EFPIA Patients W.A.I.T. Indicator 2024 Survey

Published April 2025

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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 173 innovative medicines with central-marketing authorisation between 2020 and 2023 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 2025.*

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 26 countries and 4 years of novel medicine approvals, with a historic dataset covering 10-years of data

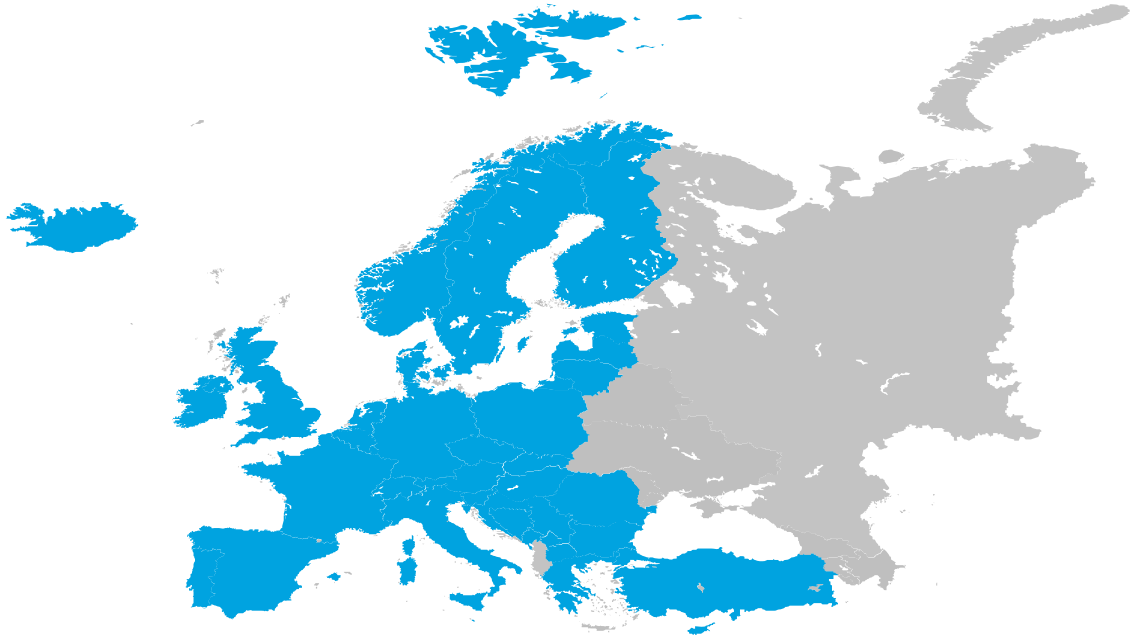
Widely referenced

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

Contents

Patients W.A.I.T. Indicator 2024 Survey: Overview and updates

W.A.I.T. is a study created to **categorise** similar systems and access routes to permit a **comparison** of European access



36 European countries

173 innovative medicines

4 year cohort (‘20-’23)

Updates in 2024

This year’s iteration of the W.A.I.T. report continues the core availability metrics, whilst also evolving to remain relevant in the current access landscape. The updates below support the continued relevance and use of the data presented.

Additional context

To clarify the scope of the W.A.I.T .Indicator report in providing data and insights on the access landscape in Europe

Reading guide

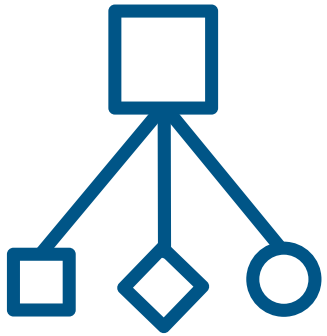
To support stakeholders in understanding the value, limitations, and use cases of each KPI

New indicators

To provide granularity on when individual patient schemes are the only access route

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

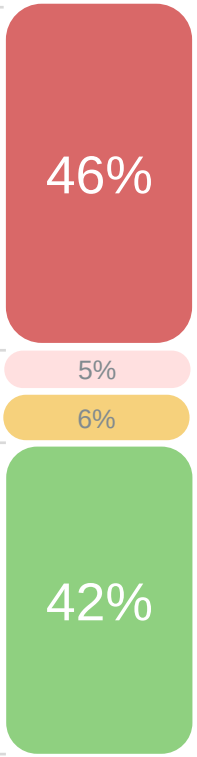
Historic landscape (2019)

Not available

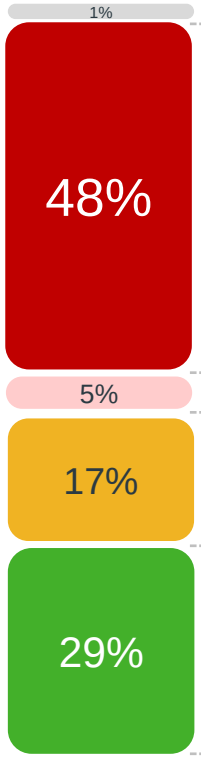
In 2019, almost half of all innovative medicines were not available to patients

Full availability

In 2019, the primary route of access to innovative medicines was via full availability (inclusion on the public reimbursement list)



Current landscape (2024)



Not available

In 2024, there has been a slight increase in unavailability, and nearly half of all innovative medicines are not available to patients

Limited availability

In 2024, a significant portion of products are only available with restrictions

Full availability

In 2024, the portion of products fully available on public reimbursement lists has decreased to 29%

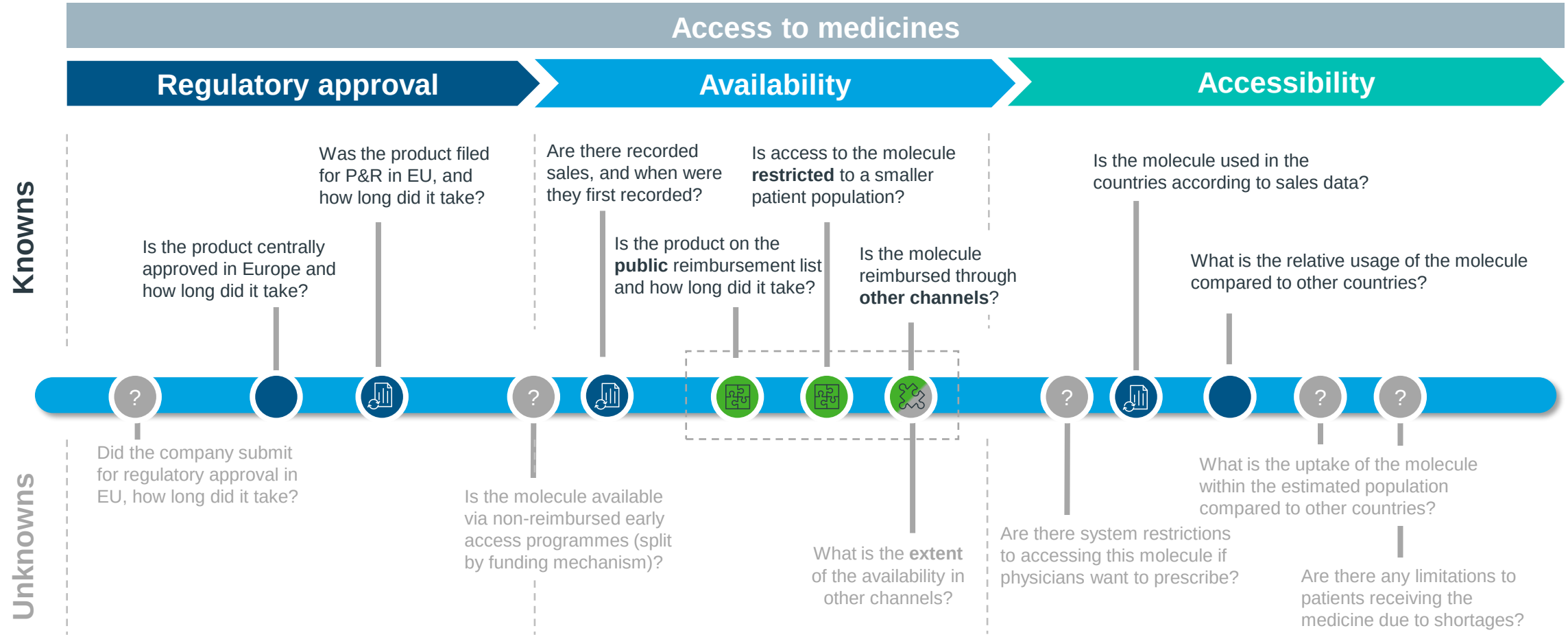
Full availability | Limited Availability | Only available privately | Not available | Data unavailable

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

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 2024 W.A.I.T. study (EU average from EU27 countries)

The Patients W.A.I.T. Indicator study 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



Part of the W.A.I.T. report | Partial coverage in W.A.I.T. report | Included in 'Root Causes' supplement

* 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'

Contents

Patients W.A.I.T. Indicator 2024 Survey: Executive summary

29% **EU average rate of full availability** remains at a **similar level** to last year (27% in 2023 study)

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

578 days **EU average time to availability** is over **1 month longer** than the previous study (531 days in 2023 study)

87% **Access disparity remains >80%** between the highest and lowest European country for multiple studies

Source: EFPIA Patients WAIT indicator (2023 and 2024)

