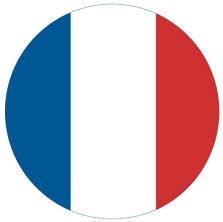
MARKET ACCESS PATHWAYS

FRANCE



Summary

1. Introduction

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Generalitat de Catalunya

Introduction
Key factors for Market Access in Europe

Clinical benefit → **Economical benefit**

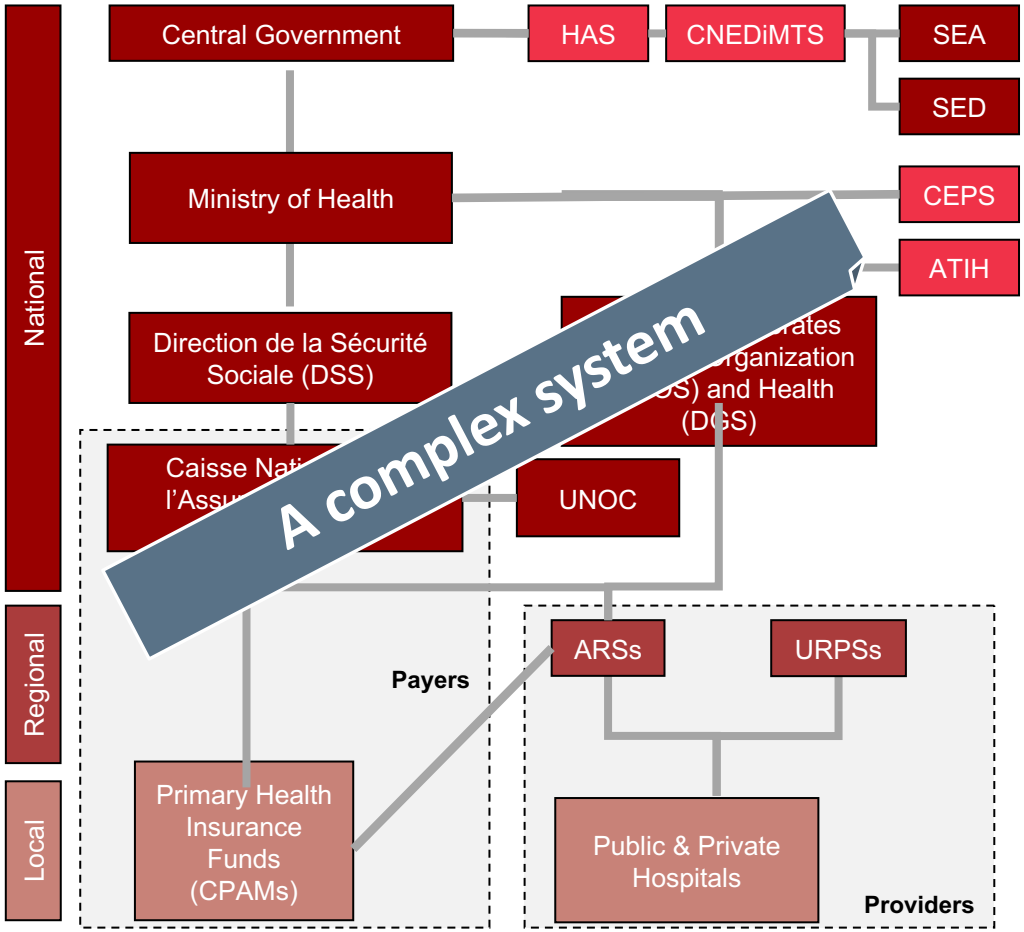
Evidence-based decisions clinical data

Decisions based on cost-effectiveness data

Decisions based on budgetary impact data

Introduction

France: A centralized healthcare system



Ministry of Health:
21 Regional Health Agencies (ARS)
101 Caisses Primaires (CPAMs)

HAS - National Independent Assessment Body (HTA) - CNEDiMTS is the Commission for the Evaluation of Medical Devices (SED), Diagnostics and Professional Acts (SEAP)

CEPS - Comité Economique des Produits de Santé - Responsible for Pricing

ATIH - Agence Technique de l'Information Hospitalière - Responsible for T2A management

UNOC - Union of Private Supplementary Insurers

The main regional bodies are the regional health agencies (ARS) and the regional unions of health professionals (liberal professionals) (URPS).

