WAIT INDICATOR 2026

Summary Analysis – Directorate Pharmaceutical Policy NIHDI

(Analysis conducted on 01 June 2026)

NIHDI
National Institute
for Health and Disability Insurance

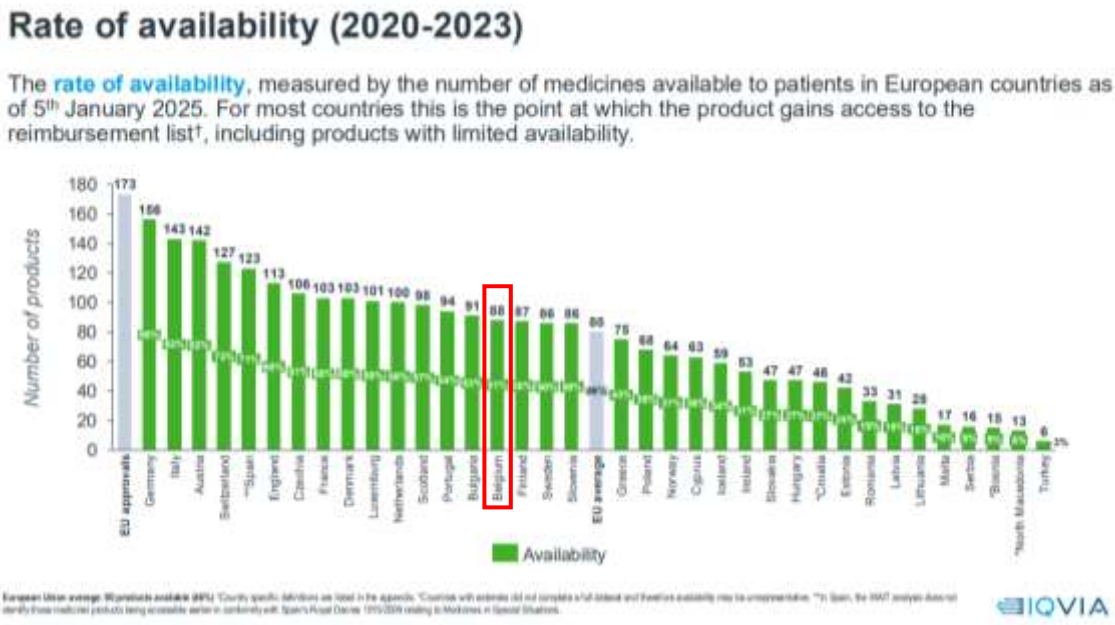
Table of contents

WAIT INDICATOR DATA 2024 – EFPIA/IQVIA

Key IQVIA EFPIA WAIT indicator data for Belgium 2024 (analysis conducted on 5 January 2025 and published in May 2025).

A total of **173** medicines were taken into account.
Of these, **88** are considered 'available' in Belgium (i.e. reimbursed and accessible to patients). The average 'delay' between marketing authorisation (MA) and reimbursement amounts to **549** days in Belgium.

At EU level the average number of available medicines is **80**.
The average 'delay' between MA and reimbursement amounts to **578** days.

