample

The two created personas (Figure 2 and 3) reflect distinct characteristics, such as age group, and different needs. Persona 1 needed information from package inserts that was neither clear, objective, or easy to find. Persona 2 represents senior users with difficulties in searching for information in medicinal package inserts, due to font size and confusing content organization. Not using digital technologies, they resort to other means such as health professionals to obtain the information they need.

For further data collection, a performance test was conducted regarding five existing medicinal leaflets, distinguished by features such as format, size, font type, and use of color, with a sample of four respondents.

The goal of this test was to measure times of opening and closing each package insert, as well as the search for information on side-effects, a topic identified as very relevant for users through data collected in the questionnaire. This test also allowed us to note general positive and negative aspects that participants mentioned about each leaflet, as well as to observe user interaction with the printed object, allowing us to identify trends and gain insights for the generative phase (tables 1 and 2).

3.2. Generative phase

The research through design process consisted in the development of low, medium, and high fidelity paper prototypes, to obtain a package leaflet that addressed identified issues in the previous phase, and in the creation of a mobile application that resulted from the development of an information architecture, wireframes, user-flows and digital prototypes.

3.2.1. The design system

The redesign of an analog physical object was considered a priority since it is a legal imposition that medicines must always be accompanied by a package insert and because data revealed these are utilized by most users and don't entirely fulfill their function. Nonetheless, it was also considered that using digital technologies in a complementary way could benefit the project since digital systems are nowadays ubiquitous to access information in more and more parts of the world. We developed a mobile application that prioritizes accessibility, usability and can be customized to fit user needs, a feature that could not be fulfilled by the leaflet. Figure 4 shows the designed system, its main features and main goals to be addressed by each component.

3.2.2. Package insert prototyping

Paper prototypes were used to test ideas to reformulate a birth control pill package insert, since it is a commonly used medicine within a group of participants from the sample, and which requires the user to frequently search for side-effects information. As shown by figure 5, paper prototypes were carried out looking for a folding system to allow the existence of separators. The main goal was for information to be possible to read while the object is partially or fully opened. Afterwards, prototypes of medium definition were developed, testing grid systems, layout and typography (figure 6).