Notes for consideration

1. **Cohort composition:** Although orphan time to availability has risen back to '2022 study' levels, the changing cohort composition compared to last year was a key driver and must be considered (the size of '2019 EMA approval' cohort was notably smaller and skewed previous results)

2. **Availability over time:** Whilst average availability improved nominally, the long-term view would suggest that the access situation has not changed significantly, and that the disparity persists

3. **Limited availability:** Limited availability has become an increasingly significant proportion of overall product availability since the 2019 study, and is of greater focus of this report

4. **W.A.I.T 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 (2020-2023 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 standarised 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)

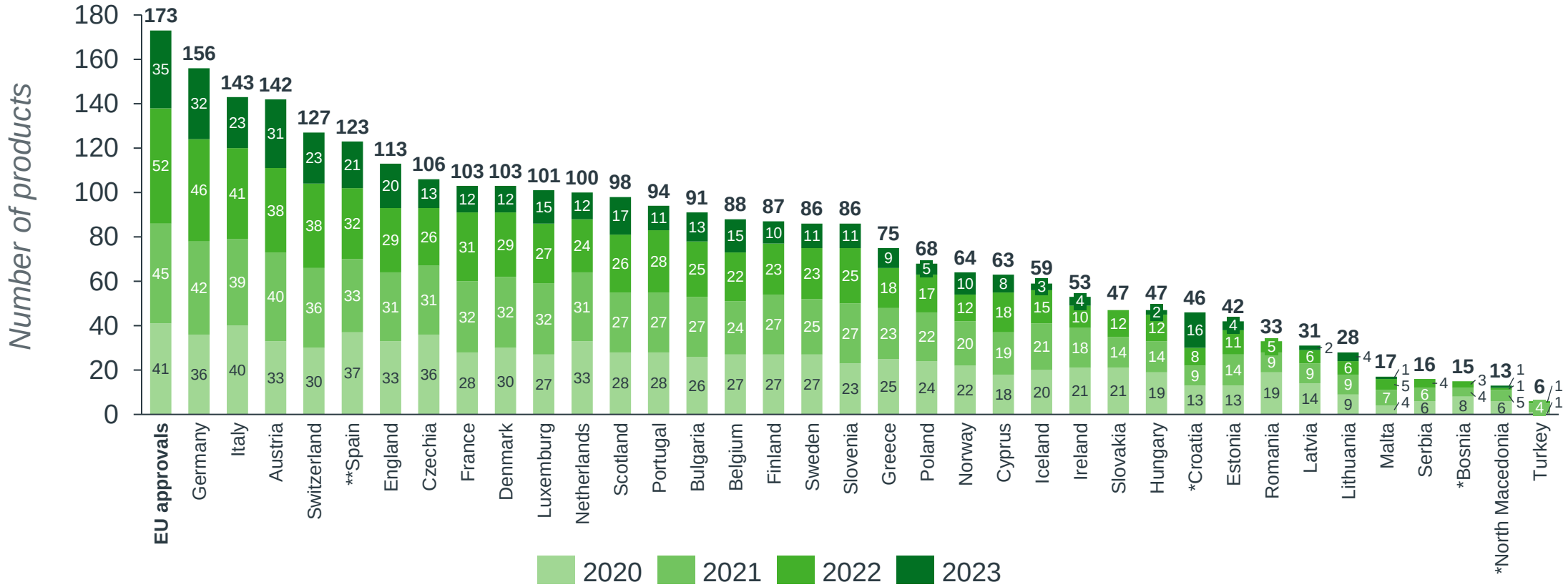
1. Overview (all products)

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 (2020-2023)

The **total availability by approval year** is the number of medicines available to patients in European countries as of 5th January 2025 (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: 80 products available (46%) †Country specific definitions are listed in the appendix. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. **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

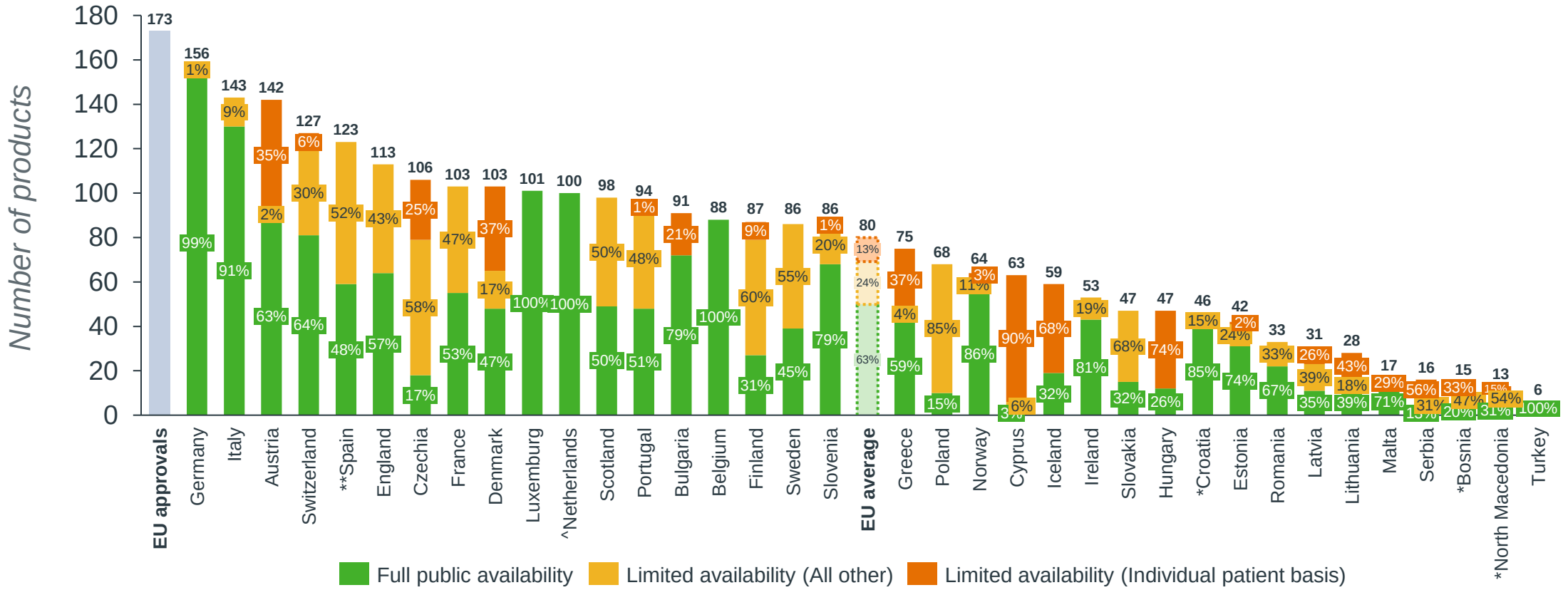
Rate of availability (2020-2023)

The **rate of availability**, measured by the number of medicines available to patients in European countries as of 5th January 2025. 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: 80 products available (46%) †Country specific definitions are listed in the appendix. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. **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.

Breakdown of availability (2020-2023)

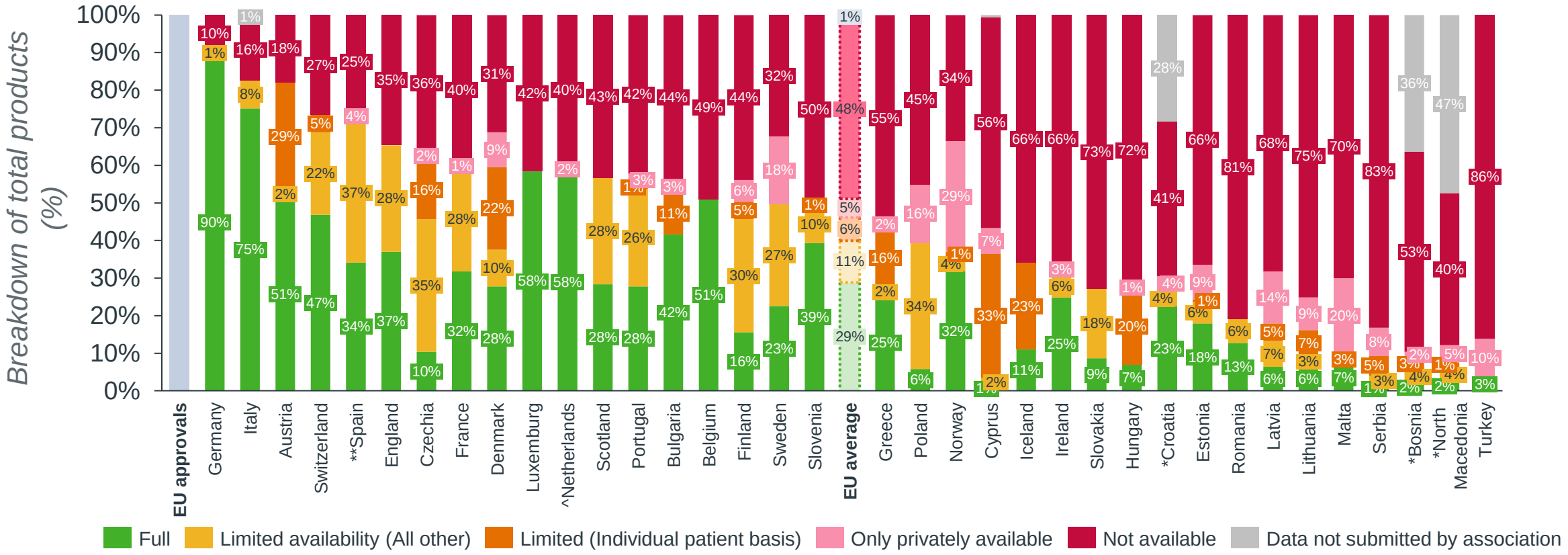
The **breakdown of availability** shows the proportion of medicines available to patients in European countries as of 5th January 2025 (for most countries this is the point at which the product gains access to the reimbursement list†) with full availability, via individual patient schemes, or with other restrictions.



