



mHealthBelgium validation pyramid

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beMedTech Mission Statement

- beMedTech unites the **manufacturers and distributors** of medical devices to emphasize their positive role within the healthcare sector.
- The members of beMedTech invest in **innovative medical technologies** and in the **education of healthcare professionals**.
- Together we contribute **responsibly** to the **quality of patient care** and the **sustainability** of the healthcare system.

Why mHealthBelgium?



History and evolution

- Action plan eHealth
 - 5Y roadmap: 2013-2018
 - By Ministry of Public Health
 - Reviewed Oct 2015: 20 action points
 - Action point 19 = mHealth
- New action plan eHealth 2019-2021
 - Approved by IMC VG 28/1/2019

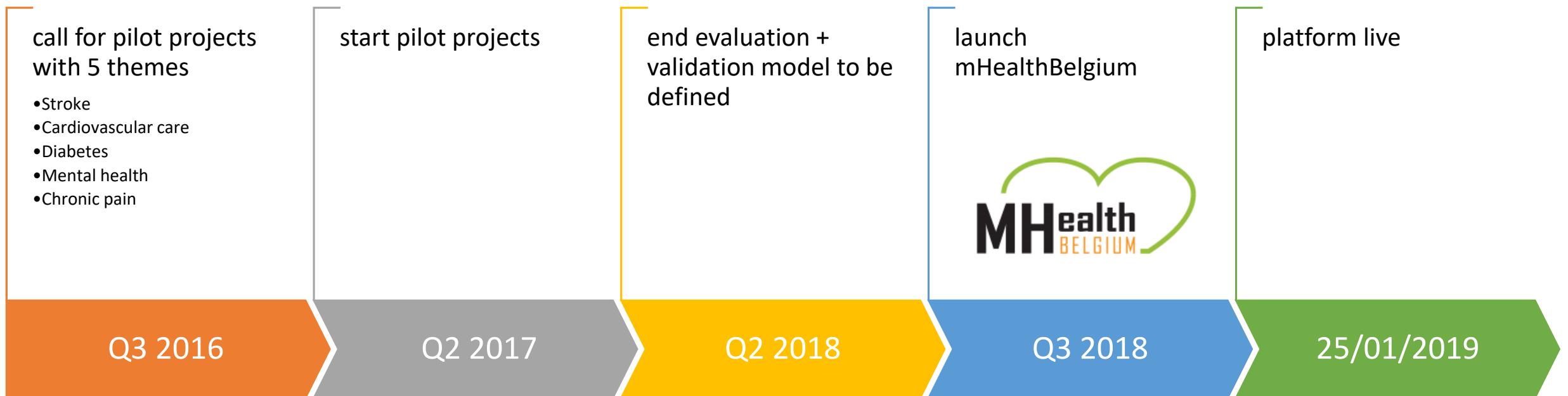


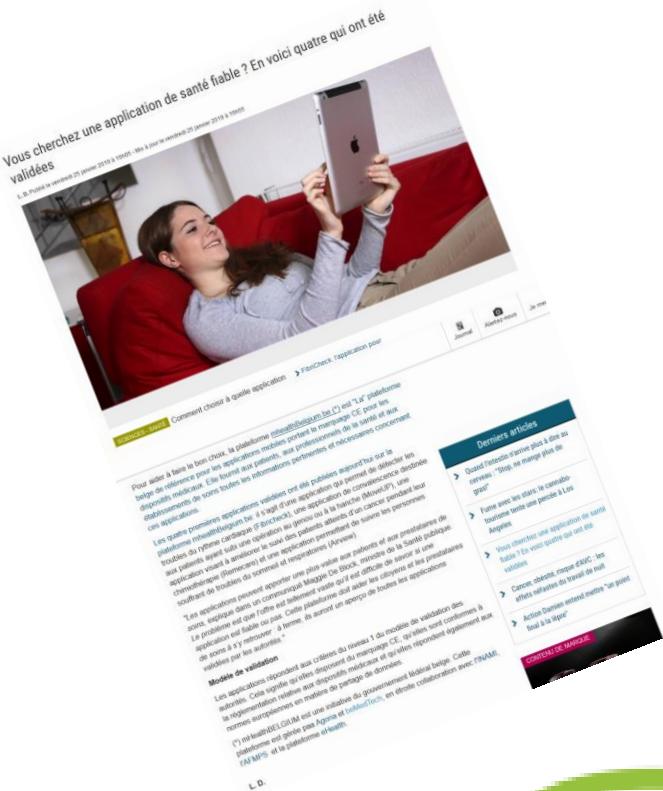
AP 19 = mHealth: why?