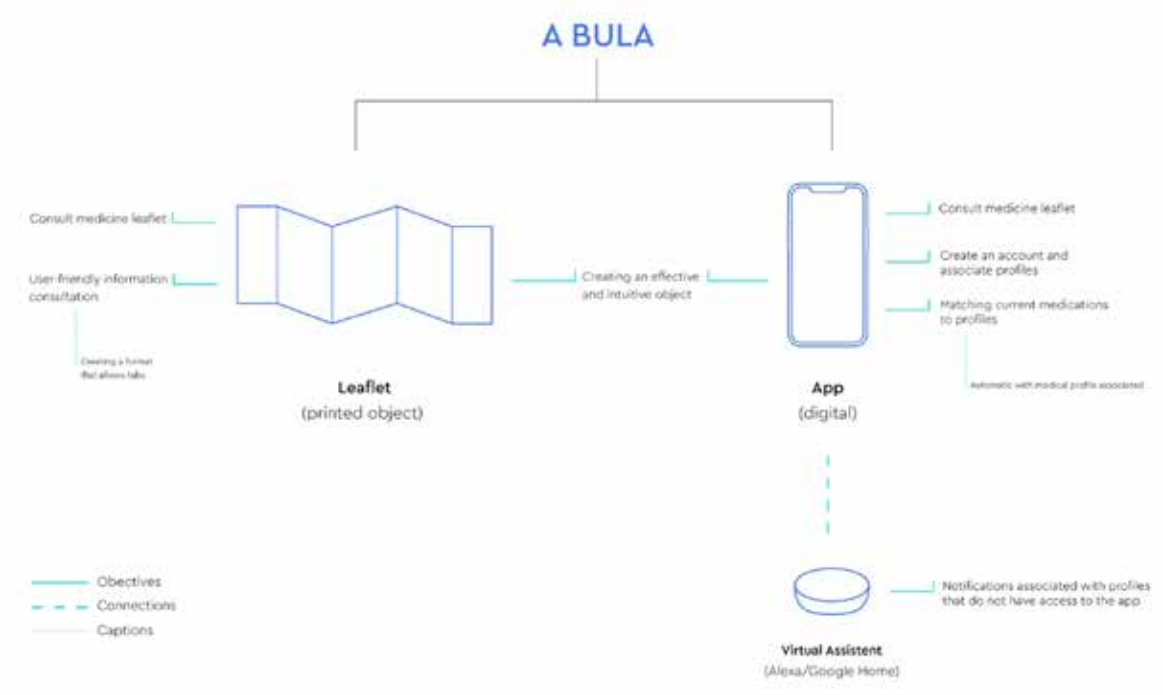

Figure 4. Map of the design system.

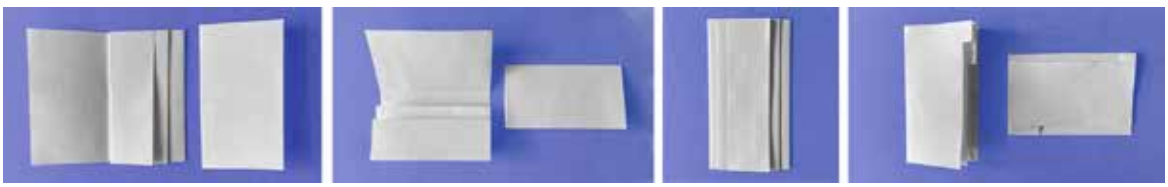

Figure 5. Research through design - format testing.

Figure 6. Leaflet planification.

Figure 7. Interaction with leaflet (storyboard part 1) - When the user comes across the package insert, the name of the medicine is the only visible information. By scrolling down the package leaflet, the reader finds the most relevant information. When the first page is fully opened, tabs will be available that lead to other pages of information.

Figure 8. Interaction with leaflet (storyboard part 2) - Continuing to leaf through, in order for the reading to be continuous, when the user turns the last page the back tabs will be visible. In this way the reader has the possibility to access all the information.

Figure 9 Interaction with leaflet (storyboard part 3) - The same happens on the last page. When turned over, the reader will see the initial page of the leaflet. For proper storage, the user will only have to make a first fold in the middle, and then the object will almost fold itself.

By creating creases and thus more intuitive folds, the leaflet can be stored in its packaging without difficulty and without the blister impairing its preservation status, a relevant issue indicated by the questionnaire respondents.

Typography size and leading were increased to make it faster and more effective to read. Compared to the original package leaflet, the format is reduced in size, aiming at reducing paper consumption. Also, the choice of paper (Ahlstrom-Munksjö - PrintClassic Thin Paper 50g, FSC® certified) considered recycling and sustainable production standards. The leaflet is only printed in black, limiting visual clutter and increasing visual contrast, thus making it more adequate when regarding universal design.

Finally, a high-fidelity prototype was made to assess the interaction with the object, and iterate where necessary. The storyboard of a hypothetical usage can be seen in figures, 7, 8 and 9.

