mHealthHUB European

Hub Talks 2021

Dialogue organized by mHealth Hub, EU, ITU, WHO

Webinar 1

Integration of mHealth into health systems

28th Jan 2021 10.30-12.00 CET

https://www.gotomeet.me/agenciacalidadsanitaria/mhealthhub

mHealth reimbursement frameworks – a comparative overview

Alexander Degelsegger-Márquez
Gesundheit Österreich GmbH

Dimitra Panteli
European Observatory on Health Systems and Policies
TU Berlin

World Health Organization

Junta de Andalucía
Consejería de Salud y Familias
AGENCIA DE CALIDAD SANITARIA DE ANDALUCÍA

This project has received funding from the European Union's Horizon 2020 research and innovation programme under the Grant Agreement No 737427

Observations

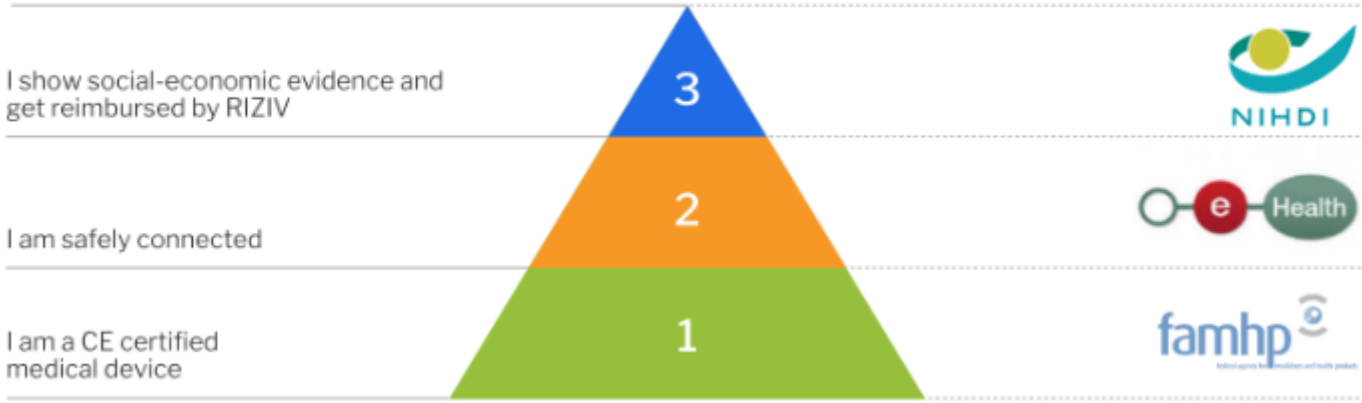
- Mobile digital health solutions abound
- Necessary to determine what apps are effective, safe, etc. → assessment challenge
  - A variety of assessment frameworks are available: MARS scale, NICE Evidence Framework, etc.
    Currently under development: CEN/ISO technical specification on 'Quality and Reliability of Health and Wellness Apps'
- How to incentivize the use of apps deemed effective?
  - No public sector intervention?
  - User guidance, e.g. through app registries
  - Financial incentives/reimbursement
    - National solutions
    - Individual payers
- Situation in many countries: Lack of clear reimbursement pathways

Goals for today

- Look at some interesting country cases with recent developments:
  - Belgium
  - England
  - France
  - (Germany – covered by BMG speakers)
- Present one approach towards a systematization of reimbursement approaches
- Discuss what we can learn from these cases