Overview

Financing of the french health system

2018

78,1%
Universal Public Health Insurance

+

13,4%
Voluntary complementary private insurance

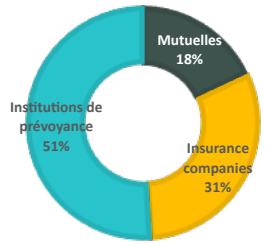
+

1,5%
Government

+

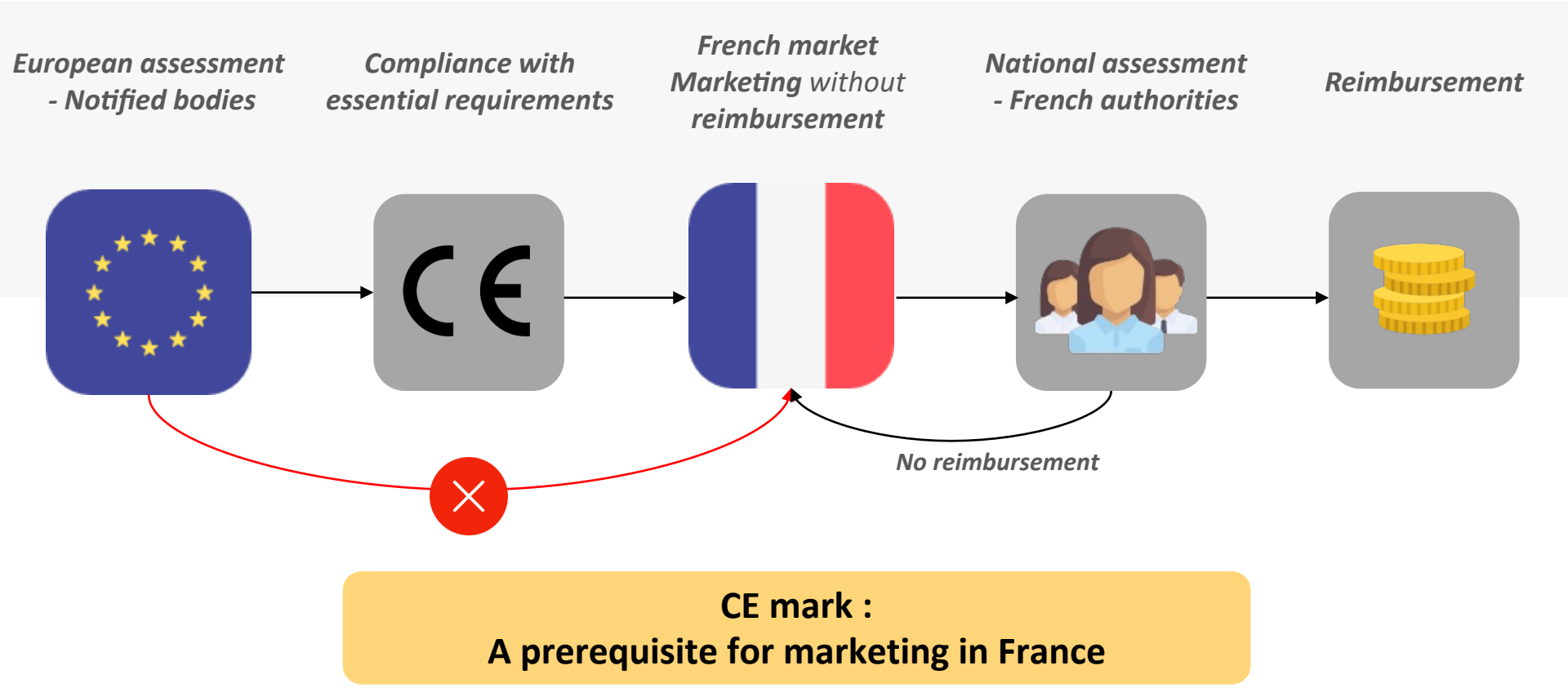
7 %
Low out-of-pocket (againt 16% in the UE)

- Mutuelles
- Insurance companies
- Institutions de prévoyances



Source : DREES

Overview
Access to the French market



CE mark :
A prerequisite for marketing in France

Overview

Public hospitals vs private clinics

3 keys of entrance : Intra-DRG or Reimbursed price on LPPR or Dedicated medical code for procedure *

Public hospitals
- University hospitals
- Regional hospitals
- Local hospitals
- Oncology centers

Public tendering rules

Group purchasing organizations

UGAP
UniHA
resah
Réseau des Acheteurs Hospitaliers
unicancer

- Group of private clinics
- Independant clinics

Bids & tenders specfic to each group / clinic

Ramsay Santé
VIVALTO SANTÉ
Almaviva santé
ELSAN
Notre Santé autrement

Play by the book :

1. Do NOT expect to penetrate sustainably the market without one of the 3 keys of entrance*
2. Private insurances are NOT key stakeholders to get successful for bids and tenders
3. Patients do NOT have the choice to select / to pay for the device / the solution paid by Social Security
4. Direct to patient communication is NOT allowed to promote an healthcare good paid by Social Security

* There is an alternative case by case possibility with some local innovation funding

