

# RIZIV/INAMI – IFB DAY

## PRICING & REIMBURSEMENT TODAY

THE  
[ ]  
SEP

### The basics

04/10/2018



# AGENDA: 8.30-12.30h

- *Welcome (8.30h)*
- *History / Social Security*
- *RIZIV / INAMI*
- *CTG / CRM & HTA*
- *SAM / TARDIS / CIVARS / e-prescription*
- *Managed Entry Agreements*
- *BeneluxA – What's next*
- *The end (12.15h)*

*Wouters Martine*

*Arickx Francis*

*Arickx Francis*

*Millecam Virginie*

*Millecam Virginie*

*Millecam Virginie*

*Arickx Francis*



National Institute for Health and Disability Insurance NIHDI

RijksInstituut voor Ziekte en InvaliditeitsVerzekering RIZIV

Institut National d'Assurance Maladie Invalidité INAMI

Landesinstitut für Kranken- und Invaliditätsversicherung LIKIV



# Social Security



## History

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Civil Houses of God and Offices of Benevolence

Societies for Mutual Assistance

Health Insurance Funds

1886 government intervention

National Unions and Trade Unions

1903 mandatory insurance – accidents at work

1937 mandatory insurance self-employed persons or family benefits

Interbellum : extension mandatory system: old age and survivor's pension, professional diseases, family benefits, annual vacation, guaranteed income disabled,...  
subsidy by government

Public Health is not sufficiently guaranteed on a basis of voluntary insurance, information and education

Local initiatives to negotiate Agreements on Prices and Fees

The Bismarck Model

## History

WW II ‘ draft agreement for social solidarity ’

WW II ‘ social pact ’

Social peace

Solidarity

All social insurances

Benefits rise

National Office For Social Solidarity

Balanced Control

28.12.1944 mandatory insurance in stead of voluntary insurance, subsidized by the government

Rapid implementation, managed by the National Unions

Organisation and execution by independent institution,  
managed by representatives of employers, employees and government

The Belgian National Office for Social Security - RijksDienst voor Maatschappelijke Zekerheid

General administration, control and partition of funds,  
managed by the National Unions

The Belgian National Insurance Fund against Sickness and Disability  
RijksFonds voor Verzekering tegen Ziekte en Invaliditeit



## History

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**9 august 1963 Law on Mandatory Insurance for Health and Disability**

replaced by Law 14 july 1994



**28.12.1944 mandatory insurance in stead of voluntary insurance, subsidized by the government**

Rapid implementation, managed by the National Unions

Organisation and execution by independent institution,  
managed by representatives of employers, employees and government

RijksDienst voor Maatschappelijke Zekerheid

General administration, control and partition of funds,  
managed by the National Unions

RijksFonds voor Verzekering tegen Ziekte en Invaliditeit

## History - objectives

**protection of the population**  
**'community has the duty to offer every person decent existence'**

**in case of**

**LOSS OF INCOME**  
**guaranteed minimum income to everyone who has no or insufficient means**  
**of existence and who cannot obtain them,**  
**neither with his own efforts nor by other means**

**EXTRAORDINARY EXPENSES**  
**possibility of obtaining (financial) support**  
**supplementary income (pension - raising children – invalidity - ...)**  
**or (partial)reimbursement of expenses (medical care,...)**

## History - Ideological Background



**Otto Eduard Leopold,  
Prince von Bismarck,  
Duke of Lauenburg**



**William Henry Beveridge,  
1st Baron Beveridge**

## History - Ideological Background



**employees and gainfully employed**

**financing is via contributions, graduated according to income**

**contributions based on wages or salaries**

**assures a standard of living**

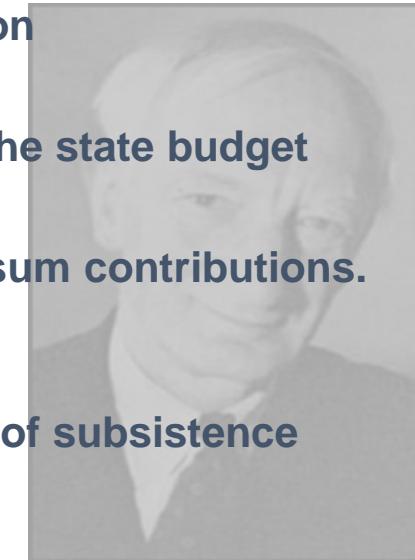
**Otto Eduard Leopold,  
Prince von Bismarck,  
Duke of Lauenburg**

**whole population**

**financed from the state budget**

**uniform, lump-sum contributions.**

**secures a level of subsistence**



**William Henry Beveridge,  
1st Baron Beveridge**

## Organisation

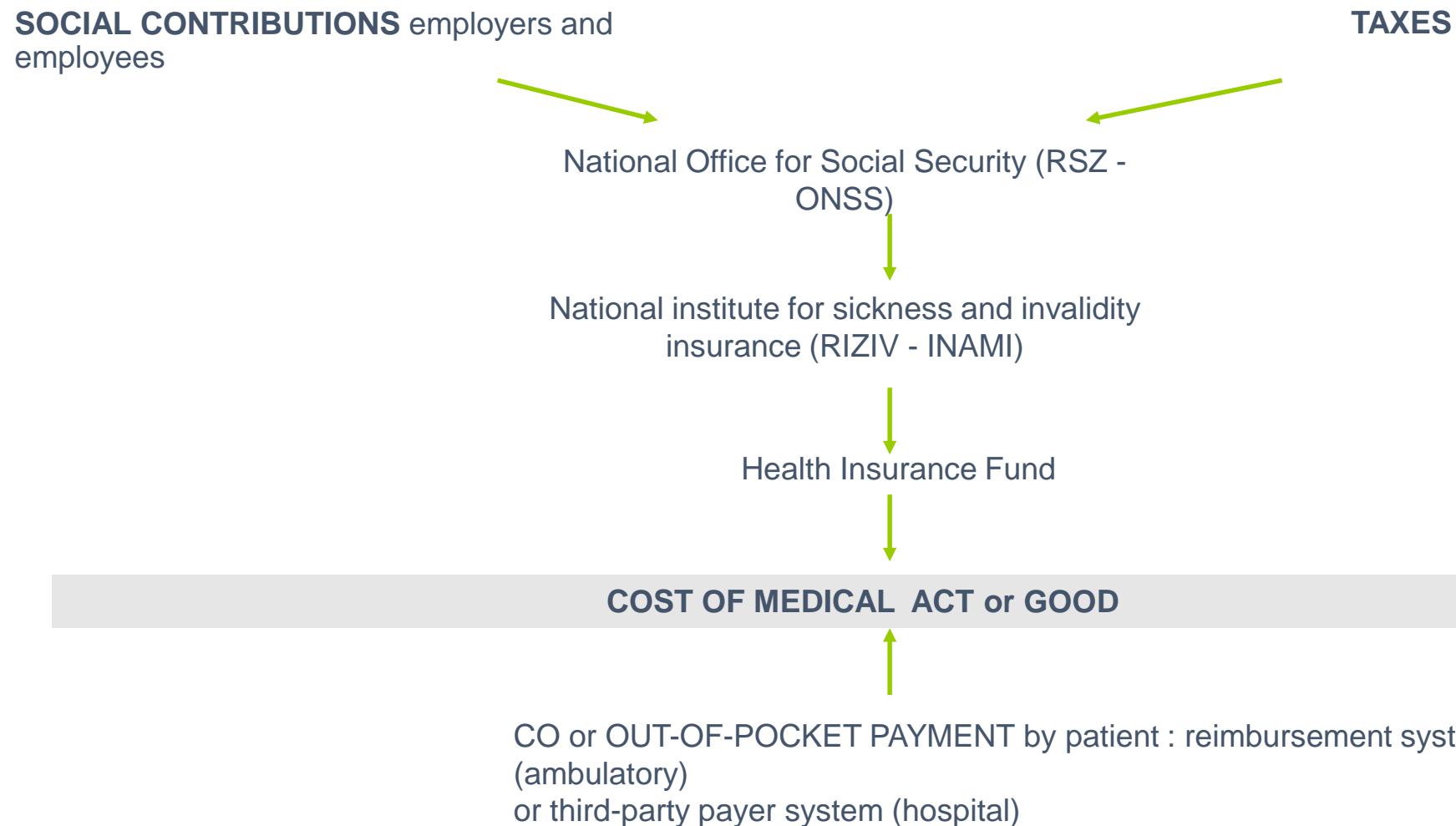
**9 august 1963 Law on Mandatory Insurance for Health and Disability**

replaced by Law 14 july 1994

Salaried persons	National Office for Social Security (RSZ - ONSS) National office for family benefits for salaried persons (RKW - ONAFTS) National employment office (RVA - ONEM) National pension office (RVP - ONP) National institute for Health and Disability Insurance (RIZIV – INAMI - NIHDI) Fund for accidents at work (FAO - FAT) Fund for professional diseases (FBZ - FMP) National office for annual vacation (RJV - ONVA)
Self-employed persons	National institute for the social insurances of self-employed persons (RSVZ - INASTI)
Civil Servants	National social security office for the local and provincial administrations (RSZPPO - ONSSAPL)



## Financing



## Financing

### Other resources

- Solidarity Contribution on pensions and additional benefits of 3,55 %

### - Alternative financing

Car Insurance (Civil Liability, ...)

Fire Insurance

Insurances Industrial accidents

Hospitalization Insurance

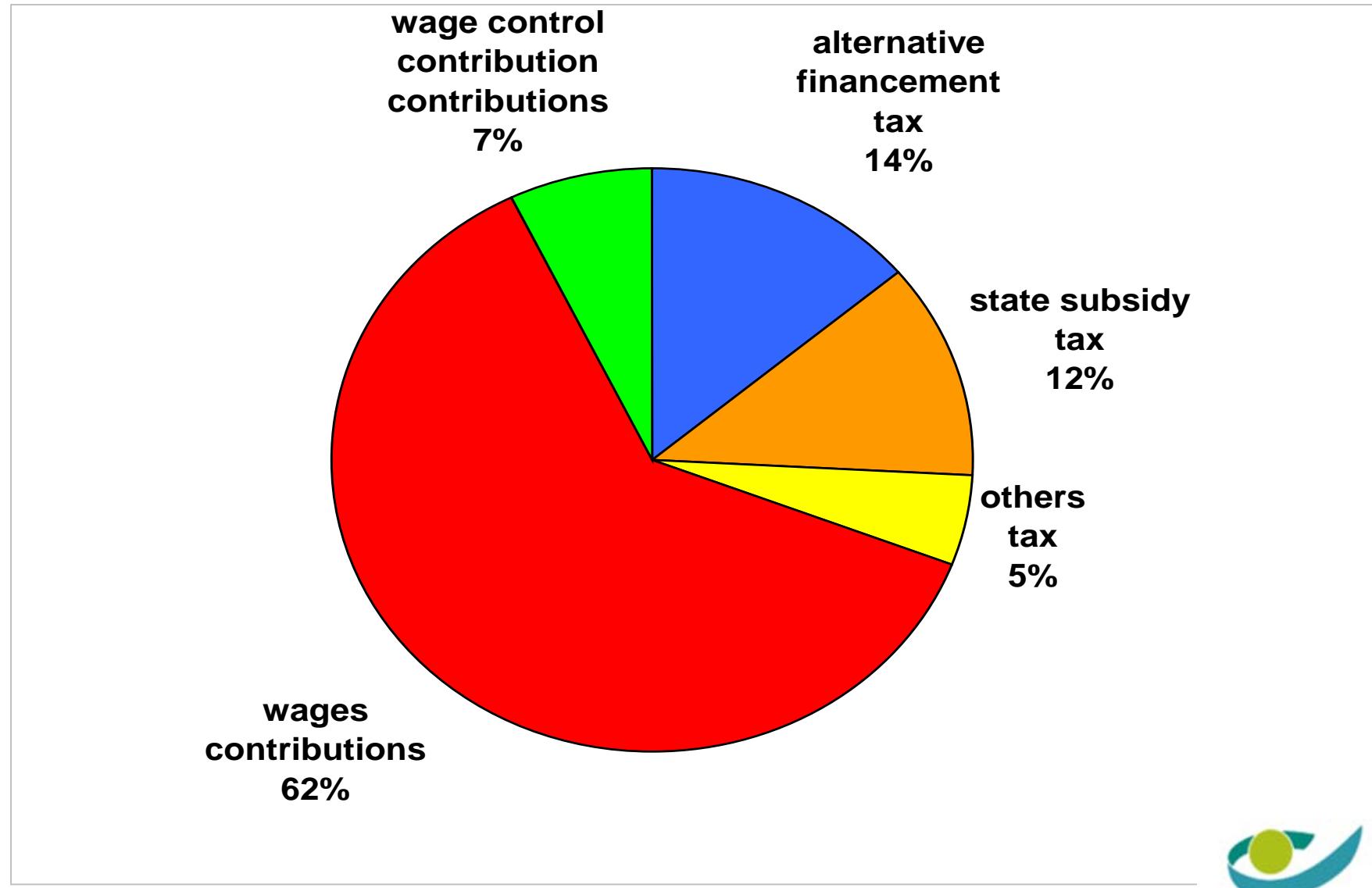
Contribution of 0.35 % to the Belgian Red Cross

### Others (not collected by NIHDI) :

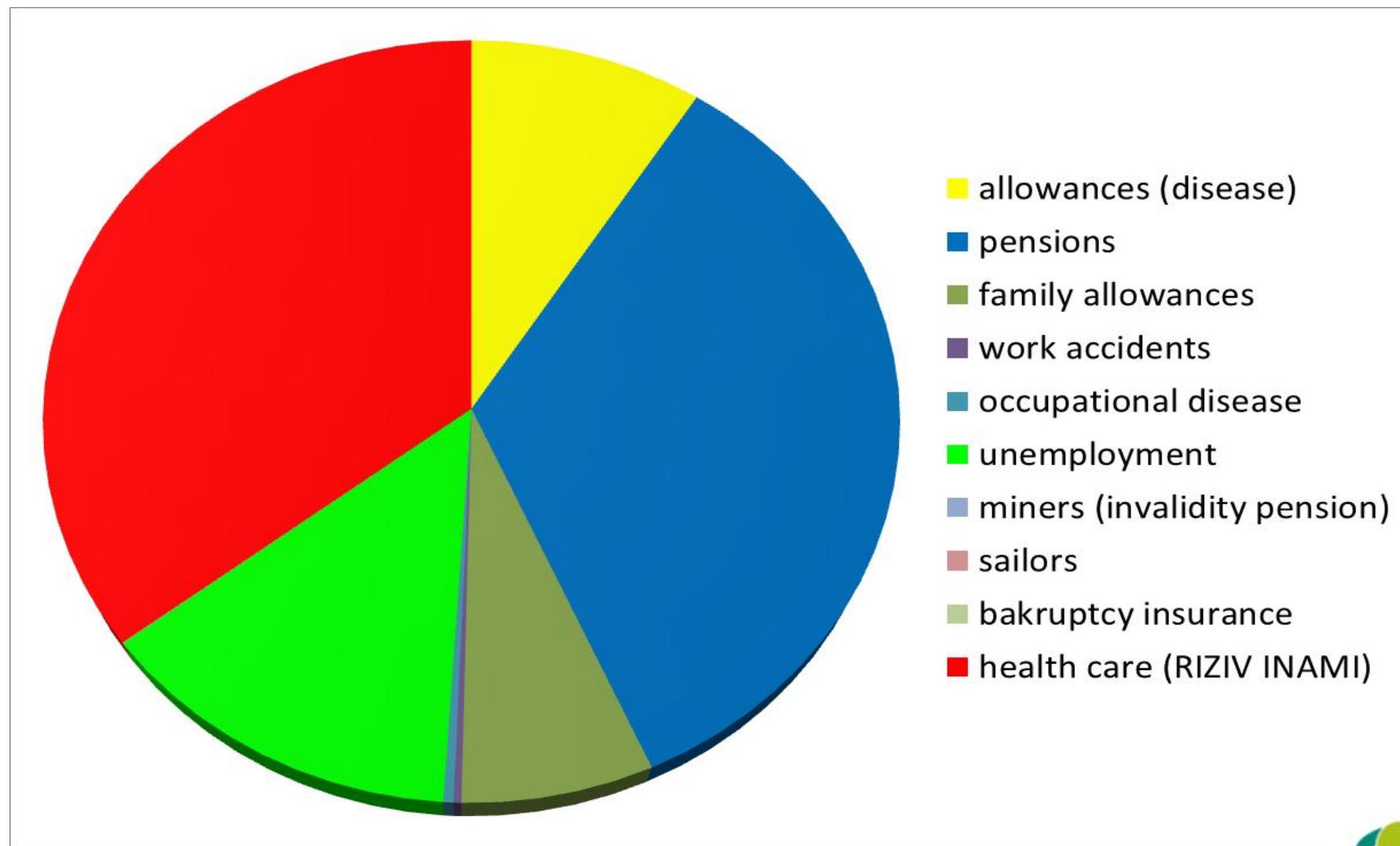
tax of 9,25% on a number of Insurance contracts.

tax for subsidizing safety fund for prevention and fighting fire and explosions

## Social Security Expenditures



## Social Security Expenditures: out



# Health Insurance



## Key Features

**SOLIDARITY** *but... drug prices, economical crisis,...*

**INSURANCE** *but... No cure no pay, risk-sharing, Pay for performance,..*

**COMPULSORY (HEALTH INSURANCE) SYSTEM**

**ACCESS** coverage ± 100 % of population access to health care and support *but.. Europe, US, refugees*

**FREEDOM OF CHOICE** for PATIENTS: freedom to chose their health care provider

**FREEDOM OF CHOICE** for HEALTH CARE PROVIDER:

therapeutic liberty: freedom of choice of diagnosis and prescription/treatment  
paid per item of service

**CONVENTION – BASED DECISION MAKING**

participation of social partners, health providers, health insurance funds, patients

**VERTICAL ORGANISATION** (decision making, budget,...) , as opposed to a horizontal integral approach

**NOMENCLATURE**: lists of reimbursed medical (diagnostic and therapeutic) acts and goods (pharmaceuticals, medical devices, nutrition, ...)

# National Institute for Health and Disability Insurance

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Administrative and financial management of the Insurance  
for Healthcare and Allowances

Organisation of access

Control all actors

Organisation of negotiations

Management of allowances



# National Institute for Health and Disability Insurance

## General Management Committee

employers org, employees org, UNIZO, Insurers + Min SocAff + Budget + SelfEmployed

accounts  
budget  
admin cost  
staff

Chief Executive Officer  
Deputy Chief Executive Officer

+ Board of Directors

Health Care

Medical Evaluation and  
Inspection

Benefits  
Allowances

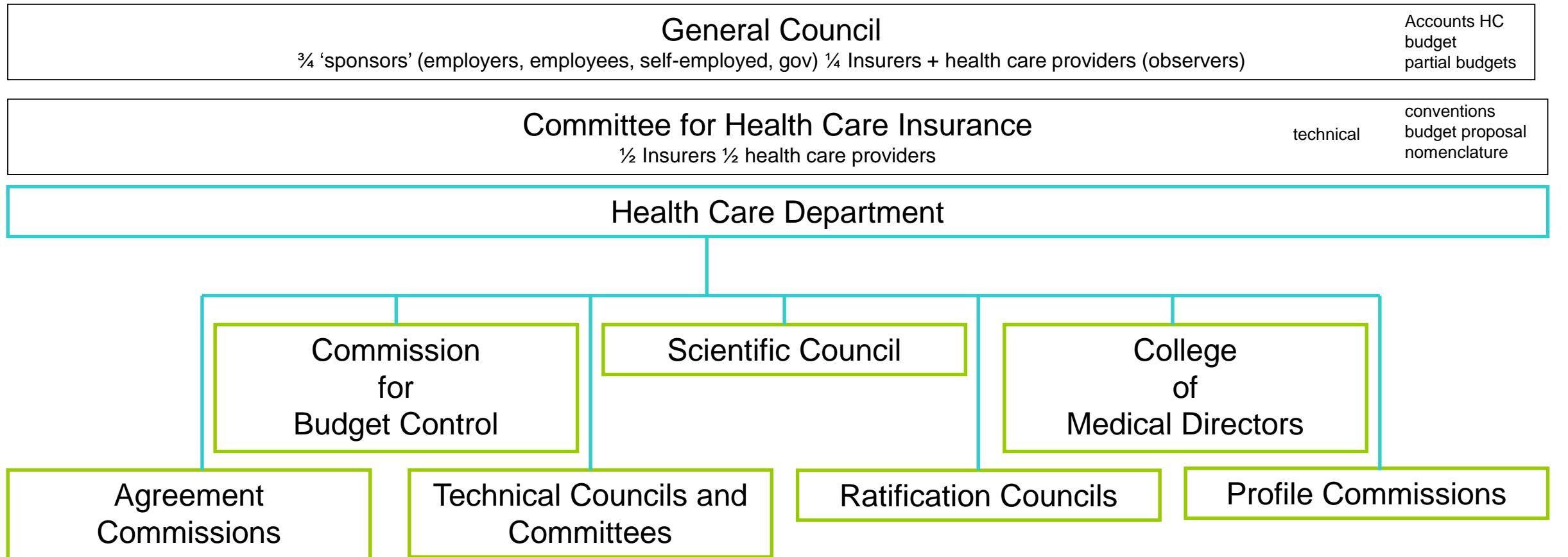
Administrative  
Inspection

Fund for medical  
accidents

General support



# National Institute for Health and Disability Insurance



Health Care Department  
Dienst voor de Geneeskundige Verzorging  
Service de Soins de Santé

Directie Internationale Relaties  
Direction Relations Internationales

Directie Verzorgingsinstellingen en - diensten  
Direction Etablissements et services de soins

Directie Farmaceutisch Beleid  
Direction Politique Pharmaceutique

Directie Onderzoek Ontwikkeling en Kwaliteit  
Direction Recherche, Développement et promotion de qualité

Directie KLAVVIDT & individuele dossiers  
Direction KLAVVIDT et dossiers individuels

Medische Directie  
Direction Médicale

Directie Juridische Zaken en Toegankelijkheid  
Direction Juridique et Accessibilité

Directie actuariaat en budget  
Direction actuariat et budget



Directie Farmaceutisch Beleid  
Direction Politique Pharmaceutique

Interne Expertise  
Expertise Interne

Beheer procedures en dossiers  
Gestions des procédures et dossiers

Beheer van informatie en Administratieve Vereenvoudiging  
Gestion d'information et Simplification Administrative

## Directie Farmaceutisch Beleid Direction Politique Pharmaceutique

Interne Expertise  
Expertise Interne

Beheer procedures en dossiers  
Gestions des procédures et dossiers

<b>Marc VanDeCastele</b>	
<b>Lies Grypdonck</b>	
<b>Piet Vancraeynest</b>	
<b>Pol Specenier</b>	
<b>Joel Daems</b>	
<b>Carine Vannecke</b>	
<b>Thierry VanHedent</b>	+ Prijzencommissie
<b>Guy Hans</b>	
<b>Anouk Waeytens</b>	+ Compagnon Diagnostics + Nut Méd
<b>Filip Van Nuffel</b>	
<b>Jean Michel Michot</b>	
<b>Catherine Lucet</b>	
<b>Maurice Lipszyc</b>	
<b>Marie Laurence Lambert</b>	
<b>Susana Da Silva Sanchez</b>	

## Directie Farmaceutisch Beleid Direction Politique Pharmaceutique

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Expertise Interne

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Beheer van informatie en Administratieve Vereenvoudiging  
Gestion d'information et Simplification Administrative

Vinciane Knappenberg	
Virginie Millecam	Secr CTG – bureau CTG
Katrien VanderVeken	Art 81
Annemie Quanten	Art 81
Catherine Adriaens	Orphans
Florence Leveque	UMN – Nut Méd
Patricia Deroux	Méd support
Veerle Van De Velde	CTG - TTRI
Els Soete	TTRI - Compagnon Diagnost -
Inneke VandeVijver	Art 81
Sebastien Therville	CTG
Blandine Divry	OCA – Nut Méd
Dominique Dethier	TFR - TRDVM
Celine Hermans	Orphans - Taxes
Laurence Touyères	CTG
Ines Dooms	CTG
Els Verstuyft	CTG

Directie Farmaceutisch Beleid  
Direction Politique Pharmaceutique

Interne Expertise  
Expertise Interne

Beheer procedures en dossiers  
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Beheer van informatie en Administratieve Vereenvoudiging  
Gestion d'information et Simplification Administrative

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[Voornaam.naam@riziv.fgov.be](mailto:Voornaam.naam@riziv.fgov.be)

## Directie Farmaceutisch Beleid Direction Politique Pharmaceutique

Interne Expertise  
Expertise Interne

Beheer procedures en dossiers  
Gestions des procédures et dossiers

### Beheer van informatie en Administratieve Vereenvoudiging Gestion d'information et Simplification Administrative

<b>Yoeriska Antonissen</b>	
<b>Nele Dhaeze</b>	
<b>Bertrand Diry</b>	
<b>Maïté Vincent</b>	
<b>Sven Ermgodts</b>	
<b>Herman Beyers</b>	Farmanet – Consensus - MFO
<b>Marc Defalleur</b>	Farmanet
<b>Joos Tielemans</b>	Farmanet
<b>Bram Putzejs</b>	Farmanet

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[CTGCRM.database@riziv.fgov.be](mailto:CTGCRM.database@riziv.fgov.be)

[farmanet@riziv.fgov.be](mailto:farmanet@riziv.fgov.be)



## Directie Farmaceutisch Beleid Direction Politique Pharmaceutique

**Karine Mangon**

**Nancy Alewaters**

**Patrick Declercq**

**Ornella Valan**

**Marleen Van Hauwermeiren**

**Sophie Famery**

**Laurent Vandemoortele**

**Pascale Glineur**

**Inge Aerts**

**Monica Bruggman**

**Quentin Dumazy**

Contact:

[specpharma@riziv.fgov.be](mailto:specpharma@riziv.fgov.be)



