

French Market: Webinar Trainings for SMEs on Reimbursement and Reaching Market

French Market Webinar



Introduction and overview of the key principles of the French healthcare system (Anouk)



IVD market and market access (Frédéric)



MD market and market access (Anouk)



Q&A (10 minutes)

Overview of the key principles of the French healthcare system

Social insurance financing, increasingly supported by taxation

A solidarity-based system: Contributions are largely based on income, while access to healthcare is based on need.

Social contributions

Employer and employee contributions: the traditional foundation of healthcare financing

CSG and dedicated taxes

The CSG, VAT and taxes on tobacco, alcohol, pharmaceutical and medical device companies

Government funding

Budget contributions to support solidarity-based schemes and compensate for contribution exemptions

Health spending is about 12% of GDP. Universal coverage (PUMa) has applied to all residents since 2016.

Source: DREES, Assurance Maladie (approximate figures)

Coverage: AMO first, AMC on top

~80%

AMO

Compulsory health insurance (Assurance Maladie). Reimburses a base tariff; 100% for long-term conditions (ALD) and maternity.

~12%

AMC

Complementary insurance (mutuelles, insurers). Covers co-payments; C2S gives free cover to low-income households.

~8%

Out-of-pocket

Remaining cost to patients. The 100% Santé reform removes it for selected dental, optical and hearing care.

A gradual shift from public to complementary health insurance funding and OOP

Share of total health consumption. Source: DREES

Care delivery: private practice and hospitals

Ambulatory care (liberal system)

- Independent GPs, specialists, nurses, physiotherapists, pharmacies and labs
- Fee-for-service, free choice of provider, with a referring GP (médecin traitant)
- Fees set by national agreements; sector 2 doctors may bill above the base tariff

Hospital care

- Public, private non-profit (ESPIC) and private for-profit hospitals
- Activity-based pricing (T2A) plus grants for emergency, psychiatry and public-interest missions
- Regional planning by the ARS; public hospitals grouped in GHT

Key reimbursement mechanisms

Tool	What it covers	How it pays
Professional act CCAM and NABM	Medical procedures by doctors: surgery, imaging, endoscopy Laboratory tests (medical biology)	Fee per act/ per test; in hospital, acts also classify the stay
LPP Liste en sus	Ambulatory: Devices and care products: dressings, wheelchairs, pumps Hospital: Costly drugs and devices used in hospital	Tariff set after HAS review and CEPS pricing
GHS	Hospital stays, grouped by diagnosis and procedures (GHM)	Flat price per stay under T2A

PLFSS 2027 : addressing a persistent Social Security deficit

-€12.7bn

Deficit target for 2027, from -€21.8bn in 2026

+2.0%

ONDAM growth (€278.7bn), vs a 3.4% trend

€5.1bn

Extra savings: €3.9bn net of new spending

Where levies grow

Employer reliefs

€3.7bn fewer general reliefs

Complementary insurers

Special contribution extended (€1.1bn)

Industry

Price cuts and reimbursement reviews, specific taxes and contributions

Public health tax

Sugar tax extended to some processed foods

Snitem

sidiv
L'industrie du diagnostic in vitro
au cœur de la santé

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L'industrie du **diagnostic in vitro**
au cœur de la santé

Financing diagnostics in France: market, innovation access and biology funding

MedTech Europe webinars for SMEs

Frédéric Fortis

October 13, 2026

What we will cover today

01



SIDIV, IVD market and general context

Who we are, and why French reimbursement works through medical biology acts

15 min

02



Financing innovation

New routine biology medical acts submissions
RIHN, the specific access pathway for innovative diagnostics

15 min

03



Financing Medical biology

The pact for medical biology and point-of-care testing (POCT)

10 min

04



SIDIV perspectives

wrap-up

Section 1

SIDIV, IVD market and French context

Who we are, what the sector represents, and why diagnostics are financed differently in France

SIDIV: the voice of the IVD industry in France



A single, representative industry body

- SIDIV brings together the companies that design, manufacture and supply in vitro diagnostic (IVD) solutions in France.
- Members span the full value chain — innovation, manufacturing and distribution — from innovative start-ups and SMEs to French mid-caps and international leaders.
- The association is the sector's reference interlocutor with public authorities, learned societies and payers.
- Our purpose: have the value of diagnostics recognized and help build a legal and economic framework fit for the sector.



€2 bn

Sector turnover in France (85% of which are covered by SIDIV members)



75+

Member companies, 61% SMEs & innovation start-ups



13,200+

Direct high-skill jobs across every region



> 70%

Of medical decisions informed by IVD

What SIDIV works to achieve

01



Recognise the IVD efficiency

Have the holistic value of IVD — patient care, organisational, economic and societal — known and recognized.

02



Position IVD in care

Place diagnostics at their right place along the patient pathway, from prevention and surveillance to diagnosis, treatment and follow-up.

03



A fit-for-purpose framework

Co-build governance, regulation and financing adapted to the specific logic of IVD.

