MEDTECH EUROPE

Belgian Market SME Training

be MedTech
Medical Technologies Academy

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BEMEDTECH

Who we are?

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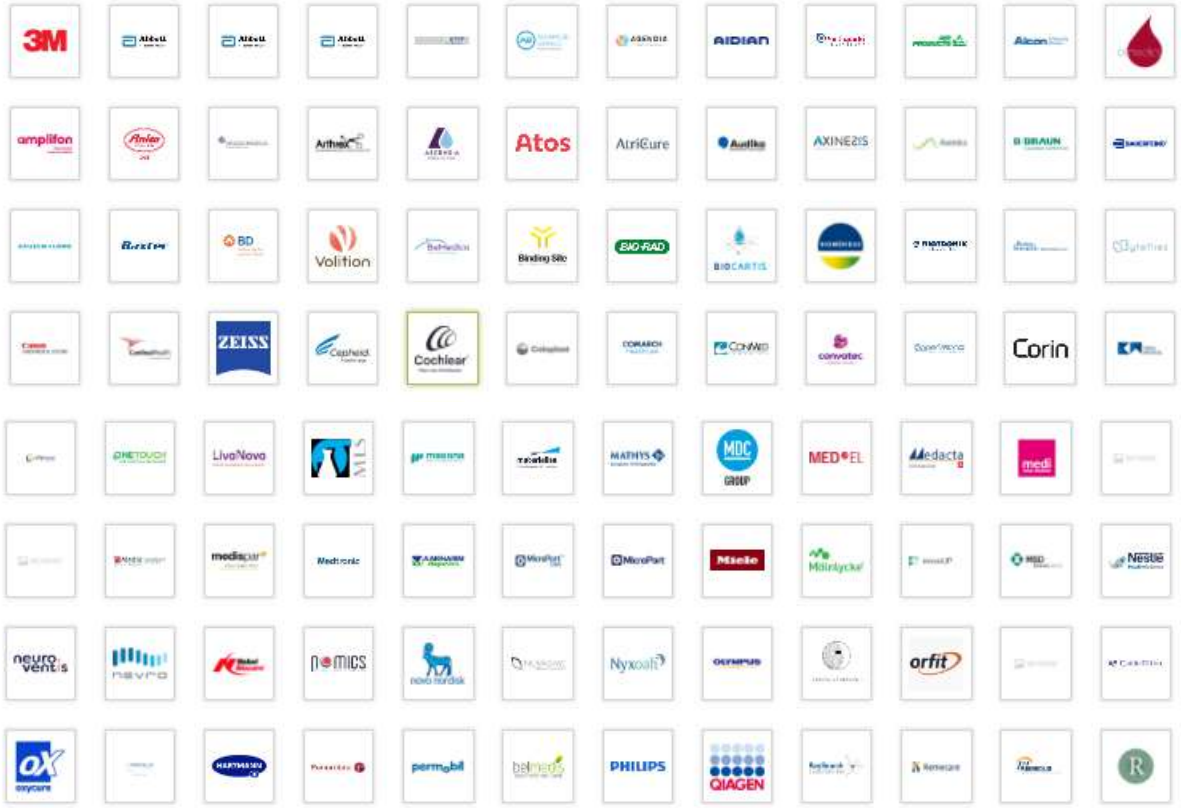
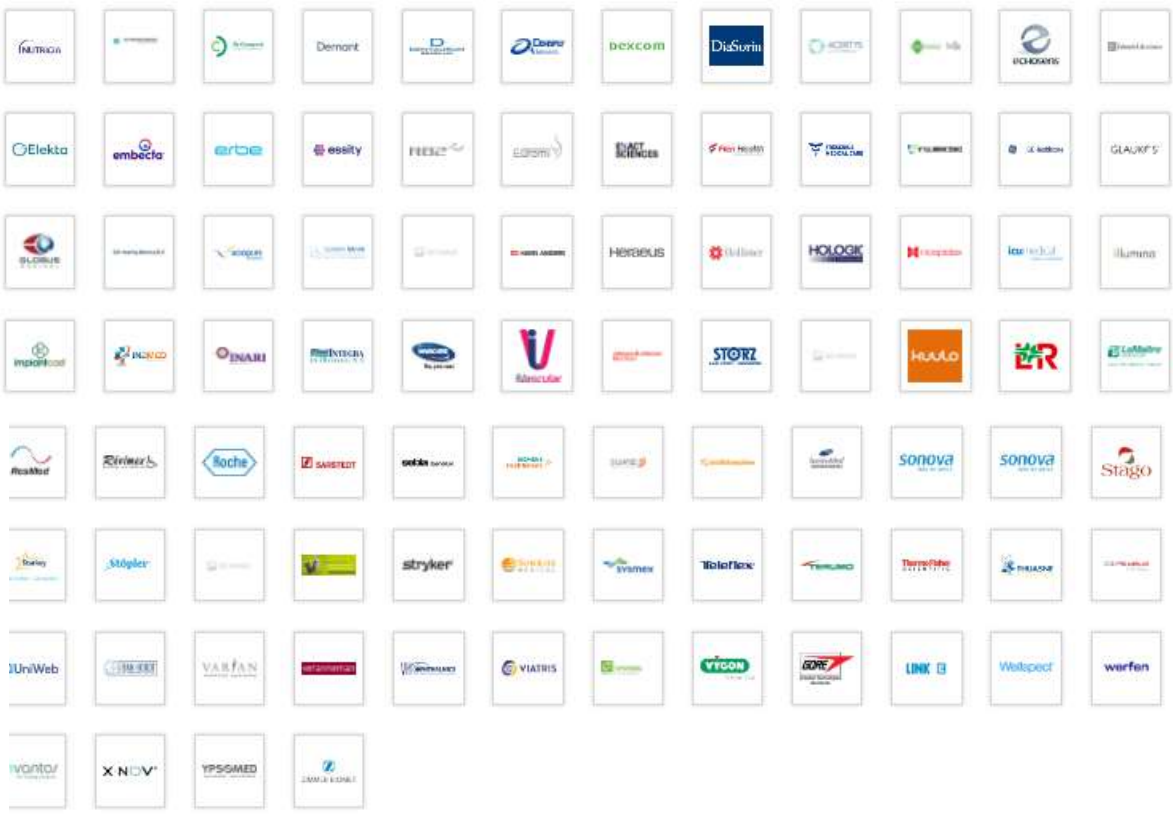
be
MedTech
Medical Technologies Belgium
175 companies
500.000 medical technologies
468

beMedTech :
175 companies, manufacturers/ distributors of
+ 500 000 medical devices, technologies and IVDs in Be





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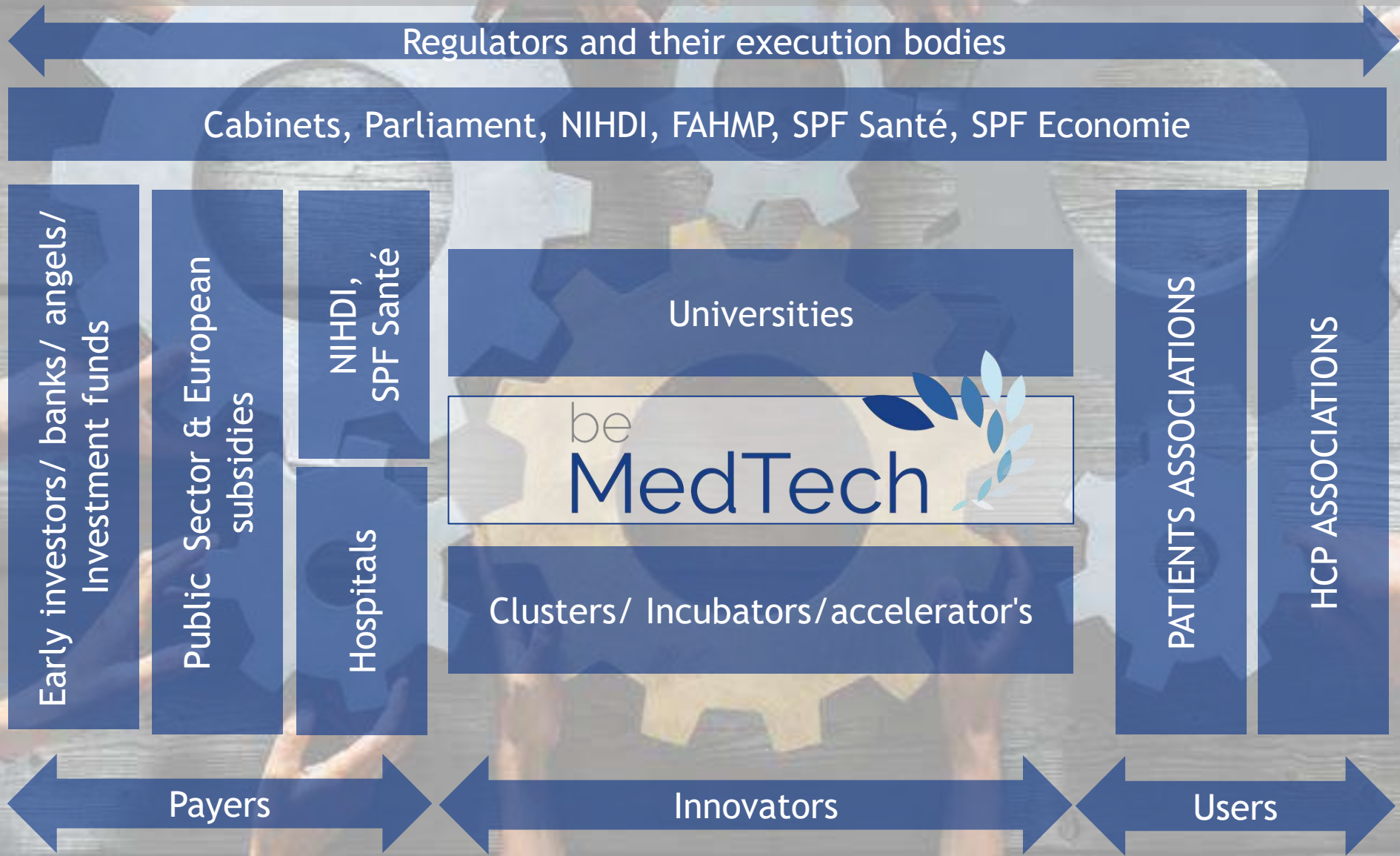
Innovation in healthcare is about adoption

