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Fast-track reimbursement in France for digital medical devices (« PECAN »)

Digital Health Delegation

French Ministry of Health and Prevention

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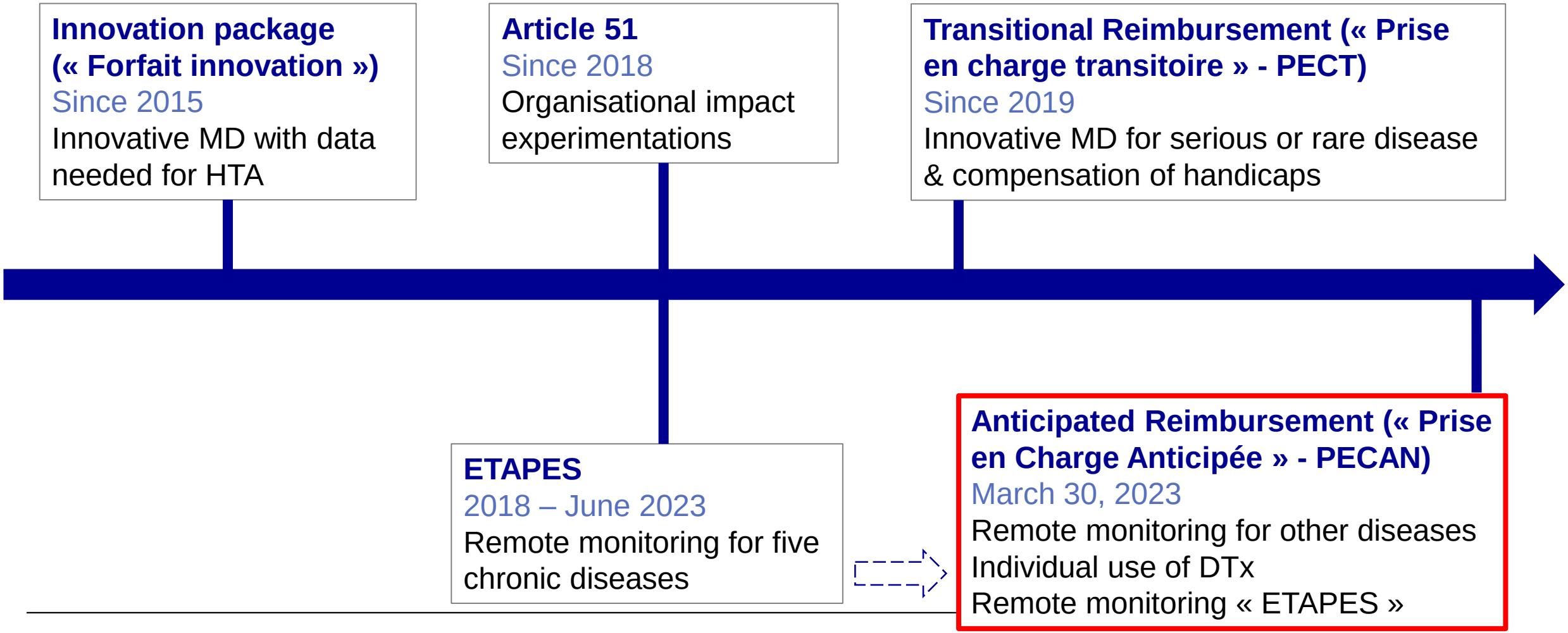
Paving the way to a fast-track DMD access in France

PRIOR EXPERIMENTATIONS TO A NATIONAL TRANSITIONAL AND TEMPORARY ONE-YEAR REIMBURSEMENT ACCESS SCHEME FOR DIGITAL MEDICAL DEVICES AND TELEMONITORING IN FRANCE



Paving the way to a fast-track DMD access in France

EXISTING NON DEROGATORY REIMBURSEMENT PROCESSES MEAN LONG DELAYS BETWEEN SUBMISSION AND ACCESS TO NATIONAL REIMBURSEMENT

Reimbursement of telemonitoring solutions (existing reimbursement process)

Allows reimbursement of telemonitoring activities by French National Health Insurance (common law)

- **Requirements :** Solutions applying for telemonitoring funding must be CE marked and comply with the ANS interoperability and security guidelines.
- **Process :** Through registration on the List of telemonitoring activities (LATM)

Reimbursement of medical devices (existing reimbursement process)

- **Allows for reimbursement digital medical devices by the French National Health Insurance (common law)**
- **Requirements :** Any medical device distributed in towns or hospitals that can demonstrate therapeutic, diagnostic or disability compensation value.
- **Process :** Through registration on the List of Reimbursable Products and Services (LPPR)

