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ASSOCIAÇÃO PORTUGUESA DA INDÚSTRIA FARMACÊUTICA

Access to IVD innovation

Albert Canela

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AliraHealth

The IVD access challenge in Portugal

90

high-value IVD tests not accessible to patients in Portugal…

Diagnóstico e progressão de Doenças Autoimunes

32 testes diferentes

Ex.: Lúpus Eritematoso Sistêmico, Cirrose biliar primária, Vasculites autoimunes, D. Graves, D. Inflamatória intestinal, …

Identificação de agente causador de infeção

32 testes diferentes, muitos sindrómicos multiparamétricos [1]

Ex.: Adenovírus, MSRA, Rotavirus, Norovirus GI/GII, Astrovirus, Sapovirus, Chlamydia trachomatis, Neisseria gonorrhoeae, Mycoplasma genitalium,…

Marcadores tumorais

5 testes diferentes

Ajuda na decisão e monitorização da terapêutica medicamentosa

8 testes diferentes

Fertilidade e Rastreios pré-Natal

3 testes diferentes

Doenças metabólicas

3 testes diferentes

Risco cardiovascular

4 testes diferentes

Ex.: Insuficiência Cardíaca

Outros

9 testes diferentes

1 – testes para deteção de múltiplos agentes em simultâneo
Source: APIFARMA, levantamento junto de associados, Mai.2023

…whereas they are reimbursed for outpatient care in most EU countries

				 
Reimbursement Code	2097 - Quantitative determination of the natriuretic peptide(s) BNP and/or NT-Pro-BNP and/or MR-Pro-ANP.	1821 – Natriuretic Peptide (ANP, BNP, NT-PROBNP) (Assay) (Blood).	90368: Peptide Natriuretico Tipo B (BNP)	No centralized tariff schedule exists.
Reimbursement Tariff	**Full coverage 19.40 €**	There is **60% copayment**, with a **40% mandatory coverage by private insurance** The price varies depending on the region. **Reimbursement tariff range: 14.56 € – 17.92 €**	**Full coverage 15.70 €**	**Positive recommendation Reimbursed through local budgets** **15-22 €**

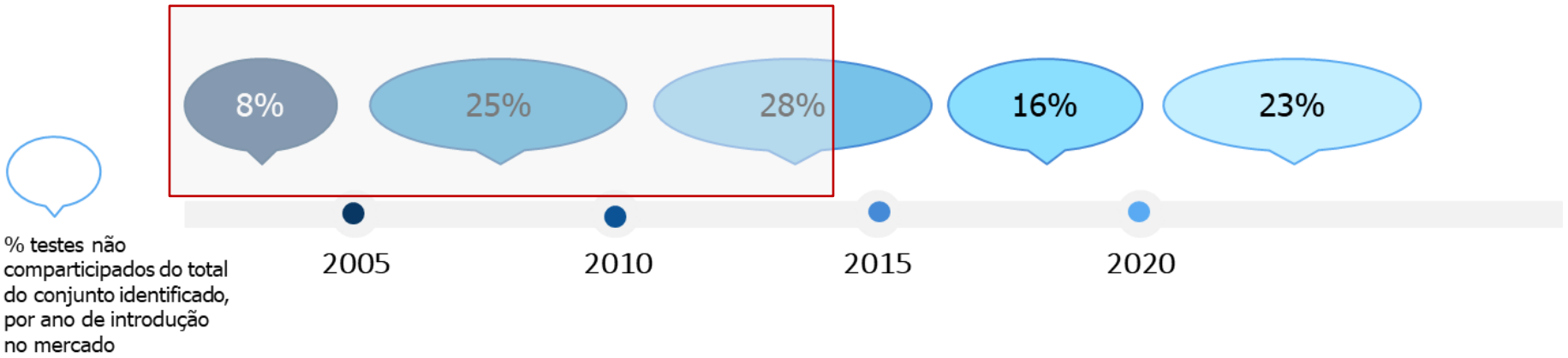
- **In Germany, blood laboratory tests**, including B-type Natriuretic Peptide Test **are reimbursed in the outpatient setting** and are **listed in the public EBM catalogue**, including the relevant tariffs.
- **In France, reimbursement of blood laboratory tests is handled through the NHS** (Assurance Maladie). **These tests are listed in the National Table of Biology (National de Codage de Biologie),** including the relevant coefficient required to calculate the final reimbursement price of each laboratory procedure.
- **In Italy,** the code is listed in the outpatient setting under the **"Nomenclatore dell'assistenza specialistica ambulatoriale"** list.
- **In the UK, the tests are recommended by NICE guidelines**. However, **no centralised tariff exists** and the price and reimbursement of each lab test can be **negotiated regionally** with the correspondent **Integrated Care System**. Similarly applies for Spain at Regional and Hospital level.

