EFPIA Patients W.A.I.T. Indicator 2025 Survey

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Foreword

Indicators measure availability, restrictions to availability and time to availability

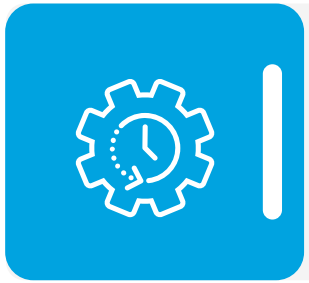
The Patients W.A.I.T. (**W**aiting to **A**ccess **I**nnovative **T**herapies) Indicator has been running in evolving formats since 2004 and has offered a comprehensive overview of public reimbursement across over 30 countries since 2018.

However, the relevance of whether an innovative molecule is included on public reimbursement lists has diminished over the years, with a rise in patient access through alternative channels and/or with restrictions.

This year's iteration of the report retains the core availability metrics, whilst adding additional context around the positioning of the report within the broader access landscape, and greater granularity on the level of restrictions to patient access (i.e. individual patient only). These updates aim to ensure the report remains relevant in new access landscape and support the accurate use of the W.A.I.T. report.

Information on the availability of 168 innovative medicines with central-marketing authorisation between 2021 and 2024 are included in the report. There is a one-year delay to permit countries to include these medicines on their public reimbursement list, meaning that the data on availability is accurate as of *January 5th 2026.*

Local pharmaceutical industry associations provide the information directly to IQVIA and EFPIA, and their definitions are included within the appendix to ensure full transparency.



Long-running

The Patients W.A.I.T. Indicator study has been running in evolving formats since 2004

Broad coverage

The Patients W.A.I.T. dataset covers 36 countries and 4 years of novel medicine approvals, with a historic dataset covering 11-years of data

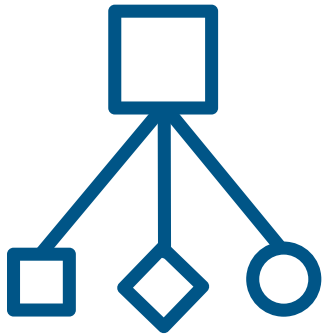
Widely referenced

The Patients W.A.I.T. report is used by all stakeholders to inform regional and national discussions on patient access

Contents

The study is based on the core concept of “availability”

Definition of availability



In this study the term ‘**availability**’ is used throughout to permit standardised measurement across 36 healthcare systems

“Inclusion of a centrally-approved medicine on the public reimbursement list in a country”

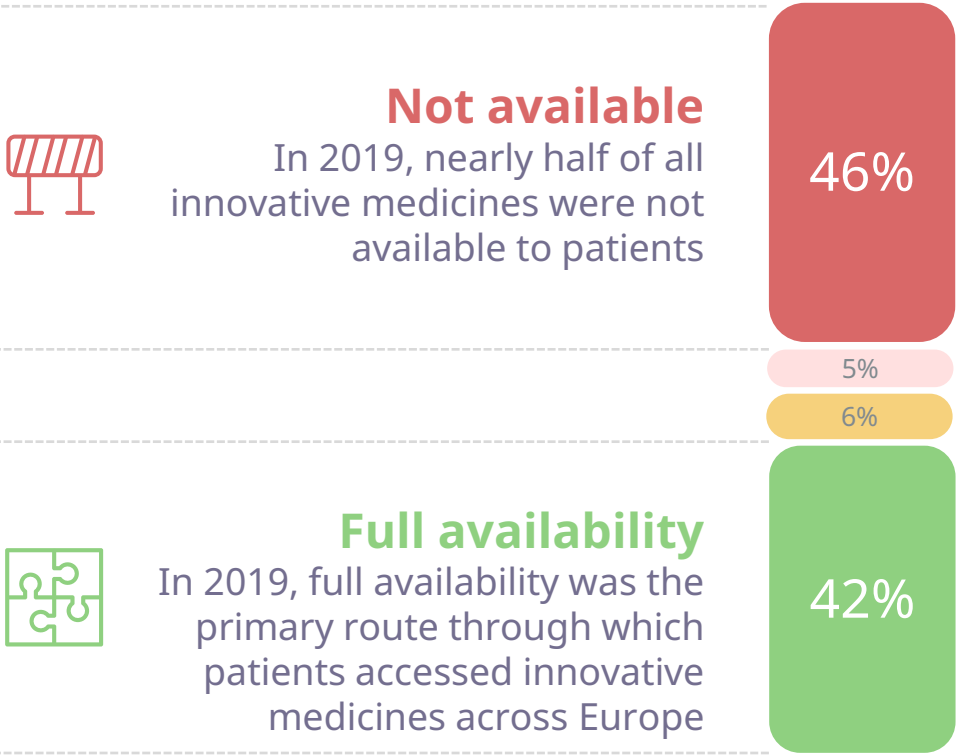
Where appropriate it takes into consideration things like managed entry agreements, line-of-therapy or formulary restrictions. However, it does not have a correlation to the use / uptake of the medicines.

Country-specific nuances should be discussed with the local associations or EFPIA directly to ensure correct interpretation of the data, please see the appendix for further details.

The access landscape in Europe has continued to evolve

Historically, full availability was the main access route; now, restrictions are commonplace

Historic landscape (2019)



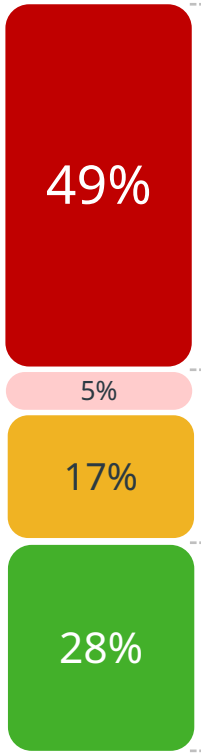
Not available

In 2019, nearly half of all innovative medicines were not available to patients

Full availability

In 2019, full availability was the primary route through which patients accessed innovative medicines across Europe

Current landscape (2025)



Not available

Unavailability has increased slightly since 2019, with close to half of innovative medicines still not available to patients.

Limited availability

In 2025, nearly a fifth of products are available under restricted conditions

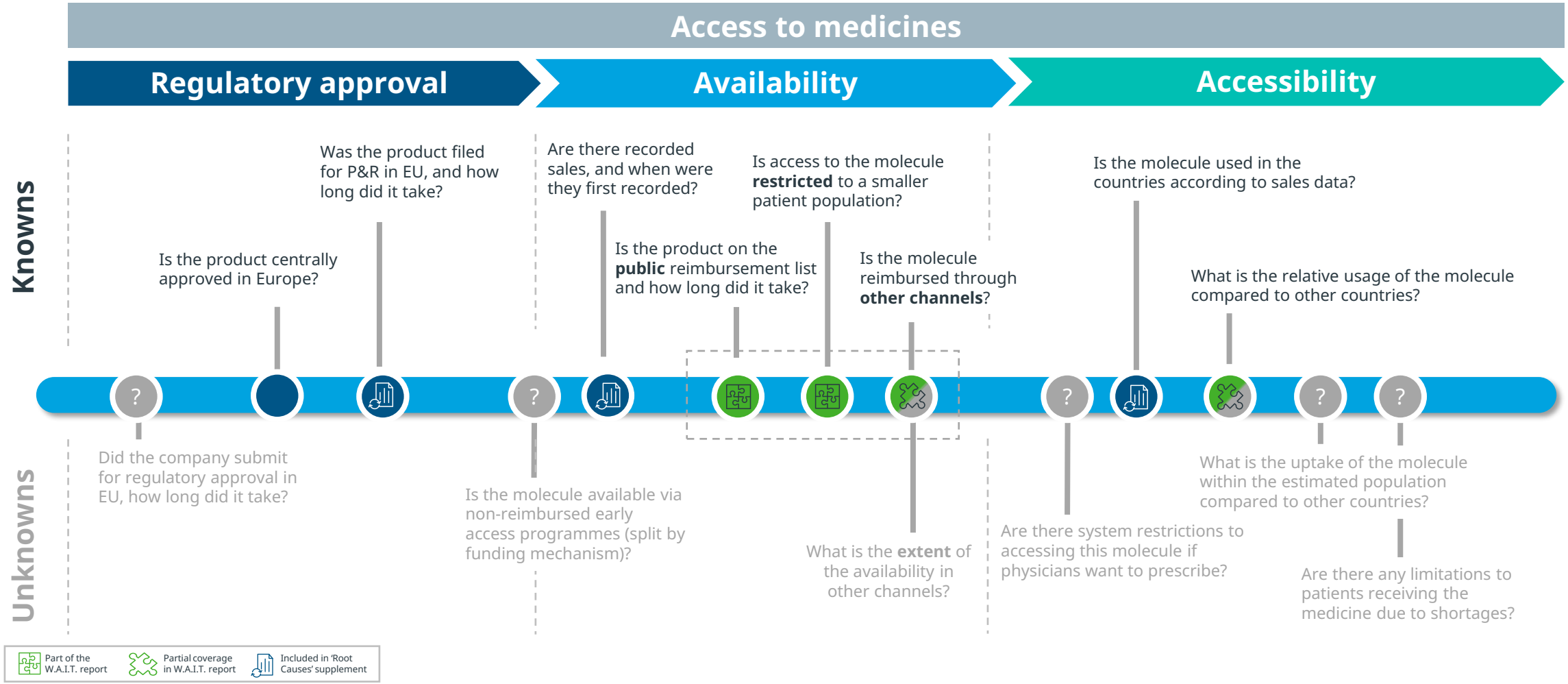
Full availability

By 2025, the share of medicines fully available on public reimbursement lists has declined substantially

Notes: EU averages of full / limited availability are calculated using absolute figures before determining the percentage. This approach ensures a more accurate representation by accounting for the varying number of available medicines in each EU country, thereby avoiding potential distortions that could arise from averaging individual country percentages. Segments total 99% due to rounding. Source: Historic landscape shows data from 2019 W.A.I.T. study (EU average availability for 24 countries: EU27 excl Cyprus, Luxembourg, and Malta); Current landscape shows data from 2025 W.A.I.T. study (EU average from EU27 countries)

The Patients W.A.I.T. Indicator provides a comprehensive view of key components of access to innovative medicines

Elements of the picture exist in other reports and studies, while others remain unknown



* In cases where public reimbursement lists and not kept up to date, companies are contacted directly to determine whether their molecule(s) are present in a country under the noted definitions of 'availability on a public reimbursement list'

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Patients W.A.I.T. Indicator 2025 Survey: Executive summary

28% **EU average rate of full availability** remains at a **similar level** to last year (29% in 2024 study)

17% **EU average rate of limited availability remains a significant proportion** of all products

597 days **EU average time to availability** is over **19 days longer** than the previous study (578 days in 2024 study)

88% **Access disparity remains >80%** between the highest and lowest European country for multiple studies

Source: EFPIA Patients WAIT indicator (2024 and 2025)

Notes for consideration

1. **Availability over time:** The availability landscape remains largely similar to the previous survey, with the overall profile of access routes broadly unchanged (full availability 28% vs 29% in 2024; limited availability remaining a significant share at 17%)

2. **Time to availability:** Delays to patient access have increased since the 2019 survey, with the average time to patient access rising from 504 days to 597 days

3. **WAIT indicator scope:** The study shows publicly listed availability and restrictions to access, and was created to permit a comparison of European access; it does not capture all nuances of patient access in all countries, but is supplemented by other referenced studies

Patients W.A.I.T. Indicators: Reading guide

	Patients W.A.I.T. Indicators	Purpose of the indicator	Limitations
Rate of availability	**Total availability by approval year**	› To show the availability of molecules *within* the 4-year cohort (2021-2024 approvals)	- Does not show the extent to which patient populations can access novel medicines
	Rate of availability	› To provide an overview of patient's potential to access novel medicines › To be used in conjunction with '***Breakdown of availability***' KPI	- Does not show the extent to which patient populations can access novel medicines
	Breakdown of availability	› To provide the most accurate picture of public availability, by showing the level of restrictions to patient access (e.g. full / limited availability, individual patient basis)	- Does not show a breakdown of the other types of limited availability (i.e. restricted to subpopulation, whilst decision pending, etc.)
	Breakdown of total availability	› To provide granular insight into public, private, and non-availability of novel medicines › To show where data on medicine availability is not available	- Does not show a breakdown of the other types of limited availability (i.e. restricted to subpopulation, whilst decision pending, etc.)
Time to availability	**Time from central approval to availability**	› To provide a consistent picture on time to availability from a standardised point in time – the European Commission's approval date › To show any outliers and fastest medicine's time to access, plus other statistical metrics	- The indicator is less representative for non-EU27 countries - A box and whisker plot can be complex to read all available data points
	Time to availability	› To provide a consistent picture of time to availability from local country authorisation dates › To show the impact of additional local authorisation procedures on time to availability › To show any outliers and fastest medicine's time to access, plus other statistical metrics › To be used in conjunction with '***Time from central approval to availability***' KPI to compare the impact of local regulatory procedures	- A box and whisker plot can be complex to read all available data points
	Median time to availability	› To provide a simple metric of time to availability for international comparison	- Does not show the ability for countries to provide rapid access in rare circumstances, nor significant delays - Outliers can skew the median, affecting the indicator's representativeness
Other	**Historic comparisons and extension**	› To highlight the improvements or declines in the two main metrics of the W.A.I.T. indicator (rate of availability and time to availability)	- The indicators only show 3 years of comparison (however, additional data exists in the public domain and can be compared)

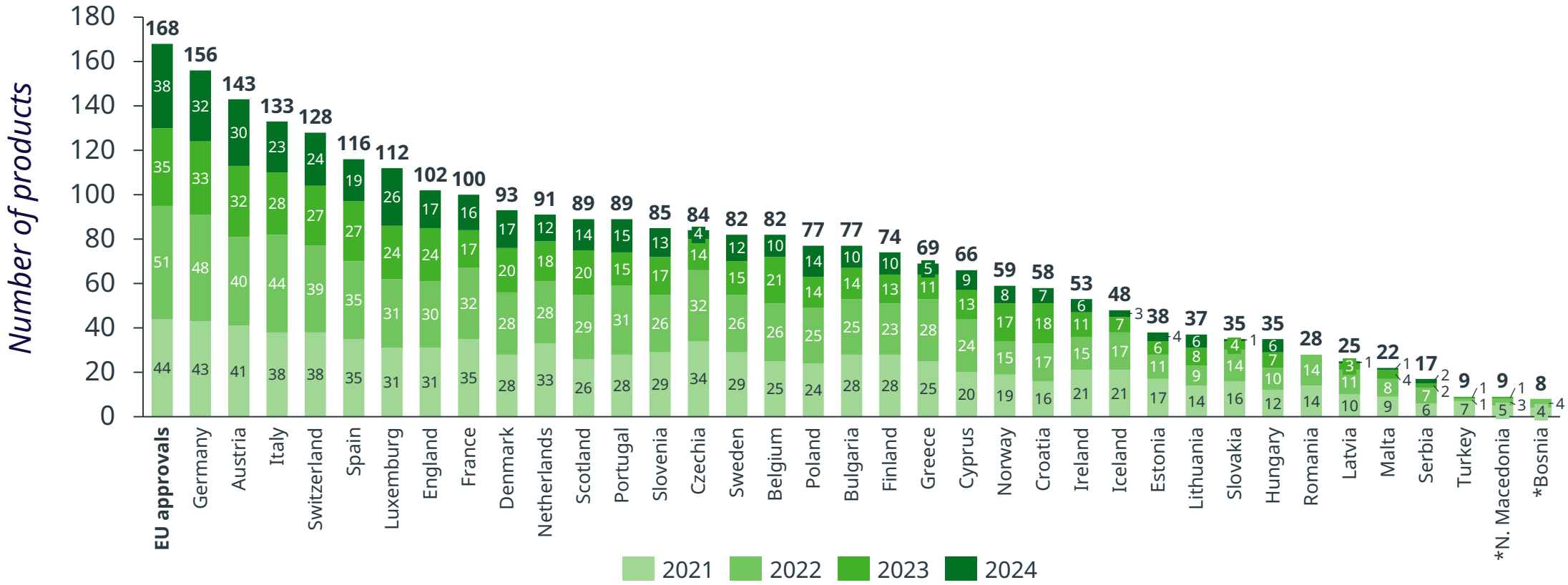
1. Overview (all products)

Indicators:

1.1. Total availability by approval year
1.2. Rate of availability
1.3. Breakdown of availability
1.4. Breakdown of total availability (countries ordered by all availability)
1.5. Breakdown of total availability (countries ordered by full availability)
1.6. Time from central approval to availability
1.7. Time to availability
1.8. Median time to availability
1.9. Key observations

Total availability by approval year (2021-2024)

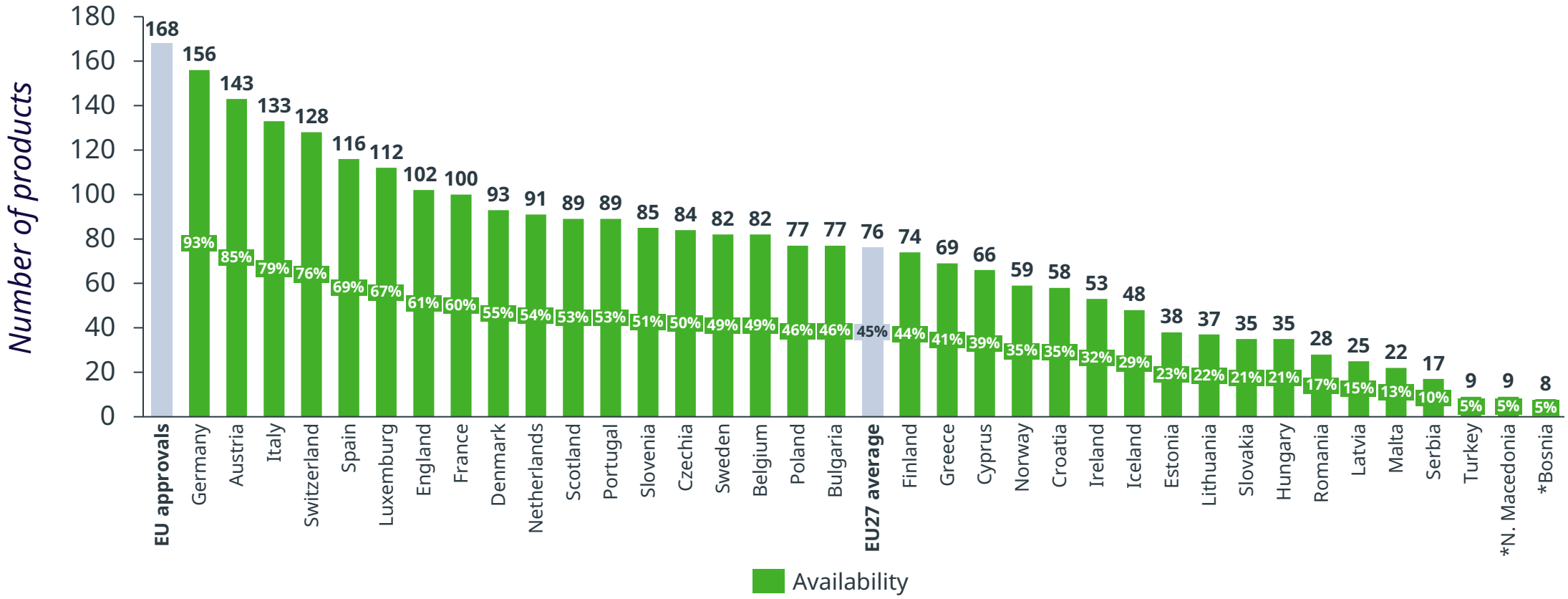
The **total availability by approval year** is the number of medicines available to patients in European countries as of 5th January 2026 (for most countries this is the point at which the product gains access to the reimbursement list†), split by the year the product received marketing authorisation in Europe.



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.

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.



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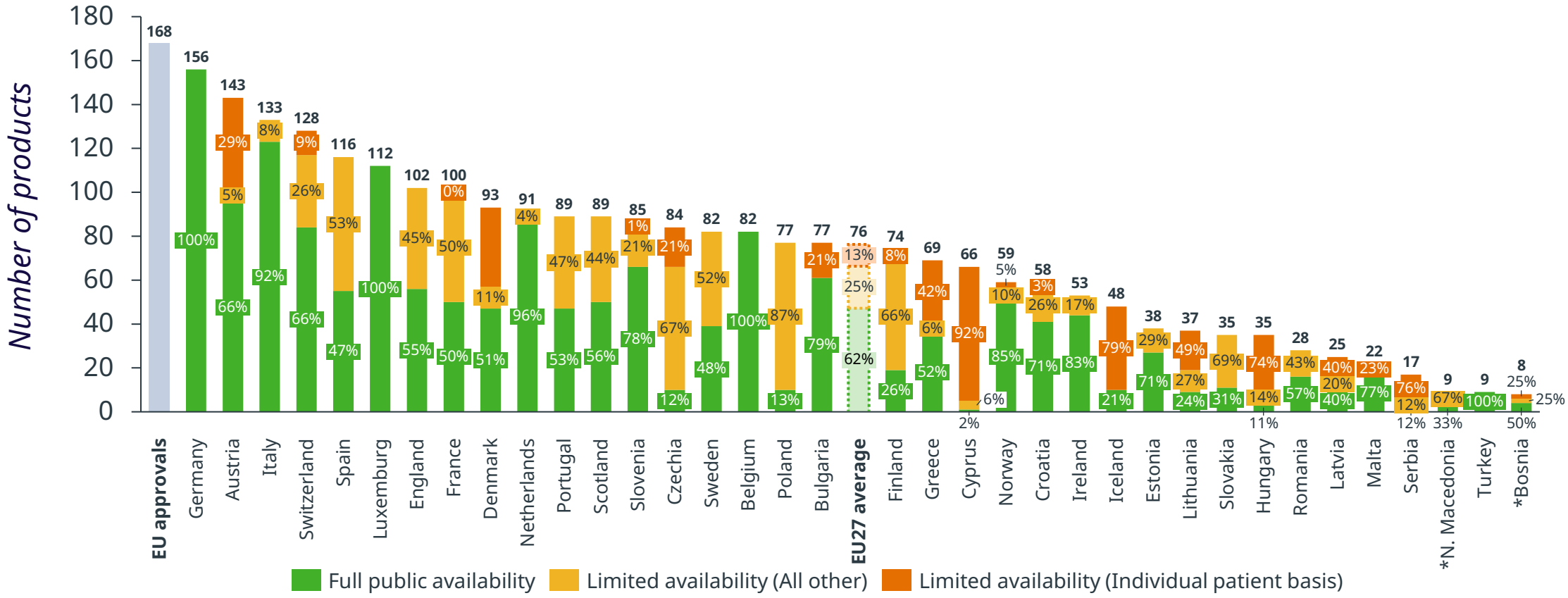
Breakdown of availability (2021-2024)

The **breakdown of availability** shows the proportion 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†) with full availability, via individual patient schemes, or with other restrictions.