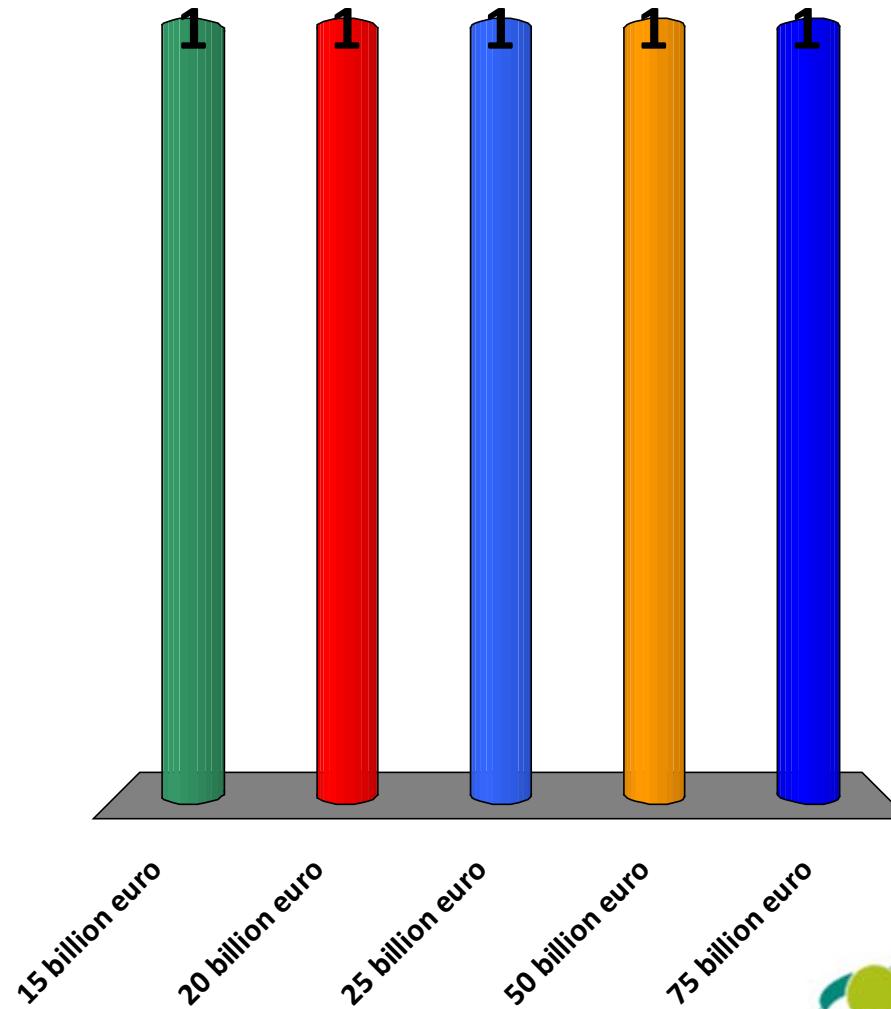
# Public Health Expenditures



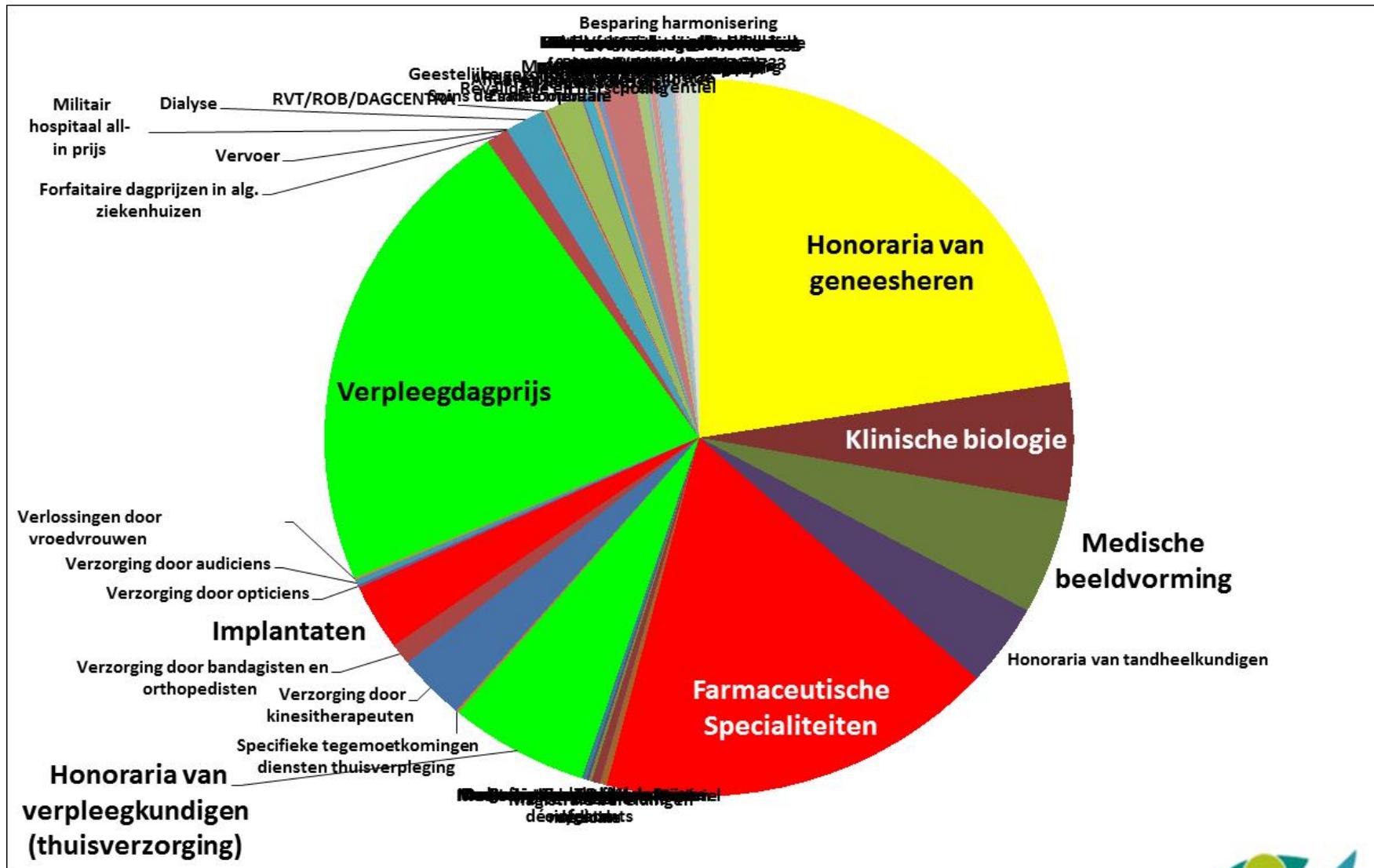


# Budget Health Insurance ?

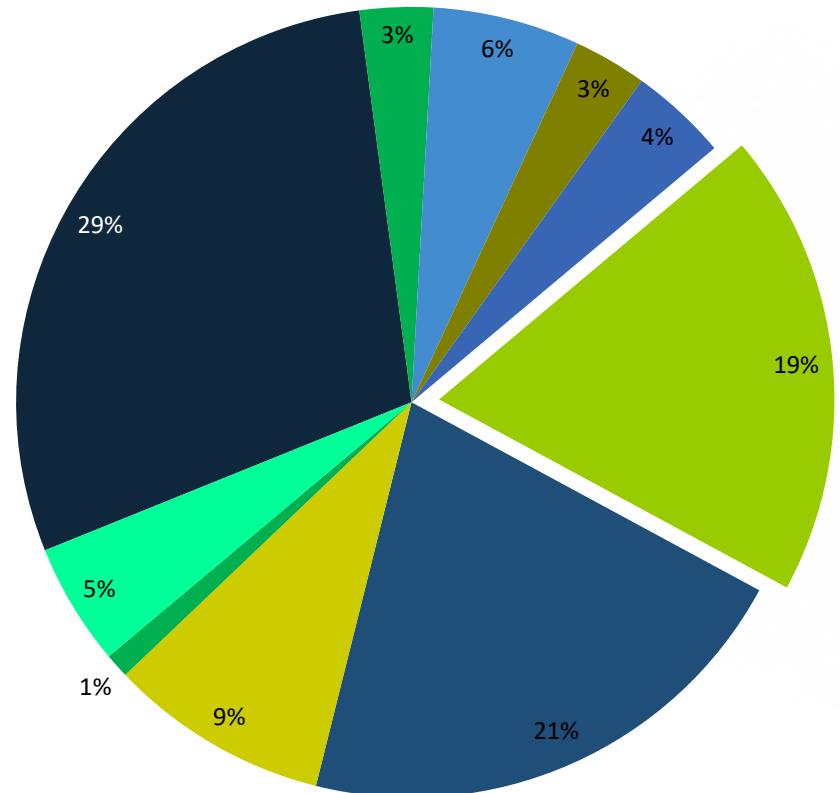
- A. 15 billion euro
- B. 20 billion euro
- C. 25 billion euro
- D. 50 billion euro
- E. 75 billion euro



## Public Health Expenditures



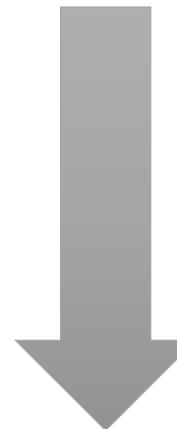
## Public Health Expenditures



Budget Health Insurance:

More or less 25 billion EURO

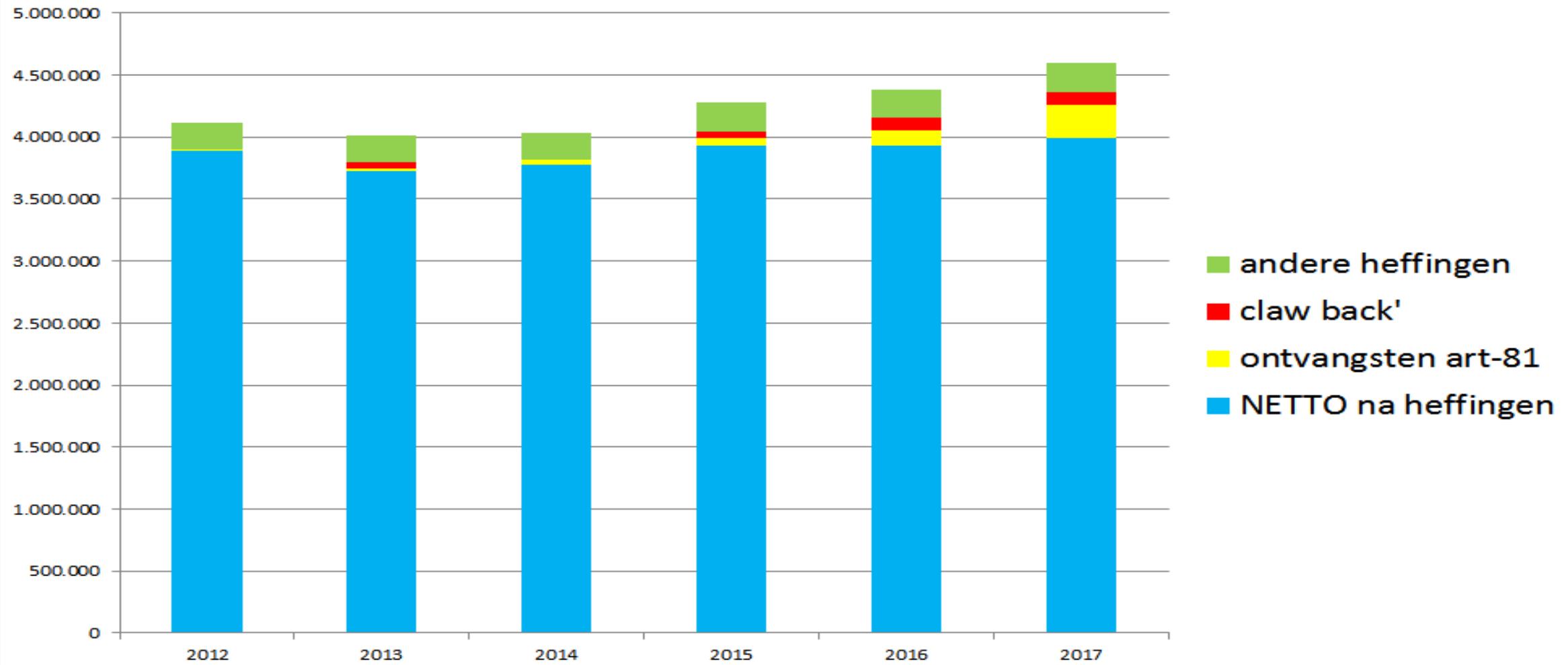
Pharmaceuticals



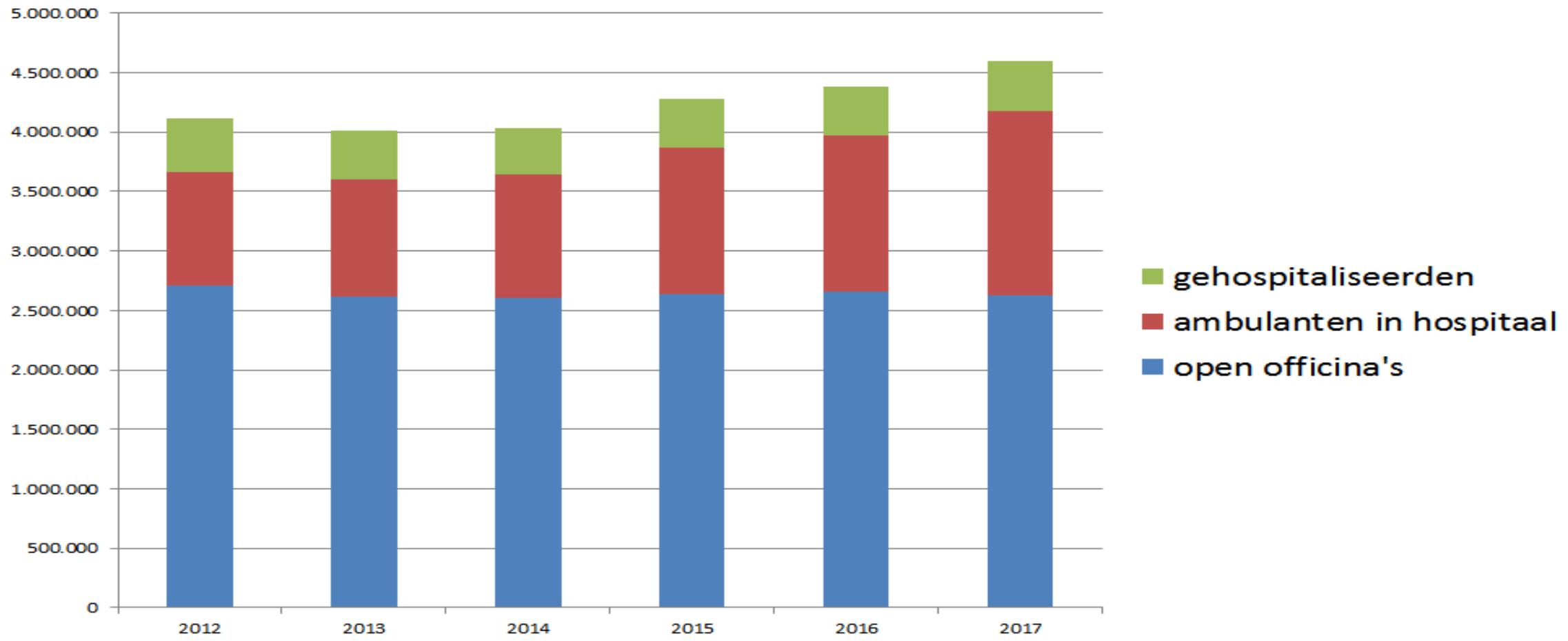
A bit more than 4 billion EURO

Source: INAMI

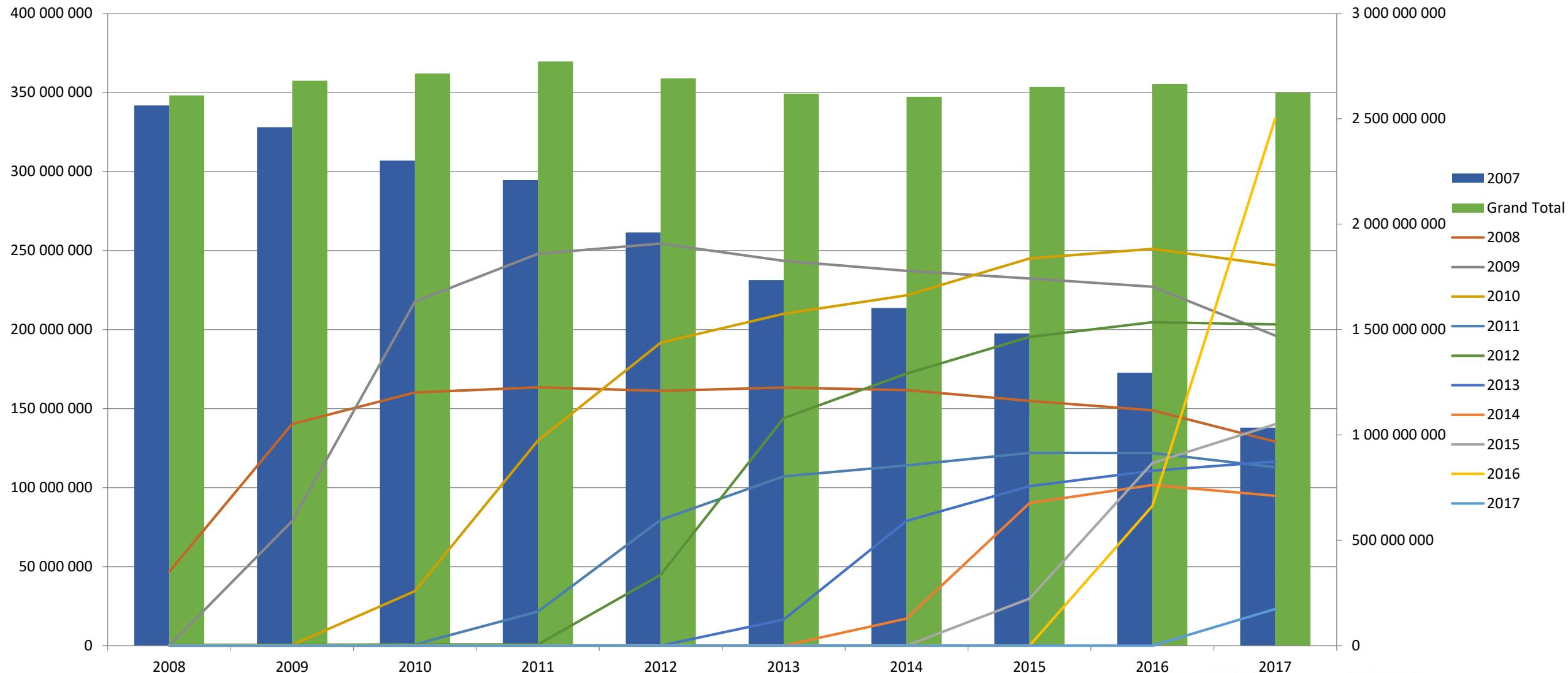
**geboekte uitgaven - inkomsten  
dépenses - recettes comptabilisées  
(000 EURO)**



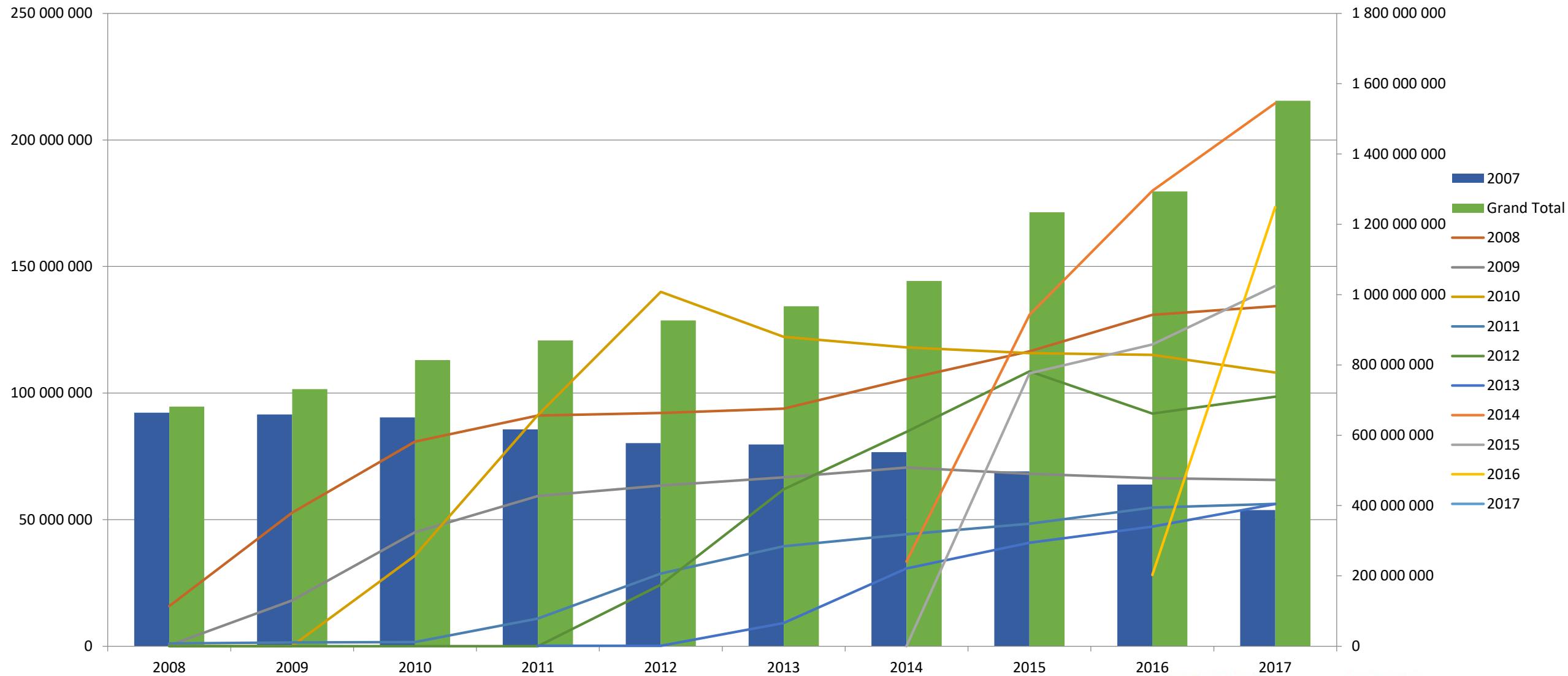
**geboekte uitgaven - inkomsten  
dépenses - recettes comptabilisées  
(000 EURO)**



# Public Pharmacy all NIHDI expendit.



# Hospital Amb. all NIHDI expendit.



# Commission Reimbursement Medicines

C.R.M.



## Key Features

### FEDERAL GOVERNMENT

Marketing Authorization

Minister of Public Health  
FAMHP

Price Setting

Minister of Economy  
Pricing Service

Reimbursement

Minister of Social Affairs

NIHDI

### FLEMISH COMMUNITY - FRENCH COMMUNITY

Health Promotion  
Preventive Measures  
Homes nursing/elderly



# Key Features - legislation

## Marketing Authorisation

- Mainly regulated at European level
- European authorisations / national autorisations

## Pricing and Reimbursement

- Regulated at national level
- European Directive 89/105 – Transparency Directive
  - Strict deadlines (90 days + 90 days)
  - Transparency:
    - Evaluation based on objective and verifiable criteria
    - Evidence Based Medicine + pharmaco-economics
- Pricing
  - Book V Section 2 of the Code of Economic Law: the law of 3 April 2013 “Setting the prices of drugs and similar products”
  - Execution regulated by the royal decree of 10th April 2014
- Reimbursement
  - Principles adopted by the government in October 2000
  - Legal basis established in law of 14th July 1994
  - Execution regulated by the royal decree of 1st February 2018



## Key Features

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**positive list** – nomenclature

**unrestricted reimbursement** versus **restricted reimbursement**  
(chapter I versus chapters II and IV)

reimbursement **ambulatory** versus **hospital** use

**differential reimbursement**

(self-employed persons versus salaried persons: modified 01 01 2008)  
(active versus preferential reimbursement group)  
(category A B C Cs Cx D)

**Maximum Billing** or **Maximum Invoice**

**Reference Reimbursement System**

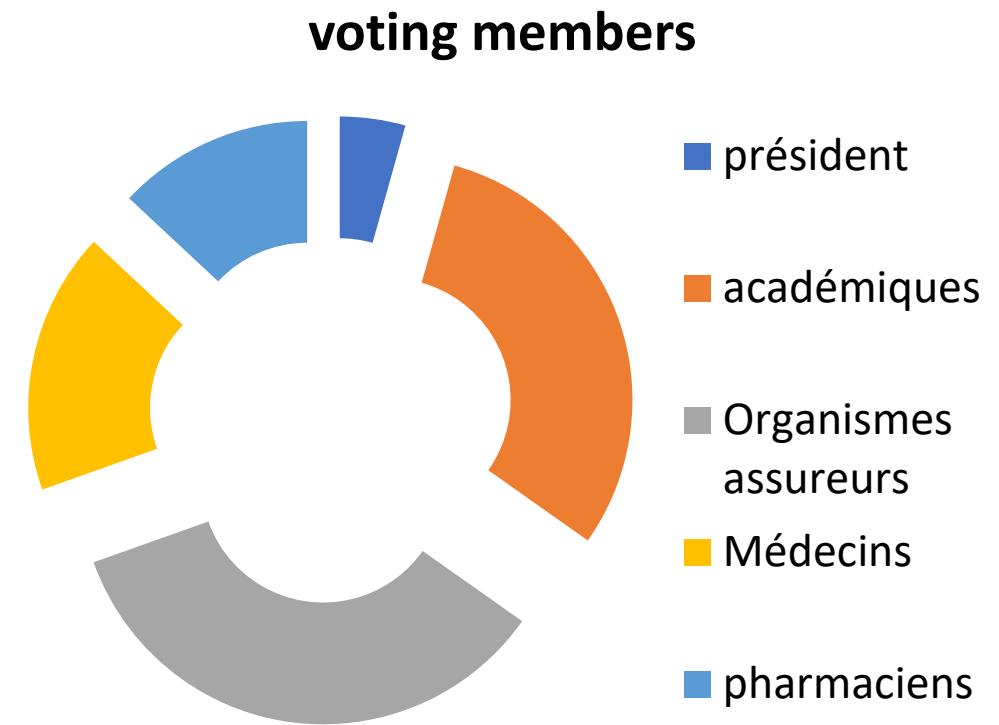
**Revision**

# Commission Reimbursement Medicines

## Members :

23 voting members :

- **President**
- 7 academics
- 8 insureurs
- 4 association physician
- 3 association pharmacist



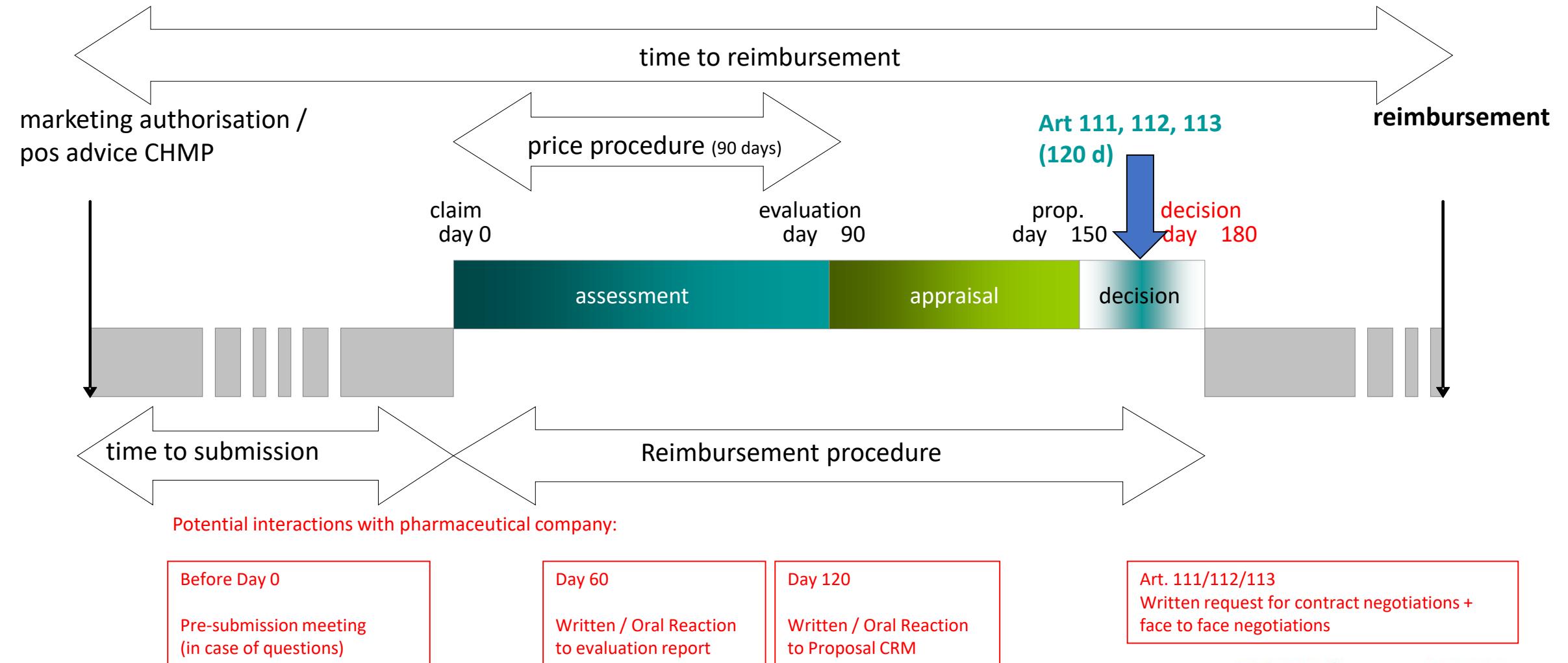
8 non voting member :

- 4 representative Minister
- 1 NIHDI (SECM)
- 2 Pharma.be - 1 Febelgen

## 3 important missions:

1. Formulation of proposals for reimbursement (no decision !)
2. Advices of Minister's Requests for Drug Reimbursement Policy
3. Formulation of proposals to the Insurance Committee on the interpretation of rules on reimbursement

# Procedure



- Minimum **18** voting members
- Proposal with a 2/3 majority  
(abstentions are not taken into counted)
- If no CRM proposal  
→ decision by the Minister of Social Affairs

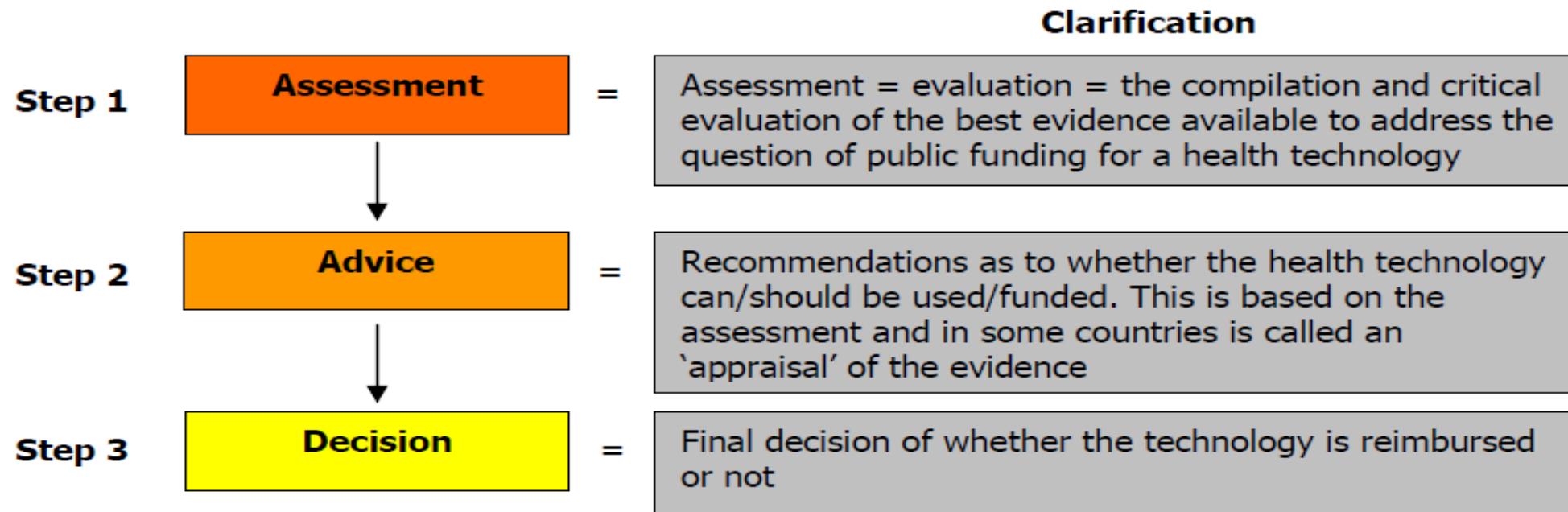


Exception: Added Value (class 1) : Simple majority !!!