Fast-track reimbursement in France for digital medical devices (« PECAN »)

IMPLEMENTED AS PART OF THE "DEPLOYMENT AXIS" OF THE DIGITAL HEALTH ACCELERATION STRATEGY

New: Launch of digital medical devices (DMD) reimbursement ("PECAN")

- **Objective: to accelerates reimbursement by the French National Health Insurance for innovative DMDs**
- Provision for "PECAN" (Prise en charge anticipée numérique) by French 2022 Social Security Funding Law (Art. 58)
- Implementation through ministerial order of March 30, 2023 by means of service desks offered by the National Digital Health Agency (ANS) and the national HTA agency (HAS)
- This fast-track enables the company to finalize the clinical trials while already being reimbursed.
- **Requirements :** Only digital medical devices for therapeutic purposes or for medical telemonitoring that are allegedly innovative can be reimbursed by the Assurance Maladie.

  More information on the application process on the G_NIUS website

Rapid access of innovations for patients

Now effective operational deployment

Remaining parallel procedures to access reimbursement through laws of general application

Which types of DMDs are in the scope of PECAN ?

Categories

- **Digital Therapeutics** (DTx), before registration on the *List of Reimbursable Products and Services (LPPR)*
- **Telemonitoring solutions**, before registration on the *List of Telemonitoring Activities (LATM)*

DMD with CE mark

Existing preliminary clinical evidence*

The solution is “mostly digital”

Compliance with data interoperability and security standards requirements

*Completed clinical study or ongoing study with intermediate results

PECAN, the new French DMD reimbursement process that accelerates the deployment of digital health solutions

PECAN PROVIDES A ONE-YEAR, NON-RENEWABLE, LUMP-SUM REIMBURSEMENT THROUGH THE NATIONAL HEALTH INSURANCE SYSTEM BEFORE GETTING REIMBURSEMENT ACCORDING TO THE LAW OF GENERAL APPLICATION

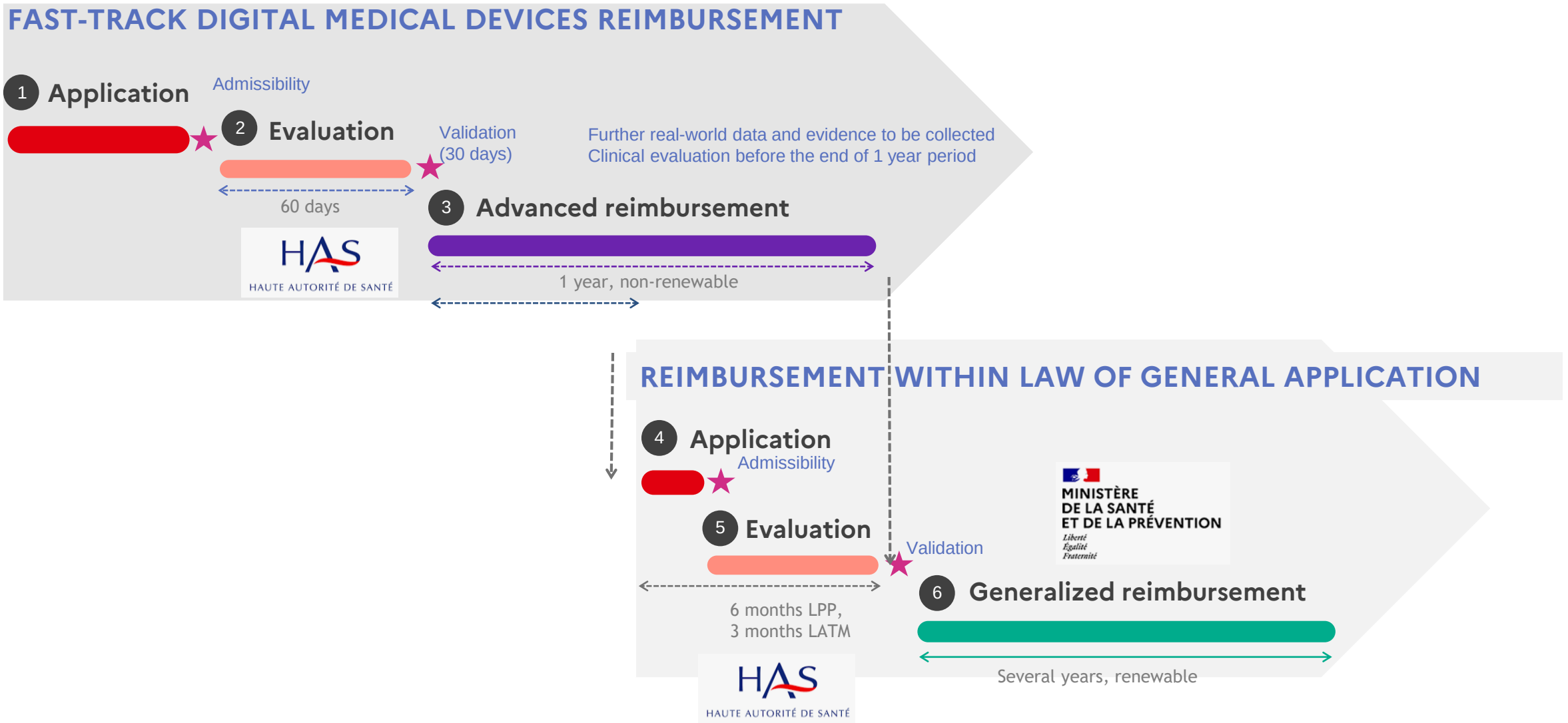
An advanced reimbursement of several months compared to the process set in law of general application