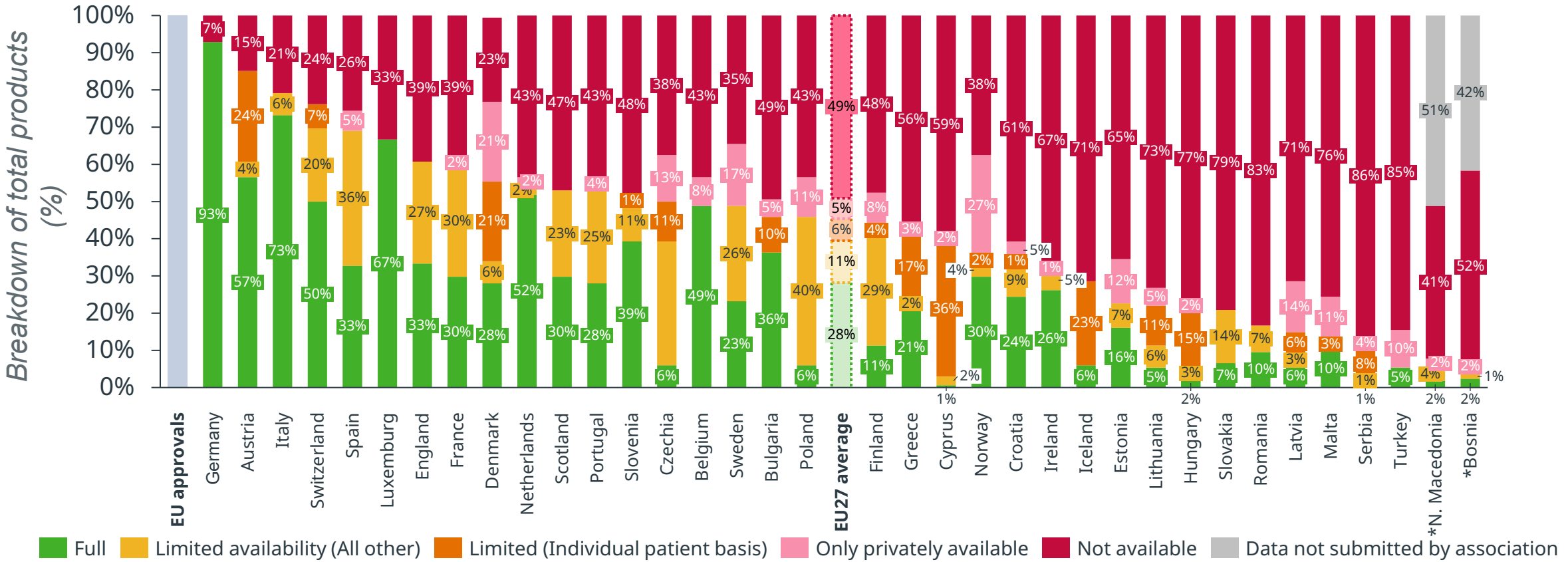


European Union average: 76 products available (45%), Limited Availability (total) (38% of available products); †Country specific definitions are listed in the appendix. Details surrounding early access schemes are provided in slide 72. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative.

Breakdown of total availability (%, 2021-2024)

(Countries ordered by all availability)

The **breakdown of total availability** is the composition 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†). This includes all medicine's status to provide a complete picture of availability.



European Union average: 76 products available (45%) ; Limited Availability (17% of all products); †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.

Breakdown of total availability (%, 2021-2024)

(Countries ordered by full availability)

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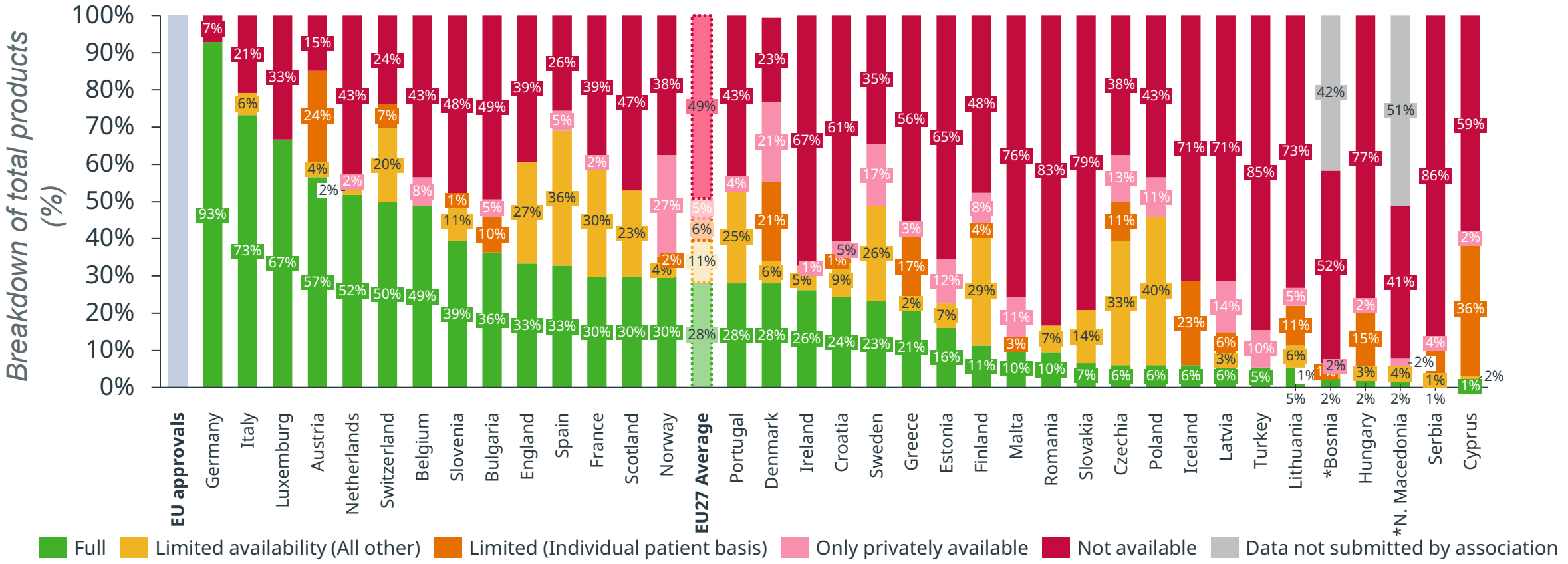
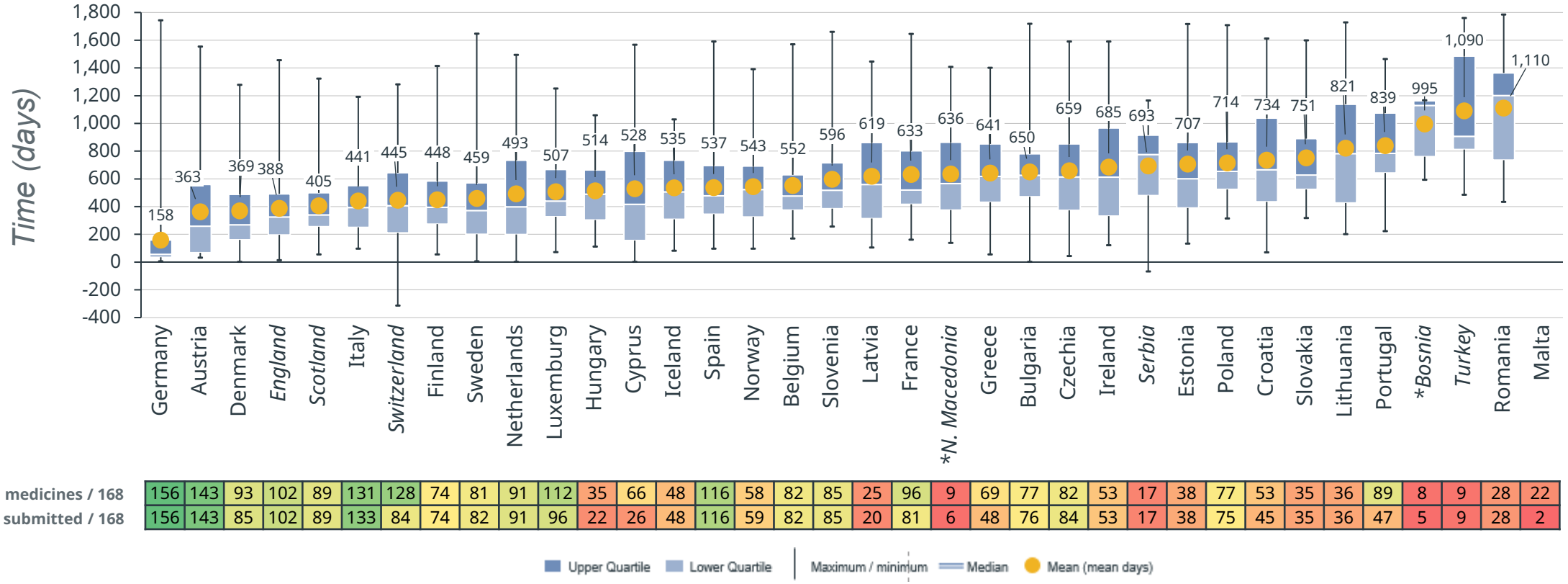


European Union average: 76 products available (45%) ; Limited Availability (17% of all products); †Country specific definitions are listed in the appendix. Details surrounding early access schemes are provided in slide 72. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative.

Time from central approval to availability (2021-2024)

The **time from central approval 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 throughout. Data is correct to 5th January 2026.



Available medicines / 168	156	143	93	102	89	131	128	74	81	91	112	35	66	48	116	58	82	85	25	96	9	69	77	82	53	17	38	77	53	35	36	89	8	9	28	22
Dates submitted / 168	156	143	85	102	89	133	84	74	82	91	96	22	26	48	116	59	82	85	20	81	6	48	76	84	53	17	38	75	45	35	36	47	5	9	28	2

Upper Quartile | Lower Quartile | Maximum / minimum | Median | Mean (mean days)

European Union average: 597 days (mean %) †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.

Time to availability (2021-2024)

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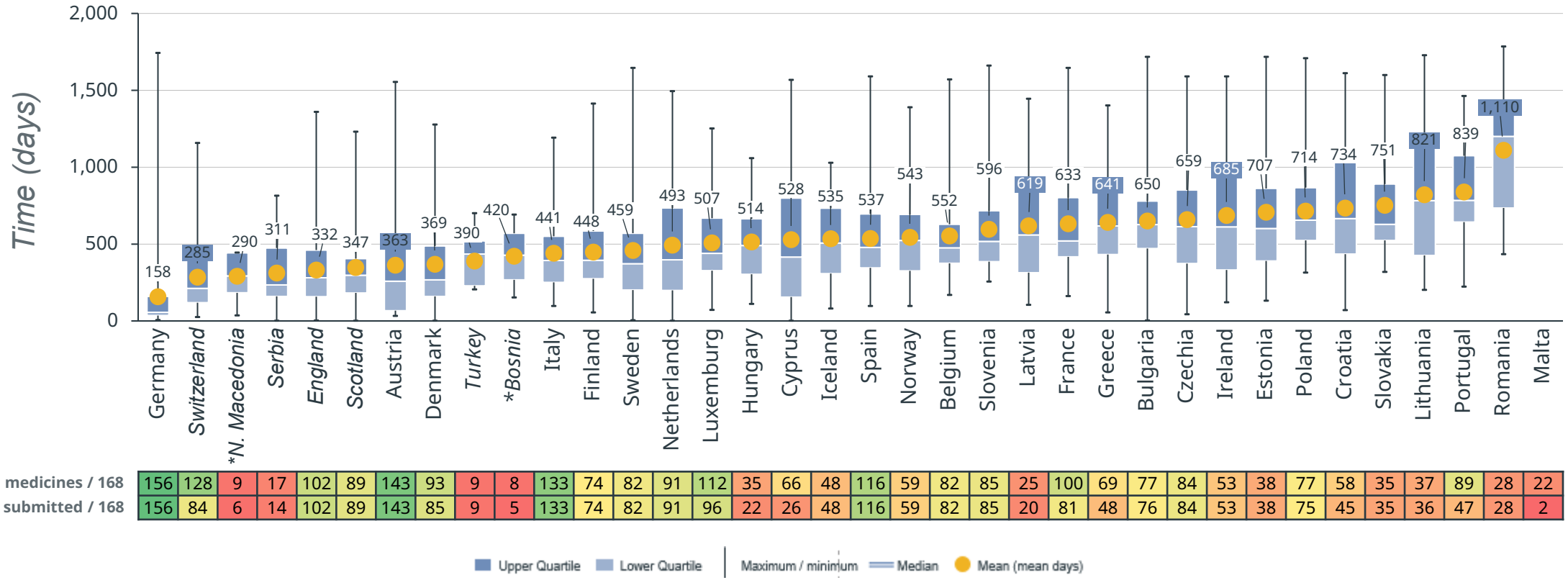

	Germany	Switzerland	*N. Macedonia	Serbia	England	Scotland	Austria	Denmark	Turkey	*Bosnia	Italy	Finland	Sweden	Netherlands	Luxemburg	Hungary	Cyprus	Iceland	Spain	Norway	Belgium	Slovenia	Latvia	France	Greece	Bulgaria	Czechia	Ireland	Estonia	Poland	Croatia	Slovakia	Lithuania	Portugal	Romania	Malta
Available medicines / 168	156	128	9	17	102	89	143	93	9	8	133	74	82	91	112	35	66	48	116	59	82	85	25	100	69	77	84	53	38	77	58	35	37	89	28	22
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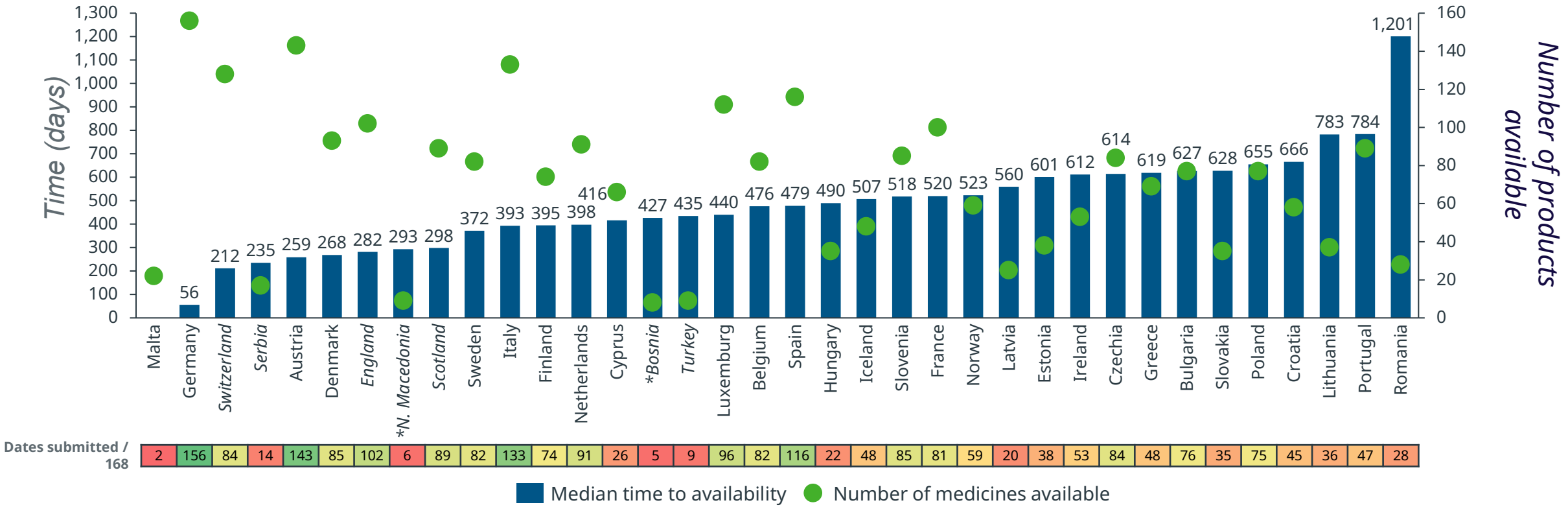
European Union average: 597 days (mean %) †Country specific definitions are listed in the appendix. Details surrounding early access schemes are provided in slide 72. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. Note: Countries with fewer than three submitted dates were excluded to avoid unreliable estimates.

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.

Key observations

Executive summary (EU27 averages)

Measure	All products	Oncology	Orphan	Non-oncologic orphan	Combination therapy
Average rate of availability	45% (46% in 2024)	51% (50% in 2024)	43% (42% in 2024)	39% (39% in 2024)	48% (55% in 2024) ↓
Average time to availability	597 Days (578 days in 2024)	655 Days (586 days in 2024) ↑	614 Days (611 days in 2024)	595 Days (607 days in 2024)	553 Days (553 days in 2024)

Key Insights

Rate of availability

- The rate of availability remains similar to the previous survey, suggesting little change in overall access at the EU level.
- As in the previous survey, availability for all products remains lower than for oncology medicines, highlighting persistent differences between product groups.

Time to availability

- Time to availability has increased slightly from the previous year, extending the average delay to patient access.
- Country-level time to availability remains highly variable, with gaps of more than two years between markets.

Notes: For the EU27 average time to availability, countries with fewer than three submitted dates were excluded to avoid unreliable estimates. As a result, Malta was excluded for the all products, oncology, orphan, and non-oncology orphan calculations, and Croatia, Cyprus, Greece, Latvia, Lithuania, Malta, and Romania were excluded for the combination therapy calculation.

Metrics key:

Text colour indicates relative position versus the current (2025) EU average (*significantly worse than current EU average* / *significantly better than current EU average*)

Arrow colour indicates significant changes versus the previous (2024) EU average (*significant improvement versus previous year* ⇅ / *significant deterioration versus prior year* ⇅)

Average calculations:
Only a difference of +/- 5% (~30 days) is considered a significant change and therefore highlighted

Countries with fewer than three submitted dates were excluded from the time to availability EU27 average.