2. Standard Market Access pathways

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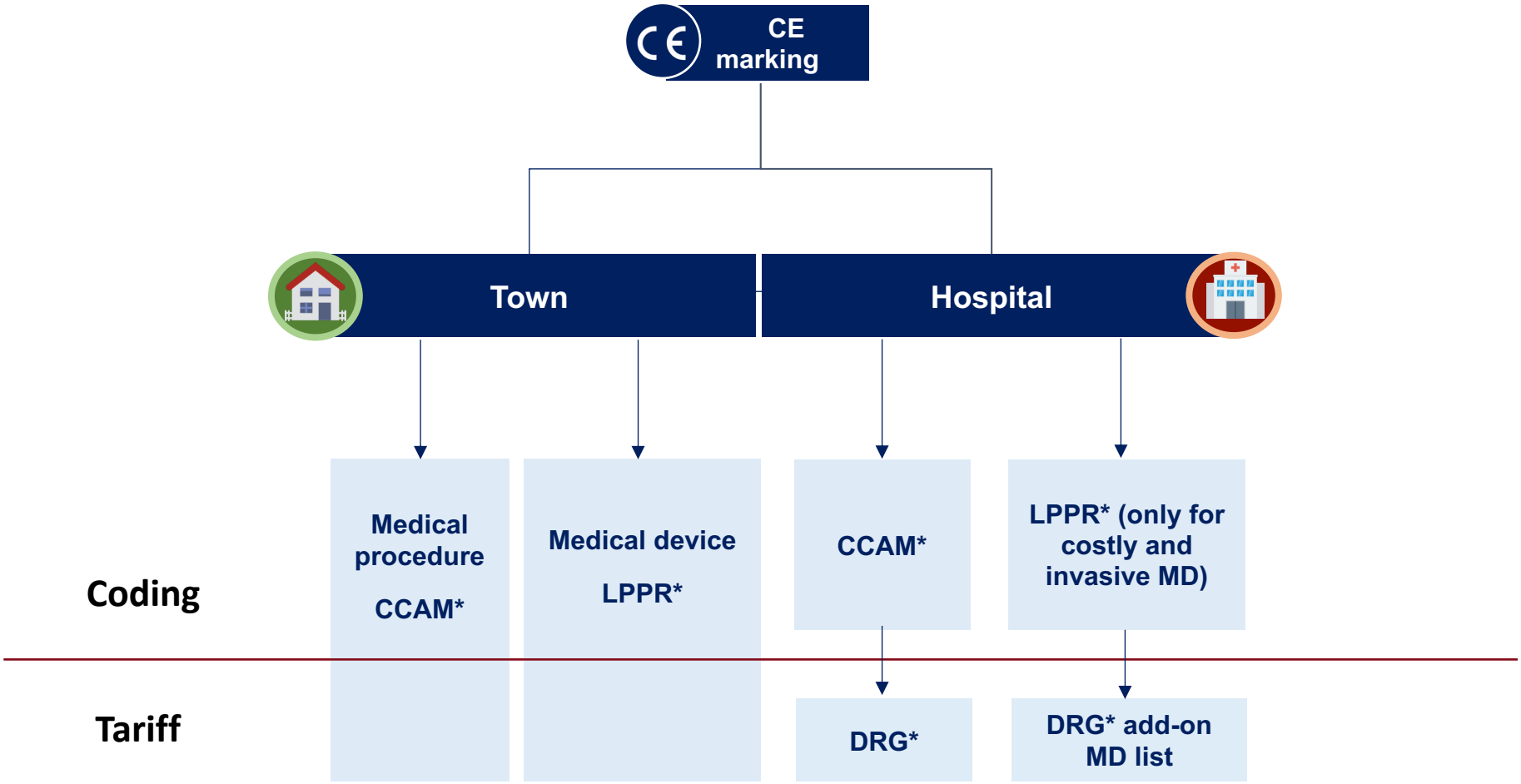
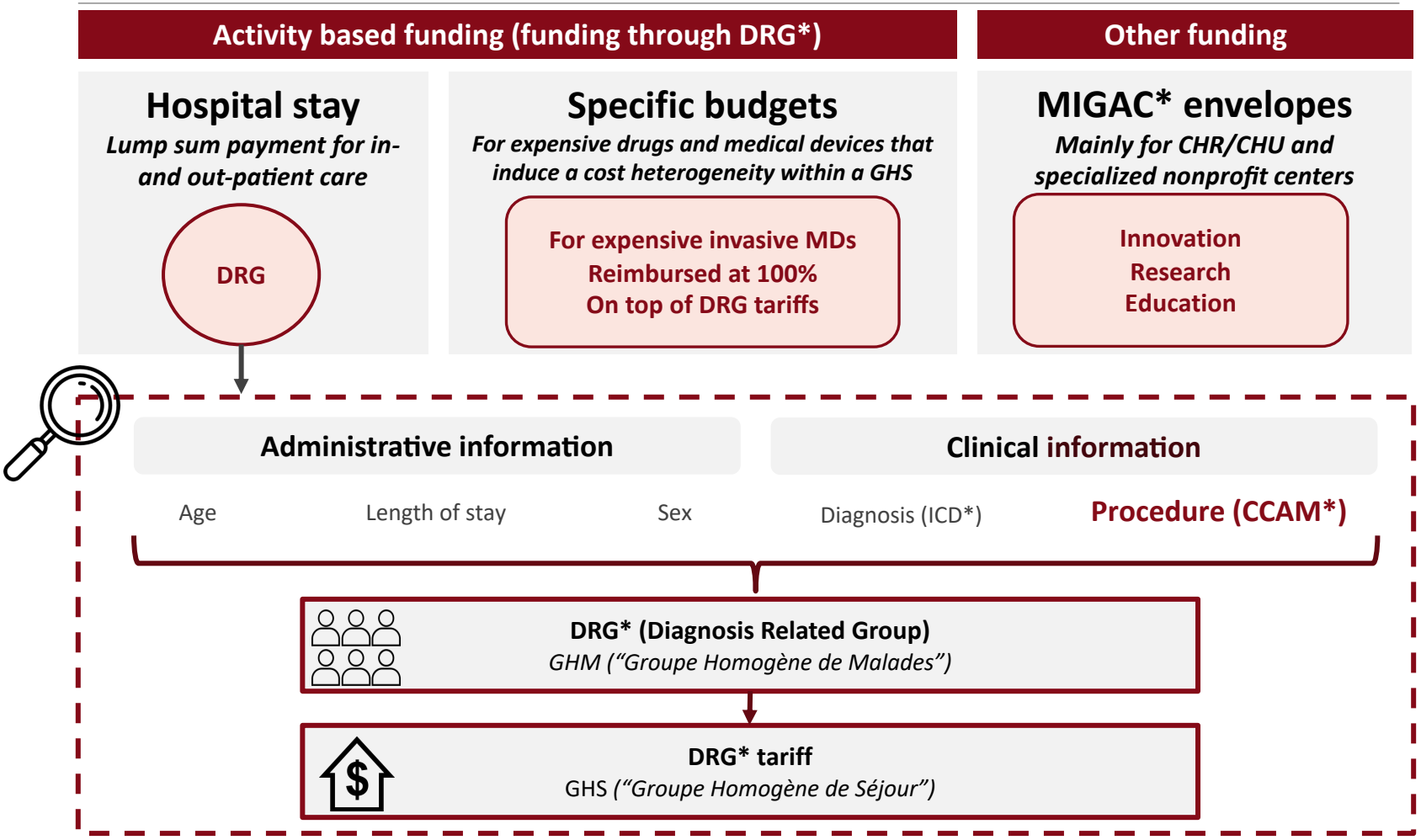
Overview
Funding in the outpatient sector and in the hospital