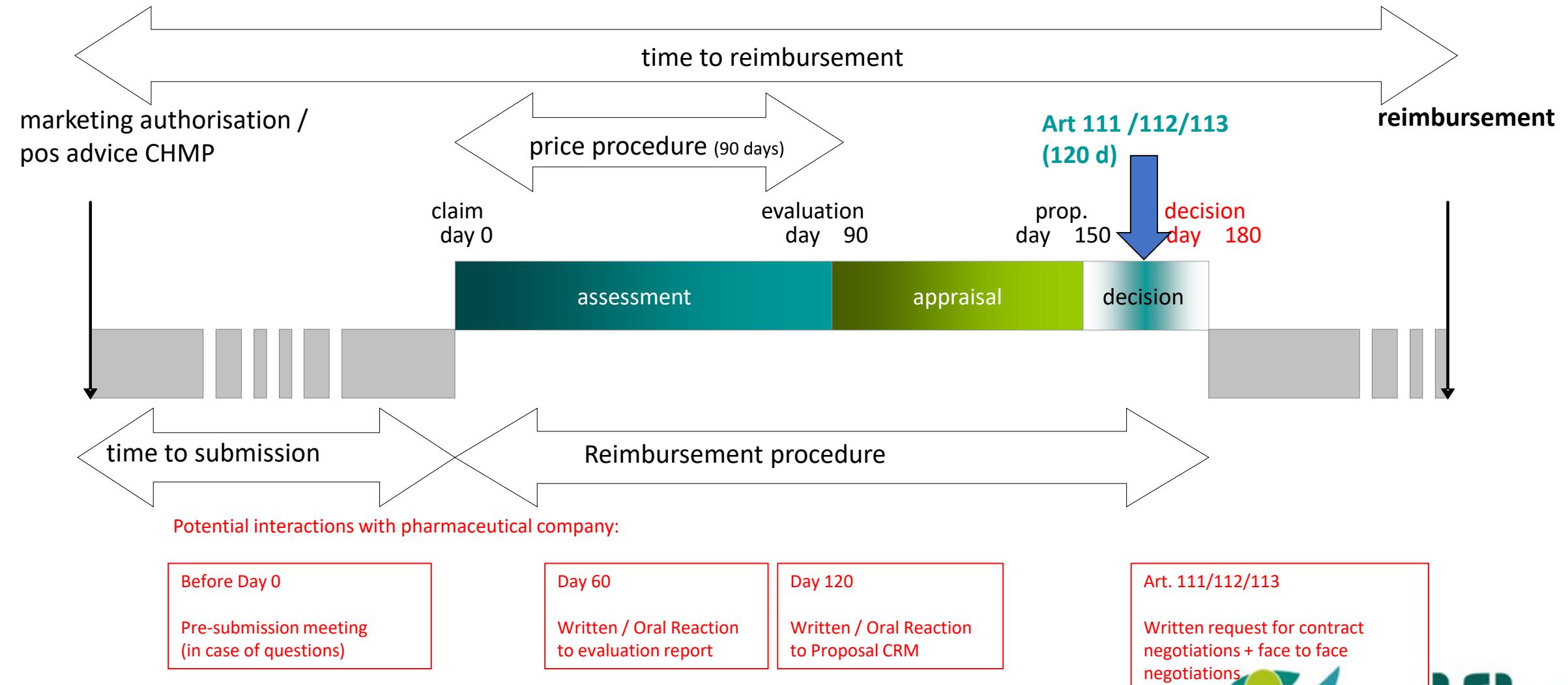
## Procedures

**Figure 9. Schematic overview of steps in a reimbursement process of pharmaceuticals**



EUnetHTA 2011 Report on Relative Effectiveness Pharmaceuticals

## Procedures

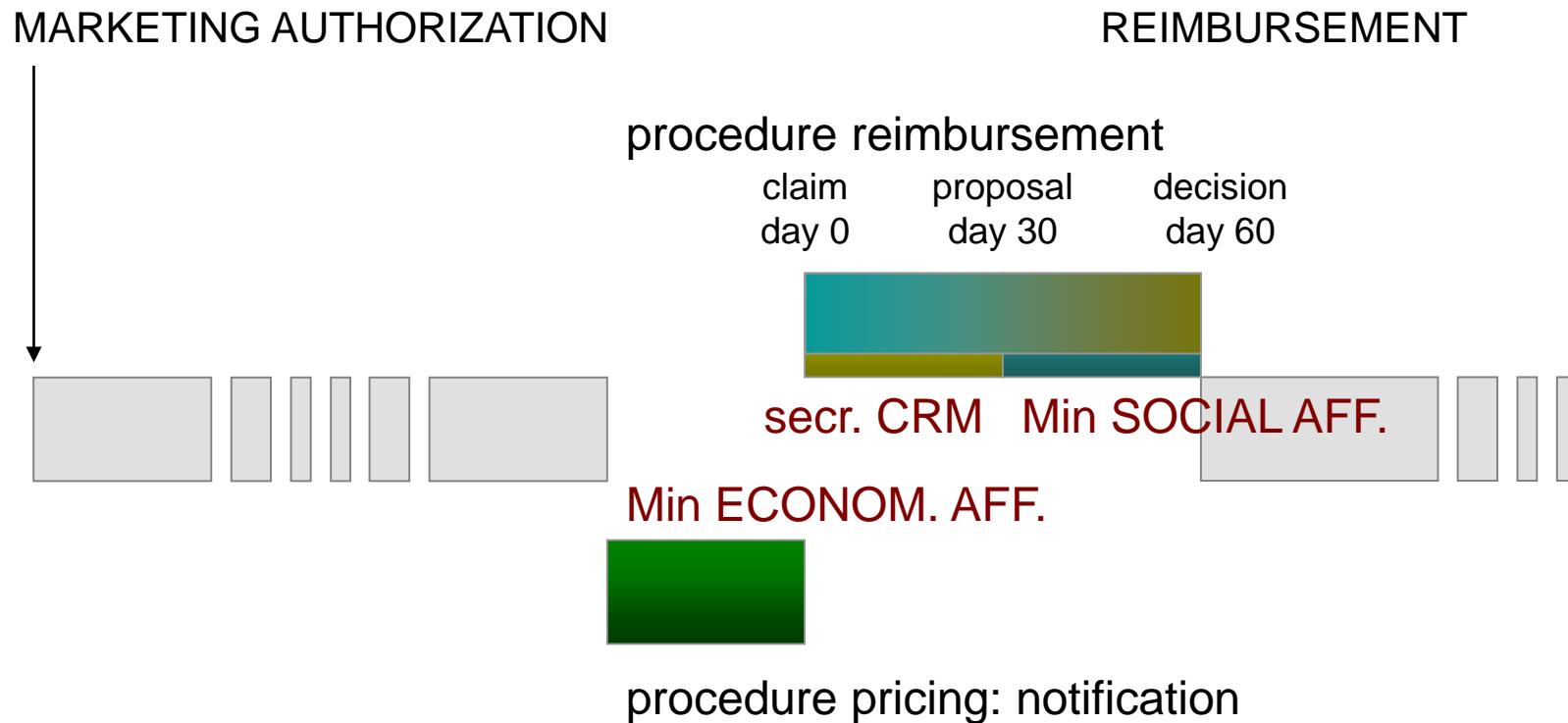


## Procedures

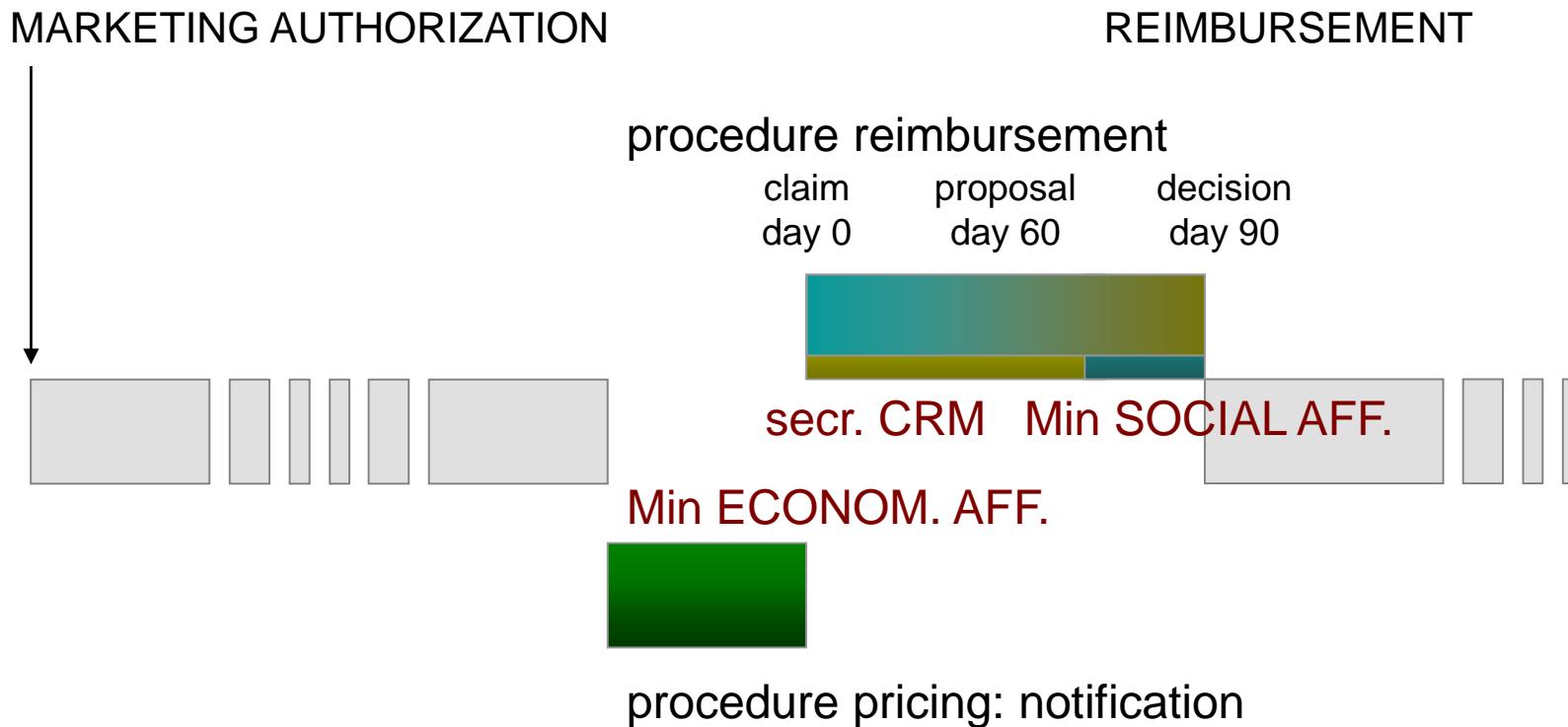
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- Class 1 (Added value) (180 days)
- Orphan (180 days)
- Class 2A (extension – administrative procedure) (60 days)
- Class 2B (No added value) (180 days)
- Biosimilars (Class 1 or Class 3B/3C) (90 or 180 days)
- Class 2C (pediatric) (90 days)
- Class 3A (administrative procedure) (60 days)
- Class 3B (generics) (90 days)
- Class 3C (generics « + ») (90 days)
- Parallel import/Parallel distribution (60 or 90 days)
- Modification « Art 59 » (New (pediatric) indication, other modification, ...) (90 or 180 days)
- Price Increase (90 days)
- Individual Revision or group review (180 days)
- ...

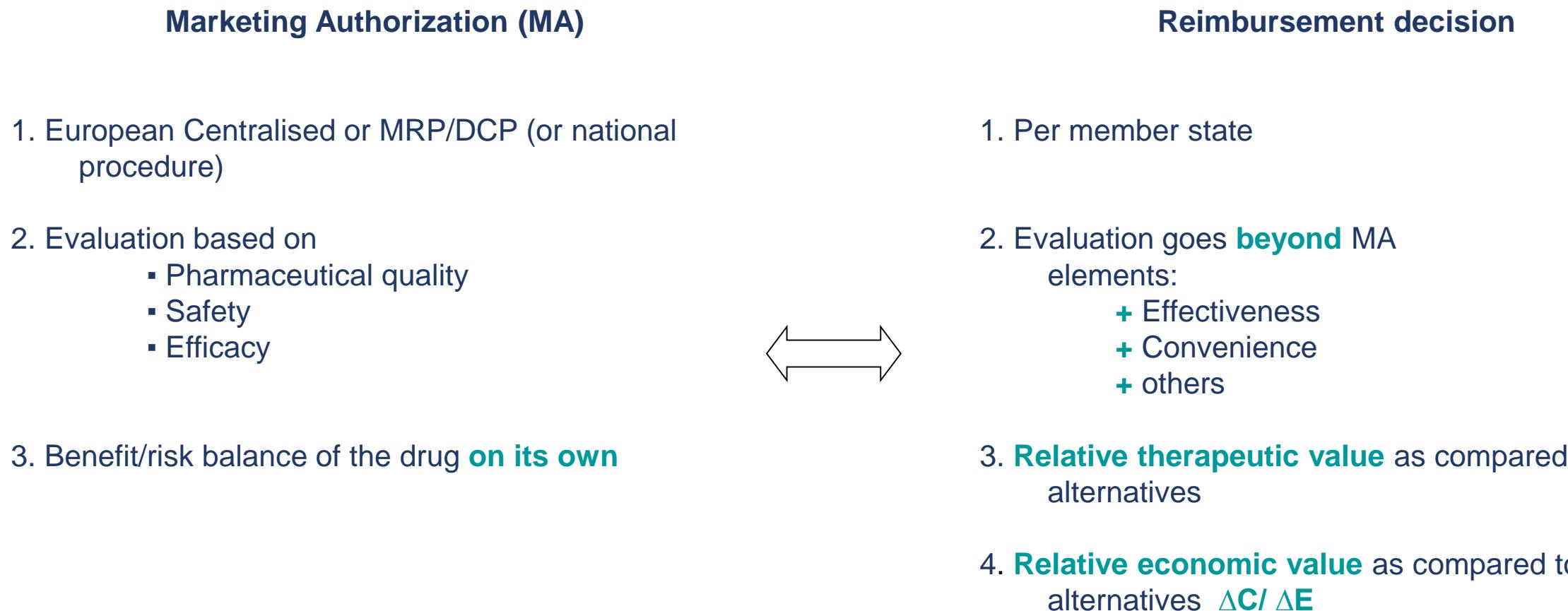
## Procedures – admin (2A, 3A, parallel distribution/import)



## Procedures without evaluation (3B/C, 2C, biosimilars)



## Evaluation and assessment



## Evaluation and assessment

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### 1. THERAPEUTIC VALUE - ADDED VALUE

= efficacy + safety + effectiveness + applicability + convenience  
as determined by

MORBIDITY - MORTALITY - QUALITY OF LIFE

class 1 added value

class 2 comparable value

class 3 generics copies

### 2. PRICE and LEVEL OF REIMBURSEMENT

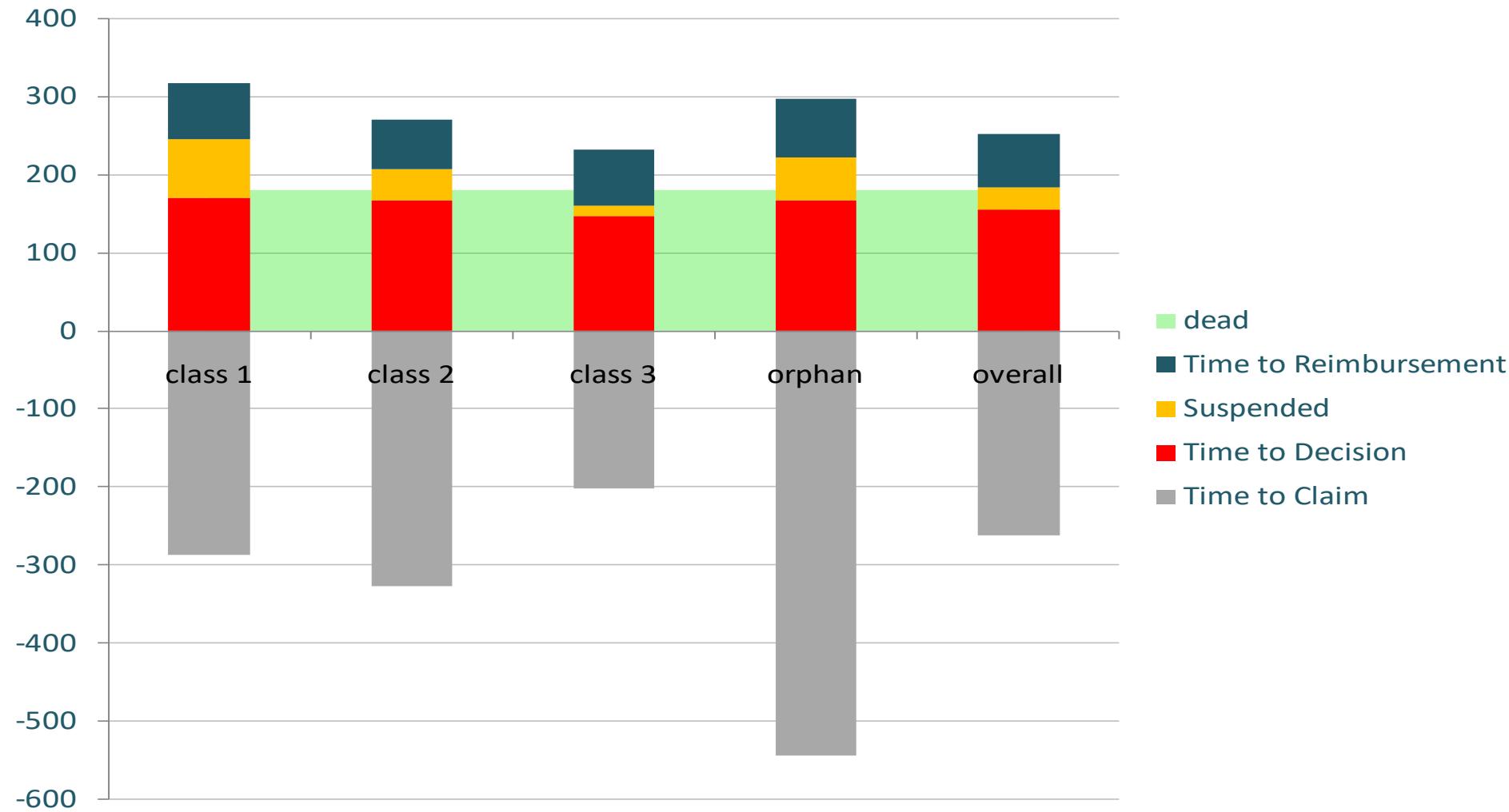
### 3. IMPORTANCE IN CLINICAL PRACTICE (social and/or therapeutic needs)

### 4. BUDGETARY IMPACT → « ability to pay »

### 5. ratio COST / THERAPEUTIC VALUE → « willingness to pay »



## Procedures – Data - time to reimbursement and access



# HTA



## **Claim of added therapeutic value**



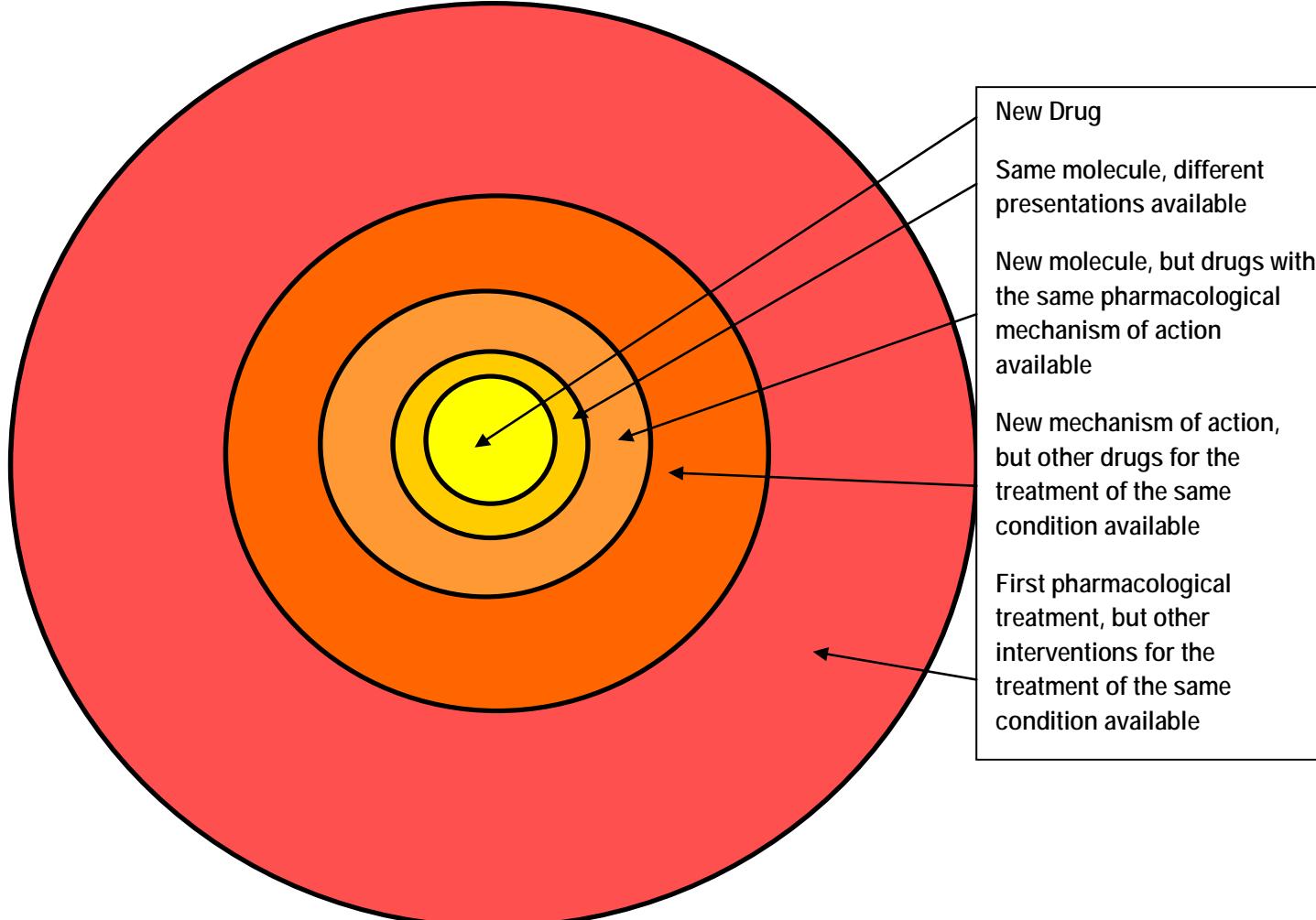
**As determined by :**

- Quality of life
- Morbidity
- Mortality

## **? Confirmed added therapeutic value**

- Assessed in the evaluation report D60/D90
- Voted at the moment of proposal
- Decided by the Minister

# Added value as compared to...



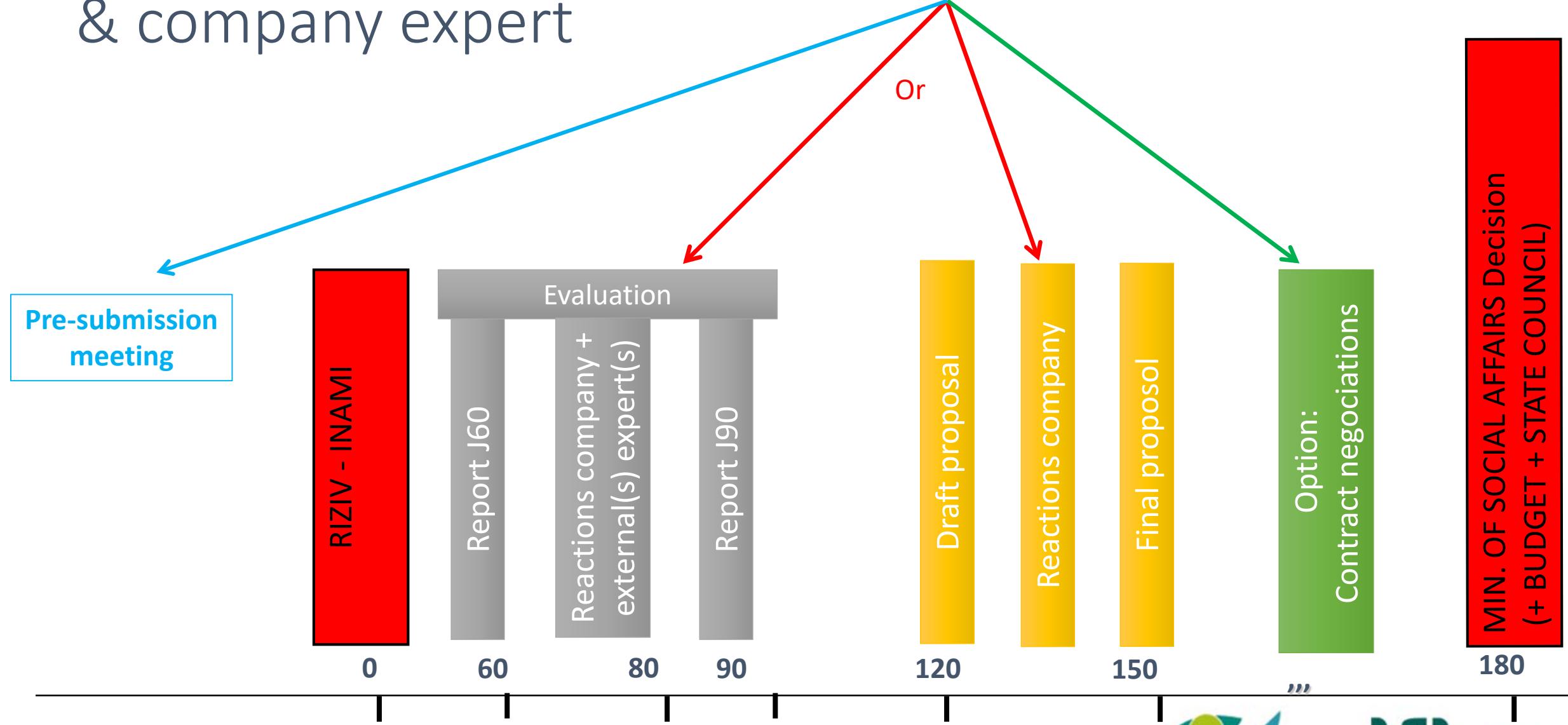
Source: EUnetHTA Joint Action 2

CTG – CRM  
evaluation report  
= first 90 days





# Possible hearing moments by company & company expert



# **ASSESSMENT REPORT**

- **Provisional Day 60**
- **Definitive Day 90**

**Prepared by internal expert(s)**

**Reaction of company + (if applicable) externals experts**

**Once approved, becomes CTG-CRM report**



**Basis for proposals of reimbursement**

**Basis for negotiations Contract Agreement discussions/Cabinet**

**Key question:**

**the relative therapeutic value, i.e. in relation to existing alternatives.**

It begins with the summary

Main message from the CTG-CRM

## **1. Therapeutic domain**

**1.1. Presentation of the disease**

**1.2. Epidemiology**

**1.3. Actual therapeutic modalities - medical and social needs**

## **2. Pharmacotherapeutic class and mechanism of action**

# Day 60/90 report: main headings

## 3. Therapeutic value and interest

### 3.1. Evidence from clinical studies

Understand clinical programme

Level of evidence

### 3.2. Evidence from clinical practice

### 3. Therapeutic value and interest

Efficacy / Efficiency

Safety

Applicability

Ease of use

## 4. Pharmaco-economics

### KCE guideline 2012

- literature review
- perspective of the evaluation
- target population
- comparators
- analytic technique
- study design
- calculation of costs
- estimation and valuation of outcomes
- modelling
- handling uncertainty and testing the robustness of the results
- discount rate

## 5. Budget impact

- viewpoint of INAMI-RIZIV and patient
- taking into account proposed modalities and epidemiology/market analysis
- yearly for first 3 years of reimbursement

### 3 levels budget impact

1° expected expenses: volume x unit cost

2° increment pharmaceutical budget:

< expenses old drug replaced	= expenses add-on drug	> expenses more co-medication
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3° increment health insurance budget:

Less consumption	More consumption
------------------	------------------

## 6. References

- By company
- \* not by company

## 7. Questions to the company

## Day 90 report

### Inclusion of pertinent (!)

- remarks and answers from the company
- possible hearing elements from the company
- remarks from the externals experts

Internal expert is writing author

Voting members can re-open discussion.