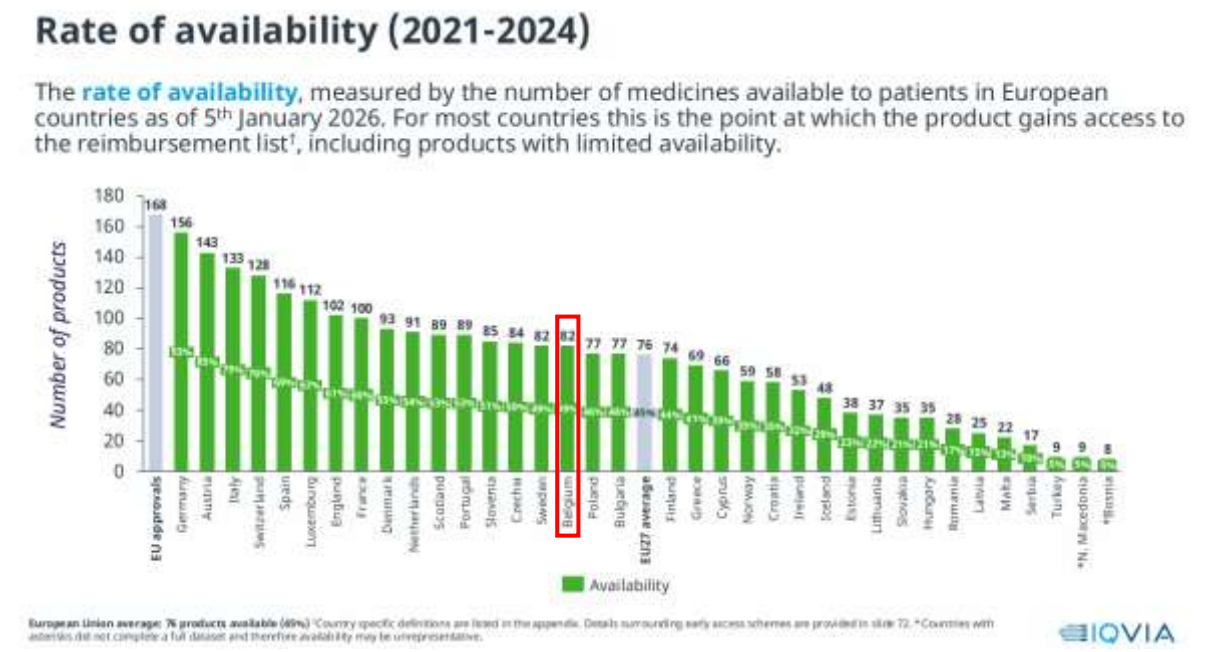


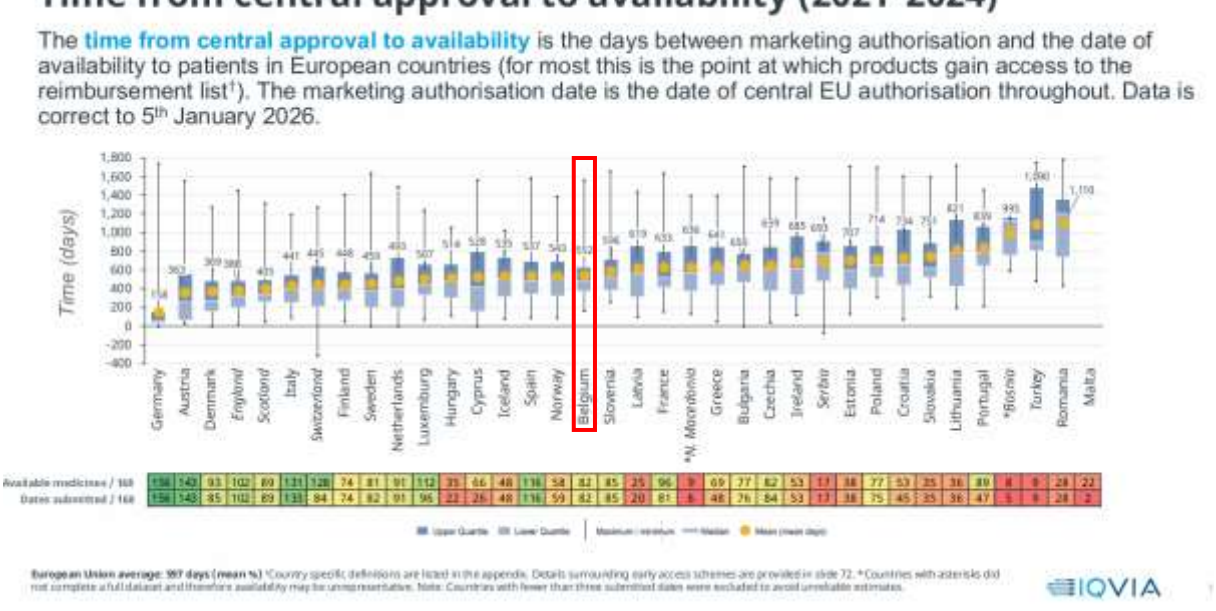
WAIT INDICATOR DATA 2025 – EFPIA/IQVIA

Key IQVIA EFPIA WAIT indicator data for Belgium 2025 (analysis conducted on 5 January 2026 and published in May 2026).

A total of **168** medicines were taken into account.
Of these, **82 (49%)** are considered 'available' in Belgium (i.e. reimbursed and accessible to patients).
The average 'delay' between marketing authorisation (MA) and reimbursement amounts to **552** days in Belgium.

At EU level, the average number of available medicines is **76**.
The average 'delay' between MA and reimbursement amounts to **597** days.





ACCESSIBILITY ANALYSIS

Of the 168 medicines included in the 2025 WAIT indicator a reimbursement claim was submitted in Belgium for 132 medicines (79%), while for 36 medicines (21%) no claim has (yet) been submitted.