*CCAM: Classification commune des actes médicaux *(Common Classification of Medical Procedures);* DRG: Groupe homogène de malades *(Diagnosis related group);* LPPR: Liste des produits et prestations remboursables *(List of reimbursable products and services)*

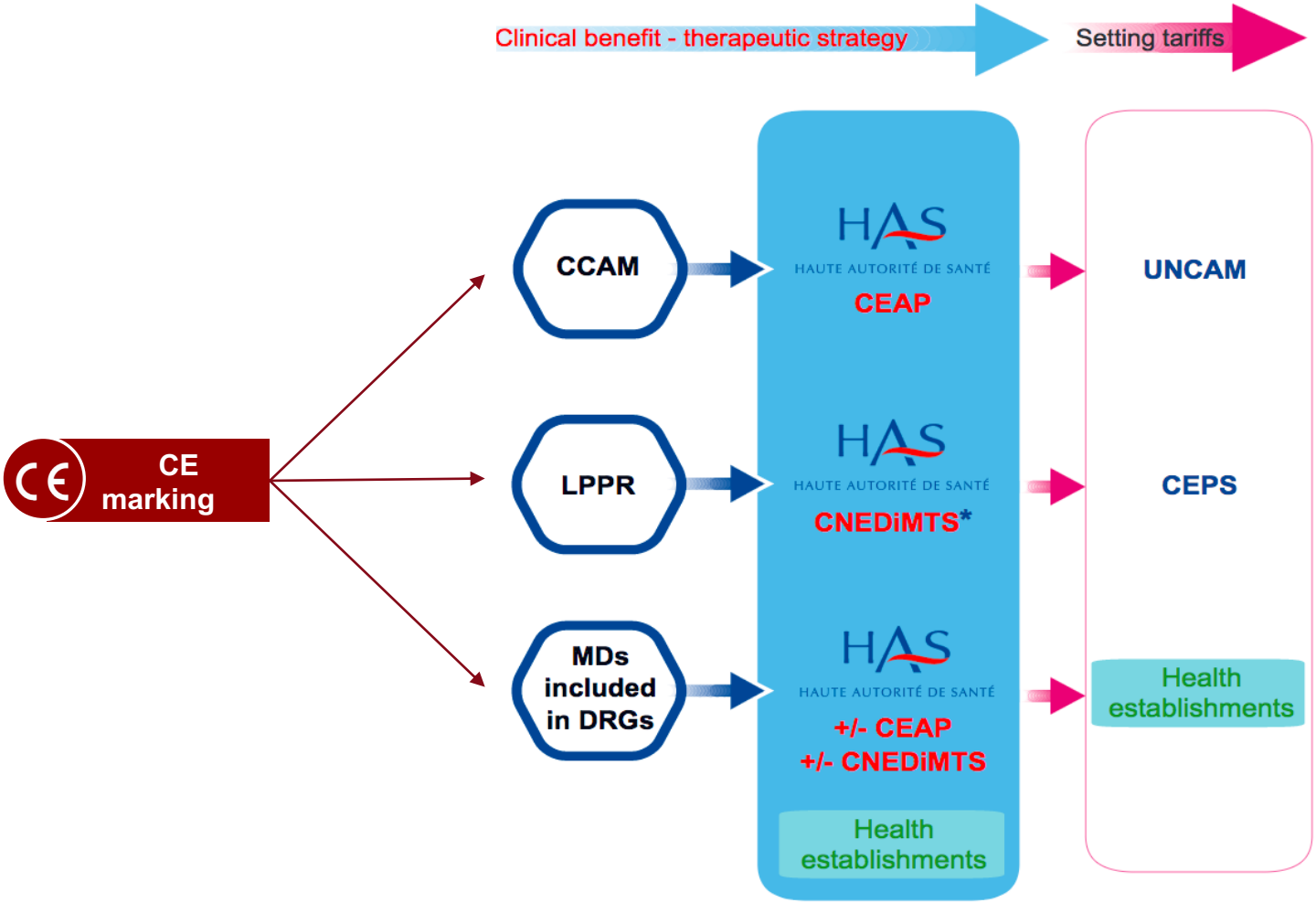
Overview
General considerations on access to the hospital market



*CCAM: Classification commune des actes médicaux *(Common Classification of Medical Procedures);* DRG: Groupe homogène de malades *(Diagnosis related group); ICD: Classification of Diseases;* MIGAC: Missions d'intérêt général et d'aide à la contractualisation *(Missions of general interest and contractual aid)*

