MEDICINES EVALUATION BOARD

Advisory Report

my ePI

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01. Introduction

INTRODUCTION

1.1 Summary

We were tasked with the job of integrating the ePI version of the patient information leaflet into a personal health environment. With the guidance of representatives from the Medicine Evaluations Board, we conducted interviews, literature reviews, persona development which resulted in the creation of a prototype.

1.2 The Client

The Medicines Evaluation Board (MEB) is responsible for assessing and monitoring the risk of medicines for human use while promoting the proper use of medicines. It is an independent medicines authority residing under the central government of the Netherlands, established in 1963, the core values of MEB are to be scientific, vigilant and connected.

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PGO.nl

1.3 The Case Study

The aim is to integrate the ePI version of the patient information leaflet into a personal health environment (PGO) that is not only accessible and inclusive, but also engaging, persuasive, and tailored to individual patient needs. PGO features should be able to: Discover medicine interactions if a patient uses multiple medicines (polypharmacy). Identify allergies to substances in the medicines. Remind/nudge the user to take their medication on time if necessary, based on input from the patient or the HCP.

ePI: Electronic product information leaflet (provides patients with essential information on how to use their medicine)

PGO: Personal health environment (a website/app that allows one to collect data about their health records)

1.4 The Problem Identification

Problem Statement:

How can we improve the personal health environment (PGO) and the deployment of the ePI module, in order to integrate the patient information leaflet into a personal health environment (PGO) that is not only accessible and inclusive, but also engaging, persuasive, and tailored to individual patient needs? We identified multiple key problems during our meeting with the client:

METHODOLOGY

2.1 Approach

To create a prototype of the ePI that is accessible for a broad target group we implemented the design thinking methodology:

Emphathise	Define	Ideate	Prototype
Literature Review	Identify Problems	Idea Generation	Design Prototype
Interview with Client	Define Target Behavior	Design Thinking	Evaluate Prototype
Interview with Target Audience	Define Determinants	Persona	Create Prototype

2.2 Literature Review

Behavior Change Theory:

Persuasive technologies are useful tools in changing people's attitudes and behaviors. Fogg's behavioral model suggests that behavior results from the interaction between motivation, ability, and triggers[1]. According to the technology acceptance model, people's adoption of a new technology is determined by their perceived ease of use and perceived usefulness[2].

People are more likely to intend to use healthcare technologies when factors such as performance expectancy, effort expectancy, social influence, and facilitating conditions, as explained by the unified theory of acceptance and use of technology, are present[3]. Primary task support and system credibility support should be given in persuasive system design[4].

Information Procession:

In terms of processing medical information, which is relatively complex, it's essential to prevent cognitive overload, as individuals possess limited cognitive capacity[5]. Using pictures in health communication can be an effective way to enhance understanding, especially for those with low health literacy[6].

Key Findings for Persuasive Design

- Essential functions should be included.
- Showcase potential benefits for using the technology.
- Provide tutorials and instructions.
- Design simple and clear interface.
- Provide trustworthy and reliable information.
- Avoid cognitive overload.
- Use pictograms and icons.

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[1] Fogg, B. J. (2009). A behaviour model for persuasive design. *Proceedings of the 4th International Conference on Persuasive Technology*, 40, doi 1145/1541948.1541999L

[2] Davis, F. D. (1989). Perceived Usefulness, Perceived Ease of Use, and User Acceptance of Information Technology. *MIS Quarterly, 13*(3), 319-340. https://doi.org/10.2307/249008

[3] Venkatesh, V., Morris, M., Davis, G. B., & Davis, F. D. (2003). User acceptance of information Technology: toward a unified view. *Management Information Systems Quarterly, 27*(3), 425. https://doi.org/10.2307/30036540

[4] Merz, M., & Ackermann, L. (2021). Design principles of persuasive systems–review and discussion of the persuasive systems design model. *AMCIS 2021 Proceedings. 3*. https://aisel.aisnet.org/amcis2021/sig_hci/sig_hci/3

[5] Lang, A. (2006). Using the Limited Capacity Model of Motivated Mediated Message Processing to Design Effective Cancer Communication Messages. *Journal of Communication, 56*(s1), S57-S80. https://doi.org/10.1111/j.1460-2466.2006.00283.x

[6] Schubbe, D., Scalia, P., Yen, R. W., Saunders, C. H., Cohen, S., Elwyn, G., ... & Durand, M. A. (2020). Using pictures to convey health information: A systematic review and meta-analysis of the effects on patient and consumer health behaviors and outcomes. *Patient education and counseling, 103*(10), 1935-1960.