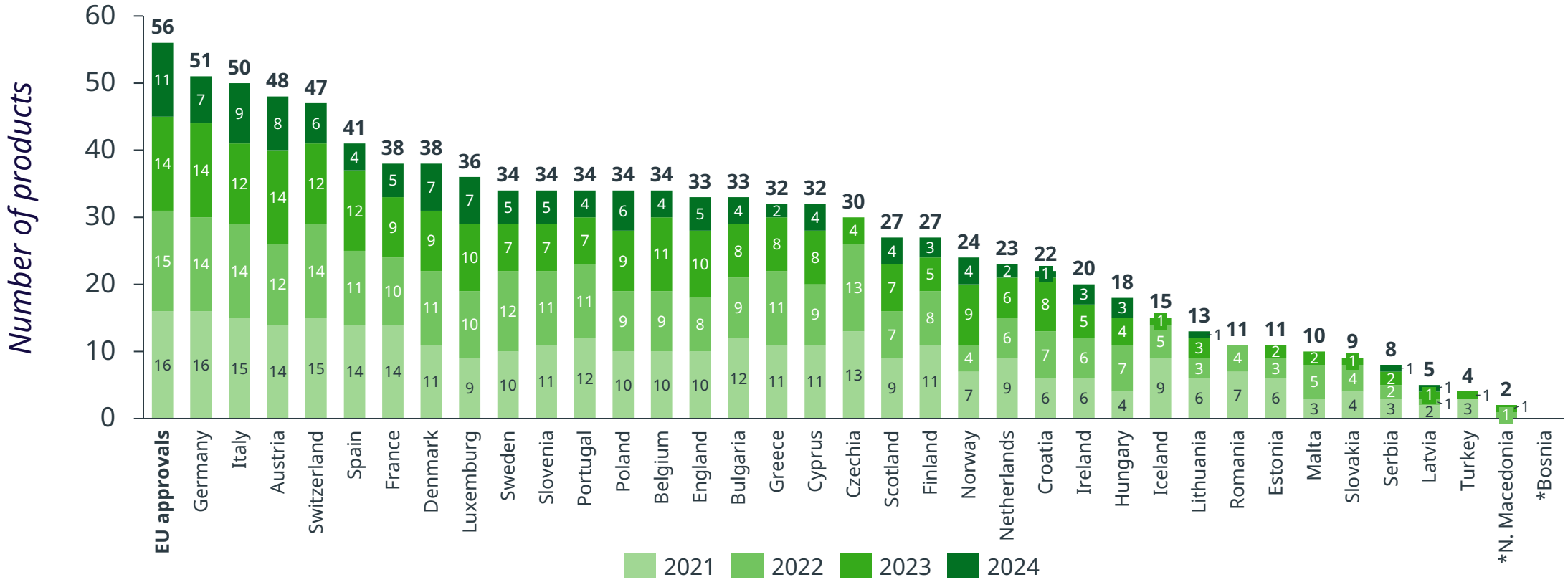
2. Oncology medicines

Indicators:

2.1. Total availability by approval year
2.2. Rate of availability
2.3. Breakdown of availability
2.4. Breakdown of total availability (countries ordered by all availability)
2.5. Breakdown of total availability (countries ordered by full availability)
2.6. Time to availability
2.7. Median time to availability
2.8. Key observations

Oncology availability by approval year (2021-2024)

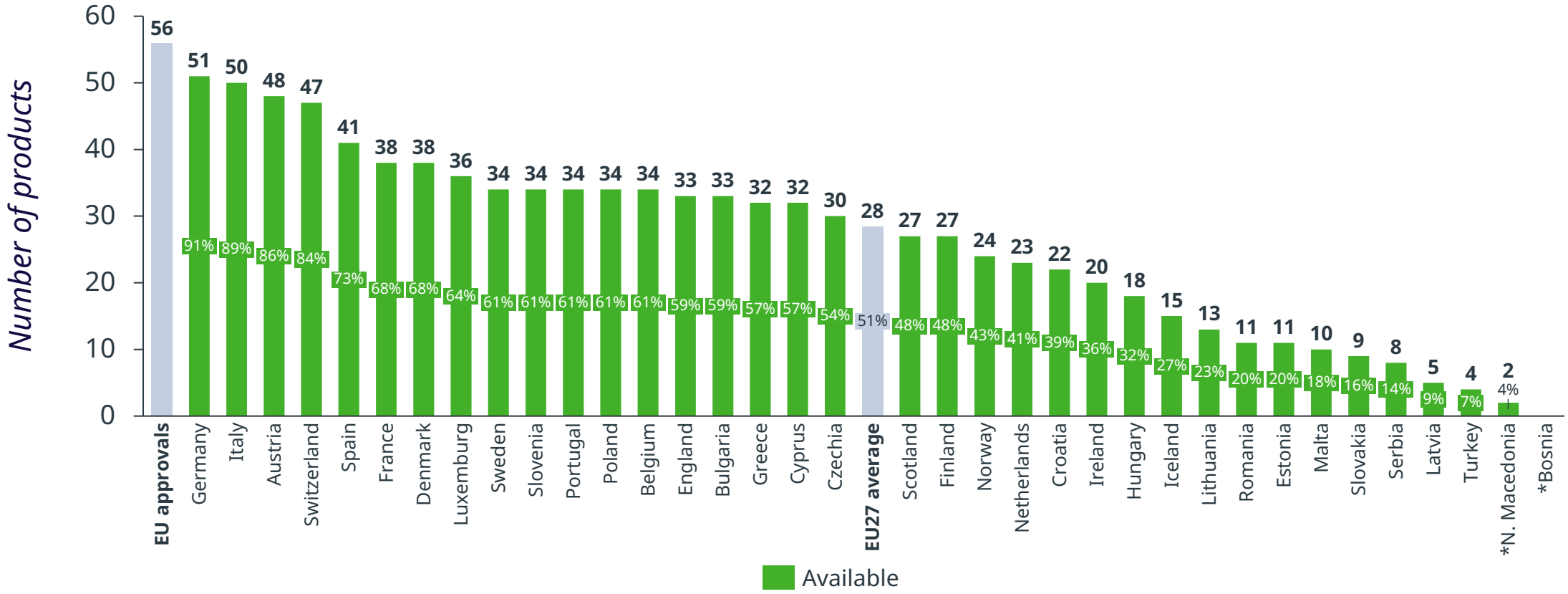
The **total availability by approval year** is the number of medicines available to patients in European countries as of 5th January 2026 (for most countries this is the point at which the product gains access to the reimbursement list†), split by the year the product received marketing authorisation in Europe.



European Union average: 28 products available (51%) †Country specific definition 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.

Oncology 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: 28 products available (51%) †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.

Oncology breakdown of availability (%, 2021-2024)

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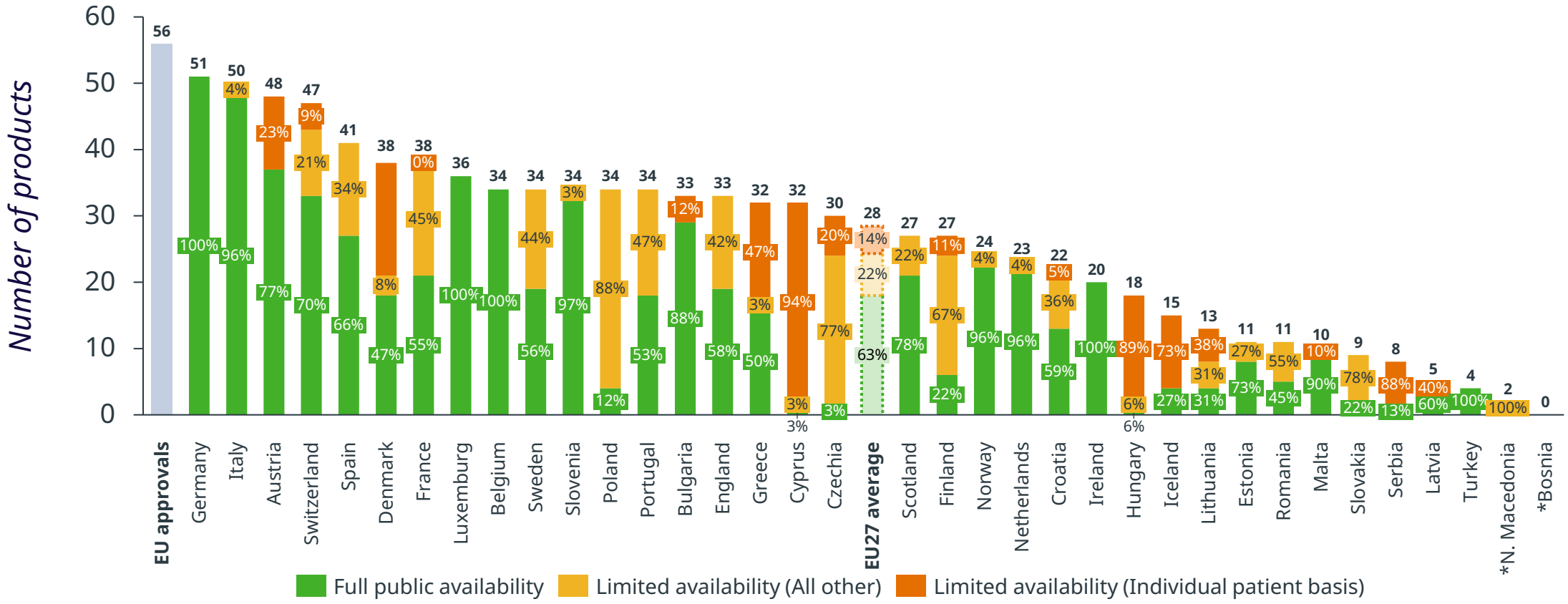
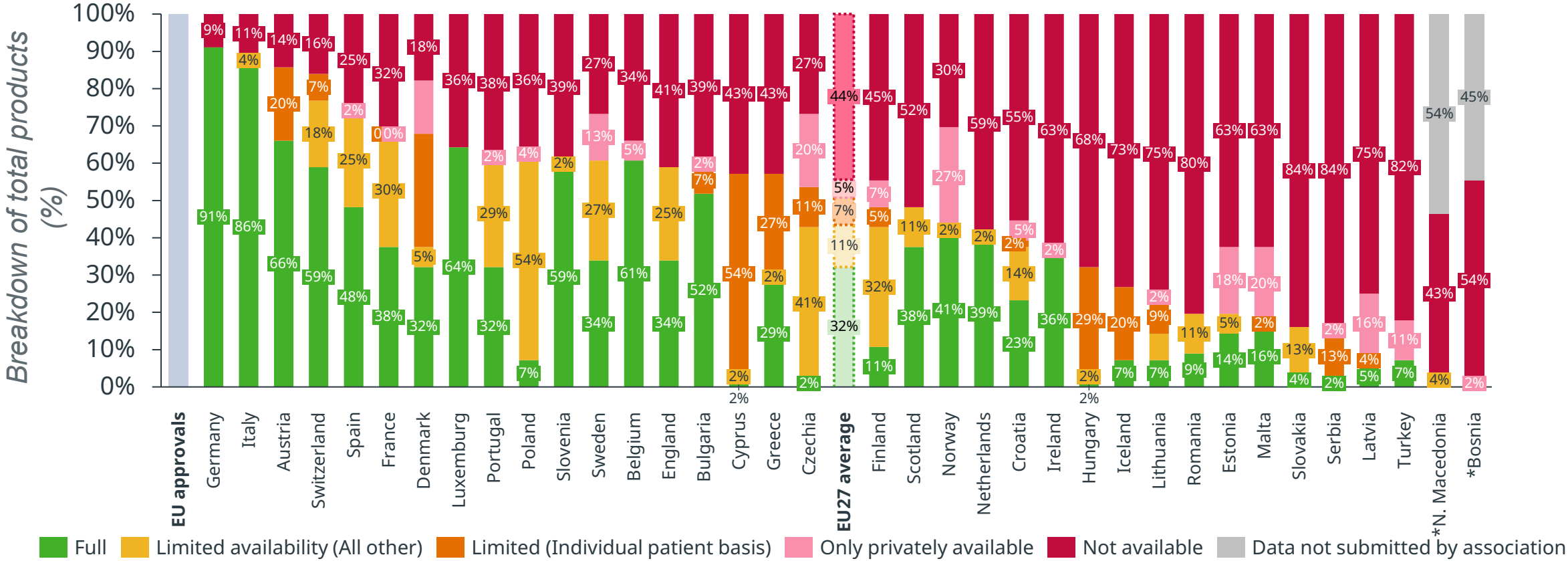


European Union average: 28 products available (51%), Limited availability (total) (36% of available products). †Country specific definitions are listed in the appendix. Details surrounding early access schemes are provided in slide 72. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative.

Oncology breakdown of total availability (%, 2021-2024)

(Countries ordered by all availability)

The **breakdown of total availability** is the composition 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†). This includes all medicine's status to provide a complete picture of availability.

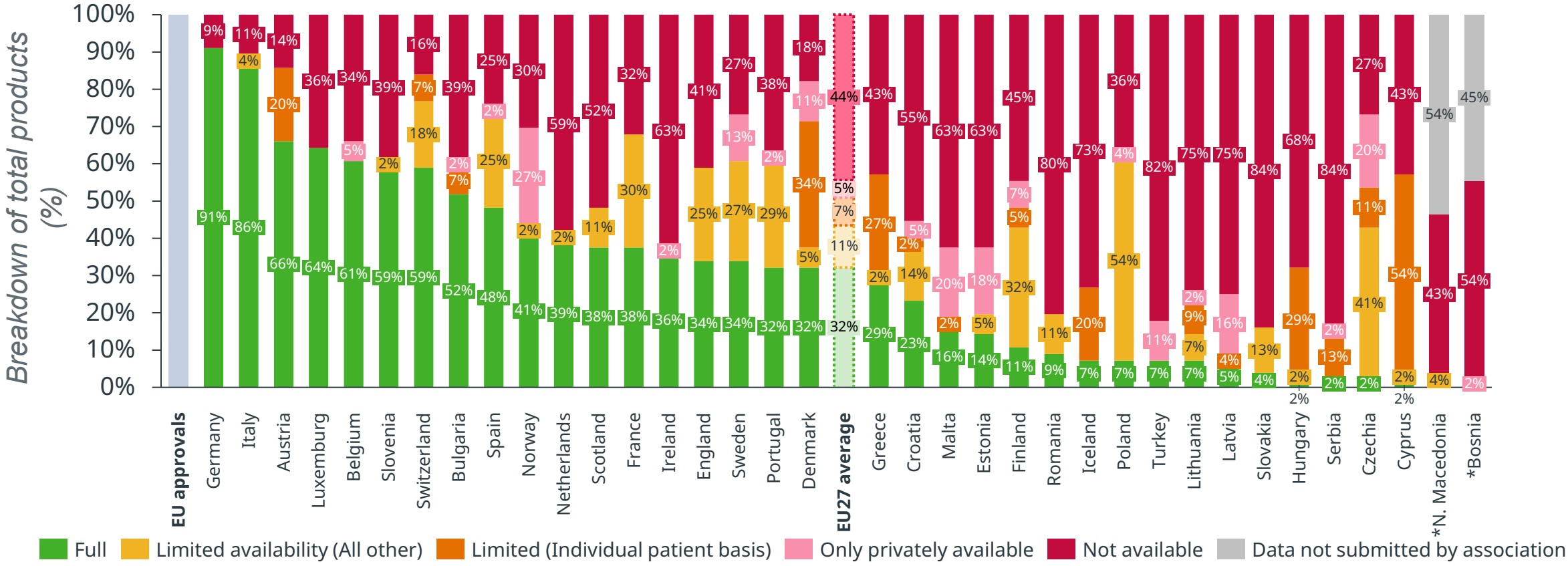


European Union average: 28 products available (51%); Limited Availability (19% of all oncology products) [1]; †Country specific definitions are listed in the appendix. Details surrounding early access schemes are provided in slide 72. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. [1] The average rate of availability is 51% and limited availability is 19%; the reason this is not represented in the chart (where segments total 50% and 18% respectively) is due to rounding.

Oncology breakdown of total availability (%, 2021-2024)

(Countries ordered by full availability)

The **breakdown of total availability** is the composition 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†). This includes all medicine's status to provide a complete picture of availability.



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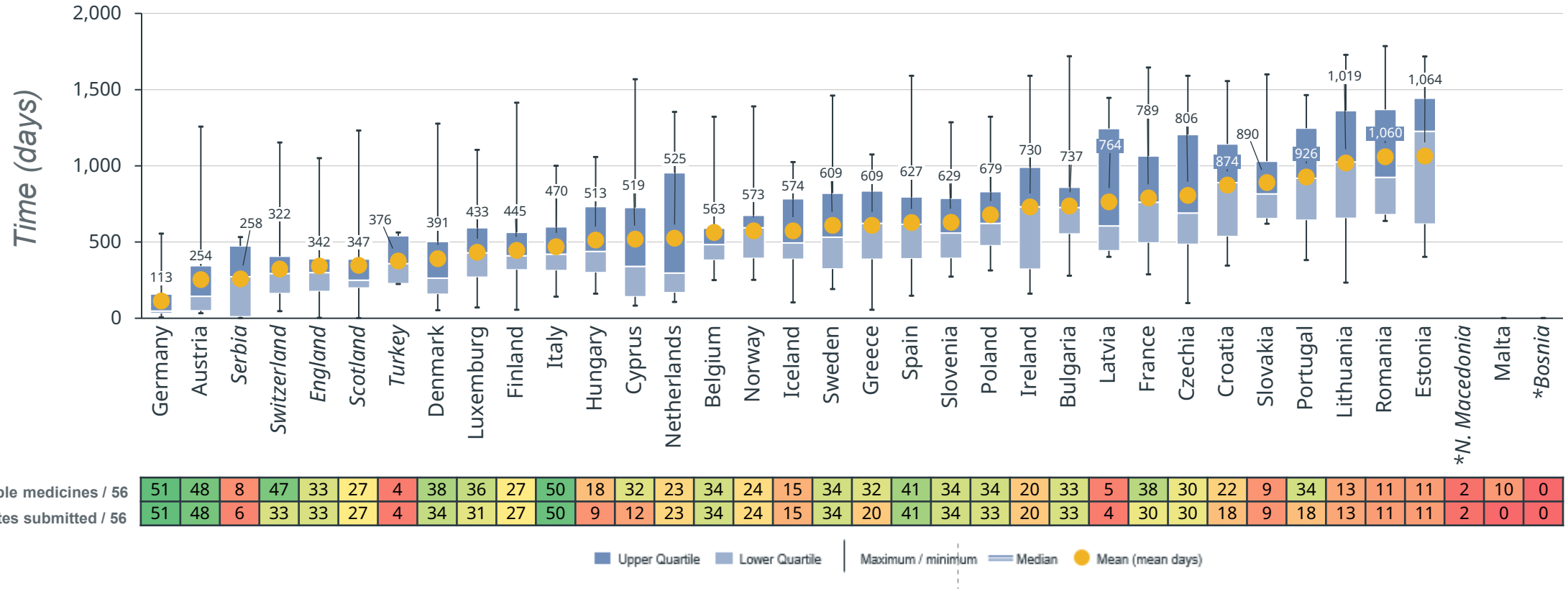
Oncology time to availability (2021-2024)

The **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.

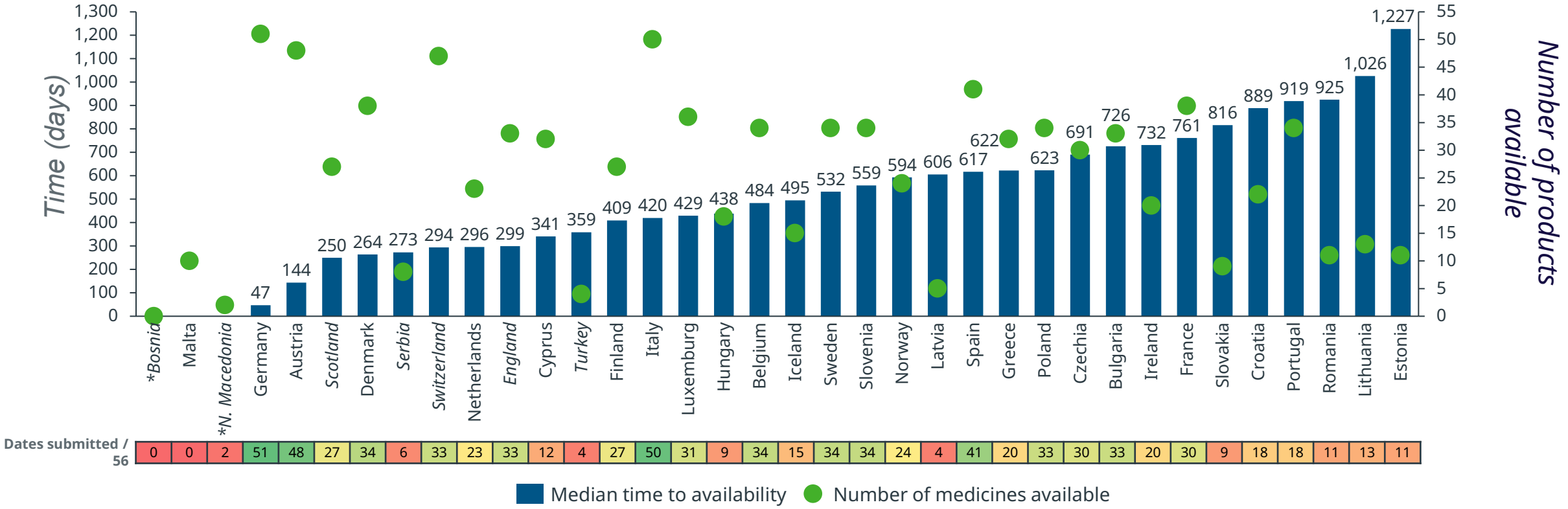


Available medicines / 56	51	48	8	47	33	27	4	38	36	27	50	18	32	23	34	24	15	34	32	41	34	34	20	33	5	38	30	22	9	34	13	11	11	2	10	0
Dates submitted / 56	51	48	6	33	33	27	4	34	31	27	50	9	12	23	34	24	15	34	20	41	34	33	20	33	4	30	30	18	9	18	13	11	11	2	0	0

European Union average: 655 days (mean) †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.

Oncology 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: 598 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.

Key observations

Executive summary (EU27 averages)

Measure	All products	Oncology	Orphan	Non-oncologic orphan	Combination therapy
Average rate of availability	45% (46% in 2024)	51% (50% in 2024)	43% (42% in 2024)	39% (39% in 2024)	48% (55% in 2024) ↓
Average time to availability	597 Days (578 days in 2024)	655 ↑ Days (586 days in 2024)	614 Days (611 days in 2024)	595 Days (607 days in 2024)	553 Days (553 days in 2024)

Key Insights

Rate of availability

- Oncology medicines remain above the overall average in terms of availability, with a gap of around 5 percentage points compared with all products.
- The relative position of oncology compared with other segments has not materially shifted since the previous survey.

Time to availability

- Oncology medicines continue to experience the longest access timelines among the major product groups.
- On average, time to availability is around two months longer than for all products, reinforcing the disconnect between availability and speed of access.

Metrics key:

Text colour indicates relative position versus the current (2025) EU average (*significantly worse than current EU average* / *significantly better than current EU average*)

Arrow colour indicates significant changes versus the previous (2024) EU average (*significant improvement versus previous year* ⇅ / *significant deterioration versus prior year* ⇅)

Average calculations:
Only a difference of +/- 5% (~30 days) is considered a significant change and therefore highlighted

Countries with fewer than three submitted dates were excluded from the time to availability EU27 average.

Notes: For the EU27 average time to availability, countries with fewer than three submitted dates were excluded to avoid unreliable estimates. As a result, Malta was excluded for the all products, oncology, orphan, and non-oncology orphan calculations, and Croatia, Cyprus, Greece, Latvia, Lithuania, Malta, and Romania were excluded for the combination therapy calculation.