Current state-of-play: Belgium

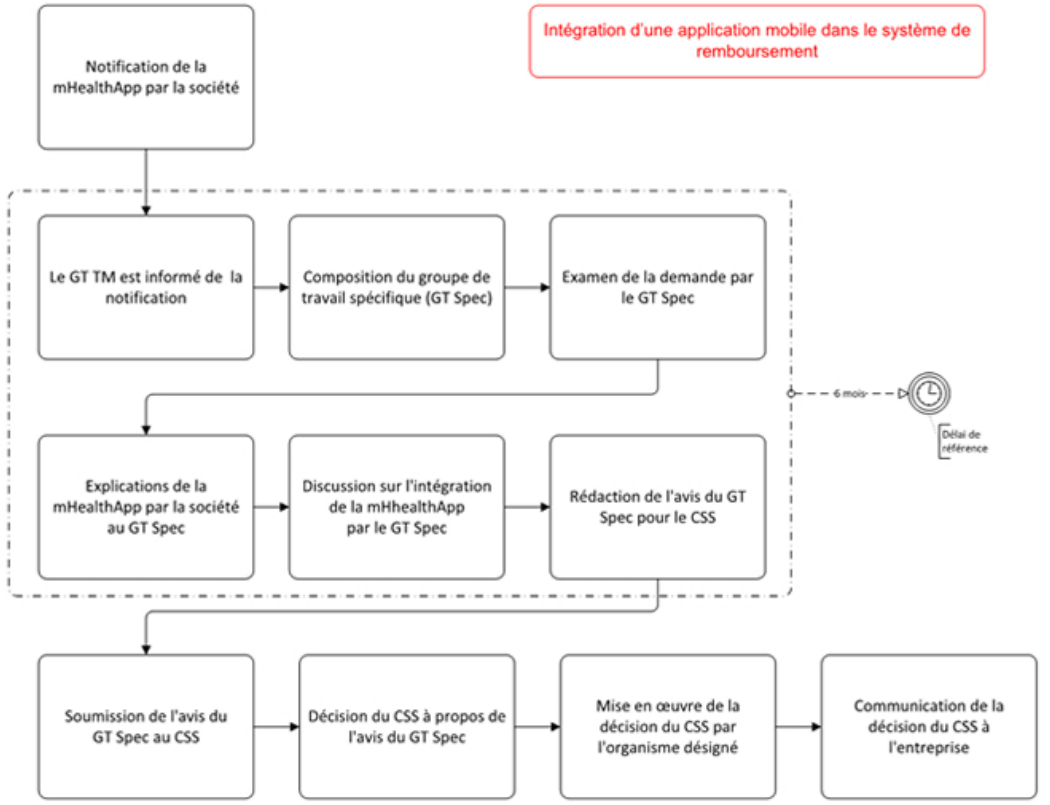
- **mHealthBelgium.be platform**
- Three-level pyramid
  - Level 1: CE certified, GDPR compliant
  - Level 2: safely connected (risk assessment performed)
  - Level 3: reserved for apps for which the social-economic added value has been demonstrated and which are financed, after approval by National Institute for Health and Disability Insurance (NIHDI) of their funding request.
- As per January 2021: 23 apps have achieved level 1, seven also level 2 and one level 3
- Level 3 goes along with reimbursement by the compulsory health care insurance



https://mhealthbelgium.be/validation-pyramid

Current state-of-play: Belgium

- Reimbursement model developed by National Institute for Health and Disability Insurance (NIHDI/INAMI)
- Process steps
  - Developer application
  - Working group set up at NIHDI
  - Working group gives a recommendation to the NIHDI insurance committee
- NIHDI funded clinical study for apps focusing on rehab after knee/hip surgery → now the first app being reimbursed and already available