2.3 Target Audience

During our client meeting, a wish for a broad target audience was discussed, in which the portal would be accessible for all. In the Netherlands, accessibility requirements are included in the Digital Government Act, which emphasizes the objective to realize digital inclusion where everyone is able to participate. Therefore our target audience consists of different ages, genders, education, etc. For this reason, interviews were conducted with different potential users from different backgrounds in order to attempt to create personas.

2.4 Target Behaviour

For the prototype, we have focussed on the two behaviors: adoption of ePI in PGO and Medical adherence. Based on the Technology Acceptance Model and target audience, the key determinants for them to adopt the prototype are perceived ease of use and perceived usefulness. Moreover, medical adherence is determined by their motivation including necessity and concerns and their ability that deals with forgetfulness and daily routine changes, according to Fogg's behavioral model and target audience.

Behaviors	Determinants	Strategies
Adoption of ePI in PGO	• Perceived ease of use • Perceived usefulness	• Simple interface design • Efficiency • Core functions • Information quality • Personalization & tailoring
Medical adherence	• Motivation • Ability	• Personalization & tailoring • Recall-promoting • Engagement in decision-making

2.5 Target Personas

Based on our two interviews with our target audience we developed two personas which allowed us to understand the user better and the key challenges they face. During our interviews we asked questions regarding four main themes:

1. Technology/ app usage.
2. Medication usage, tracking and side effects.
3. Current ePI and PGO knowledge.
4. What features they would like to see implemented in the prototype.

Based on the answers from our interviews we developed our personas. Our key takeaways from our interviews were:

- Although they are digitally literate they want to use technology that is simple and easy to navigate.
- They are open to using new health technology if it fulfills their needs and makes their life easier.
- They would like to see a reminder feature which will prompt them to take their medication on time.
- They are open to technologies that explains their medications, possible side effects and medical interaction effects.
- Desire for accurate and quick advice.

2.5 Target Personas

Basic information

Marie Bootsma

"Archetype"

- Age: 63
- Gender: Female
- Occupation: Program director
- Location: Den Haag

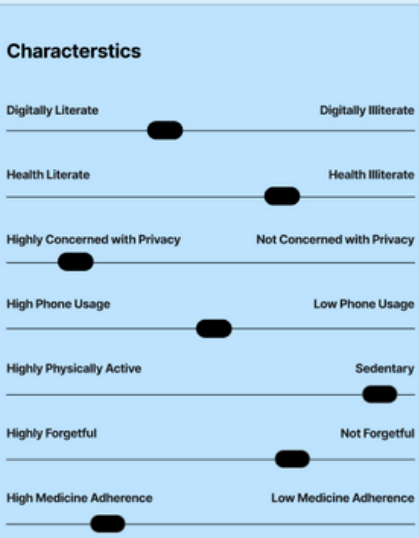
Bio

Marie is a 63-year-old, high educated, project manager and mother of two who is to some degree tech-savvy, is not active on social media and relies heavily on her smartphone for various aspects of her daily life. She's been using smartphones for years and has a strong preference for apps that simplify her tasks, such as whatsapp. Additionally, she uses a step counter app on her smartphone but doesn't use any other health tracking apps or notifications for her medicine intake.

Marie is diligent about her medication, but has concerns about its side effects and potential interactions. She is taking her medication twice a day for the past 27 years. The side effects she is experiencing is fatigue and an increase in weight. She tracks her medication intake by taking them at fixed times - one in the morning when she wakes up and the other before going to bed. Sarah doesn't actively track much in her life and hasn't considered the benefits of tracking until now.

Marie is interested in new technologies that could make her medication management more convenient. She gains information about her medications from her doctor and pharmacist and is unsure if she has any allergies related to her medications as it has never been investigated. Marie is not familiar with ePI (electronic Patient Information). She prefers reading the informational leaflet inside the medication box when starting a new medication but is open to electronic versions.

Characterstics



Basic information

Joost Klein

"Archetype"

- Age: 22
- Gender: Male
- Occupation: Full time student
- Location: Amsterdam

Bio

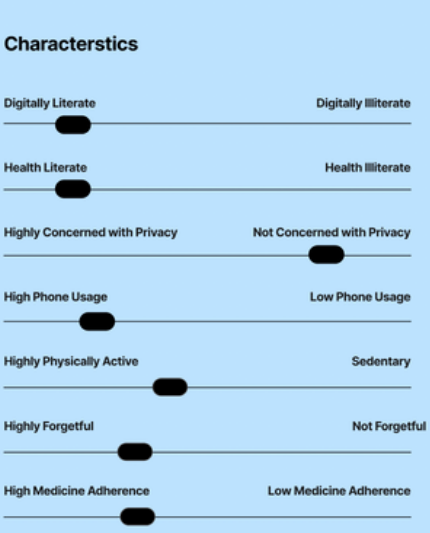
Joost is a 22 year old, highly educated student who is tech-savvy and active on social media. He is highly digitally literate as he studies computer science at university. He uses his smartphone and his wearable fitness tracker to keep up to date with his health.