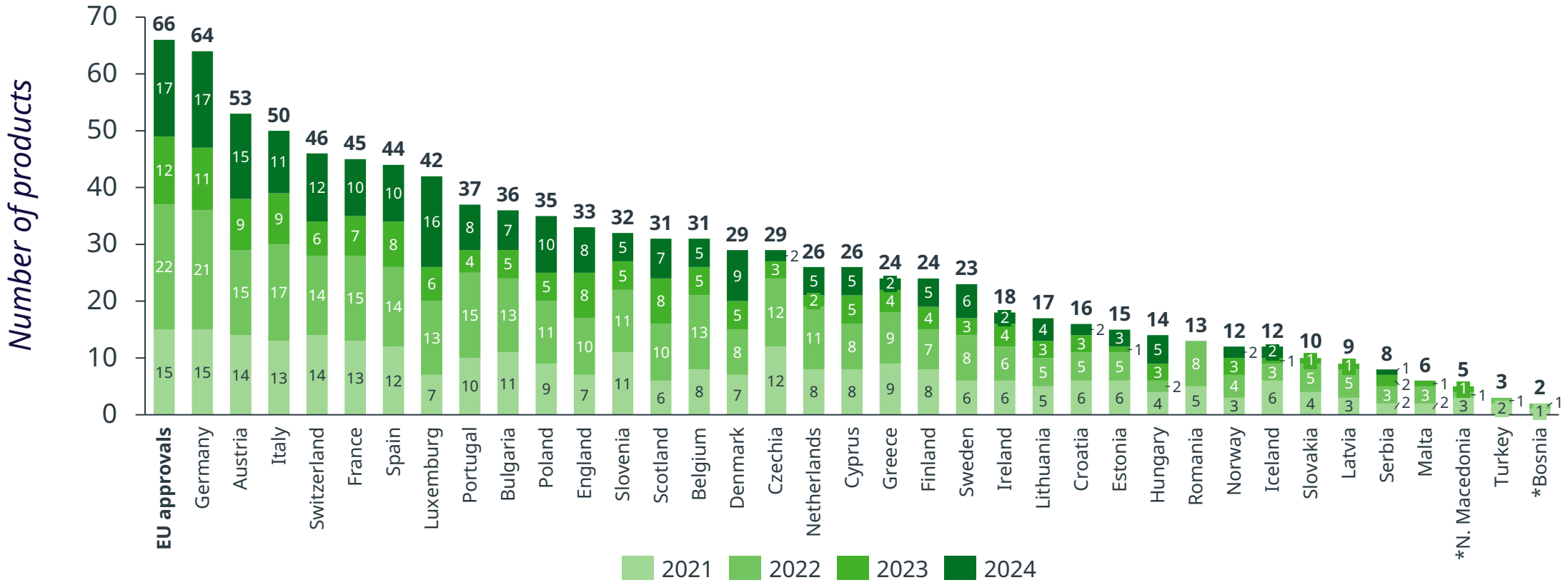
3. Orphan medicines

Indicators:

3.1. Total availability by approval year
3.2. Rate of availability
3.3. Breakdown of availability
3.4. Breakdown of total availability (countries ordered by all availability)
3.5. Breakdown of total availability (countries ordered by full availability)
3.6. Time to availability
3.7. Median time to availability
3.8. Key observations

Orphan availability by approval year (2021-2024)

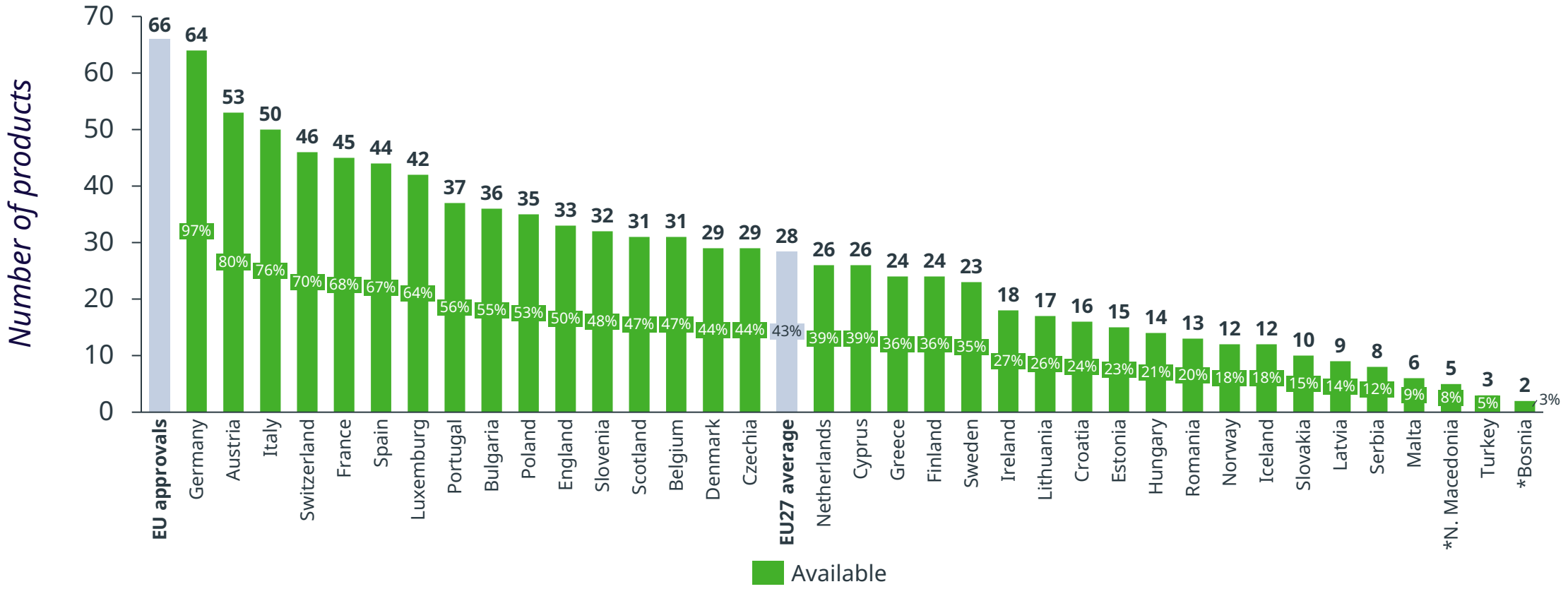
The **total availability by approval year** is the number of medicines available to patients in European countries as of 5th January 2026 (for most countries this is the point at which the product gains access to the reimbursement list†), split by the year the product received marketing authorisation in Europe.



European Union average: 28 products available (43%) †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.

Orphan rate of availability (2021-2024)

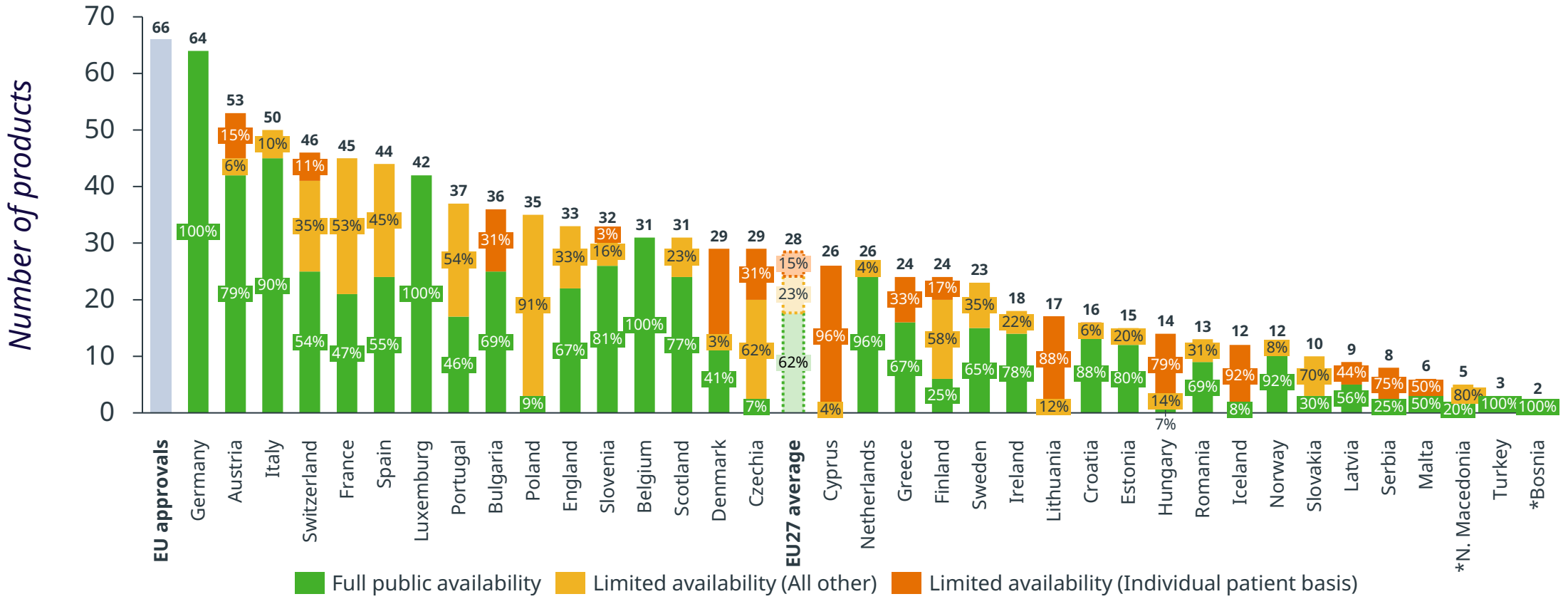
The **rate of availability**, measured by the number of medicines available to patients in European countries as of 5th January 2026. For most countries this is the point at which the product gains access to the reimbursement list†, including products with limited availability.



European Union average: 28 products available (43%) †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.

Orphan breakdown of availability (%, 2021-2024)

The **breakdown of availability** shows the proportion 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†) with full availability, via individual patient schemes, or with other restrictions.

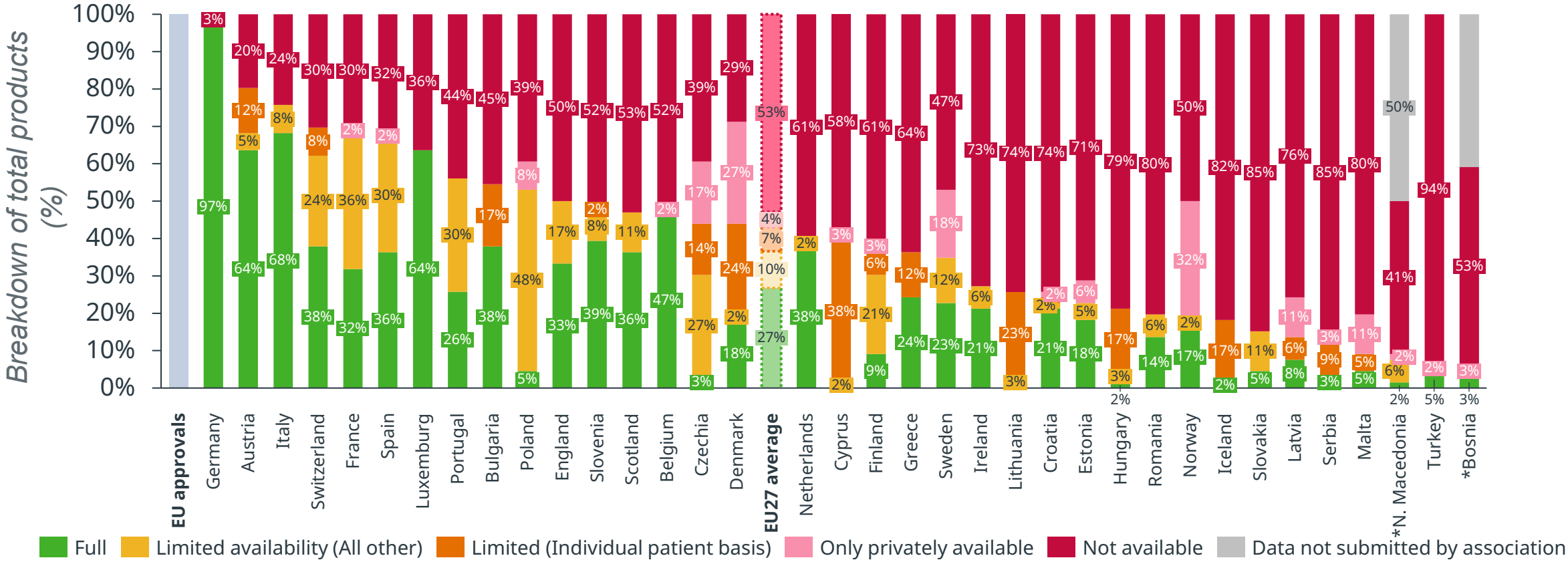


European Union average: 28 products available (43%), Limited availability (total) (38% of available products). †Country specific definitions are listed in the appendix. Details surrounding early access schemes are provided in slide 72. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. ¹The average rate of limited availability is 38%; the reason this is not represented in the chart (where segments total 39%) is due to rounding.

Orphan breakdown of total availability (%, 2021-2024)

(Countries ordered by all availability)

The **breakdown of total availability** is the composition 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†). This includes all medicine's status to provide a complete picture of availability.

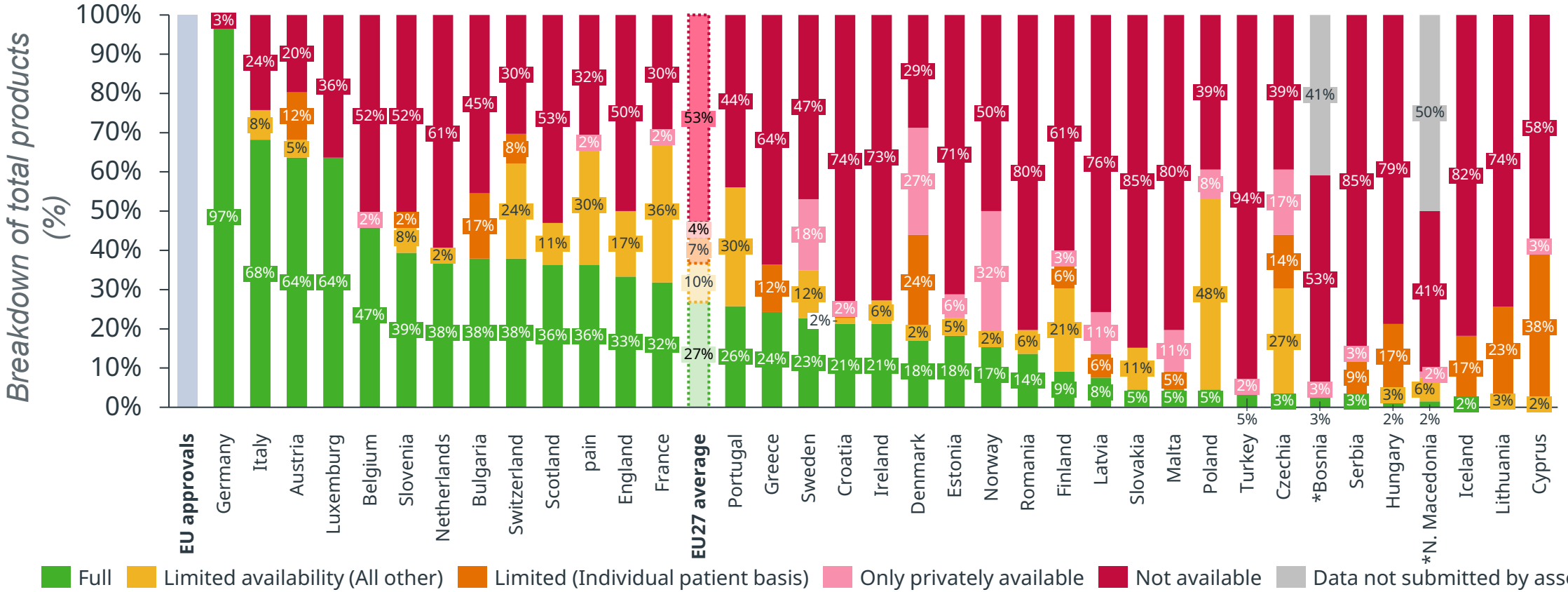


European Union average: 28 products available (43%); Limited Availability (16% of all orphan products) [1]; †Country specific definitions are listed in the appendix. Details surrounding early access schemes are provided in slide 72. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. [1] The average rate of availability is 43% and limited availability is 16%; the reason this is not represented in the chart (where segments total 44% and 17% respectively) is due to rounding.

Orphan breakdown of total availability (%, 2021-2024)

(Countries ordered by full availability)

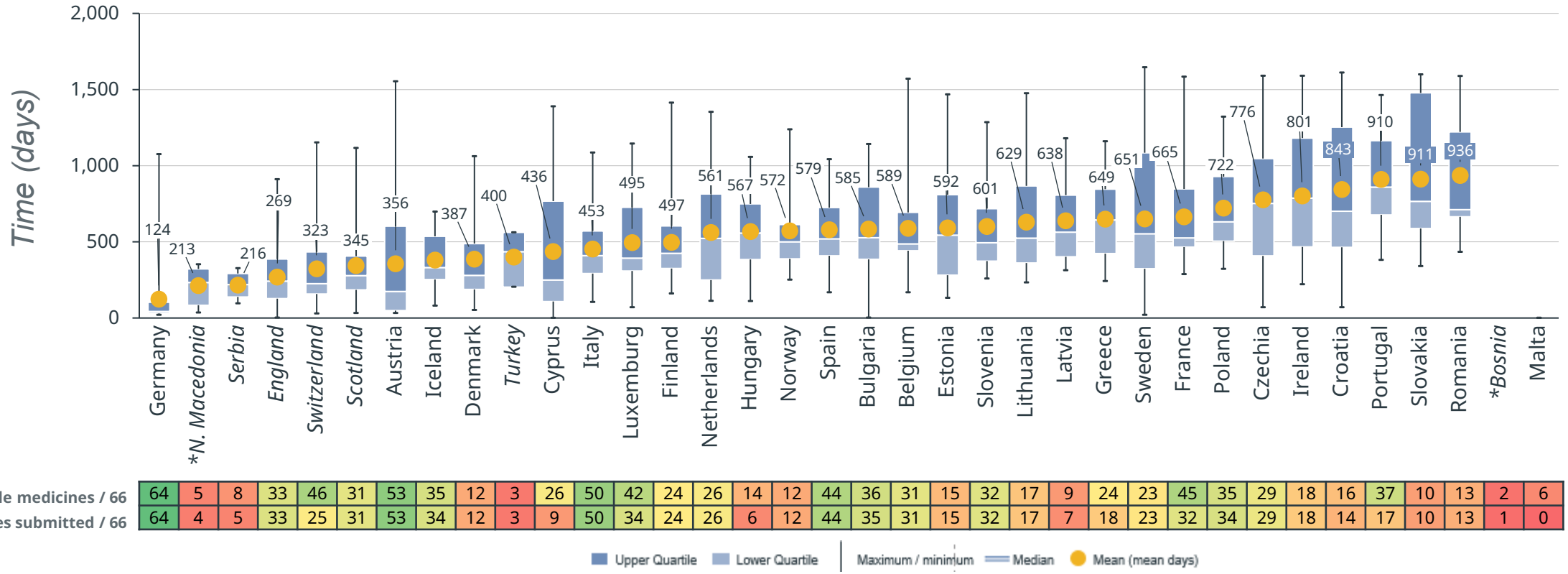
The **breakdown of total availability** is the composition of medicines available to patients in European countries as of 5th January 2026 (for most countries this is the point at which the product gains access to the reimbursement list†). This includes all medicine's status to provide a complete picture of availability.



European Union average: 28 products available (43%) [1]; Limited Availability (17% of all orphan products); †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. [1] The average rate of availability is 43% and limited availability is 16%; the reason this is not represented in the chart (where segments total 44% and 17% respectively) is due to rounding.

Orphan time to availability (2021-2024)

The **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.

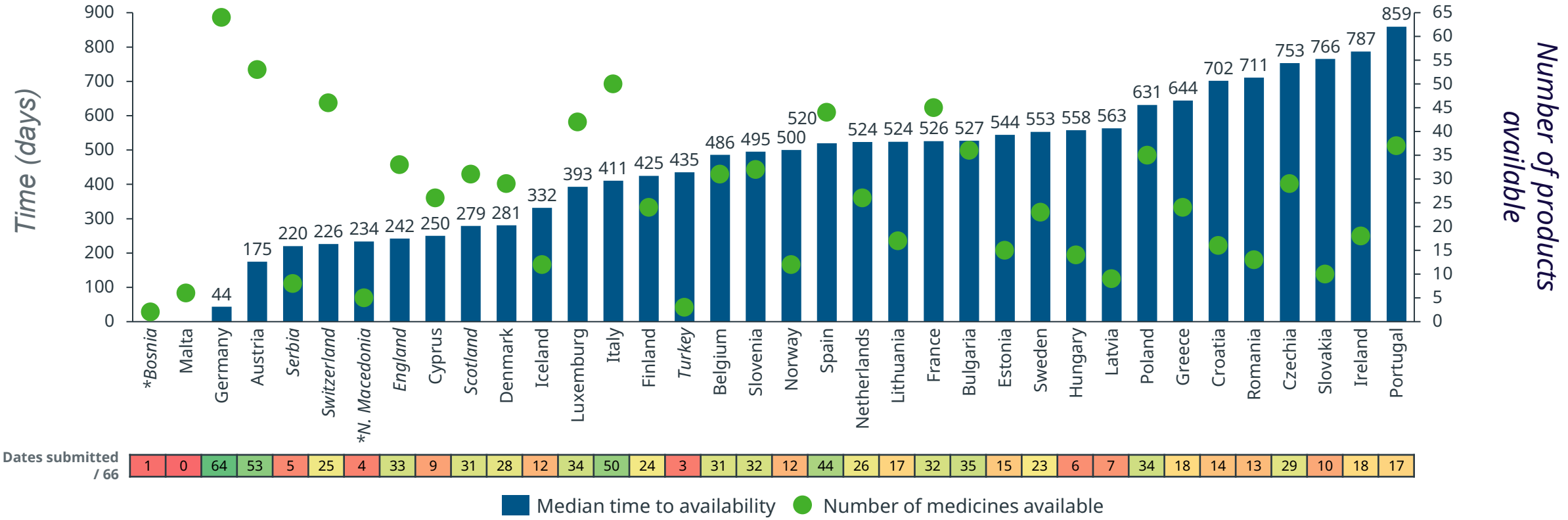


Available medicines / 66	64	5	8	33	46	31	53	35	12	3	26	50	42	24	26	14	12	44	36	31	15	32	17	9	24	23	45	35	29	18	16	37	10	13	2	6
Dates submitted / 66	64	4	5	33	25	31	53	34	12	3	9	50	34	24	26	6	12	44	35	31	15	32	17	7	18	23	32	34	29	18	14	17	10	13	1	0

European Union average: 614 days (mean) †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.