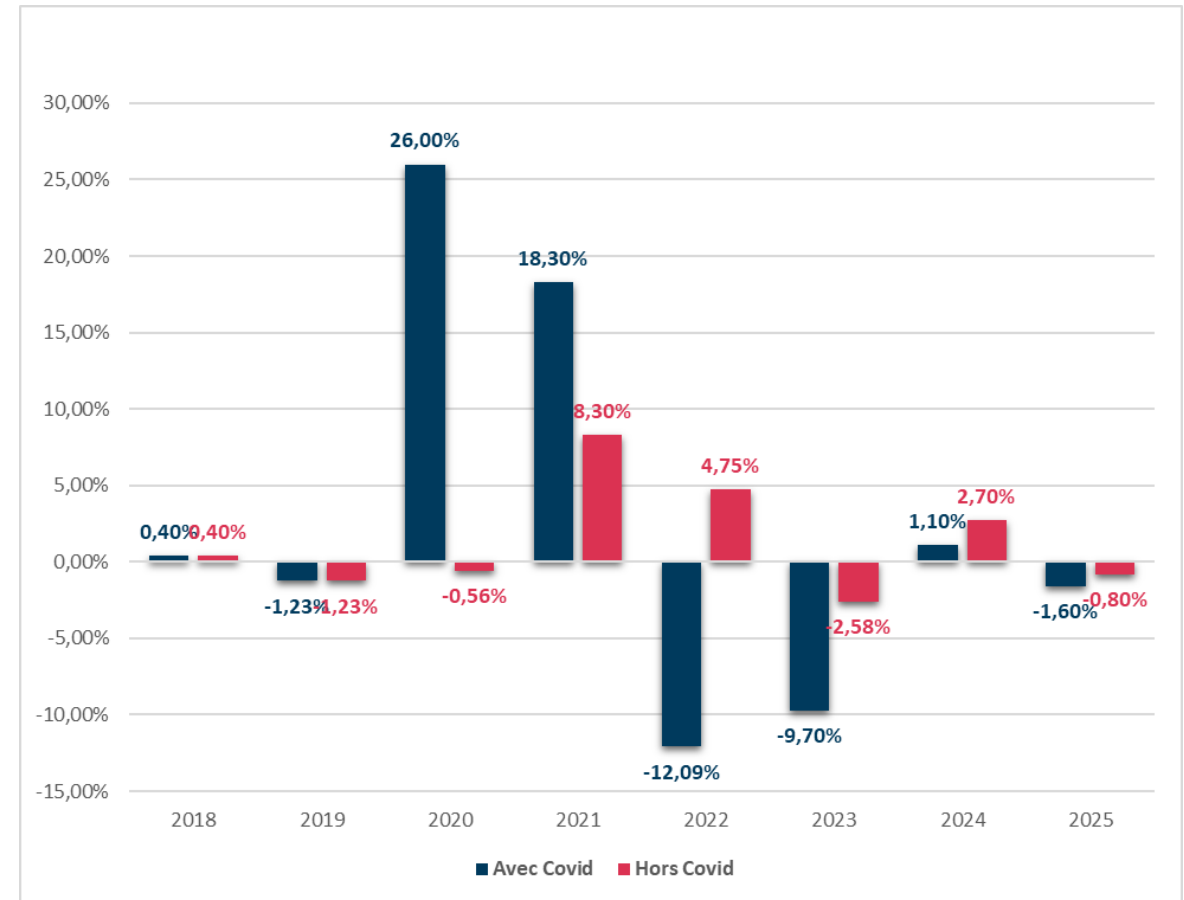
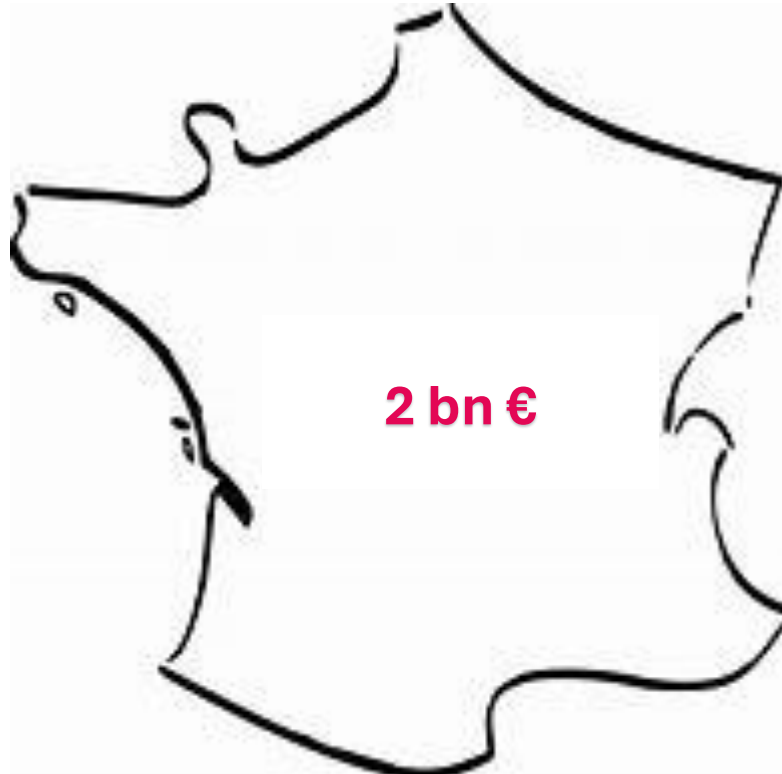
04



Secure the industrial base

Objectivise industrial stakes upstream of tariff decisions to protect supply and innovation.

IVD market annual evolution since 2018



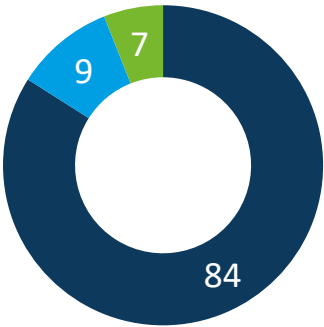
With Covid

Without Covid

A market built on reagents, instruments and services

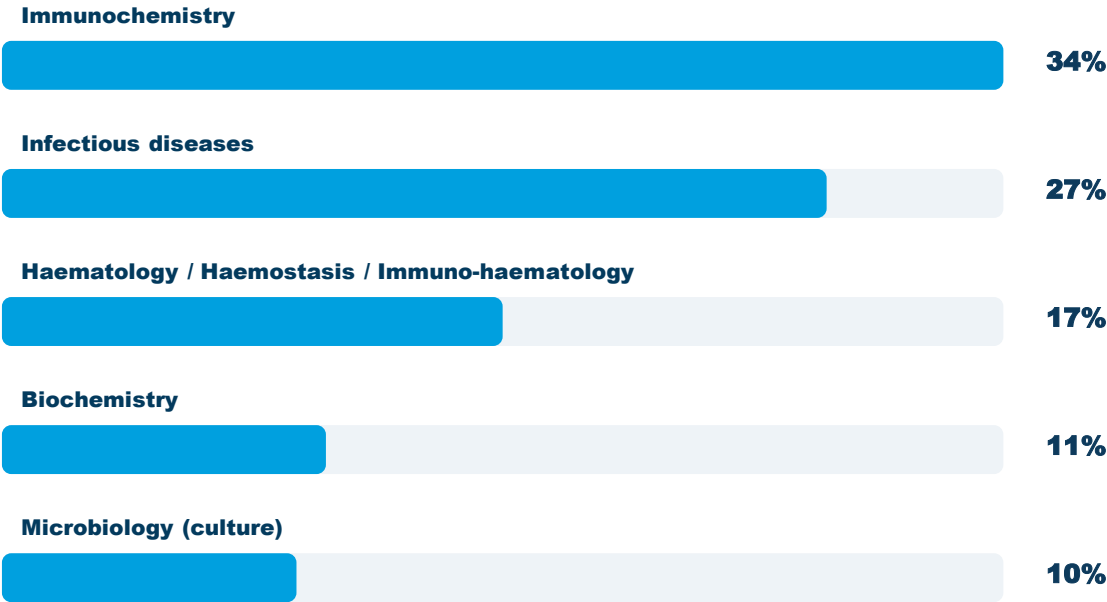
IVD revenue is concentrated in the reagents used for each test, complemented by instruments and support services.