Joost has taken two forms of medication for over a year now, one is taken every morning and one is taken just once a week. Joost uses google calendar notifications to remind him to take his weekly medicine as he is forgetful. But he does not use any form of reminders to take his daily medication as it is a part of his daily routine. However, he occasionally forgets to take his daily medication due to changes in his routine or external distractions.

He briefly experienced minor side effects within the first few weeks of taking his medication but they subsided soon after. Joost is not aware of the ePI and does not read the physical information leaflet as he believes it is time consuming and sometimes complex. He receives his information regarding his medication dosage and possible side effects through in person conversations with his doctor and pharmacists.

He is interested in a new technology which allows him to contact medical professionals quickly if he has any questions regarding his medication usage, or more specifically if he forgets to take his medication what he should do next. He also believes an application in which he could be reminded to take his medication would be useful.

Characterstics



RESULTS

3.1 User Journey

Discovery Phase

Learns about the portal from a friend/ health care professional or online research.

First visit to the portal

Welcomed by the start page where they can choose to sign up.
If they choose to sign up they can input their information and create a profile.

Medication Information input

Can choose to input their current medications which they use, the dosage, the quantity along with their food/drink and current symptoms.

Notification setting selection

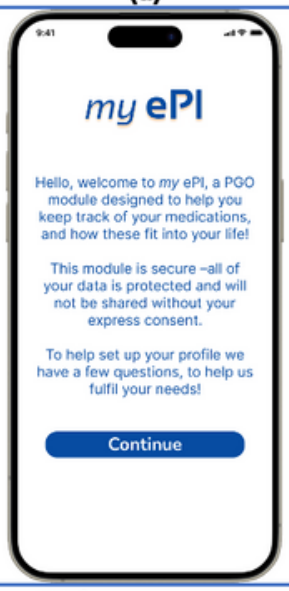
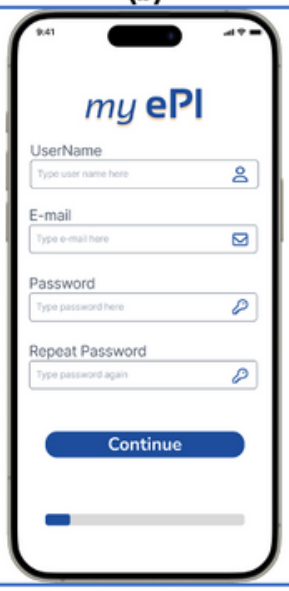
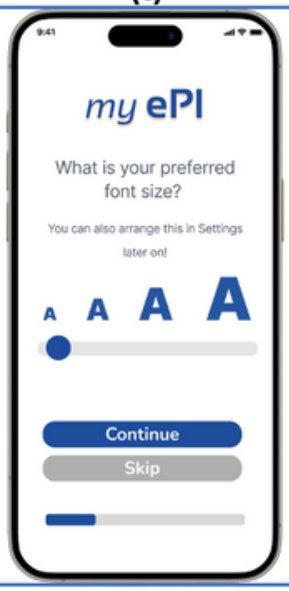
User decides their notification/ reminder settings.