Source: Kassenärztliche Bundesvereinigung, 2023; EBM list; L´Assurance Maladie, 2023. Amendments to the national convention for laboratory directors; NICE, 2023; Alira Health analysis.

It takes too long to access IVD innovation in Portugal

Time-to-reimbursement for Drugs **1-2** Years

Time-to-reimbursement for Diagnostics **>10** Years



Over 50% of innovative tests are not reimbursed after 10 years in the market

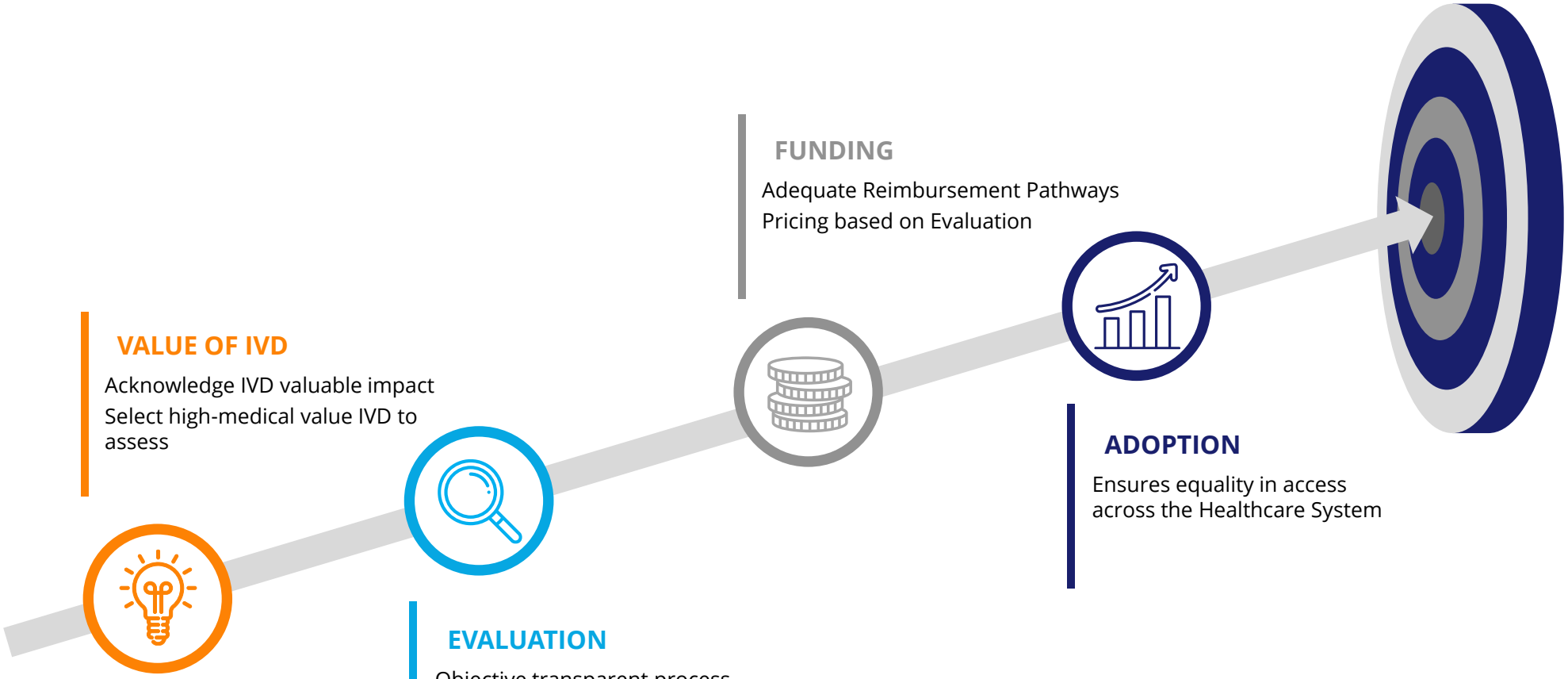
The Ministry of Health calls for a change