Orphan 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: 525 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.

Key observations

Executive summary (EU27 averages)

Measure	All products	Oncology	Orphan	Non-oncologic orphan	Combination therapy
Average rate of availability	45% (46% in 2024)	51% (50% in 2024)	43% (42% in 2024)	39% (39% in 2024)	48% ↓ (55% in 2024)
Average time to availability	597 Days (578 days in 2024)	655 ↑ Days (586 days in 2024)	614 Days (611 days in 2024)	595 Days (607 days in 2024)	553 Days (553 days in 2024)

Key Insights

Rate of availability

- At EU level, availability for orphan medicines sits below oncology but broadly in line with the overall average.
- Beneath this average, outcomes remain highly uneven, with a small number of countries accounting for much of the stronger orphan availability observed.

Time to availability

- Time to availability for orphan medicines is longer than for all products, but shorter than for oncology.
- At country level, timelines diverge sharply, with differences of more than two years between faster- and slower-access markets.

Metrics key:

Text colour indicates relative position versus the current (2025) EU average (*significantly worse than current EU average* / *significantly better than current EU average*)

Arrow colour indicates significant changes versus the previous (2024) EU average (*significant improvement versus previous year* ⇅ / *significant deterioration versus prior year* ⇅)

Average calculations:
Only a difference of +/- 5% (~30 days) is considered a significant change and therefore highlighted

Countries with fewer than three submitted dates were excluded from the time to availability EU27 average.

Notes: For the EU27 average time to availability, countries with fewer than three submitted dates were excluded to avoid unreliable estimates. As a result, Malta was excluded for the all products, oncology, orphan, and non-oncology orphan calculations, and Croatia, Cyprus, Greece, Latvia, Lithuania, Malta, and Romania were excluded for the combination therapy calculation.

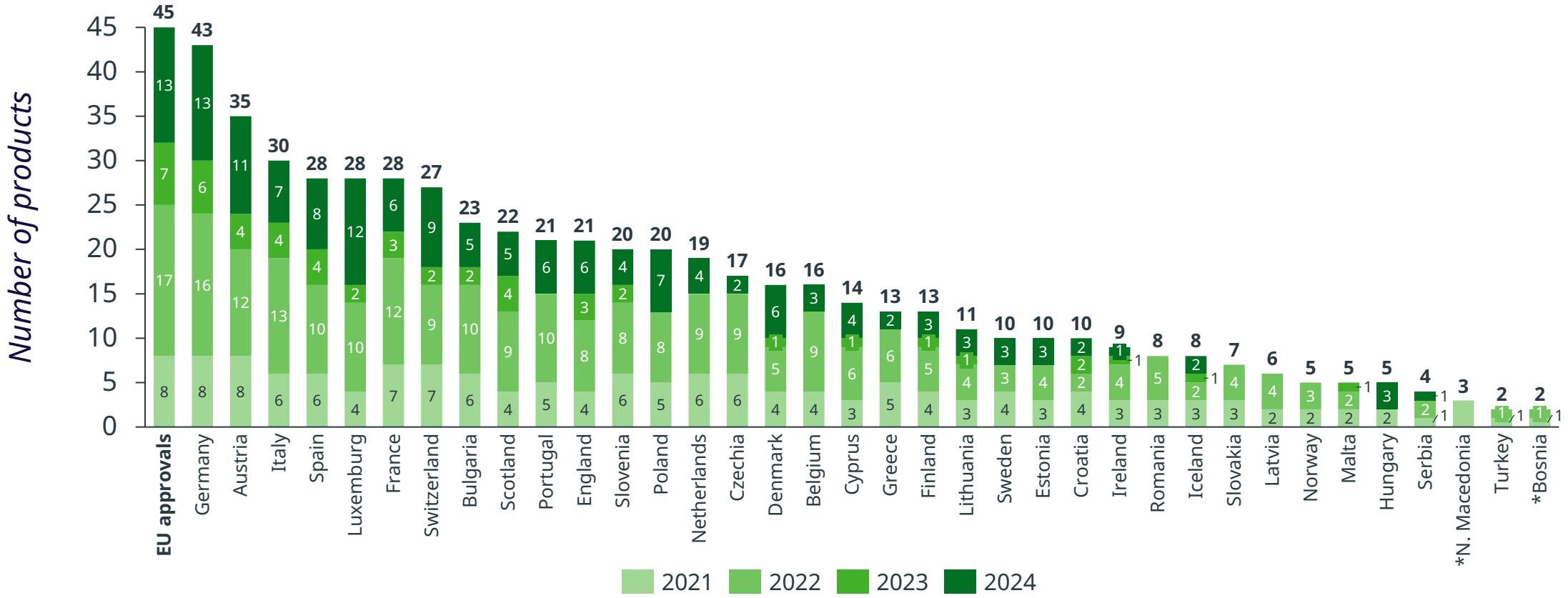
4. Non-oncology orphan medicines

Indicators:

4.1. Total availability by approval year
4.2. Rate of availability
4.3. Breakdown of availability
4.4. Breakdown of total availability (countries ordered by all availability)
4.5. Breakdown of total availability (countries ordered by full availability)
4.6. Time to availability
4.7. Median time to availability
4.8. Key observations

Non-oncology orphan availability by approval year (2021-2024)

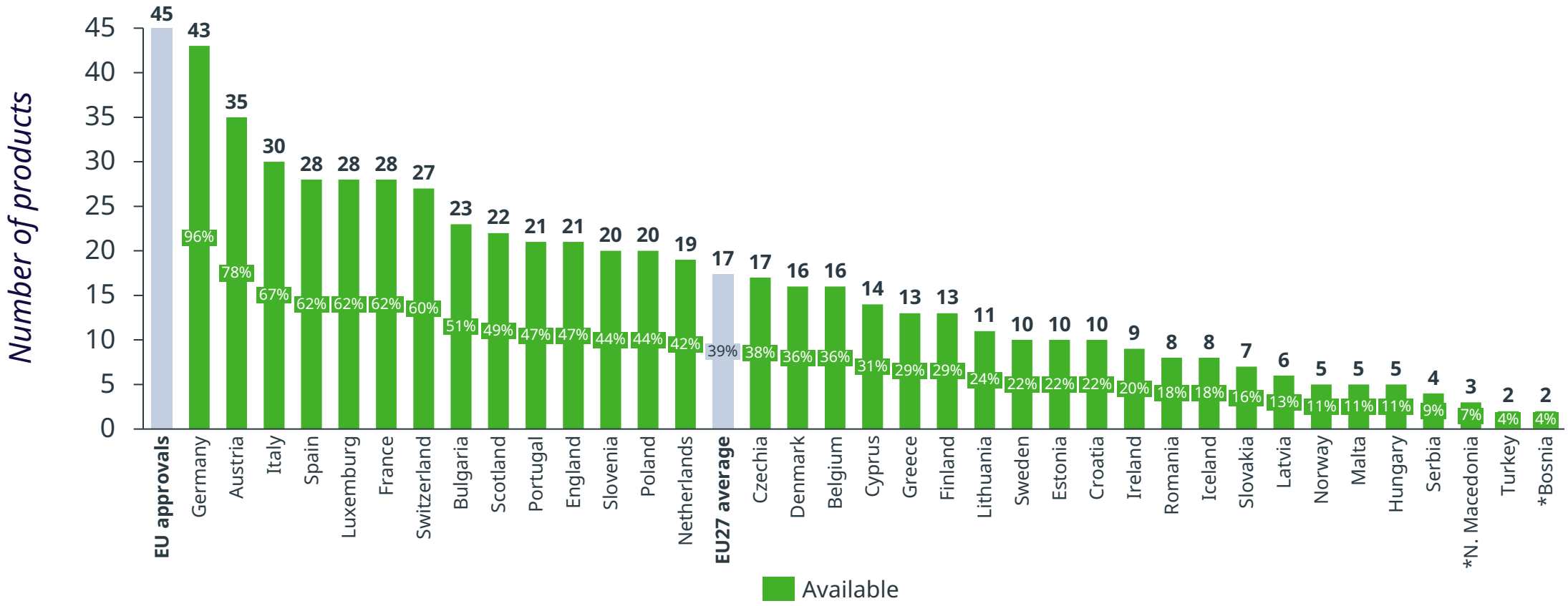
The **total availability by approval year** is the number of medicines available to patients in European countries as of 5th January 2026 (for most countries this is the point at which the product gains access to the reimbursement list†), split by the year the product received marketing authorisation in Europe.



European Union average: 17 products available (39%) †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.

Non-oncology orphan rate of availability (2021-2024)

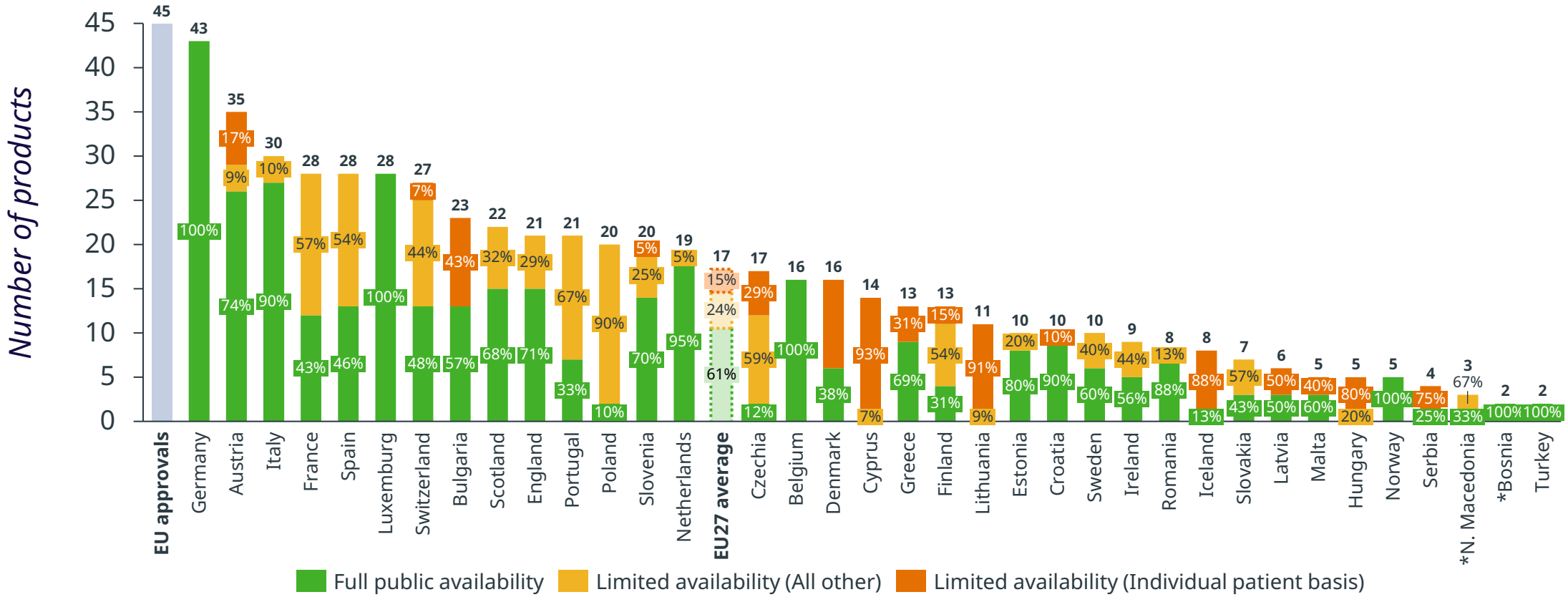
The **rate of availability**, measured by the number of medicines available to patients in European countries as of 5th January 2026. For most countries this is the point at which the product gains access to the reimbursement list†, including products with limited availability.



European Union average: 17 products available (39%) †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.

Non-oncology orphan breakdown of availability (%, 2021-2024)

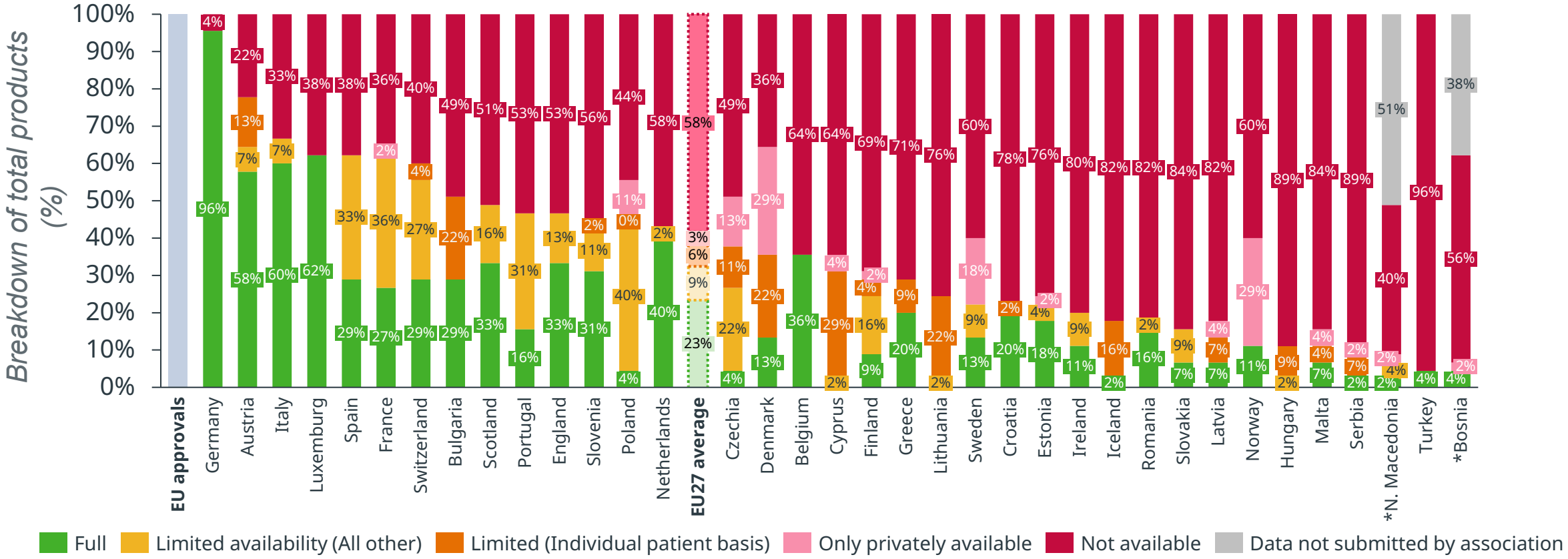
The **breakdown of availability** shows the proportion of medicines available to patients in European countries as of 5th January 2026 (for most countries this is the point at which the product gains access to the reimbursement list†) with full availability, via individual patient schemes, or with other restrictions.



European Union average: 17 products available (39%), Limited availability (total) (39% of available products) †Country specific definitions and early access schemes are listed in the appendix. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. ¹The average rate of limited availability is 39%; the reason this is not represented in the chart (where segments total 40%) is due to rounding.

Non-oncology orphan breakdown of total availability (%, 2021-2024) *(countries ordered by all availability)*

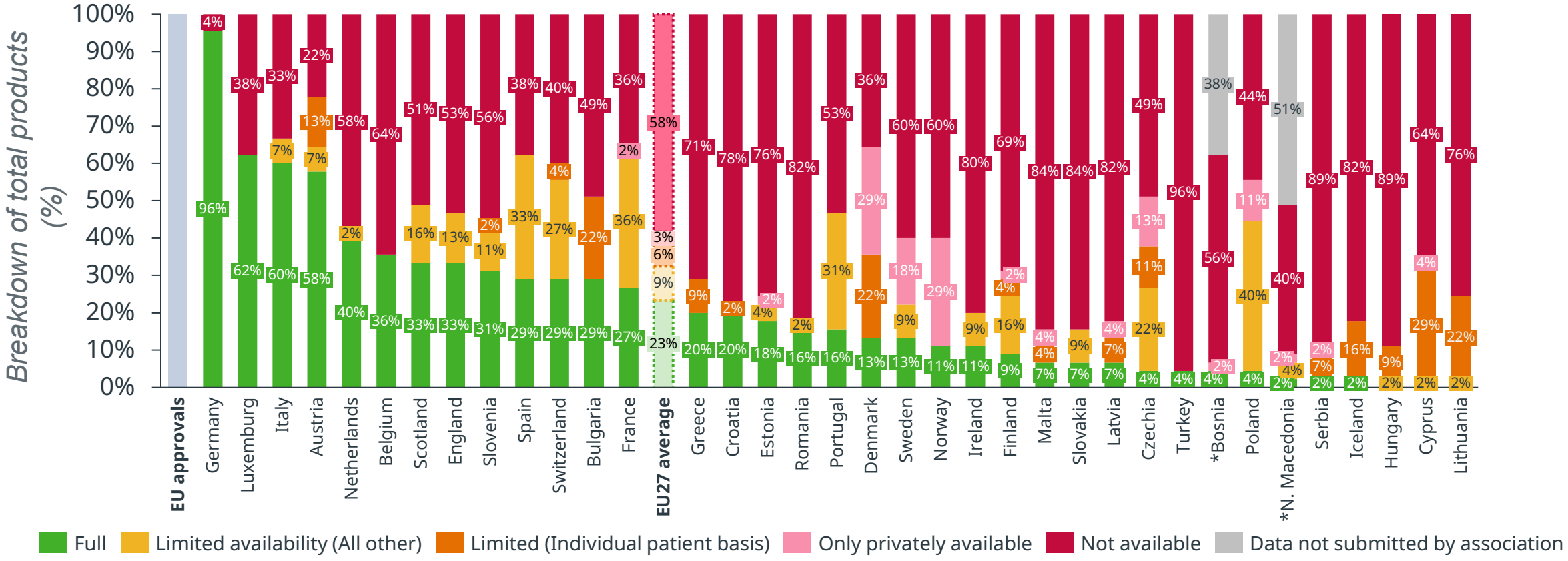
The **breakdown of total availability** is the composition of medicines available to patients in European countries as of 5th January 2026 (for most countries this is the point at which the product gains access to the reimbursement list†). This includes all medicine's status to provide a complete picture of availability.



European Union average: 17 products available (39%); Limited Availability (15% of all non-onco orphan products)[1]; †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. [1] The average rate of availability is 39%; the reason this is not represented in the chart (where segments total 38%) is due to rounding.

Non-oncology orphan breakdown of total availability (%, 2021-2024) *(countries ordered by full availability)*

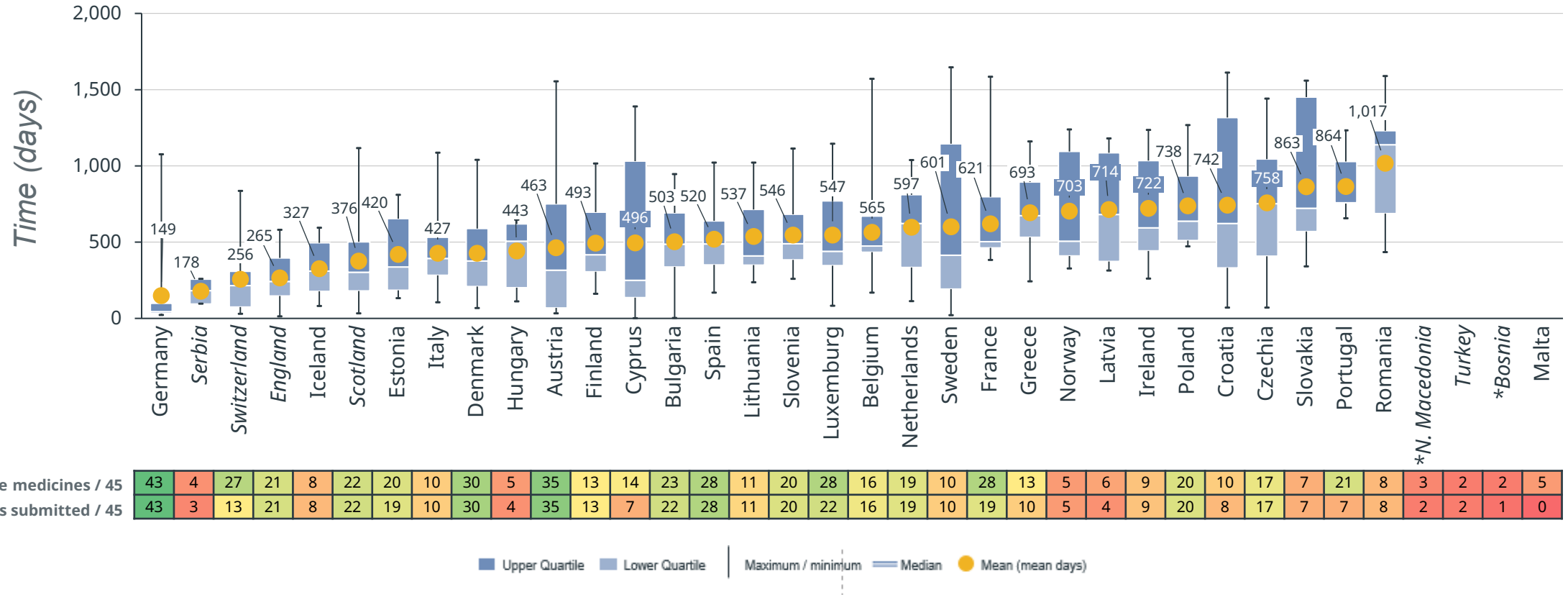
The **breakdown of total availability** is the composition of medicines available to patients in European countries as of 5th January 2026 (for most countries this is the point at which the product gains access to the reimbursement list†). This includes all medicine's status to provide a complete picture of availability.



European Union average: 17 products available (39%); Limited Availability (15% of all non-onco orphan products) [1]; †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. [1] The average rate of availability is 39%; the reason this is not represented in the chart (where segments total 38%) is due to rounding.

Non-oncology orphan time to availability (2021-2024)

The **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.