Standard Market Access pathways

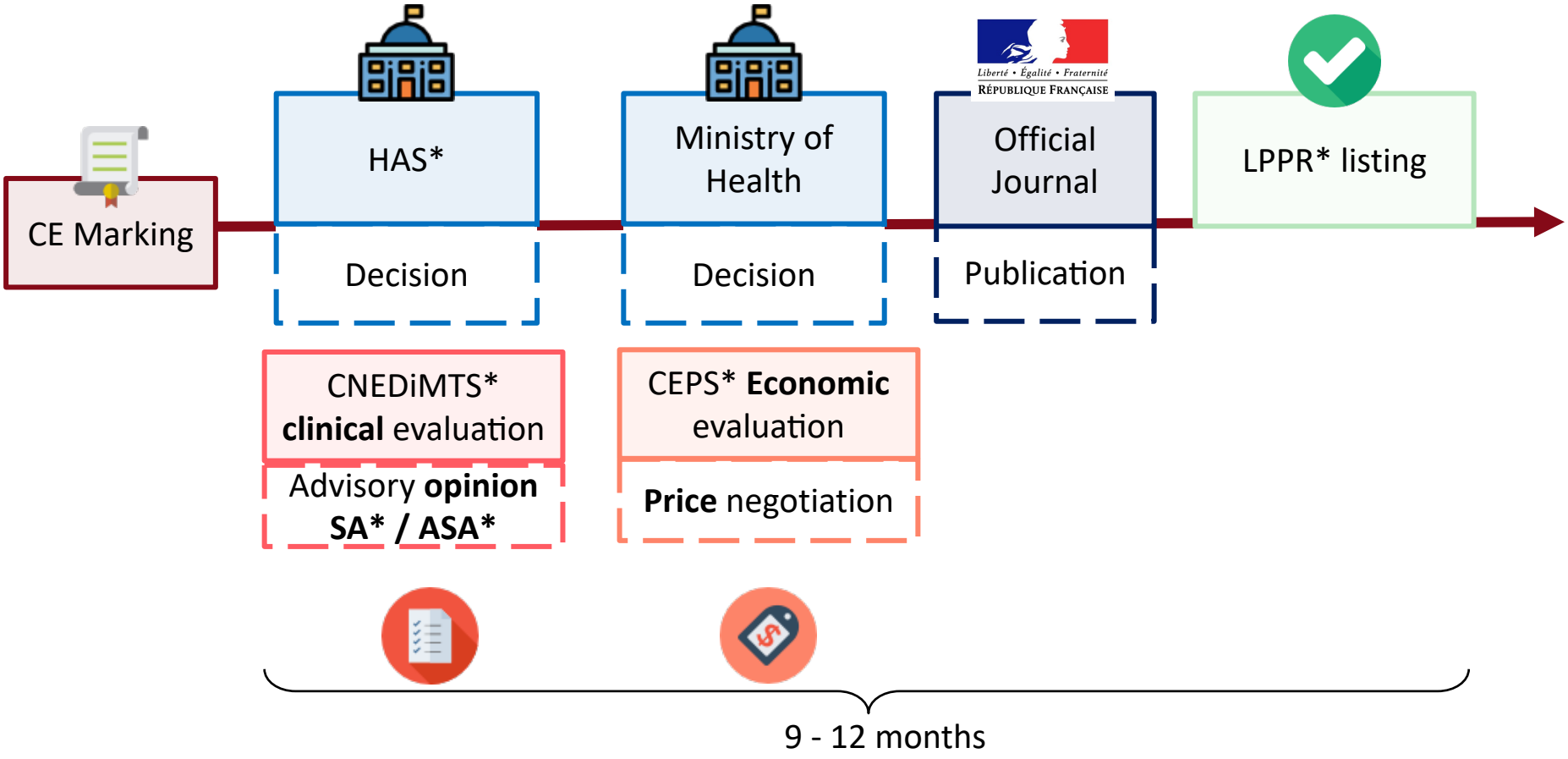
Medical device market access: How to process?



** CCAM: Common Classification of Medical Procedures; CEPS: Economic Committee for Health Products; CNEDMITS: Authority assessing medical devices; DRG: Diagnosis Related Group; LPPR: List of Reimbursable Products and Services; UNCAM: National Union of Health Insurance Funds*

Standard Market Access pathways

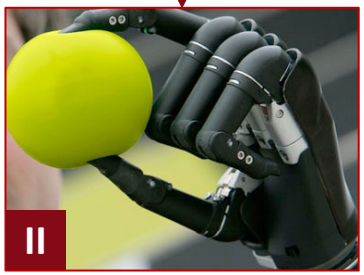
LPPR listing

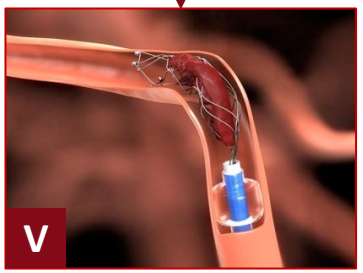


* ASA: Amélioration du Service Attendu (*Expected clinical added value);* CEPS: Comité Economique des Produits de Santé *(Economic Committee for Health Products);* CNEDIMTS: Commission nationale d'évaluation des dispositifs médicaux et des technologies de santé *(Authority assessing medical devices);* HAS: Haute Autorité de Santé *(High Authority of Health);* LPPR: Liste des produits et prestations remboursables *(List of reimbursable products and services);* SA: Service Attendu *(Expected clinical value)*

LPPR

LPPR
List of reimbursable products and services





5 titles

Title I: Medical devices for life support, dietary foods and articles for dressings.