“Não podemos ficar para trás na inovação e na tecnologia ao serviço da saúde”

“O que está em causa não é limitar o acesso, é garantir o acesso universal a todos os que precisam”

Manuel Pizarro, Ministro da Saúde, durante a sua intervenção na abertura do Fórum Dispositivos Médicos 2023

Successful access to innovation requires few key steps



VALUE OF IVD

Acknowledge IVD valuable impact
Select high-medical value IVD to assess

EVALUATION

Objective transparent process
Assess Clinical/Economical/Societal benefit vs SoC
Leads to recommendation decision

FUNDING

Adequate Reimbursement Pathways
Pricing based on Evaluation

ADOPTION

Ensures equality in access across the Healthcare System

PATIENT ACCESS TO INNOVATION

Significance of HTA in decision-making regarding IVD reimbursement

Health technology assessment (HTA) is a systematic and multidisciplinary **evaluation of** the properties of health technologies and interventions assessing their **clinical, economical and societal impact**. The process aims to determine the value of a health technology and **support the decision-making** process for its acceptance from a healthcare system.

HTA not yet developed
(e.g., HTA is not done for IVDs)

HTA with a limited influence
(e.g., less used for IVDs, or HTA decisions are not really impacting reimbursement decision-making)

HTA plays a more important role
(e.g., HTA has a decision influencer role, positive recommendation influences reimbursement decision)

HTA Funding Mandate
Reimbursement fully depends on positive HTA decision

Source: Alira Health analysis.

Portugal has a well-established HTA process…but for Drugs

Figura 2 - PRM e PDC iniciados em 2012 por EMR
(Fonte: *Coordination Group for Mutual Recognition and Decentralized Procedures www.hma.eu/cmdh.html)*)

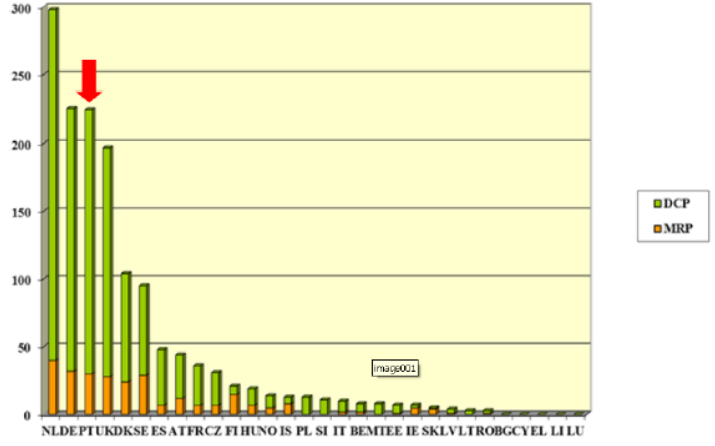


Figura 1 - Países com avaliação sistemática de tecnologias de saúde aplicada também aos dispositivos médicos