Driving adoption through ecosystem collaboration



Driving adoption through ecosystem collaboration

Agenda

1. Market overview & Macro Context

2. Governance & Institutional Landscape

3. Market Access Pathways

4. Strategic Outlook

Market overview & macro context

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1. Market overview in Macro Context	Belgian Healthcare & Economic Key Figures MedTech Market Size & Growth Profile Key Segments & National Footprint
2. Governance & Institutional Landscape	Belgian Health System Architecture (Federal vs. Regional Competences) Key Regulatory & Public Institutions (INAMI/RIZIV, FAMHP/AFMPS, KCE) Decision-Making Ecosystem & Key Stakeholders
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4. Market Drivers & Strategic Outlook	Key Growth Drivers & Unmet Clinical Needs Future Challenges & Strategic Opportunities

Population, demographics and health care expenditure

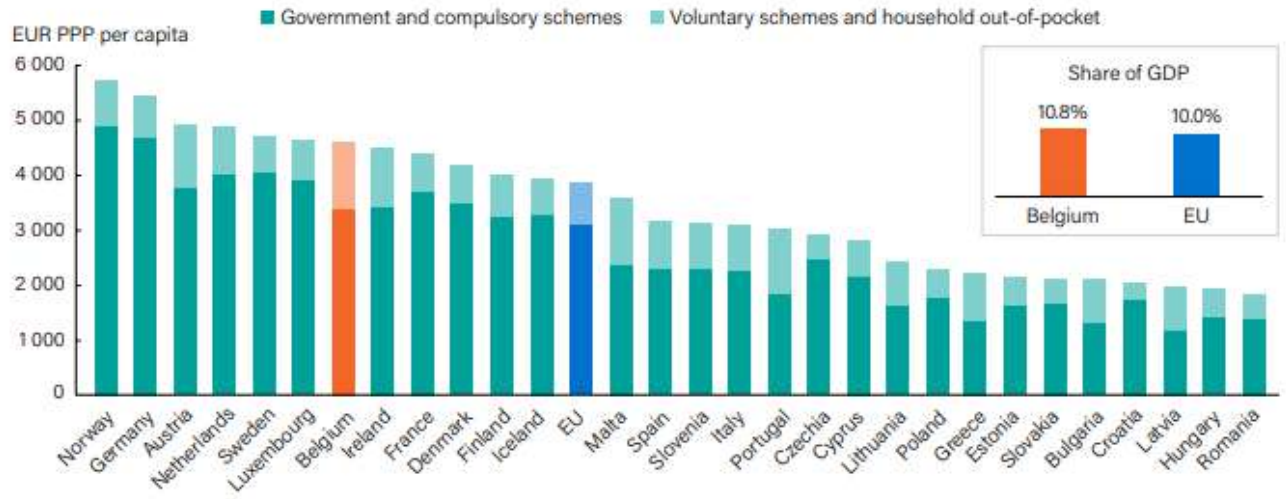
11,8M
Inhabitants (2026)

82,5
Life expectancy (years)

49,3%
Men

10,8%
Health spend, % of GDP

Figure 9. Health expenditure per capita is nearly 20 % above the EU average

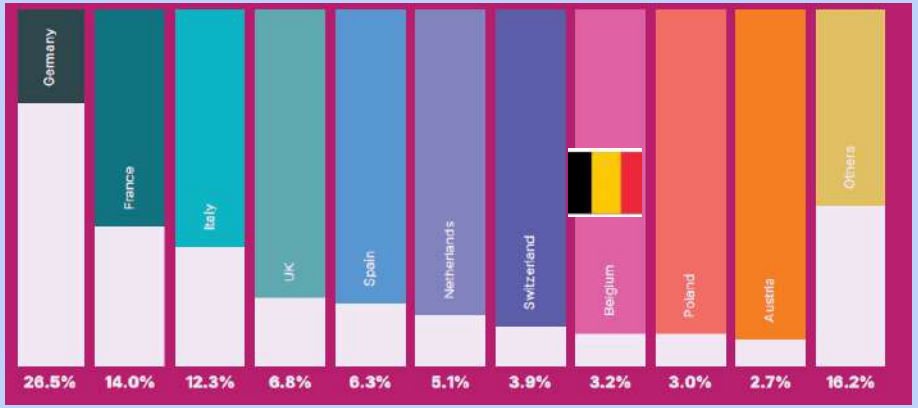


Note: The EU average is weighted (calculated by OECD).
Sources: OECD Data Explorer (DF_SHA); Eurostat Database (demo_gind). Data refer to 2023.

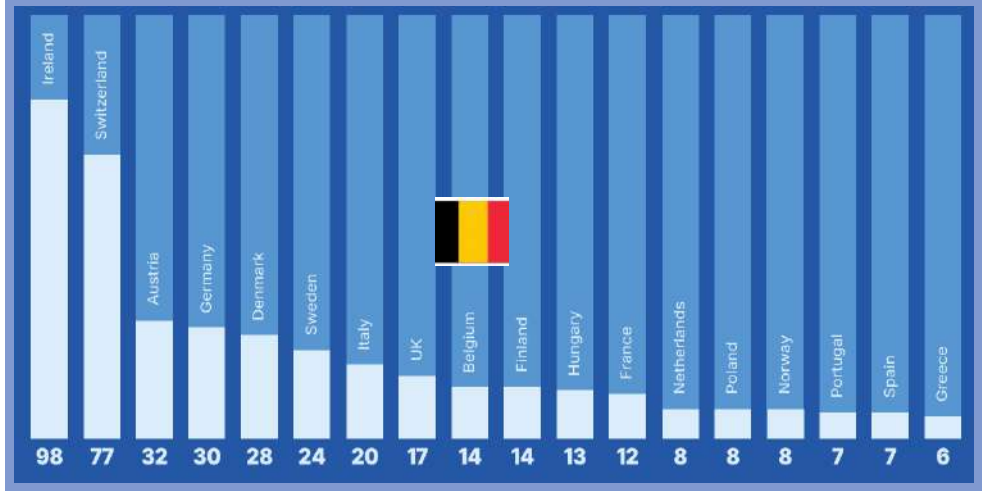
- Population is ageing: ~20% aged 65+ today, projected to exceed 25% by 2050
- Life expectancy of 82.5 years is among the highest in the EU
- Compulsory social health insurance covers **99% of residents**; ~78% of spending is publicly financed

MedTech Market Size & Import Dynamics

MARKET Belgian market estimated at 5,44 bio€



EMPLOYEMENT FTE directly employed in MedTech industry per 10,000 habitants in 2022



5,44 bio €
Estimation market size

10%
Domestic production

4,0%–5,8%
Annual growth

>90%
Import reliance

Sources:
- U.S. International Trade Administration – Belgium Medical Devices
- MedTech Europe Facts & Figures

European gateway & ecosystem

- **#1 Logistics Hub for Europe:** Over two-thirds (>66%) of medical equipment imported into Belgium is re-exported to neighboring EU markets.

- **Niche manufacturing champions:** Focused local ecosystem specializing in radiation therapy (IBA), medical imaging (Agfa HealthCare), orthopedics, and prosthetics.

- **Dense ecosystem:** Backed by active industry federations connecting university hospitals, incubators, and public authorities.