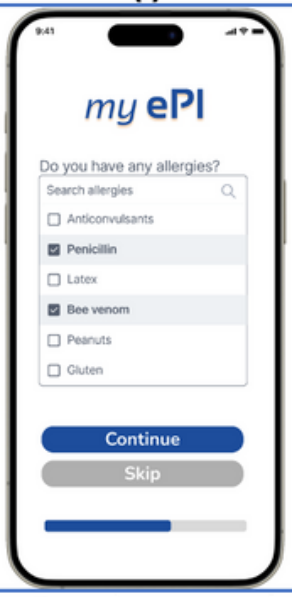
3.2 Prototype Walkthrough

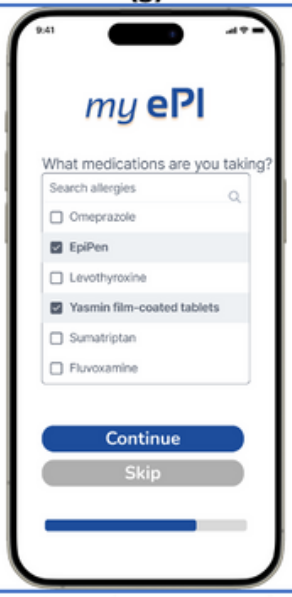
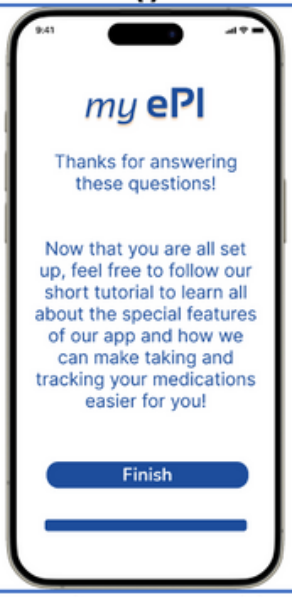
For the full prototype, go to:
https://www.figma.com/file/fJBk28RJWXgIPp1AO56DUy/ePI-app?type=design&node-id=147%3A6016&mode=design&t=QDMfhQdXjrDMPdUc-1

1. Start Page	
Screens	
Features	– Authority bias evoked with use of symbols.
Links	– Clicking "Log in" leads to *screen 2.* – Clicking "Sign up" leads to *screen 3(a).*

2. Log In Page	
Screens	
Features	– Log in with DigiD: evokes authority bias as well as system credibility support. – Multiple Sign in options reduces effort expectancy as people don't have to remember a new username and password if they do not want to.
Links	– Clicking "Log in" leads to *screen 4(a).* – Clicking "Sign up" leads to *screen 3(a).*

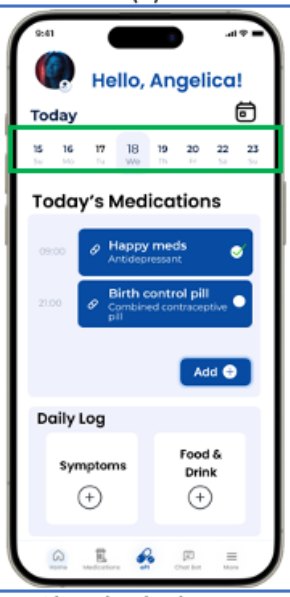
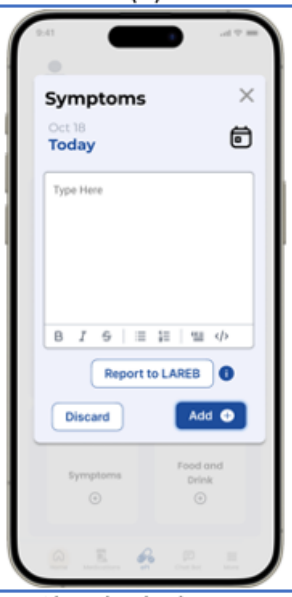
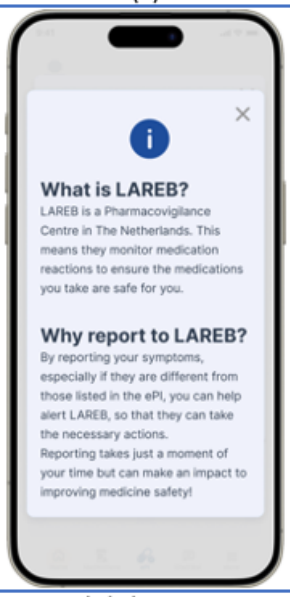
3. Sign Up: Intake Survey			
	(a)	**(b)**	**(c)**
Screens			
Features	– Welcome message with statement of security for system credibility support.	– Uses icons to reduce cognitive load and effort expectancy as users recognise the symbols. Also helpful for those with low literacy.	– Font adjustment for increased accessibility and personalisation. – Having the option to skip reduces the effort expectancy if a user does not wish to answer at that moment.
Links	– Clicking "Continue" leads to *screen 3(b)*.	– Clicking "Continue" leads to *screen 3(c)*.	– Clicking "Continue" saves details and leads to *screen 3(d)*. – Clicking "Skip" just leads to *screen 3(d)*.