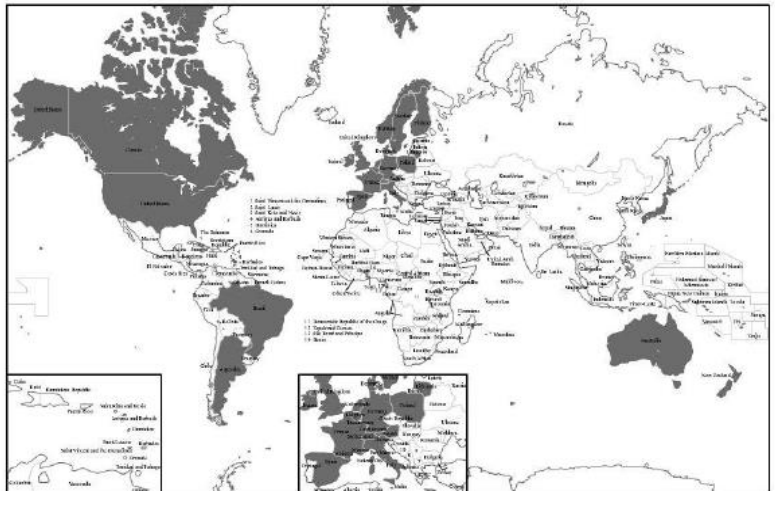


Tabela 1 - Princípios a ter em conta na Avaliação de Tecnologias de Saúde (ATS)
(Fonte: Adaptado de Tim Wilsdon and Amy Serota, Final Report: *A comparative analysis of the role and impact of Health Technology* Assessment, CRA-Charles River Associates, My 2011)

Estrutura	Categoria	Princípios	Descrição dos princípios
Decisão sobre uma tecnologia	Âmbito e Prioridade	1	A ATS deve ser um exercício transparente e sem viés.
		2	A ATS deve incluir todas as tecnologias relevantes
		3	Deve existir um sistema claro de priorização para ATS e os custos devem ser proporcionados
	Métodos	4	A ATS deve incorporar métodos apropriados em função do objetivo pretendido
		5	A ATS deve permitir uma variedade alargada de evidências e de impactos
		6	A perspetiva social deve ser considerada na ATS
		7	A ATS deve caracterizar de forma explícita a incerteza das estimativas efetuadas
	Processo	8	O envolvimento dos *stakeholders* relevantes deve ser considerado por quem conduz ATS
		9	Os resultados da ATS devem ser comunicados de forma apropriada aos diferentes decisores
		10	A avaliação deve permitir que a submissão de novos dados
		11	A ATS deve identificar as áreas de evidência em que o desenvolvimento no futuro seja mais adequado
	Impacto	12	A ATS deve ser conduzida dentro dos prazos
		13	As decisões de acesso, preços e financiamento devem refletir os resultados da ATS de forma clara e transparente, por forma a garantir a sua implementação
		14	O impacto dos resultados da ATS e a sua utilização devem ser monitorizados.

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Portugal has a well-established HTA process…but for Drugs

PROCESSOS APROVADOS

301 Aprovações em 2018

40 Novas substâncias activas/novas Indicações (46 processos)

66 Novas Apresentações (novas dosagens, novas formas farmacê

12 Biossimilares

177 Genéricos

APROVAÇÕES POR ÁREA TERAPÊUTICA

12 Oncologia

7 Cardiovascular

4 Anti-infecciosos

3 sangue

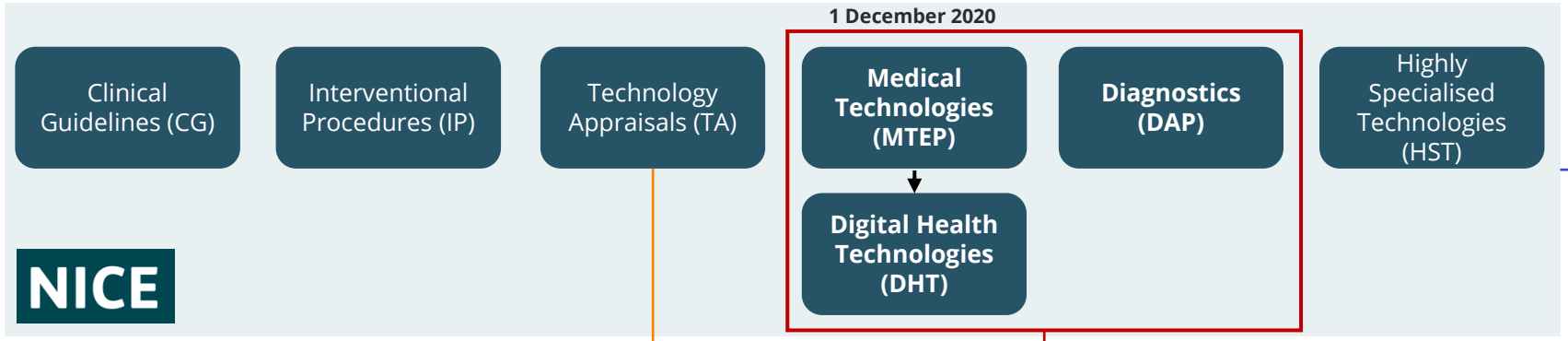
2 Hipertensão Pulmonar

Doenças raras
Aprovados oito novos medicamentos órfãos:
5 oncologia
1 atrofia muscular espinhal,
1 síndrome hemolítico urémico atípico
1 hemoglobinúria paroxística noturna.