Revenue structure



- Reagents
- Instruments, consumables & software
- Services (maintenance & training)

Within reagents (84% of turnover)



The French specificities

In France, IVD is reimbursed through the medical biology act — not the device



France — the act-based model

- The IVD test is inseparable from the medical biology act it feeds, including 3 steps
 - pre-analytical (sample collection and preparation)
 - analytical
 - post-analytical (results validation and interpretation).
- Reimbursement flows to the professional act, not to the device.
- The technology share inside the act is neither separately identified nor valued.
- The manufacturer is considered as a supplier — outside tariff arbitrations yet fully exposed to their effects.
- Tariff dialogue for medical biology acts runs through CNAM and DSS depending on the channel (routine or innovative medical biology act).
- Rigid annual filing window for new routine act submissions



Elsewhere in Europe

- Several systems use dedicated reimbursement codes updated frequently (e.g. quarterly catalogue revisions).
- The technology component is more visible, and the link between assessment and reimbursement is more direct.
- Manufacturers are, in varying degrees, associated with the pricing process.
- Continuous or frequent filing removes the artificial delays created by rigid annual windows to file a reimbursement dossier.



Why it matters: because value is captured at act level, the diagnostic industry is structurally invisible in funding decisions — the root cause behind every issue in the following sections.

Differences between public and private sectors

For routine medical biology acts (not innovative)

	 Private sectors	 Public sectors
Hospitalized patients	NABM CCAM common law reimbursement = Lists of medical biology acts with code / description / price	GHS = package for the comprehensive care of a patient at the hospital
Patients in consultation		NABM CCAM
Patients in emergency department	“ Forfait urgences” = package for the comprehensive care of a patient in the emergency department	

Section 2

Financing Innovation

New routine biology medical acts submissions

RIHN, the specific access pathway for innovative diagnostics for which data collection is still needed

A pathway of 2 to 5 years — often longer

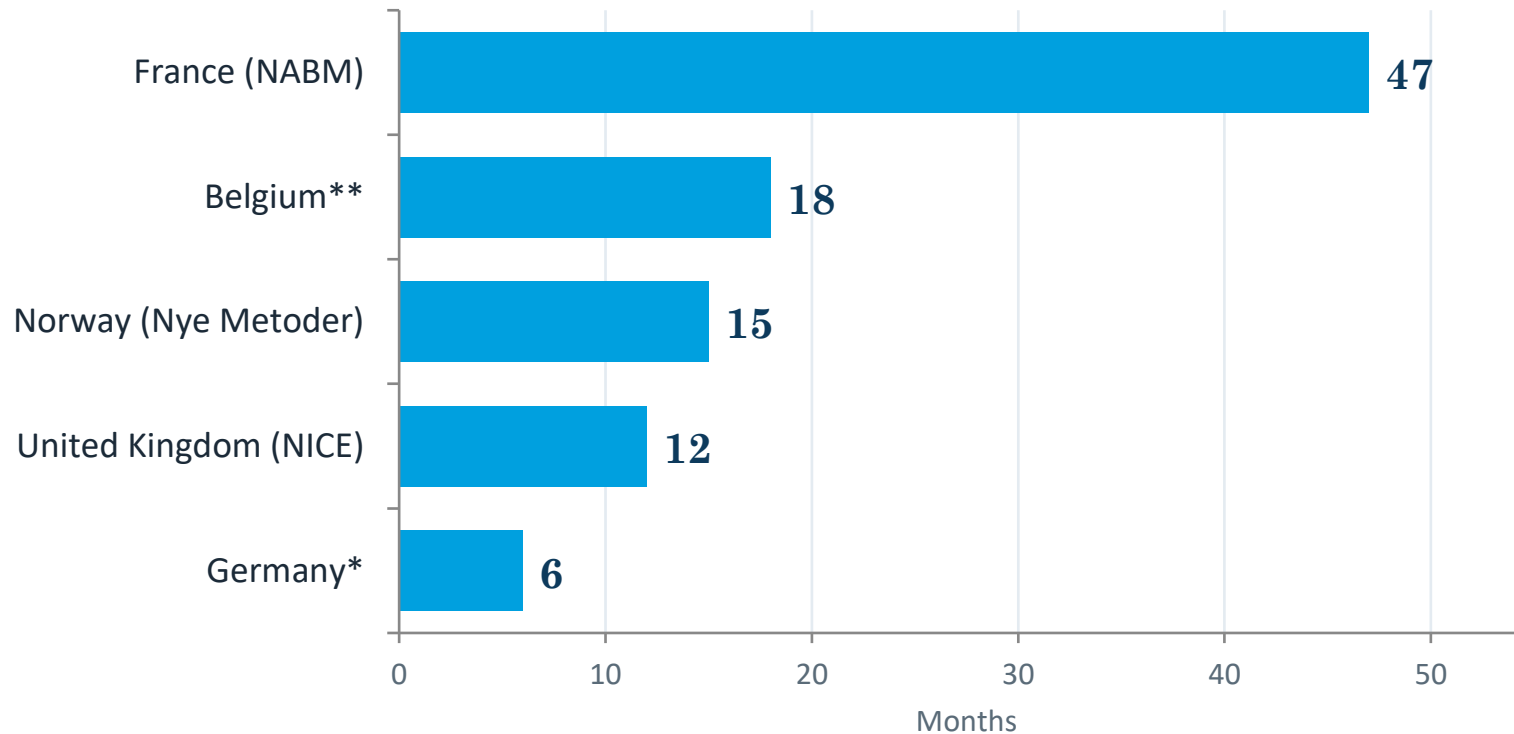
For new routine biology medical act (for which no additional data collection is necessary), five steps stack up to reach common-law reimbursement (NABM/CCAM). The post-assessment pricing phase is the weakest link — and neutralizes any upstream acceleration.



A long reimbursement process to introduce new routine professional acts which slows down patients' access, with a lack of clarity and predictability throughout the entire process

France lags of access for reimbursement

Time to full patient access to a new routine biology medical act (estimated, months). Rigorous assessment elsewhere is delivered without France's redundancy and delay.