- Upcoming technology
- Need for new framework
 - Quality
 - Privacy
 - Evidence
- Goal = integrate mHealth applications in Belgian healthcare system



AP 19 = mHealth: evolution





MHealth BELGIUM

be
MedTech

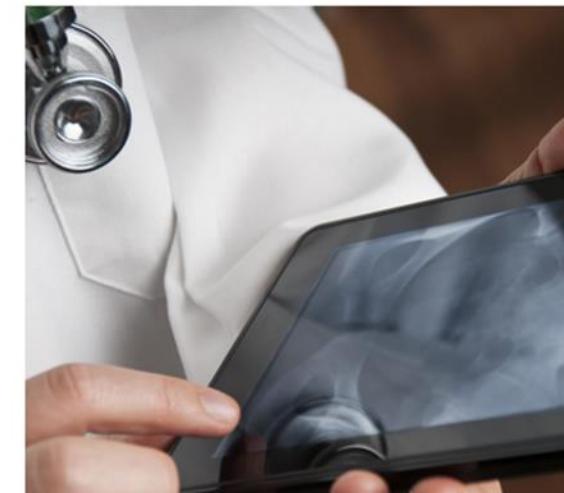
mHealthBelgium platform: what? who?

- www.mhealthbelgium.be
- In 3 languages: NL – FR – EN
- Information for
 - Broad public
 - Health care professionals
- List of validated apps
 - No full market scan
 - Company driven

The screenshot shows the top portion of the mHealth Belgium website. At the top right are language links: 'Inloggen', 'FR', and 'EN'. Below them is the mHealth Belgium logo, which includes a stylized green heart shape above the text 'mHealth BELGIUM'. The main navigation menu is located below the logo, featuring links for 'Home', 'Over ons', 'Publiceer je app', 'Alle applicaties', 'F.A.Q.', and 'Contacteer ons'. The background of the header is a light green color.

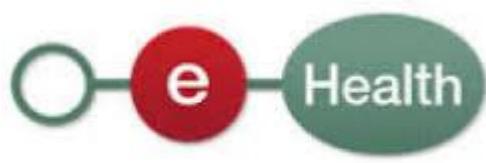
MOBILE HEALTH BELGIUM

MHealth Belgium is het Belgische platform voor mobiele applicaties die zijn CE-gemarkeerd als medisch hulpmiddel. Het platform reikt patiënten, zorgprofessionals en zorginstellingen alle relevante en noodzakelijke informatie aan over die mobiele applicaties. De informatie heeft betrekking op CE-markering, de AVG, naleving van de beveiligings- en authenticatieregels en op de manier waarop de app wordt gefinancierd.

