MYCB1®

ALETTA 1.0
USER GUIDELINE

Version Number	1.2
Date of version	12-2-2021
Software Author	Ernesto Diringuer
Job title	Founder & CEO
Manual	Sau-Han Wong
Job Title	IT Documentation Manager
Classification	Restricted
Intended recipient	Users of ALETTA

MYCB1

Table of Contents

Version control

Version Number	Author	Date	Change description
1.0	Sau-Han Wong	7-1-2021	Initial draft
1.1	Sau-Han Wong	12-2-2021	Added screenshots app
1.2	Ernesto Diringuer	15-02-2021	Review
1.3	Ernesto Diringuer	09-03-2021	Update

MYCB1®

Term	Definition
Pharmacist	Person who is professionally qualified to prepare and dispense medicinal drugs.
Clinician	Doctor who has direct contact with Patients, diagnoses any illnesses and writes prescriptions for medicinal drugs.
Patient	Person receiving or registered to receive medical treatment from a clinician.
Authorized Third Party	External organization that is authorized by MYCB1 to use the ALETTA Dashboard to access statistical data.
Prescription	An instruction written by a medical practitioner that authorizes a Patient to be issued with a medicine or treatment.
ALETTA App	ALETTA mobile app running on iOS or Android mobile phone.
ALETTA Dashboard	Web-based portal of ALETTA

MYCB1®

DISCLAIMER

The main functionality of ALETTA is to be a Patient Diary, using the validated questionnaire ED-5Q by EuroQol Research Foundation.

It is not a medical device, and is not intended to diagnose, treat, cure, or prevent any disease.

The Clinician must be aware of possible bias or inconsistency in the Patient's data, and ALETTA is only a complement to the clinical data workflow following Patient-reported outcome best practices.

ALETTA 1.0 is in Beta phase and is for demonstration purposes only. This User Guideline is to facilitate demonstrations and should be treated confidentially.

MYCB1 B.V.

Science Park 106

1098 XG Amsterdam

Netherlands

MYCB1.COM

INFO@MYCB1.COM

+31(0)20 723 5860

TRADEMARKS

Intellectual Property Office, trademark number UK 00917920511, EUIPO European Union Intellectual Property Office, registered no. 017920511, USPTO US Trademark Registration Nr 5888892, Government of Canada Registration Number 1936702, WIPO Madrid The International Trademark System, Registration number 1491657. Benelux Office for Intellectual Property registration and filing number 1428198.

1 Preface

ALETTA is a cloud base IT data management platform developed by MYCB1 Group B.V, that is built in with the validated questionnaire ED-5Q, a standardized instrument for measuring generic health status that is designed for self-completion and as such captures information directly from the respondent, thereby generating data that conforms with the general requirement of all Patient Reported Outcome (PRO) measures. ED-5Q is short and easy to use by the Patient and Clinician.

The ED-5Q is used to describe and value health-related quality of life and is developed by the EuroQol Group. ED-5Q has been used in clinical trials, population studies, and real-world settings for over 30 years. It is recommended for use by many health technology assessment bodies. The findings are used to help inform decision making by healthcare authorities, providers and organisations.

MYCB1 is a ISO 27001:2017 and NEN 7510-1:2017 certified IT platform. Further information regarding the scope of this certification and the statement of applicability of the Information Security Management System can be obtained by contacting Brand Compliance at brandcompliance.com, an organization accredited by the Dutch Accreditation Council (In 2010 the Dutch government appointed the Dutch Accreditation Council as the national accreditation body based on European Regulation 765/2008).

1.1. ALETTA 1.0

ALETTA 1.0 is still in the development phase at the time of writing and is for demonstration purposes only. Comments regarding the documentation can be sent to ALETTA@MYCB1.COM.

1.2 Description of the User

This user guideline facilitates the demonstration of ALETTA and describes the following intended users:

- The Pharmacist: a person who is professionally qualified to prepare and dispense medicinal drugs.
- The Clinician: a doctor having direct contact with Patients, diagnoses any illness and writes prescription for medicinal drugs.
- The Patient: a person receiving or registered to receive medical treatment from a Clinician.
- An authorized Third Party that uses health statistical reports.

No prerequisite skills are needed in order to use this guideline.

1.3 Obtaining Documentation and Information

1.3.1 Internet

The latest version of the documentation is available at the following address: ALETTA.MYCB1.COM

1.3.2 Ordering Documentation

Documentation, user instructions and technical information can be ordered by calling MYCB1 at +31(0)20 723 5860.

2 Description of ALETTA

2.1 Purpose

ALETTA provides a way of collecting Patient-reported outcomes during a medical treatment and reports this directly to the Clinician and Pharmacist enabling the healthcare professionals to gain direct insight into the data collected.

