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Pharmaceutical policy : status, challenges, some reflections from a payor's perspective

BRIEC: Pharma of the Future – Opportunities of changing Business Models

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I. ”It’s the economy, stupid”. The health of the economy, the budget for health, health of the health budget.

The Belgian government household

Revenue
Where does the money come from?

267.4

Tax & other revenue
173.7

Social contributions
93.7

Financing balance

267.4 293.5

Deficit
24.6

Gross debt
567.0

Expenditure
Where does the money go?

293.5

Transfers

Regions & communities	81.5
Europe	9.1
Other transfers	1.2

Federal expenditure

Social Security	147.3
Federal Govt.	41.9
Interest charges	12.3

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1944 85% social contributions / 15% government

1985 70% social contributions / 30% government

2024 60% social contributions / 40% gov./alt. financing

2026 Budget: Focus on social security

Figures in billion euros | Approved 3/2026

Revenue

Where does the money come from?

148.0

Social security revenues **93.7**

Federal gov. funding **54.3**

- Social contrib. **85.5**
- Regions & commun. **0.4**
- Other **7.8**
- Federal dotation **27.1**
- Alt. financing **27.2**

Expenditure

Where does the money go?

147.3

- Pensions **72.3**
- Unemploy. & career breaks **4.6**
- Admin. costs **3.0**
- Incapacity for work **15.9**
- Health care **41.3**
- Other **10.1**

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Table 1 – Financing balance (deficit) of Entity I

	2026	2027	2028	2029	2030	2031
Entity I (EUR m)	**-25,680**	**-30,344**	**-34,259**	**-38,521**	**-40,883**	**-44,711**
Entity I (% of GDP)	**-3.9**	**-4.4**	**-4.8**	**-5.3**	**-5.4**	**-5.7**
of which federal government (EUR m)	-25,818	-33,152	-35,999	-41,421	-43,144	-46,243
of which federal government (% of GDP)	-3.9	-4.8	-5.1	-5.6	-5.7	-5.9
of which social security (EUR m)	-44	1,394	196	708	69	-661
of which unallocated measures (EUR m)	183	1,415	1,544	2,192	2,192	2,192
Primary balance Entity I (% of GDP)	-2.0	-2.3	-2.5	-2.7	-2.6	-2.7

Entity I = federal government + social security + unallocated measures. 2026 at budget review 2026: -24,530 EUR m (-3.7% of GDP).

Table 2 – Public debt (debt-to-GDP ratio, % of GDP)

	2025	2026	2027	2028	2029	2030	2031
Entity I – debt (% of GDP)	**84.3**	**86.3**	**88.1**	**90.2**	**92.4**	**94.9**	**97.8**
Change in debt ratio (pp of GDP)	+2.4	+2.1	+1.8	+2.1	+2.2	+2.5	+2.9
of which endogenous factors (pp)	1.0	1.2	1.4	1.9	2.4	2.6	3.0
of which exogenous factors (pp)	1.4	0.9	0.4	0.2	-0.2	-0.2	-0.1
General government – debt (% of GDP)	**107.9**	**110.7**	**112.7**	**114.9**	**117.1**	**119.8**	**122.8**
Change in debt ratio (pp of GDP)	+4.0	+2.9	+1.9	+2.2	+2.3	+2.6	+3.0

2025: outturn (National Accounts Institute). 2026 onwards: Monitoring Committee estimates, July 2026.

Table 3 – Consolidated interest charges of Entity I

	2026	2027	2028	2029	2030	2031
Interest charges (EUR m)	**12,541**	**14,591**	**16,621**	**18,628**	**20,936**	**23,453**
Interest charges (% of GDP)	1.9	2.1	2.3	2.5	2.8	3.0

Fixed (?) budgetary framework for health insurance

Before the November 2025 budget conclave

Source: Federal government

	2025	2026	2027	2028	2029
Growth norm (%)	2.50%	2.00%	2.00%	2.60%	3.00%
Growth norm (€)	899,562	756,039	784,118	1,052,928	1,263,383
Budget target — current prices	39,752,155	41,275,720	42,686,660	44,421,785	46,356,568
Savings outside norm		-125,000	-125,000	-200,000	-350,000
Growth after savings	**899,562**	**631,039**	**659,118**	**852,928**	**913,383**
Cumulative legislature	899,562	1,799,124	2,430,163	3,089,281	3,942,209
Real growth incl. savings	2.50%	1.67%	1.68%	2.11%	2.17%
Δ vs. 2.5% lower norm	0	192,185	398,004	372,432	173,356
Δ vs. 2.5% + extra savings		317,185	523,004	572,432	523,356

Decisions from the November 2025 budget conclave

- Growth norm for 2028 and 2029 reduced to 2.5%
  - -€40m in 2028 / -€153m in 2029
  - Of which 0.5% is reserved to fund the social agreement for federal healthcare wage sectors + priority healthcare objectives
- €125m increase in co-payments from 1 July 2026
  - Proceeds (via lower insurance reimbursement) used for the social agreement (€100m) + priority initiatives + strengthening health administration capacity