European Union average: 80 products available (46%), Limited Availability (total) (37% of available products); ^Netherlands did not submit complete information on restrictions to available medicines meaning LA* is not captured in these countries.
†Country specific definitions are listed in the appendix. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. **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.

Breakdown of total availability (%, 2020-2023) *(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 2025 (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: 80 products available (46%); Limited Availability (17% of all products); ^Netherlands did not submit complete information on restrictions to available medicines meaning LA* is not captured in these countries. †Country specific definitions are listed in the appendix. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. **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

Breakdown of total availability (%, 2020-2023) *(countries ordered by full availability)*

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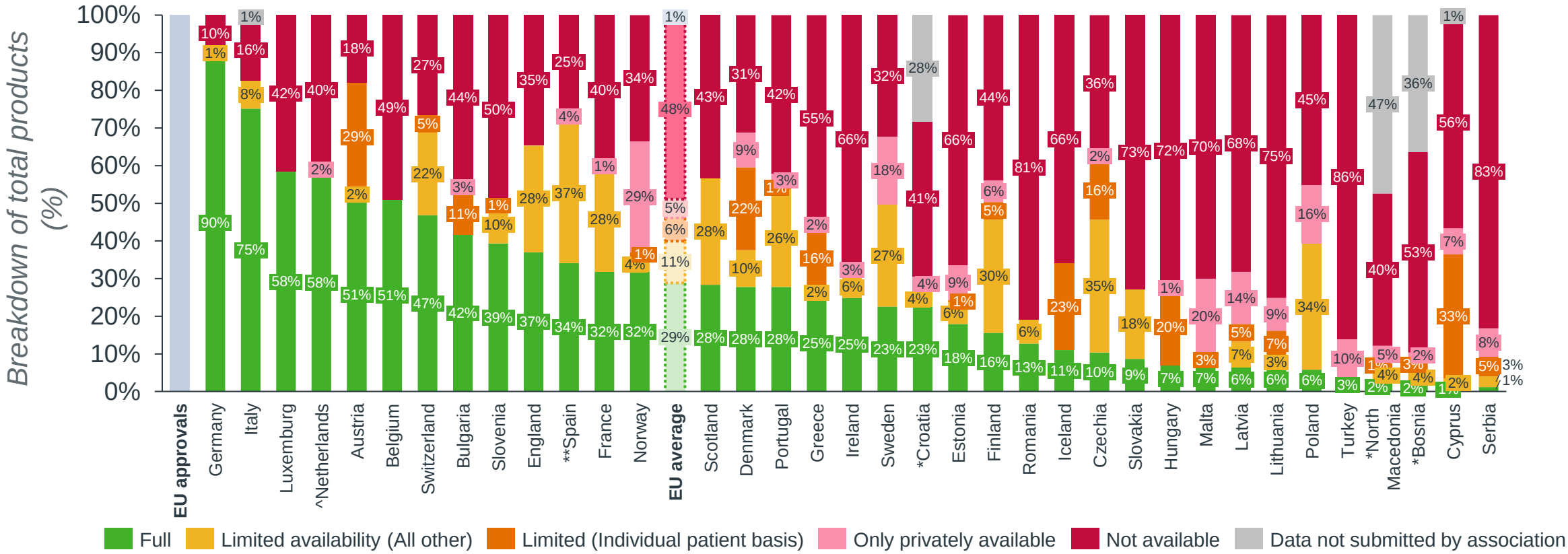

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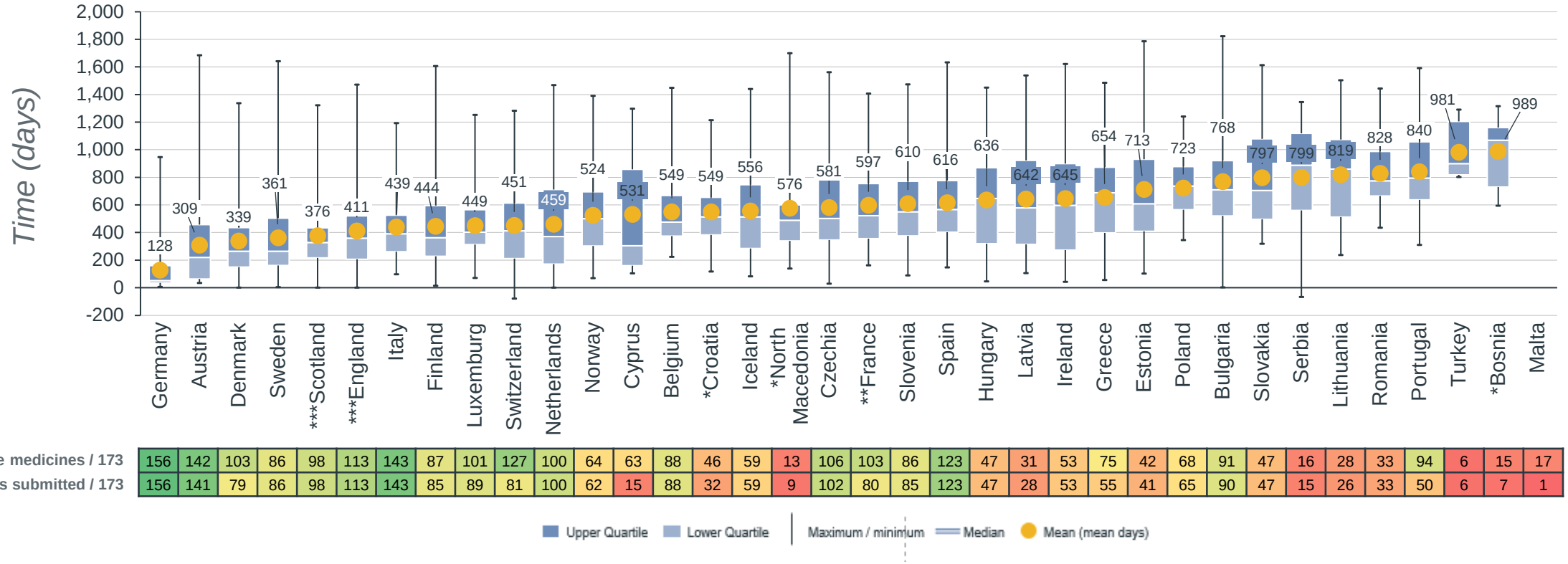
Time from central approval to availability (2020-2023)

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 2025.