**Germany: intermediate hospital access via NUB from ~6 mo. **Belgium: first access via pilot Convention (~15-18 mo).*

Three invariants of high-performing systems



Agile continuous or frequent filing — no artificial windows



A direct, predictable link between assessment and reimbursement



Published methods, transparent timelines and deliberations, formal industry consultation

RIHN

The main derogatory support mechanism for innovative medical biology for which data collection is still needed



Key features

- ✓ Mechanism launched in 2015
- ✓ Allows early, temporary and derogatory reimbursement of innovative medical biology acts
- ✓ Financed by a fixed budget ("MERRI") : 521M€ in 2025 and 2026
- ✓ Medical biology acts are reimbursed at ~ 40% of their value
- ✓ ~600 acts are blocked on the LAHN list, awaiting HAS assessment (~20 HAS assessments per year) an annual tariff discount (20% in 2025, then 10%/yr) that erodes reimbursement



RIHN 2.0

- Reform launched 2024.
- Objectives :
 - Streamline the process (acts entry and exit)
 - Ensure data collection that will allow HAS evaluation
 - Speed up the reimbursement process
 - Allow manufacturers to file acts in the mechanism



Main RIHN points for attention :

- **Continuity of reimbursement of the ~600 LAHN acts whose clinical utility is already established (awaiting HAS assessment in the context of the annual tariff discount)**
- **Make the RIHN 2.0 mechanism operational, sustainable and compatible with the specific characteristics of the IVD sector**
- **Finance the RIHN outflows in the public sector where acts are financed through packages for the comprehensive care of a patient**

The real challenge is the access pathway



The issue is the fracture of the market-access and reimbursement journey — illegible, unpredictable, sequential, long and full of gaps.



Inefficient sequencing

Europe / ANSM (CE mark) → HAS → payer runs in silos. Data already validated for CE marking is re-examined at following steps.



Misaligned doctrines

The gap between EU IVDR requirements and French funding logic creates major legal and economic uncertainty.



Missing IVD expertise

Agencies lack dedicated skills to absorb files and grasp technological shifts — genomics, POCT, AI, medico-economics.

Three flagship proposals



A permanent inter-agency liaison committee — a functional single window, at constant law



Reinforced IVD & medico-economic expertise at HAS and ANSM



Transparency of pricing and proportionality of assessment

Pragmatic reforms proposed by SIDIV

At constant law



01

Single functional window

A permanent inter-agency liaison committee (ANSM, HAS, DGS, DGOS, DSS, CNAM) — no new structure.



02

Filing “as they come”

Remove rigid windows for NABM inscription; move to continuous filing, as already exists for RIHN 2.0.



03

Proportionality

Stop re-examining data already validated at CE marking; focus on French clinical & economic added value.



04

Reinforced expertise

Dedicated IVD and medico-economic skills; consider micro-costing and budget-impact analyses.



05

Transparency

Publish IVD-specific methods; open deliberations; associate industry with act pricing.



06

Align with Europe

Mirror the EU priority (breakthrough innovations, HTA); clarify LDT and POCT; anticipate AI-enabled technologies.

Section 3

Financing medical biology

**The pact for medical biology
and point-of-care testing**

The pact for the future of medical biology

A national mission (IGAS) is reshaping how medical biology is organised and financed. SIDIV contributes an industrial reading, in support of the biologists' unions.



A specific logic

IVD follows its own logic, distinct from drugs and therapeutic devices. It cannot be assessed with the same grid.

Governed by the EU IVDR (Reg. 2017/746)



A driver of efficiency

Early, better-targeted decisions mean avoided hospitalisations and fewer unnecessary acts — value well beyond the test itself.

> 70% of medical decisions



A European stake

Attractiveness is decided at EU level (Ex breakthrough innovations).
National fast-track schemes should mirror the EU priority CE-marking route (ex : reimbursement pathways, clinical studies authorizations, ...)

Aligned with EU reform of MDR / IVDR

The core of the problem :

~600

acts on the out-of-nomenclature list (LAHN)

~20

files assessed per year at current pace

< 2%

of healthcare expenditure (DREES 2024)

~47 mo

to first patient access vs ~6 mo in Germany

Shared diagnosis, plus an industrial dimension



What SIDIV supports

- ✓ Two ring-fenced envelopes to exit the old RIHN — one hospital, one community.
- ✓ A smoother assessment gateway: no annual cap, fast-track for urgent acts, filing “as they come”.
- ✓ Companion tests listed within three months of the linked therapy's approval.
- ✓ A single window bringing together ANSM, HAS, DGS, DGOS, DSS and CNAM.
- ✓ Systematic use of medico-economic value in assessment and pricing.



What SIDIV adds: the industrial angle

- The technology component of the act must be explicitly identified and valued — not diluted in a fee designed for professional work alone.
- Manufacturers must be formally associated with act pricing (NABM & CCAM), with a review clause working both ways.
- Reinforced resources and IVD expertise at HAS and at the bodies that set tariffs.
- Fast track for breakthrough innovations (reimbursement process)
- End of annual tariff discount for the ~600 acts blocked on the list of derogatory reimbursement until HAS assessment

Point-of-care testing: value and a funding gap

Point-of-care testing (POCT / EBMD) brings the analysis close to the patient. A February 2026 decree opens it to new settings — but it needs a dedicated economic model.

Why it matters



Relieves emergency departments

Faster decisions, fewer avoidable hospitalizations.



Fights antimicrobial resistance

Right pathogen, right antibiotic — fewer inappropriate prescriptions.



Reaches medical deserts

Supports “going-to” outreach and territorial equity of access.



Prepares for epidemics

Mass screening, early cluster detection and epidemiological follow-up.



The gap in the model on the table

- The scheme concentrates value on the supervising biologist alone, through the standard act fee.
- But POCT relies on a chain — physicians and nurses who run the test, and manufacturers who equip and connect it.
- Tariff neutrality : no dedicated funding line for the technology component or the contribution of healthcare professionals; devices financed by pushing costs onto industry.