Budget target (government agreement norm) vs. PROMES 2.18 baseline projections

Nominal expenditure, in thousand euros

	2025	2026	2027	2028	2029
a. Budget target (norm) – NIHDI calculation	**39 812 150**	**41 360 705**	**42 828 569**	**44 578 920**	**46 541 131**
- amount not to be spent	-200 018	-200 018	-200 018	-200 018	-200 018
- amount not to be spent: claw forward	80 363				
- comp. receipts Art. 111/81	-2 000 515	-2 125 151	-2 249 787	-2 374 423	-2 499 059
	37 691 980	**39 035 536**	**40 378 764**	**42 004 479**	**43 842 054**
Growth		3.6%	3.4%	4.0%	4.4%
b. PROMES 2.18 (calibrated to Sept. 2024 technical estimates)	**39 973 483**	**41 920 515**	**43 884 873**	**45 870 744**	**48 139 940**
- comp. receipts Art. 111/81	-2 000 515	-2 257 121	-2 519 887	-2 782 378	-3 094 329
- underutilisation and reserved amounts 2025	-144 549				
- 2025 budget: MIRA decisions (note ARGV 2025/11)	-216 802	-216 802	-216 802	-216 802	-216 802
- 2025 budget: claw forward (note ARGV 2025/11)	80 363				
	37 691 980	**39 446 592**	**41 148 184**	**42 871 563**	**44 828 810**
Growth		4.7%	4.3%	4.2%	4.6%
Difference (a)-(b)	**0**	**-411 057**	**-769 420**	**-867 085**	**-986 756**

Type of care	In millions of euros			Average annual growth rate (%)
	2025	2035	2025-2035	2025-2035
Physicians' fees – total	11 675	13 814	2 182	1.7
- Clinical biology	1 540	1 669	130	0.8
- Medical imaging	1 770	1 863	93	0.5
- Consultations and home visits	3 571	4 664	1 093	2.7
- Special services, surgery	3 500	3 975	475	1.3
- Other: gynecology, monitoring, other fees	1 252	1 643	391	2.8
Dentistry	1 621	1 978	356	2.0
Pharmaceutical products (net)	6 988	10 401	3 412	4.1
Home nursing care	2 239	3 109	869	3.3
Physiotherapy	1 335	2 093	758	4.6
Hospitalisations – daily rate	8 629	10 686	2 057	2.2
Medical centres	389	886	498	8.6
Maximum billing	351	391	40	1.1
Low-variability care	463	546	83	1.7
Other	4 019	4 696	677	2.3
Total*	37 666	48 599	10 933	2.6

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3.1 Normberekening 2027 aan de hand van juni/juni index

Strikte normberekening / Calcul strict de la norme	**2027** 000 EUR
Globale begrotingsdoelstelling 2025 Objectif budgétaire global 2025	44.203.203
Compensatie volledige ontvangsten art. 111/81 + korting geneesmiddelen - 2026 Montant compensation recettes totales art. 111/81 - 2026	-2.000.208
Strikte norm / Norme stricte	***42.202.995***
Reële groeinorm 2 % Norme de croissance réelle 2 %	844.060
Sub-totaal / Sous-total	***43.047.055***
Gezondheidindex (2,80%) Indice santé (2,80%)	671.142
Spilindexmassa 2026 (meerkost in 2027 t.o.v. doelstelling 2026) Masse indice pivot 2026 (surcoût en 2027 par rapport objectif 2026)	199.337
Spilindexmassa 2027 Masse indice pivot 2027	267.684
Sub-totaal / Sous-total	**44.185.218**
Compensatie volledige ontvangsten art. 111/81 + korting geneesmiddelen - 2027 Montant compensation recettes totales art. 111/81 - 2027	2.083.754
Voorstel Begrotingsdoelstelling 2027 **Proposition Objectif budgétaire 2027**	**46.268.972**

	OMSCHRIJVING -LIBELLE	2022 in p 2022 geboekte uitgaven dépenses comptables 000 EUR	2023 in p 2023 geboekte uitgaven dépenses comptables 000 EUR	2024 in p 2024 geboekte uitgaven dépenses comptables 000 EUR	2025 in p 2025 geboekte uitgaven dépenses comptables 000 EUR	2026 in p 2026 Technische raming Sept 2026 Calculs techniques Sept 2026 000 EUR	2027 in p 2026 Technische raming Sept 2026 Calculs techniques Sept 2026 000 EUR	2027 in p 2027 Technische raming Sept 2026 Calculs techniques Sept 2026 000 EUR
3.	- Farmaceutische verstrekkingen Fournitures pharmaceutiques							
	a) Farm. specialiteiten - Spécialités pharm.	5.158.534	5.661.917	6.110.008	6.588.064	6.763.181	7.100.811	7.122.475
	a.1 Economische marge - Marge économique (**)					*163.840*	*173.683*	*178.546*
	a.2 Basishonorarium - Honoraires de base (*)					*591.168*	*560.704*	*576.526*
	a.3 Honorarium per behandeling - Honoraires par traitement (*)					*10.015*	*34.691*	*35.670*