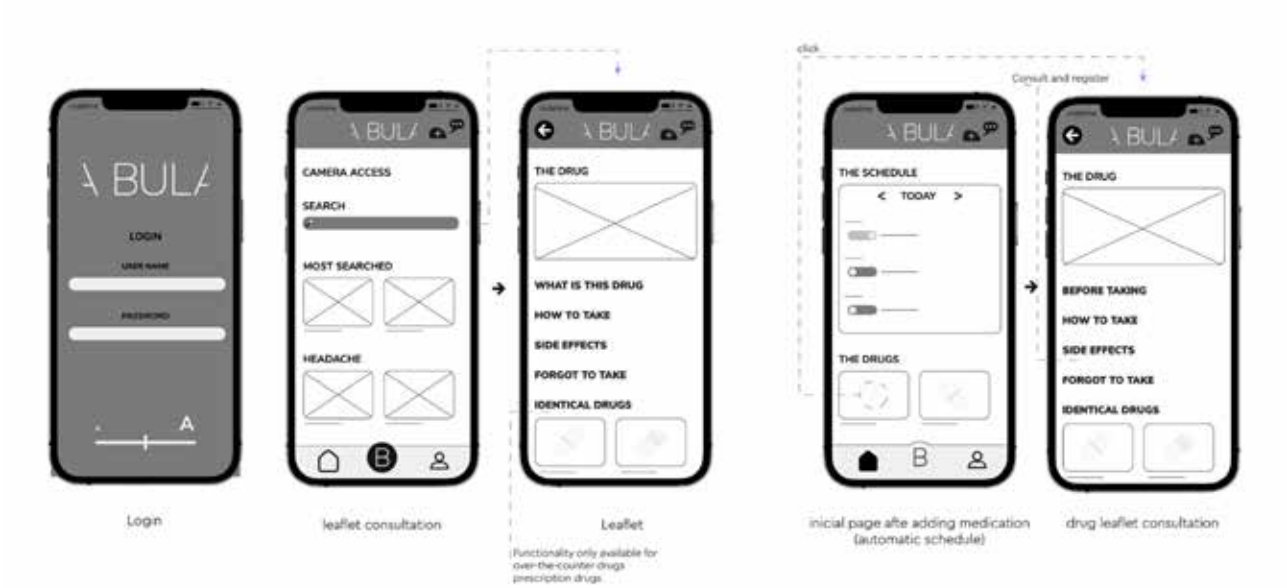

Figure 10. Mobile application wireframes - Main screens and features.

3.2.3. Mobile application

The developed app addresses the goal to complete the design system with a digital component of reliable sources that facilitates searching and accessing the more relevant contents of medicinal leaflets. Also, due to the legal impossibility of improving some negative aspects of package leaflets mentioned by respondents, the mobile application intends to serve as a complement to unblock impediments such as language clarity, medical terms, and drug components.

In an initial phase, we mapped an information architecture, making it possible to add and discard essential and non-essential app functionalities. To facilitate the interface design process we then designed wireframes so information could be organized and screens could be structured (figure 10).

The interaction with the application starts with the registration of a user account that requires only username and password, and unless the user indicates it, no personal information will be requested (although it is possible to associate a medical profile and current medication). When creating an account or logging in, users can increase or reduce the font size displayed on screen.

After log in, it is possible to search for a medicine to see the contents of the package insert displayed in an easy to read, categorized, and hierarchized manner, informed by the most relevant topics previously indicated by questionnaire respondents. Searching can be done by text, photograph of the medicine's box or by pathologies. Suggestions of the most searched package inserts and by pathologies are also visible on this screen.
Considering customization, the user also has the possibility of associating medicinal leaflets to various profiles, allowing for quicker access, as well as medicine taking schedules and treatment duration.

Another accessibility feature is the possibility to connect to a virtual assistant, allowing for voice interaction with the system: the user can ask questions about medicine information, and listen to notifications to take medication.

The following step of the generative phase was the creation of a visual identity system, contributing to communicate in a clear, coherent, and direct way. The logo is based on a visual metaphor of the package leaflet, facilitating the identification of the theme that the system is about.