Section 4

SIDIV perspectives

What SIDIV will do — and what we ask



SIDIV in action

- ✓ Collaborate with relevant stakeholders (HAS, DGS, healthcare professionals) to shape an efficient RIHN 2.0 mechanism
- ✓ Bring proposals to the institutional tables — IGAS missions, institutional concertations, learned-society coalitions.
- ✓ Bring together stakeholders — biologists, clinicians, payers, patient voices — around shared, workable solutions.
- ✓ Meet decision-makers to present our proposals
- ✓ Respond to the HAS's consultations on the draft evaluation reports prior to their publication



Our main asks to public authorities

- Recognise and value the technology component of the diagnostic act.
- Associate manufacturers formally with act pricing (NABM & CCAM).
- Set up a permanent inter-agency liaison committee — at constant law.
- Ring-fence a dedicated 2027 POCT envelope, distinct from conventional biology.
- Resource HAS and pricing bodies with genuine IVD expertise.
- Ensure the continuity of reimbursement of the LAHN acts whose clinical utility is already established until HAS assessment
- Reshape the RIHN 2.0 mechanism
- Finance the RIHN outflows in the public sector
- Develop fast-track pathways for urgent situations

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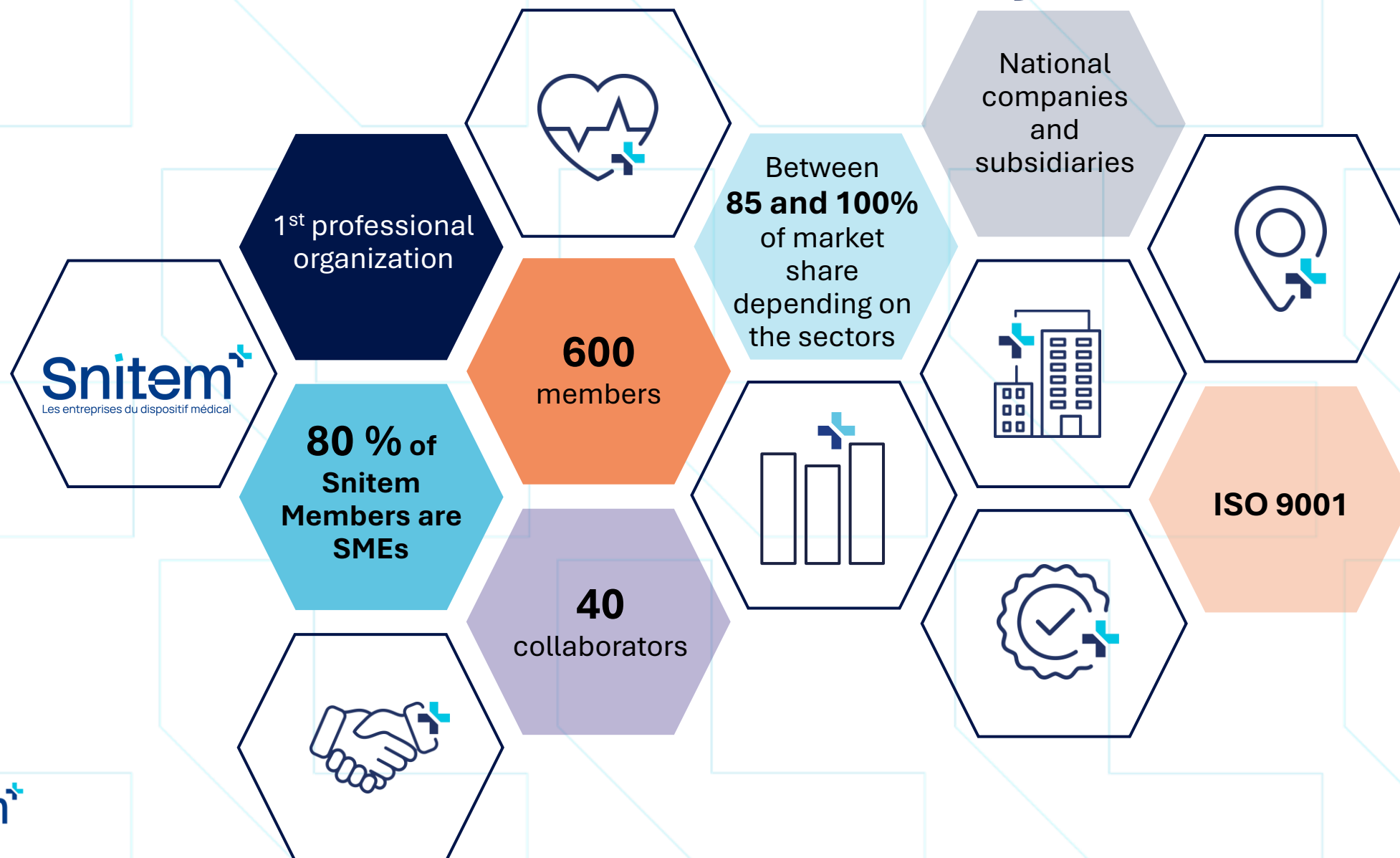


Q&A (10 minutes)

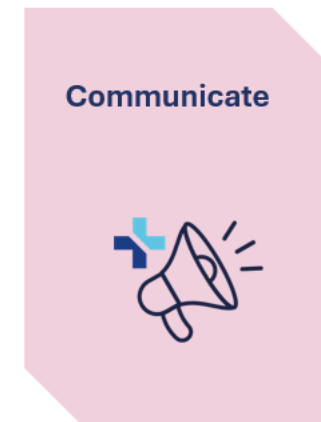
Understanding medical device reimbursement procedures in France

Snitem : SERVING THE MEDICAL DEVICE INDUSTRY

Snitem, the French medtech industry association



Areas of expertise and priorities



Medical Device Companies in France

€35,7
billion



In revenue in 2025

2nd
in Europe

With a 12,8% market
share



1,500
compagnies

including 95% de SMEs



90 200

directs jobs

410



Manufacturing sites

Source: Snitem 2026 Panorama of Medical Device Companies

Agenda

01

Introduction

02

Standard reimbursement pathways

- ➔ GHS: the hospital's "all-inclusive" tariff
- ➔ LATM: reimbursement of remote patient monitoring
- ➔ LPP: reimbursement in community and hospital settings
- ➔ CCAM: funding of professional procedures

03

Early access schemes

- ➔ The Forfait Innovation (FI)
- ➔ PECT (transitional coverage)
- ➔ PECAN (early coverage for digital devices)

04

Institutional stakeholders

05

Key takeaways

- ➔ Back up slides



01

Introduction

Context and fundamentals

The 3 questions to ask **BEFORE** anything else

Your reimbursement strategy starts here

01

What type of use?