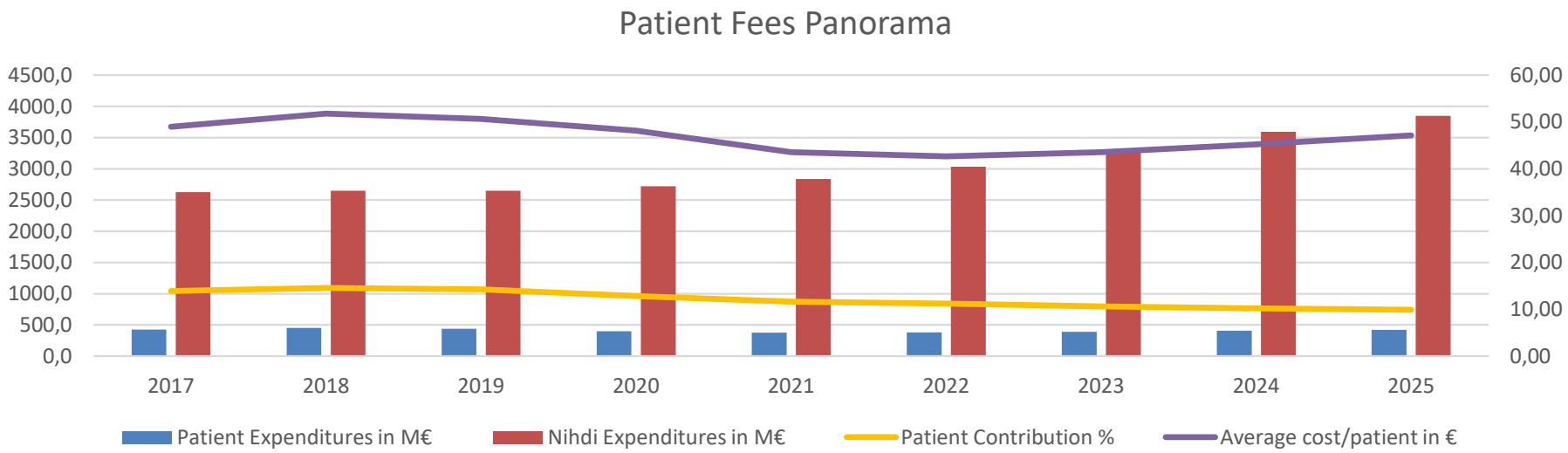
4.2.2 Bijkomende inspanning farmaceutische specialiteiten 2027

In 000 EUR	**TR sept**
Norm	46.268.972
Ontvangsten artikel 81/111	-2.003.391
Korting geneesmiddelen	-80.363
Niet te besteden bedrag	-252.333
S/totaal	**43.932.885**
Correctie wet ziekenhuizen	-3.004.417
S/totaal	**40.928.468**
17,30%	**7.080.625**
Farmaceutische specialiteiten - Netto	7.122.475
Bijkomende inspanning	**-41.850**

Om het vast aandeel van 17,3% van de geautoriseerde uitgaven te respecteren, dient er binnen de sector farmaceutische specialiteiten een bijkomende inspanning van 41.850 duizend euro gerealiseerd te worden.

Patient Contribution

Year	2017	2018	2019	2020	2021	2022	2023	2024	2025
Patient Expenditures in millions	443,3	470,3	457,7	413	388,9	398,4	411,7	427,6	440,8
MAF	-18,99	-18,96	-17,37	-12,154	-13,984	-15,537	-19,905	-19,021	-18,862
Effective Patient Expenditures	424,31	451,34	440,33	400,846	374,916	382,863	391,795	408,579	421,938
Nihdi Pharmacies Expenditures	2626,2	2647,4	2649,6	2719	2839	3032,8	3293,8	3592,7	3849,3
Patient Share	16,15%	17,04%	16,61%	14,74%	13,21%	12,62%	11,89%	11,37%	10,96%
# Unique Patient	8,66	8,71	8,69	8,32	8,60	8,98	8,99	9,03	8,95
Cost per patient	48,96 €	51,78 €	50,66 €	48,15 €	43,57 €	42,62 €	43,54 €	45,21 €	47,11 €



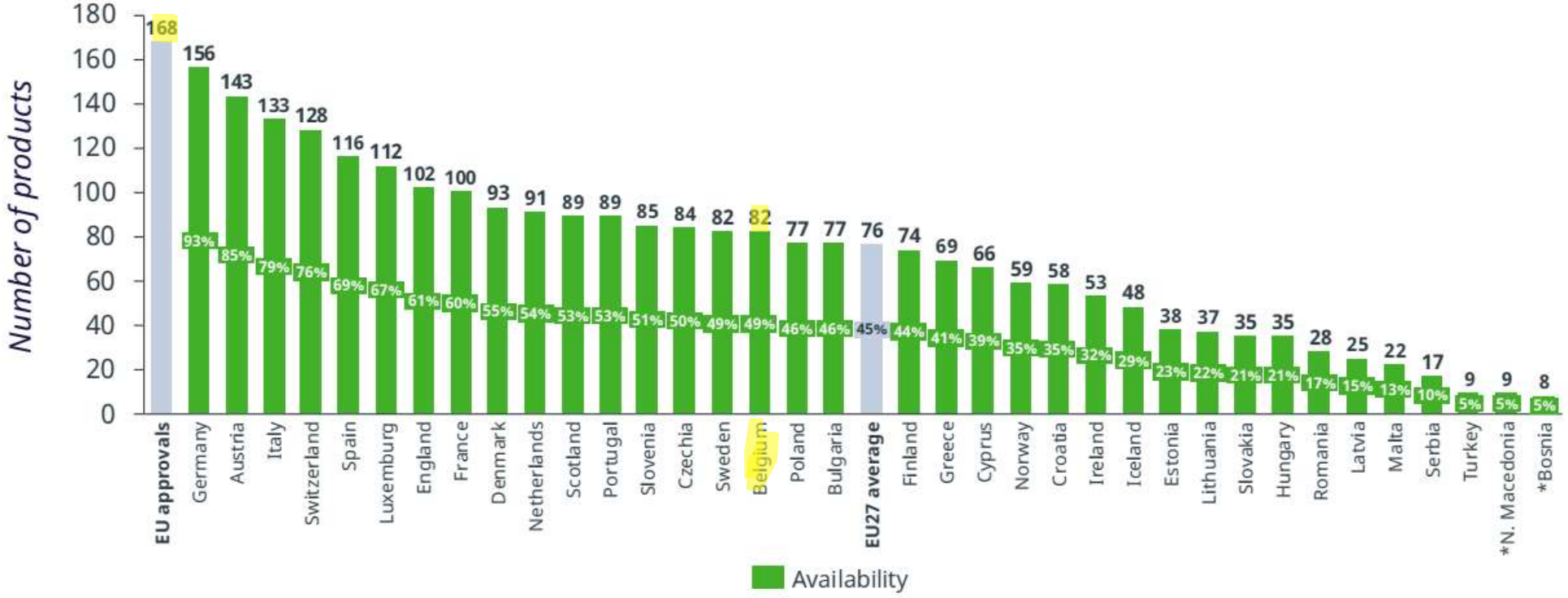
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II. What's the state of access to innovation ?