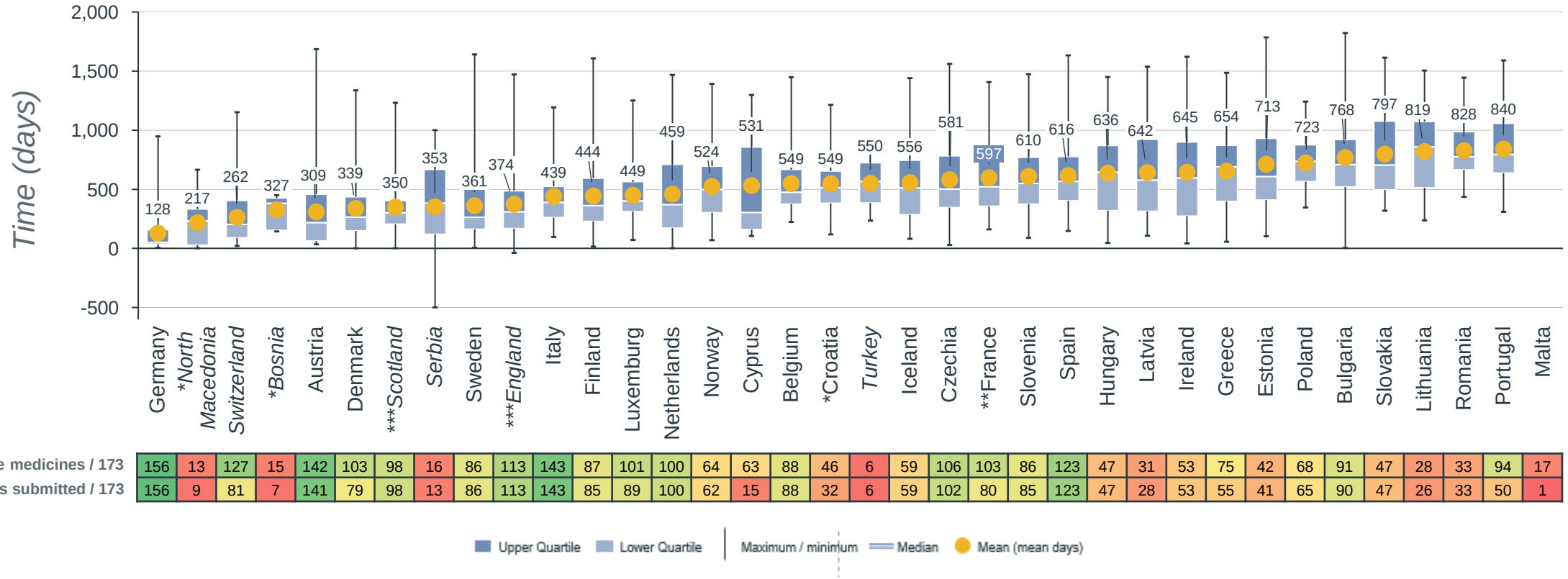


	Germany	Austria	Denmark	Sweden	***Scotland	***England	Italy	Finland	Luxemburg	Switzerland	Netherlands	Norway	Cyprus	Belgium	*Croatia	Iceland	*North Macedonia	Czechia	**France	Slovenia	Spain	Hungary	Latvia	Ireland	Greece	Estonia	Poland	Bulgaria	Slovakia	Serbia	Lithuania	Romania	Portugal	Turkey	*Bosnia	Malta
Available medicines / 173	156	142	103	86	98	113	143	87	101	127	100	64	63	88	46	59	13	106	103	86	123	47	31	53	75	42	68	91	47	16	28	33	94	6	15	17
Dates submitted / 173	156	141	79	86	98	113	143	85	89	81	100	62	15	88	32	59	9	102	80	85	123	47	28	53	55	41	65	90	47	15	26	33	50	6	7	1

European Union average: 578 days (mean %) (Note: Malta is not included in EU27 average as only 1 date was submitted in total) †Country specific definitions are listed in the appendix. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative **For France, the time to availability (597 days, n=80 dates submitted) includes products under the Accès précoce system (n=4 dates submitted) for which the price negotiation process is usually longer. If one considers that products under the Accès précoce system are directly available (time to availability = 0), the average time to availability is 570 days. ***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.

Time to availability (2020-2023)

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 2025.

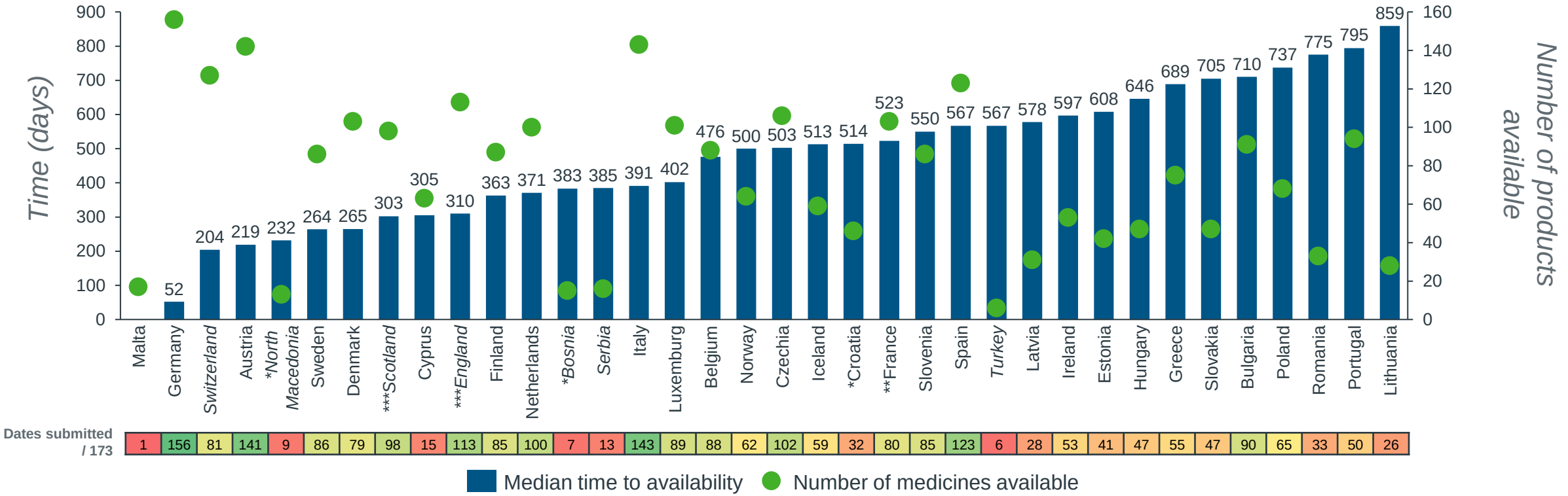


	Germany	*North Macedonia	Switzerland	*Bosnia	Austria	Denmark	***Scotland	Serbia	Sweden	***England	Italy	Finland	Luxemburg	Netherlands	Norway	Cyprus	Belgium	*Croatia	Turkey	Iceland	Czechia	**France	Slovenia	Spain	Hungary	Latvia	Ireland	Greece	Estonia	Poland	Bulgaria	Slovakia	Lithuania	Romania	Portugal	Malta
Available medicines / 173	156	13	127	15	142	103	98	16	86	113	143	87	101	100	64	63	88	46	6	59	106	103	86	123	47	31	53	75	42	68	91	47	28	33	94	17
Dates submitted / 173	156	9	81	7	141	79	98	13	86	113	143	85	89	100	62	15	88	32	6	59	102	80	85	123	47	28	53	55	41	65	90	47	26	33	50	1

European Union average: 578 days (mean %) (Note: Malta is not included in EU27 average as only 1 date was submitted in total †Country specific definitions are listed in the appendix. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative **For France, the mean time to availability (597 days, n=80 dates submitted) includes products under the Accès précoce system (n=4 dates submitted) for which the price negotiation process is usually longer. If one considers that products under the Accès précoce system are directly available (time to availability = 0), the average time to availability is 570 days. ***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. In this analyses, MHRA dates have been used for 2021, 2022 and 2023 products and EMA dates used for 2020 products

Median time to availability (2020-2023)

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 2025.



European Union average: 518 days (median) (Note: Malta is not included in EU27 average as only 1 date was submitted in total) †Country specific definitions are listed in the appendix. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative ** For France, the median time to availability (523 days, n=80 dates submitted) includes products under the Accès précoce system (n=4 dates submitted) for which the price negotiation process is usually longer. If one considers that products under the Accès précoce system are directly available (time to availability = 0), the median time to availability is 499 days. ***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. In this analyses, MHRA dates have been used for 2021, 2022 and 2023 products and EMA dates used for 2020 products

Key observations

Executive summary (EU27 averages)

Measure	All products	Oncology	Orphan	Non-oncologic orphan	Combination therapy
Average rate of availability	46% (43% in 2023)	50% (52% in 2023)	42% (35% in 2023) ↑	39% (32% in 2023) ↑	55% (54% in 2023)
Average time to availability	578 Days (531 days in 2023) ↑	586 Days (553 days in 2023) ↑	611 Days (542 days in 2023) ↑	607 Days (530 days in 2023) ↑	553 Days (433 days in 2023) ↑

Key Insights

Rate of availability

- Europe's average rate of availability has increased by 3% compared to last year's cohort, however the increase may reflect a smaller share of orphan products in this year's cohort
- Orphan medicines are still less likely to receive reimbursement in Europe, in contrast to non-orphan medicines

Time to availability

- The average delay from marketing authorisation to reimbursement can vary by a factor greater than 7x in Europe, from as little as 4 months to 28 months (~2.5 years)
- Many countries with low data availability appear high in the indicator, but it is important to take into account the small number of available medicines that the figure represents

Metrics key:

Text colour indicates relative position versus the current (2024) EU average (*significantly worse than current EU average* / *significantly better than current EU average*)

Arrow colour indicates significant changes versus the previous (2023) 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

Malta is not included in EU27 average for time to availability as only 1 date was submitted in total