**! Basis for proposals of reimbursement**

**! Basis for negotiations Contract Agreement discussions/Cabinet**

# PROPOSAL

# PROPOSAL

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1. Therapeutic Value : class 1, 2 or 3
2. Conditions for reimbursement ( chapter IV)
3. Price & reimbursement basis or “cost” & uncertainties”
4. Category for reimbursement (A, B, C, Cs, Cx, Fa, Fb)
5. Other Modalities ( hospital use, public pharmacy, tarification hospital, ....)

## MOTIVATION

---

### 1. THERAPEUTIC VALUE - ADDED VALUE

= efficacy + safety + effectiveness + applicability + convenience  
as determined by

MORBIDITY - MORTALITY - QUALITY OF LIFE

class 1 added value

class 2 comparable value

class 3 generics copies

### 2. PRICE and LEVEL OF REIMBURSEMENT

### 3. IMPORTANCE IN CLINICAL PRACTICE (social and/or therapeutic needs)

### 4. BUDGETARY IMPACT → « ability to pay »

### 5. ratio COST / THERAPEUTIC VALUE → « willingness to pay »

# Zoom on the latest legal changes

1st july 2014

1st april 2018 (New R.D. 1.2.2018)

1st july 2018

# 1.7.2014

- Introduction of an external expert in some procedure (class 1, orphan, new indication, ...)
- CRM can propose a MEA in some procedure (class 1, orphan, new indication, ...)
- Introduction final evaluation report (R90)
- ....

# 1.4.2018

- Introduction of an expert with clinical experience/practice with the medicine in some procedure (class 1, orphan, new indication, ...)
- More administrative procedure (class 2A, 3A)
- Pediatric indications procedure (without price decrease)
- Contract negotiation possible after a negative proposal only at the request of the Minister
- Contract possible for a file class 2B when the reference medicine is reimbursed with a contract
- Presubmission meeting in CTG
- ...

# 1.7.2018

- Decision Tree for CRM in procedure Art 59 (New indication)
- More administrative procedure (biosimilars)
- Parallel distribution (new procedure)
- EPAR in the file & in the assessment report
- Loop procedure

**2002-2018 :**

**→ 7.500 post/year**

**15.962 files**

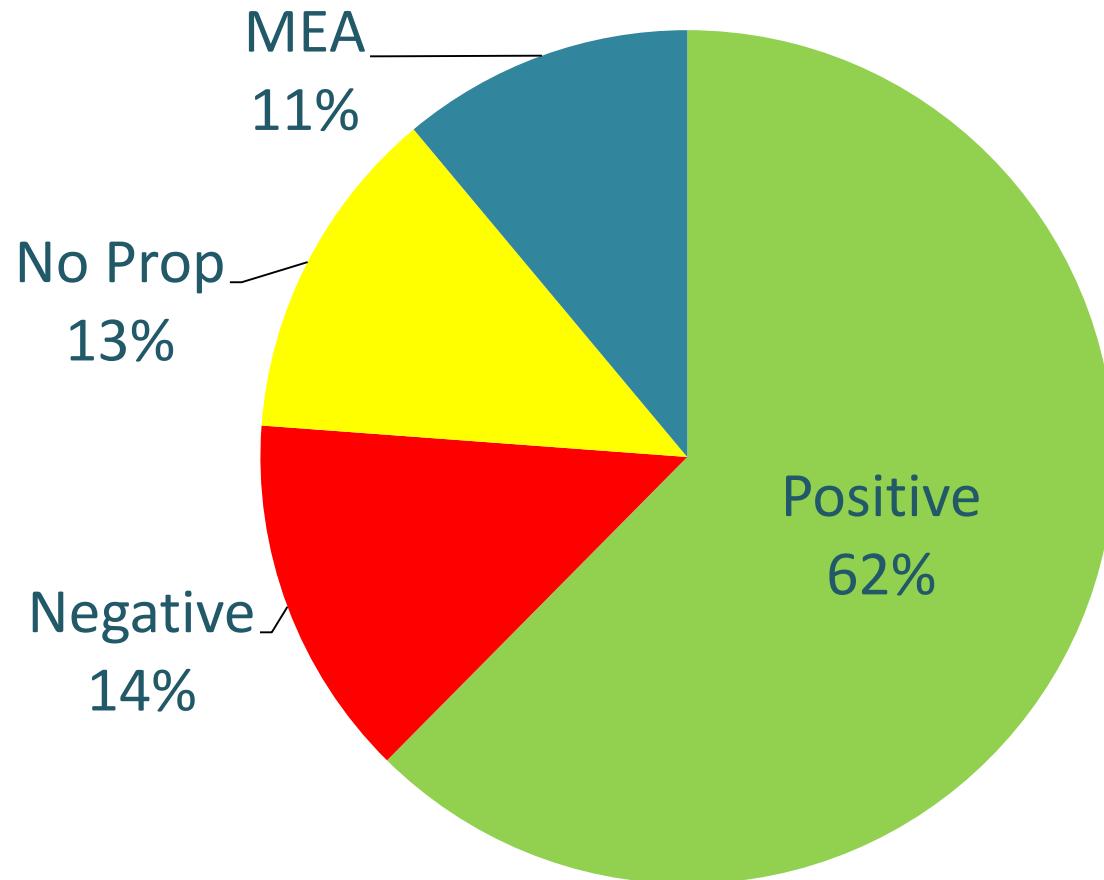
**424 meetings**

**→ +/- 90 proposals / month**

A picture is worth a thousand words



Proposal Commission Reimbursement Medicines for all type files (2016) :

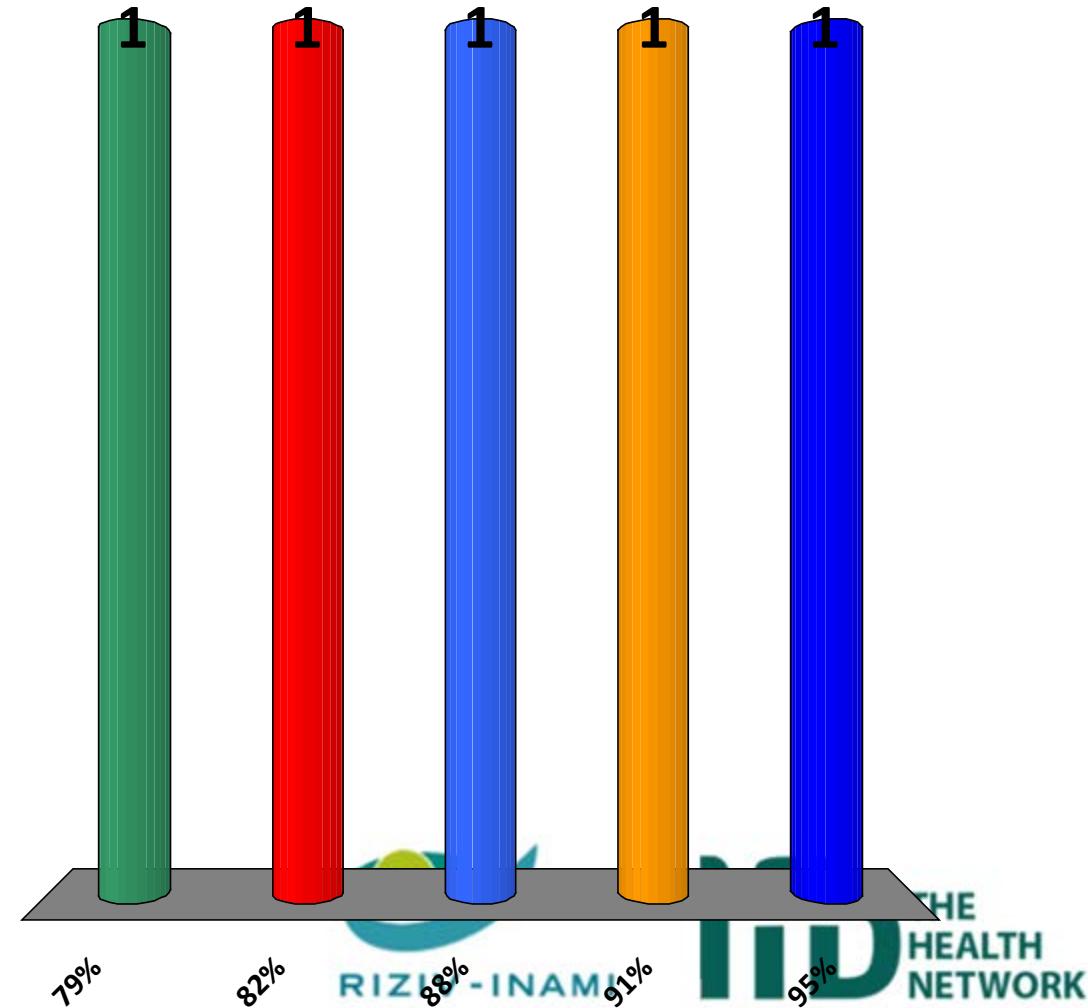


**CTG CRM Proposals:**

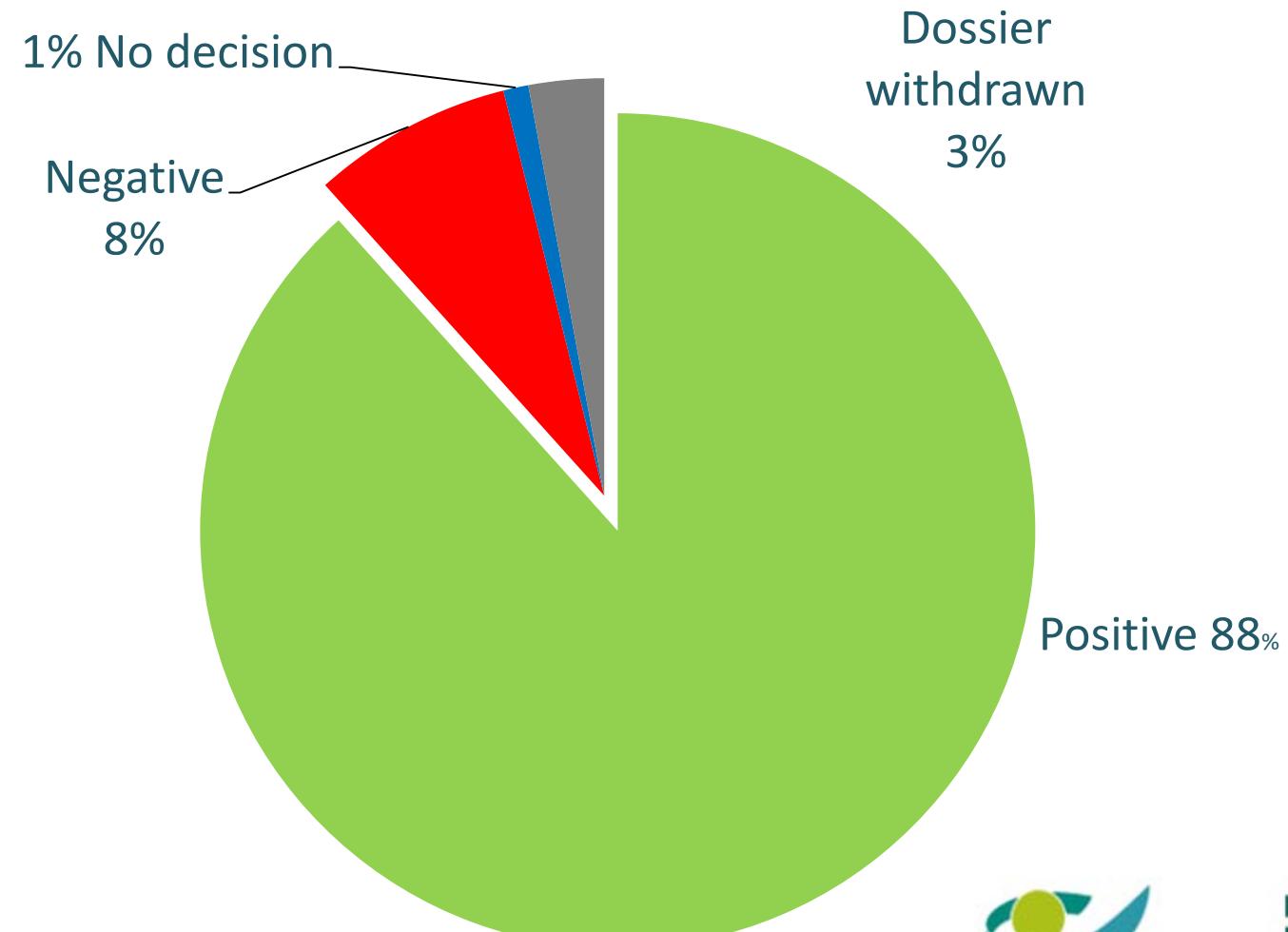
- Positive 186 (62%)
- MEA 33 (11%)
- Negative 41 (14%)
- No proposal 38 (13%)

# How many have become a positive decision (with & without MEA)

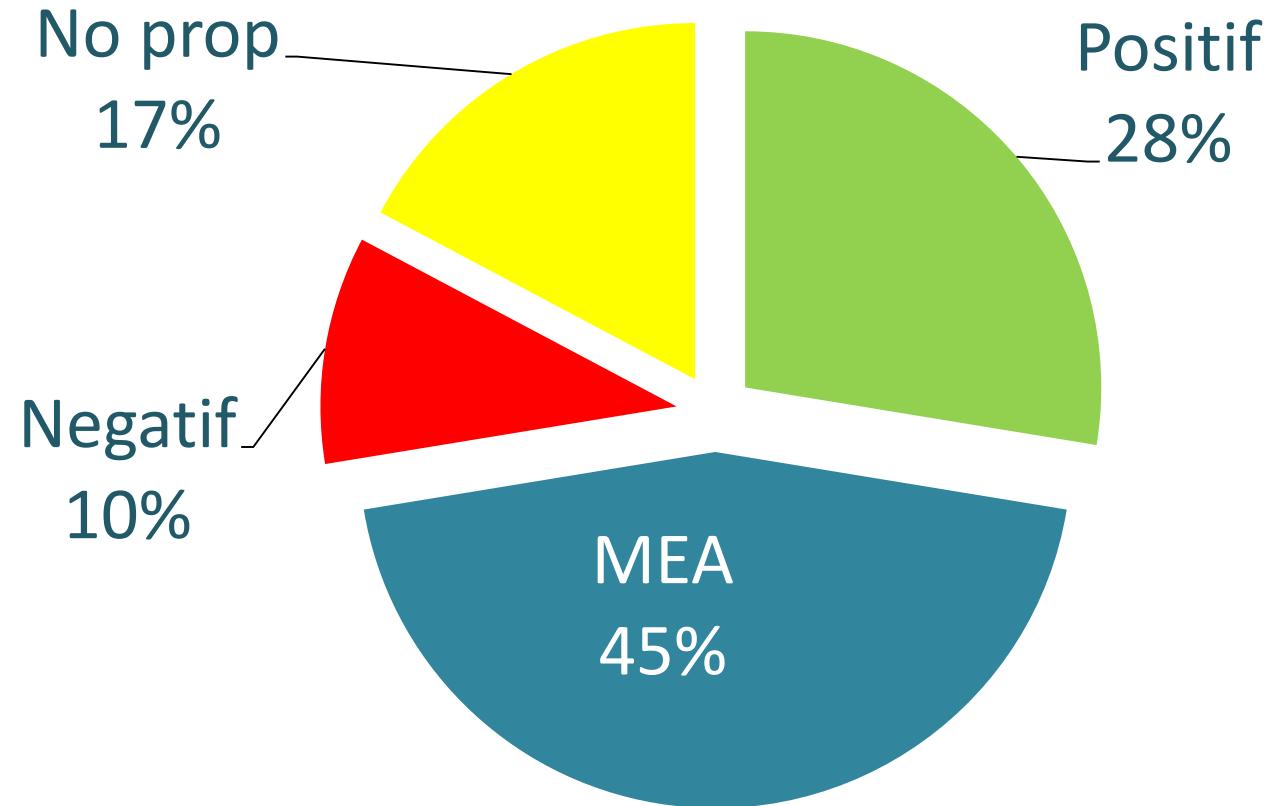
- A. 79%
- B. 82%
- C. 88%
- D. 91%
- E. 95%



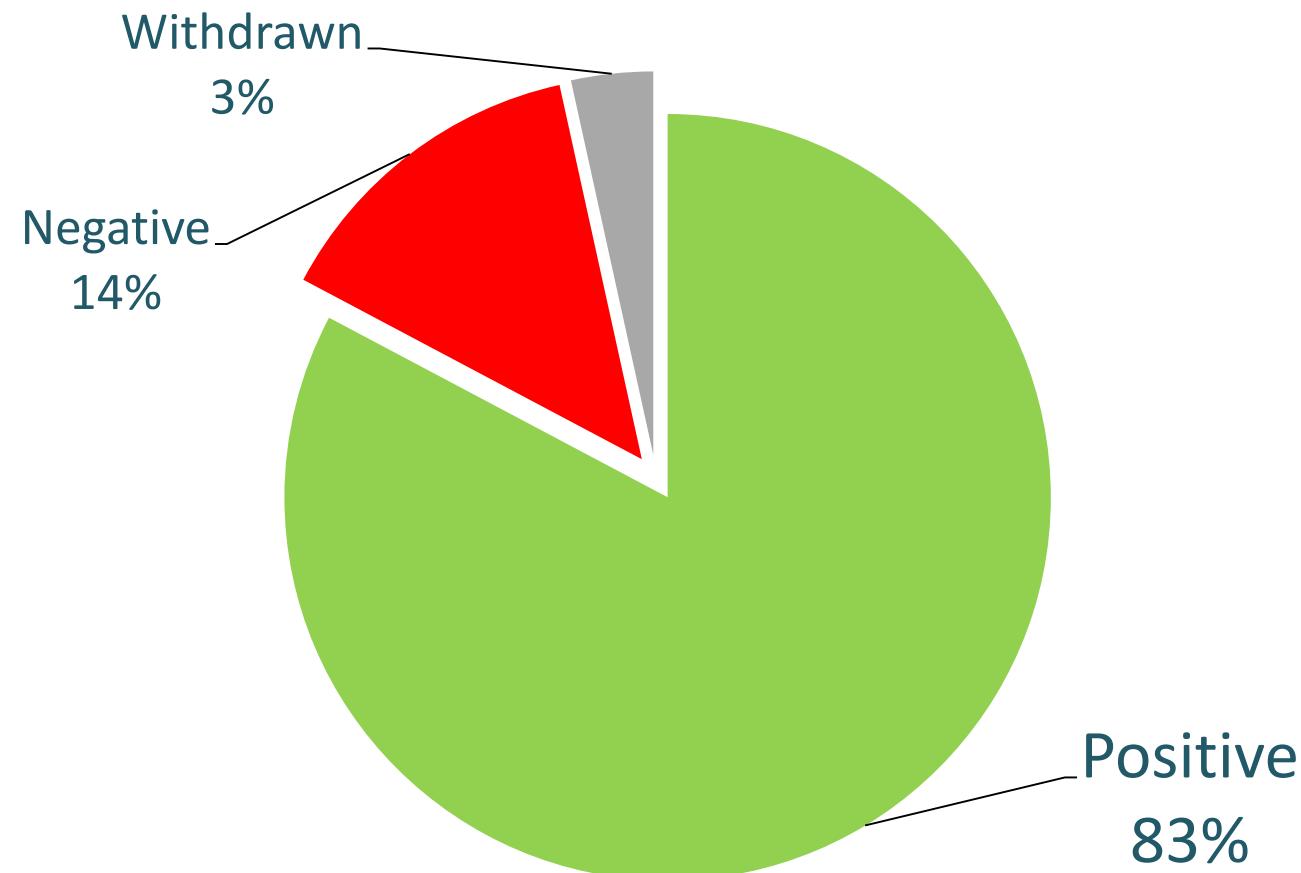
## Decisions Minister Social Affairs for all type files (2016)



## Class 1: Proposal CRM



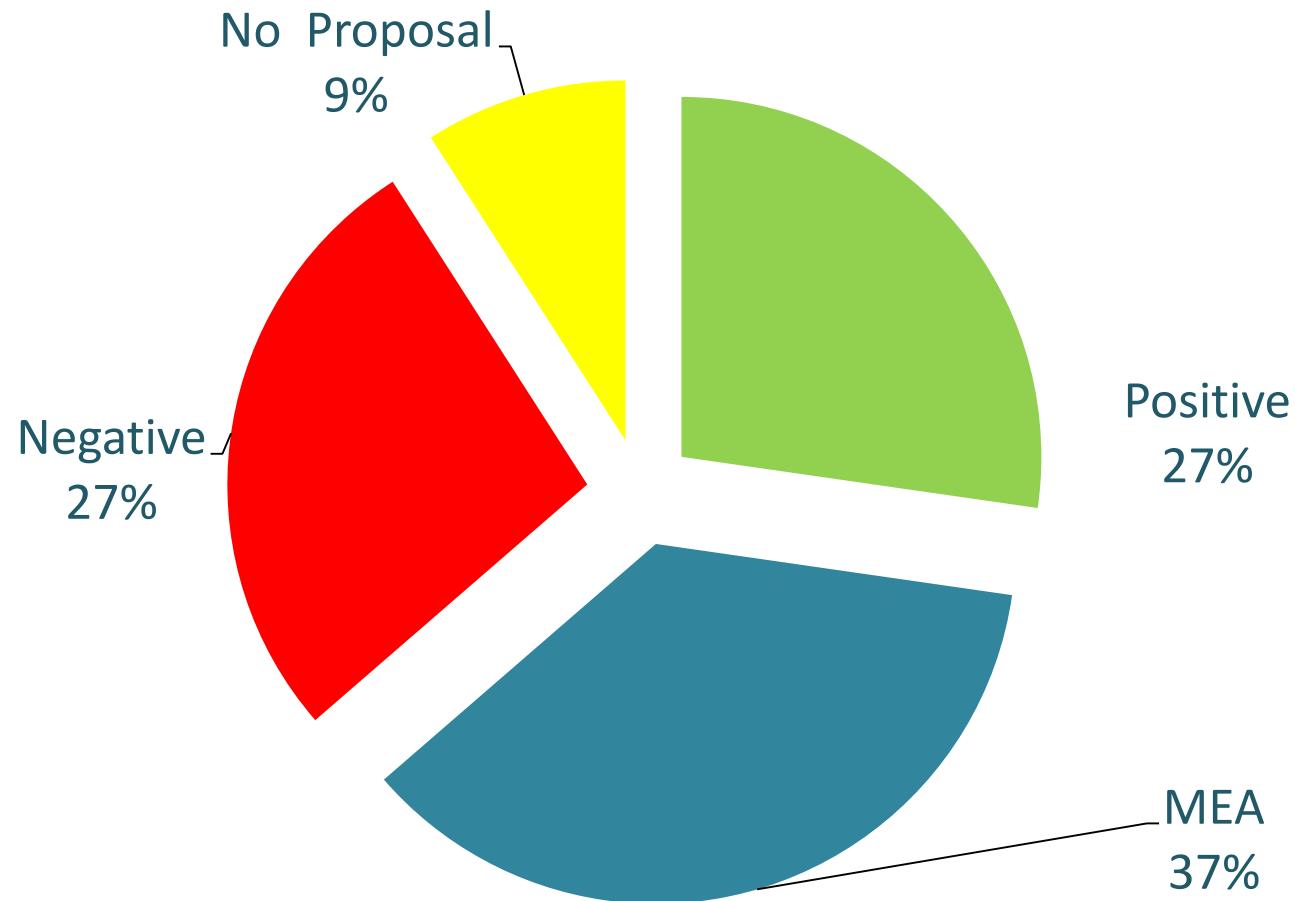
## Class 1: Decision Minister



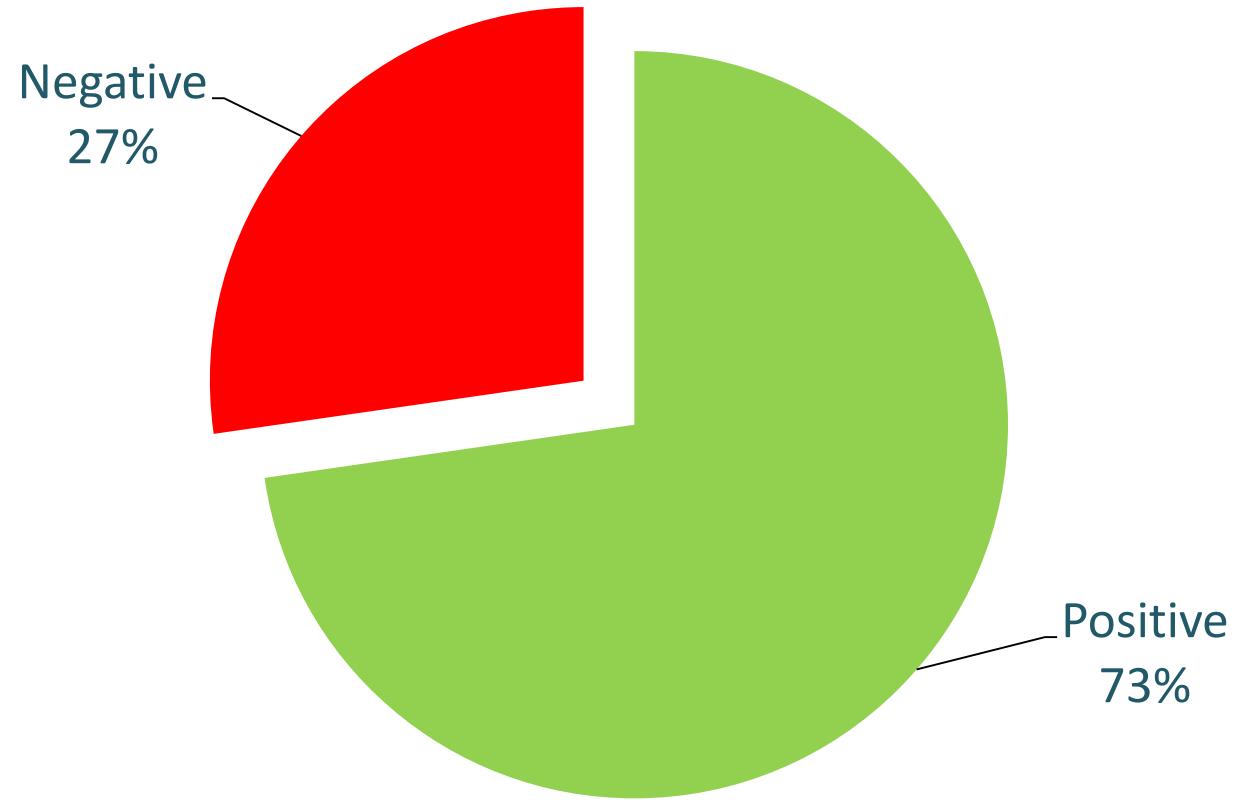
# Class 1: Proposal / Décision

2016		Positive décision Min		Négative décision Min		Withdrawn (company)		Total
	CTG CRM proposal	%	%	%	%	%	%	
Prop. positive	8	100%						8
Prop. contrat	12	92,30%	1	7,70%				13
Prop. négative			2	66,70%	1	33,30%		3
No proposition	4	80%	1	20%				5

## Orphan: Proposal CRM



## Orphan: Decision Minister



# Orphan: Proposition / Décision

2016		Positive décision Min		Négative décision Min		Total
		%		%		
CTG CRM proposal						
Prop. Positive	3	100%	-	-	3	
prop. Contrat	3	75%	1	25%	4	
Prop. Négative	1	33,30%	2	66,70%	3	
No Proposition	1	100%	-	-	1	