WAIT-indicator on access to medicines. WAIT or WANT? Doomed or keep calm and carry on?

Rate of availability (2021-2024)

The **rate of availability**, measured by the number of medicines available to patients in European countries as of 5th January 2026. For most countries this is the point at which the product gains access to the reimbursement list†, including products with limited availability.

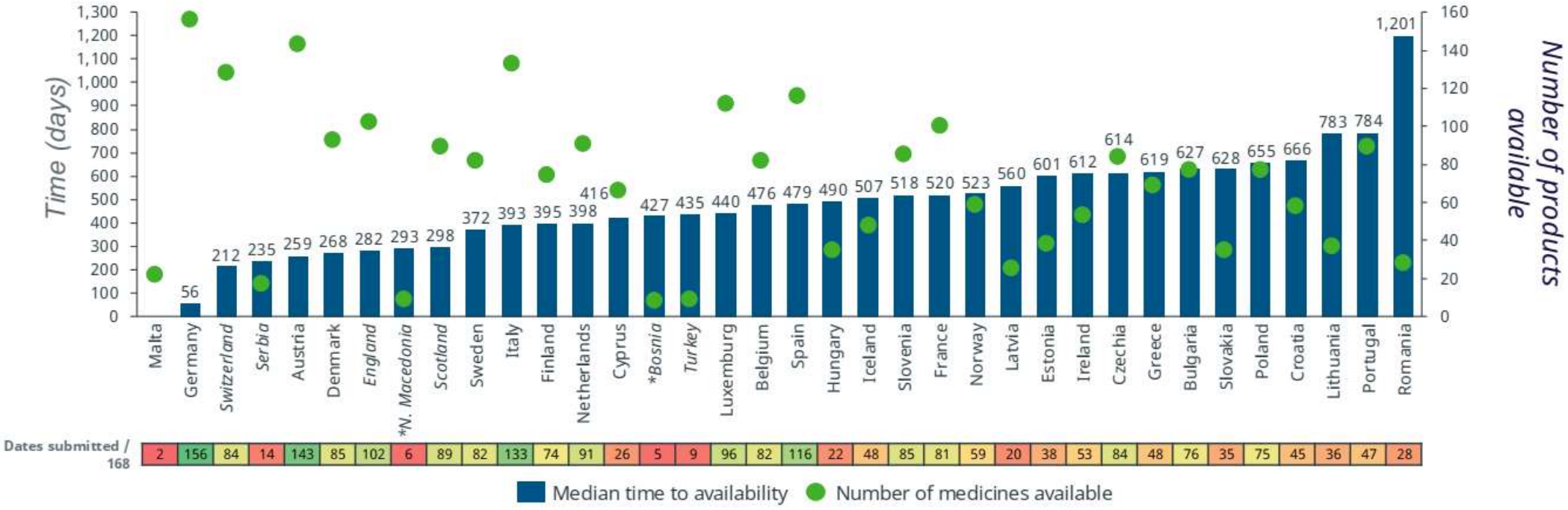


European Union average: 76 products available (45%) †Country specific definitions are listed in the appendix. Details surrounding early access schemes are provided in slide 72. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative.

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Median time to availability (2021-2024)

The **median time to availability** is the days between marketing authorisation and the date of availability to patients in European countries (for most this is the point at which products gain access to the reimbursement list†). The marketing authorisation date is the date of central EU authorisation in most countries, except for countries shown in italics where local authorisation dates have been used. Data is correct to 5th January 2026.



European Union average: 532 days (median) †Country specific definitions are listed in the appendix. Details surrounding early access schemes are provided in slide 72. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. Note: Countries with fewer than three submitted dates were excluded to avoid unreliable estimates.