Title II: Orthoses and external prostheses.

Title III : Invasive medical devices, implants and tissue grafts of human origin.

Title IV: Vehicles for the physically disabled.

Title V : Invasive medical devices not eligible under Title III.

Standard Market Access pathways

Pricing

Reimbursement is conditioned by a positive HAS* opinion (sufficient SA*).

Tariffs are quite related to the level of ASA* (*vs.* comparator) given by the HAS*.

HAS

CEPS – Comité Économique des Produits de Santé

ASA I (major) **ASA II (important)** **ASA III (moderate)**	>	**Chance for the device to get a higher tariff than therapeutic alternatives**
ASA IV (minor)	=	**Same tariff than comparators**
ASA V (absence)	≤	**Possibly same tariff but risk to get a lower tariff than therapeutic alternatives**

* ASA: Amélioration du Service Attendu (*Expected clinical added value);* CEPS: Comité Economique des Produits de Santé *(Economic Committee for Health Products);* HAS: Haute Autorité de Santé *(High Authority of Health);* SA: Service Attendu *(Expected clinical value)*

3. Innovation pathways

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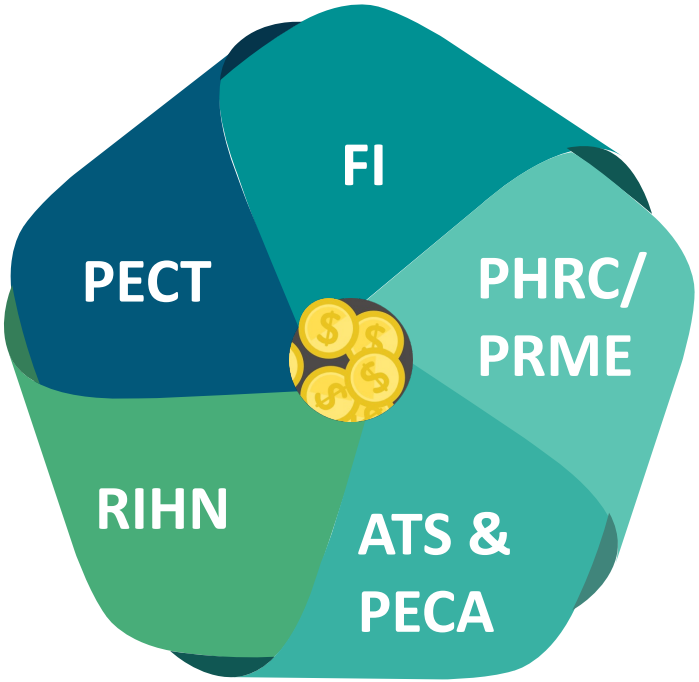
Innovation pathways

France has several pathways to promote innovation

Innovation Package

Early access (« Prise en charge transitoire »)



Hospital clinical research program/ Medico-economic research program

Framework for innovative non-nomenclature procedures

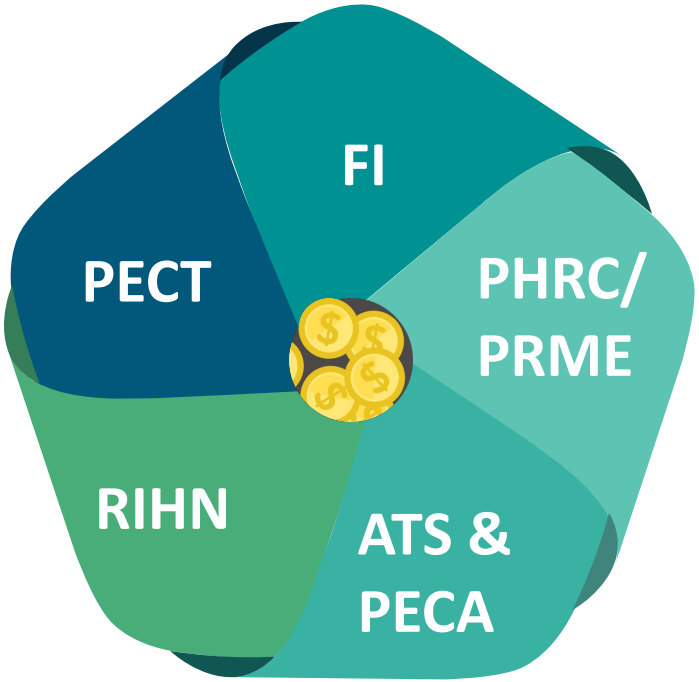
Digital Health solutions

Innovation pathways

France has several pathways to promote innovation

Innovation Package

Early access (« Prise en charge transitoire »)



Hospital clinical research program/
Medico-economic research program

Framework for innovative non-nomenclature procedures

Digital Health solutions

Innovation pathways

PECT: Early access

PECT: Early Access
An anticipated reimbursement for innovation

Principles of PECT
- Fast-track reimbursement.
- Preliminary to LPPR listing.

Commitments
Application for registration on the LPPR **within 12 months.**

Benefits
Accelerated procedure: **< 5 months from** submission of the application.
Allows **to anticipate a registration on the LPPR**, before obtaining study results.

Eligibility criteria
1. **Severe and/or rare disease or compensation for a disability**.
2. No relevant comparator (e.g. not used in clinical practice) / no relevant therapeutic alternative (**unmet medical need**).
3. Significant **improvement in clinical status** or disability compensation (huge expected clinical added value *vs*. clinical practice in France).
4. **Innovation**, novelty character.
5. **Clinically relevant efficacy** and **acceptable potential adverse effects**.