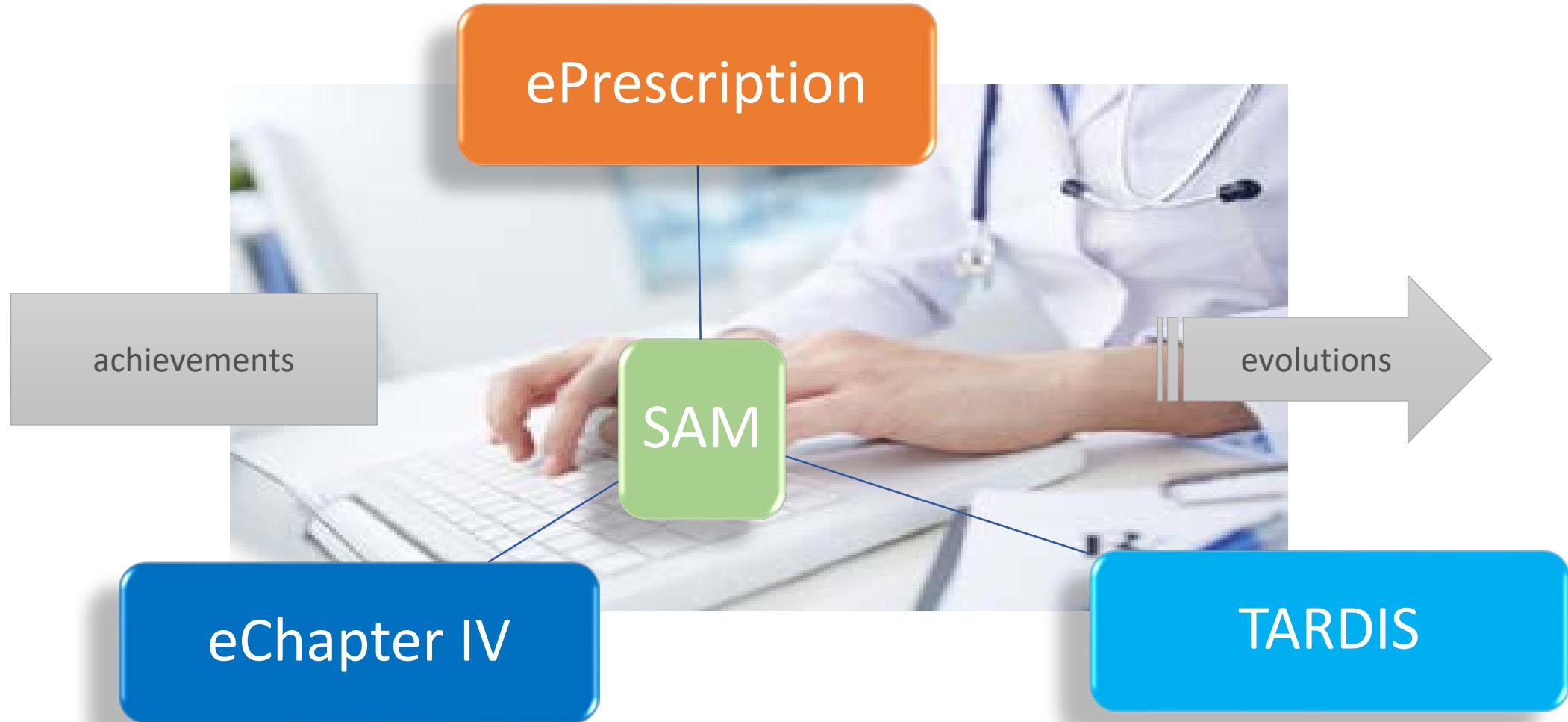


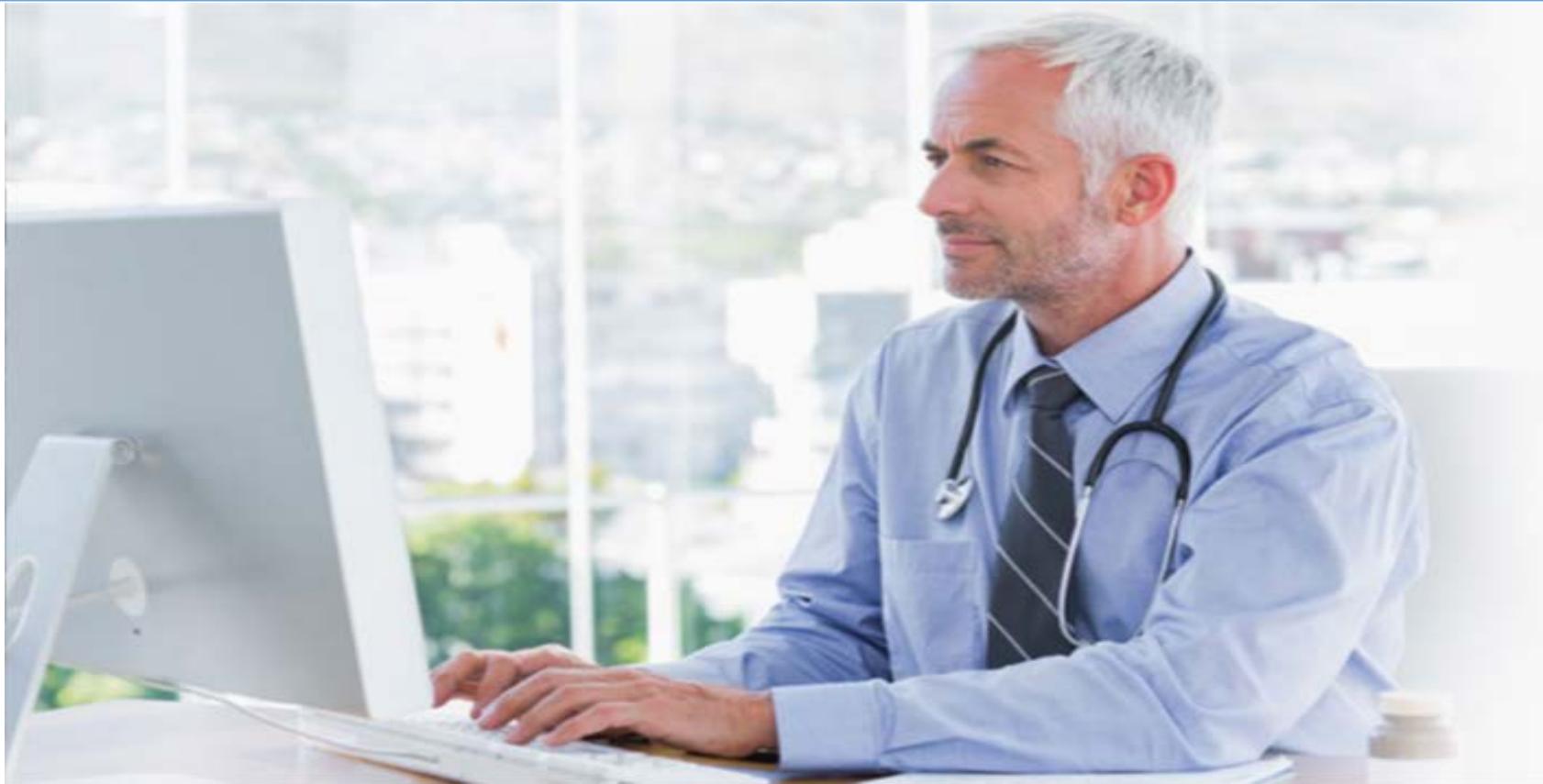
## Medicines, Healthcare and eHealth

Yoeriska Antonissen  
Coordinator unit Knowledge and information management and administrative simplification  
Pharmaceutical policy department - Health care department (NIHDI)



## The main services regarding medicines





ePrescription

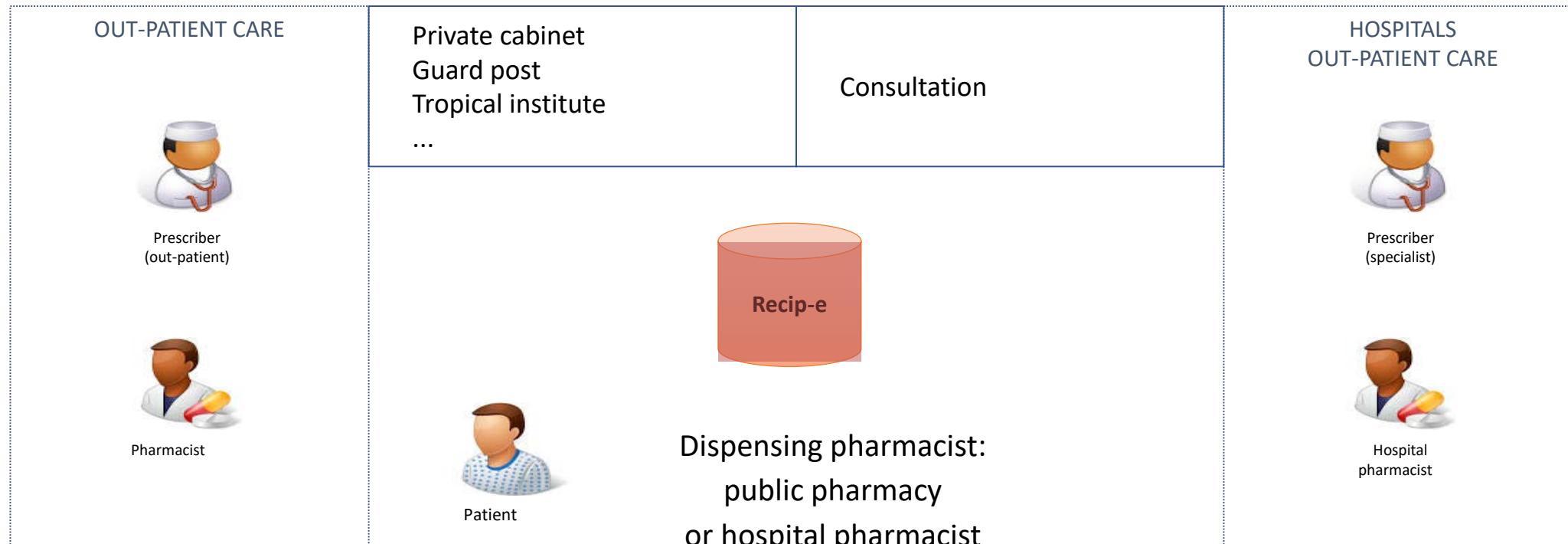


June 1st 2018:  
Not yet enforceable

# Scope mandatory e-prescription

Ambulatory prescriptions for medicines

Out-patient care prescriber (GP, specialist, dentist, midwife)



## Exceptions

e-prescription is not mandatory:

1° for prescribers that have reached the age of 62 years at June 1<sup>st</sup> 2018

2° in 2 settings:

- at the patient's home
- by extension: in residential care

3° in case of emergencies or force majeur:

- Urgent medical help is undisputable
- Foreign prescriber without NISS (NISSbis)
- Foreign patient without NISS (NISSbis)
- Etc.

These situations and conditions are detailed in an “emergency protocol” (draft available)

## No exception?

e-prescription is mandatory

1° software tool

2° hospital IT system

3° PARIS (online web application on the eHealth platform)

## Dematerialization path



## Dematerialization path

Until further notice:

No complete dematerialization in 2018

The identification of an e-prescription continues to be based on the barcode or RID that must be presented to the pharmacist by the patient:

- standard: “proof of e-prescription” on paper
- possible: a digital version (of photo) of the “proof of e-prescription” on smartphone or tablet
- if necessary: manually written RID

 B E P 1 8 W B A 2 D Y S	
PREUVE DE PRESCRIPTION ELECTRONIQUE	
Veuillez présenter ce document à votre pharmacien pour scanner le code-barres et vous délivrer les médicaments prescrits.	
Prescripteur: Emma Peeters Nr INAMI : 9.99999.99.999	
Bénéficiaire: Mertens Marc NISS : 48.10.24.000.00	
Contenu de la prescription électronique	
1	Medica caps 14 x 150 mg 2/j pendant 1 semaine
2	
3	
4	
5	
Attention : Aucun ajout manuscrit à ce document ne sera pris en compte.	
Date: 27.01.2017	
Délivrable à partir du: 15.02.2017	

## Dematerialization path

Objectives: As from mid-2019, it is possible

1° to procure medicines in each pharmacy without the need of a paper version of the “proof of e-prescription”

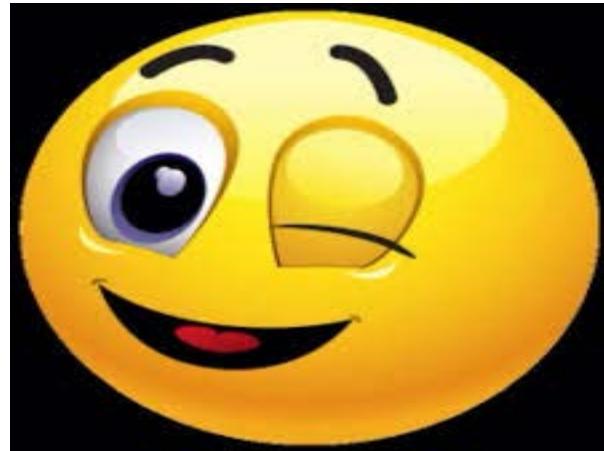
- Multiple solutions will provide for realistic options for the broad variety of patient types /situations
- Alternatives for the “proof of e-prescription” will be put in place progressively
- The patient will participate in the management of his/her prescriptions (for ex. by means of the Personal Health Viewer)

However, (information on) paper will remain possible at patient's request.

2° to make “mobile” e-prescriptions (tablet or smartphone)

Requires an alternative authentication procedure without local eHealth certificate

## Dematerialization path



Sorry, no spoilers  
More info asap

# Current situation (September 2018)

Type of prescriber	Nº				
	feb-17	dec-17	jan-18	mei-18	sep-18
Doctors:					
GP		9.729	9.871	10.490	10.534
Specialist		734	883	2.578	2.263
Total	9.335	10.467	10.754	13.068	12.797
Dentist	1.767	3110	3.132	3.512	3.606
Midwife	0	1	0	4	0
Hospitals	14	22	22	116	122

Type of prescriber	Nº of e-prescriptions				
	feb-17	dec-17	jan-18	mei-18	sep-18
Doctors:					
GP			3.079.778	3.601.869	3.542.722
Specialist			57.453	72.077	143.846
Total	2.560.201	3.137.401	3.601.869	3.686.568	3.646.917
Dentist	14.657	31.619	33.716	35.009	37.185
Midwife	0	2	0	9	0
Hospitals	106.891	141.898	170.930	375.594	734.457
<b>Total:</b>	<b>2.681.749</b>	<b>3.310.920</b>	<b>3.878.592</b>	<b>4.097.180</b>	<b>4.418.559</b>

## Future evolutions

### New generalized prescription validity rules (Q1-2 2019?)

The period during which a prescription can be executed by a pharmacist will be restricted  
This will apply for all medicines: reimbursed or not reimbursed

A prescription will be executable during 3 months (standard rule)  
Unless the prescriber indicates a longer period (max. 1 year in the future)  
Unless the prescriber indicates a shorter period

The same rules apply in the context of reimbursement

The prescriber can still create multiple prescriptions during one consultation

- but no longer needs to calculate a suitable later execution date for each prescription to guarantee reimbursement during the period until the next consultation
- he/she simply indicates an end date = the date of the following “check-up” moment

For public health reasons/to prevent overconsumption:

During the same month, the pharmacist may not deliver more packs than necessary for 6 month's treatment

## Improvement path

### Shift towards the use of data from a single authentic data source on medicines

Guarantee that the therapeutic intention of the prescriber  
is correctly presented at the level of the software of the dispensing pharmacist  
(and vice versa)

Guarantee an optimal interoperability for the identification of a medical treatment between all softwares and data exchange systems



The data on medicines originate from a single authentic validated data source  
= the authentic data source on medicines (SAM)

Upcoming legal obligation for software providers  
within the context of e-prescription



## eChapter IV & TARDIS



## Electronic requesting procedure

### eChapter IV

#### How?

- Certified software with chapter IV module
- CIVARS (web application - eHealth platform)

#### For which paragraphs?

Possible for all paragraphs stipulating a prior authorization  
No mandatory use

Unless for:

Paragraphs with a mandatory electronic procedure  
(temporary reimbursement):

- New Hepatitis C medicines
- New oncology medicines
- ...

### “TARDIS” procedure

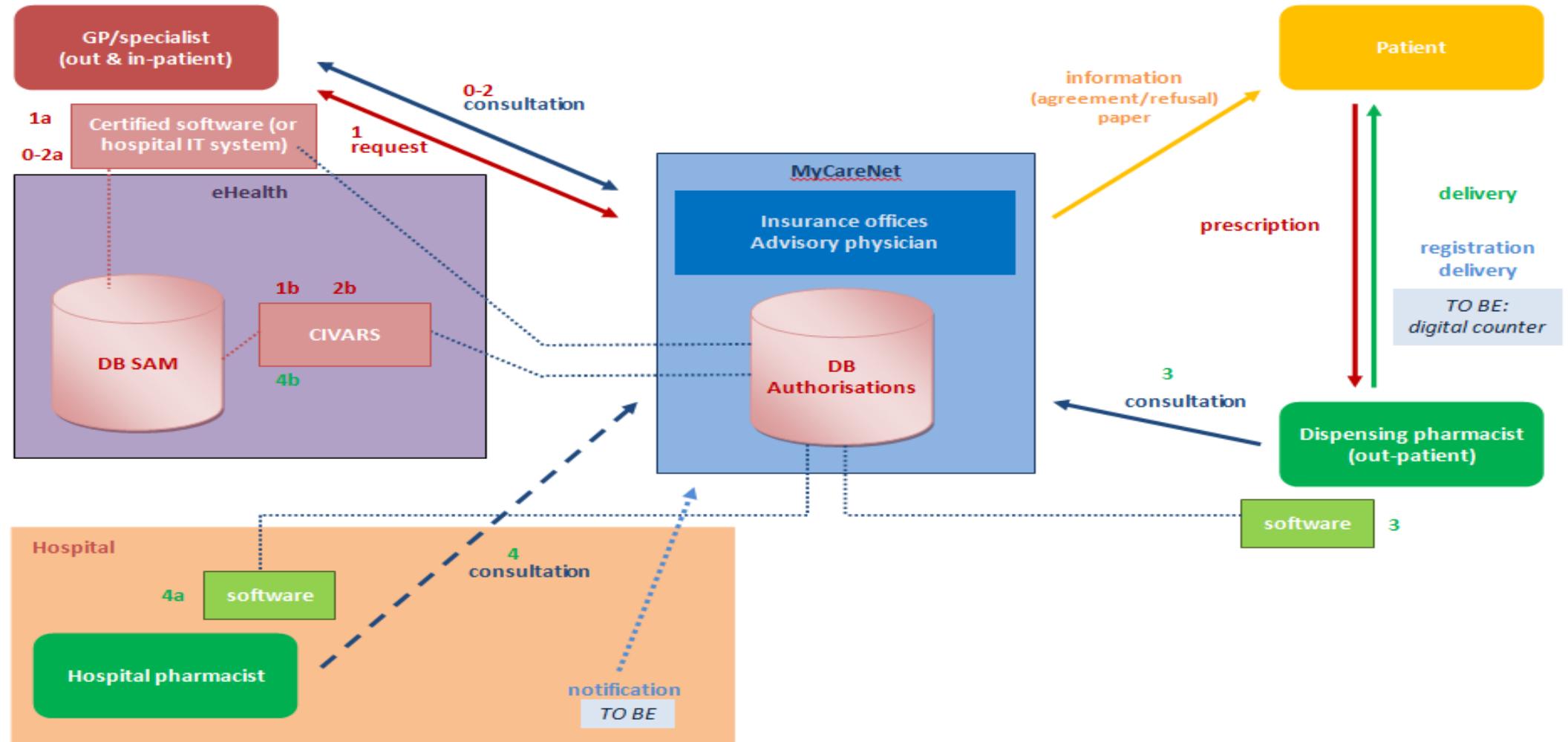
#### How?

TARDIS (web application - eHealth platform)

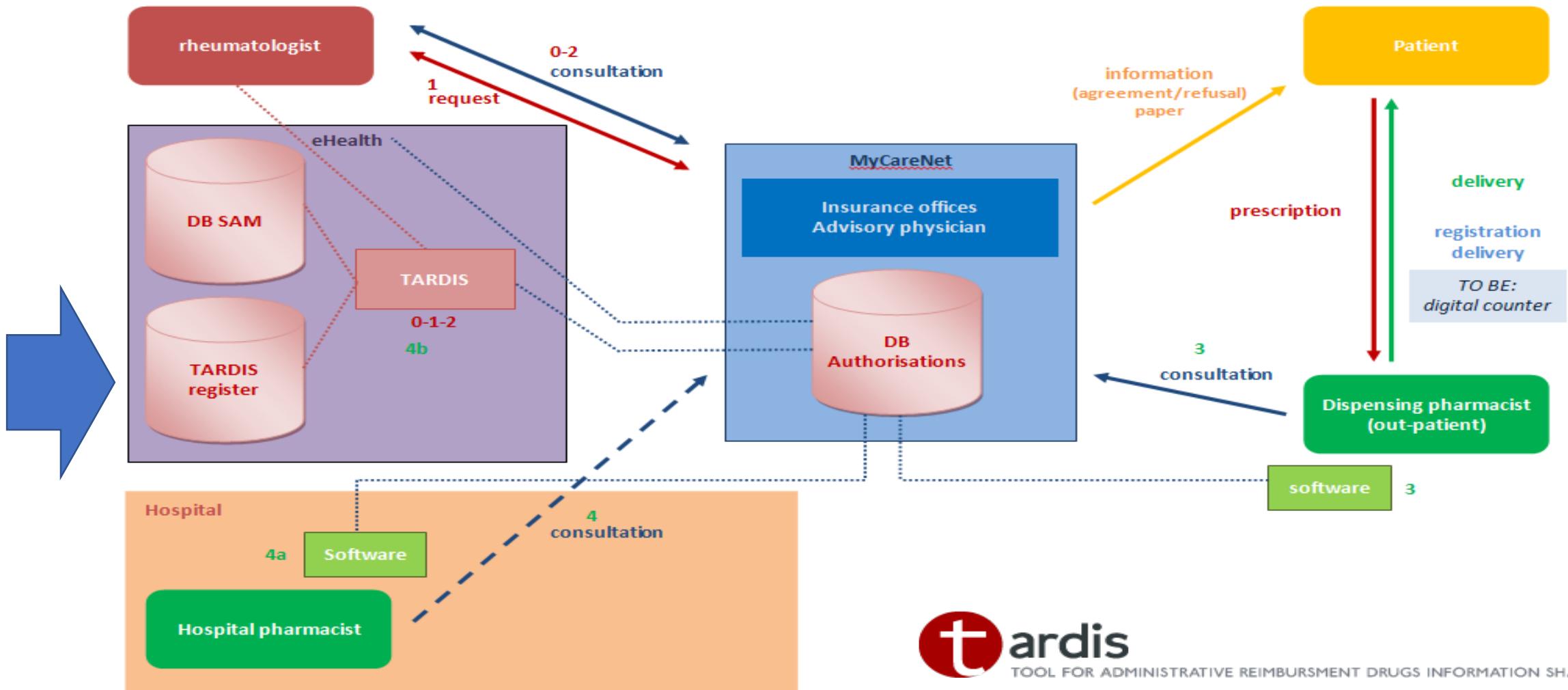
#### For which paragraphs?

Mandatory for paragraphs on rheumatoid arthritis

# Electronic requesting procedure



# TARDIS procedure



**tardis**  
TOOL FOR ADMINISTRATIVE REIMBURSMENT DRUGS INFORMATION SHARING



## Data collection

### eChapter IV

Data from the insurance offices are used

- for monitoring purposes
- data collection for paragraphs with a mandatory electronic procedure (temporary reimbursement):
  - New Hepatitis C medicines
  - New oncology medicines
  - ...

### “TARDIS” procedure

TARDIS allows:

- to introduce clinical patient data
- to create a national patient register

TARDIS allows to use real-life patient data for

- individual follow-up of the patient
- epidemiologic analysis
- care benchmarking
- health care policy (fine-tuning of the reimbursement conditions)

# SAM Source Authentique des Médicaments



SAM 1.0 → SAM 2.0



## SAM 1.0

= authentic data source for medicines

= the reference database for commercialized medicines (reimbursable and non-reimbursable)

Monthly update

Mainly used for the electronic chapter IV procedure

Structured version of chapter IV

- Text of all chapter IV paragraphs in “database” format (split up in blocks of text + checkboxes)
- Structured “administrative” data required for request processing (process type, authorization model, maximum quantity, duration,...)
- Other structured data needed for automatic controls (requesting specialist, exclusions, age, ...)

## SAM 2.0

### A new data model - Why?

- Improve performance
- Improve data quality (strengthened consistency and integrity controls)
- Allow several data providers (each and independently responsible for their part of the database)
- A more generic data model allowing the integration of future reimbursement schemes

### A broader scope

All authorized medicines (commercialised or not, reimbursed or not)	→ brand name and INN prescription
Substances and TMF formulas	→ compound prescription
Health products (<> medicines)	→ prescription of health products
Prices of authorized medicines	
Reimbursement legislation data (NIHDI)	→ tarification & eChapter IV

# SAM 2.0 sustained improvement path

## Use of a structured posology

Medicines & INN groups  
Linked to  
indication(s) > patient type (ex. age, renal function, ...) > posology  
Expressed in a “medical” and “patient oriented” format



Software can propose posology > Increased conviviality for the health care actor  
Understandable for the patient

ePrescription

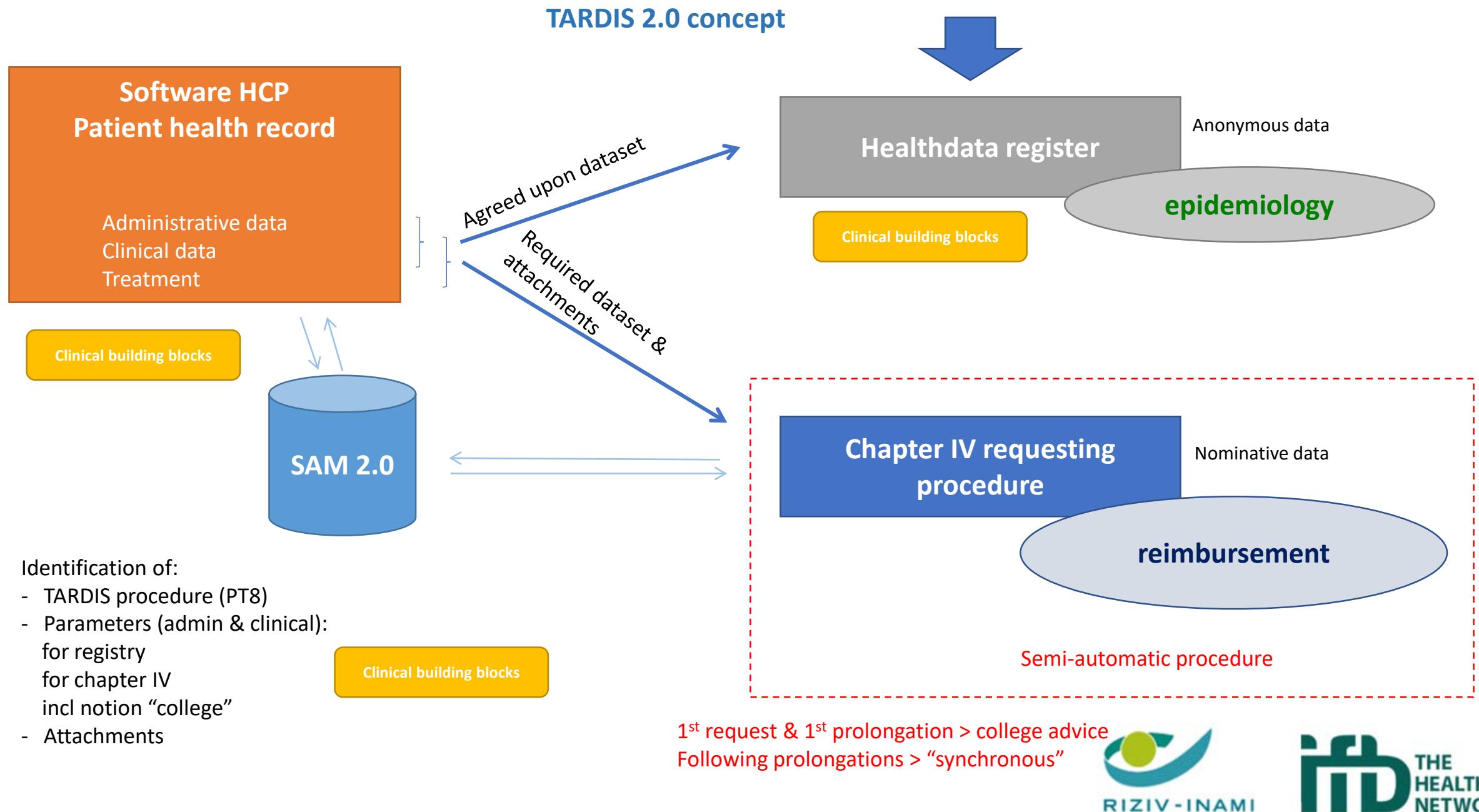
Medication scheme

## TARDIS – The next generation

- Progressive scope extension:
  - other therapeutic indications
  - other medicines
  - other disciplines
- 5th management agreement 2016 – 2018 between the State and the NIHDI:  
scope extension to orphan drugs