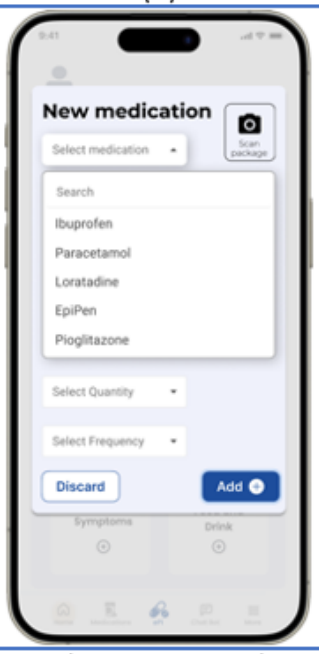
3. Sign Up: Intake Survey			
	(d)	**(e)**	**(f)**
Screens			
Features	– Use of icons to reduce cognitive load and effort expectancy as well as aid those with less literacy. – Drop down menu for gender to reduce effort.	– Drop down menu for both height and weight to reduce effort. – Adjustable units to support those not used to the metric system (e.g., foreigners). – Having the option to skip reduces the effort expectancy.	– Drop down menu for that offers suggestions and searches as you type to reduce effort. – Having the option to skip reduces the effort expectancy.
Links	– Clicking “Continue” saves details and leads to *screen 3(e)*.	– Clicking “Continue” saves details and leads to *screen 3(f)*. – Clicking “Skip” just leads to *screen 3(f)*.	– Clicking “Continue” saves details and leads to *screen 3(g)*. – Clicking “Skip” just leads to *screen 3(g)*.

3. Sign Up: Intake Survey			
	(g)	**(h)**	**(i)**
Screens			
Features	– Drop down menu for that offers suggestions and searches as you type to reduce effort. – Having the option to skip reduces the effort expectancy.	– Drop down menu to reduce effort. – Adjustable units to reduce effort. – Having the option to skip reduces the effort expectancy.	– Exit message with autonomy support language.
Links	– Clicking "Continue" saves details and leads to *screen 3(h).* – Clicking "Skip" just leads to *screen 3(h).*	– Clicking "Continue" saves details and leads to *screen 3(i).* – Clicking "Skip" just leads to *screen 3(i).*	– Clicking "Finish" redirects users to *screen 4(a).*

4. Home Tab and Pop-ups

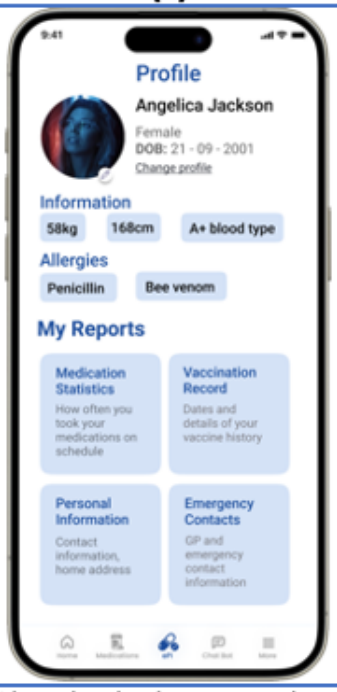
If "home" icon in the navigation bar at the bottom of the screen is clicked on any screen, user is directed to *screen 4(a)*.

	(a)	(b)	(c)
Screens			
Features	– Simple design to reduce cognitive overload. – Large font for increased accessibility. – Click on circle next to medication name to confirm it has been taken –this automatically reduces the quantity in your "medicine cabinet".	– Simple design to reduce cognitive overload. – Use of icon to reduce cognitive load and effort expectancy as well as aid those with less literacy. –	– Explaining to users to increase trust. – Making it clear it is their choice through autonomy supportive language.
Links	– Click on image in top left corner to redirect to *screen 5(a)*. – Click calendar icon in top right corner to lead to *screen 4(e)*. – Click a day on the scrolling date section (see green box) to access previous day overviews. – Click on each medication to lead to medicine overview popup (example on *screen 6(c)).* – Click "Add" to open popup on *screen 4(d)*. – Click "Symptoms" to lead to *screen 4(b)*. Clicking on "Food & Drink" would open a similar pop-up.	– Click calendar icon in top right corner to lead to *screen 4(e)*. – Click on "x" in top right corner or "Discard" in the bottom left corner to return to *screen 4(a)*. – Click on "Report to Lareb" to open a pop-up asking for consent before sending off. – Click on "i" icon to lead to *screen 4(c)*. – Click "Add" to save entry to daily log and return to *4(a)*.	– Click on "x" in top right corner to return to *screen 4(a)*.

4. Home Tab and Pop-ups		
	(d)	(e)
Screens		
Features	– Drop down menus that search as you type to reduce effort. – Ability to scan product to reduce effort and for those with less health literacy.	– "Download history" button allows users to self-monitor as well as improve doctor-patient interactions.
Links	– Click on "Scan Package" square to open *screen 6(e)*. – Click on "Discard" to return to *screen 4(a)*. – Click on "Add" to lead to *screen 6(a)*.	– Click on "Close" to return to *screen 4(a)*. – Click on "Download history" to lead to *screen 5(a)*. – Click on "Update daily log" to lead to a pop-up like *screen 4(b)* specific to the date selected.