IQVIA

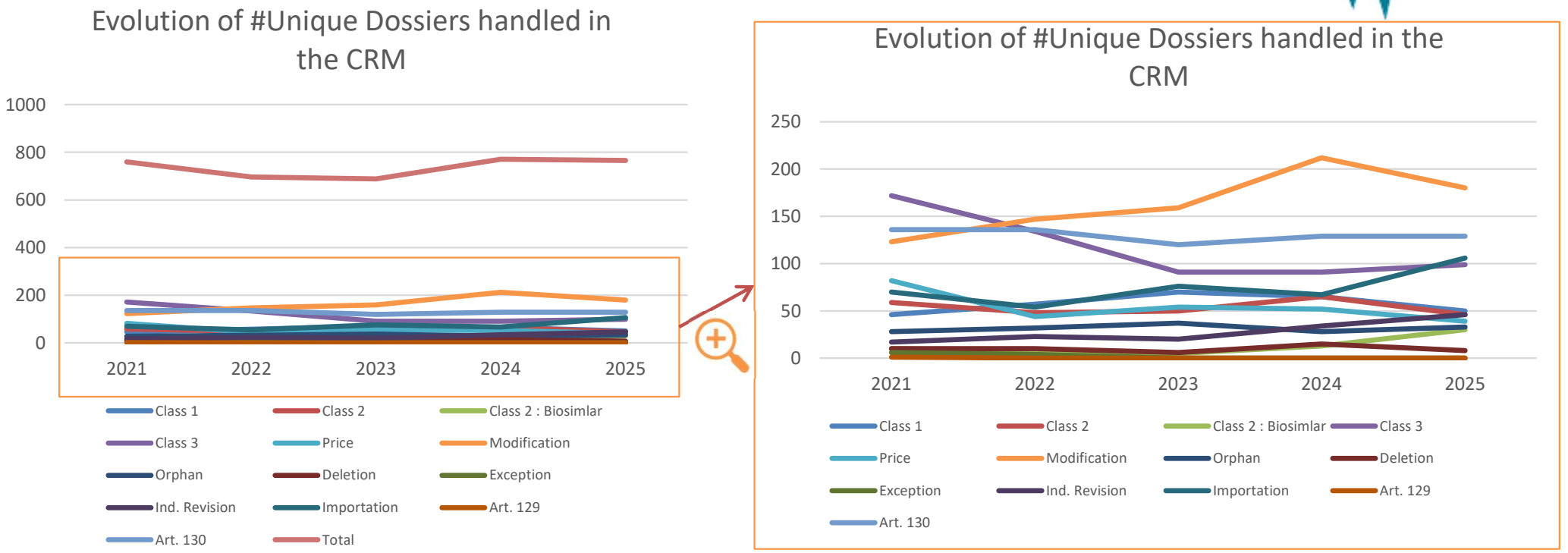
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Some reflections, based on RIZIV-INAMI analysis

- 21% of the medicines available not filed for reimbursement
- For those filed:

  Of the 132 medicines for which a claim was submitted:
  - 87 medicines (66%) are already reimbursed
  - 15 dossiers (11%) are still ongoing,
  - 17 dossiers (13%) were closed and have (not yet) been resubmitted:
    1 dossier (1%) due to non-submission or lack of response following suspension
    16 dossiers (12%) due to voluntary withdrawal by the company,
  - 13 dossiers (10%) received a negative decision
- Of those not filed: 33% no reimbursed alternative (50% for subcategory orphan drugs), which indicates unmet medical need (oncology, metabolic disorders, immunology, neurology)
- Timeline: on average 196 days before reimbursement claim, and on average 145 days of suspensions. More than 50% out of control of RIZIV-INAMI.

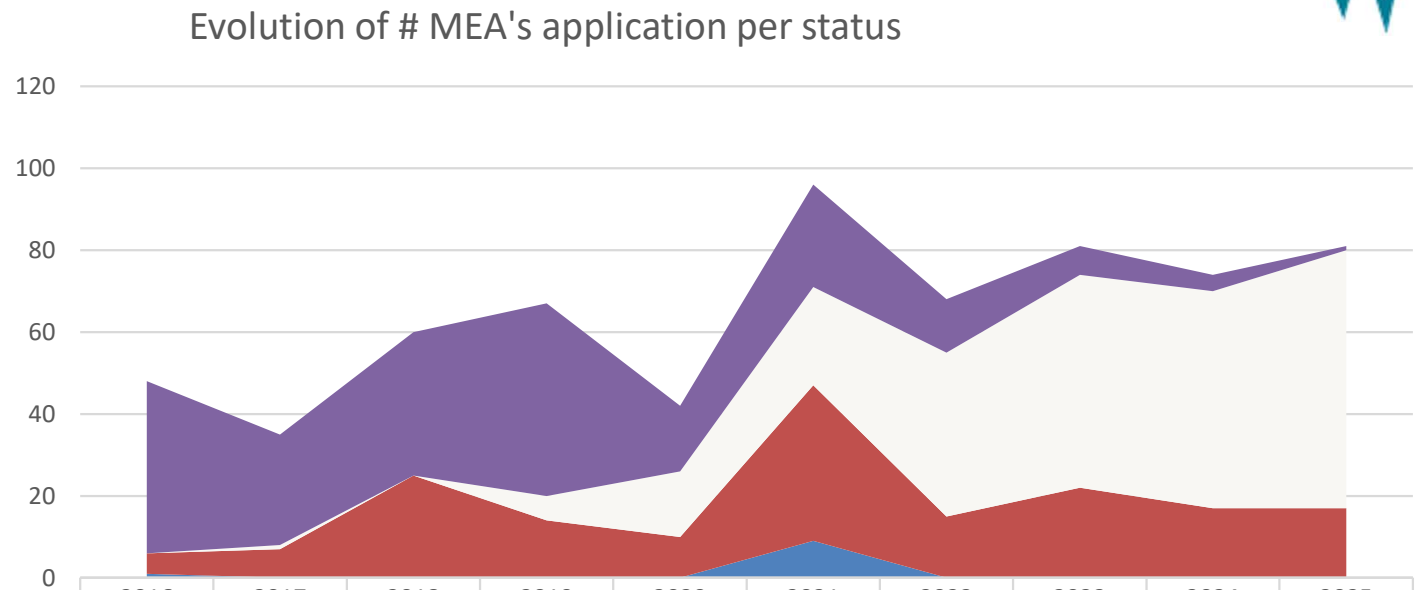
CRM: continuous flow of reimbursement decisions



Given 2021 was an exceptional year due to the heavy workload and delays caused by the Covid crisis : there is a clear trend of increasing incoming unique dossiers by the CRM.