A new TARDIS tool:

- A new generic SAM 2.0 based architecture
- Compatible with healthdata.be registers
- Additional element in the electronic procedure: integration of a prior advice organ (Orphan colleges)



## TARDIS 2.0 architecture

No new TARDIS 2.0 web application

Only a web service will be available for integration in the IT systems of hospitals and softwares

→ encourage integrated business processes

Use of healthdata.be technologies for data collection and collection of follow-up data

→ 1 data flow

# Information



e-prescription:

- <http://www.riziv.fgov.be/fr/themes/cout-remboursement/par-mutualite/medicament-produits-sante/prescrire-medicaments/Pages/prescrire-medicaments-patients-ambulatoire.aspx>
- <http://www.inami.fgov.be/nl/themas/kost-terugbetaling/door-ziekenfonds/geneesmiddel-gezondheidsproduct/geneesmiddel-voorschrijven/Paginas/default.aspx>

SAM webportal :

- <http://www.samportal.be/nl/sam>
- <http://www.samportal.be/fr/sam>

Additional questions: [yoeriskaantonissen@riziv.fgov.be](mailto:yoeriskaantonissen@riziv.fgov.be)

# Managed Entry Agreements: The Belgian Experience

*a payer's perspective*



# Background



## General Principle

### Rationale

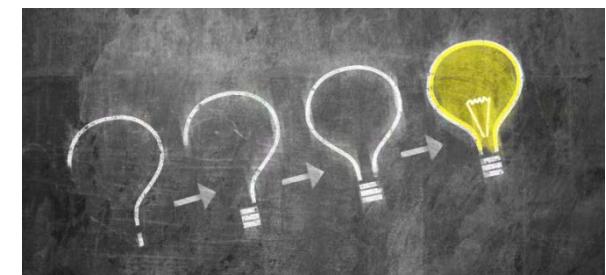
- New generation pharmaceuticals (orphan drugs, CAR-T therapy..) that often meet **Unmet Medical Need** but associated with **exuberant price tags** while having a significant degree of **clinical uncertainty**
- Growing need for *alternative systems* that can **limit their budgetary impact** while **ensuring early access for patients**

### Principle

- Agreements try to link the price of a medicinal product to its **specific added value** and to the **willingness-to-pay**
- **Temporary reimbursement** based on conditions set out in contract

### Goal

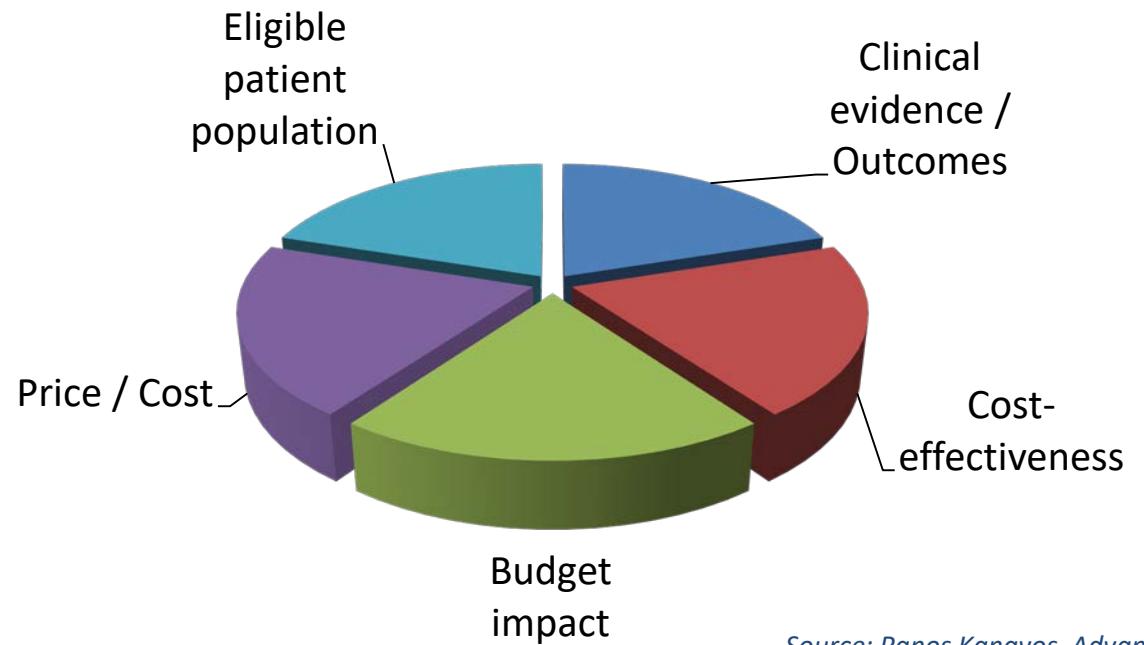
- **Access to promising therapies for patients**
- **Access to the 'market' for pharmaceutical company**
- Manage **(clinical) uncertainties**
- Manage **budget**



## General Principle

### Types and sources of uncertainty

- Matter of Cost
- Matter of Value  
& cost in relation to value



### And how to deal with them

- Budget compensation (for budgetary risks + clinical uncertainties)
  - Evidence gathering
    - Contractual obligations
    - Registries
- ! New opportunities (eg Healthdata.be)

Source: Panos Kanavos, Advance-HTA Capacity building workshop, Warsaw 2014.

## General Principle - Taxonomy

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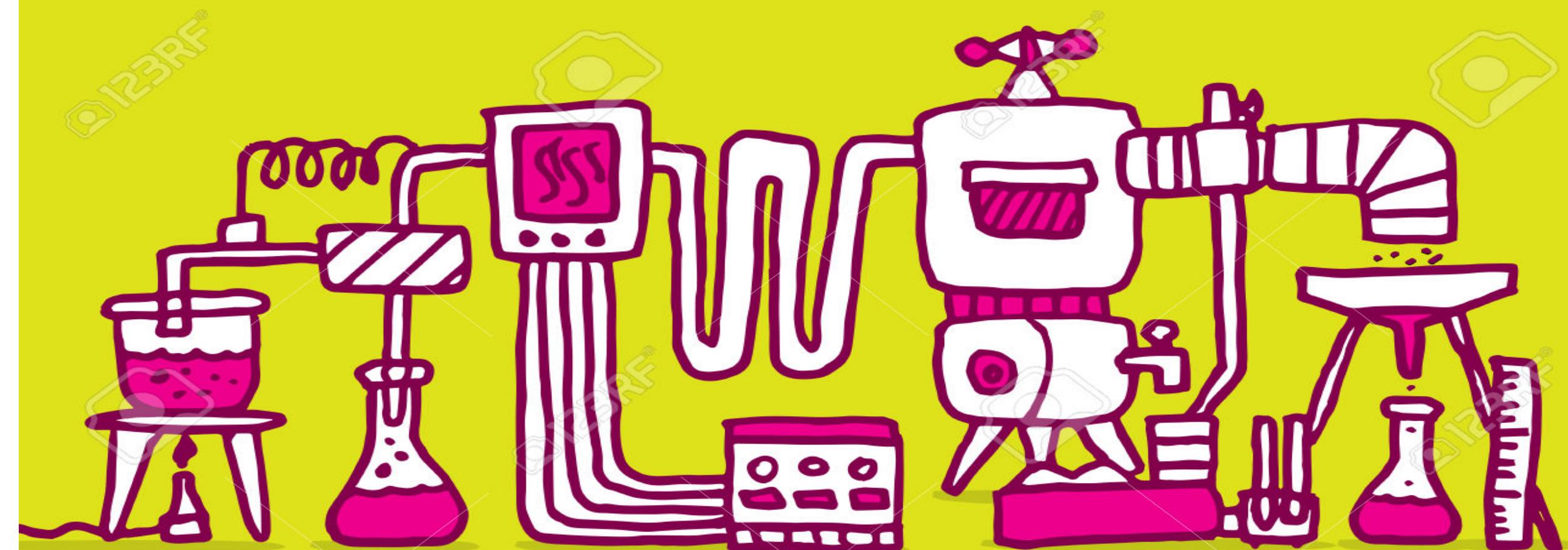
### Performance based schemes

- Price, level and/or nature of reimbursement are **related to the actual future performance** of the product in either the research or “real-world” environment
- Conditioned by a pre-specified endpoint or **definition of response that dictate** whether the payer will cover the treatment or the manufacturer

### Financial schemes

- Arrangement whereby the pharmaceutical company offers a ‘rebate’ on sales or volume exceeding a **pre-agreed threshold**
- Conditioned by a set of **pre-specified budget caps, discounts or restrictions**

# Process



## Legislation

### The procedure, time limits, conditions: Royal Decree Dec 21, 2001

Start date MEAs in Belgium:

**Art. 81** and following, as modified by the RD of Feb 11, 2010

Modification:

July 2014: **Art. 81bis**

**April 2018 : Art 111 and following by the new RD of 1 Feb 2018**



### The principles: Law on Compulsory Health Insurance July 14, 1994

Art 35bis § 7

"If the CRM (Commission for Reimbursement of Medicines) considers the proposed **basis for reimbursement disproportionate to the assessment of the criteria** mentioned in § 2

or if she is of the opinion that enrolling the medicine in the list of reimbursable medicines implies **uncertainties on a budgetary level**, the Commission, or the applicant can propose to the Minister to **establish an agreement** with the Institute [...], providing with rules for **compensation** for the compulsory health and disability insurance."

## Legislation

21 december 2001 - Koninklijk besluit tot vaststelling van de procedures, termijnen en voorwaarden inzake de tegemoetkoming van de verplichte verzekering voor geneeskundige verzorging en uitkeringen in de kosten van farmaceutische specialiteiten

### **Hoofdstuk V. Overeenkomsten met het Instituut.**

Art 111. De aanvrager kan overeenkomstig artikel 35bis, § 7 van de wet, op eigen initiatief, aan de Minister zijn wens kenbaar maken een overeenkomst met het Instituut af te sluiten voor specialiteiten waarvoor de Commissie geen definitief voorstel heeft kunnen formuleren binnen de termijn bedoeld in artikel 35bis, § 3, tweede lid, van de wet.( In dit geval zal het definitief beoordelingsrapport, goedgekeurd door de Commissie, als uitgangspunt voor de besprekingen in de werkgroep dienen.) (KB 3 juni 2014)

Art 112. De aanvrager kan overeenkomstig artikel 35bis, § 7, van de wet, na voorstel van de Commissie om een overeenkomst af te sluiten, aan de Minister zijn wens kenbaar maken een overeenkomst met het Instituut af te sluiten voor specialiteiten waarvoor de Commissie een voorstel tot overeenkomst heeft geformuleerd volgens de bepalingen van artikel 35bis, § 7 van de wet.

21 décembre 2001 - Arrêté royal fixant les procédures, délais et conditions en matière d'intervention de l'assurance obligatoire soins de santé et indemnités dans le coût des spécialités pharmaceutiques

### **Chapitre V. Conventions avec l'Institut.**

Art 111. Le demandeur peut de sa propre initiative, conformément à l'article 35bis, § 7 de la loi, communiquer au Ministre son souhait de conclure une convention pour les spécialités pour lesquelles la Commission n'a pas pu formuler une proposition définitive dans le délai visé à l'article 35bis, § 3, alinéa 2, de la loi. (Dans ce cas, le rapport d'évaluation définitif approuvé par la Commission sert de point de départ pour la discussion du groupe de travail.) (AR 3 juin 2014)

Art 112. Le demandeur peut, après proposition de la Commission de conclure une convention, conformément à l'article 35bis, § 7, de la loi, communiquer au Ministre son souhait de conclure une convention pour les spécialités pour lesquelles la Commission a formulé une proposition de convention visée à l'article 35bis, § 7 de la loi.

**Art. 113.** De aanvrager kan overeenkomstig artikel 35bis, § 7, van de wet, na **gemotiveerd voorstel van de Minister** om een overeenkomst af te sluiten, aan de Minister zijn wens kenbaar maken een overeenkomst met het Instituut af te sluiten voor specialiteiten waarvoor de Commissie een **negatief definitief voorstel** heeft geformuleerd binnen de termijn bedoeld in artikel 35bis, § 3, tweede lid, van de wet.

**Art. 113.** Le demandeur peut, après **proposition motivée du Ministre** de conclure une convention, conformément à l'article 35bis, § 7 de la loi, communiquer au Ministre son souhait de conclure une convention avec l'Institut pour des spécialités pour lesquelles la Commission a formulé une **proposition définitive négative** dans le délai visé à l'article 35bis, §3, alinéa 2 de la loi.



## UNMET MEDICAL NEED

### Scope

- Medicines with a reimbursement application in **class 1** (claim for added therapeutic value)
- Medicines with a reimbursement application as **orphan drug**
- Medicines with a reimbursement application for a **new indication** for which a **therapeutic or social need** exists
- Medicines for which **reference drug is reimbursed by MEA**

## OUTCOME ASSESSMENT

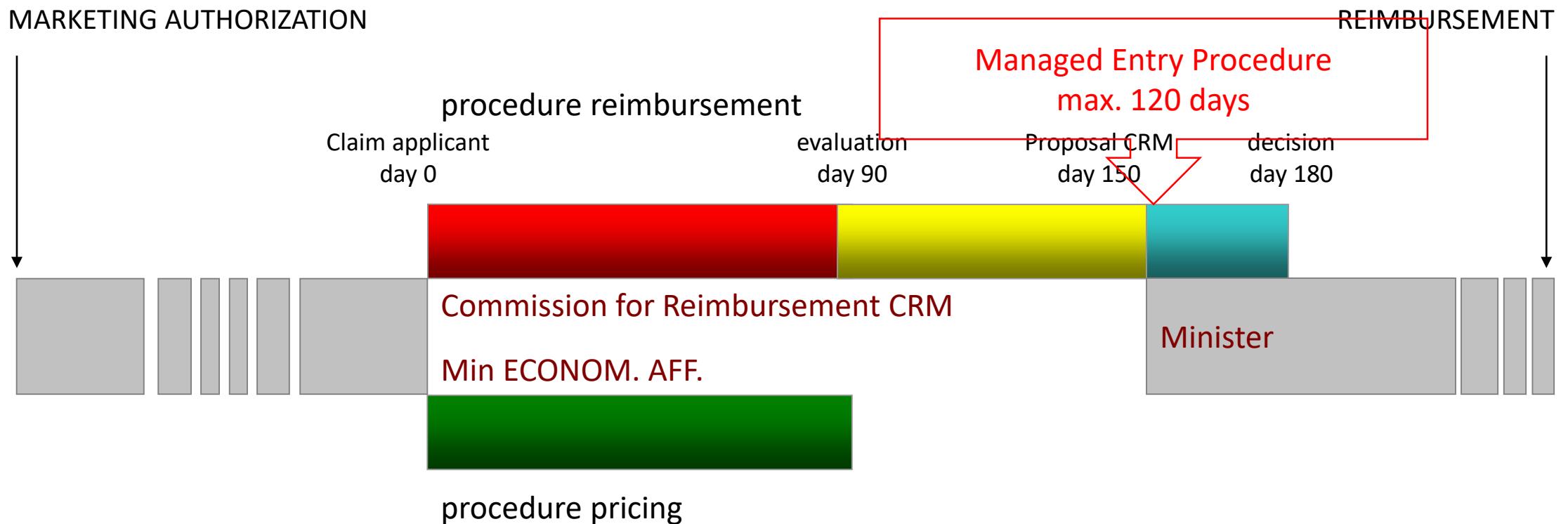
### Duration of convention

- **Temporary** enlisting (3 years max. + possibility of prolongation) during which gathering of new and/or additional clinical evidence or information on the **balance price/cost versus added (therapeutic) value**

# The reimbursement procedure

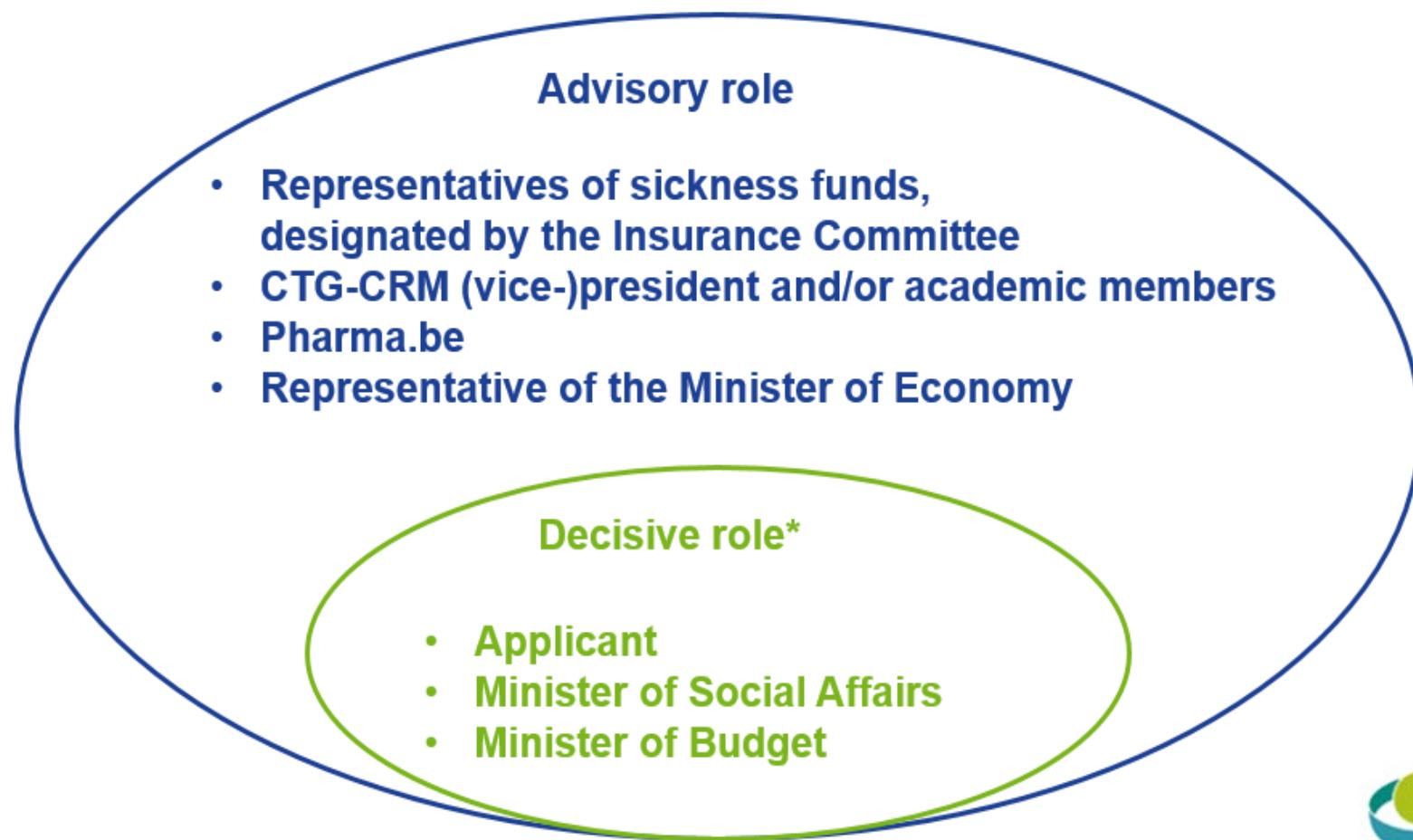
Negotiations are embedded in reimbursement legislation

No separate process



## Composition of the Permanent Taskforce

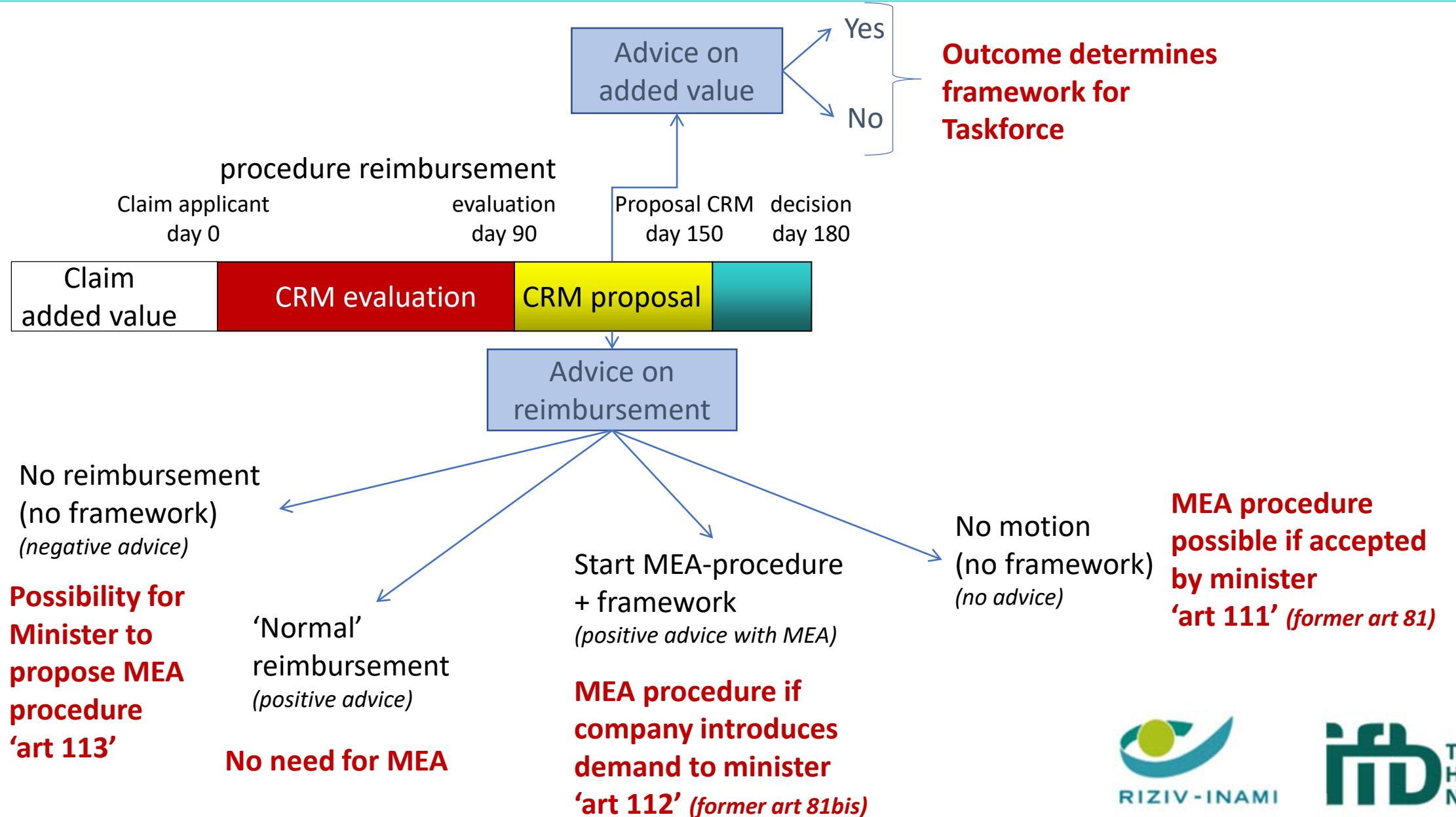
President: Chief Executive of the Health Care Department or his representative (NIHDI)



Source: KCE Report .



## Decision tree



## Content “Art. 111/112/113 request”

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### Obligatory

- Request clock stop 120 days
- Motivation to start MEA-negotiations (Art. 111, 113)
- Budgetary compensation mechanism (Art. 112)

### “Desirable”

- Estimated turnover first 3 years of reimbursement (ex-factory level)
- Requested reimbursement modalities incl. text Chapter IV new §
- Budgetary compensation mechanism in line with requested reimbursement modalities (Art. 111, 113)
- Requested validity duration of convention
- Cost of drug at end of MEA (“art. 15 clause”)
- “Relevant” clinical information (Art. 111) → no intention of re-doing CRM evaluation

## Content “Art. 111/112/113 convention”

### Legislation

- RD 1.2.2018 Art. 115

### Overview

- Reimbursement modalities including list price & reimb criteria
- Uncertainties to be solved during convention + submission date evaluation report
- Modalities concerning declaration turnover + execution budgetary compensation mechanisms
- Date entry into force and duration of convention
- Modalities in case convention is not respected
- Budgetary compensation mechanisms
- Modality on cost of medicine after MEA



End of MEA

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### Legislation

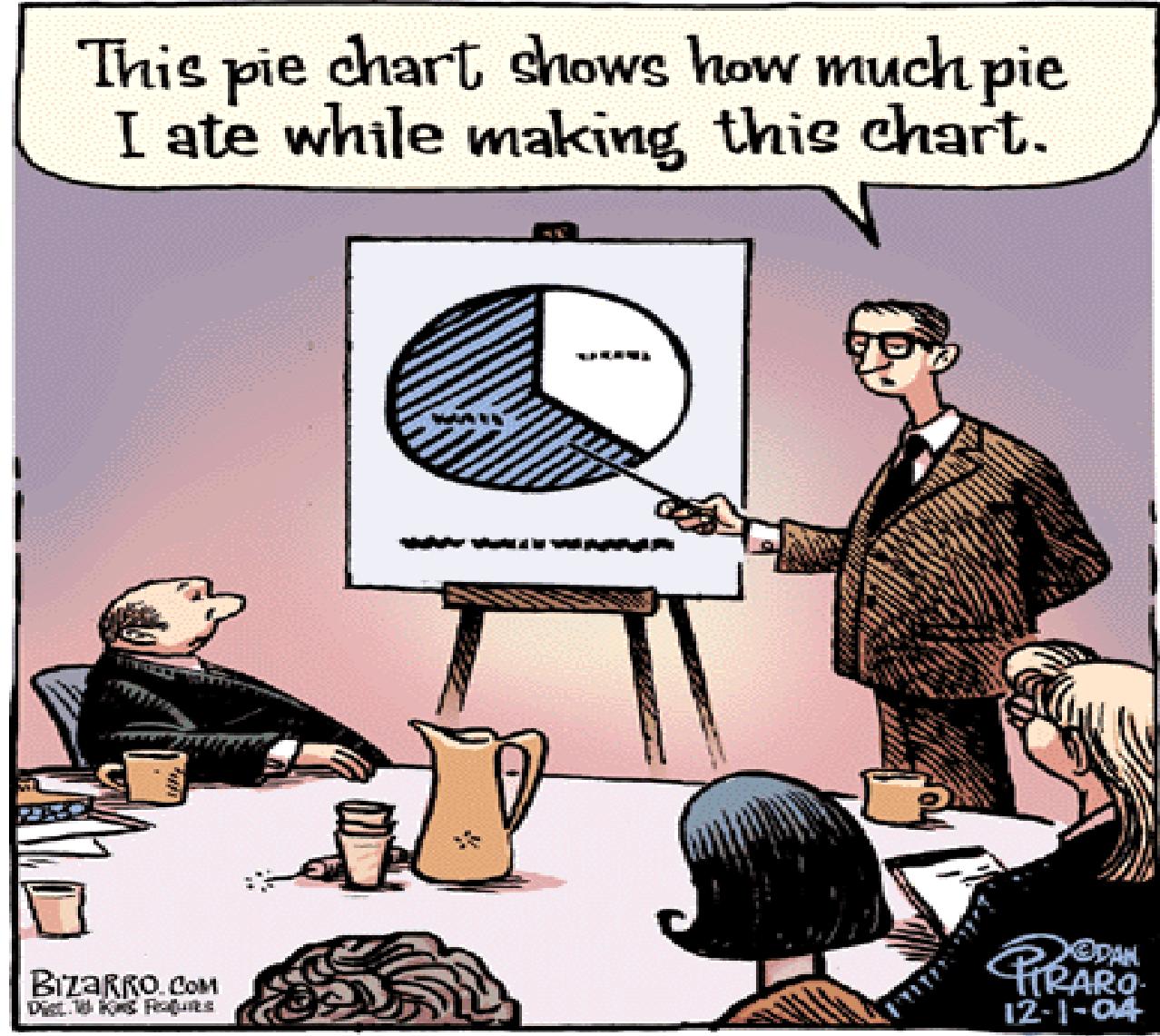
- RD 1.2.2018 Art. 117

### Opportunities Taskforce

- Prolongation without changes till max. 3 years
- Prolongation with changes till max. 3 years
- Submission 'new' CRM application in which case the convention is extended
  - with max. 1 year (until end of CRM procedure)
  - under conditions of last year of convention