- **Individual use**
 - whose function continues **beyond the HCP's procedure**
 - whose function **does not continue beyond the HCP's procedure**
 - **Collective use** (hospital equipment)
- ⇒ **The answer determines the reimbursement pathway**



02

Where will it be used?

- **In hospital:**
 - ⇒ covered by GHS tariffs
- **In the community:**
 - At home
 - In private practice
 - ⇒ LPP and/or CCAM



03

Level of clinical evidence?

- **Sufficient:**
 - ⇒ Standard coverage
- **Insufficient:**
 - ⇒ Early access scheme / no coverage



02

Standard reimbursement pathways

Different pathways depending on your device

4 funding pathways: which one for my MD?

Each device follows a different path

1

Hospital

GHS

Homogeneous Hospital Stay Groups

- MD included in the hospital tariff
- No specific assessment required
- E.g. dressings, scalpels, defibrillators...

Intra-GHS list

Specific categories
(defibrillators, stents...)

2

Hospital / Community

LPP

List of Reimbursable Products and Services

- Individual-use MDs in the community or in hospital
- E.g. insulin pump, prosthesis, wheelchair

Add-on list (liste en sus)

Innovative, costly MDs used in hospital

3

Hospital / Community

LATM

List of Remote Medical Monitoring Activities

- Remote medical follow-up by a healthcare professional
- DMD (digital medical device) – individual-use software
- Collects data and generates alerts
- E.g. RPM DMD for heart failure

4

Hospital / Community

CCAM

Common Classification of Medical Procedures

- Funding through the associated medical procedure

GHS: the hospital's “all-inclusive” tariff

Homogeneous Hospital Stay Groups — basic hospital funding

1

✚ How does it work?

- The hospital receives a global tariff per type of stay (GHS = Homogeneous Hospital Stay Group)
 - ➡ *Example: simple appendectomy ≈ €2,345 in public / ≈ €1,112 in private hospitals*
- This tariff covers EVERYTHING: staff, premises, equipment, drugs, MDs (except innovative / very costly products ⇒ funded as add-ons)
- The hospital freely negotiates prices with manufacturers through tenders

Dedicated funding for innovation may exist within hospitals:

Examples:

- **MERRI** (Teaching, Research, Referral and Innovation Missions), including the **PHRC** (Hospital Clinical Research Programme)
- **AC** (contractual support funding)
- **FIR** (Regional Intervention Fund)
- **Innovation envelope / budget**

What this means :

- ✓ Immediate access after CE marking — no HAS assessment required*
- ✓ Your MD competes in hospital tenders
- ✓ Target hospital buyers

✚ * Note – intra-GHS list:

- Some MDs (defibrillators, intracranial stents...) must ALSO be listed on the intra-GHS list
- Requires an assessment by the CNEDiMTS (HAS committee)

LPP: reimbursement in community and hospital settings

List of Reimbursable Products and Services — the main route for individual-use MDs

2

What is the LPP?

- “Positive” list of products and services reimbursed by the National Health Insurance
- For individual-use products: in the community, at home, or in hospital on top of GHS tariffs

2 listing routes:

Generic description: your product fits an existing category

⇒ **about 2 months (self-registration)**

Brand name: “innovative” product with no existing category

⇒ **6 months (regulatory deadline) for CNEDiMTS assessment + CEPS pricing**

The 5 titles of the LPP:

Title I: home treatments, daily living aids, dressings

Community

Title II: orthoses and prostheses

Community

Title III: implantable MDs used in hospital (> 30 days)

Hospital

Title IV: vehicles for disabled people (wheelchairs)

Community

Title V: invasive MDs in hospital (< 30 days)

Hospital

Add-on list (liste en sus):

- Innovative and costly MDs, **funded ON TOP OF the hospital GHS**
- Specific listing criteria (e.g. heterogeneous use across the country)
- Any MD on the add-on list must also be listed on the LPP

LATM: reimbursement of remote patient monitoring

List of Remote Medical Monitoring Activities (DMD + medical procedure)

3

✚ What is a remote monitoring DMD?

- **Medical device software** (within the meaning of MDR 2017/745) that collects patient data, analyses it and **generates alerts** for the healthcare professional
- It is not the data collection accessory (scales, sensor...): the **software** is the MD

✚ The 4 steps of RPM:

- 1 **Collection** — physiological data via digital or non-digital collection accessories
- 2 **Transmission** — to the software platform
- 3 **Analysis + alert** — **THE key function of the MD: no alert, no MD!**
- 4 **Medical response** — the monitoring physician adjusts patient management

Listing on the LATM

- **Generic line:** your software fits an existing category → individual code application + ANS certification
- **Brand name:** innovative product → ANS certification + CNEDiMTS assessment

Pricing (2 flat fees)

- **Technical fee** (company operating the device): decreasing with the active patient base, set according to the type of impact demonstrated
- **Operator fee** (monitoring HCP): €11 or €28/month/patient (possible increase depending on complexity)



E.g.: heart failure, diabetes, kidney failure, cardiac conditions (PCI, MCI)

CCAM: funding of professional procedures

The Common Classification of Medical Procedures

- For an MD requiring the involvement of a healthcare professional
- The MD is funded **INDIRECTLY** through the reimbursed medical procedure
- Examples: surgery, radiology, specialist consultation...

4

✚ If the professional procedure does not yet exist:

HAS assessment

HCN ranking

UNCAM pricing and decision

> 1,000 days

└─ Uncertain, lengthy process if the procedure does not yet exist:

- HAS does not assess every request
- Timelines are loosely regulated
- Little transparency on the process

✚ Dedicated workshop available on replay
Procedure-related MDs: navigating complex coverage procedures

The background features a dark blue field with several lighter blue geometric shapes. A large square is positioned in the upper right. A diagonal line runs from the top left towards the bottom right. In the bottom left corner, there is a square with a blue border. The text is overlaid on these elements.

03

Early access schemes

Enabling early market access for innovations

Early access schemes

When standard coverage is not yet available

- These are funding arrangements **ahead of standard coverage**.
- For **innovative MDs** that already have a minimum of data likely to support a presumption of innovation and a favourable benefit/risk balance.

+ These three schemes fit into different stages of development:

FI

Forfait innovation

Early development phase



PECT · PECAN

PECT and PECAN

The application must be made no earlier than one year before the standard coverage submission.



The Forfait innovation (FI)

For MDs at an early stage of development

+ What is it?