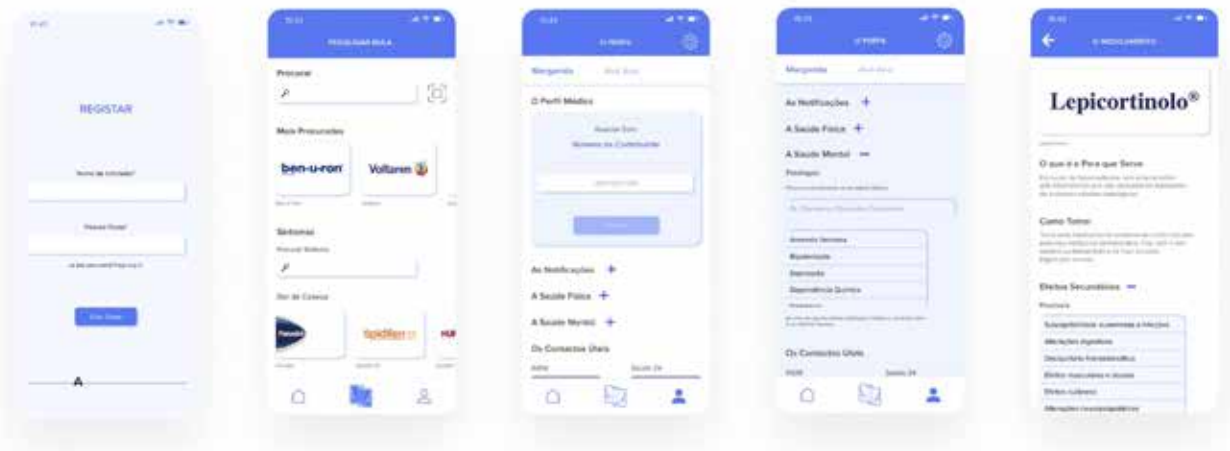

Figure 11. Mobile application prototype - Different features and possibilities of interaction with the app.

Figure 12. Logo deployment for different contexts

Figure 13. Mobile application prototype - Color implementation.

The graphic interface uses a color palette that facilitates usability. Two shades of blue were used as main colors, complemented with a shade of yellow for illustrations and a green tonality for selection indications. Color is also used in success and error messages, producing a green or red tonality in interface illustrations (figure 13)

3.3. Evaluation phase

The evaluative process was divided in two phases, the first one to evaluate the printed leaflet, and the second meant to evaluate the mobile application.

The printed package insert was subjected to performance tests to evaluate usability and effectiveness. Six participants evaluated the original and the proposed package leaflet. Regarding counterbalancing procedures, the sample was equally divided by gender and age group. Participants manipulated the two package leaflets to perform tasks, not knowing which would be which, and on different days to eliminate the learning factor. Due to technical constraints leaflets were printed on 80 g/m2 paper, instead of the proposed 50 g/m2 paper.

All tests took place under the same conditions and face-to-face, making it possible to record the interaction of each participant's hands with the leaflets and take note of participants' emotions and comments.

Usability Datalogger v5.1.1. and Microsoft Excel were used to record the time each participant took to perform the tasks, level of ease to perform them, or even if they did not complete them. The proposed tasks regarded various possibilities of interaction (e.g. open the leaflet, find a topic) and different degrees of difficulty.

Results show very different levels of task performance for each leaflet (figure 14). The proposed package insert produced better performances in completing tasks. From this evaluation it was also possible to detect issues with the prototype (as in task 4, indicating a search for information that was found on the package insert's reverse side) which allowed for posterior development of an improved prototype.

After a performance test with each leaflet, each participant was asked to complete a questionnaire presented in Usefulness & Ease of Use (TAM) format so that, on a Likert scale of 1 to 7, respondents would indicate their level of agreement with statements read by the test evaluator. Levels of perceived ease of use and usefulness referring to interactions with the original leaflet are significantly low when compared to results with the designed package insert (figure 15).

Finally, participants were asked to fill out a Self-Assessment Manikin (SAM) test, regarding three dimensions: dominance, arousal, and pleasure. Each participant should indicate on a scale of 1 to 9 their feelings related to each dimension. Resulting data relating to the interaction with the proposed package leaflet is more positive than when the interaction was carried out with the original package leaflet (figure 16). With the proposed leaflet, participants felt that they were in mastery of the tasks.