5. Profile Page and Example Sub-Page

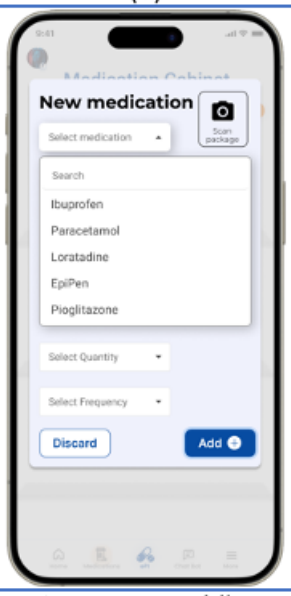
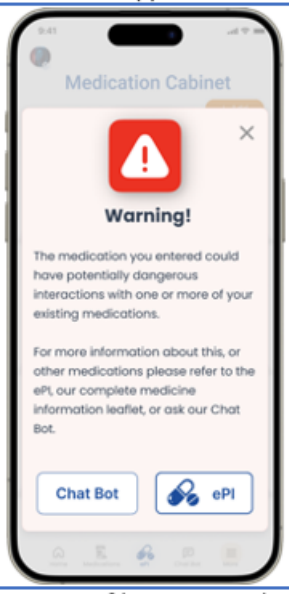
If the profile picture icon is clicked on any page, user is directed to *screen 5(a)*.

	(a)	(b)
Screens		
Features	– Simple design to reduce cognitive overload. – Clear descriptions of each section to ensure ease of use. – "My Reports" allow users to self-monitor as well as improve doctor-patient interactions.	– Simple design to reduce cognitive overload. – Use of icons to reduce cognitive load and effort expectancy as well as aid those with less literacy.
Links	– Click on pen icon to edit profile picture. – Click on "Change profile" to edit personal information. – Click on ant of the reports to open them up (e.g., click on "Medication Statistics" to open *screen 5(b)*).	– Click on pen icon to edit profile picture. – Click on "Change profile" to edit personal information. – Click on "Go back" to return to *screen 5(a)*. – Click on "Open Medication Statistics" to view the report. – Click on "Download Medication Statistics" to download the report. – Click on "Edit Medication Statistics" to edit the report.

6. Medication Tab and Pop-ups

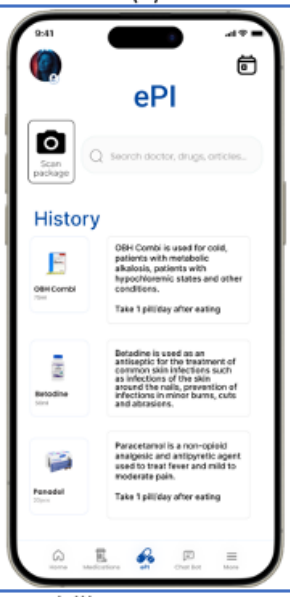
If "Medication" icon in the navigation bar at the bottom of the screen is clicked on any screen, user is directed to *screen 6(a)*.

	(a)	(b)	(c)
Screens			
Features	– Simple design to reduce cognitive overload. – Design is meant to resemble a medicine cabinet (using elements that are familiar to users). – Ability to customise medication names and descriptions to help those with low health literacy. – Warning icon to remind you when your medication is running low. – Medication bottles used to show how much medication the user has left.	– Use of icons to reduce cognitive load and effort expectancy as well as aid those with less literacy. – Direct link to start an email to your pharmacist or doctor (based on information user inputs in settings).	– Use of icons to reduce cognitive load and effort expectancy as well as aid those with less literacy. – Ability to customise medication names and descriptions to help those with low health literacy. – Link to ePI for more information using a consistent logo. – Simple design to reduce cognitive overload. 
Links	– Click on medicine bottle or box under to open information pop up (e.g., *screen 6(c)*). – Click on pen icon to customise medication name and description. – Click on alert icon to see pop-up of low medication (this also pops-up when you hit a self-set quantity of medication).	– Click on "x" in top right corner to return to *screen 6(a)*. – Click on email hyperlink to open mail app in phone.	– Click on "x" in top right corner to return to *screen 6(a)*. – Click on "See more information" or ePI logo to open *screen 7(a)*. – Click on pen icon to customise medication name and description.

6. Medication Tab and Pop-ups			
	(d)	(e)	(f)
Screens			
Features	– See *screen 4(d)*.	– Allows users to scan package – good for people with low health literacy.	– Use of icons to reduce cognitive load and effort expectancy as well as aid those with less literacy. – Link to ePI for more information using a consistent logo. – Link to Chat Bot for people with questions.
Links	– Click on "Scan Package" square to open *screen 6(e)*. – Click on "Discard" to return to *screen 6(a)*. – Click on "Add" to lead to *screen 6(a)*.	– Click on white circle to scan content and lead back to *screen 6(d)*.	– Click on "x" in top right corner to return to *screen 6(a)*. – Click on "Chat Bot" to lead to *screen 8(a)*. – Click on "ePI" to lead to *screen 7(a)*.