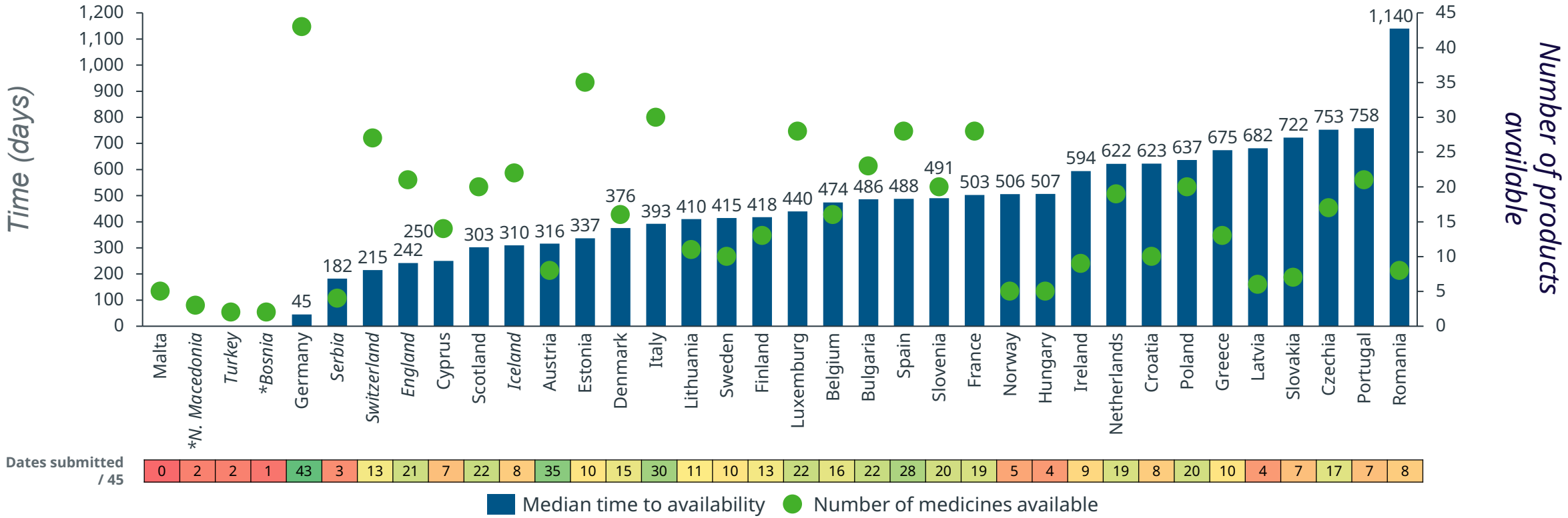


	Germany	Serbia	Switzerland	England	Iceland	Scotland	Estonia	Italy	Denmark	Hungary	Austria	Finland	Cyprus	Bulgaria	Spain	Lithuania	Slovenia	Luxemburg	Belgium	Netherlands	Sweden	France	Greece	Norway	Latvia	Ireland	Poland	Croatia	Czechia	Slovakia	Portugal	Romania	*N. Macedonia	Turkey	*Bosnia	Malta
Available medicines / 45	43	4	27	21	8	22	20	10	30	5	35	13	14	23	28	11	20	28	16	19	10	28	13	5	6	9	20	10	17	7	21	8	3	2	2	5
Dates submitted / 45	43	3	13	21	8	22	19	10	30	4	35	13	7	22	28	11	20	22	16	19	10	19	10	5	4	9	20	8	17	7	7	8	2	2	1	0

European Union average: 595 days (mean) †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.

Non-oncology orphan 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: 521 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.

Key observations

Executive summary (EU27 averages)

Measure	All products	Oncology	Orphan	Non-oncologic orphan	Combination therapy
Average rate of availability	45% (46% in 2024)	51% (50% in 2024)	43% (42% in 2024)	39% (39% in 2024)	48% ↓ (55% in 2024)
Average time to availability	597 Days (578 days in 2024)	655 ↑ Days (586 days in 2024)	614 Days (611 days in 2024)	595 Days (607 days in 2024)	553 Days (553 days in 2024)

Key Insights

Rate of availability

- At EU level, non-oncologic orphan medicines record the lowest availability across the product segments, significantly lower than that of all products.
- Unlike other segments, higher availability outcomes for non-oncologic orphans remain limited to very few countries, with most markets clustered at lower levels.

Time to availability

- Time to availability remains broadly stable, with a slight decrease compared with the previous survey.
- In contrast to rate of availability, time to availability for non-oncologic orphan medicines sits broadly in line with the overall average.

Metrics key:

Text colour indicates relative position versus the current (2025) EU average (*significantly worse than current EU average* / *significantly better than current EU average*)

Arrow colour indicates significant changes versus the previous (2024) EU average (*significant improvement versus previous year* ↑↓ / *significant deterioration versus prior year* ↑↓)

Average calculations:
Only a difference of +/- 5% (~30 days) is considered a significant change and therefore highlighted

Countries with fewer than three submitted dates were excluded from the time to availability EU27 average.

Notes: For the EU27 average time to availability, countries with fewer than three submitted dates were excluded to avoid unreliable estimates. As a result, Malta was excluded for the all products, oncology, orphan, and non-oncology orphan calculations, and Croatia, Cyprus, Greece, Latvia, Lithuania, Malta, and Romania were excluded for the combination therapy calculation.

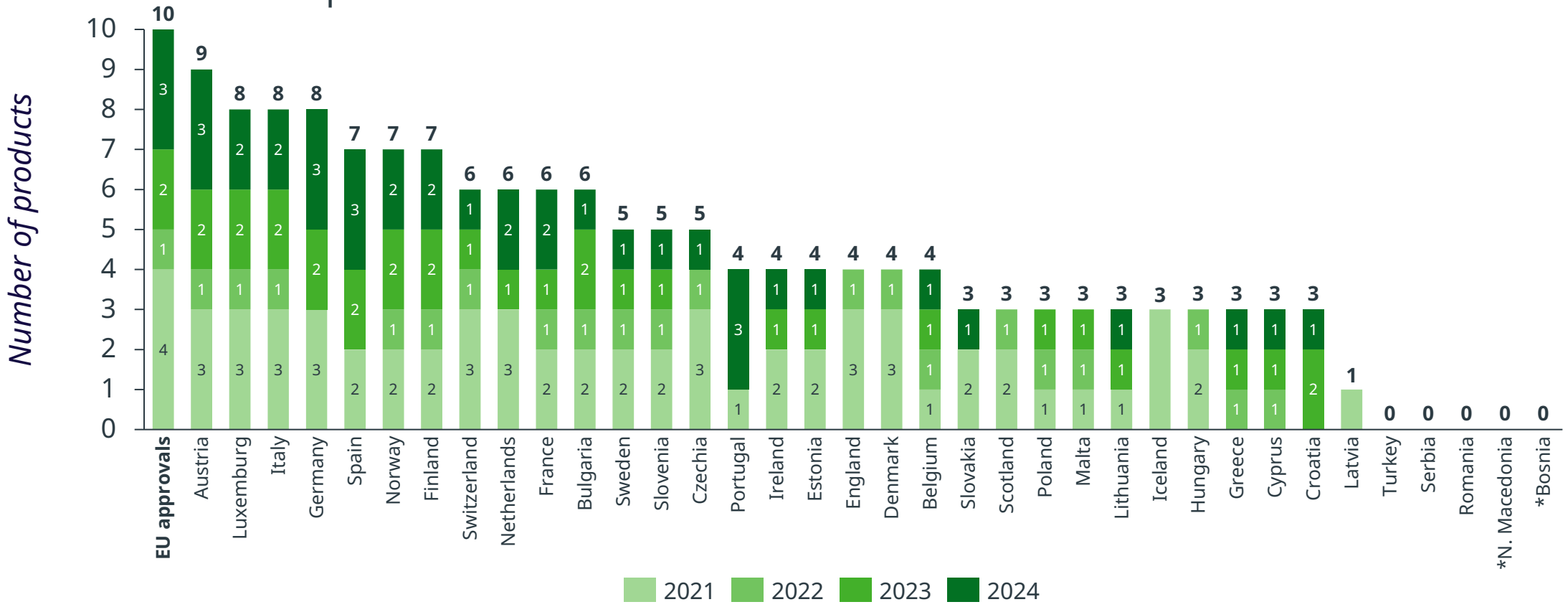
5. Combination therapies

Indicators:

5.1. Total availability by approval year
5.2. Rate of availability
5.3. Breakdown of availability
5.4. Breakdown of total availability (countries ordered by all availability)
5.5. Breakdown of total availability (countries ordered by full availability)
5.6. Time to availability
5.7. Median time to availability
5.8. Key observations

Combination therapies availability by approval year (2021-2024)

The **total availability by approval year** is the number of fixed dose combination 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†), split by the year the product received marketing authorisation in Europe.



European Union average: 5 products available (48%) Combination products can include innovative branded / generic combinations. †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.

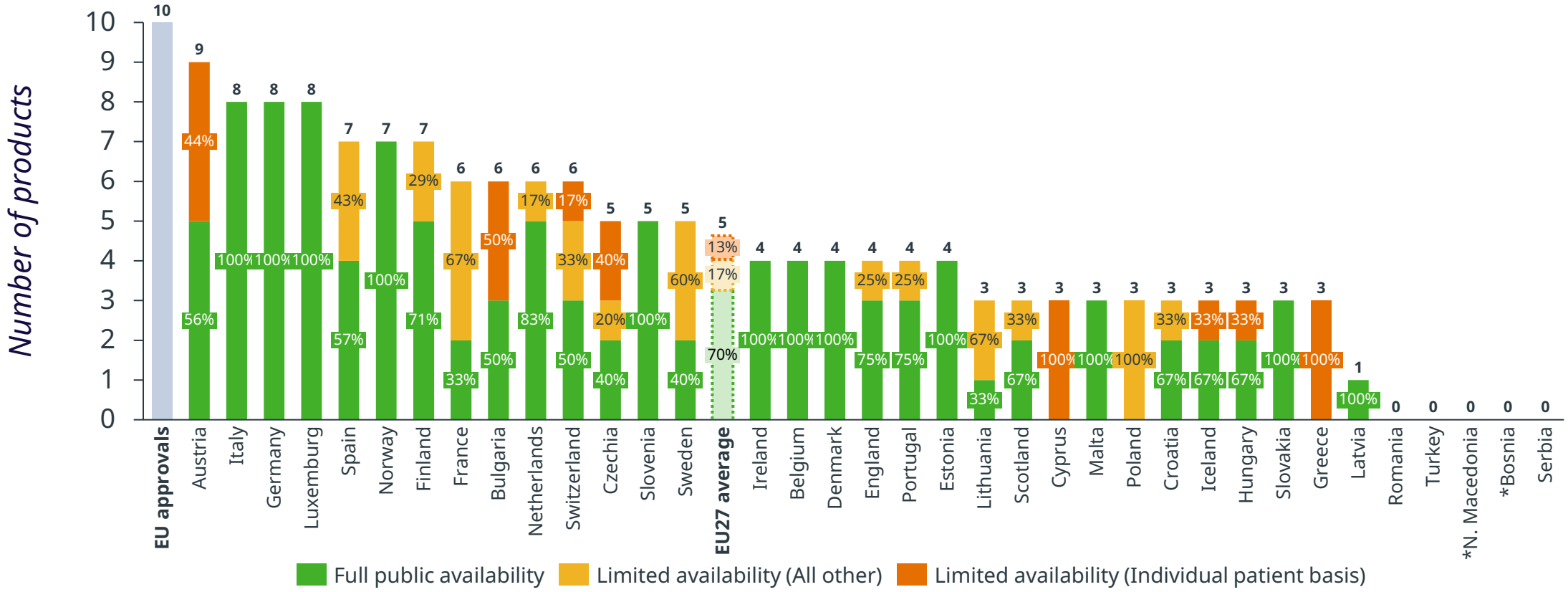
Combination therapies rate of availability (2021-2024)

The **rate of availability**, measured by the number of fixed dose combination 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: 5 products available (48%) Combination products can include innovative branded / generic combinations; †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.

Combination therapies breakdown of availability (%, 2021-2024)

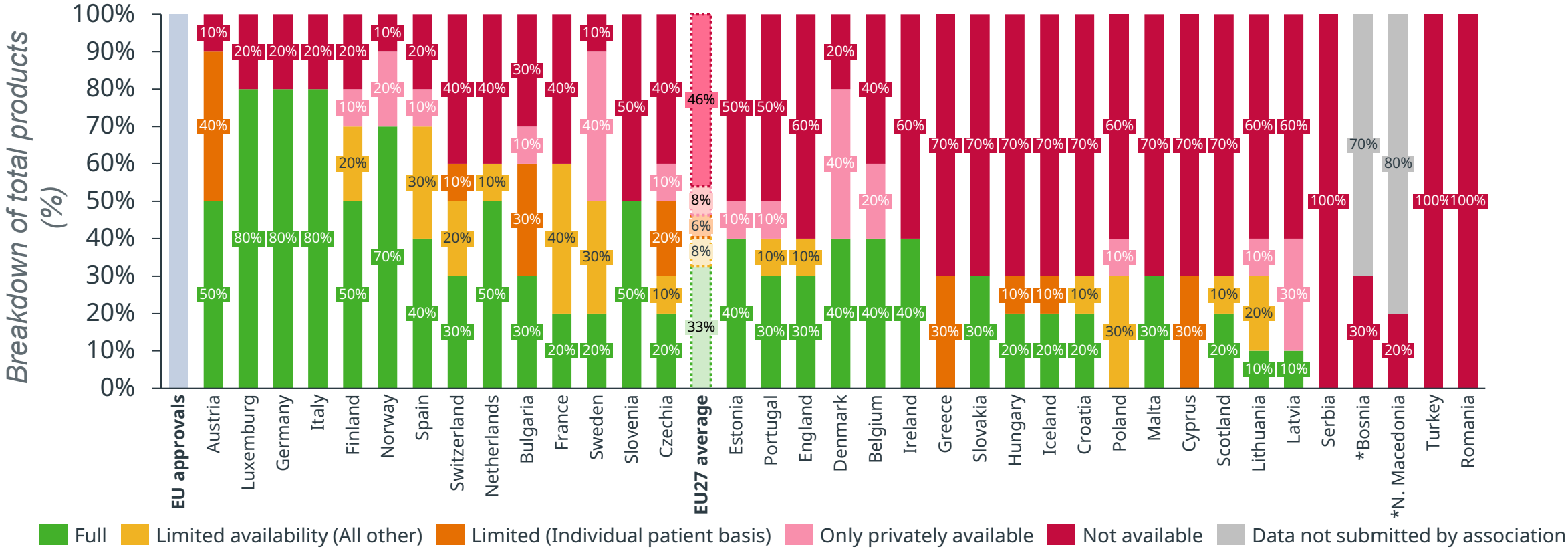
The **breakdown of availability** shows the proportion of medicines available to patients in European countries as of 5th January 2026 (for most countries this is the point at which the product gains access to the reimbursement list†) with full availability, via individual patient schemes, or with other restrictions.



European Union average: 5 products available (48%), limited availability (total) (30% of available products). Combination products can include innovative branded / generic combinations; †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.

Combination therapies breakdown of total availability (%, 2021-2024) *(countries ordered by all availability)*

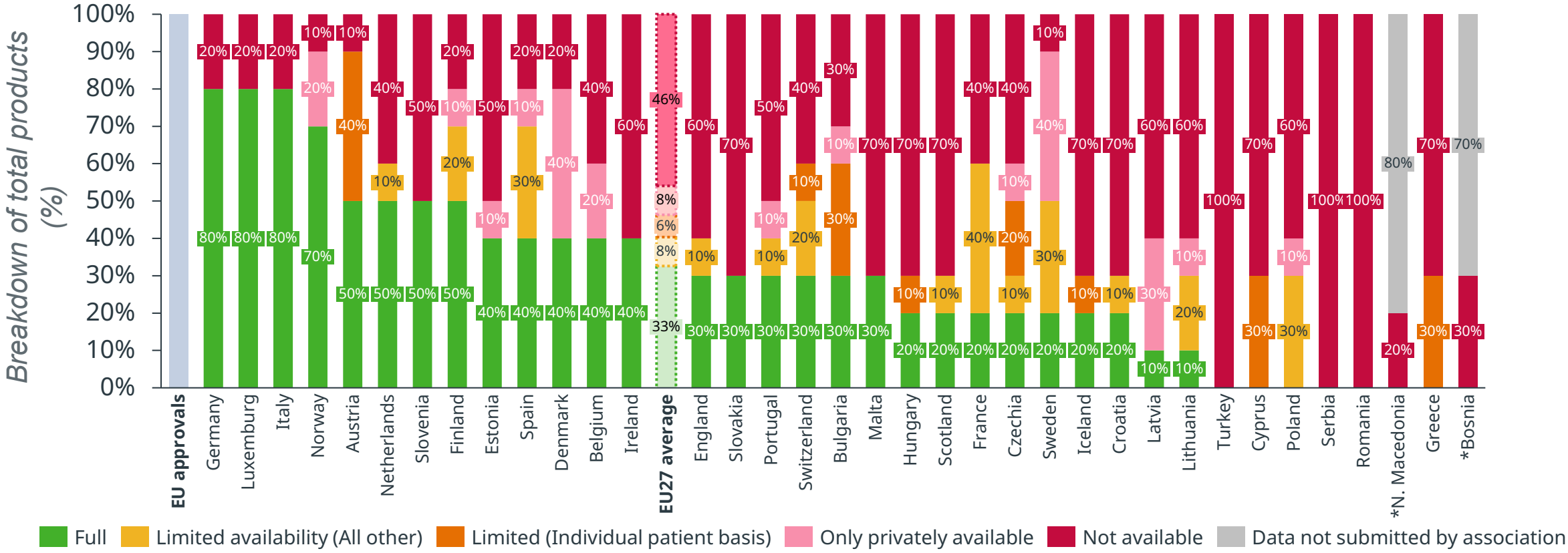
The **breakdown of total availability** is the composition of medicines available to patients in European countries as of 5th January 2026 (for most countries this is the point at which the product gains access to the reimbursement list†). This includes all medicine's status to provide a complete picture of availability.



European Union average: 5 products available (48%); Limited Availability (14% of all combination therapies) [1]; Combination products can include innovative branded / generic combinations; †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. [1] The average rate of availability is 48%; the reason this is not represented in the chart (where segments total 47%) is due to rounding.

Combination therapies breakdown of total availability (%, 2021-2024) *(countries ordered by full availability)*

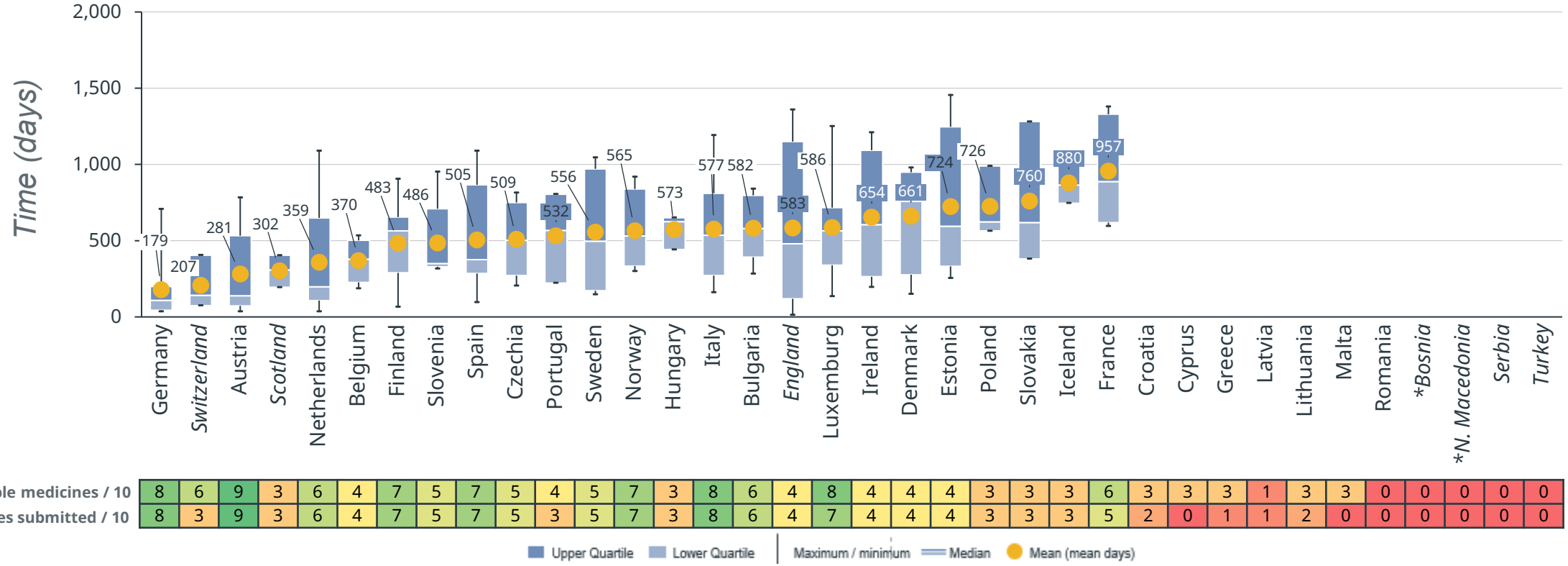
The **breakdown of total availability** is the composition of medicines available to patients in European countries as of 5th January 2026 (for most countries this is the point at which the product gains access to the reimbursement list†). This includes all medicine's status to provide a complete picture of availability.



European Union average: 5 products available (48%); Limited Availability (14% of all combination therapies) [1]**;** Combination products can include innovative branded / generic combinations; †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. [1] The average rate of availability is 48%; the reason this is not represented in the chart (where segments total 47%) is due to rounding.