Source: SiNATS 2018 annual activity report

Example of an established HTA: England

The Medical Technologies Evaluation Programme and Diagnostics Assessment Programme are most relevant to IVD



The funding mandate for pharmaceuticals is long established.

When NICE recommends that a treatment be funded by the NHS, the regulations require that the period within which the health service must comply will be stated in the recommendations as **3 months**, except when particular barriers to implementation within that period are identified.

The **MedTech funding mandate** launched on 1 April 2021 and has selected a total of 11 technologies for inclusion across 2 selection rounds. Technologies are selected on the basis that they are:

- **Effective**: demonstrated through positive NICE medical technology guidance or diagnostic guidance, published by 30 June 2021.
- **Cost-saving** within three years of implementation: as demonstrated by NICE modelling and published in a NICE resource impact template.
- **Affordable** to the NHS: the NICE budget impact analysis total costs should not exceed £20 million in any of the first three years.

NICE have recently launched **Early Value Assessments for MedTech.**
These are **early evaluations for groups of technologies** that may not have a full evidence base yet, but **show promise in priority areas for health and social care in the UK.**

Example of an established HTA: Italy

Successful diagnostics HTA drive the recommendation of IVD technology and facilitate its adoption

National HTA for Diagnostics

- **Every 6 months healthcare manufacturers can apply to the PNHTADM for new tests to be assessed**. After a screening the Steering Committee will forward the assessment to collaborating centers, the AGENAS or the ISS that will be responsible for conducting HTA.
- **If the healthcare technology is approved, the MoH and AGENAS will recommend the technology and contact the LEA in order to define reimbursement fees.**

Regional/ local HTA processes

- Although National HTA leads to LEA inclusion, the process takes a long time. As such, **regional or local assessments may be initiated (mini-HTA- usually budget impact) to enable fast coverage in specific regions.**
- Key criteria in discussions with payers are budget impact, clinical outcome and evidence, KOL opinions/ buy-in play a significant role.

Manufacturer Application
Manufacturers apply and are assessed by the Italian National HTA Program for Medical Devices (PNHTADM) and SC (Steering Committee).

Technology Assessment
Once technologies have been prioritized for assessment, the SC decides which are to be assigned to collaborating centres, central government agencies (e.g., AGENAS) or the Italian National Institute of Health (ISS).

Process Follow-up
The SC evaluates the AC recommendations and comes to a final decision regarding approval. All of the documentation is published on the MoH and AGENAS websites for public consultation, including a formal appeal process.

Appraisal Process
Based on the HTA report, the appraisal process calls for the AC (Appraisal Commission) to evaluate and provide a score for each evaluation criteria (Need, Added Clinical Value, Sustainability, Acceptability, Implementability and Feasibility). Four different recommendations can emerge out of the appraisal process:

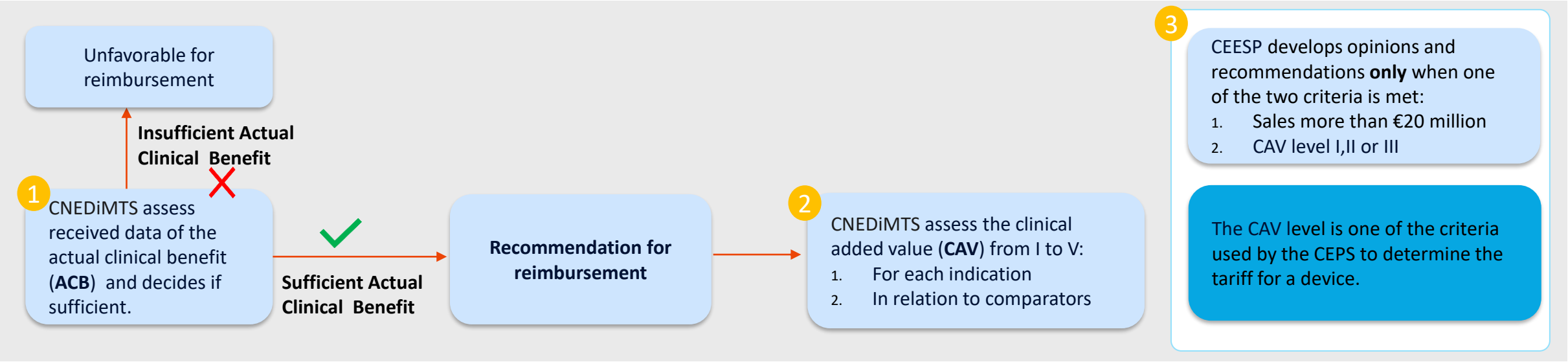
- Rejected
- Recommended
- Recommended for research purposes only
- Recommended provided that additional evidence is generated