- Exceptional coverage of an MD or procedure that is **innovative and at an early stage**, for a limited period
- Condition: **conduct a clinical or health-economic study** during the coverage period
- Available even **without CE marking** (development phase)

+ Timeline

195 to 255 days

Regulatory review period

Players: HAS (assessment) +
Ministry (decision)

+ Key points

- It is the earliest route
- Generates data to prepare the standard coverage file
- **Note:** cannot be combined with other public funding
- Part of the study cost must be funded by the company

+ Eligibility criteria

Innovation	Novelty (breakthrough innovation)	Relevant study protocol	Obtaining the data missing for standard coverage
	Clinical or health-economic benefit		Comparative (unless impossible)
	Risk already characterised		Feasibility
	Early diffusion phase		

PECT: transitional coverage

For innovative MDs, just before standard coverage

+ What is it?

- Exceptional funding for MDs intended to **treat a serious disease or compensate for a disability**
- **Conditions:** CE marking + commitment to file for LPP listing within 1 year

+ Pricing

- If the MD is already on the LPP for another indication → **LPP tariff applies**
- Otherwise → **compensation set by the ministers**
- **Rebates:** after the PECT, repayment of any “overpayment” relative to the standard tariff obtained

+ Key points

- The PECT is a bridge between innovation and standard reimbursement
- Ideal route for CE-marked MDs that do not yet have sufficient data for the LPP
- **Maximum duration: 1 year**, non-renewable

PECT criteria

Treatment of a **serious or rare disease** or compensation for a **disability**;

No relevant comparators, so that the product meets an **unmet or poorly met health need**;

Significant improvement in patients' health status or disability compensation;

Presumption of innovation (novelty beyond a mere technological upgrade);

Presumption of **clinically relevant efficacy** with acceptable adverse effects.

PECAN: early coverage for digital devices

Specific to therapeutic DMDs (LPP) and remote monitoring DMDs (LATM)

+ What is it?

- Exceptional funding, **just before** standard coverage, for therapeutic or remote monitoring digital MDs
- **Conditions:** CE marking + presumption of innovation + ANS certification
- **Duration: 1 year maximum from submission of the file to the CNEDiMTS**, non-renewable
- Commitment to file for standard coverage within **6 months (LPP) or 9 months (LATM)**

+ Pricing

- **Therapeutic DMD (LPP):** €435 incl. VAT for the first 3 months, then €38.30/month — capped at €780 incl. VAT/year/patient
- **RPM DMD (LATM):** technical fee aligned with the LATM scale (max €50 incl. VAT/month/patient)

+ Key points

- The PECAN is designed for innovative digital MDs **for therapeutic or remote monitoring purposes**
- For any other type of digital MD, the PECT is the route to consider

PECAN criteria

Presumption of innovation (clinical or organisational)

Interoperability of data export



04

The stakeholders

The main institutional players involved in market access

Authorities in an MD's reimbursement pathway

From clinical assessment to publication in the Official Journal



Standard coverage



Early access



ANS

French Digital Health Agency

- Certifies compliance of DMDs with the security and interoperability framework

LPP / LATM

PECAN / PECT



HAS / CNEDiMTS

National Committee for the Evaluation of Medical Devices and Health Technologies

- Assesses the MD's expected benefit (SA) / benefit of the medical service (IPM)
- ± Assigns the level of innovation
- Positive opinion = key to listing

Intra-GHS / LPP / LATM / CCAM

FI / PECAN / PECT



CEPS

Economic Committee for Health Products

- Negotiates pricing terms with the manufacturer
- Criteria: level of innovation, European competitors' prices, target population

LPP



HCN and UNCAM

HCN: High Council for Nomenclatures

- Ranking of professional procedures

UNCAM: National Union of Health Insurance Funds

- Pricing and final decision

CCAM



Ministry

Ministry of Labour, Health and Solidarity

- Final listing decision
- Publication in the Official Journal (JORF)

Intra-GHS / LPP / LATM / CCAM

FI / PECAN / PECT



05

Key takeaways

The essentials in diagrams

The key questions to ask

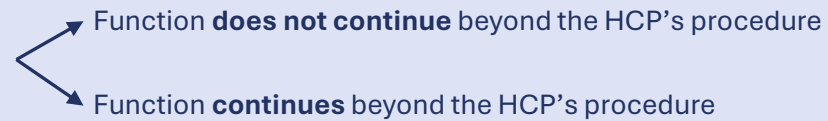
Over to you!

MD

1 WHAT IS THE MD USED FOR?

Collective use (equipment)

Individual use

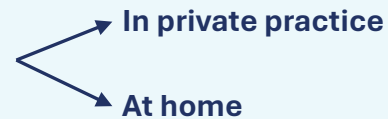


→ Eligibility (or not) for a reimbursement list

2 WHERE WILL IT BE USED?

In hospital

In the community



→ Payer and funding arrangements

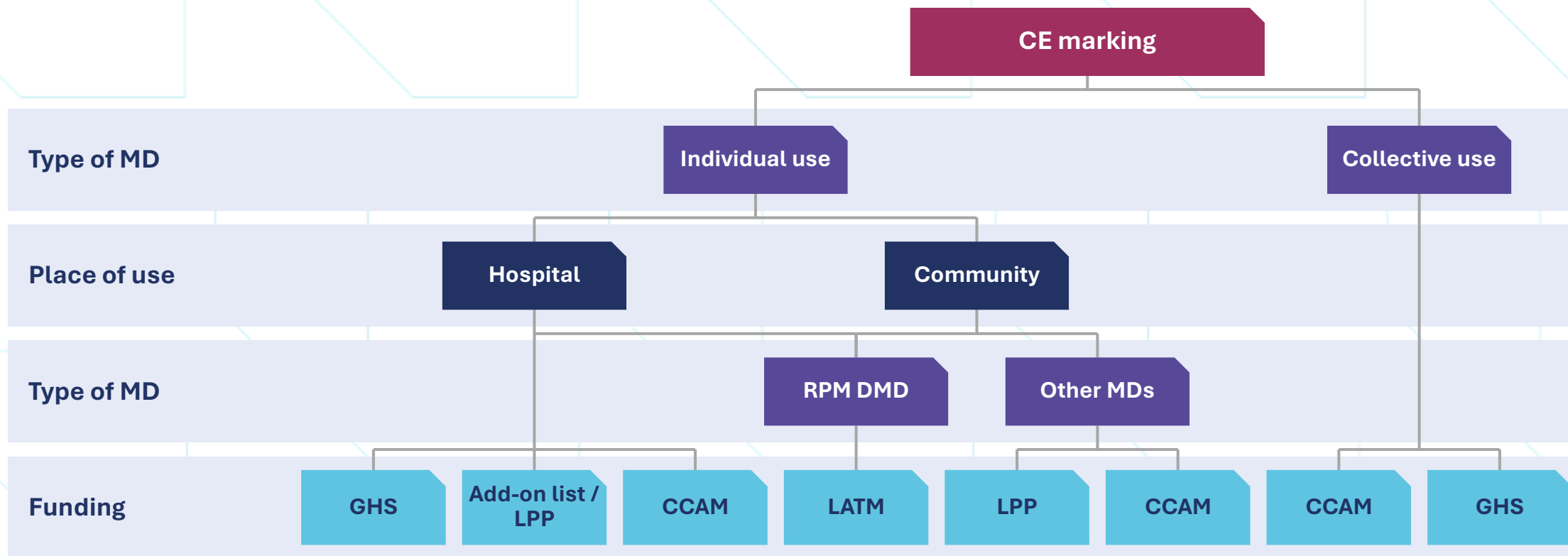
3 WHAT LEVEL OF EVIDENCE?