Of the 132 medicines for which a claim was submitted:

- 54 (41%) are orphan medicines
- 49 (37%) belong to Class 1 (with a claim for therapeutic added value)
- 28 (21%) belong to Class 2 (no added value – claim submitted by the company)
- 1 (1%) belongs to the radiopharmaceutical class

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

Request Type	**Reimbursed**	**Not Reimbursed**	**Ongoing**	**Withdrawn**	**Closed**	**Total**
Orphan	33	5	8	7	1	**54**
Class 1	28	8	6	7		**49**
Class 2	25		1	2		**28**
Radiopharma	1					**1**
Total	**87**	**13**	**15**	**16**	**1**	**132**

Of the 87 reimbursed medicines, 51 are temporarily reimbursed through a contract (due to scientific and financial uncertainties) representing 59%. These are presented below by class.

17 in Class 1 (therapeutic added value):

Akeega	Camzyos	Elrexfio	Enhertu	Fruzaqla
Jaypirca	Jemperli	Kerendia	Mounjaro	Opdualag
Padcev	Retsevmo	Rybrevant	Tecvayli	Trodelvy
Tukysa	Vyepti			

9 in Class 2:

Adtralza	Aquipta	Balversa	Brukinsa	Cibinqo
Ebglyss	Imjudo	Tevimbra	Zilbrysq	

25 in the Orphan class:

Adzynma	Amvuttra	Aspaveli	Bylvay	Carvykti
Columvi	Ebvallo	Evrysdi	Finlee	Imcivree
Kinpeygo	Kimmtrak	Livmarli	Livtencity	Minjuvi
Pemazyre	Qalsody	Qinlock	Rystiggo	Spexotras
Talvey	Tepkinly	Tibsovo	Upstaza	Vyvgart

NEW MEDICINES COMPARED TO THE PREVIOUS YEAR

Each year a number of medicines considered innovative are analysed by EFPIA; this year this amounted to 168. Compared to the previous year some medicines are no longer included and new medicines have been added.

In the current WAIT indicator 30 new medicines are included compared to the previous analysis (see below).

Adzynma	Agamree	Akantior	Altuvoct	Artesunate amivas
Balversa	Casgevy	Elahere	Eladynos	Fabhalta
Filspari	Fruzaqla	Hympavzi	Iqirvo	Litfulo
Loqtorzi	Omjjara	Piasky	Pluvicto	Qalsody
Rystiggo	Skyclarys	Spexotras	Truqap	Velsipity
Vyloy	Winrevair	Yuvanci	Zilbrysq	Zokinvy

Of these, 15 are already reimbursed, 9 medicines are still ongoing, 3 medicines were not reimbursed and 3 medicines were withdrawn by the company.

Request Type	**Reimbursed**	**Not Reimbursed**	**Ongoing**	**Withdrawn**	**Total**
Class 1	1	1	2		**4**
Class 2	6		1		**7**
Orphan	7	2	6	3	**18**
Radiopharma	1				**1**
Total	**15**	**3**	**9**	**3**	**30**

MEDICINES WITHOUT A REIMBURSEMENT CLAIM

Below, 36 of the 168 medicines for which no reimbursement claim has been submitted are presented. These products are nevertheless included in the 2025 WAIT indicator report of EFPIA.

Alhemo	Anzupgo	Awiqli	Cejemly	Copiktra	Elzonris
Emblaveo	Enjaymo	Enspryng	Exblifep	Hyftor	Inaqovi
Jeraygo	Krazati	Loargys	Lyfnua	Lytenava	Lytgobi
Nulibry	Obgemsa	Ordspono	Pyrukynd	Quviviq	Rayvow
Rezzayo	Ryzneuta	Skytrofa	Tabrecta	Tecovirimat SIGA	Vafseo
Voydeya	Vumerity	Xofluza	Zegalogue	Ztalmy	Zynyz

These products were further analysed and are presented in the table below.
For the column 'Alternatives BE' the analysis was strictly limited to at least one therapeutically relevant alternative that is effectively reimbursed by the NIHDI; if no such alternative exists, this is explicitly indicated.

Product	**Indication**	**Domain**	**ATC**	**Orphan**	**Alternatives BE**	**MA year**
Alhemo	Haemophilia A/B (prevention of bleeding)	Haematology	B02	No	Hemlimbra	2024
Anzupgo	Chronic hand eczema	Dermatology	D11	No	Alitretinoin	2024
Awiqli	Diabetes (insulin)	Metabolic	A10	No	Levemir, Xultophy	2024
Cejemly	Non-small cell lung cancer (NSCLC)	Oncology	L01	No	Tecentriq	2024
Copiktra	Chronic lymphocytic leukaemia (CLL) / Small lymphocytic lymphoma (SLL) and follicular lymphoma (FL)	Oncology	L01	No	Zydelig	2021 withdrawn in 2026
Elzonris	Blastic plasmacytoid dendritic cell neoplasm (BPDCN)	Oncology	L01	Yes	**No**	2021
Emblaveo	Bacterial infections	Infectious diseases	J01	No	Azactam	2024
Enjaymo	Cold agglutinin disease	Immunology	L04	Yes	**No**	2022
Enspryng	Neuromyelitis optica	Immunology	L04	Yes	Ultomiris	2021
Exblifep	Bacterial infections	Infectious diseases	J01	No	Cefepime	2024