Recommendation
The National LEA Commission of the MoH determines coverage policies. HTA reports inform decisions on updating the LEA and provide guidance regarding the appropriateness and the conditions under which the benefits will be publicly funded.

Example of an established HTA: France

Centralized decision –clinical and economical commitees- leads to inclusion into national reimbursement list

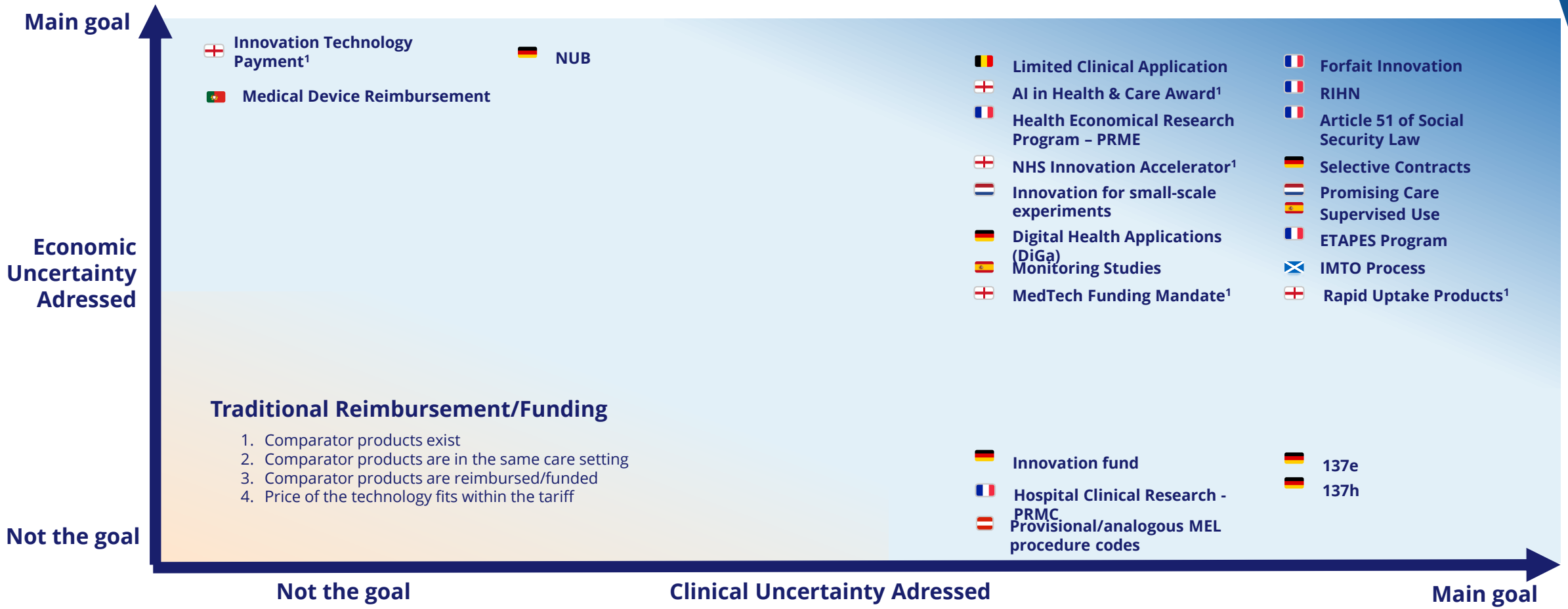
- Health technology assessment has an important role for market access of IVD in France.
- The key HTA organization is the **National Authority for Health (HAS)**.
- The **CNEDiMTS and CEESP** are the HAS committees which **assess MDs and IVDs** in view of their reimbursement by the national Health Insurance.
- **Most assessments are integrated into the reimbursement process** (for IVD: creation of CCAM and NABM codes, add-on reimbursement).
- A diagnostics-specific committee within HAS is under development.