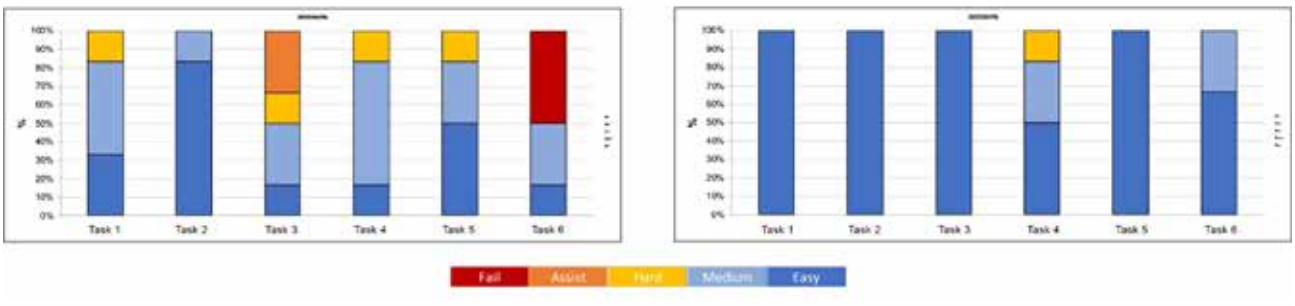

Figure 14. Participants task performance data with original (left) and proposed leaflet (right).

	Perceived Usefulness & Ease of Use	M	Strongly disagree 1	2	3	4	5	6	Strongly agree 7
1	Using this product enables me to accomplish tasks more quickly.	2,4							
2	Using this product improves my current performance.	2,3							
3	Using this product increases my productivity.	2,7							
4	Using this product makes me more effective.	2,9							
5	Using this product makes it easier to do my work.	3,0							
6	I find this product useful.	5,0							
7	Learning to operate this product was easy for me.	3,4							
8	I found it easy to get this product to do what I want it to do.	3,0							
9	My interaction with this product was clear and understandable.	2,6							
10	I found this product to be flexible to interact with.	3,3							
11	It was easy for me to become skillful at using the system.	3,1							
12	I found the system easy to use.	2,3							
	USEFULNESS	3,0							
	EASE OF USE	3,0							

	Perceived Usefulness & Ease of Use	M	Strongly disagree 1	2	3	4	5	6	Strongly agree 7
1	Using this product enables me to accomplish tasks more quickly.	6,6							
2	Using this product improves my current performance.	6,6							
3	Using this product increases my productivity.	6,7							
4	Using this product makes me more effective.	6,9							
5	Using this product makes it easier to do my work.	6,4							
6	I find this product useful.	6,9							
7	Learning to operate this product was easy for me.	6,0							
8	I found it easy to get this product to do what I want it to do.	6,3							
9	My interaction with this product was clear and understandable.	5,9							
10	I found this product to be flexible to interact with.	6,6							
11	It was easy for me to become skillful at using the system.	6,4							
12	I found the system easy to use.	6,6							
	USEFULNESS	6,7							
	EASE OF USE	6,3							

Figure 15. Questionnaire's data representation of the full sample considering the original (left) and the new leaflet (right).