Hyftor	Facial angiofibroma (TSC)	Immunology	L04	Yes	Rapamune	2023
Inaqovi	Acute myeloid leukaemia (AML)	Oncology	L01	No	Venclyxto	2023
Jeraygo	Resistant hypertension	Cardiovascular	C02	No	Spironolacton	2024
Krazati	NSCLC KRAS mutation	Oncology	L01	No	**No**	2024
Loargys	Arginase-1 deficiency	Metabolic	A16	Yes	**No**	2023
Lyfnua	Chronic cough	Respiratory	R05	No	**No**	2023
Lytenava	Neovascular macular degeneration (AMD)	Ophthalmology	S01	No	Beovu	2024
Lytgobi	Cholangiocarcinoma	Oncology	L01	No	Pemazyre	2023
Nulibry	Molybdenum cofactor deficiency	Metabolic	A16	Yes	**No**	2022
Obgemsa	Overactive bladder	Urology	G04	No	Toviaz	2024
Ordspono	Follicular lymphoma and diffuse large B-cell lymphoma (DLBCL)	Immunology	L04	No	Columvi	2024
Pyrukynd	Pyruvate kinase (PK) deficiency	Metabolic	A16	Yes	**No**	2022
Quviviq	Sleep disorders / insomnia	Neurology	N05	No	**No**	2022
Rayvow	Migraine	Neurology	N02	No	Naratriptan	2022
Rezzayo	Fungal infections	Infectious diseases	J02	Yes	Anidulafungine	2023
Ryzneuta	Neutropenia	Haematology	L03	No	Accofil	2024
Skytrofa	Growth hormone deficiency	Endocrinology	H01	Yes	Ngenla	2022
Tabrecta	NSCLC MET mutation	Oncology	L01	No	**No**	2022
Tecovirimat SIGA	Orthopoxvirus infections	Infectious diseases	J05	No	**No**	2022
Vafseo	Anaemia in chronic kidney disease (CKD)	Haematology	B03	No	Aranesp	2023
Voydeya	Paroxysmal nocturnal haemoglobinuria (PNH) with anaemia	Immunology	L04	Yes	Ultomiris	2024
Vumerity	Multiple sclerosis	Immunology	L04	No	Tecfidera	2021
Xofluza	Influenza	Infectious diseases	J05	No	**No**	2021

Zegalogue	Hypoglycaemia	Endocrinology	H04	No	Baqsimi	2024 withdrawn in 2026
Ztalmy	CDKL5 deficiency epilepsy	Neurology	N03	Yes	**No**	2023
Zynyz	Anal cancer / Merkel cell carcinoma	Oncology	L01	No	Bavencio	2024

Of these products, 15 obtained a marketing authorisation (MA) in 2024, 8 in 2023, 8 in 2022 and 5 in 2021. The relatively high number of recent MAs (2023–2024; 23 out of 36, or 64%) suggests that a proportion of these products may still be in an early stage of market access. Taking into account the observed average time between obtaining an MA and the submission of a reimbursement claim (approximately 190 days, as further calculated below), it can be expected that a number of these products may still be subject to a reimbursement claim in the coming year.

Conversely there are also 'older' products (2021–2022; 13 out of 36 or 36%), which suggests that for a proportion of the medicines no reimbursement claim is structurally submitted.
For some of these medicines, therapeutic alternatives are already available on the Belgian market which may provide a possible explanation for the absence of a reimbursement claim. For other products, mainly orphan medicines, the issue may be related to very small patient populations.

The analysed products are heterogeneously distributed across different therapeutic domains with a clear dominance of oncology (22.2%). Infectious diseases and neurology each follow with 13.9% while haematology accounts for 11.1% of the products. The remaining domains are less represented and generally include only one or a few products.

Approximately one third of the products (33.3%) have no reimbursed alternative in Belgium mainly within oncology, metabolic disorders, immunology and neurology. This indicates a significant presence of unmet medical need.

In addition, 11 of the 36 products (approximately 30.6%) have an orphan designation according to the European register. Among these orphan medicines approximately half (6/11) do not have a reimbursed alternative in Belgium which further highlights the importance of treatments for rare diseases.