- To enable **derogatory DMD reimbursement** by **National Health Insurance**, innovations need to:
  - have completed **clinical studies** (finalized or almost finalized, with intermediate results from interim analysis) and are in the process of finalizing the demonstration of clinical and/or organizational benefits
- **Accepted shared risk:**
  - Funding is based on the **potential of the DMD,** not existing evidence which is brought a year later

Accelerate the deployment of presumed innovative solutions

- **Simplified** HAS admissibility **requirements**
- **An accelerated process to access reimbursement**:
  - The HTA application with HAS and the submission of interoperability/ security requirements proof with ANS are done simultaneously
  - The clinical evaluation (by the medical device Commission of the French HTA Agency HAS "CNEDiMTS") and ANS evaluations work at the same time

What are the steps to access DMD reimbursement ?



*No CNEDiMTS sessions between mid-July and September, 2nd half of December

Different approaches for fast track access for DMDs in the EU

BOTH GERMAN AND FRENCH NATIONAL REGULATIONS SUPPORT BROADER AND FASTER ACCESS FOR PATIENTS ACCESS TO INNOVATIVE DMDS, USING DIFFERENT SCOPES AND CATEGORIES OF DIGITAL HEALTH APPLICATIONS

German Digital Healthcare Act

DiGA Fast Track :

- DMD **for therapeutic uses** (DTx)
- DMD **class I and IIa**

- BfArM **evaluates** DiGA applicants for their potential **positive health effects**
- One year transitional rebate at **manufacturer's rate**
- **clinical study** done during provisional listing

Social Security Funding Law 2022 + March 2023 order

PECAN :

- DMD **for therapeutic uses** (DTx) or telemonitoring
- DMD **class I, IIa, IIb and III**

- DMD presumed to be innovative, especially in terms of **clinical benefit or improvement for the organization of care,** as assessed by HAS (CNEDiMTS)
- Need to pursue data collection throughout deployment
- One year transitional reimbursement period, predefined price **package**

Other European countries are actively working on the implementation of similar procedures

To go further

More information on PECAN

- PECAN ministerial order of March 30, 2023 Link
- PECAN information sheet on G_NIUS Link
- PECAN Webinar Replay Link (in French only)

Guidelines by the National Health Technology Assessment Authority (HAS):

- Submission guidelines Link
- Evaluation principles by the CNEDiMTS of individual use medical device for their access to reimbursement Link (In French)
- Medical device evaluation by the CNEDiMTS (Medical Device and Health Technology Evaluation Committee): Guide to the specific features of clinical evaluation of a connected medical device (CMD) in view of its application for reimbursement Link
- Methodology for the clinical development of medical devices Link
- Analysis grid for the AI component in medical devices Link
- Real-world studies for the assessment of medicinal products and medical devices Link
- Guidelines for telemonitoring on 5 chronic diseases (as in ETAPES) Link (In French)
- Functional classification, according to their intended use, of digital solutions used in the context of medical and paramedical care Link
- Organisational impact for map for health technology assessment Link

Guidelines by the National eHealth Agency (ANS):

- Repository of Interoperability and Security of Digital Medical Devices Link
- Interoperability and Security standards for Digital Medical Devices (DMDs) Link and requirements Link
- Compliance certification platform Link