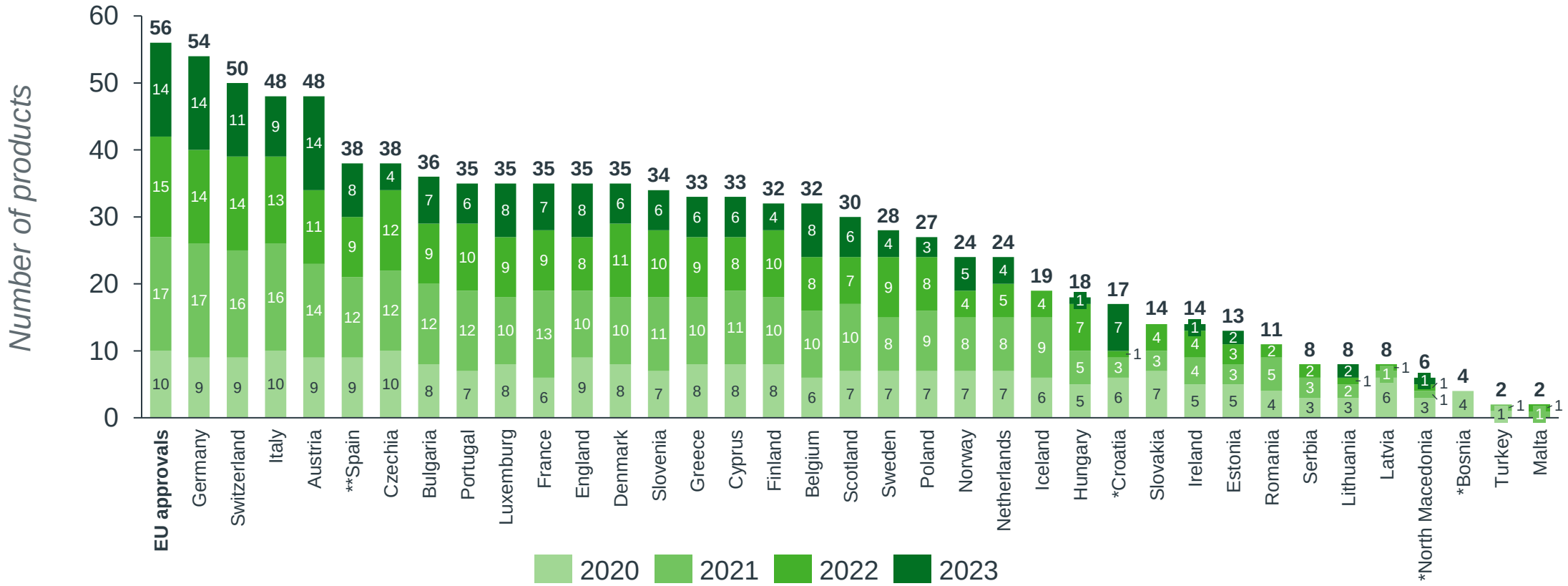
2. Oncology medicines

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 (2020-2023)

The **total availability by approval year** is the number of medicines available to patients in European countries as of 5th January 2025 (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 (50%) †Country specific definitions are listed in the appendix. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. **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

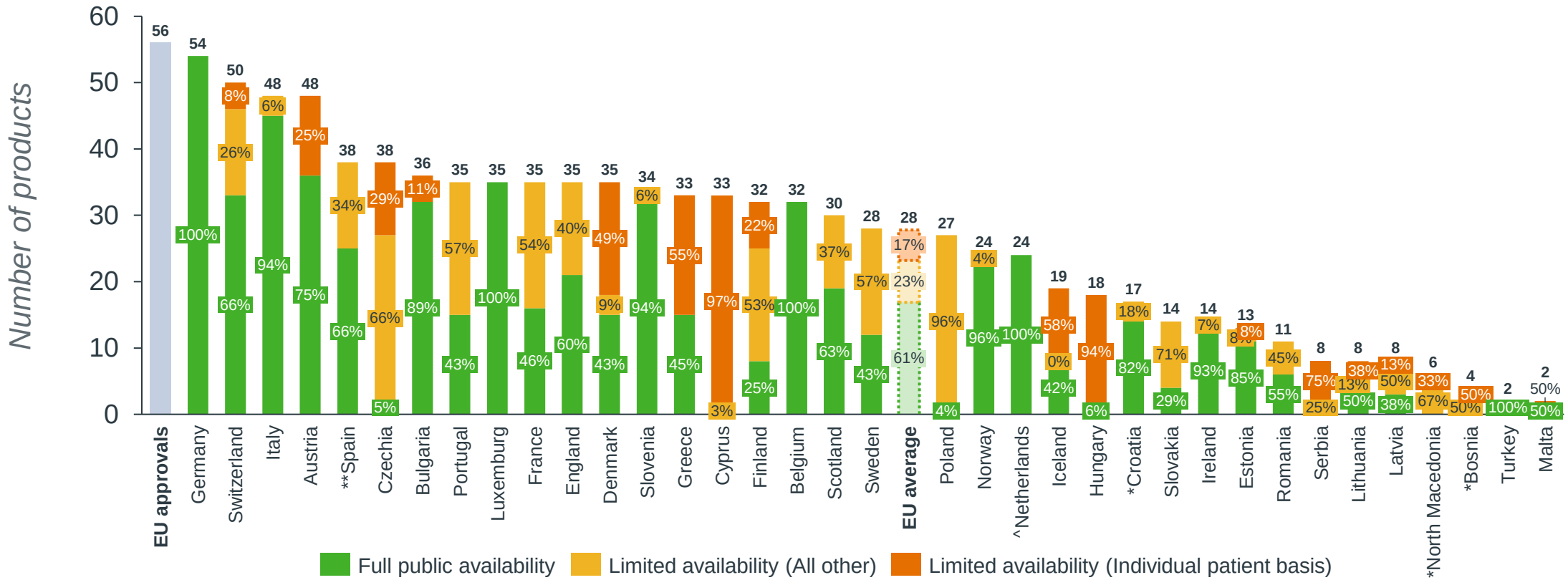
Oncology rate of availability (2020-2023)

The **rate of availability**, measured by the number of medicines available to patients in European countries as of 5th January 2025. 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 (50%) †Country specific definitions are listed in the appendix. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. **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

Oncology breakdown of availability (%, 2020-2023)

The **breakdown of availability** shows the proportion of medicines available to patients in European countries as of 5th January 2025 (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 (50%), Limited availability (total) (40% of available products). ^Netherlands did not submit complete information on restrictions to available medicines meaning LA* is not captured in these countries.
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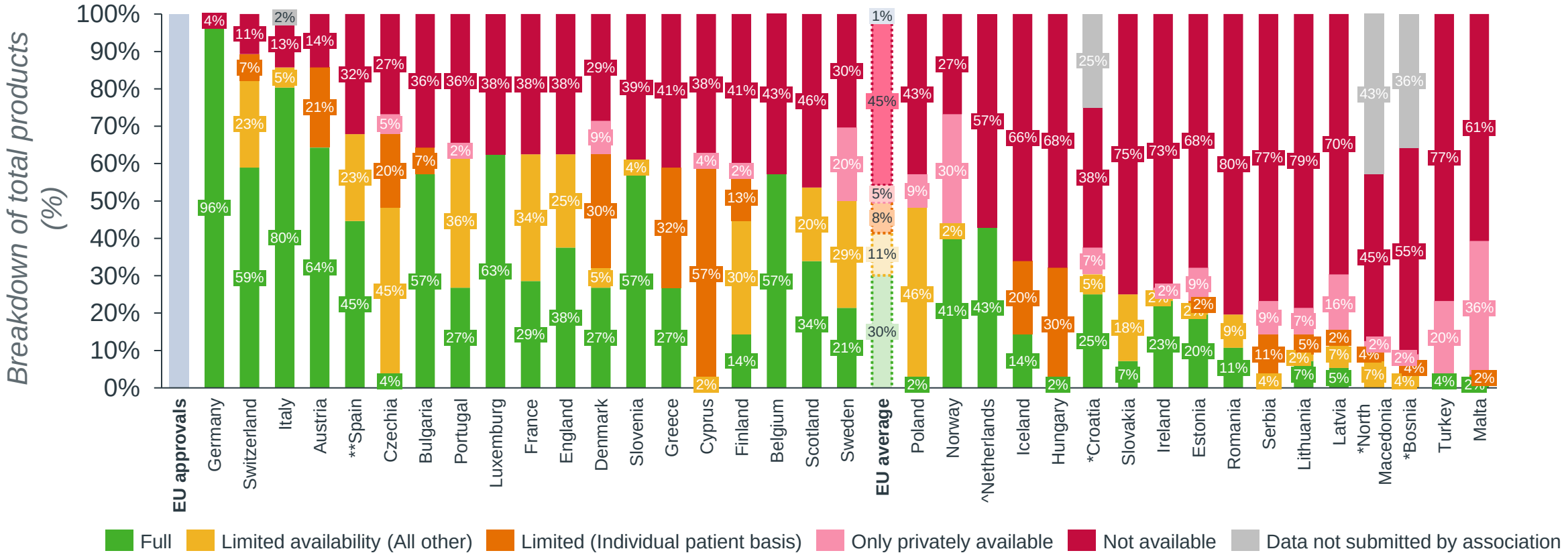
Oncology breakdown of total availability (%, 2020-2023) *(countries ordered by all availability)*