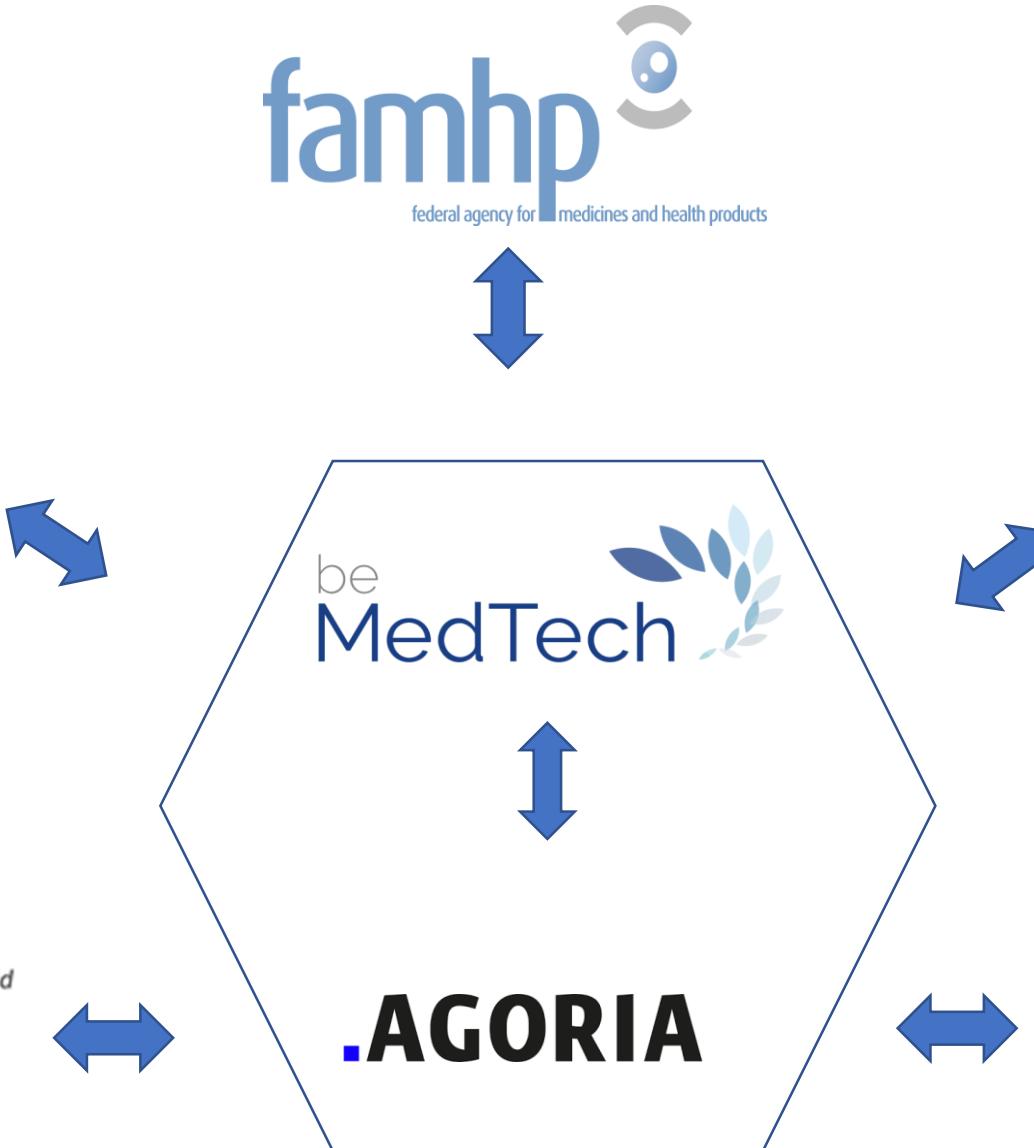




Minister van Sociale Zaken en Volksgezondheid
MAGGIE DE BLOCK



.AGORIA



.AGORIA

Federation of
the technology
industry

Carole ABSIL



Steven VANDEPUT



both passionate about digital health

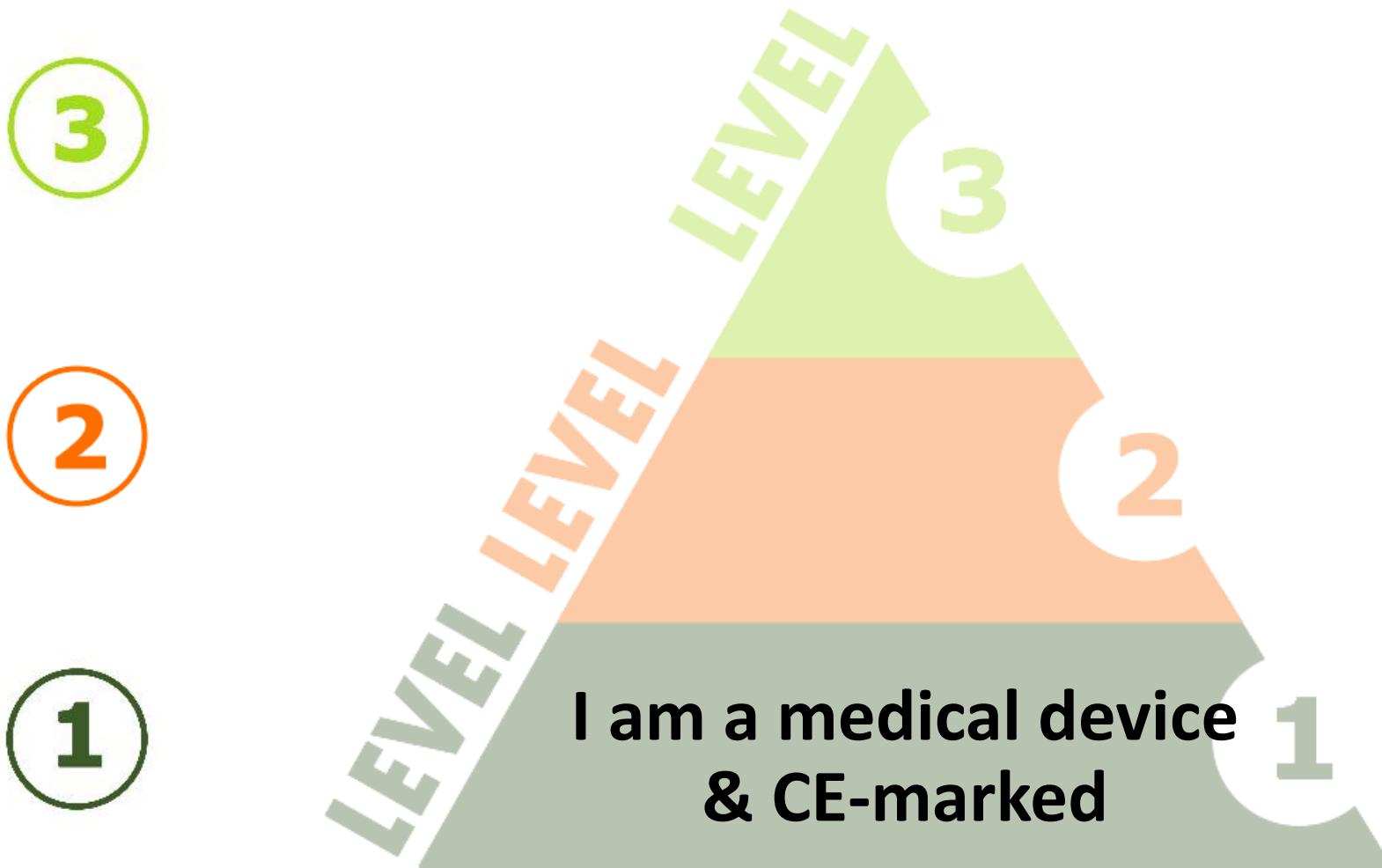


Federation of
the medical
technologies

Validation pyramid







3

2

1



3

2

1



I am a medical device

- Voluntary notification of the mobile app at the Federal Agency for Medicines and Health Products (FAMHP), thereby confirming the **CE marking** and compliance with the rules and regulations for medical devices
- The company (putting this app on the market) declares its compliance with the EU General Data Protection Regulation (**GDPR**)



I am safely connected

- The app must comply with the level 1 before applying this stage.
- The app will have to perform a risk assessment (performed by an independent organization) and be tested, if applicable, on basic services of the Federal eHealth Platform. **Applicable basic services, such as, authentication, identification, relationship or security.**



M2 criteria

1. App classification: category 1-2-3 (cfr GDPR rules)
 - ▣ Processing data: yes / no
 - ▣ Personal data: sensitive or not
2. Identification of caretaker: by Social Security Identification Number (SSIN)
3. User authentication: 2-factor authentication required (at least level 400)
4. Verification (if needed)
 - ▣ Check informed consent by patient
 - ▣ Check therapeutic relationship patient – HCP
5. Interoperability: use of international standards (eHealth box)

M2 in practice

Timing

- 3 steps

- Risk assessment tool:

By July 2019

- Input: questionnaire about app functionality
 - Output: extensive checklist of all things to be fulfilled