**PECT : prise en charge transitoire / LPPR: nomenclature of medical devices and services*

PECT: Early Access
Example

The very first Medtech early transitional funding (PECT)

NEOVASC REDUCER System (Coronary sinus reduction system)

- **Positive HAS opinion** 42 days after the complete application
- **Published in the JO on March 07, 2022** 142 days after the complete application

Innovation pathways

Digital Health's Market Access

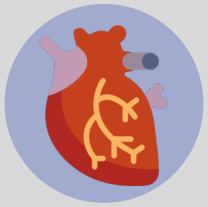
Digital Health's Market Access

France : Long history of experimentation in telemedicine (ETAPES)

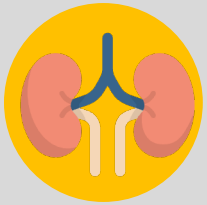
2014

Launching the first experimentation enabling Remote Patient Monitoring (RPM) reimbursement.

Monitoring patients affected by one of **5 chronic diseases :**



Heart failure



Renal failure

Respiratory failure

Diabetes

Implantable heart prostheses

Digital Health's Market Access
Transition to common law

Recent **regulatory updates** regarding **Remote Patient Monitoring (RPM) solutions** and **Digital Therapeutics (DTx).**

Experimentation

étapes télémédecine

ETAPES program

Transition into the common Law

Until June 30, 2023

Sustainable reimbursement

RÉPUBLIQUE FRANÇAISE

Specific RPM* list (new)

\+ Creation of an early access pathway for digital health solutions (upcoming in 2023)

\+ Clarification of the already existing reimbursement process for Digital Therapeutics (DTx)

**RPM: Remote Patient Monitoring*

Digital Health's Market
Different types for different pathways

A **digital medical device** is any software that meets the definition of a medical device set forth in the EU Regulation 2017/745. It may require the use of a data collection accessory.

Digital therapeutics (DTx)

Scientifically validated treatments based on a **digital medical device** (mobile apps, connected devices) **without remote patient monitoring feature**.

⇒ **Prevent**, **manage** or **treat** a medical condition or disease.

Remote Patient Monitoring (RPM) activity

Digital medical device
collect, analyze and transmit physiological, clinical or psychological data and issue alerts.
+
Medical monitoring
analyses the data and alerts transmitted by a digital medical device.

⇒ **Detect** worsening of the patient's health condition, **modify** the disease management.

**RPM: Remote Patient Monitoring*

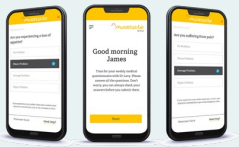
Digital Health's Market
Examples

deprexis®

deprexis® is a **digital psychotherapy accessible online**. Its a **software** used by patients independently, without any interface with health professionals.

DTx

moovcare By Sivan



Moovcare® is a **web application** that detects relapse or complications during follow-up of lung cancer patients.

DTx

diabeloop

The DBLG1 System is an **external hybrid closed-loop medical device** connecting **continuous glucose monitor**, **patch insulin pump** and a hosting Diabeloop **algorithm**.