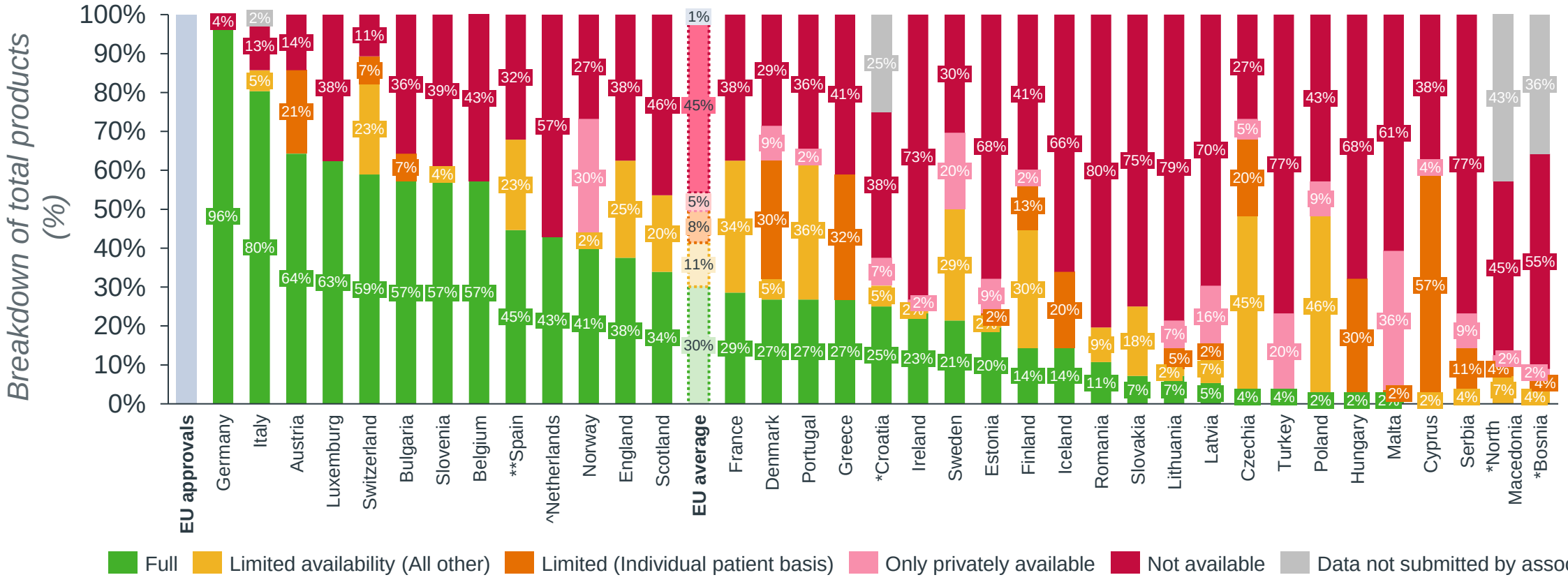
The **breakdown of total availability** is the composition of medicines available to patients in European countries as of 5th January 2025 (for most countries this is the point at which the product gains access to the reimbursement list†). This includes all medicine's status to provide a complete picture of availability.



European Union average: 28 products available (50%)[1]; Limited Availability (19% of all oncology products); ^Netherlands did not submit complete information on restrictions to available medicines meaning LA* is not captured in these countries. †Country specific definitions are listed in the appendix. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. **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. [1] The average rate of availability is 50%; the reason this is not represented in the chart (where segments total 49%) is due to rounding.

Oncology breakdown of total availability (%, 2020-2023) *(countries ordered by full availability)*

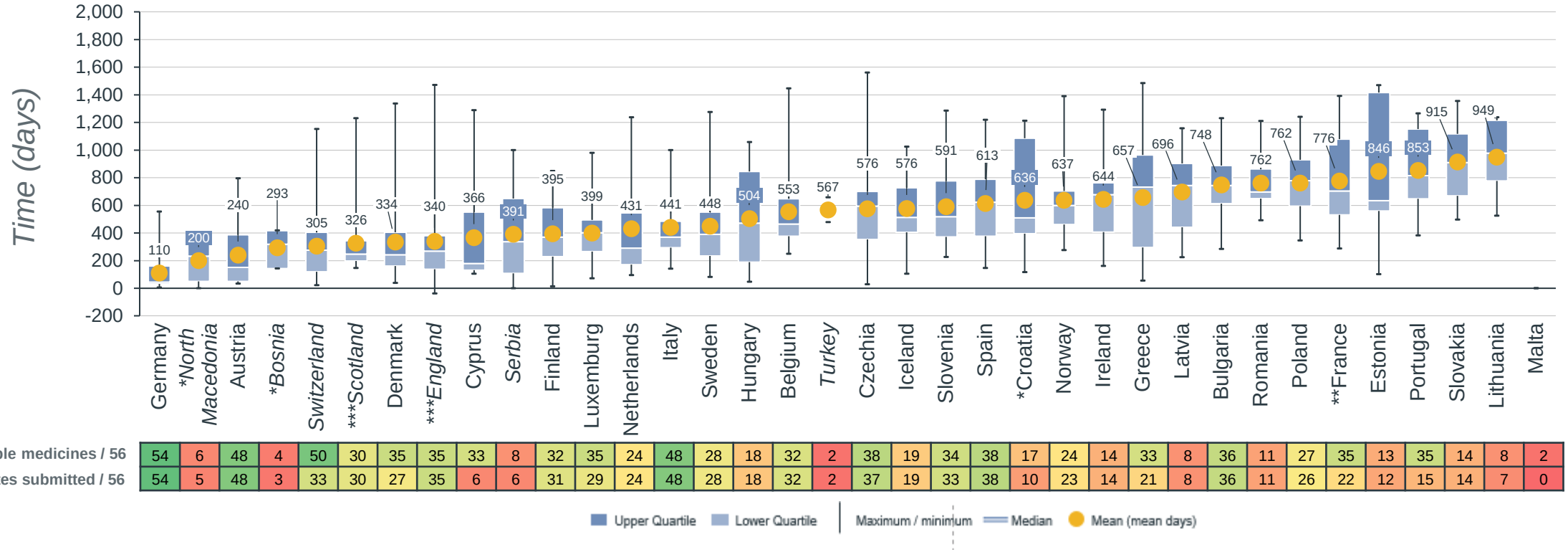
The **breakdown of total availability** is the composition of medicines available to patients in European countries as of 5th January 2025 (for most countries this is the point at which the product gains access to the reimbursement list†). This includes all medicine's status to provide a complete picture of availability.



European Union average: 28 products available (50%)[1]; Limited Availability (19% of all oncology products); ^Netherlands did not submit complete information on restrictions to available medicines meaning LA* is not captured in these countries. †Country specific definitions are listed in the appendix. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. **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. [1] The average rate of availability is 50%; the reason this is not represented in the chart (where segments total 49%) is due to rounding.

Oncology time to availability (2020-2023)

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 2025.

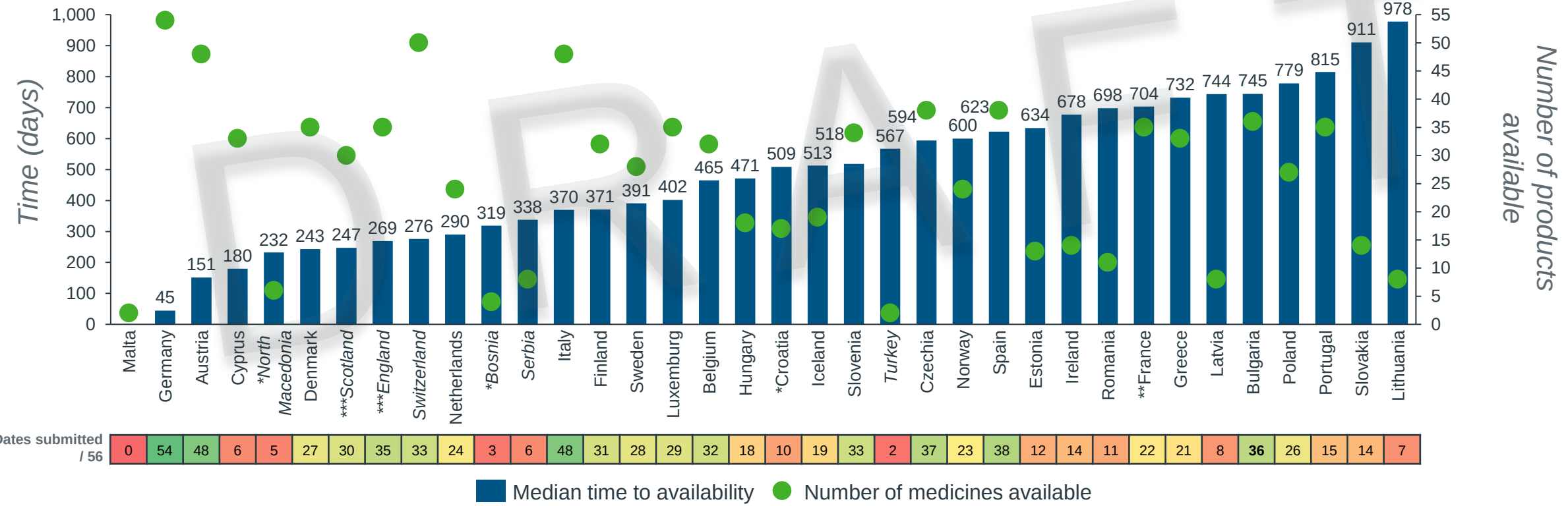


	Germany	*North Macedonia	Austria	*Bosnia	Switzerland	***Scotland	Denmark	***England	Cyprus	Serbia	Finland	Luxemburg	Netherlands	Italy	Sweden	Hungary	Belgium	Turkey	Czechia	Iceland	Slovenia	Spain	*Croatia	Norway	Ireland	Greece	Latvia	Bulgaria	Romania	Poland	**France	Estonia	Portugal	Slovakia	Lithuania	Malta
Available medicines / 56	54	6	48	4	50	30	35	35	33	8	32	35	24	48	28	18	32	2	38	19	34	38	17	24	14	33	8	36	11	27	35	13	35	14	8	2
Dates submitted / 56	54	5	48	3	33	30	27	35	6	6	31	29	24	48	28	18	32	2	37	19	33	38	10	23	14	21	8	36	11	26	22	12	15	14	7	0

European Union average: 586 days (mean) (Note: Malta is not included in EU27 average as only 1 date was submitted in total) †Country specific definitions are listed in the appendix. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. **For France, the mean time to availability (776 days, n=22 dates submitted) includes products under the Accès précoce system (n=1 dates submitted) for which the price negotiation process is usually longer. If one considers that products under the Accès précoce system are directly available (time to availability = 0), the average time to availability is 754 days. ***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. In this analyses, MHRA dates have been used for 2021, 2022 and 2023 products and EMA dates used for 2020 products

Oncology median time to availability (2020-2023)

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 2025.