Combination therapies time to availability (2021-2024)

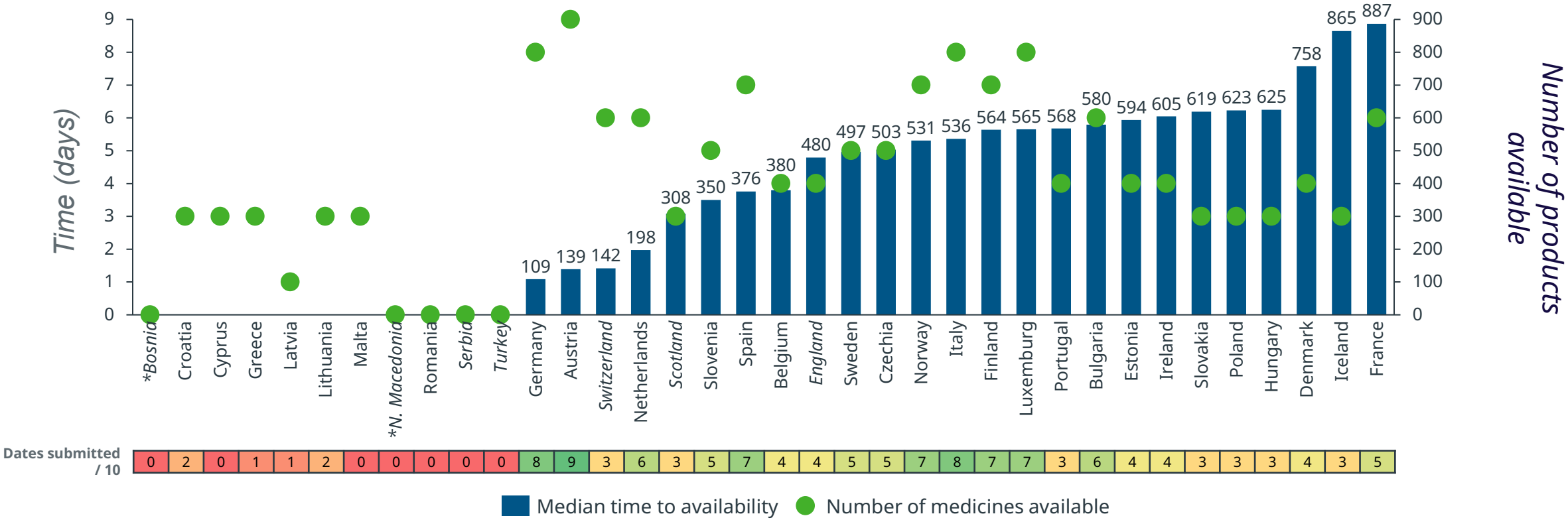
The **time to availability** is the days between marketing authorisation and the date of availability of fixed dose combination medicines to patients in European countries (for most this is the point at which products gain access to the reimbursement list†). The marketing authorisation date is the date 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: 553 days (mean) Combination products can include innovative branded / generic combinations; †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.

Combination 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: 504 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.

Key observations

Executive summary (EU27 averages)

Measure	All products	Oncology	Orphan	Non-oncologic orphan	Combination therapy
Average rate of availability	45% (46% in 2024)	51% (50% in 2024)	43% (42% in 2024)	39% (39% in 2024)	48% (55% in 2024) ↓
Average time to availability	597 Days (578 days in 2024)	655 Days (586 days in 2024) ↑	614 Days (611 days in 2024)	595 Days (607 days in 2024)	553 Days (553 days in 2024)

Key Insights

Rate of availability

- At EU level, combination therapies sit marginally above the overall average in terms of availability.
- Cautious interpretation is suggested as this segment includes very few products, making results sensitive to individual observations.

Time to availability

- Time to availability for combination therapies remains broadly similar to the previous year, and significantly shorter than the overall average.
- As with availability, findings should be interpreted with caution, reflecting the limited number of products included in this segment.

Metrics key:

Text colour indicates relative position versus the current (2025) EU average (*significantly worse than current EU average* / *significantly better than current EU average*)

Arrow colour indicates significant changes versus the previous (2024) EU average (*significant improvement versus previous year* ⇅ / *significant deterioration versus prior year* ⇅)

Average calculations:
Only a difference of +/- 5% (~30 days) is considered a significant change and therefore highlighted

Countries with fewer than three submitted dates were excluded from the time to availability EU27 average.

Notes: For the EU27 average time to availability, countries with fewer than three submitted dates were excluded to avoid unreliable estimates. As a result, Malta was excluded for the all products, oncology, orphan, and non-oncology orphan calculations, and Croatia, Cyprus, Greece, Latvia, Lithuania, Malta, and Romania were excluded for the combination therapy calculation.

6. Historic comparisons and extension

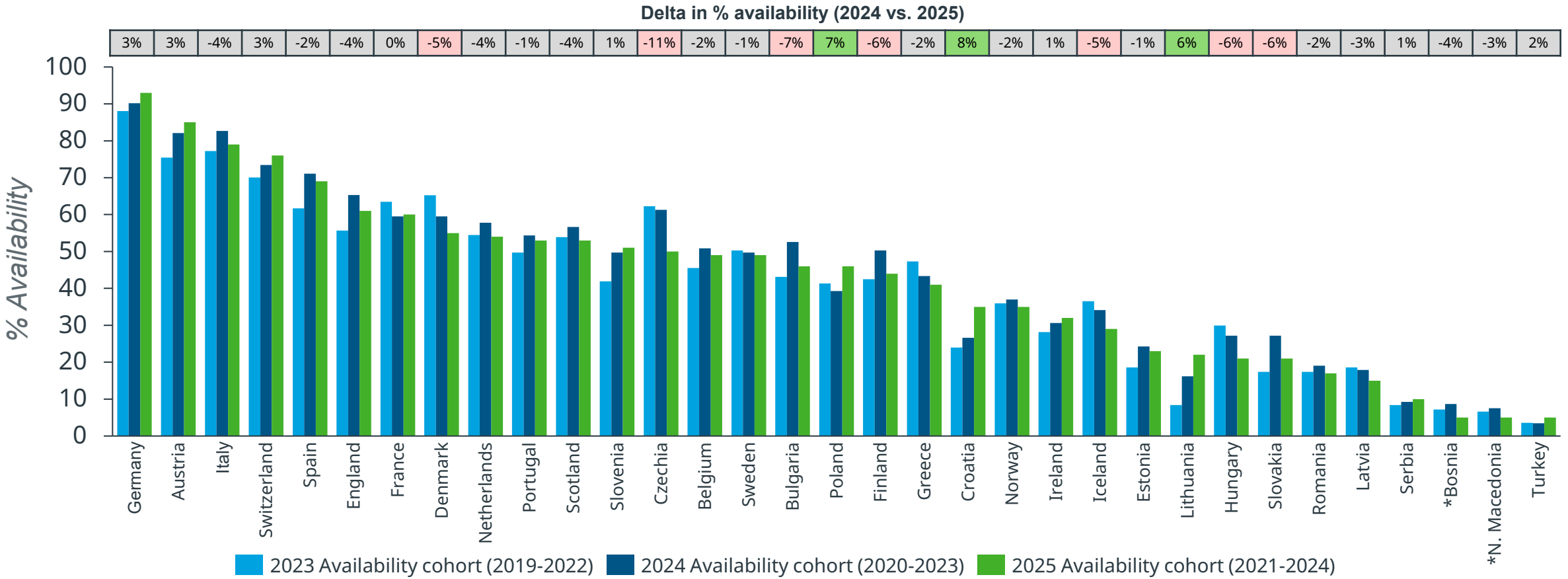
Indicators:

6.1. Comparison of availability versus prior studies (2023 – 2025)

6.2. Extended period of total availability (2014 – 2024)

Comparison of rate of availability (2023 study – 2025 study)

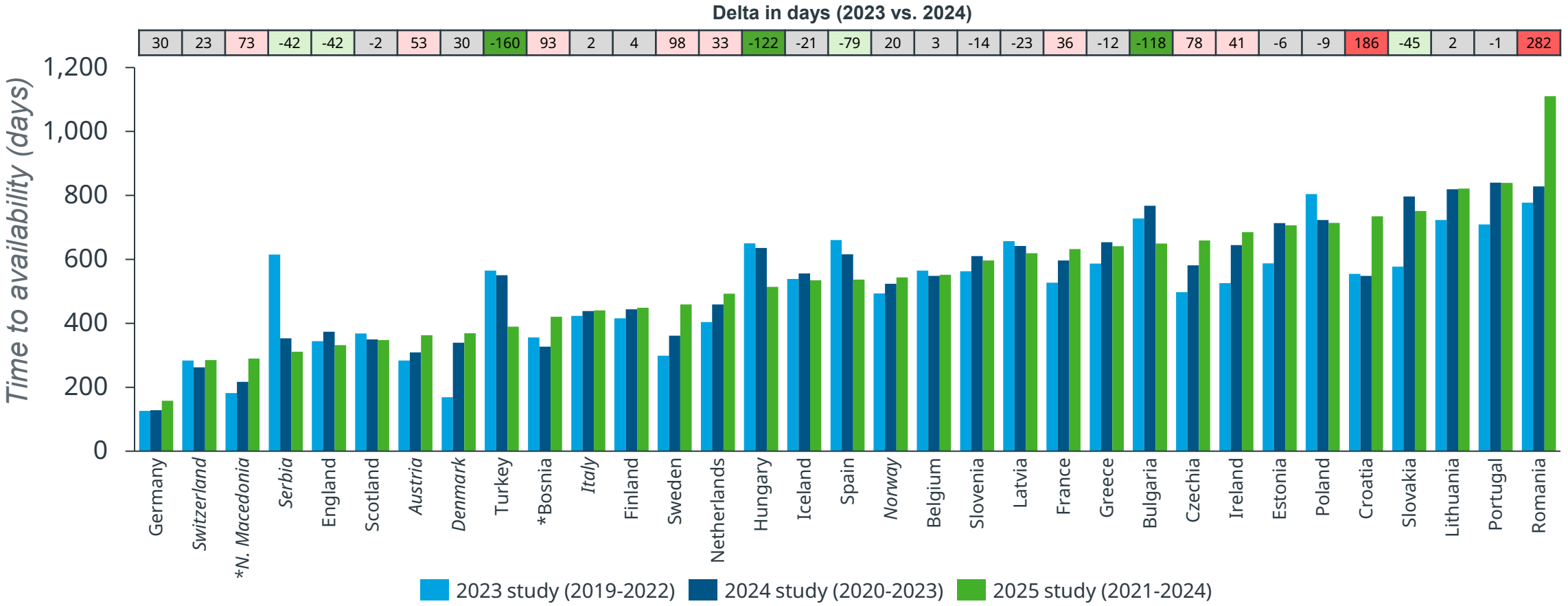
The **comparison of rate of availability**†, measured by the number of medicines available to patients in European countries as of 5th January 2026, compared to the rate of availability in previous (comparable) studies. Figures are based on the historic statistics published in the indicators.



Increases of <=5% are not considered to be statistically significant and are therefore highlighted in grey. Italy, England and Croatia have deltas of <5% but are listed as 5% here due to rounding. Note: Netherlands has retrospectively corrected 2020 data; †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. Differences in availability rates between years may appear as 0% due to rounding. This rounding effect can result in minor discrepancies that do not reflect significant changes.

Comparison of time to availability (2023 study – 2025 study)

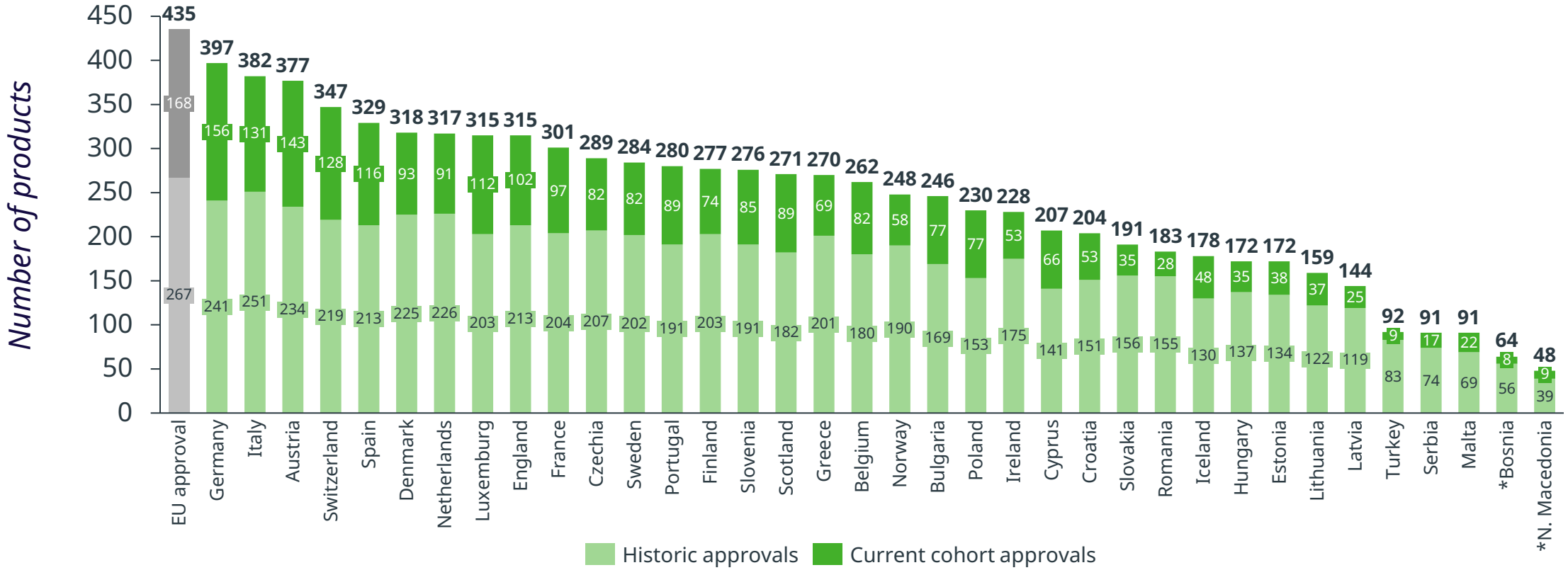
The **comparison of time to availability** is the days between marketing authorisation and the date of availability to patients compared to previous comparable studies. Figures are based on the historic statistics published in the indicators.



Changes of <=30 days are not considered to be statistically significant and are therefore highlighted in grey. 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; †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.

Extended period of total availability (2014-2024)

The **extended period of total availability** is the number of medicines available to patients in European countries (for most countries this is the point at which the product gains access to the reimbursement list†), split by the year the product received marketing authorization. It shows the additional data available within the Patients W.A.I.T. dataset that is not included within the standard 4-year rolling cohort.



European Union average: 256 products available (59%) †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.

Contents

Study metrics, definitions, and notes

Full methodology and definitions by country are available

Core metrics

The Patients W.A.I.T. Indicator shows 2 main metrics for innovative medicines within a 4 year rolling cohort:

1.) Rate of availability, measured by the number of medicines available to patients in European countries. For most countries this is the point at which the product gains access to the reimbursement list (this does not necessarily indicate uptake / usage).

2.) The time to availability*, measuring the average time between marketing authorisation and availability, using days from the date of marketing authorisation to the day of completion of post-marketing authorisation administrative processes (whether it is attributable to companies or competent authorities).

Availability definition

Description	Status
Full reimbursement through a national reimbursement system	Available
Full automatic reimbursement by a hospital budget (e.g. Nordic system)	
Limited reimbursement to specific subpopulations of approved indication	Available (marked LA^)
Limited reimbursement while decision is pending (where system permits)	
Availability through a special program (e.g. managed entry agreements)	
Limited reimbursement on a named patient basis (individual patient)	Available (Individual patient basis)
Available only within the private market at the patient's expense	Only privately available
Not reimbursed, or not reimbursed while awaiting decision	Not available

Notes and caveats

Source of information: EFPIA member associations, who either refer to information available from official sources, gather the information directly from member companies or in some cases use IQVIA sales data.

Local authorisation exceptions: Countries where local marketing authorisation dates are used to calculate the time to availability are: Bosnia and Herzegovina, England, North Macedonia, Scotland, Serbia, Switzerland and Turkey.

Completeness: Some country associations did not submit full datasets. Countries substantially limited data sets are: Bosnia (42% complete) and North Macedonia (51% complete). This is noted on slides with an asterisk (*).

Average calculations: The EU averages noted throughout are for the 27 countries in the European Union. EU averages of full / limited availability are calculated using absolute figures before determining the percentage. This approach ensures a more accurate representation by accounting for the varying number of available medicines in each EU country, thereby avoiding potential distortions that could arise from averaging individual country percentages

* **The Patients W.A.I.T. Indicator is not a measurement of the delays as defined in the "Transparency" Directive (directive 89/105/EEC)**. Delays under the "Transparency" Directive reflect the number of days that national competent authorities need to make their decisions regarding price and inclusion of medicines in the positive list, where applicable. These delays do not include the time needed to prepare submissions under relevant national regulations, which may also include clock-stops for supply of additional information during the process; neither do "Transparency" Directive delays include time required to complete other formalities before a new medicine can be made available in a given country. ^ LA = Limited Availability

Method and data availability

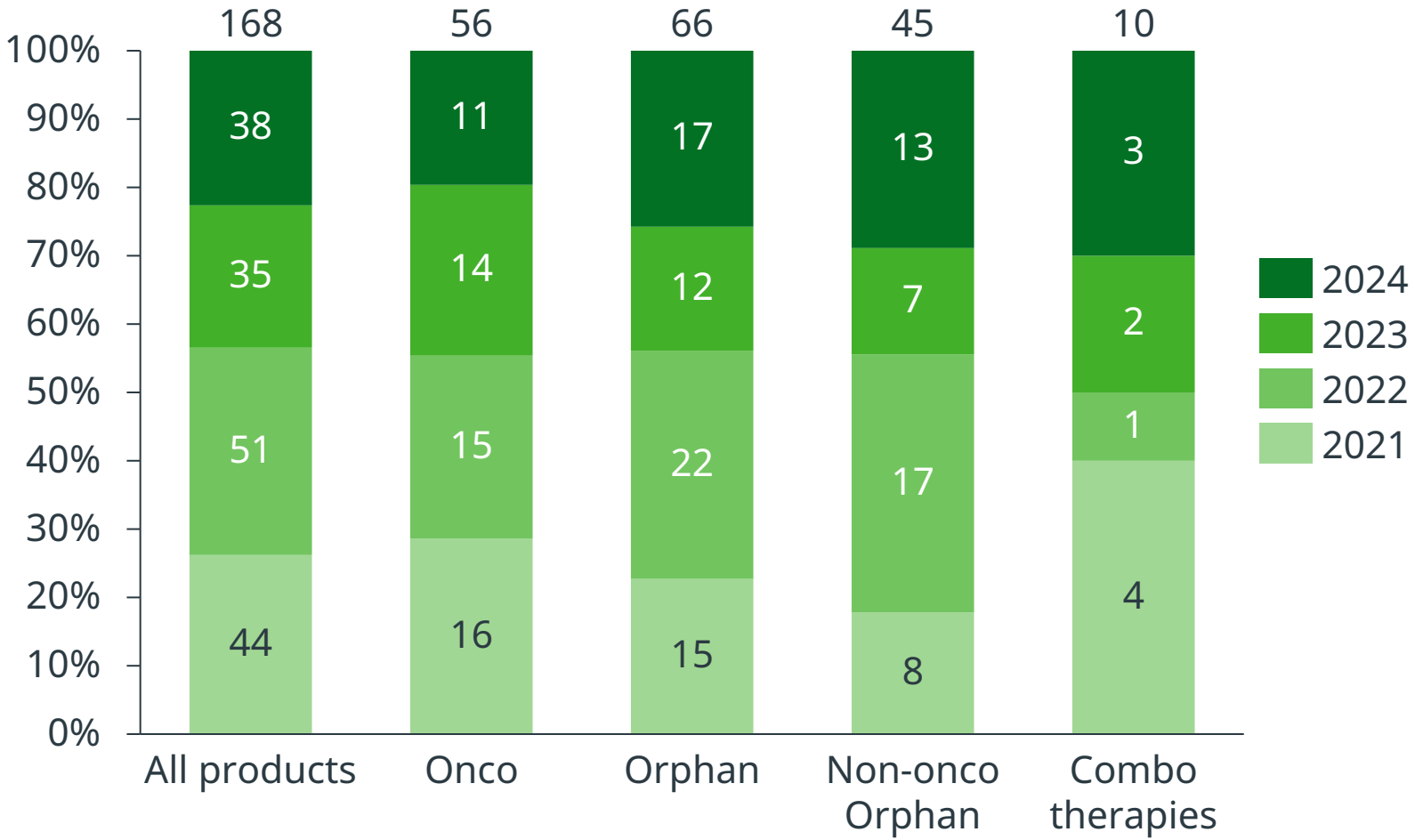
Process for product selection

EMA list	Products in scope	Full data cohort (11-years)	Report cohort (4-years)
• List of all historic Marketing Authorisations for human and veterinary medicines (European Public Assessment Reports) accessed November 2025 • Human medicines only	• Products with authorisation year: 2014, 2015, 2016, 2017, 2018, 2019, 2020, 2021, 2022, 2023, 2024 • Status: Authorised • Non-generic; Non-biosimilar; no vaccines • Include combinations (both products can have already been approved before) • Remove ATC K & T* • Exclude specific ATC V products**	• Removed products with an active substance approved pre-2014 • New combination products (those containing already approved active substances are included) • New formulations were excluded • New indications of already approved active substances, leading to a separate marketing authorisation only for an orphan drug are included • For molecules with multiple names from the same company only one molecule is included	• Medicines in the 4-year rolling cohort 2021 – 2024^ • Exclude products that have been withdrawn prior to analysis

* Removal ATC class exclusions: K = Hospital Solutions; V = Various, T = Diagnostics; Oncology definition used throughout = L1 & L2 & L3B1 & V3C & Proleukin
** In previous years, all products within ATC-V class have been excluded from the WAIT indicator; However, the criteria has been adapted to exclude ATC-V products that are allergens, diagnostic agents, general nutrients, contrast media, diagnostic radiopharmaceuticals, surgical dressings, and all other non-therapeutic products; Other new innovative therapeutics that are classified within ATC-V should be considered for inclusion.
^ Note: Products included in the WAIT indicator are aligned with products included in EFPIA Access Hurdles Portal

Study composition and category definitions

By year of marketing authorisation



Definitions:

- Products with central marketing authorisation, sourced from EMA EPARs (last accessed November 2025)
- Orphan status from EMA on orphan medical products (OMP) status
- Oncology products flagged using IQVIA MIDAS Oncology market definition: L1 & L2 & L3B1 & V3C & Proleukin
- Combination products include any product with more than one molecule, including branded / generic combinations in fixed doses.