DTx

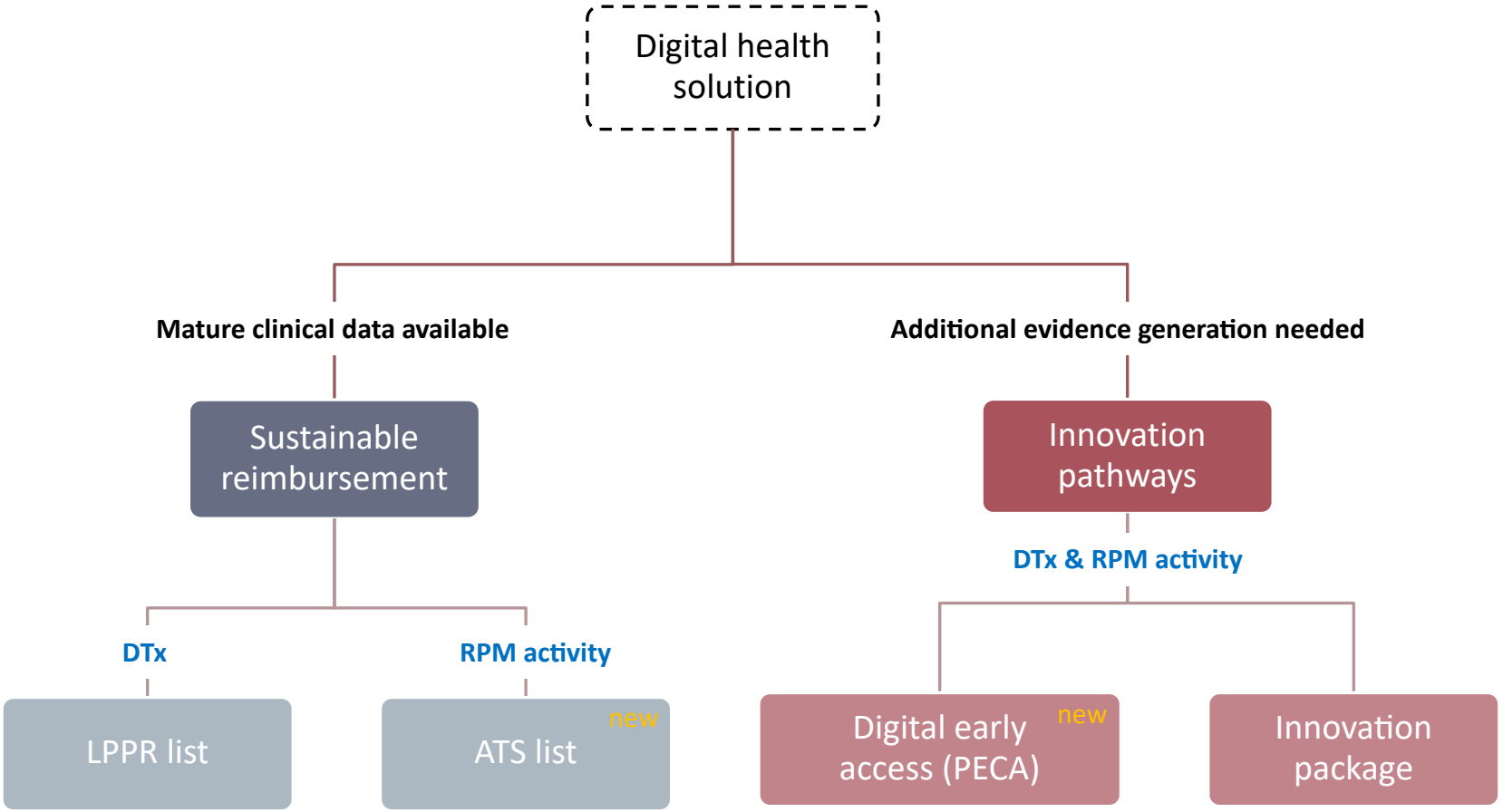
diabeo

Diabeo® is a medical device **software and associated service** to assist in processing by insulin in a basal-bolus regimen coupled with **remote medical monitoring**.

RPM

**RPM: Remote Patient Monitoring*

Digital Health's Market Access
Pathways



LPPR: List of reimbursed products and services / RPM: Remote Patient Monitoring / PECA: Pise en Charge Anticipée / ATS: Activité de télésurveillance

4. How to optimize your French Market Access ?

How to optimize your French Market Access?
Pitfalls to avoid / Questions to ask

Not thinking about reimbursement because you don't have enough data.

- What are the HAS clinical level of requirements in my therapeutic area/device category ?
- Is there an innovation pathway that can help me develop/fund my pivotal clinical trial ?
- Is there a specific indication for which there is a high unmet need to focus on first ?

Not anticipating your Market Access strategy (even before the CE marking ++).

- What is the purpose of use of my medical device (Collective/Personal, Hospital/Town) ?
- To which Market Access pathway my device is eligible for (LPPR/ATS, Brand name/Generic line…) ?
- What are the HAS clinical requirements (specific to my device category/indication) ?

Not integrating the tariffication parameter in your development strategy.

- What is my comparator ?
- What is my target ASA level ?
- What is my target population ?

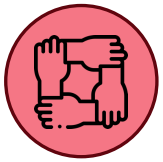
** ASA: Added Expected value / *LPPR: List of reimbursed products and services / RPM: Remote Patient Monitoring / ATS: Activité de télésurveillance*

5. Go To Market Services

Go-To-Market

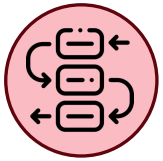
Your top 5 tactical needs

Enhancing the probability to get reimbursement with a premium price in due time

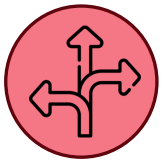


Building-up a community of early adopters willing to commit as an influencing supporter

Optimizing the timeframe of reimbursement submission to setup a commercial pre-launch



Planning the full commercial setup by assessing the best sales/marketing option



Flexibility: Speed up, slow down when necessary without incurring additional costs

Go-To-Market

The benefits of go-to-market to support market access

Targetting KOLs, reference centers and academic stakeholders to obtain support needed for reimbursement.

Gathering feedback from French early adopters to assist in the reimbursement process by health authorities

Trigger local funding in university hospitals to purchase innovative devices awaiting reimbursement

Identify potential partners/profiles at an early stage in order to kickoff just after the announcement of reimbursement

N.B. : At this early stage of market penetration, a full time employee based in France is NOT cost effective

6. MediTech Access / IGES Medtech

A Local + Global specificity

- Meditech Access has **a local vision in an international context,** in partnership with European partners.
- This partnerships allows us to deal with **National or European projects**: decrypting and scheduling key phases, global responses to all market access issues and pitfalls in Europe.

A six-part supply of services for European Market

STRATEGY AT LOCAL, NATIONAL & EUROPEAN LEVELS

PUBLIC AFFAIRS

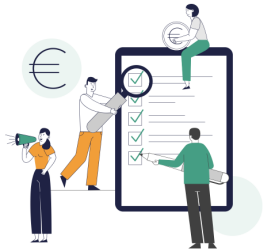
PRICING & NEGOTIATIONS

MEDICAL WRITING

TRAINING

DUE DILIGENCE & BUSINESS DEVELOPMENT

Market Access pathways in France
Conclusion



- Progress has been made in recent years in the introduction of innovative technologies (early access mechanisms for innovative medical devices, Digital Health's market access, implementation of the 2030 health innovation plan, widespread coverage of remote monitoring…) ;
- Innovations are currently being finalized: improved registration of procedures (High Council for Nomenclatures) ;
- However, much work remains to be done, particularly to simplify the reimbursement process for new technologies and reduce the time to market

Thank you!

Questions