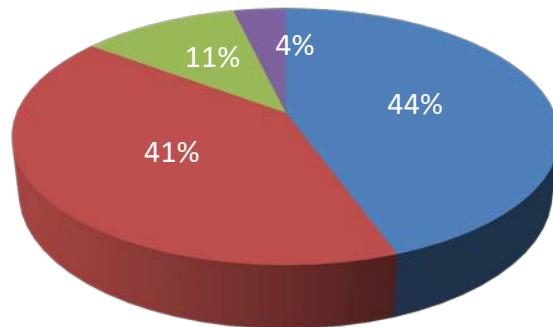
# Belgian facts & figures



## Dossier “Artikel 111/112” overeenkomsten

### Totaal aantal “artikel 111/112”-aanvragen ontvangen (periode april 2010 tot en met eind december 2016): 172

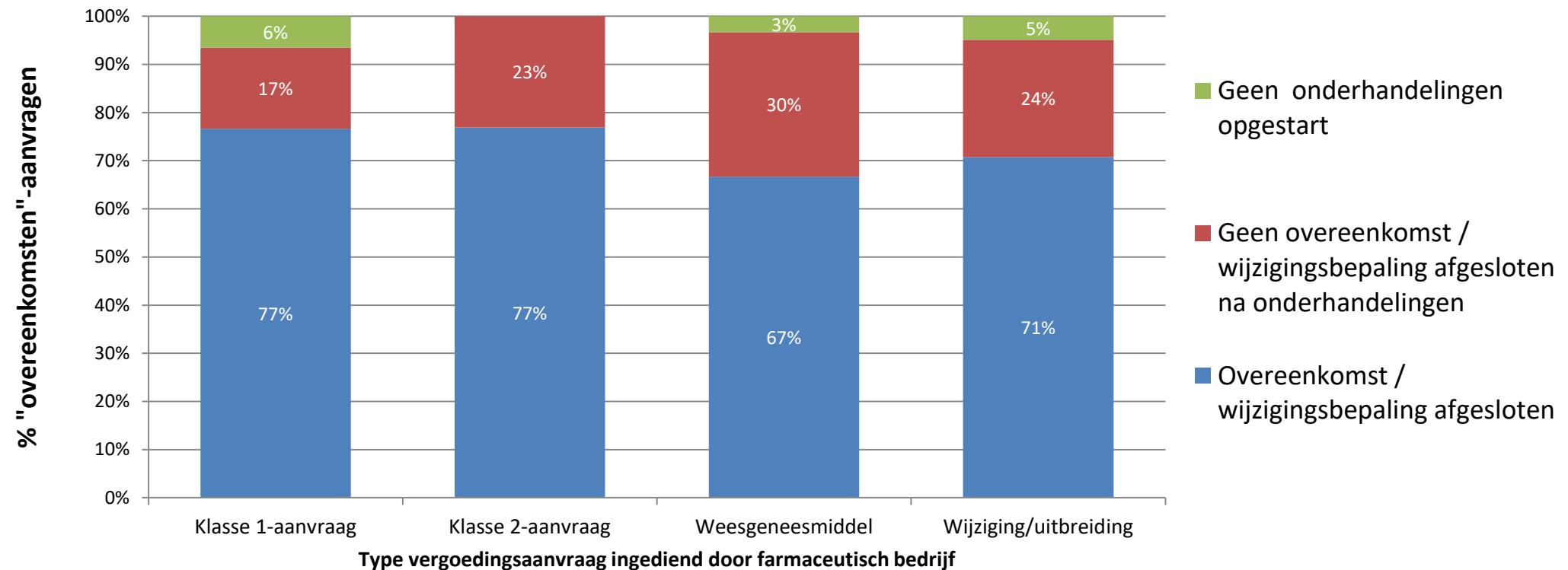
“artikel 81/81bis”-aanvragen (na CTG-procedure) die eindigden in een overeenkomst of wijzigingsbepaling bij een lopende overeenkomst:	(118)	(69%)
<i>Een overeenkomst of wijzigingsbepaling “artikel 81 of 81bis” werd afgesloten en was óf nog geldig óf afgelopen eind december 2016.</i>		
• nog steeds geldig: <i>Een overeenkomst “artikel 81 of 81bis” werd afgesloten en was nog geldig eind december 2016.</i>	91	53%
• afgelopen: <i>Een overeenkomst “artikel 81 of 81bis” werd afgesloten en was afgelopen eind december 2016.</i>	27	16%
<b>“artikel 81/81bis”-aanvragen waarvoor geen overeenkomst werd afgesloten</b>		
<i>De onderhandelprocedure werd opgestart, maar er kon geen akkoord gevonden worden, waardoor geen overeenkomst werd afgesloten.</i>		
“artikel 81”-aanvragen waarvoor nooit een onderhandeling werd opgestart <i>Een onderhandelprocedure werd door het bedrijf aangevraagd, maar werd geweigerd door de betrokken minister.</i>	8	5%
“artikel 81/81bis”-aanvragen met lopende onderhandeling <i>De onderhandelprocedure was lopende eind december 2016.</i>	11	6%



- Definitieve inschrijving na nieuwe CTG procedure (12/27)
- Nieuwe overeenkomst na nieuwe CTG procedure (11/27)
- Schrapping van de lijst na nieuwe CTG procedure (3/27)
- Schrapping van de lijst (geen nieuwe CTG procedure) (1/27)

## Dossier “Artikel 111/112” overeenkomsten

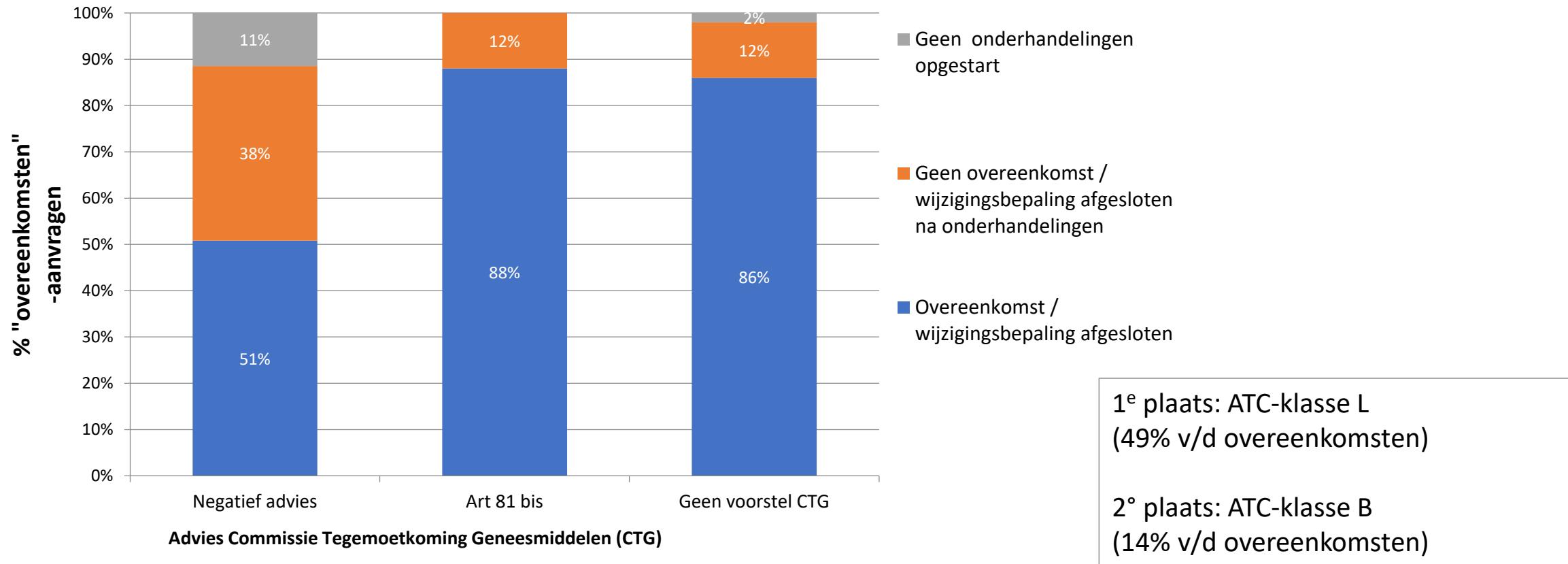
Overzicht van de “overeenkomsten”-aanvragen afhankelijk van het type vergoedingsaanvraag ingediend door farmaceutisch bedrijf



- In 77% (59/77) van de klasse 1-aanvragen, wordt een overeenkomst afgesloten.
- In 67% (20/30) van de aanvragen voor een weesgeneesmiddel komt het tot een overeenkomst.

## Dossier “Artikel 111/112” overeenkomsten

### Overzicht van de “overeenkomsten”-aanvragen afhankelijk van het advies van de CTG

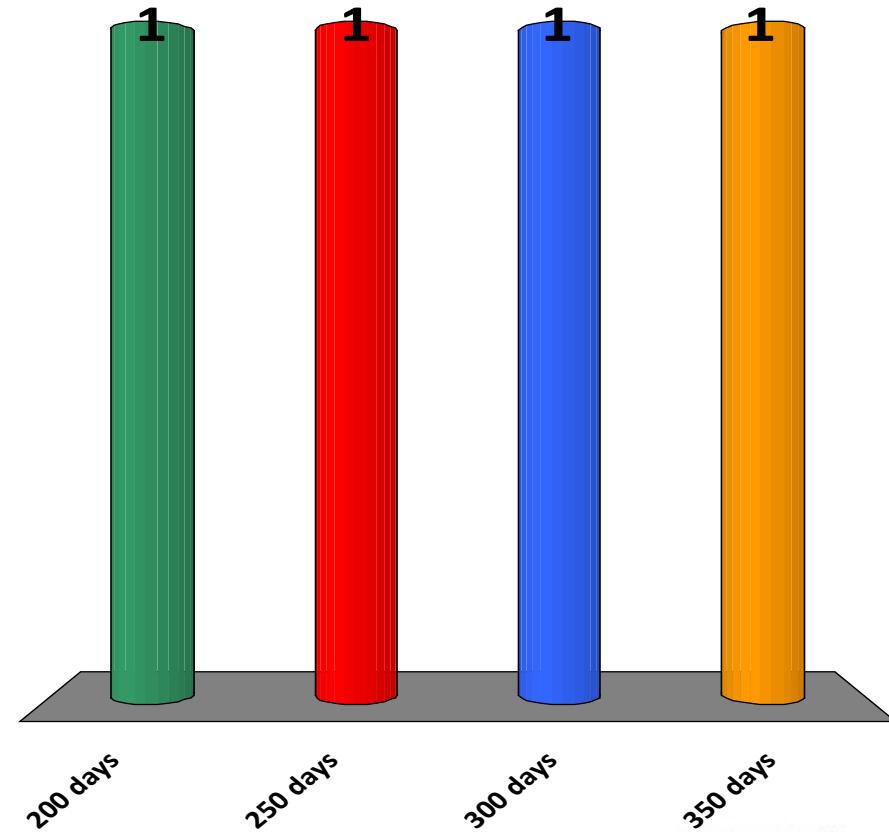


Na voorstel artikel 111/112 van CTG → overeenkomst in 88% v/d gevallen

Na geen advies van CTG → overeenkomst in 86% v/d gevallen

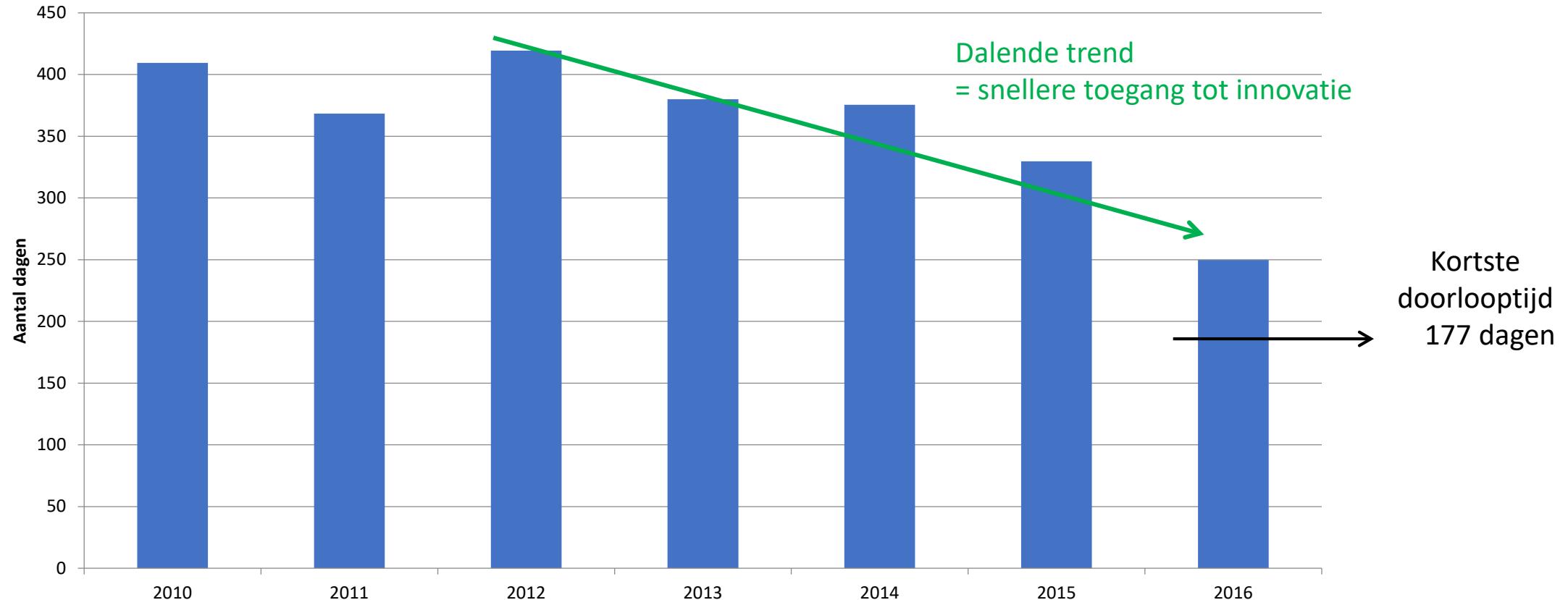
# Time between the submission of the file and the entry into force of the decision (in 2016)

- A. 200 days
- B. 250 days
- C. 300 days
- D. 350 days



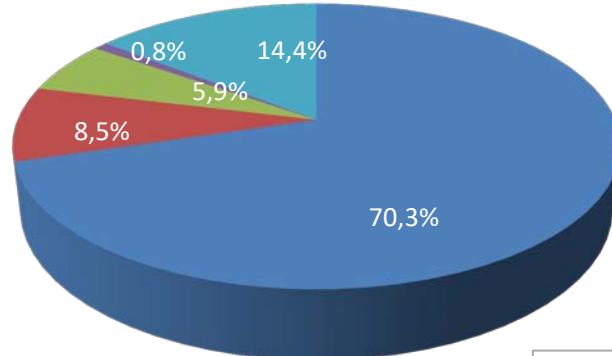
## Dossier “Artikel 111/112” overeenkomsten

*Evolutie van de tijd tussen indiening terugbetalingsdossier en inwerkingtreding vergoeding*



## Dossier “Artikel 111/112” overeenkomsten

### Type budgettair compensatiemechanisme



- Preferable easy one / not too complicated
- Provide certainty over budget spent and cost/price paid

- Percentage omzet
- Vast bedrag per eenheid
- Vast bedrag
- Prijsdaling andere specialiteit
- Ander (eg combinatie)

1 budgettair compensatiemechanisme in 85,6 % v/d gevallen  
Combinatie compensatiemechanismen in 14,4 % v/d gevallen

Budgettaire compensatie:  
123,5 miljoen euro in 2016

Het aandeel van de uitgaven voor specialiteiten waarvoor een overeenkomst afgesloten werd stijgt jaarlijks door een stijgend aantal overeenkomsten, grotere volumes en hogere prijzen van geneesmiddelen onder overeenkomst.

## FLEXIBLE BUDGETING

Geen afzonderlijk “overeenkomsten-budget”, wel een “budget-controlerend-mechanisme”



Practical tips



- Our role:

In general : organization, follow-up, secretariat and communication

→ Contact only by professional channels

→ We answer questions on process & organization but not on content

During meetings: president & ‘voice’ of taskforce

- Constructive attitude
- Negotiate during meetings
  - No new elements after last meeting
  - In case of doubt: new meeting will be organized if possible within timelines
- No ‘renegotiations’ of CRM report or proposition
- Focus not only on € (% refund)
- Someone with decision making power or mandate should be present at meetings



## Propositions by company

- Should be clear: to the point but complete
  - Include clear motivations and calculations (we  Excel)
- Do not wait for meeting minutes to send new proposition
  - Meeting minutes are 'goodwill' of administration
- Send proposition on time
  - By e-mail
  - Include all elements: no new elements during meeting

- Address all uncertainties: be as complete as possible
  - If company believes the available information is not adequate: clearly motivate and explain reason
- Include sales numbers: as recent as possible
  - If meeting takes place: keep update at hand
- Introduce on time
- 1 original + 2 copies + CD Rom (no USB) + e-mail to  
[ctg-crm.contrat@riziv.fgov.be](mailto:ctg-crm.contrat@riziv.fgov.be) (documents in Word file)

Belgium Netherlands  
Luxembourg Austria Ireland

Collaboration Initiative  
on the reimbursement of medicines



# 1

# the Initiative



*Brood hal, Brussels*

## proof of concept for the ‘coalition of the willing’

- Health Technology Assessment
- Horizon Scanning
- Exchange of information on pharmaceutical markets, prices and disease specific cross border registries
- Pricing and reimbursement including joint negotiation

## proof of concept for the ‘coalition of the willing’

- Letter of intent signed by Ministers
  - Mandate to deliver proposals for cooperation on HTA, Horizon Scanning and Pricing and Reimbursement topics
  - To perform pilots on these topics
- Expensive medicines
  - High cost per patient
  - High budget impact
- Voluntary
  - Consensus based cooperation
  - Reimbursement decisions are national competence

## proof of concept for the ‘coalition of the willing’

- Main goal: To ensure access to innovative drugs at affordable cost
- Cooperation is part of the policy-mix
- Information gathering on global markets benefits from joint approach
- National context determines course of action
- Joint negotiations only in select cases
- What works?
  - Setting clear, common goals
  - Mutual benefit needs to be clear
  - Pragmatic approach
    - Focus on desired outcomes
    - Lean organisational structure

# 2

# the Work



*Keizersgracht, Amsterdam*

- Based on previous experience/expertise with MEDEV, EUnetHTA, JA2, informal collaboration,...
- Coherent and compatible with Joint Action 3
- ‘testing’ models for implementation:
  - Mutual recognition of Assessments (operational)
  - Joint ‘writing’/editing (operational)
  - Sharing expertise (operational), eg. Dutch ‘Wetenschappelijke AdviesRaad’ of ZIN acts as external expert in Belgian reimbursement procedure

- Based on the Dutch methodology, used for short-listing candidates for ‘financial arrangements’
- Preparing for joint early dialogues, joint HTA, joint negotiations,..
- Methodology scientifically to be consolidated and documented by KCE (Belgium) (KCE Study 2015-57 (HSR) Horizon Scanning Methodology)
- Brussels Meeting June 27th 2017  
Invitation for participation from the 4 Ministers

## Exchange of information and knowledge

- Drug consumption
- Prevalence and burden of disease
- Best practices in (health budget) management (e.g. hep. C approach, reference pricing, generic policy, biosimilar policy,...)
- Post marketing evidence gathering (e.g. registries)
- Policy questions (e.g. KCE-ZIN Study 2013-03-HSR\_on drug pricing scenarios)

- By structural exchange of information and testing through pilots of procedures or scenarios for joint negotiations that lead to financial arrangements and contracts
- That are compatible with and respect national legislation and competence and responsibility of the different stakeholders in the decision making process
- That respect confidentiality of the commonly negotiated financial details (..nothing changes compared with today..)

**THIS IS NOT JOINT PROCUREMENT**



- Objective is
  - to create an overall ‘win’ situation
  - for patients: accelerated access
  - for authorities: economy of scale, knowledge building (joint registries), joining expertise
  - for companies: faster access, lower administrative burden
- and then the reality..

# 3

# Today



*Along the Alzette, Luxembourg*

- Objective is to examine and test in practice true collaboration
- Feasibility and added value (lessons learned) of the collaboration in the different areas will be documented (terms of reference and communication), evaluated and shared with stakeholders and other interested Member States
- Therefore need to be able to work in ‘serene’ environment (discretion equals NOT intransparency), based on mutual understanding and trust
- Commitment to play an active role on EU level (EUNetHTA JA3, MoCA, Senior Party, EU presidency, etc..)

- Cooperation entails ‘only’ 37,5 million inhabitants
- Large interest from Industry
  - “Cooperation could lead to higher, instead of lower prices”
  - Interest of many individual companies
- Commitment to success
  - Only one chance to build a solid cooperation
- Cooperation is not the solution to all problems
- Joint negotiations require Proof of concept
  - Terms of reference
  - Review of current pilots

# 4

# Tomorrow

*Domkirche St. Stephan zu Wien, Vienna*



- Expansion is welcome, but:
  - It's not a 'set menu'
    - Step-wise approach in participation
    - Different mandate/contribution for information scanning vs. Joint negotiations needed
  - Reimbursement systems need to align
  - Political will is essential
  - Voluntary participation

# Succes Factors

5

*Domkirche St. Stephan zu Wien, Vienna*



## Key Success factors

- Mutual and common understanding on value and appraisal assessments.
- Benefits must be clear for all partners (economies of scale and knowledge building; fast access; less red tape ...).
- Pragmatic approach, trust and mutual commitment.
- Political support (responsibility and accountability).
- Solid founded and well documented framework.

### Sufficient investment in project development:

- horizon scan,
- priority setting,
- topic selection,
- establishing value framework for negotiations,
- synchronizing national procedures,
- project monitoring and management,
- communication ...

---

# What's next







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Insights into health care and entitlement reform.  
[full bio →](#)

Opinions expressed by Forbes Contributors are their own.

**OPINION**

5/16/2014 @ 10:01PM | 10.439 views

# Sure, We'll (Eventually) Beat Cancer. But Can We Afford To?

**Paul Howard**, Contributor[+ Comment Now](#)   [+ Follow Comments](#)

Matt Herper's [tour de force](#) article in the latest *Forbes* magazine suggests that companies and researchers are – perhaps – [turning the tables](#) on cancer using novel immunotherapies that are producing nearly unheard of outcomes even in late stage disease. The trillion dollar question: Can we afford to win the war on cancer, given current trends in drug development and pricing?



Share

DURE GENEESMIDDELLEN VOOR ZELDZAME ZIEKTES ONDER VUUR

# Miljoenen voor pillen die maar een beetje werken

Er zitten heel wat peperdure geneesmiddelen in de pijplijn, waaronder nieuwe behandelingen tegen kanker die boven de 100.000 euro per patiënt zullen kosten. 'Voor elk geneesmiddel zouden we de vraag moeten stellen wat het opbrengt. Doen ze bijvoorbeeld het aantal ziekenhuisopnames bij een bepaalde patiëntengroep dalen? Zo kan je medicijnen ook onderling vergelijken.'

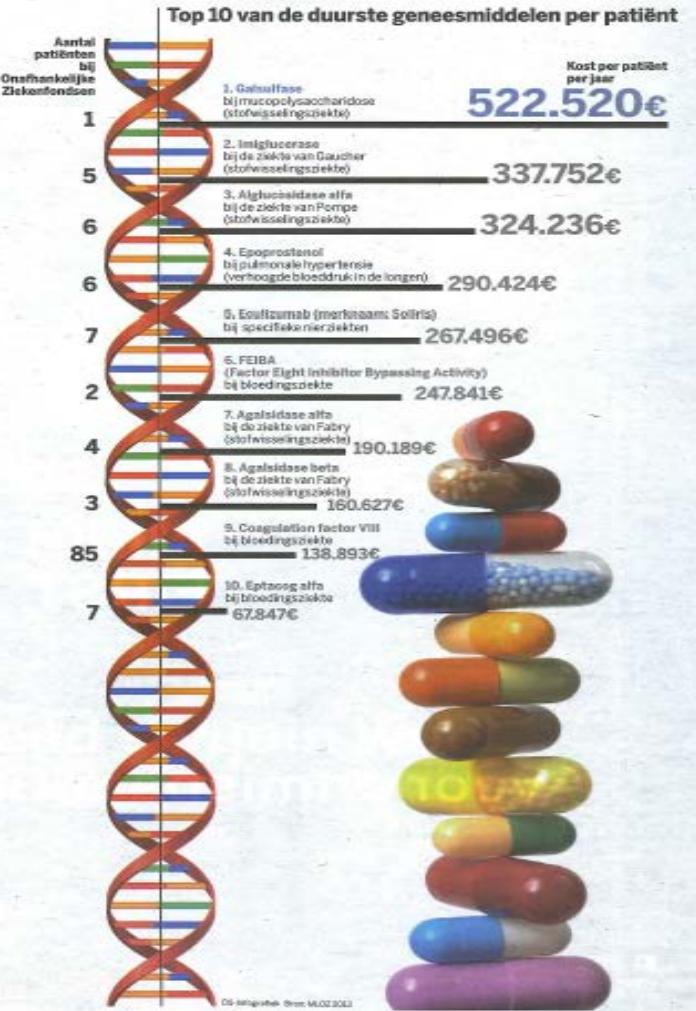
VAN ONZE REDACTRICE  
**MARIE ECKER**

**BRUSSEL** | Veel van de medicijnen zijn ontwikkeld voor de zogenoemde 'ultraarclzame' ziekten, vaak aandoeningen die door een genetisch defect worden uitgelokt en die een heel specifieke therapie van toepassing hebben. 'De geneesmiddelen die de pan uittragen. De farmaceutische industrie moet hun ontwikkelingskosten doorsrekken aan een heel kleine groep patiënten', zegt Carlo Van Hul, geneesheids-expert bij de Onafhankelijke Ziekenfondsen. Toch stelt Van Hul zich vandaag op een debat van de Onafhankelijke Ziekenfondsen in Brussel om te vragen bij de exuberante prijzen. De kwestie is dan ook bemoedigend actueel. Er zitten heel wat peperdure geneesmiddelen in de pijplijn, waaronder nieuwe behandelingen tegen kanker die boven de 100.000 euro per patiënt zullen kosten. Van Hul wijst er ook op dat er veel meer mogelijkheden zijn om te komen tot. Bij m'n therapie wordt bij patiënten met een erfelijke aandoening gennmaatride ingespoten. In Duitsland wordt een eerste gentherapie terughetaald voor patiënten met problemen aan de sliekhuid. Prijskaartje: 830.000 tot 1,2 miljoen euro voor de (enmallige) behandeling.

Die opheldert het duurste geneesmiddel Soliris - dat in de top 10 van de duurste geneesmiddelen staat - bevecht eerder hoe gevoelig geneesmiddelenprijs liggen. Het aHUS-patiëntje Viktor had het nodig om te overleven maar de hoge prijs die het farmabedrijf erover had, beperkte de behandeling door de ziekenverzekerder. 'Wij kunnen maatregelen moeten nemen, anders worden de uitgaven voor geneesmiddelen onhoudbaar', zegt Van Hul. 'Bijvoerbaarheid heeft en regelmatig nagaan of de duur medicijnen de prijs wel waard zijn.' Dan zegt ook Lieven Annemans, professor geneesmiddelen-economie (UGent): 'Voor elk geneesmiddel zouden we de vraag moeten stellen

wat het ophovert. Doen ze bijvoorbeeld het aantal ziekenhuisopnames bij een bepaalde patiëntengroep dalen? Zo kan je medicijnen ook onderling vergelijken.' 'Bovendien hoort de overheid duidelijk aan te geven waar haar grenzen liggen. Wat is de maximale prijs die de overheid bereid is te betalen voor een bepaalde gezondheidswinst die een geneesmiddel oplevert? Dat bedrag moet natuurlijk worden aangepast aan de nood voor een behandeling. Zijn signalen geofft farmaceutische industrie horwt bij de ontwikkeling van hun nieuwe producten?' De Belgische farmaceutische industrie moet voorlopig al streng worden gewaakt over de 'kosteneffectiviteit' van nieuwe medicijnen. 'De uitgaven voor nieuwe en duur geneesmiddelen zullen daarom niet exploderen. De middelen zijn doeltreffend en dus worden er veel kosten bespaard. Patiënten kunnen sneller terug aan het werk, dat is goed voor iedereen', zegt voorzitter Stefan Pieters. 'Het klopt wel dat de nieuwe middelen vaak voor kleine patiëntengroepen worden ontwikkeld, wat ze dus maakt. Maar eigenlijk is het goed dat de farmaceutische industrie die kleine patiëntengroepen niet verget. De overheden moedigen de ontwikkelingen van zulke medicijnen overigens daarom ook aan.'

Nieuwe behandelingen tegen kanker zullen boven de 100.000 euro per patiënt kosten



## Waarom is Soliris zo duur?

OPINIE – 07/05/13, 07u22

**Dirk Van Duppen, gezondheidsspecialist voor de PVDA en auteur van 'De Cholesteroloorlog' legt uit waarom geneesmiddelen zo duur zijn.**

In de discussie over terugbetaling van het peperdure geneesmiddel Soliris voor Viktor met de zeldzame immuunziekte hemolytisch uremisch syndroom (aHUS), ontbreekt de kernvraag: 'Waarom zijn deze geneesmiddelen zo duur?' (DM 4/5). Volgens de industrie zelf bedragen de onderzoeks- en ontwikkelingskosten van een innovatief geneesmiddel zoals Soliris één miljard euro.