In conclusion for both orphan and non-orphan medicines additional factors are likely to play a role such as therapeutic positioning, availability of alternatives and market size.

Most Favoured Nation (MFN)

It should also be noted that recent international pricing developments such as the 'most favoured nation' (MFN) principle may have a potential impact on the accessibility of medicines in Europe.

The MFN principle which has been recently introduced and is still under development implies that medicine prices in certain countries are aligned with the lowest price applied in comparable countries. As a result, European prices are increasingly used as a reference at a global level.

Although the concrete impact on accessibility remains uncertain at present, the literature indicates that such pricing mechanisms may influence the launch behaviour of pharmaceutical companies for example through delays or selective introduction of medicines in certain countries.

The current results of the WAIT indicator cannot however be directly attributed to this development, but it represents a potential factor that may play a role in the future in access to innovative medicines.

TIMELINE ANALYSIS

Request Type	Average time to first claim	Average time of procedure	Suspensions	Receivability	Average time to first reimbursement
Class 1	196	307	139	9	575
Class 2	201	271	121	6	531
Orphan	189	315	163	8	604
Radio	273	206			479
Total	**196**	**299**	**145**	**8**	**573**

The table above provides for the medicines included in the 2025 WAIT indicator a detailed overview of the different time intervals in the pathway towards reimbursement.

Firstly, the time between the initial marketing authorisation (MA) of the medicines and the first reimbursement claim (for medicines that are now reimbursed) is presented. This amounts to an average of **196 days**.

Secondly, the time between the reimbursement claim that resulted in a positive decision and the first effective reimbursement is presented, irrespective of the number of reimbursement submissions (including resubmissions). This corresponds to the duration of the reimbursement process including suspensions and amounts to an average of **299 days**.

Finally, the total time between the initial marketing authorisation (MA) and the first reimbursement is presented, covering the entire pathway including any consecutive reimbursement submissions (such as resubmissions). This total timeline amounts to an average of **573 days**.

The total timeline consists of three components: the period prior to submission, the duration of the reimbursement process and the period between the decision and its effective implementation. These components are further explained below.
Overall, more than 50% of this timeline falls outside the control of national authorities.

On the one hand, this includes the period up to the submission of the reimbursement claim by the company (time to first claim). This shows that a significant part of the total timeline (on average approximately 196 days) can be attributed to the period prior to submission.

On the other hand, this period also includes suspensions due to inadmissibility **(on average 8 days)** as well as suspensions of the dossier during the reimbursement process: in the context of responses to assessment reports, the absence of a price at the Federal Public Service Economy, reactions to a draft proposal or contract negotiations **(on average 145 days).**

Furthermore, it includes the effective duration of the reimbursement process itself (a maximum of 180 calendar days excluding suspensions), as well as the time between consecutive submissions such as resubmissions, which may prolong the total time between MA and reimbursement.

Finally, the time between the notification of the decision and its entry into force following publication is also taken into account which may still amount to an average of 2 to 3 months.

RESPONSE TO THE WAIT INDICATOR 2025 – EFPIA/IQVIA

Finally, a comparison can be made between the data based on the national NIHDI analysis and the data published by EFPIA.

According to the IQVIA EFPIA WAIT indicator 2025 for Belgium (analysis conducted on 5 January 2026 and published in May 2026) 168 medicines were taken into account. Of these, 82 medicines are considered 'available' (i.e. reimbursed and accessible to patients). The average 'delay' between marketing authorisation (MA) and reimbursement amounts to 552 days according to EFPIA.

At EU level, the average number of available medicines is 76 and the average "delay" between MA and reimbursement amounts to 597 days.

Based on the national analysis, of the 168 medicines taken into account, a reimbursement claim was submitted for 132 medicines. Of these, 87 medicines (66%) are already reimbursed. The average 'delay' between marketing authorisation (MA) and reimbursement amounts to 573 days including suspensions.

	NIHDI	**EFPIA/IQVIA (Belgium)**
Number of medicines (in scope)	168	168
Number with reimbursement claim	132	N/A
Number available/reimbursed	87 (66%)	82 (49%)
Average time MA → reimbursement	573 days (incl. suspensions)	552 days

This comparison suggests that the national analysis and the EFPIA data present a similar overall picture but that differences in methodology (such as the inclusion of suspensions, the time between the decision and the entry into force of reimbursement and the number of reimbursement claims submitted) may have an impact on the reported timelines and availability figures.

According to both NIHDI data and EFPIA data, the timelines and the number of available medicines in Belgium are in line with the EU average.