HAS Process takes roughly one year

Taxonomy for ACPI's in Europe – Fast-track innovation funding

Alira Health supported Medtech Europe in mapping the existing pathways for accelerated access across European countries



Note: Swiss pathways not included in the list; Program in Wales to add when more information received [1]Part of the Accelerated Access Collaborative, the umbrella department overseeing different programs, including 3 ACPI's.

Note: Taxonomy of Value-Based Access Programs MedTech Europe; Alira Health Analysis

Applicable Pathways by Device Type

ACPI Name	Inpatient Device	Digital Device	IVD
1. Provisional/analogous MEL Procedure Codes	X		
2. Limited Clinical Application	X		
3. Validation Pyramid Level M3 Light		X	
4. AI in Health and Care Award	X	X	
5. MedTech Funding Mandate	X	X	X
6. NHS Innovation Accelerator	X	X	X
7. Small Business Research Initiative	X	X	X
8. NHS Insights Prioritisation Program	X	X	
9. Rapid Uptake Products	X	X	X
10. Article 51 of Social Security law	X	X	
11. Health Economic Research Programme	X		
12. Hospital Clinical Research Programme	X		
13. Forfait Innovation	X		X
14. Repository of Innovative Acts Outside the Nomenclature of Biology and Anatomical Pathology			X
15. Remote Monitoring Programme		X	
16. Transitional Coverage	X	X	X
17. 137e - Trial Regulation	X		

ACPI Name	Inpatient Device	Digital Device	IVD
18. 137h – Trial Regulation for Highly Invasive Medical Devices	X		
19. Digital Health Applications		X	
20. Innovation Fund	X	X	X
21. NUB	X		X
22. Selective Contracts	X	X	X
23. Innovation for Small-scale Experiments	X	X	X
24. Promising Care	X	X	X
25. Appropriate Care	X	X	X
26. Efficiency Research Programme	X		X
27. Medical Device Reimbursement	X		
28. IMTO Process by Health Technology Scotland	X	X	X
29. Accelerated National Innovation Adoption	X	X	X
30. Monitoring Studies	X		
31. Supervised Use	X		
32. Analogue CHOP code nomenclature	X		X
33. Coverage with Evidence Development	X	X	X
34. Individual Sickness Fund	X	X	X
35. NHS Wales	X	X	X

Takeaways

- IVD requires dedicated transparent HTA process (selection, evidence, criteria,…)
- Positive recommendation should lead to funding endorsement
- IVD outpatient coverage is well established; supports increasing role of Primary Care
- Flexible fast-track reimbursement facilitates early adoption of innovation
- Involve all relevant stakeholders, including patients and technology providers

The WHO resolution – Strengthening Diagnostics Capacity

"Building sustainable primary health care to achieve universal health coverage"…"and that diagnostics are important to ensure quality, comprehensive and integrated primary health care eveywhere and for everyone"

URGES member states to:

1. **To consider establishing national diagnostics strategies**
2. **To consider health technology assessment for the evaluation of diagnostics**
3. **To consider a national list of essential diagnostics and update it regularly**
4. **To extend the scope of diagnostic services, making them available, accessible and affordable at Primary Care level**
5. **To invest in diagnostic services, including selection and use of essential IVDs**
6. **To prioritize and review rapidly clinical evidence for new diagnostic interventions**
7. **…**

World Health Organization (WHO) 76th World Health Assembly, May 30th 2023

Muito obrigado!

Albert Canela

Director – Market Access & Commercial Strategy

albert.canela@alirahealth.com

Alira Health – Innovative Funding Pathways Full Report