ALETTA has the following benefits for a clinical practice:

- Enhance decision-making
- Complement Patient management
- Identify issues for discussion ahead of the clinical consultation
- Improving the efficiency of the clinical encounter
- Identify issues for discussion that would not normally be addressed
- Access to real-time data and feedback
- Analyze Patient trends on a timeline

ALETTA 1.0 works only with MYCB1 Cannabis prescription medicines.

2.2 Scope of ALETTA 1.0

ALETTA 1.0 will be used by MYCB1 B.V. in The Netherlands and MYCB1 GmbH in Germany.

2.3 System Requirements

The ALETTA Dashboard can be accessed via the web browser. The following browsers are supported: Chrome 87 and higher, Safari 14 and higher for MacOS, Safari 3 and higher for Windows, Mozilla Firefox 84 and higher. The preferred browser is Chrome.

The ALETTA app is only available in a controlled environment at the time of writing. Please contact MYCB1 for instructions on how to download and install the app. ALETTA 1.0 is compatible with Android 6 and higher and iOS 11 and higher.

2.4 Process Overview

ALETTA includes a mobile app for Patients, a Dashboard for clinicians (Doctors), a Dashboard for the Pharmacy and a Dashboard for statistical analysis.

The high level workflow process is as follows: a Doctor diagnoses the illness of the Patient and decides to give the Patient a prescription for medicinal drugs as part of the medical treatment. The Pharmacy of the Patient receives the prescription automatically via the FarmaSys network (The Netherlands) or via fax or post or directly from the Patient when he/she visits the Pharmacy (Germany). Upon which the Pharmacy manufactures the MYCB1 medicine. When the medicine is ready, the Pharmacy creates a unique barcode (lot number) linking the Patient to the medicine and records the lot number in the ALETTA Dashboard. The Patient then picks up the drugs at the Pharmacy (The Netherlands and Germany) or the Pharmacy sends the drugs via post to the Patient (Germany). The Patient scans the barcode sticker on the drugs packaging with the ALETTA app on his/her mobile phone. This verifies that the medication is authentic and activates the questionnaire ED-5Q on the app. The Patient is now ready to report his/her health status during the usage of the drugs. ALETTA collects this data and makes it insightful for the Doctor via the ALETTA Doctor Dashboard.

3 Information for the Patient

3.1 Secure information processing

ALETTA safeguards the personal data of the Patient from tampering and unauthorized access. All communication between the app and ALETTA server is secured via HTTPS. Authentication is done on a personal and medicine level. Personal authentication is performed by the Pharmacy which verifies the identity of the Patient manually before an account is created for the Patient to use the ALETTA app.

Furthermore, the ALETTA app includes proprietary medicine authentication technology as a counterfeit medicine-detection tool. Before the Patient is allowed to use the app, the Patient needs to scan the medicine. ALETTA will then verify the authenticity of the MYCB1 medicine. After successful verification, the Patient can proceed to use the app.

MYCB1 complies with the international standard for information security ISO 27001:2017 and the standard for information security for the Dutch healthcare sector NEN 7510-1:2017. Further information regarding the scope of this certification and applicability of the management system requirements can be obtained by contacting the certified organization Brand Compliance at brandcompliance.com.

3.2 How to Use ALETTA correctly

The ALETTA app requires the Patient to fill in the ED-5Q questionnaire on a frequent basis according to the doctor's instructions, during the usage of the prescribed MYCB1 medicine. The questionnaire consists of simple questions in 5 dimensions to address the Patient's Quality Of Life. It's important that the Patient itself answers the questions to ensure authentic answers. This guarantees the treating doctor that the questionnaire has been filled in correctly.

3.2.1 Physical Impaired Patients

In case the Patient is unable to fill in the ED-5Q questionnaire on the app him/herself due to physical impairment (bad eyesight, unable to handle the mobile app on the phone physically or other), the Patient is advised to ask somebody to assist him/her by reading the questions aloud and filling in the answers for the Patient directly. This needs to be done every time the Patient needs to report his/her health status.

3.3 Potential Health Consequences

There are no potential health consequences when using the ALETTA application or mobile app. It is not a medical device, and is not intended to diagnose, treat, cure, or prevent any disease.

4 Using ALETTA

ALETTA distinguishes the following users:

- Backend users: Super Administrator, Administrator (Pharmacy), Doctor and Authorized Third Party
- Mobile app user: Patient

The Dashboard login webpage is the same for all backend users and is available through the following web url: ALETTA.MYCB1.COM.

UNDER CONSTRUCTION