https://www.inami.fgov.be/

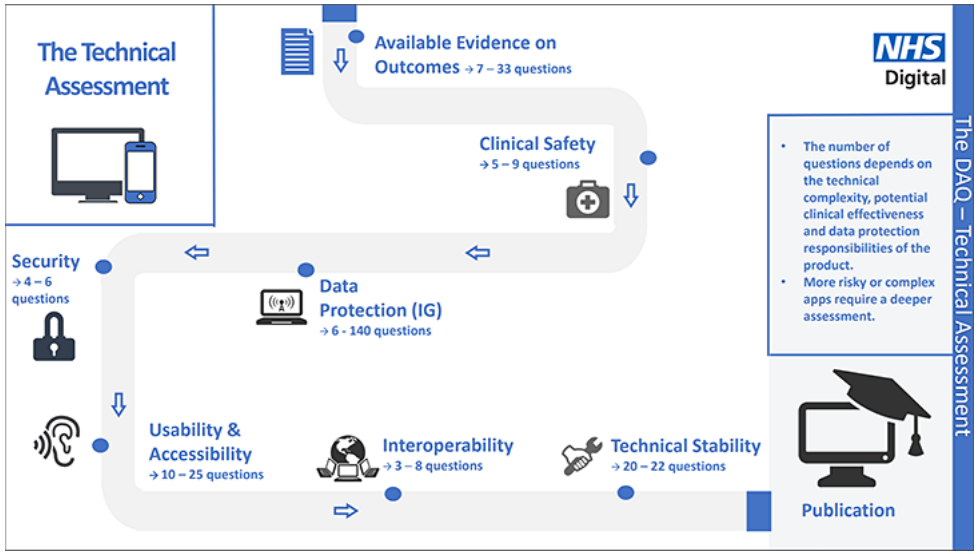
Current state-of-play: England

- **NHS Apps Library (NHS Digital)**
- Collecting all the apps assessed against national standards
- Inclusion in the Library != reimbursement
- Facilitates decision-making on reimbursement by the Clinical Commission Groups and NHS Trusts
- In addition, as guidance for CCGs/Trusts and developers: NICE Evidence standards framework and Medical Technologies Evaluation Programme
- myCOPD as the only nationally reimbursed app (via an instrument called Innov. and Tech. Payment)

Sleepio

An online sleep improvement programme, clinically proven to help you fall asleep faster