Sufficient

Insufficient

→ Standard / Early access / none

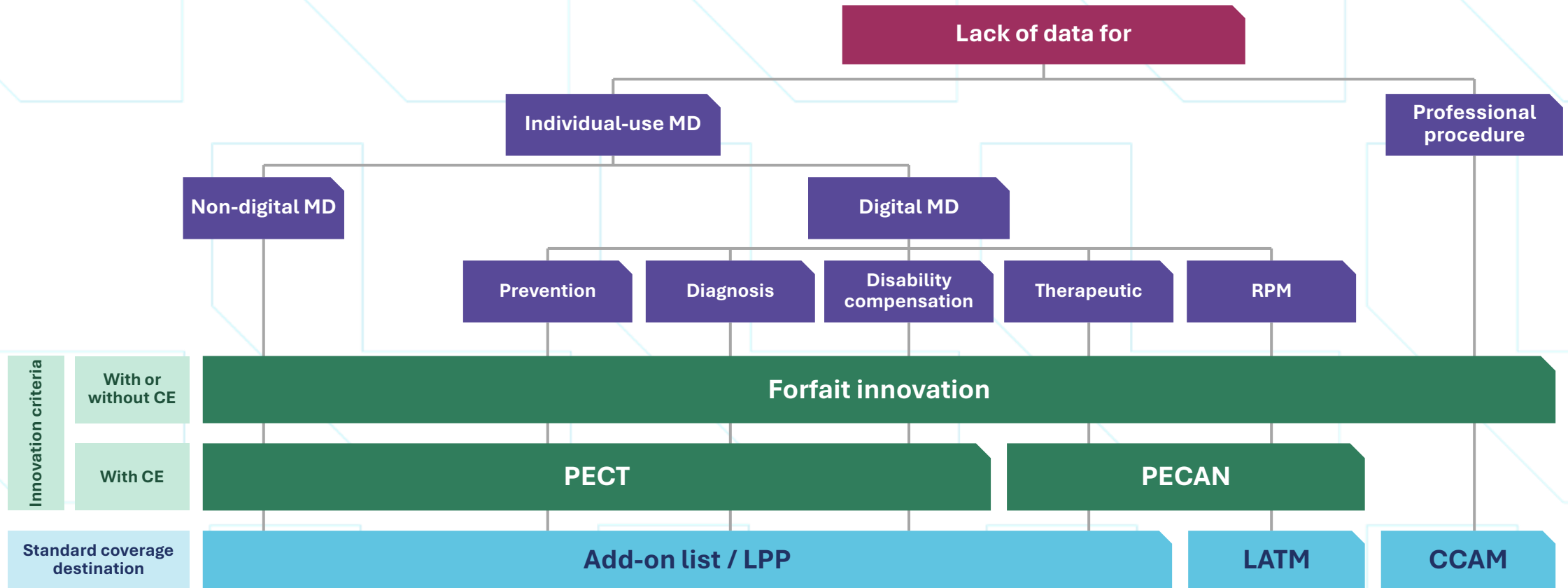
Standard coverage



CCAM = Common Classification of Medical Procedures
GHS = Homogeneous Hospital Stay Group
LATM = List of Remote Medical Monitoring Activities

LPP = List of Reimbursable Products and Services
RPM = Remote patient monitoring
DMD = Digital medical device

Early access pathways



LATM = List of Remote Medical Monitoring Activities • **LPP** = List of Reimbursable Products and Services • **RPM** = Remote patient monitoring
PECT = Transitional coverage • **PECAN** = Early coverage for digital devices • **CCAM** = Common Classification of Medical Procedures

Glossary of acronyms

AC	Contractual support funding (<i>Aides à la contractualisation</i>)	IPM	Benefit of the medical service (<i>Intérêt de la prestation médicale</i>)
ALD	Long-term condition (<i>Affection de longue durée</i>)	JORF	Official Journal of the French Republic
ANS	French Digital Health Agency (<i>Agence du numérique en santé</i>)	LATM	List of Remote Medical Monitoring Activities
CCAM	Common Classification of Medical Procedures	LPP	List of Reimbursable Products and Services
CE	CE marking (Conformité Européenne)	MD	Medical device
CEPS	Economic Committee for Health Products	MDR	Medical Device Regulation (Regulation (EU) 2017/745)
CNEDiMTS	National Committee for the Evaluation of Medical Devices and Health Technologies (HAS)	MERRI	Teaching, Research, Referral and Innovation Missions
DMD	Digital medical device	NB	Notified Body
FI	Innovation funding scheme (<i>Forfait innovation</i>)	PECAN	Early coverage for digital devices (<i>Prise en charge anticipée du numérique</i>)
FIR	Regional Intervention Fund	PECT	Transitional coverage (<i>Prise en charge transitoire</i>)
GHS	Homogeneous Hospital Stay Group (DRG-type tariff)	PHRC	Hospital Clinical Research Programme
HAS	French National Authority for Health	RPM	Remote patient monitoring
HCN	High Council for Nomenclatures	SA	Expected clinical benefit (<i>Service attendu</i>)
HCP	Healthcare professional	UNCAM	National Union of Health Insurance Funds

Thank you

French Market Webinar



Introduction and overview of the key principles of the French healthcare system (Anouk)



IVD market and market access (Frédéric)



MD market and market access (Anouk)



Q&A (10 minutes)