Rising dossiers types concern Biosimilars, Parallel Importations, Individual Revisions.

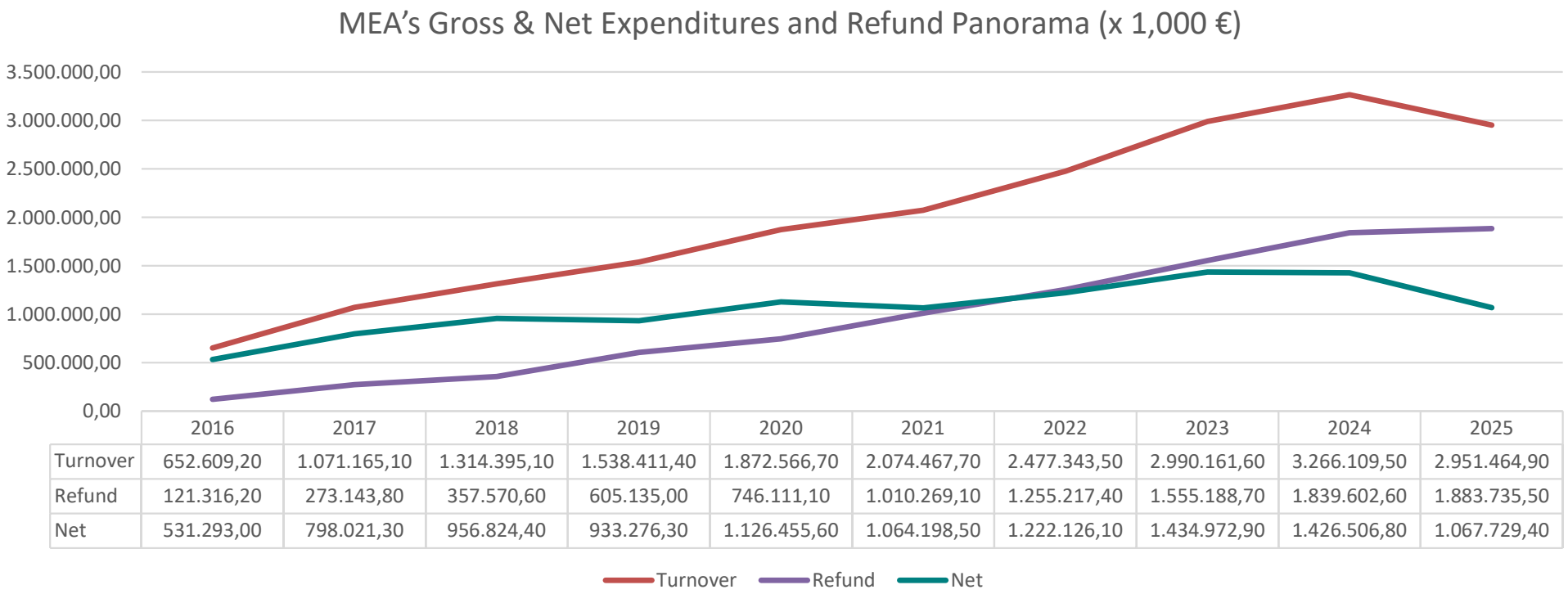
Managed Entry Agreements



	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025
Expired Convention	42	27	35	47	16	25	13	7	4	1
Ongoing Convention	0	1	0	6	16	24	40	52	53	63
No Convention (negotiation failed)	5	7	25	14	10	38	15	22	17	17
No Convention (not negotiated)	1	0	0	0	0	9	0	0	0	0

Given 2021 was an exceptional year due to the heavy workload and delays caused by the Covid crisis: there is a clear trend of increasing MEA's applications