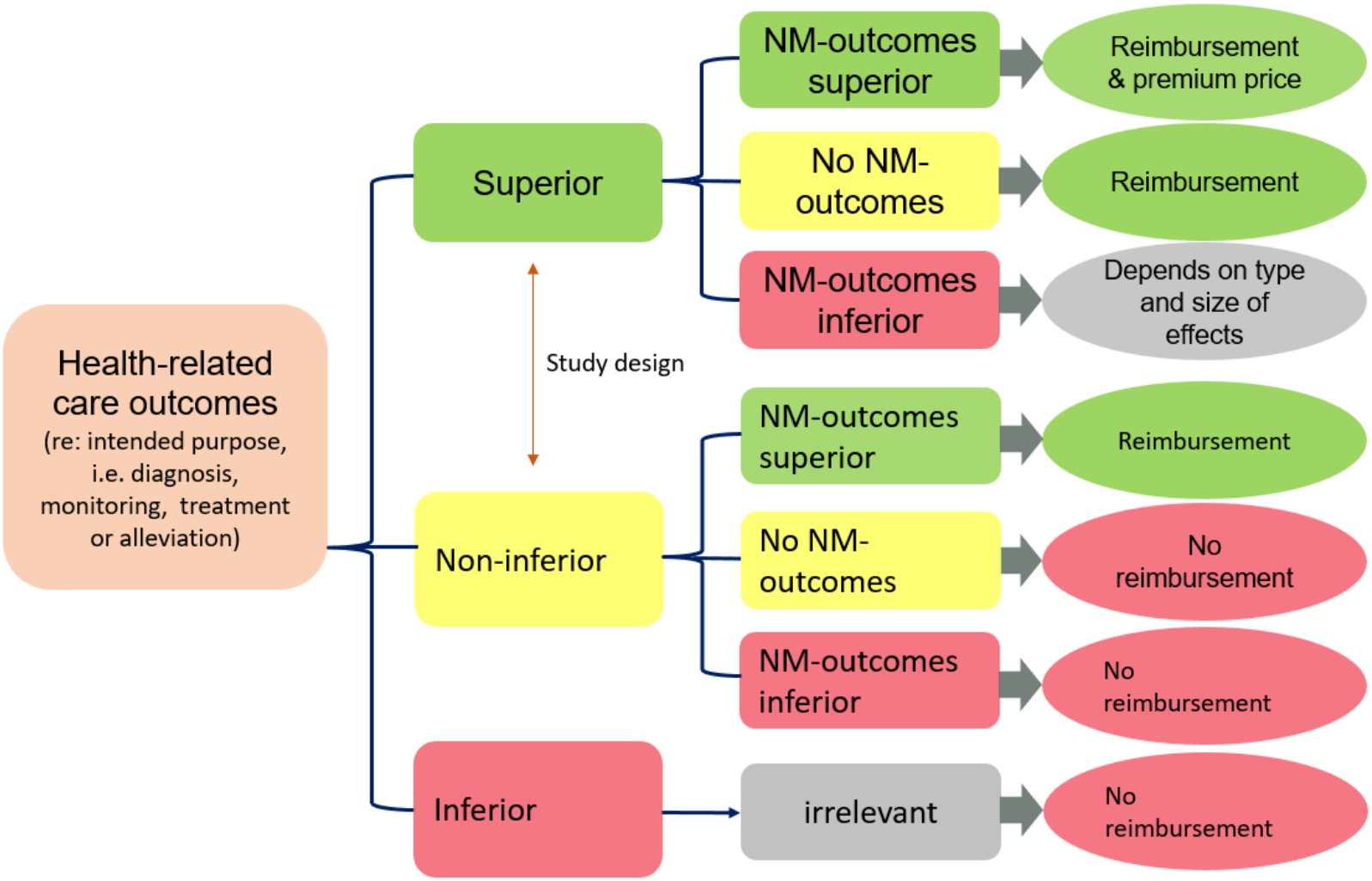
Free in some areas



Current state-of-play: France

- Reimbursement via inclusion in the French List of Products and Healthcare Services Qualifying for Reimbursement (LPPR list)
- Evidence requirements specified in the HAS Assessment principles to determine the reimbursement eligibility of medical devices for individual use, evaluated by the Medical Device and Health Technology Committee (CNEDIMTS)
  - Following this procedure, in August 2020, a web and mobile app for telemonitoring of lung cancer patients is included in the LPPR list;
  - positively evaluated for three years with Added Clinical Value (ASA) level III (moderate improvement) compared to the conventional care, monitoring by imaging and medical face to face consultations.
  - A sub-section for “web applications and telemonitoring software” has been added to LPPR; reimbursable tariff of € 500 for a three-month prescription, negotiated between the French Healthcare Products Committee and the manufacturer on the basis of the ASA level
  - Physicians prescribe the application and inscribe patients

Current state-of-play: France



Based on French National Authority for Health (HAS) – January 2019: Medical device evaluation by the CNEDiMTS. Guide to the specific features of clinical evaluation of a connected medical device (CMD) in view of its application for reimbursement;

Current state-of-play: summary

Mode of reimbursement			
contract-based	programme-based	catalogue-based	registry-based
Unit of analysis			
individual applications		groups of applications	
Decision-making			
decentralised	mix/conditional	centralised	