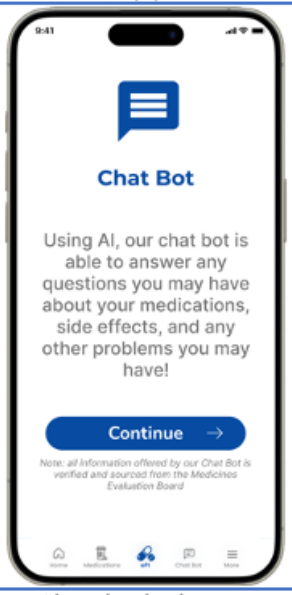
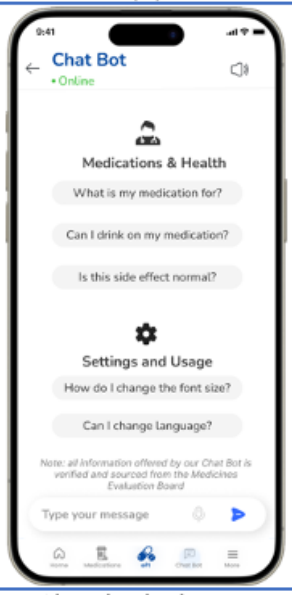
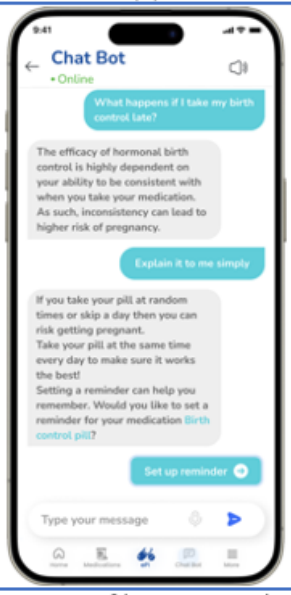
7. ePI tab and Pop-ups

If "ePI" icon in the navigation bar at the bottom of the screen is clicked on any screen, user is directed to *screen 7(a)*.

	(a)	(b)	(c)
Screens			
Features	– Ability to scan product to reduce effort and for those with less health literacy. – Simple design to reduce cognitive overload. – Search bar that searches as you type to reduce effort. – Ability to see and revisit previously searched medications.	– Ability to scan product to reduce effort and for those with less health literacy.	– Simple design to reduce cognitive overload. – Search bar that searches as you type to reduce effort. – Click on circle next to "I have taken this medicine" to confirm it has been taken – this automatically adds it to your medicine statistics.
Links	– Click on "Scan Package" to lead to *screen 7(b)*. – Click on any of the boxes with medications searched previously to open up their ePIs (see *screen 7(c)* as an example).	– Click on white circle to scan content and lead back to the search result (see *screen 7(c)* as an example).	– Click on "Go back" to return to *screen 7(a)*. – Click on any of the drop-down buttons to expands sections.

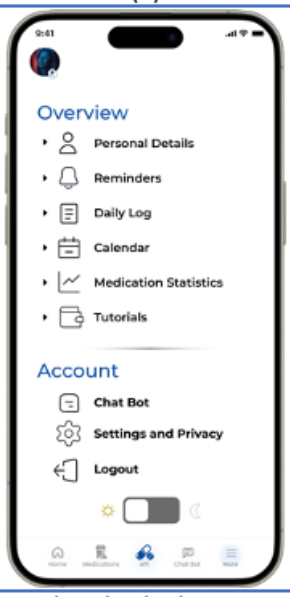
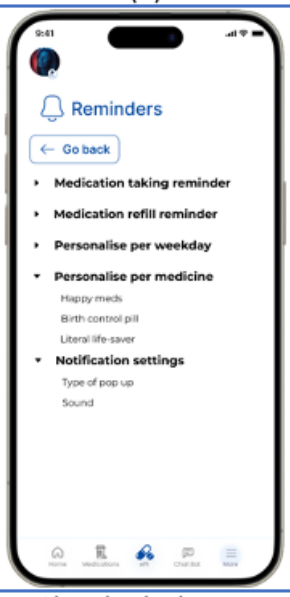
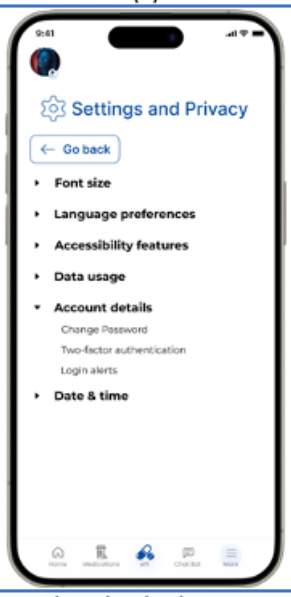
8. Chat Bot Tab and Example

If "Chat Bot" icon in the navigation bar at the bottom of the screen is clicked on any screen, user is directed to *screen 8(a)*.