Sources:
- U.S. International Trade Administration – Country Commercial Guide (https://www.trade.gov/country-commercial-guides/belgium-medical-devices
- Agence Belge du Commerce Extérieur (BHD / Foreign Trade Statistics) https://wits.worldbank.org/trade/comtrade/en/country/BEL/year/2021/tradeflow/Exports/partner/ALL/product/901890

Governance & institutional landscape

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Federal Authorities

King
Federal Government (Prime Minister, Ministers, Secretaries of State)
Federal Parliament (Senate, Chamber of Representatives)

The Communities

Flemish Community

French Community

German-speaking Community

The Regions

Flanders Region

Brussels-Capital Region

Walloon Region

Governance: split between federal and federated levels

Federal state

- National compulsory health insurance (managed by NIHDI) → reimbursement of health care
- Sets the overall hospital working budget (BFM) and general organisation rules
- Regulates health products (FAGG), health activities and professionals

Federated entities

- Organisation of mental health care, primary care and rehabilitation
- Elderly living facilities, household support, social care
- Health promotion and disease prevention (< 3%)
- Recognition & education of HCP
- Planning, recognition & funding of **infrastructure** of hospitals

Belgium's social security system : mix of both worlds

Bismarck

- Multiple non-profit "sickness funds" (mutualities) act as insurers
- Financed jointly by employer + employee payroll contributions
- Care delivered by **mostly** private doctors and hospitals, fee-for-service

Beveridge

- ~~Single national health service, run and owned largely by the state~~
- Financed through general taxation, not payroll contributions
- ~~Government employs or contracts most providers directly~~

1851
Belgium recognizes mutual aid societies (mutualities)

1894
Legal foundation strenghtened for mutualities

1945
Social Pact makes sickness insurance compulsory for employers

1964
° NIHDI
Co-governance NIHDI + all inhabitants

1980s
State reform: health insurance = federal, generic medicines, hospital financing

1990s
New mutualities law (further clarificaiton roles & financing)
Quality tools
Acces safeguards

How the healthcare system is financed

1

National social security scheme collecting contributions

2

Main revenue streams: social contributions and taxation

3

Complementary sources: co-payments and private insurance

- Employers and employees pay **social security contributions**, pooled at federal level and allocated to health insurance among other branches
- Alternative financing from **general taxation** (notably VAT) supplements contributions as wage-based revenue has stagnated
- Patients contribute through **co-payments** (“remgeld/ticket modérateur”), capped for vulnerable groups

Foundation:
Four pillars of the Belgian health care organization

1.Compulsory solidarity

2.Free choice

3.Mixed provision

4.Shared governance

The HCP landscape

General practitioners

- First point of contact, but no official gatekeeping
- Practice independently
- Increasingly organised in group practices and multidisciplinary teams

Specialists

- Practice in hospitals or private practice
- Largely paid via fee-for-service nomenclature.
- Practice independently

Hospitals

- Mostly private non-profit
- Financed through a mixed budget (fixed budget of financial means and fee-for-service).

Allied care

- Dentists, nurses, physiotherapists, psychologists, and other professions complete the care pathway out and inpatient.

Pharmacists

- Take up a more and more competences (vaccinations,…)

Key Regulatory & Public Institutions @ Federal level

NIHDI

Payer & Regulator

Manages compulsory health insurance and reimbursement (for medical devices).

afmps fagg
agence fédérale des médicaments et des produits de santé
federaal agentschap voor geneesmiddelen en gezondheidsproducten

Safety & Quality

Responsible for the registration, clinical trials, and vigilance (of medical devices)

Health
Food Chain Safety
Environment

Federal Public Service

Manages Belgian healthcare policy, hospital financing, emergency medical assistance coordination

Market Access pathways

3

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Regulatory requirements & compliance

- **FAMHP / AFMPS Competence:** Federal agency supervising clinical investigations, national register database, materialovigilance, and market surveillance in Belgium.

- **Notification & registration obligations:** Mandatory online registration via notifications portal before placing any Class I, IIa, IIb, III or IVD device on the Belgian market.

- FAGG AFMPS Procedures here

Many different funding mechanisms depending on product portfolio

In-Vitro Diagnostics

Medical Equipment Systems

Implants & Invasive Devices

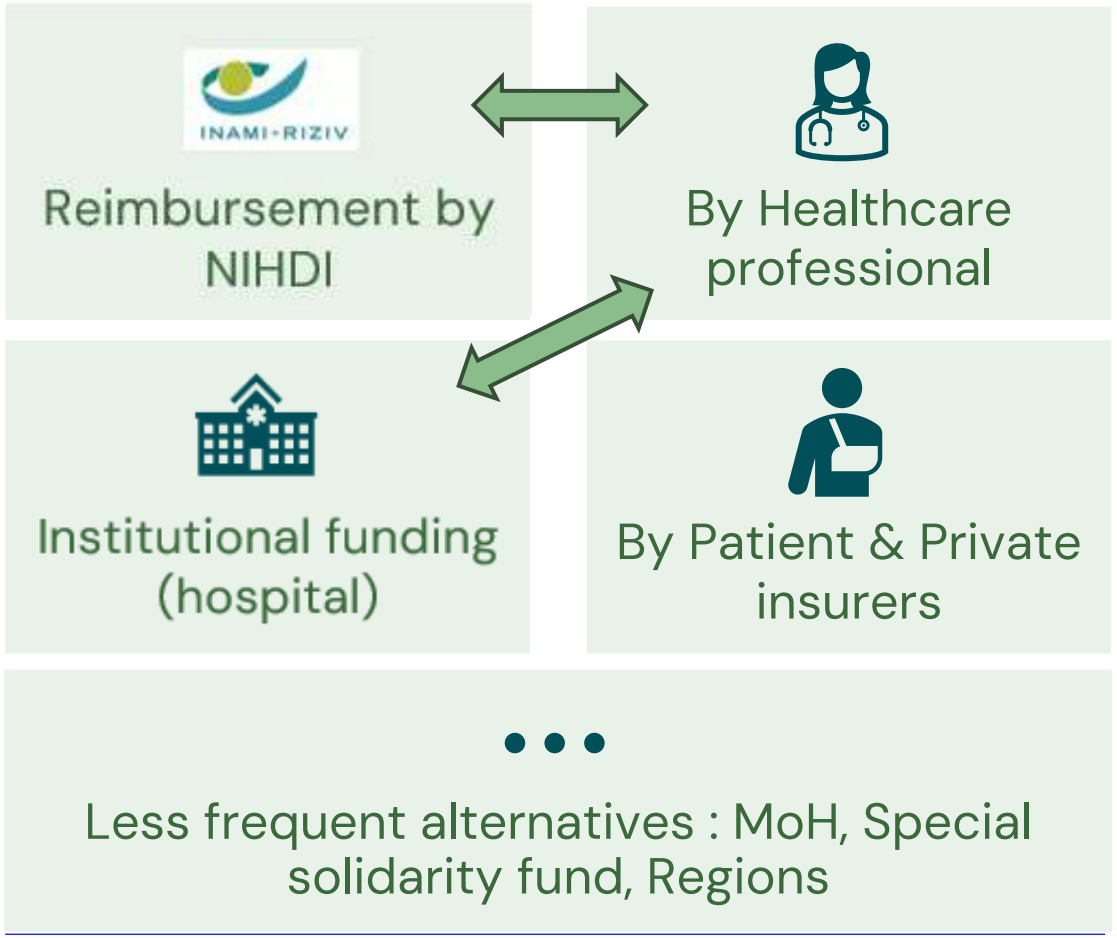
Medical Consumables

Digital Medical Technologies

Service Technologies Home Assistance

The financing of MedTech in Belgium is diverse and depends on many variables

- ❑ Who is interested in my technology?
- ❑ Who is the payer?