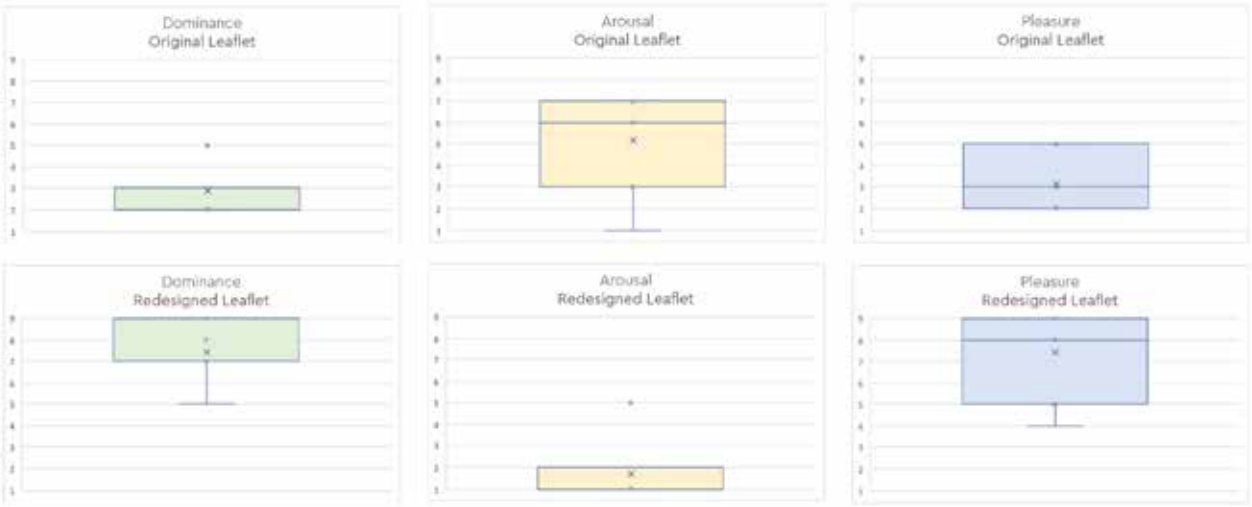

Figure 16. SAM numerical responses representation of the full sample considering the original (top) and the new leaflet (bottom).

To evaluate the mobile application we conducted a heuristic evaluation, the only method that does not rely on the participation of a sample. The heuristics, related to graphical interfaces, were consistency, efficiency, feedback, and easy error recovery. The different types of consistency were visual, functional, internal and external.

Regarding efficiency, user navigation was considered such as user dialogs with the product/system, reducing user short-term memory, minimization, designing to capture the user's attention and readability. Considering feedback the main topic was error messages. For the easy recovery of errors, topics such as avoiding the use of keyboard for text input, reporting the error in question in the correct place, as well as the error being properly identified were taken into account.

After the evaluation tests data analysis, a new version of the printed leaflet was designed to address encountered problems (figure 18). Tabs were highlighted in shades of gray to make them more visible and a reference was added in the first page when the package insert is open, to highlight the information available on the back of the object.

Conclusion

As leaflets are the main source of information for medication users, it was necessary to understand whether this usage is carried out effectively. Based on data obtained through different methods and by a research through design process, it was possible to propose a format that, subjected to evaluation tests, was considered by the sample to be more effective when compared to the original.

Figure 17. Efficiency - Considering the way we hold our devices, as in ergonomic terms, it was meant to use comfortable areas for touch on a screen called the 'thumb zone' to facilitate user interaction with the main functions.

Figure 18. Final leaflet prototype details.

Although data from the exploratory phase showed that most participants assumed that textual content in a grid made it easier to read and search for information, our results point out other strategies that can be adopted to make search for information significantly easier. Even though the original medication visual language was not changed, changes made regarding layout, information organization and folding format made it possible for participants to consider that searching for information is carried out faster and with more clarity.

Regarding further research, it will be necessary to subject the final package insert prototype to evaluation tests. Those tests should consider the following: participant samples should be larger even though the identified tendencies were satisfactory for the goals set for this project; the format and proposed design strategies should be adapted to variable volumes of information, and to different medication leaflets; it will be necessary to print the same number of leaflets as the number of participants that make up the sample so that each one can perform evaluation tests with the same level of paper conservation.

Also, further user research is needed to deepen understanding about the nature of information retrieval. It will be relevant to do a targeted study with the part of the sample that declared not consulting package leaflets, in order to understand where, how and why these users obtain information, allowing for the identification of pain points that could be addressed by the created design system.

Concerning the application component, further evaluation should be conducted, to identify opportunities for the design system to function in a complementary way.

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