Reimbursement of Digital Health Solutions: Belgium

Reimbursement of Digital Health is advancing in Belgium:

mHealthBelgium is the Belgian platform for mobile applications that are CE-marked as a medical device.
This one-stop-shop platform centralises all relevant, necessary and validated app information for patients, healthcare professionals and healthcare institutions in 3 languages (Dutch, French, English). Visitors can easily find information on CE-marking, GDPR compliance, compliance with security and authentication rules and if and how the app is financed.

The platform is constructed around a validation pyramid with 3 levels. An app always enters at the lower level M1 and can climb in the hierarchy via M2 towards the top level M3.

mHealthBelgium is an initiative of the Federal Belgian Government with multiple stakeholders involved. The full implementation and coordination is executed by beMedTech (sector federation of industry of medical technologies) & Agoria (Belgium's trade association representing companies active in the technology sector), in close cooperation with 3 national authorities:

- Federal Agency for Medicine and Health Products (FAMHP): the competent authority responsible for safety, quality and efficacy of drugs and health products, responsible for level M1
- eHealth Platform: federal eHealth organization building the infrastructure for information exchange in healthcare, responsible for level M2
- NIHDI: National Institute for Health and Disability Insurance, responsible for reimbursement of healthcare products and services, responsible for level M3

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Some extra information regarding the 3 levels of the validation pyramid:

- M1 is the basis level considering 3 simple requirements:
  - Mobile app is CE certified as a medical device
  - Voluntary notification of the mobile app at the Federal Agency for Medicines and Health Products (FAMHP)
  - The application and its mother company declare that they are compliant with the EU General Data Protection Regulation (GDPR).
- Under M2, the app will have to perform a risk assessment on compliance with security and authentication rules and, if connected to other health systems, be tested (by an independent organization) on basic services of the Federal eHealth Platform. Applicable basic services are a. o. authentication, identification, therapeutic relationship or security
- M3 is reserved for applications which are financed by the NIHDI. This financing can be based on proven clinical and health economic benefit, but also on recognition of promising technology warranting temporary financing to collect the data.

The latter doesn't exclude that mobile health applications can also be financed by other means than the NIHDI. For instance, hospitals could finance them out of their budgets, patients or healthcare professionals could finance the application out of pocket, or sick funds could (partially) support the use of the app.

Currently, 8 apps are published on the mHealthBelgium portal, all in level M1. M2 is under development and will be ready by September 2019, while for M3 the first reimbursement files have been submitted and initial discussions took place for some pilot cases.

Looking to other EU countries, Belgium seems the only one having such national quality system in place and is consequently a forerunner regarding mhealth in Europe.

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