Belgian market entry & reimbursement system

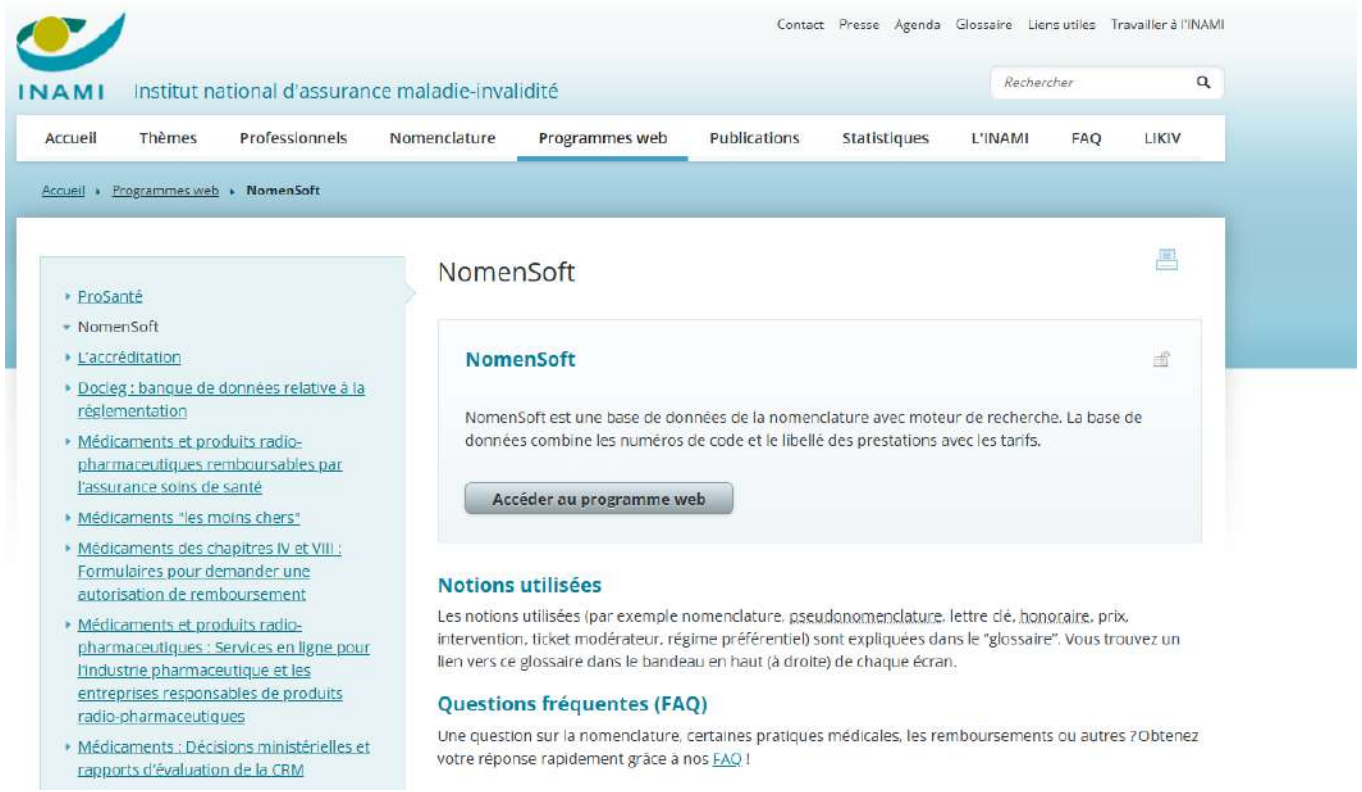
- Distinction between
  - non-reimbursed & direct hospital procurement
  - and official reimbursement tracks via INAMI / RIZIV
- **INAMI Nomenclature & Listing:** Technical and clinical dossier submission to RIZIV/ INAMI for explicit coding
- **Innovation Funding :** Importance of the HCP's power
- Exceptional:
  - Fast-track mechanisms for digital health / mHealth (Level 1 to Level 3 validation pyramid)
  - Innovative medical technology conventions

Reimbursement by RIZIV INAMI (NIHDI in En)

- The **National Institute for Health and Disability Insurance** manages the compulsory health insurance scheme
- It negotiates **agreements** with healthcare providers and mutualities, sets nomenclature codes and reimbursement tariffs
- It runs dedicated commissions and councils where the government, mutualities, provider representatives and industry are consulted
- The RIZIV/INAMI manages both **inpatient and outpatient reimbursement**
- It monitors the total healthcare budget (= 45 billion €)

Belgian nomenclature

- In Belgium, the **nomenclature** (often referred to as the INAMI nomenclature) is the **official list of health services, treatments, and medical or paramedical procedures** that are reimbursed by mandatory health insurance.
- **Nomensoft** is the database
  - Description
  - Reimbursement
  - Patient participation



Source: https://www.inami.fgov.be/fr/programmes-web/nomensoft

Reimbursement procedures per product type (implant, invasive, IVD, non-invasive,…) can be found online

- Prestations de soins individuelles
- Soins dans les hôpitaux
- Hospitalisation à domicile pour des traitements oncologiques et antimicrobiens
- Soins en maisons de repos
- Soins dans des centres spécialisés
- Soins à domicile (services intégrés)
- Soins dans les maisons médicales
- Soins de santé mentale
- Soins palliatifs
- L'infirmier à domicile doit vérifier l'identité de son patient s'il applique le tiers payant
- La télémédecine et les applications mobile Health
- Médicaments
- Dispositifs médicaux / matériel médical
  - Dispositifs médicaux non implantables
  - Implants et dispositifs médicaux invasifs
  - Bandagisterie
- Produits de santé
- Radiopharmaceutiques
- Ticket modérateur d'un produit radio-pharmaceutique
- Fonds spécial de solidarité
- Notre intervention dans le cadre de la détection précoce de certaines affections malignes
- Comment demander un remboursement pour un traitement de logopédie ?

Dispositifs médicaux / matériel médical

L'assurance soins de santé rembourse, totalement ou partiellement, certains dispositifs médicaux (dont des implants) et du matériel médical (bandagisterie).

Sur cette page :

- Remboursement de dispositifs médicaux et du matériel médical
- Contacts

Remboursement de dispositifs médicaux et du matériel médical

L'assurance soins de santé rembourse, totalement ou partiellement, certains dispositifs médicaux et du matériel médical. Ils se répartissent en 3 groupes :

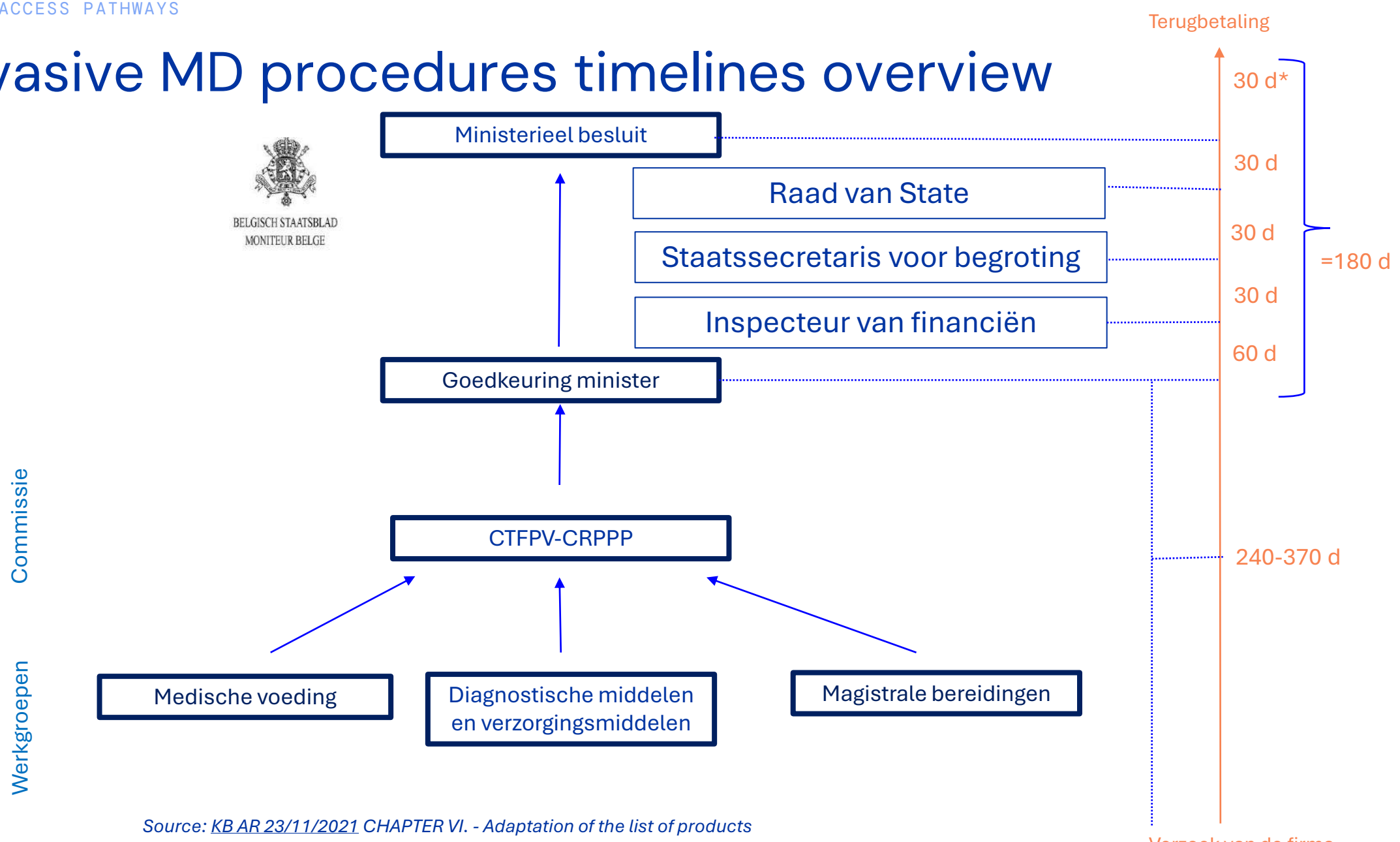
- des dispositifs médicaux non implantables délivrés par le pharmacien ou, dans certains cas, par un autre fournisseur (non pharmacien)
- des implants et des dispositifs médicaux invasifs
- bandagisterie : si les conditions sont remplies, la mutualité intervient dans le prix de certaines prestations réalisées par des bandagistes.