	(a)	(b)	(c)
Screens			
Features	– Simple design to reduce cognitive overload. – Disclaimer under "Continue" button for system credibility support.	– Simple design to reduce cognitive overload. – Disclaimer under "Continue" button for system credibility support. – Use of icons to reduce cognitive load and effort expectancy as well as aid those with less literacy. – Suggested questions to reduce effort (dialogue support: suggestion).	– Use of icons to reduce cognitive load and effort expectancy as well as aid those with less literacy. – Allows users to set up reminders or other functions selected by the chat bot.
Links	– Click "Continue" to lead to *screen 8(b)*.	– Type message and click on send icon or click on suggested questions to lead to *screen 8(c)*. – Click on back arrow in top left corner to return to *screen 8(a)*. – Click on speaker icon in top right corner to have options played out (accessibility feature). – Click on microphone next to type message to record it instead (accessibility).	– Click on back arrow in top left corner to return to *screen 8(a)*. – Click on speaker icon in top right corner to have options played out (accessibility feature). – Click on microphone next to type message to record it instead (accessibility). – Click on "Set up reminder" to lead to *screen 9(b)*.

9. More Tab and Example Screens

If "More" icon in the navigation bar at the bottom of the screen is clicked on any screen, user is directed to *screen 9(a)*.

	(a)	(b)	(c)
Screens			
Features	– Simple design to reduce cognitive overload. – Use of icons to reduce cognitive load and effort expectancy as well as aid those with less literacy. – Ability to switch between day and night mode (good for those with eyesight conditions).	– Simple design to reduce cognitive overload. – Use of icons to reduce cognitive load and effort expectancy as well as aid those with less literacy. – High level of customisation to ensure that the triggers occur at the right time and in the right form, for each medication.	– Simple design to reduce cognitive overload. – Use of icons to reduce cognitive load and effort expectancy as well as aid those with less literacy. – Ability to review how your data is being used (system credibility support). – Ability to customise accessibility details to ensure anyone is able to use the module.
Links	– Click on any of the options under "Overview" to open up separate screen (see *screen 9(b)* as an example). – Click on any of the options under "Account" to open separate screen (see *screen 9(c)* as an example).	– Click on any of the options to lead to a page that allows you to customise. – Click on "Go back" to return to *screen 9(a)*.	– Click on any of the options to lead to a page that allows you to customise. – Click on "Go back" to return to *screen 9(a)*.

04. Conclusion

CONCLUSION

4.1 Limitations

During our client meeting, a wish for a broad target audience was discussed. In which the portal would be accessible for all. In the Netherlands, accessibility requirements are included in the Digital Government Act, which emphasizes the objective to realize digital inclusion where everyone is able to participate. Therefore our target audience consists of different ages, genders, education, etc. For this reason, interviews were conducted with different potential users from different backgrounds in order to attempt to create personas.

4.2 Recommendations

Although the prototype contains the wishes of the client, it does mean that there is room for improvement. Hence, we present the following recommendations for the Medicne Evaluation Board:

Login Process

- Create a simple, clean, and user-friendly login process.
- Offer multiple login options, such as Google and DigiD, alongside password creation.
- Provide tutorial videos for each login option, especially for DigiD, to assist users.
- Improve accessibility by accommodating various login preferences.

Product Information Leaflet

- Offer a concise medication purpose summary in product information leaflets (PILs) to prevent cognitive overload.
- Incorporate instructional images and videos explaining medication usage for user understanding.
- Creating segments of longer PILs to enhance content digestibility and ease of comprehension.

Trustworthiness and Data Security

- Include disclaimers indicating official register approval of medication information within the portal to encourage users' trust in the prototype.
- Implement disclaimers during the login process to assure users that their data is secure and won't be shared with third parties.

Long-Term Implementation

- If health and privacy regulations allow it, enable data sharing with secondary caregivers to assist in managing medical information, enhancing the app's accessibility.
- Improve dietary influence awareness by providing confirmed dietary information regarding medication and food interactions. This can be Implement alerts for emergency interactions.

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As a team we wish the Medicine Evaluation Board nothing but success for the future.