European Union average: 540 days (median) (Note: Malta is not included in EU27 average as only 1 date was submitted in total) †Country specific definitions are listed in the appendix. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative **For France, the median time to availability (704 days, n=22 dates submitted) includes products under the Accès précoce system (n=1 dates submitted) for which the price negotiation process is usually longer. If one considers that products under the Accès précoce system are directly available (time to availability = 0), the median time to availability remains 704 days. ***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. In this analyses, MHRA dates have been used for 2021, 2022 and 2023 products and EMA dates used for 2020 products

Key observations

Executive summary (EU27 averages)

Measure	All products	Oncology	Orphan	Non-oncologic orphan	Combination therapy
Average rate of availability	46% (43% in 2023)	50% (52% in 2023)	42% ↑ (35% in 2023)	39% ↑ (32% in 2023)	55% (54% in 2023)
Average time to availability	578 ↑ Days (531 days in 2023)	586 ↑ Days (553 days in 2023)	611 ↑ Days (542 days in 2023)	607 ↑ Days (530 days in 2023)	553 ↑ Days (433 days in 2023)

Key Insights

Rate of availability

- Oncology's products rate of availability has slightly deteriorated compared to last year's cohort, showing that on average 50% of these products are available in Europe, down from 52%
- In line with last year's cohort, the rate of availability of four countries (DE, CH, AT, IT) is higher than 80% and significantly above the rest of the countries considered in the analysis

Time to availability

- The average time to availability for oncology products continues to increase: 33 days slower than last year's report and 66 days slower than the 2022 cohort
- The average delay from marketing authorisation to reimbursement for oncology products varies from 4 to 34 months (>2.5 years) from the fastest to the slowest country considered in the analysis

Metrics key:

Text colour indicates relative position versus the current (2024) EU average (*significantly worse than current EU average* / *significantly better than current EU average*)

Arrow colour indicates significant changes versus the previous (2023) 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

Malta is not included in EU27 average for time to availability as only 1 date was submitted in total

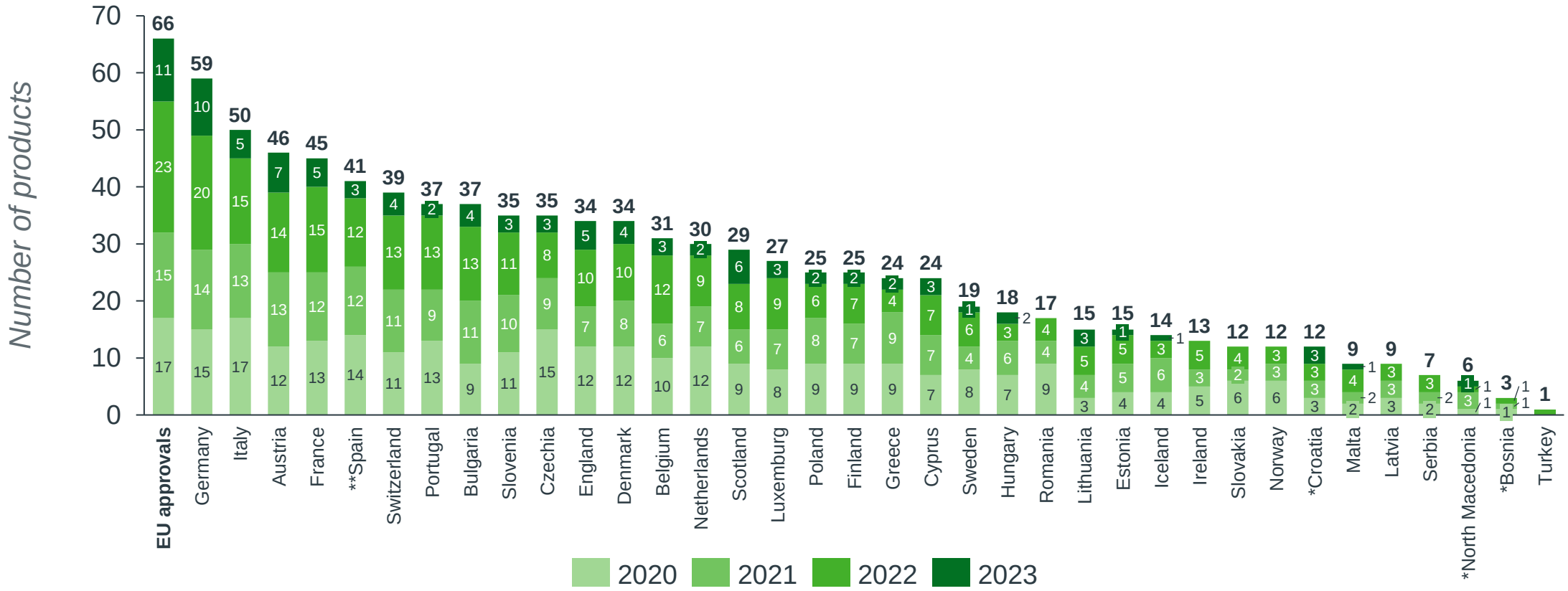
3. Orphan medicines

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 (2020-2023)

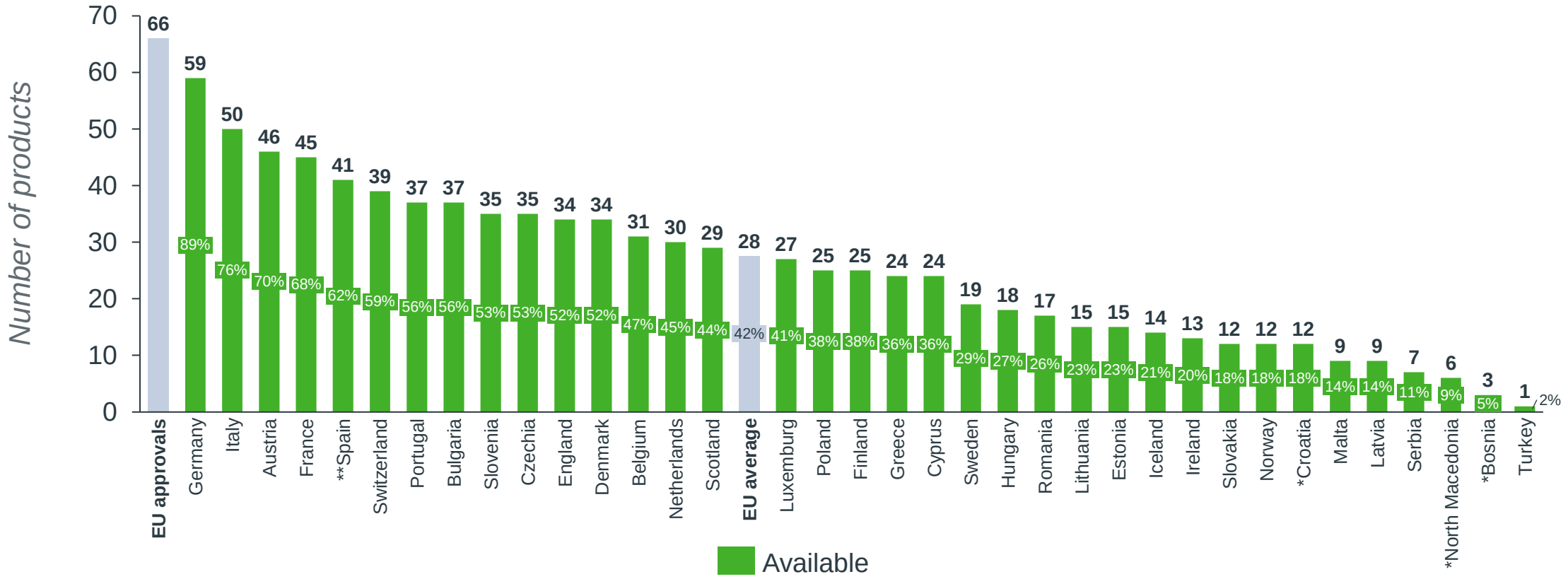
The **total availability by approval year** is the number of medicines available to patients in European countries as of 5th January 2025 (for most countries this is the point at which the product gains access to the reimbursement list†), split by the year the product received marketing authorisation in Europe.