Contacts

Vous trouvez des données de contact spécifiques sur les pages de détails vers lesquelles renvoient les différents liens.

Source: RIZIV INAMI Website: https://www.inami.fgov.be/fr/themes/soins-de-sante-cout-et-remboursement/les-prestations-de-sante-que-vous-rembourse-votre-mutualite/dispositifs-medicaux-materiel-medical

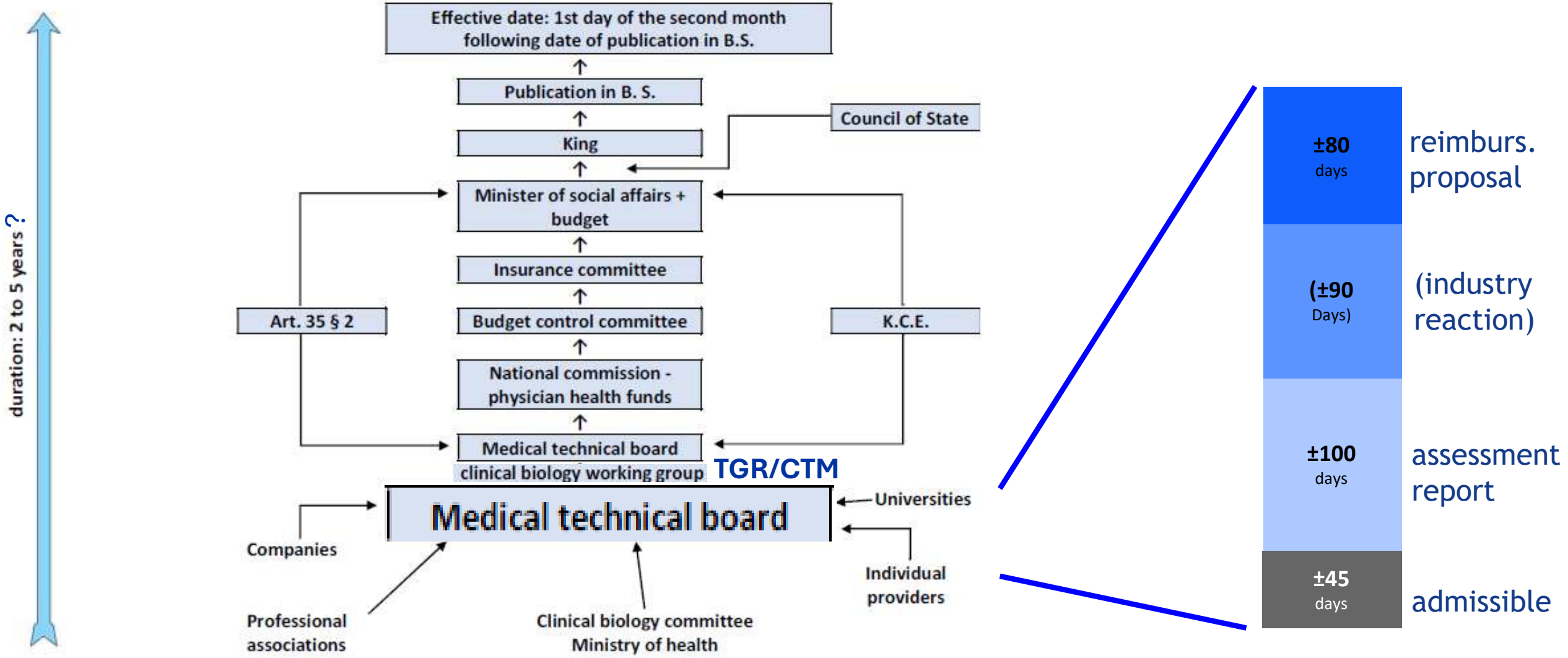
Non-invasive MD procedures timelines overview



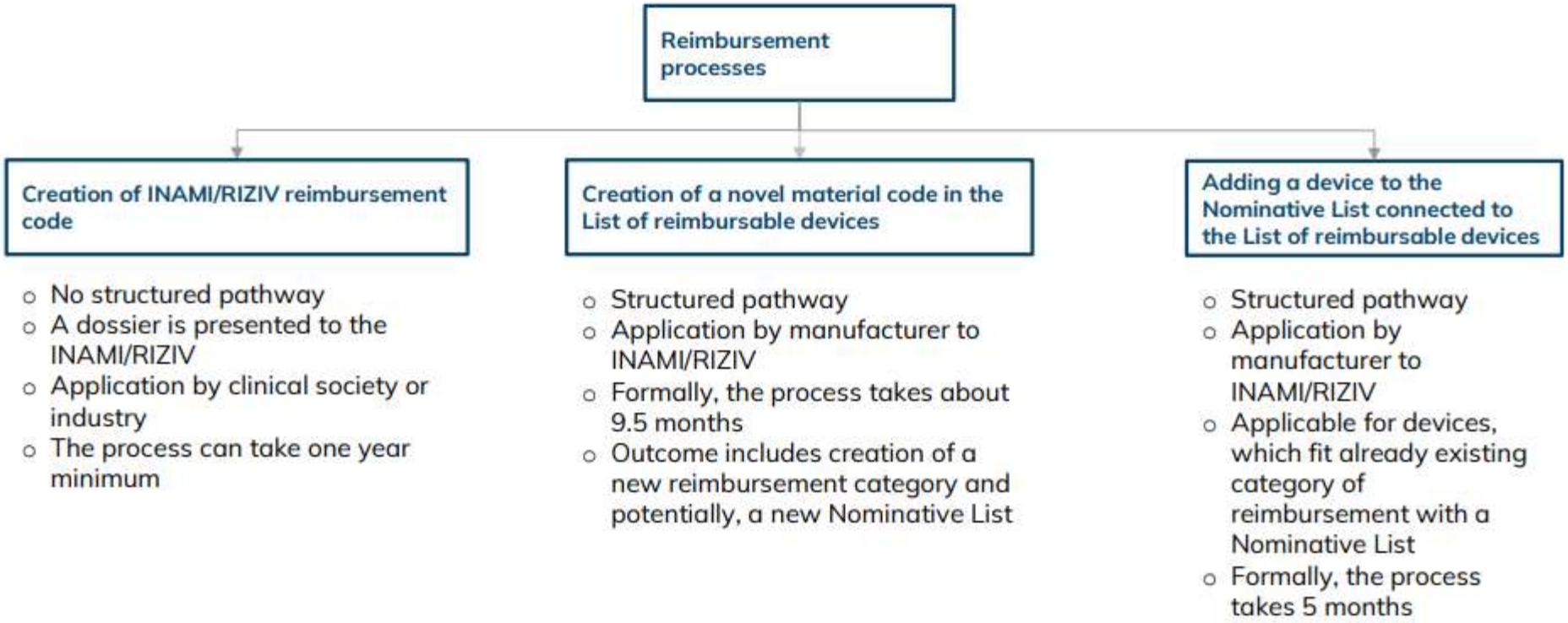
Source: KB AR 23/11/2021 CHAPTER VI. - Adaptation of the list of products

* de eerste dag van de maand volgend op het verstrijken van een termijn van tien dagen vanaf de dag volgend op de publicatie in het Staatsblad

IVD overview reimbursement procedure



Belgium has 3 main reimbursement change route with different evidence and process



Source : MTRC report 2026

NIHDI reimbursement depends on the type of medical device.

Separated from medical « act »

with or without a list of devices and prices

eg implants

Included in the reimbursement of the medical « act »

with or without a nominative list of devices and their price

eg IVD

Specific **convention**

eg Diabetes, N-CPAP, home hospitalization …

Care trajectory financing

eg Diabetes type 2, renal insufficiency, …

RIZIV–INAMI

Key NIHDI decision-makers involved in medical device reimbursement

RIZIV-INAMI

Medical Direction

- **Conventions and agreement committees** (Audiciens, Opticiens, ...)
- **CTIIMH/CRIDMI:** implants and invasive devices
- **WG mHealth**: mobile medical apps
- **Revalidation agreements**
- **With Drs: agreements - nomenclature** (TGR/CMT): IVD,...

Pharmaceutical policy direction

- **CTFPV/CRPPP**: glucometers, tensiometers, medical nutrition, infusion pumps, catheters ...

College of medical directors

- **Conventions**: dialysis material, diabetes sensors, sleep apnoe,...

+ insurance committee and general council

NIHDI decision-making follows a consultation-based model across its various bodies.