Managed Entry Agreements



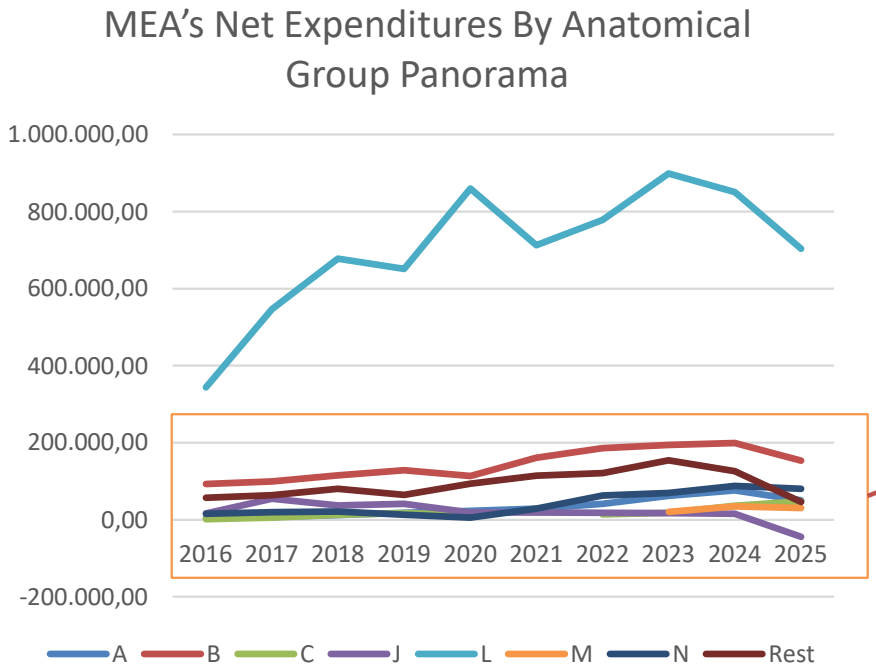
	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025
Turnover	652.609,20	1.071.165,10	1.314.395,10	1.538.411,40	1.872.566,70	2.074.467,70	2.477.343,50	2.990.161,60	3.266.109,50	2.951.464,90
Refund	121.316,20	273.143,80	357.570,60	605.135,00	746.111,10	1.010.269,10	1.255.217,40	1.555.188,70	1.839.602,60	1.883.735,50
Net	531.293,00	798.021,30	956.824,40	933.276,30	1.126.455,60	1.064.198,50	1.222.126,10	1.434.972,90	1.426.506,80	1.067.729,40

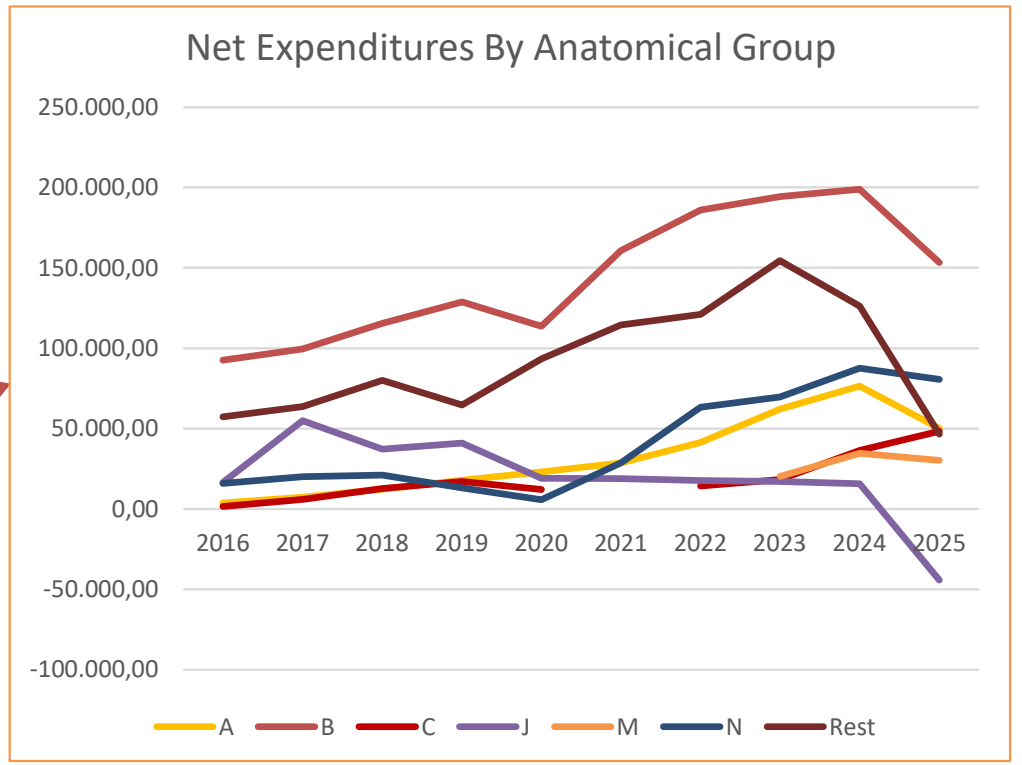
Trends in expenditure related to MEAs:

- Turnover increased by 1B since 2021; rebates by 800M.
- Comparison 2024-2025: pace of growth has slowed.
- Overall, increasing share of rebates.

Caveat: At present, 98% of expected turnover for 2025 MEA's has been reported. As a result, the share of rebates (SoR) is overestimated and Net expenditures are underestimated for that year. A similar pattern was observed in the previous MORSE report: SoR for 2024 stood at 64% and stand now at 56%.

Managed Entry Agreements





Trends :

- Clear Domination of antineoplastic and immunomodulating agents
- However these expenditures are proportionnaly decreasing
- Proportional Substantial Increases in Alimentary & Metabolism, Cardiavoscular

Caveat: At present, 98% of expected turnover for 2025 MEA's has been reported. As a result, the share of rebates (SoR) is overestimated and Net expenditures are underestimated for that year. A similar pattern was observed in the previous MORSE report: SoR for 2024 stood at 64% and stand now at 56%.