Een studie over de ontwikkelingskost, recent gepubliceerd in het prestigieuze British Journal of Medicine haalt dit cijfer onderuit. De studie schat de reële O&O-kost voor de firma die het product op de markt brengt op 250 miljoen euro. Het basisonderzoek voor de ontwikkeling van monoklonale antilichamen, de nieuwe klasse geneesmiddelen waartoe Soliris behoort, werd gevoerd door samenwerkende wetenschappers van verschillende universiteiten, gefinancierd met overheids geld. Alexion is zelf een spin-off van de Yale-universiteit.

“

**Alexion, dat zijn winst bijna uitsluitend uit Soliris haalt, boekte vorig jaar nettowinst van 255 miljoen dollar**

### MEER OVER

Gezondheid

[DSM-5, de boekrecensie](#)

[Op naar een alternatief voor etikettendiagnostiek](#)

[Hoe kunnen we de Brusselse zorg beter organiseren?](#)

[De keuze van Angelina Jolie is nog niet voor iedereen weggelegd](#)



U bent hier: > Startpagina > Test-Aankoop geeft 573 geneesmiddelen een slecht rapport

## PERSBERICHTEN

# Test-Aankoop geeft 573 geneesmiddelen een slecht rapport

17 februari 2014

De gemiddelde Belg slikt heel wat geneesmiddelen. Hij gaat er van uit dat alle medicatie in onze apotheken werkt en perfect veilig is, maar dat is een misvatting. Een team van arts en apothekers van Test-Aankoop beoordeelde zo'n 4000 geneesmiddelen. Over 15% ervan stelt Test-Gezondheid zich ernstige vragen. Van 460 producten bestaan er ernstige twijfels of ze wel werken of voldoende veilig zijn, en van 113 raden de experten het gebruik ten stelligste af. Omdat de consument over onvoldoende betrouwbare informatie beschikt om de voor- en de nadelen van geneesmiddelen goed in te schatten, biedt Test-Aankoop hem nu via [www.test-aankoop.be/databankgeneesmiddelen](http://www.test-aankoop.be/databankgeneesmiddelen) een module aan met een beoordeling van de medicatie die op onze markt verkrijgbaar is.

## Test-Aankoop beoordeelt 4000 geneesmiddelen

Er zijn maar liefst 7000 geneesmiddelen op de markt in ons land. Deze zijn echter niet allemaal even nuttig. De waarde van sommige producten is betwistbaar, en een aantal geneesmiddelen zijn zelfs ronduit af te raden! De consument is zich hiervan niet bewust. Zo slikt de gemiddelde Belg dus heel wat geneesmiddelen zonder dat hij de

## GERELATEERD

[Rekenmodule](#)

[Databank geneesmiddelen](#)

Dossier

[Zelfmedicatie: praktische tips voor kleine kwaaltjes](#)

# Europe



**Marketing Authorisation** is European competence  
**Pricing and Reimbursement (Appraisal)** remain a national competence

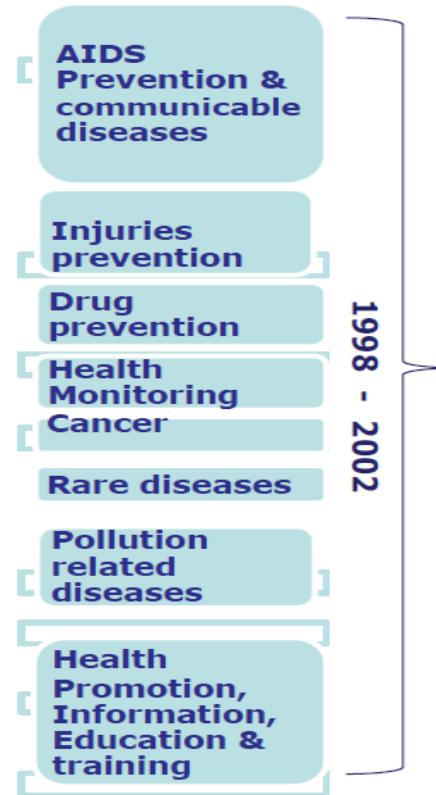
## Enhanced Cooperation

NMCAPR  
MEDEV  
Joint Action





# EU Health actions and Programmes



- **Community action in the field of health 2003-2007**

**EUR 312 million**



- **2<sup>nd</sup> Community action in the field of health 2008-2013**

**EUR 321,5 million**



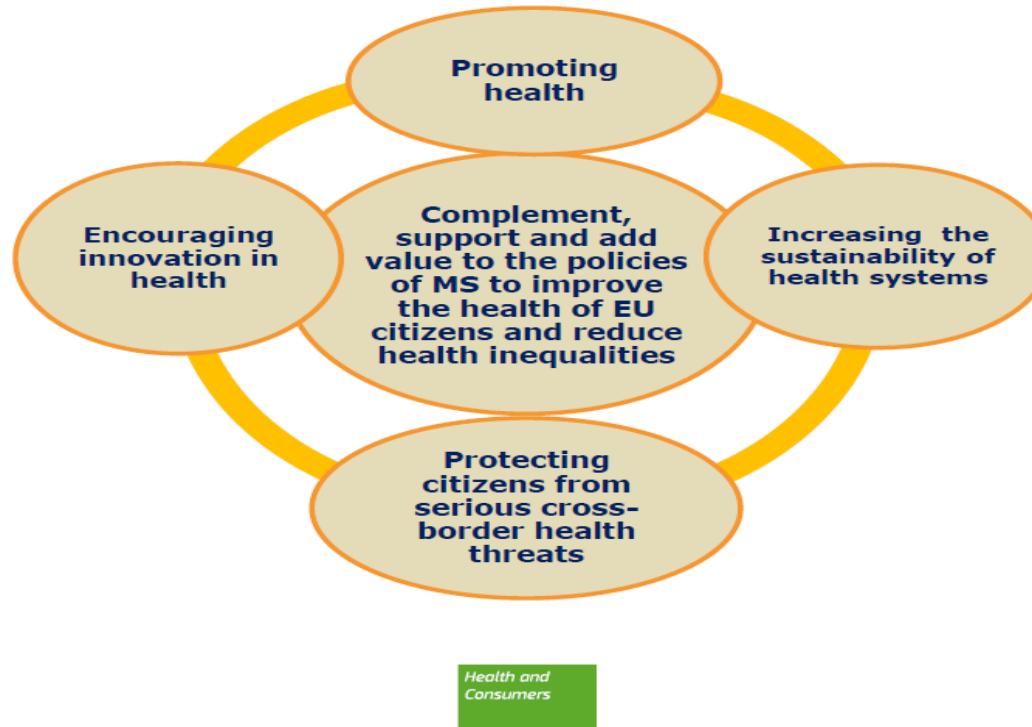
- **3<sup>rd</sup> Union action in the field of health 2014-2020**

**EUR 449,4 million**





## The scope of the Programme



### 3) Contributing to innovative, efficient and sustainable health systems

- **Health Technology Assessment**
- **Up-take of health innovation and e-health solutions**
- **Health workforce** forecasting and planning (number, scope of practice, skills), mobility/migration of health professionals
- Mechanism for **pooled expertise and good practices** assisting Member States in their health systems reforms
- Health in an ageing society, including European Innovation Partnership on **Active and Healthy Ageing**
- **Legislation** in the field of **medical devices, medicinal products** and **cross-border healthcare**
- **Health information** and knowledge system including **Scientific Committees**

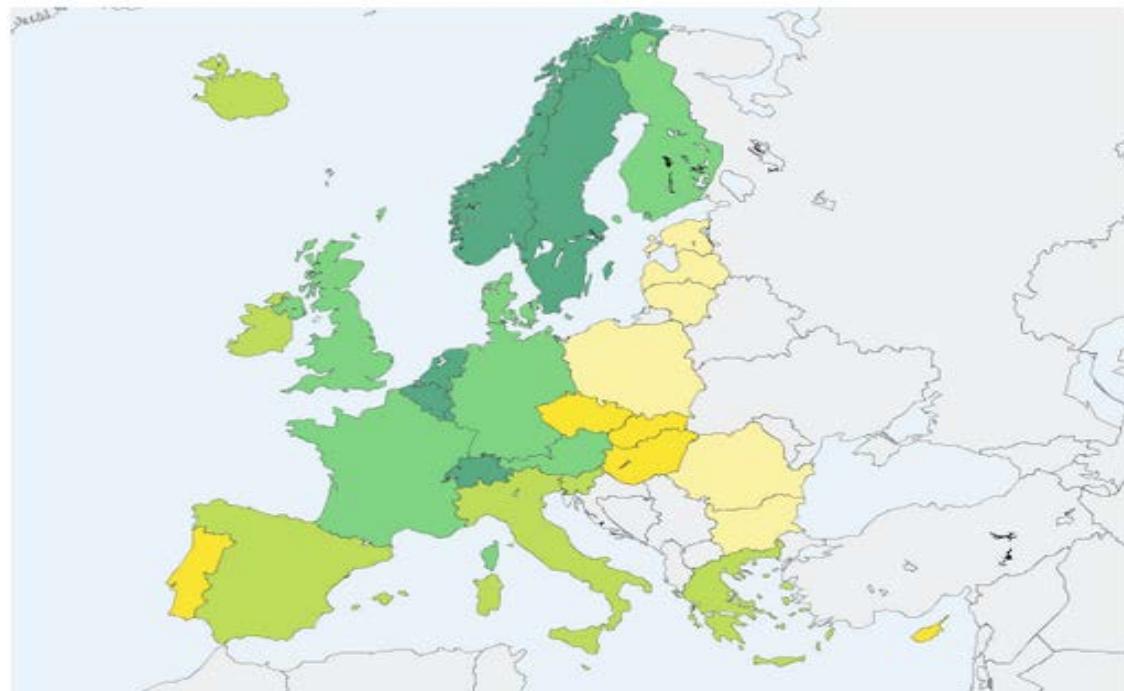
## Issues

### Reality of a Europe

Resources

Expertise

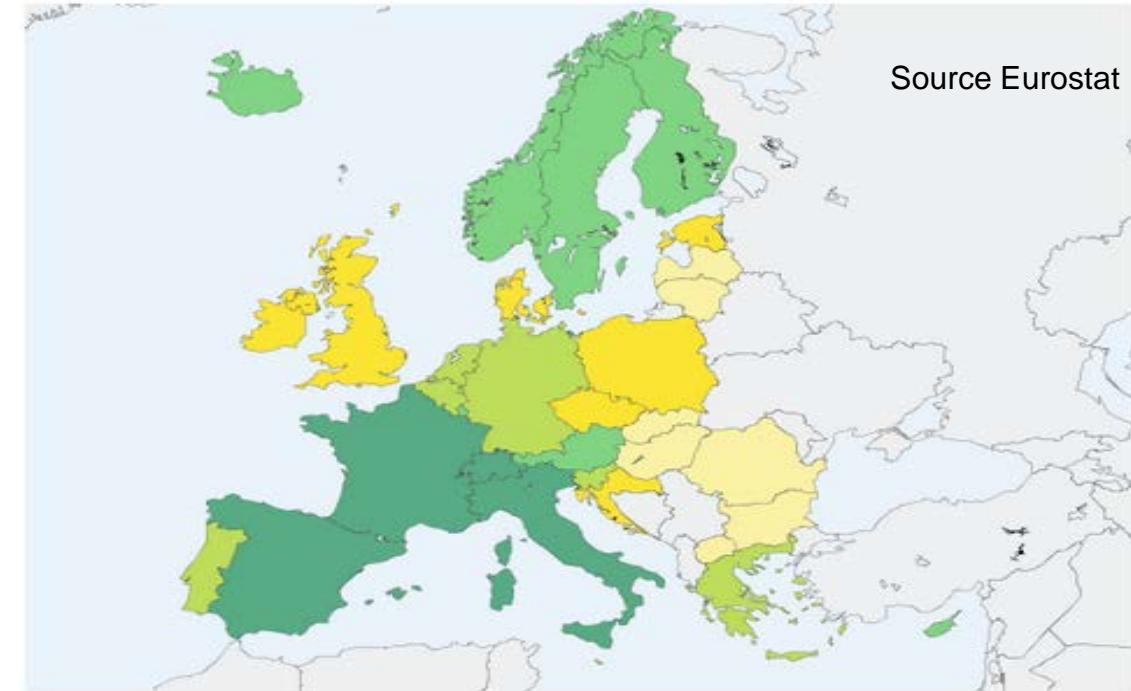
Organisation of Health Insurance



Total expenditure on social protection per head of population. PPS

Legend ( Series: 2007 )

1352.2 - 2428.7	2428.7 - 4700.6	4700.6 - 7054.4
7054.4 - 8640.2	8640.2 - 13231.3	N/A



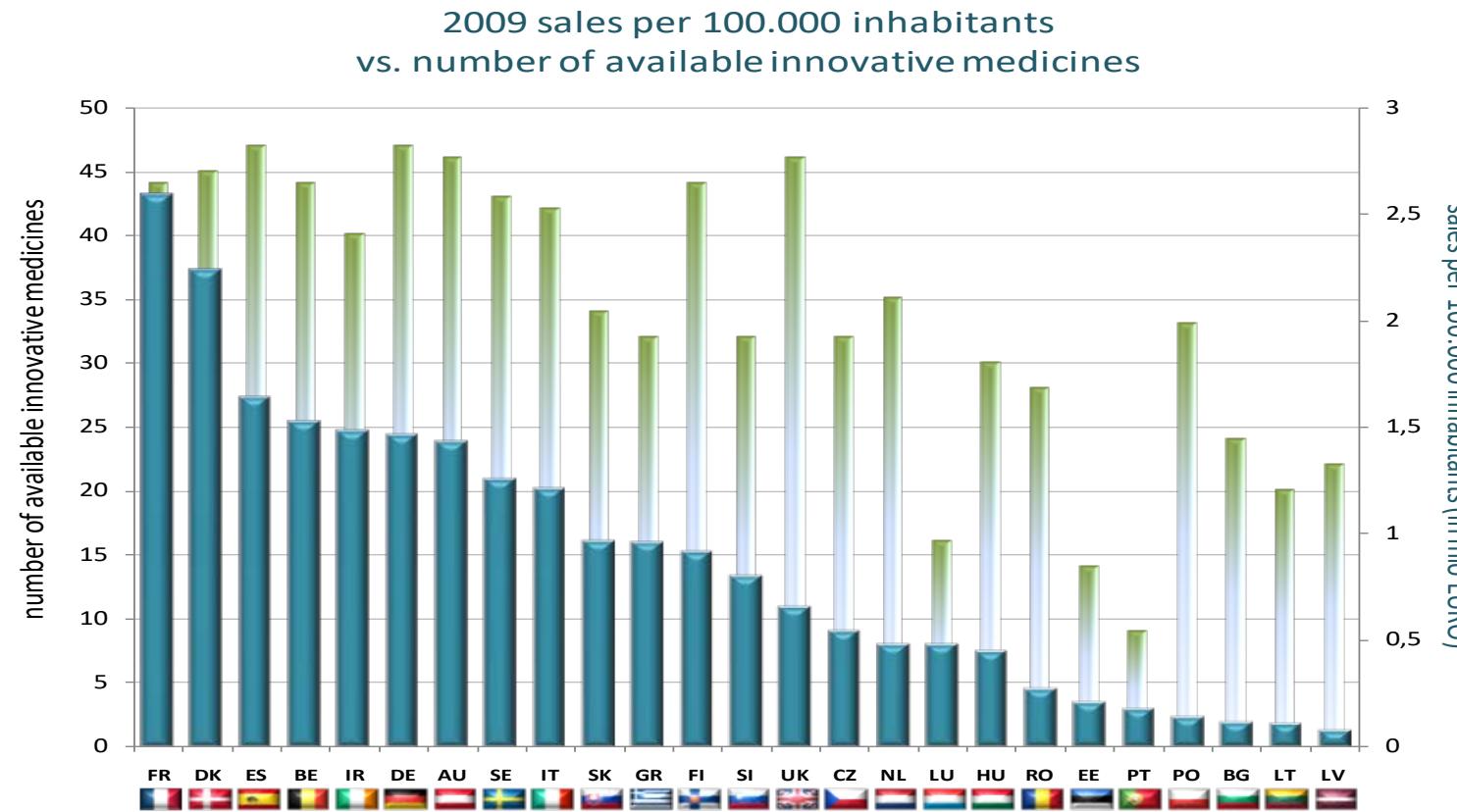
Life expectancy at birth, by gender - (years) - Females

Legend ( Series: 2008 )

76.52 - 78.98	78.98 - 82.3	82.3 - 82.67
82.67 - 83.28	83.28 - 85.43	N/A

## Issues

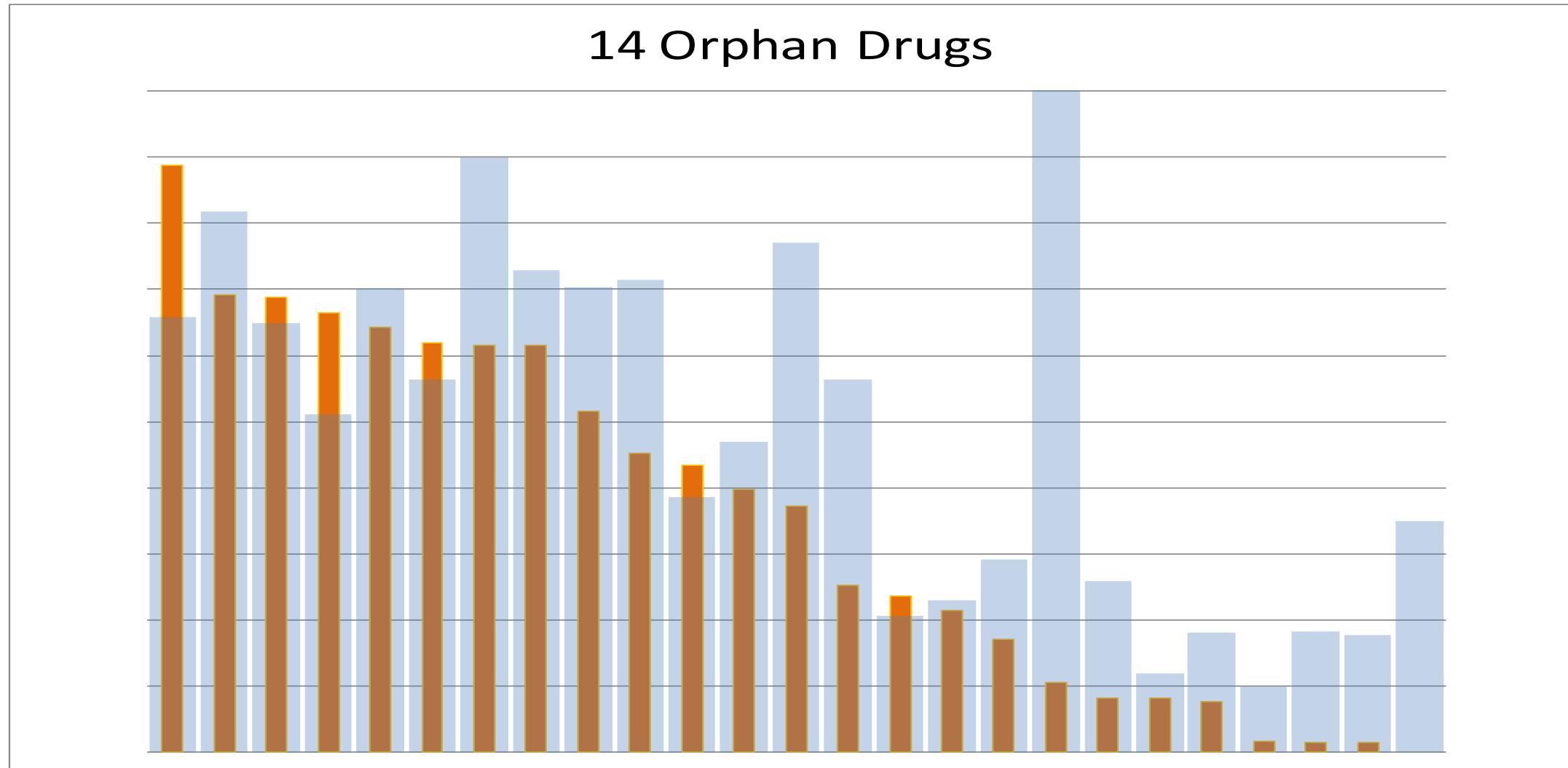
*There are important differences in uptake of innovative products across EU countries with no apparent link with availability*



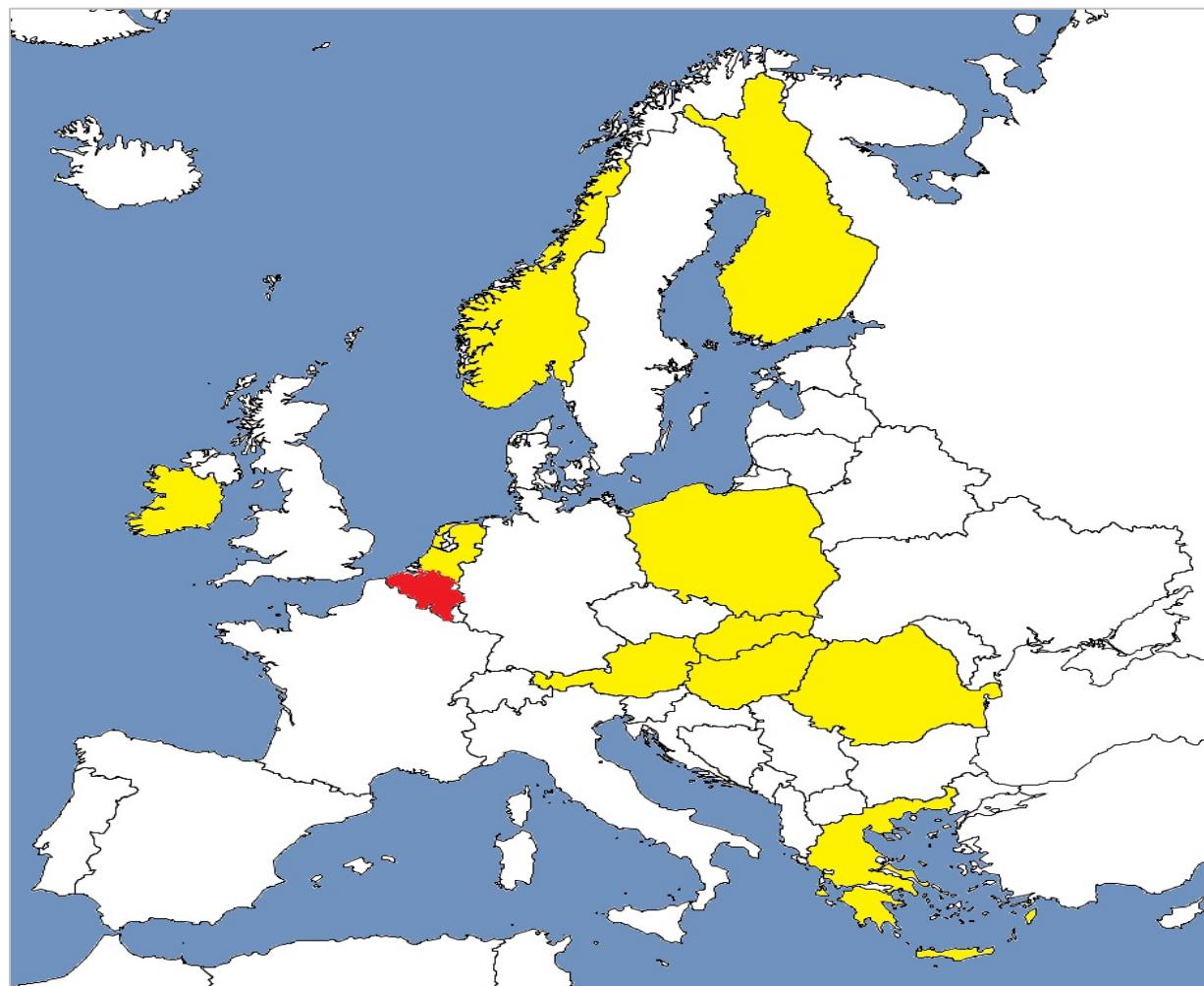
Source: Study supporting INAMI RIZIV in understanding and measuring pharmaceutical innovation across the European Union



## Orphan Drugs: Access and availability

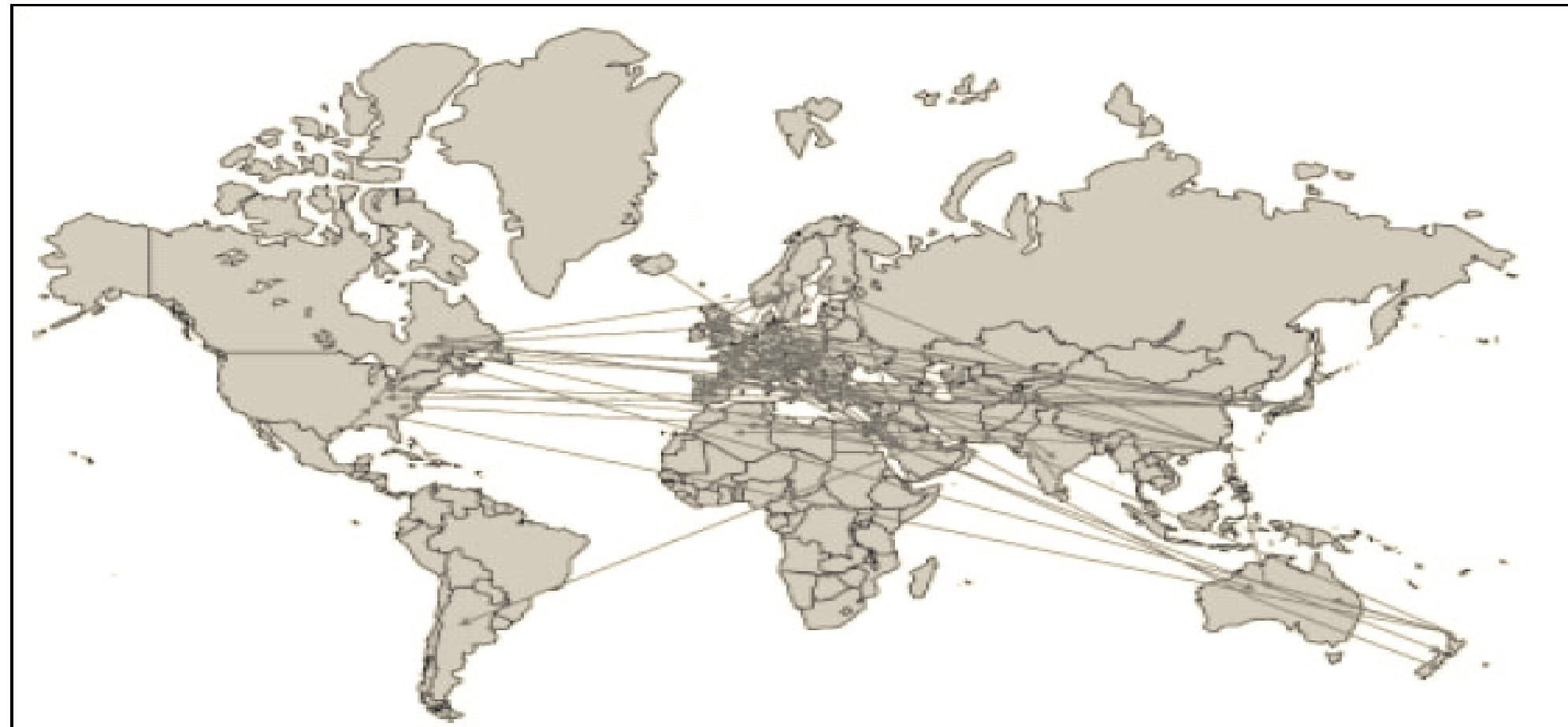


## External Price Referencing



+ ...

## External Price Referencing





EUROPEAN  
COMMISSION

Brussels, 31.1.2018  
COM(2018) 51 final

2018/0018 (COD)

Proposal for a

**REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

**on health technology assessment and amending Directive 2011/24/EU|**

# **EU Commission released yesterday a Proposal for a Regulation on Health Technology Assessment (HTA)**

Published on February 1, 2018





Harvey Wiley and the Crusading Chemists

спасибо  
спасибо  
*hədənkt*  
*dziękuje*  
*obrigado*

**danke** 謝謝  
**thank you**  
*sukriya* kop khun krap  
*terima kasih*  
감사합니다

ngiyabonga  
teşekkür ederim  
*dank je*  
*gracias* *gracias*  
*mochchakkeram*  
*go raibh maith agat*  
*grazie* *arigatō*  *MERCI*  
*dakujem* *мерси*

**merci**