CONCERTATION MODEL

= Decision-making by consensus

(HCP-HCO-Insurers)

- Minimum Quorum presence from the different benches
- Members with Voting rights

This concertation model does not promote changes in care processes.

PROS

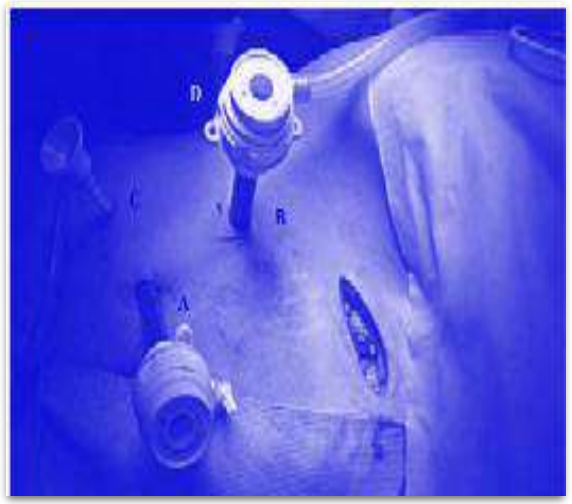
- ✓ Implication of the field
- ✓ Strong impact of stakeholders – much more than government
- ✓ Stakeholders must take decisions and look for compromise
- ✓ Balanced, compromise

CONS

- ☒ Complicated and (very) slow
- ☒ **Different interests**
- ☒ **Conservative**
- ☒ **Incremental changes**
- ☒ **Silos financing**

Institutional funding (hospital)

Budget of Financial Means (BFM part B2): eg consumables and not-reimbursed invasive MDs



Lump sum or capped reimbursement: eg most invasive MDs (CRIDMI list cat. II)

Reimbursement per product: eg most implants (CRIDMI list cat. I) with or without nominative list

Investments by Hospital/Physicians (via honoraria) or regionally: eg radiology machines (MES)

Patient may (or not) have an OOP
And <u>if possible</u>: Patient can fully pay himself for the MD (possibly covered by private insurance)

Hospital Payment Combines Procedure Fees, Device and Medicine Fees, Ward Funding

The same fee-for-service payment mechanism is applicable to outpatient specialist (ambulatory) settings

Source : MTRC report 2026

Market Drivers

- Key Growth Drivers
- Future Challenges & Strategic Opportunities

4

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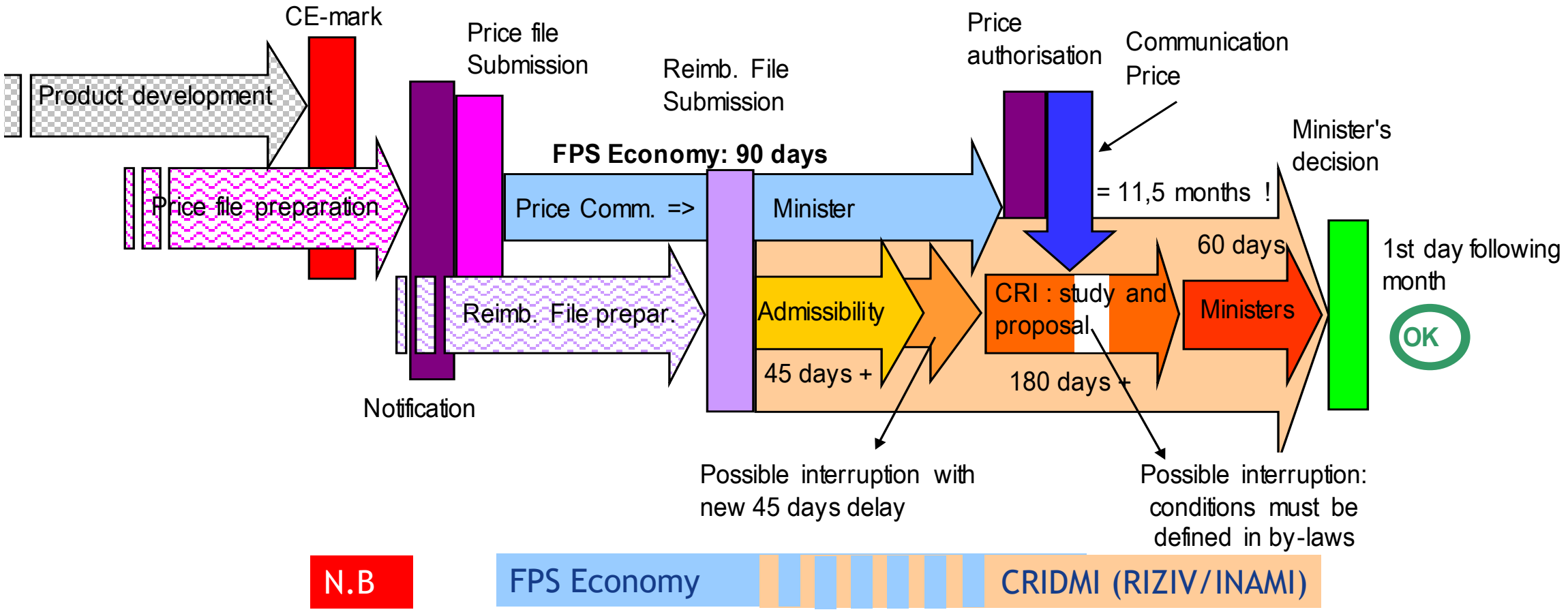
1. Key growth drivers

Create patient and company value by preparing a financing strategy

KEY MARKET DRIVERS

1. Engage with payers **early in product development**
2. Define of a path to **financing**/reimbursement
3. Understand **how payers will assess** your product, as early as the concept stage to use payers' feedback and to shape the technology into a marketable product

Procedures are long and complex
Planning your financing strategy upfront is key !



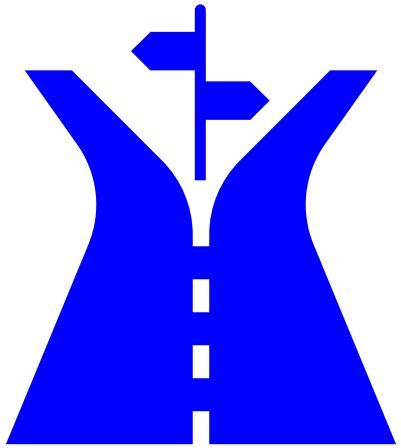
Optimized procedures to market an implant (or invasive MD) : from development to reimbursement in Be

Analyze the possible options for financing your technology before deciding whether reimbursement is the way forward

Checklist:

- Is there a reimbursement ?
- What is the procedure?
- Are there (binding) timelines?
- What is the impact of this reimbursement on your technology's price ?
- Is reimbursement requested in public tenders ? Should it be requested?
- Can patients, users, hospitals, HCP, finance it themselves?
- Benchmark with surrounding countries

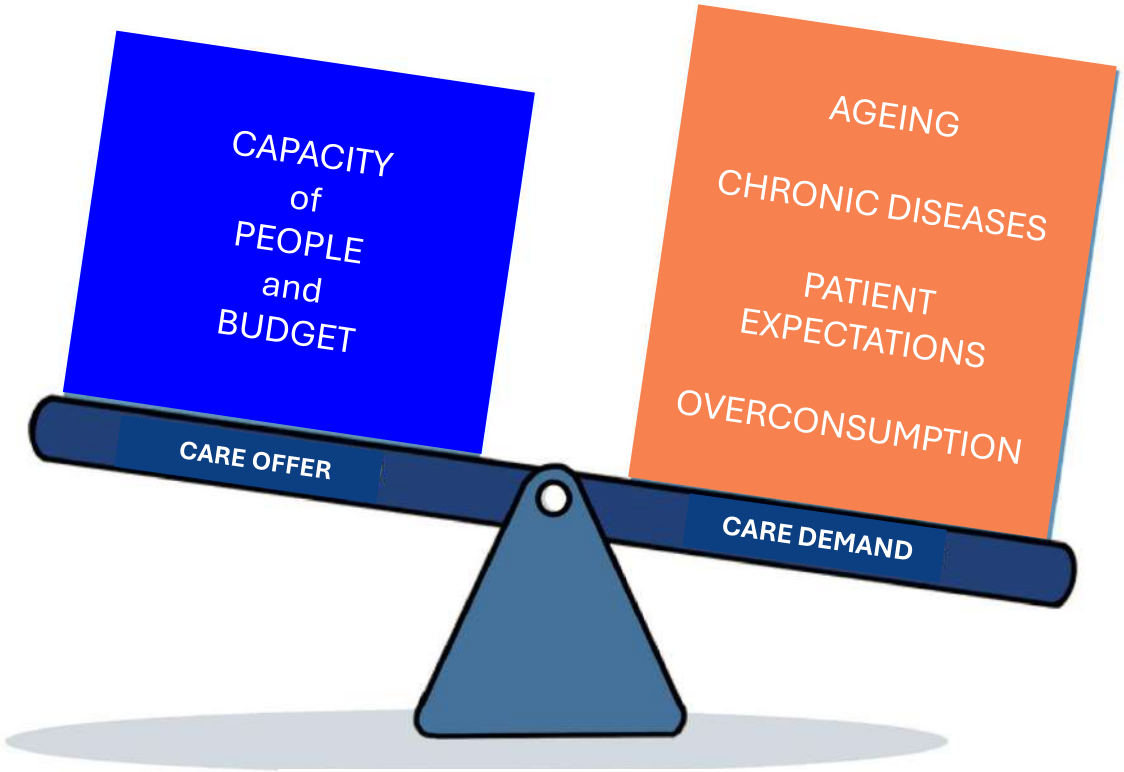
Seeking reimbursement is not always necessary to access patients/users