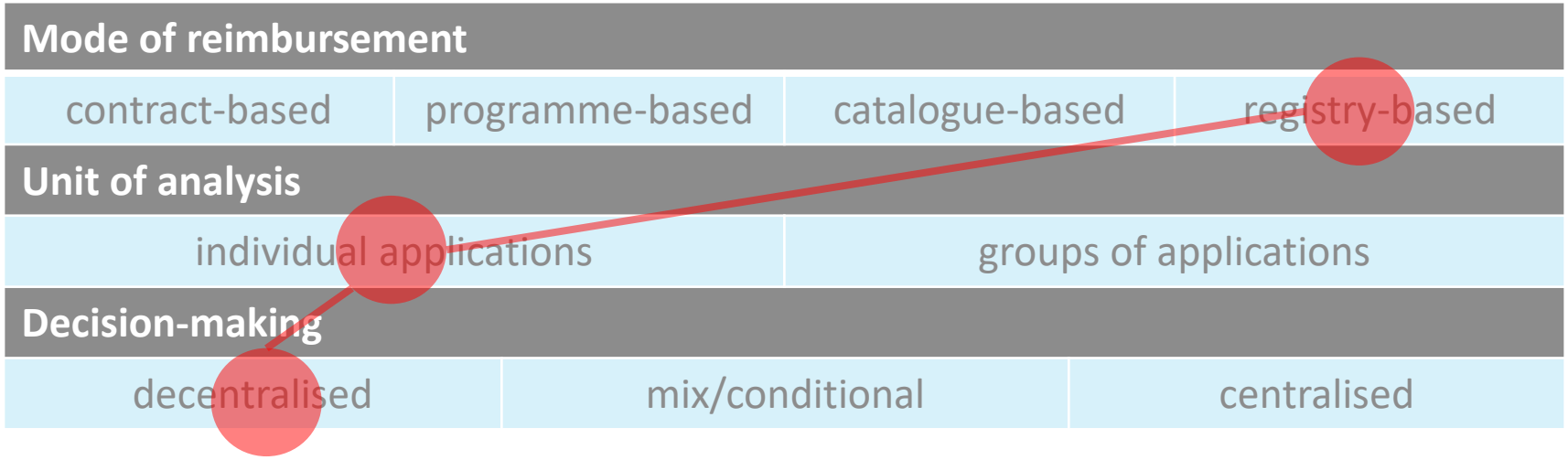
Current state-of-play: summary

Belgium

Mode of reimbursement			
contract-based	programme-based	catalogue-based	registry-based
Unit of analysis			
individual applications		groups of applications	
Decision-making			
decentralised	mix/conditional		centralised