Rank	ATC4	Type of medicine	Total_Exp	Hospital Exp.	Pharmacies Exp.	Rank Hosp.	Rank Pharm.	% Total	Cumul
1	**L01F**	**Antibody-based cancer treatment** – immunotherapy and antibodies that target cancer cells	1381,1	1381,1	0,0	1	134	16,3%	16,3%
2	**L04A**	**Immunosuppressants** – for autoimmune diseases (arthritis, Crohn's, psoriasis, MS) and transplants	1024,5	351,3	673,2	4	1	12,1%	28,4%
3	**L01E**	**Targeted cancer pills** – block proteins that drive cancer cell growth	536,5	529,2	7,3	2	52	6,3%	34,7%
4	**N07X**	**Other nervous system drugs** – e.g. for rare diseases (hereditary amyloidosis) and MS	389,1	386,4	2,7	3	77	4,6%	39,3%
5	**B01A**	**Blood thinners** – prevent blood clots, thrombosis and stroke	330,1	35,0	295,1	19	3	3,9%	43,2%
6	**A10B**	**Diabetes drugs (excl. insulin)** – lower blood sugar in type 2 diabetes, e.g. GLP-1 drugs	319,1	2,6	316,5	56	2	3,8%	47,0%
7	**J06B**	**Antibodies from donor blood** – for immune deficiencies; also RSV protection in babies	239,9	225,2	14,7	5	39	2,8%	49,8%
8	**L02B**	**Hormone therapy for cancer** – blocks hormones that fuel breast or prostate cancer	224,9	202,1	22,8	7	31	2,7%	52,5%
9	**L01X**	**Other cancer drugs** – e.g. cell therapy (CAR-T) and PARP inhibitors	223,8	219,8	4,0	6	66	2,6%	55,1%
10	**B02B**	**Drugs against bleeding** – clotting factors and related drugs, mainly for haemophilia	222,7	101,8	120,9	10	7	2,6%	57,7%
11	**J05A**	**Antivirals** – treatment of e.g. HIV, hepatitis and influenza	218,1	50,5	167,6	16	6	2,6%	60,3%
12	**C10A**	**Cholesterol-lowering drugs** – e.g. statins, to prevent heart and vascular disease	203,2	1,5	201,7	65	4	2,4%	62,7%
13	**R07A**	**Other respiratory drugs** – mainly the new treatment for cystic fibrosis	183,7	183,7	0,0	8	134	2,2%	64,9%
14	**R03A**	**Inhalers** – open the airways in asthma and COPD	181,5	5,9	175,6	44	5	2,1%	67,0%
15	**R03D**	**Other asthma drugs** – e.g. biological injections for severe asthma, and montelukast	121,3	15,2	106,0	31	10	1,4%	68,5%
16	**N06A**	**Antidepressants** – for depression and anxiety disorders	120,2	21,9	98,3	23	11	1,4%	69,9%
17	**C10B**	**Cholesterol-lowering combinations** – two cholesterol-lowering drugs in one tablet	114,0	0,4	113,6	88	8	1,3%	71,2%
18	**A02B**	**Stomach acid reducers** – for heartburn, reflux and stomach ulcers	113,2	2,8	110,4	55	9	1,3%	72,6%
19	**S01L**	**Eye injections for macular degeneration** – against abnormal blood vessel growth in the retina	102,9	102,9	0,0	9	125	1,2%	73,8%
20	**A10A**	**Insulins** – for type 1 and advanced type 2 diabetes	94,9	2,4	92,5	58	12	1,1%	74,9%
21	**N05A**	**Antipsychotics** – for e.g. schizophrenia and bipolar disorder	91,8	13,0	78,9	33	13	1,1%	76,0%
22	**A16A**	**Drugs for rare metabolic diseases** – e.g. enzyme replacement therapy (Fabry, Gaucher, Pompe)	81,1	78,8	2,2	11	86	1,0%	76,9%
23	**J07B**	**Viral vaccines** – e.g. influenza, shingles, HPV and COVID-19	79,7	3,0	76,8	54	14	0,9%	77,9%
24	**M09A**	**Drugs for rare muscle diseases** – mainly gene and RNA therapy for spinal muscular atrophy (SMA)	78,3	78,3	0,0	12	134	0,9%	78,8%
25	**N02C**	**Migraine drugs** – to stop attacks (triptans) or prevent them (e.g. CGRP antibodies)	78,1	1,8	76,3	62	15	0,9%	79,7%

III. Challenges

Point n'est besoin d'espérer pour entreprendre, ni de réussir pour persévérer: a few personal reflections

- MFN and its impact on filing, price targets and transparency
- "Grow the cake": fix the budget and financing mechanism, keep on investing while at the same time challenging the existing package in terms of value and courage to de-reimburse to liberate resources
- Break the budgetary silo's: both from temporal perspective (pluriannual framework) and sectoral perspective (transversality and health(care) objectives, unmet needs)
- Strengthen the HTA within and outside the pharmaceutical budget, with a broadened view on returns for society.
- Accelerate access, but through implementable and effective risk-sharing and outcome-based financing mechanisms and hard stops when value is below expectations. Promising: early and fast access medicines.
- Fundamental: solve the health data issues and FAIR data challenges
- No sustainable access without a right ecosystem and whole-of-government big deal with industry, both at national and EU level: reward R&D, clinical studies and production; work toward strategic interdependence; use force of scale of a market of 450 mio publicly insured EU patients.

60 jaar RIZIV, Onze bakens voor de toekomst

Mei 2024



https://www.riziv.fgov.be/nl/riziv/60-jaar-riziv-onze-bakens-voor-de-toekomst