- Reimbursement = price-control + restrictions in use
- "*Free market*" As long as patients/users can buy and pay themselves
- If "successful adoption" of the technology, mutualities will feel pressure from patients/users/public/MoH to reimburse it

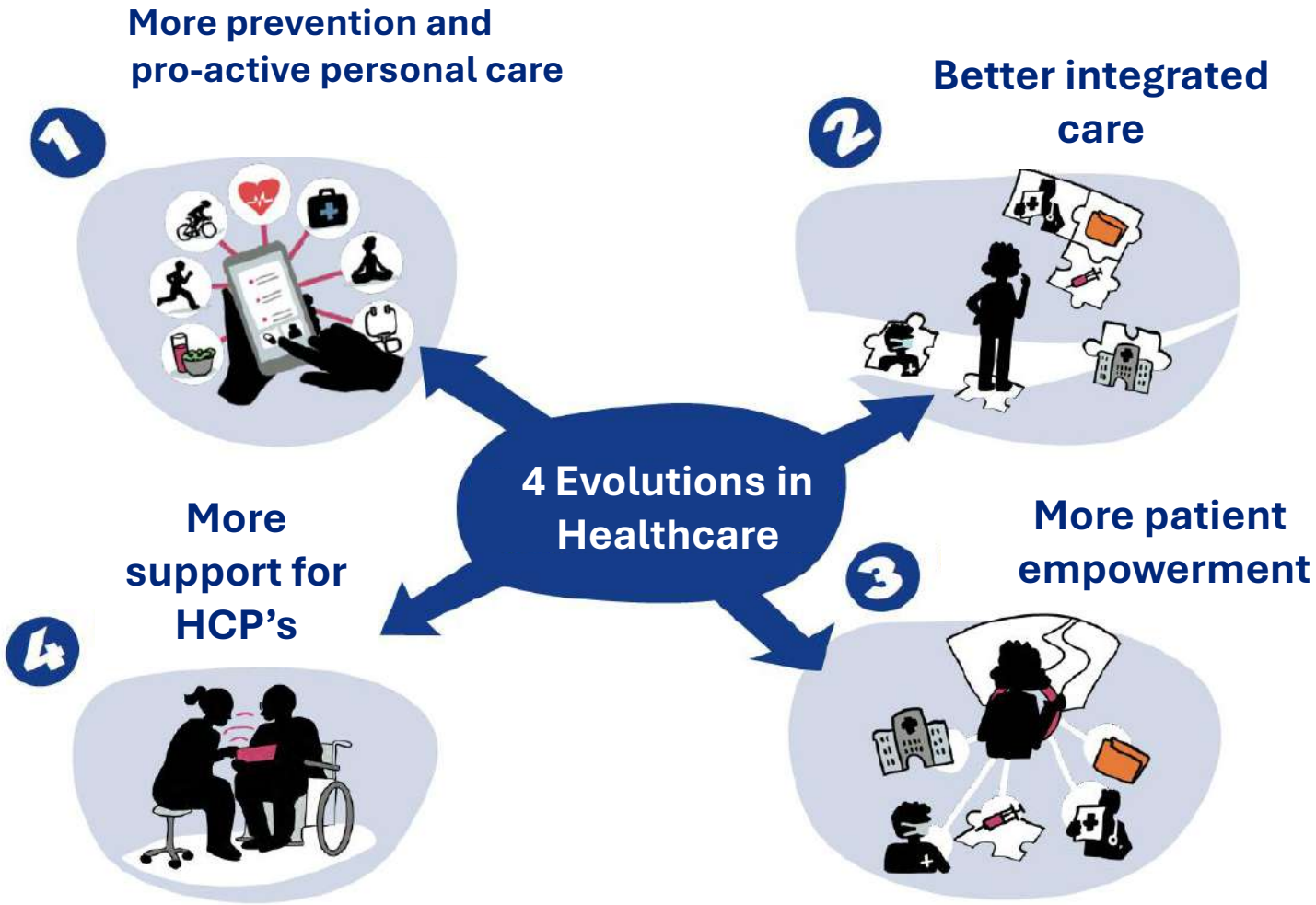
2. Trends, Challenges & Strategic Opportunities

The disbalance between offer and demand of care offers opportunities for medtech



TODAY

Belgian healthcare system follows other western countries general trends



Source: https://www.bemedtech.be/news/zuurstof-voor-de-zorg-memorandum-2024

Shift in procurement practices is an important trend

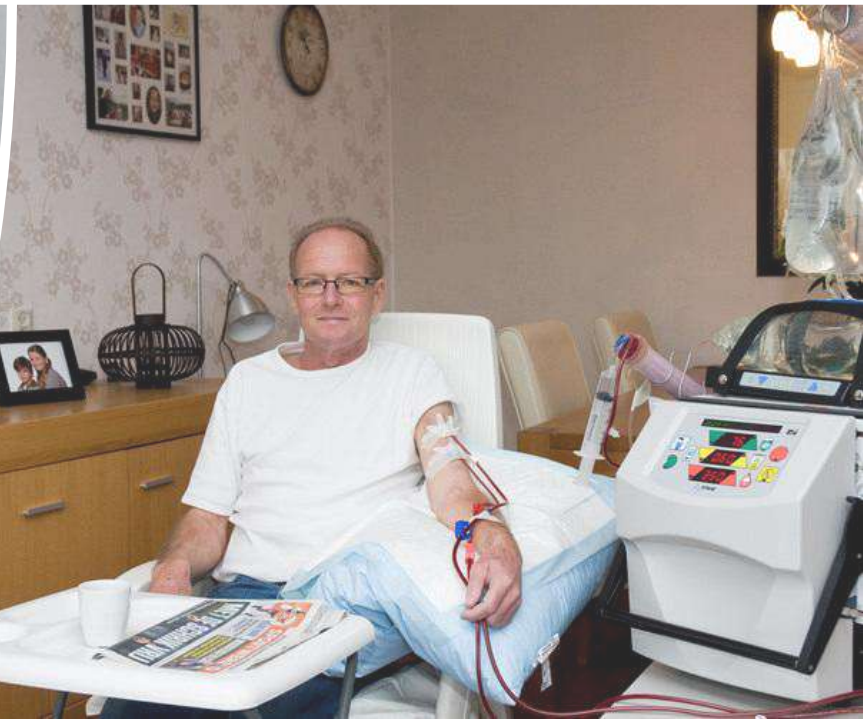
From Physician-led decision-making, head of nurses, hospital pharmacist, …

Towards Purchasing led by hospital/network management and/or centralized procurement

Quality of care, sustainability, VBHC?, …

Home is the ‘privileged’ care setting

- CPAP treatment for sleep apnea
- Oxygen therapy for COVID or COPD
- Medical nutrition for cancer
- Infusion therap: AB/chemo
- Home dialysis
- …