Note: figures are subject to change versus previous year's due to product withdrawals

Products included in the study: 2021-2024 approvals (n=168)

Abecma	Drovelis/Lydisilka	Iqirvo	Nulibry	Ryeqo	Vabysmo
Adtralza	Ebglyss	Jaypirca	Obgemsa	Rystiggo	Vafseo
Adzynma	Ebvallo	Jemperli	Omjjara	Ryzneuta	Vanflyta
Agamree	Eladynos	Jeraygo	Omvoh	Saphnelo	Vazkepa
Akantior	Elahere	Kapruvia	Ontozry	Scemblix	Velsipity
Akeega	Elfabrio	Kerendia	Opdualag	Sibnayal	Veoza
Alhemo	Elrexfio	Kesimpta	Opfolda	Skyclarys	Verquvo
Altuvoct	Elzonris	Kimmtrak	Ordspono	Skytrofa	Voraxaze
Amvuttra	Emblaveo	Kinpeygo	Orgovyx	Sogroya	Voxzogo
Anzupgo	Enhertu	Klisyri	Orladeyo	Sotyktu	Voydeya
Aquipta	Enjaymo	Koselugo	Orserdu	Spevigo	Vumerity
Artesunate Amivas	Enspryng	Krazati	Padcev	Spexotras	Vydura
Aspaveli	Evkeeza	Litfulo	Pemazyre	Sunlenca	Vyepti
Awiqli	Evrenzo	Livmarli	Piasky	Tabrecta	Vyloy
Balversa	Evrysdi	Livtencity	Pluvicto	Talvey	Vyvgart
Bimzelx	Exblifep	Loargys	Pombiliti	Tavneos	Wegovy
Breyanzi	Fabhalta	Loqtorzi	Ponvory	Tecovirimat SIGA	Winrevair
Briumvi	Filspari	Lumykras	Pyrukynd	Tecvayli	Xenpozyme
Brukinsa	Filsuvez	Lunsumio	Qalsody	Tepkinly	Xofluza
Byfavo	Finlee	Lupkynis	Qinlock	Tepmetko	Yorvipath
Bylvay	Fruzaqla	Lyfnua	Quviviq	Tevimbra	Yselty
Camzyos	Hemgenix	Lytenava	Rayvow	Tezspire	Yuvanci
Carvykti	Hyftor	Lytgobi	Retsevmo	Tibsovo	Zegalogue
Casgevy	Hympavzi	Minjuvi	Rezzayo	Trodelvy	Zilbrysq
Cejemly	Imcivree	Mounjaro	Roclanda	Truqap	Zokinvy
Cibinqo	Imjudo	Nexpovio	Roctavian	Tukysa	Ztalmy
Columvi	Inaqovi	Nexviadyme	Rukobia	Uplizna	Zynlonta
Copiktra	Inrebic	Ngenla	Rybrevant	Upstaza	Zynyz
Abecma	*Drovelis/Lydisilka	Iqirvo	Nulibry	Ryeqo	Vabysmo

* Drovelis and Lydisilka were treated as one product for the purpose of this analysis as there are multiple authorisations for the same active substance combination on the same date

Products included in the study: 2021-2024 approvals (n=168)

Oncologics (n=56)

Abecma	Minjuvi
Akeega	Nexpovio
Balversa	Omjjara
Breyanzi	Opdualag
Brukinsa	Orgovyx
Carvykti	Orserdu
Cejemly	Padcev
Columvi	Pemazyre
Copiktra	Pluvicto
Ebvallo	Qinlock
Elahere	Retsevmo
Elrexfio	Rybrevant
Elzonris	Scemblix
Enhertu	Spexotras
Finlee	Tabrecta
Fruzaqla	Talvey
Imjudo	Tecvayli
Inaqovi	Tepkinly
Inrebic	Tepmetko
Jaypirca	Tevimbra
Jemperli	Tibsovo
Kimmtrak	Trodelvy
Koselugo	Truqap
Krazati	Tukysa
Loqtorzi	Vanflyta
Lumykras	Vyloy
Lunsumio	Zynlonta
Lytgobi	Zynyz

Orphans (n=66)

Abecma	Lunsumio
Adzynma	Minjuvi
Agamree	Ngenla
Akantior	Nulibry
Altuvoct	Omjjara
Amvuttra	Ordspono
Artesunate Amivas	Pemazyre
Aspaveli	Pyrukynd
Bylvay	Qalsody
Carvykti	Qinlock
Casgevy	Rezzayo
Columvi	Roctavian
Ebvallo	Rystiggo
Elahere	Scemblix
Elzonris	Skyclarys
Enjaymo	Skytrofa
Enspryng	Sogroya
Evrysdi	Spexotras
Fabhalta	Talvey
Filspari	Tavneos
Filsuvez	Tepkinly
Finlee	Tibsovo
Hemgenix	Upstaza
Hyftor	Voraxaze
Imcivree	Voxzogo
Inrebic	Voydeya
Iqirvo	Vyloy
Kimmtrak	Vyvgart
Kinpeygo	Winrevair
Koselugo	Xenpozyme
Livmarli	Yorvipath
Livtencity	Zokinvy
Loargys	Ztalmy

Non-oncologic orphans (n=45)

Adzynma	Ngenla
Agamree	Nulibry
Akantior	Ordspono
Altuvoct	Pyrukynd
Amvuttra	Qalsody
Artesunate Amivas	Rezzayo
Aspaveli	Roctavian
Bylvay	Rystiggo
Casgevy	Skyclarys
Enjaymo	Skytrofa
Enspryng	Sogroya
Evrysdi	Tavneos
Fabhalta	Upstaza
Filspari	Voraxaze
Filsuvez	Voxzogo
Hemgenix	Voydeya
Hyftor	Vyvgart
Imcivree	Winrevair
Iqirvo	Xenpozyme
Kinpeygo	Yorvipath
Livmarli	Zokinvy
Livtencity	Ztalmy
Loargys	

Combination therapies (n=10)

Akeega	Opdualag
Drovelis/Lydisilka	Roclanda
Emblaveo	Ryeqo
Exblifep	Sibnayal
Inaqovi	Yuvanci

Notes: Segments are not mutually exclusive; * Drovelis and Lydisilka were treated as one product for the purpose of this analysis as there are multiple authorisations for the same active substance combination on the same date

Country specific definitions of products with availability

Country	Definition of availability
Austria	A medicine is available if it is included in the reimbursement system (EKO) or available through the Austrian pharmacies list
Belgium	Medicine is available if it is listed on the official website of INAMI-RIZIV as a definitive reimbursement or as a temporary reimbursement (code T) under a Managed Entry Agreement
Bosnia	Accessibility on the public reimbursement list
Bulgaria	Accessibility on the public reimbursement list
Croatia	Accessibility on the public reimbursement list
Cyprus	Accessibility on the public reimbursement list
Czechia	Product present on the market either (a) reimbursed or (b) not reimbursed but covered by patient or by individual patient approval by insurance funds
Denmark	***REFINED*** A product is considered available on the Danish market, when approved for reimbursement by the Danish Medicines Agency or received a recommendation from the Danish Medicines Council.
England	Medicines are deemed available if NICE has issued a positive recommendation or is associated with a commissioning policy as reported on the NHS England high cost drugs commissioning list. For the remaining medicines, IQVIA sales data are analysed to determine if routinely available.
Estonia	A pharmacy product is available if it is reimbursed (pharmacy products) or added to the hospital service list.
Finland	***REFINED*** Medicines are considered available if there is a positive decision by HILA or a positive recommendation either by COHERE or FINCCHTA, or a conditionally positive COHERE recommendation is followed by a procurement decision. For the remaining medicines hospital formulary decisions and sales data is analysed to determine if products are routinely available through hospital budget.
France	Accessibility on the public reimbursement list
Germany	Following marketing authorisation, prescription drugs automatically receive reimbursed status
Greece	Accessibility on the public reimbursement list
Hungary	Medicines are either reimbursed through the indication linked reimbursement system, or available by special finance system (item based) or financed by hospital budget
Iceland	Accessibility on the public reimbursement list
Ireland	Accessibility on the public reimbursement list, through a hospital setting or other public scheme
Italy	A product is available if it has received reimbursement status
Latvia	Accessibility on the public reimbursement list
Lithuania	Accessibility on the public reimbursement list
Luxembourg	***REFINED*** Accessibility on the public reimbursement list (retail drugs + Products D) or commercialized list for Products H (hospital drugs)
Malta	Accessibility on the public reimbursement list
Netherlands	Accessibility on the public reimbursement list
North Macedonia	Product is available via specially allocated budget for all eligible patients
Norway	***REFINED*** The medicines has received a positive reimbursement decision by NoMA (out-patient drugs), or the Decision Forum (hospital products), and are made available for patients.
Poland	In most cases a medicine is available if it gains access to the reimbursement list; some medicines are financed via state budget and the date of accessibility would be the date of tender results published by governmental payers.
Portugal	Accessibility on the public reimbursement list
Romania	For 98% of reimbursed medicines, accessibility is considered to be at therapeutic protocol publication (as the HCP cannot prescribe the product until the therapeutic protocols are published). For the remaining 2% of reimbursed medicines that don't need therapeutic protocols, accessibility is after publication in the reimbursement list.
Scotland	Medicines are deemed available if SMC has issued a positive HTA recommendation. For the remaining medicines, IQVIA sales data are analysed to determine if routinely available.
Serbia	Accessibility on the public reimbursement list
Slovakia	***REFINED*** Availability according to: 1) Reimbursement list valid from January 1, 2026, or 2) DRG list valid for the year 2026 for drugs used during hospitalization (hospital-only products).
Slovenia	A medicine is available if it is reimbursed through the regular system, or automatically reimbursed
Spain	Accessibility on the public reimbursement list
Sweden	***REFINED*** A medicine is classified as available (nationally reimbursed) if it was marketed in Sweden as of December 12th 2025 (listed as supplied in FASS) and: is indicated for a disease included in the communicable disease program, or had received a positive TLV decision (prescribed drugs), or - had received a positive recommendation from the New Therapies (NT) Council (hospital drugs), or - had not received an NT-recommendation and is not part of national managed introduction (hospital drugs).
Switzerland	The medicine gained market approval by Swissmedic. Delay calculated using local market authorisation and dates from admission into the specialty list.
Turkey	A medicine is available if it gains access to the reimbursement list (SSI HIC Annex 4/A).

Country specific definitions of products with limited availability (1 of 2)

Country	Definition of limited availability
Austria	Products outside reimbursement system (EKO), but reimbursed on individual pre-approval (No Box)
Belgium	No products are reported to have limited availability
Bosnia	There are no restrictions on availability
Bulgaria	Reimbursement is only granted for specific subpopulations of the approved indications, for individual patients on a named patient basis or there is limited reimbursement while a decision is pending.
Croatia	Products are available for specific patient cohorts (reimbursement guidelines outline specific criteria describing patient eligibility for treatment).
Cyprus	Reimbursement is only granted, on an individual name patient basis or for specific subpopulations of the approved indications.
Czechia	Reimbursed only if: (a) prescribed by specific speciality of physician; (b) specific setting (e.g. Centers of excellence) (c) hospital product only
Denmark	***REFINED*** Products that have received a partial recommendation by the Danish Medicines Council or are on the Interregional Forum's list of product with individual access as well as products that have received conditional reimbursement or single reimbursement on widely used medicines on the Danish Medicines Agency's list.
England	Recommended for a restricted patient cohort relative to licensed indication, either: (a) through an optimised NICE decision (including optimised CDF decisions) or an individual funding request. (b) where at least one indication is recommended for use but either optimised, not recommended, or no decision reached to date for another indication.
Estonia	Only reimbursed for restricted patient cohort.
Finland	***REFINED*** Medicines are considered to have limited availability if a) HILA has granted reimbursement as restricted; b) COHERE's or FINCCHTA's recommendation is restricted for certain subpopulations / indications / named patient use; or if hospital procurement decision includes limitations or are regional only.
France	Some innovative products without competitors can be made available prior to market authorisation under the Early Access program.
Germany	There are no restrictions on availability meaning drugs are reimbursable in all patient populations.
Greece	Only reimbursed for restricted patient cohorts, or case by case reimbursement if the responsible committee judges its use necessary.
Hungary	Medicine is available through a Name Patient Program (access depends on application for individual use)
Iceland	Products are available to the patients with full reimbursement, but only through individual reimbursement, which can be applied for on individual basis by the patient's doctor.
Ireland	Subject to Managed Access Protocol
Italy	A product has limited availability if it has not received the reimbursement status (decision is pending) but it is dispensed, generally, via hospital for a specific subpopulation, subject to medical advice. It is not at patient's expense
Latvia	Limited reimbursement to specific subpopulations of the approved indications; individual reimbursement (limited reimbursement on the named patient basis)
Lithuania	Only reimbursed for limited indications (compared to what was approved at market authorisation)
Luxembourg	A medicine is indicated for a specific population of patients who meet clearly defined criteria, such as contraindications to standard treatments, medical precautions, or personal preferences. Access to the medicine requires documented evidence in the patient's medical record confirming their eligibility at the time of the request for reimbursement or treatment.
Malta	Limited availability means on a named patient basis or similar or at times approved on a named patient basis for subpopulations.
Netherlands	Only reimbursed under certain therapeutic conditions (annex 2 on the positive reimbursement list).
North Macedonia	Product is available via specially allocated budget for limited number of patients
Norway	The Association has only information on limited availability for specific subpopulation of the approved indication. We have no access to public information on limited availability to individual patients (named patient basis), or a group of patients while decision is pending
Poland	Only reimbursed for limited indications (compared to what was approved at market authorisation)
Portugal	Product is only available on a patient by patient basis and after an Exceptional Authorisation has been granted, usually while public financing decision is pending (i.e., during the assessment process)
Romania	Reimbursement is only granted for specific subpopulations of the approved indications, for individual patients on a named patient basis or there is limited reimbursement while a decision is pending. Limited availability refers also to MEA.
Scotland	Recommended for a restricted patient cohort relative to licenced indication by SMC using their HTA process (through submission or resubmission)

Country specific definitions of products with limited availability (2 of 2)

Country	Definition of limited availability
Serbia	***REFINED*** Products are reimbursed with significant restriction on the number of patients. There are two types of limited availability: 1) where medicine is listed as reimbursed but in reality not all patients can get it because Health Fund buys limited number of packs per year so there are special Committees tasked with approving therapy 2) where medicine is not publicly listed as reimbursed, but you can still get it from Health Fund free of charge on a name basis (e.g. Article 9 of the Rulebook allowing hospitals to buy non-reimbursed medicines for patients that have no other therapeutic options on reimbursement list)
Slovakia	***REFINED*** Drugs included in the reimbursement list may have limitations (prescription limitations defining the specialist who can prescribe the drug) or indication limitations (specification of the reimbursed subpopulation).
Slovenia	Only reimbursed for restricted patient cohort
Spain	Only reimbursed for restricted patient cohort
Sweden	Only reimbursed for restricted patient cohort
Switzerland	For products pending reimbursement, patients have restricted reimbursement access. Such restricted access includes 'individual reimbursement' regulated by Art. 71a-b of KVV ordinance.
Turkey	Products only available through a "Named Patient Scheme". These medicines do not require TITCK (Turkish Medical Agency) approval but are reimbursed (SSI HIC Annex 4/C).

Country specific definitions of the availability date (1 of 2)

Country	Definition of the availability date
Austria	The first date of availability on the public reimbursement list or Austrian Pharmacies list
Belgium	The first date of availability on the public reimbursement list available on the website of the payer INAMI-RIZIV: https://webappsa.riziv-inami.fgov.be/ssp/ProductSearch
Bosnia	The first date of availability on the public reimbursement list
Bulgaria	In general, new innovative products are eligible for reimbursement as of 1st January following the year they have been included in PDL, however there are nuances and exceptions.
Croatia	The first date of availability on the public reimbursement list
Cyprus	The time that the product is available on the public reimbursement list
Czechia	The first date of availability on the public reimbursement list. If not reimbursed, date of first availability on the market.
Denmark	The time to availability is measured as the number of days between the central marketing authorisation and the first date for the decision by the Danish Medicines Agency or by the Danish Medicines Council.
England	For medicines with a positive NICE recommendation, the accessibility date is the date of publication of the Final Draft Guidance produced by NICE (oncology medicines), or date of published guidance + 90 days (non-oncology medicines). Oncology medicines benefit from earlier funding. The remaining medicines are assessed to determine whether access achieved through NHS England specialist commissioning routes. For these cases accessibility will be date of inclusion onto NHS England High Cost drugs commissioning list. All medicines not subject to NICE assessment, or NHS England specialist commissioning, are assessed using IQVIA sales data, with accessibility determined by reported sales.
Estonia	Availability date of reimbursement list and date of inclusion to the health service list or state project tender decision time.
Finland	***REFINED*** The date of availability is the first day of reimbursement following HILA's positive decision, or the date when the procurement contract becomes valid following either COHERE's or FINCCHTA's recommendation. For the remaining medicines, it is the date when regular sales are recorded as started.
France	The first date of availability on the public reimbursement list
Germany	Date of market entry listed in the LauerTaxe
Greece	The first date of availability on the public reimbursement list
Hungary	The date when the therapy is available for the first patient. This is the earliest date that the therapy is available on the public reimbursement list or the date the first patient received the therapy in Named Patient Program.
Iceland	The first date of availability on the public reimbursement list
Ireland	The first date of availability on the public reimbursement list
Italy	The first date of availability on the public reimbursement list
Latvia	The first date of availability on the public reimbursement list
Lithuania	The date of the decision to include the medicine into the public reimbursement list
Luxembourg	***REFINED*** The date of the decision to include the medicine into the public reimbursement list (retail drugs + Products D) or commercialized list for Products H (hospital drugs)
Malta	The first date of availability on the public reimbursement list
Netherlands	The first date of availability on the public reimbursement list
North Macedonia	The Positive Drug List has not been revised for more than 10 years. Therefore, availability dates are provided on a case by case basis.
Norway	The first date of availability on the public reimbursement list; or for hospital products, the date of the positive decision in Decision Forum
Poland	The first date of availability on the public reimbursement list, except for HIV / haemophilia drugs (financed by state budget) where availability date is date of publication of tender results or date of first order received from companies.
Portugal	The first date of availability on the public reimbursement list
Romania	Date of publication of government decision (for medicines that don't need therapeutic protocols elaboration or update) or therapeutic protocols (for the majority of medicines) in the Official Journal.
Scotland	For medicines with a positive SMC recommendation, the accessibility date is the date of published guidance. For remaining medicines, IQVIA sales data is analysed to determine month of routine availability.

Country specific definitions of the availability date (2 of 2)

Country	Definition of the availability date
Serbia	The first date of availability on the public reimbursement list
Slovakia	***REFINED*** The first date of availability on the reimbursement list (published on a monthly basis) or on the DRG list for hospital-only drugs (published annually starting January 1st and valid for the remainder of the respective year).
Slovenia	The first date of availability on the public reimbursement list
Spain	The first date of availability on the public reimbursement list
Sweden	For medicines indicated for diseases included in the communicable disease program: date of marketing in Sweden (supplied in FASS); For nationally reimbursed prescription medicines with a TLV decision: date of TLV decision; For nationally reimbursed hospital drugs with an NT-recommendation: date of NT recommendation; For nationally reimbursed hospital medicines lacking an NT-recommendation and not part of national managed introduction: date of marketing in Sweden (supplied in FASS)
Switzerland	The date of full availability is the first date of availability on the public reimbursement list (specialty list). The time to availability is the duration from Marketing Authorization Swissmedic until the admission into the specialty list.
Turkey	The date of full availability is the first date of availability on the public reimbursement list; the date of limited availability is the first date of availability on the list of products reimbursed through “Named Patient Scheme”

Country specific early access schemes

Some countries operate early access pathways that can enable patient access outside the standard reimbursement route. These pathways are not captured in the core time-to-availability indicator. Where local industry associations have provided a description of their early access pathway, this is summarised below; where early access dates have been submitted, an alternative time-to-availability measure (including early access) is also shown. This is not an exhaustive list of early access schemes across Europe.

Country	Summary of scheme
France	France operates the Accès précoce scheme, which can apply to products with a longer price negotiation process; products covered by this scheme may therefore have a longer negotiation period. In this study, when Accès précoce dates are included (n = number of Accès précoce dates submitted), the mean time to availability is 486.7 days (n=16) for all products, 542.5 days (n=9) for oncology, 431.4 days (n=10) for orphan, 432.7 days (n=5) for non-oncology orphans, and 854.8 days (n=1) for combination therapies.
Spain	In Spain, the WAIT analysis does not identify those medicinal products being accessible earlier in conformity with Spain's Royal Decree 1015/2009 relating to Medicines in Special Situations
England and Scotland	In the UK, MHRA's Early Access to Medicines Scheme provides access prior to marketing authorisation but is not included within this analysis, and would reduce the overall days for a small subset of medicines.
Portugal	Portugal operates the Programa de Acesso Precoce (PAP) scheme. In this study, products covered by PAP are recorded with the availability status "Limited reimbursement while decision is pending"; availability dates captured under this status can precede the formal reimbursement date, as PAP provides interim access while HTA and reimbursement decisions are finalised (typically where there is significant unmet need and no viable therapeutic alternatives). As a result, inclusion of PAP availability dates may impact the time-to-availability metric for a subset of medicines.

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