- Online platform to test the required checks (free)

By Sept 2019

- ‘Exam’ to proof you fulfill all requirements / criteria

- Integrated within mhealthbelgium platform

I show clinical evidence & financed by RIZIV / INAMI

- Level 3 is reserved for applications which have proven clinical and health economic benefit.
- Clear willingness to provide reimbursement but different way of thinking and different financing models than current MD.



STAKEHOLDER INTERACTION

RIZIV / INAMI

eHealth platform

FAGG / AFMPS



TIMING

RIZIV / INAMI

case by case

Under development
Full mode from Oct
2019

eHealth platform

Now active

FAGG / AFMPS



Status and future



Situation
now: 7 apps
in level M1

The image shows a screenshot of the MH health BELGIUM website. At the top left is the logo 'MH health BELGIUM' with a green heart icon. The top navigation bar is green and contains links for 'Home', 'About us', 'All apps', 'F.A.Q.', and 'Contact us'. Below the navigation bar is a large photograph of a woman with long blonde hair from behind, looking towards the left. To the right of the photo is a section titled 'HEALTH APPS' enclosed in an orange border. This section contains a list of four categories: 'Pathology', 'Functions', 'Users', and 'Languages'. Below this list are seven app icons, each with its name underneath:

- AirView™ Cloud-based patient management system (AIRVIEW)
- COMUNICARE
- FibriCheck
- moveUP
- mySugr
- REMECARE
- Syndo CONNECTING PEOPLE WHO CARE (Syndo Health)

Future

- Platform
 - Further development with M2 test services
 - Improve flows and enrich content (but keep it simple)
- Communication
 - Reach out & spread the word
 - More apps on platform in different levels
 - Connect via other websites / tools e.g. personal health viewer