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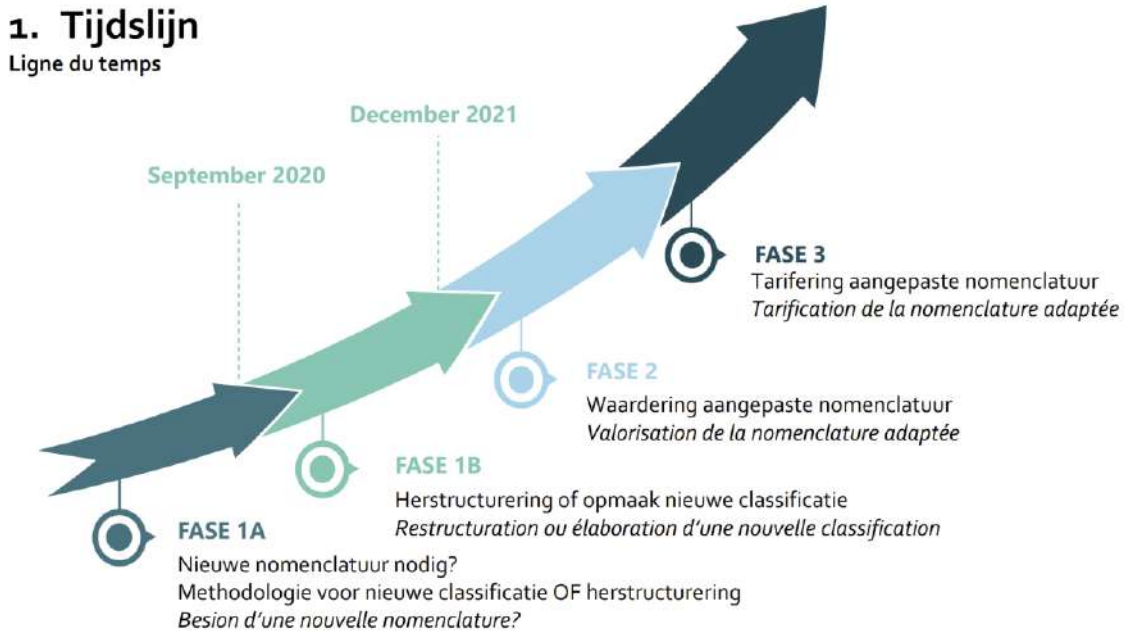
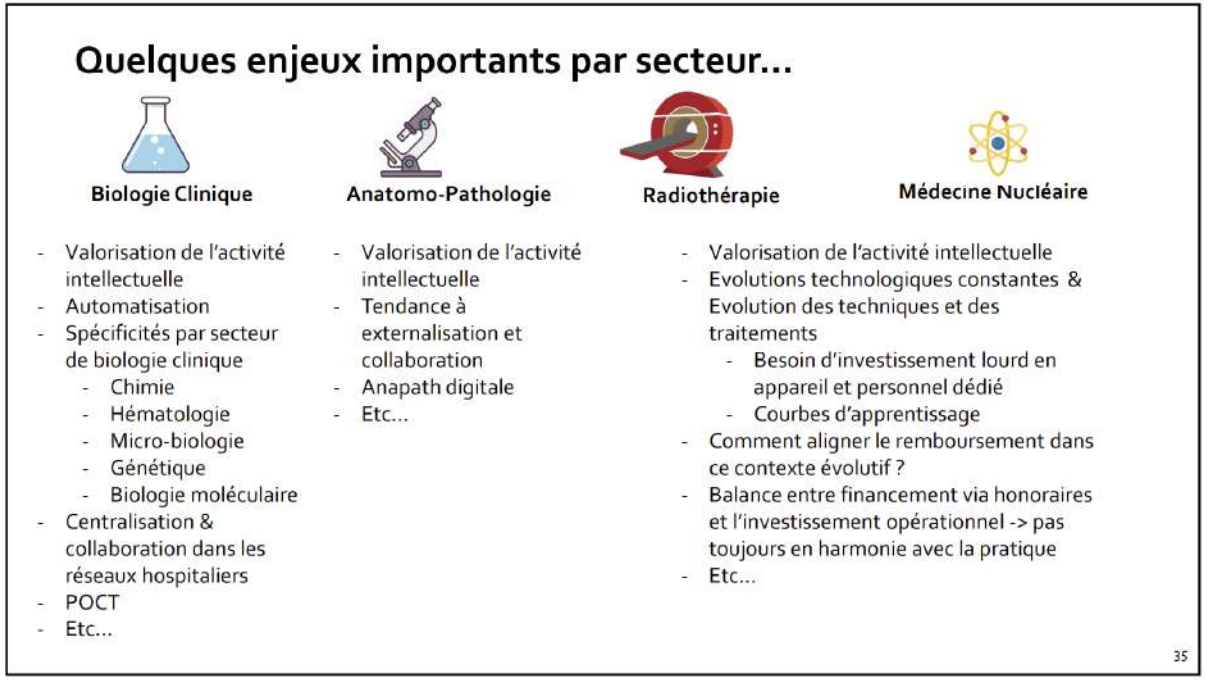
Change in patient care, diagnosis, monitoring, …

Reform of the Belgian Nomenclature is ongoing and will have impact on the market





Budgets, Debt and Geopolicals

"If we're going to make further cost savings in healthcare, we'll need to be told how to do it."

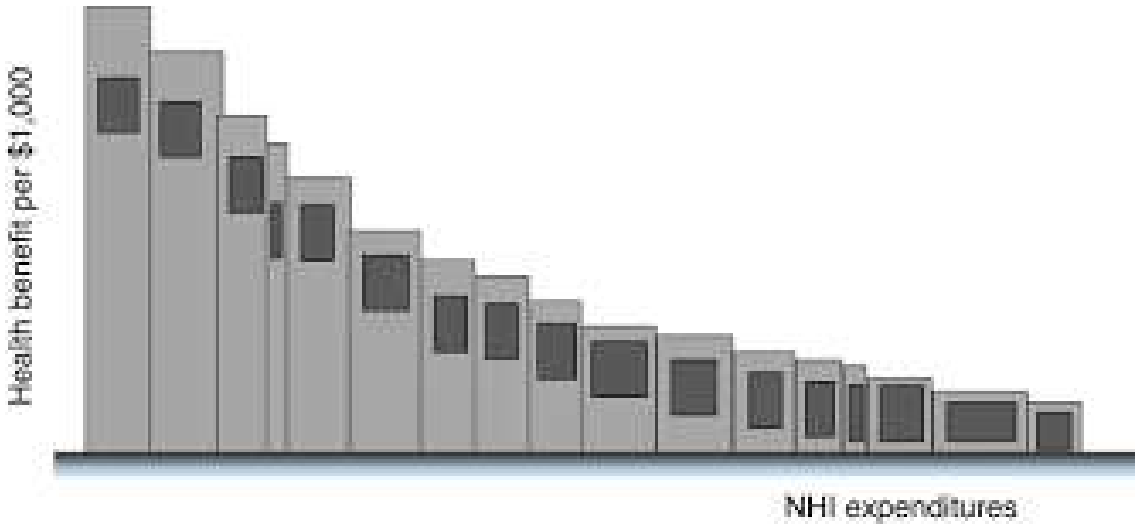
Pedro Facon
(CEO RIZIV INAMI)
25-07- 2026

Après avoir été le "Monsieur Covid" du gouvernement, Pedro Facon occupe depuis le 1er janvier le poste d'administrateur général de l'Inami. ©cameriere ennio

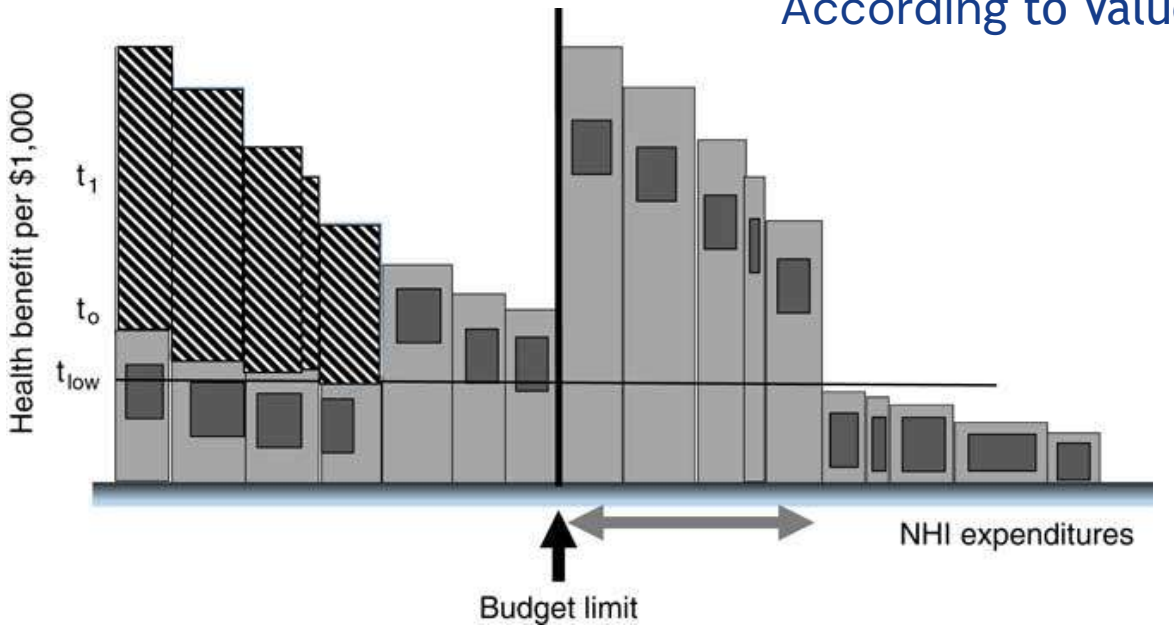
Source: https://www.lalibre.be/belgique/politique-belge/2026/07/25/si-on-veut-encore-realiser-des-economies-dans-la-sante-il-faudra-nous-dire-comment-faire-U7MORZDMMNGA3MDKMCIG4FANTU/

Changes in the Bookshelf model ?

According to Timing



According to Value



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#StrongerTogether

Thank you
for your trust.