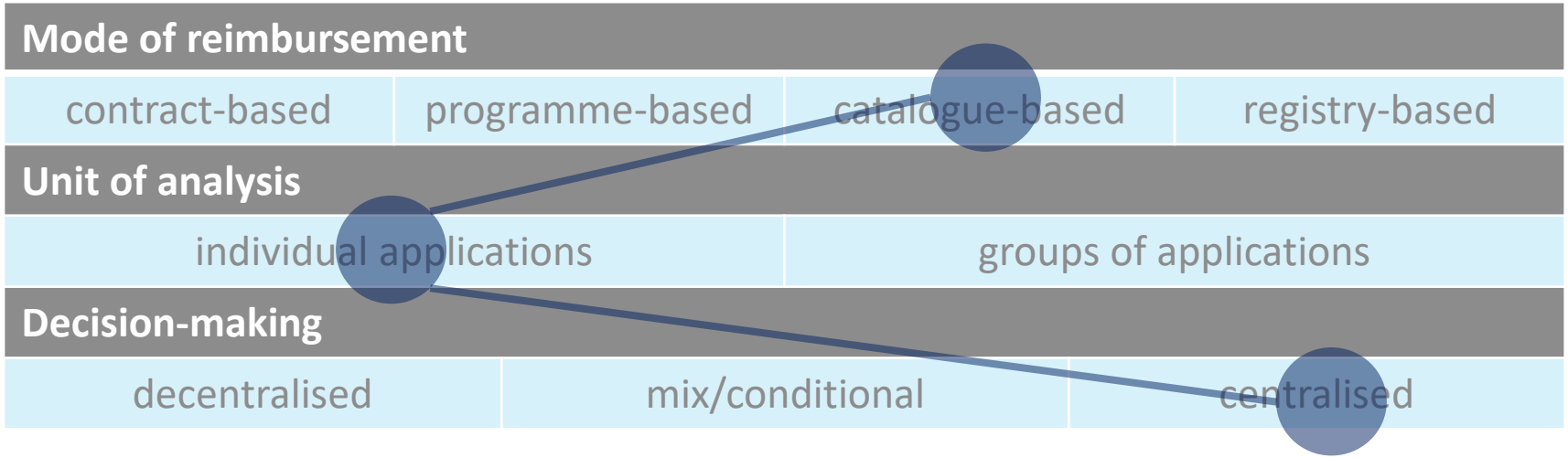
Current state-of-play: summary

England



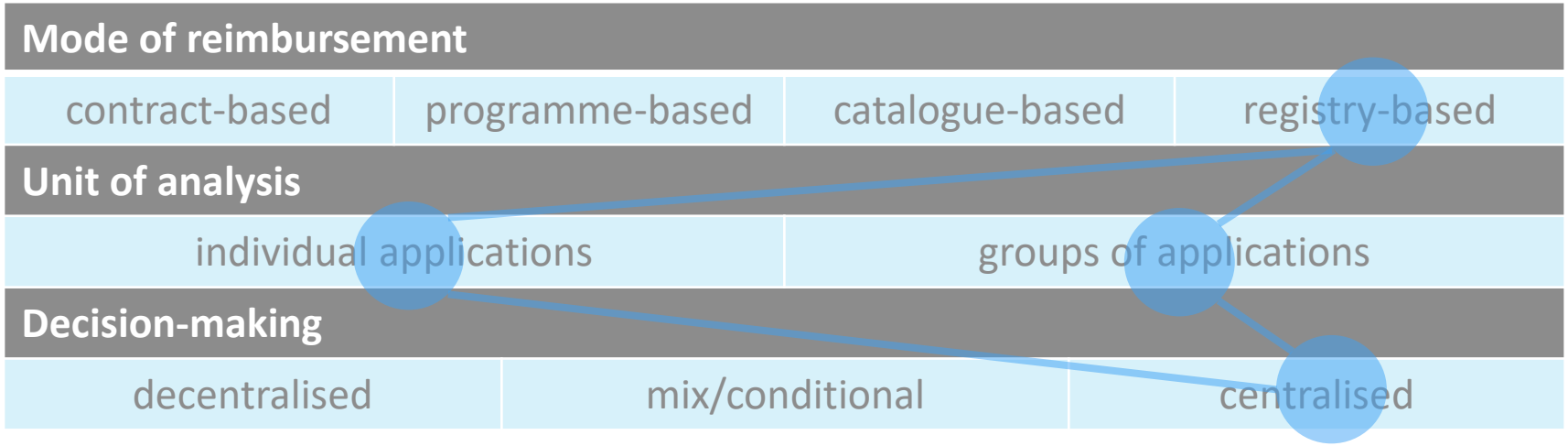
Current state-of-play: summary

France



Current state-of-play: summary

Germany



	Producer	Payer	Physician	Patient
Registry-based reimbursement (vs catalogue inclusion)				
Advantages	Better planning	Transparency, planning	Transparency, orientation	Transparency, orientation
Disadvantages	More formalisation	Register regime has to be set up	New/different regime	-
Groups of applications (vs individual applications)				
Advantages	Less relevant to be first in class	Decreased workload	Guidance	Guidance
Disadvantages	Late entry possible but price fixed	Group definition and revision	How to decide within group?	How to decide within group?
Centralised decision-making (vs decentralised)				
Advantages	Less workload for market entry	Less decision-making costs	NA	Avoids patchy app landscape
Disadvantages	Less room for negotiation	Less flexibility	NA	Less tailored to local needs

Five key questions

1. **What evidence is required and who is paying for the evidence provision?** If the producer/supplier is paying, how to avoid piggybacking by new/second entrants?
2. **How to set prices?**
   - Fee for app? Fee for subscription? Fee for usage? Fee for care package? Fee for Outcomes?
   - Fixed maximum prices? On what basis: development and production cost component? Costs for evidence provision? ‚Innovation bonus' (for being first and paying for evidence)?
   - Thresholds?
   - How do different types of effect (improved medical outcomes vs social or organisational effects) affect reimbursability and pricing?
   - How to set prices for apps that are replacing other treatment vs apps that are complementary or even additional?
3. **Regulating/limiting market entry (e.g. medication diaries)? On what basis?**
4. **International dynamics: what does a market entry in e.g. Germany entail for a specific application's pricing in another country?**
5. **What are the options for international cooperation (e.g. mutual recognition agreements)?**

Key messages

- Despite inevitable differences in reimbursement frameworks that relate to the differences in health systems, we need international exchange, particularly:
  1. we need to think about best practices with regard to quality criteria and to linking evidence requirements for market access and reimbursement
  2. we need to think about dynamics in pricing (a bit like in the case of medicinal products)
  3. we might think about mutual recognition of reimbursement decision making similarities to the medical product situation: developers hope to close the gap between market approval and reimbursement → opportunity for fair pricing

Thank you

alexander.degelsegger@goeg.at

info@mhealth-hub.org

mHealthHUB European

Hub Talks 2021

Dialogue organized by mHealth Hub, EU, ITU, WHO

World Health Organization

Junta de Andalucía
Consejería de Salud y Familias
AGENCIA DE CALIDAD SANITARIA DE ANDALUCÍA

This project has received funding from the European Union's Horizon 2020 research and innovation programme under the Grant Agreement No 737427