European Union average: 28 products available (42%) †Country specific definitions are listed in the appendix. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. **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

Orphan rate of availability (2020-2023)

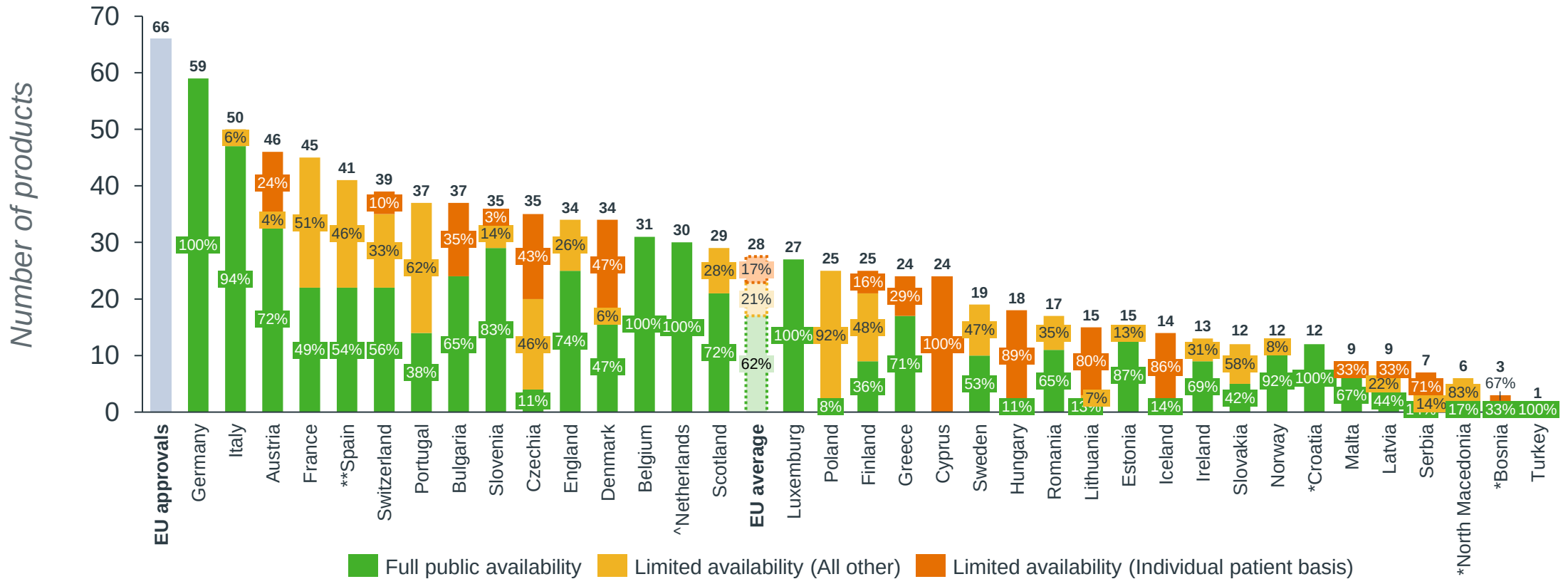
The **rate of availability**, measured by the number of medicines available to patients in European countries as of 5th January 2025. For most countries this is the point at which the product gains access to the reimbursement list†, including products with limited availability.



European Union average: 28 products available (42%) †Country specific definitions are listed in the appendix. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. **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

Orphan breakdown of availability (%, 2020-2023)

The **breakdown of availability** shows the proportion of medicines available to patients in European countries as of 5th January 2025 (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.

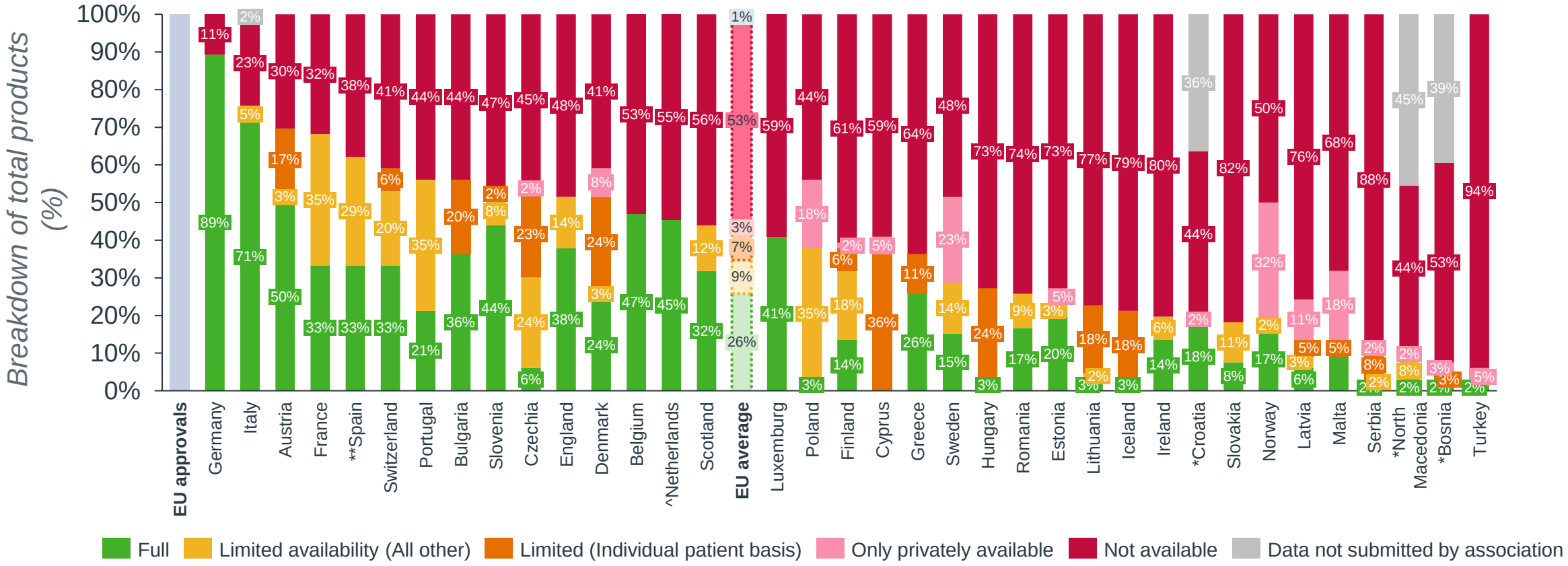


European Union average: 28 products available (42%), Limited availability (total) (38% of available products). ^Netherlands did not submit complete information on restrictions to available medicines meaning LA* is not captured in these countries.
†Country specific definitions are listed in the appendix. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. **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

Orphan breakdown of total availability (%, 2020-2023)

(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 2025 (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.

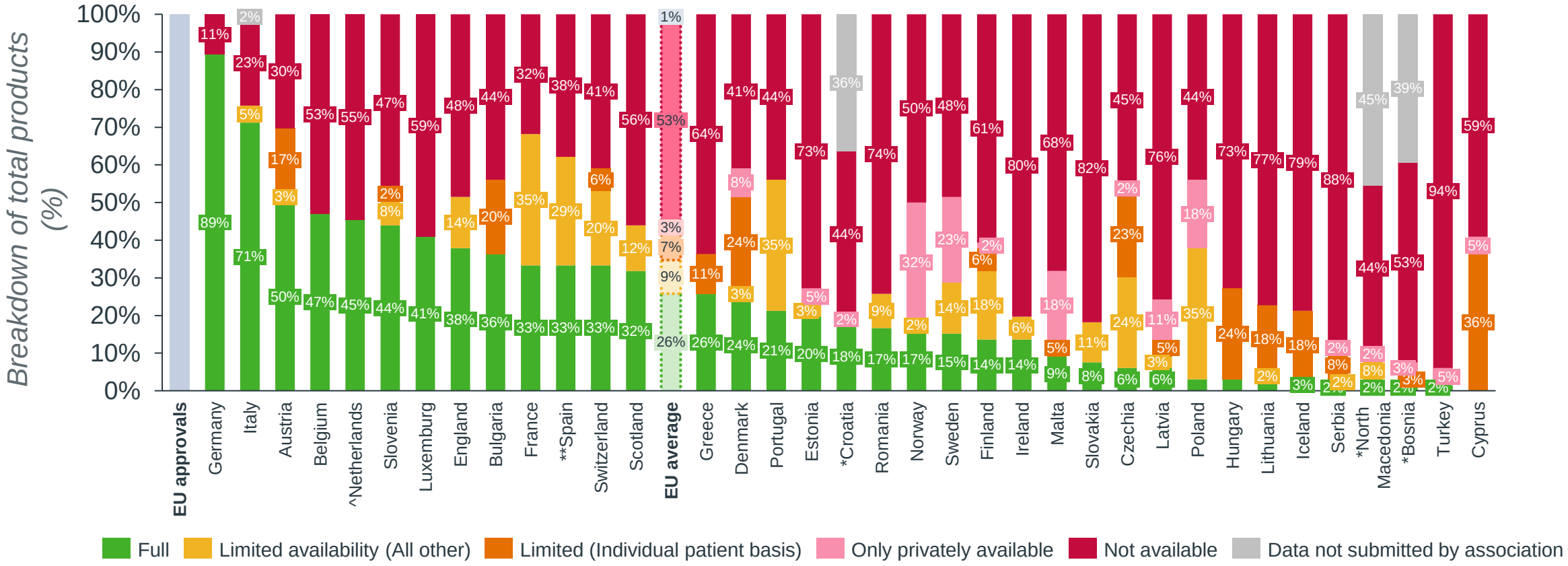


European Union average: 28 products available (42%); Limited Availability (16% of all orphan products); ^Netherlands did not submit complete information on restrictions to available medicines meaning LA* is not captured in these countries. †Country specific definitions are listed in the appendix. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. **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

Orphan breakdown of total availability (%, 2020-2023)

(countries ordered by full availability)

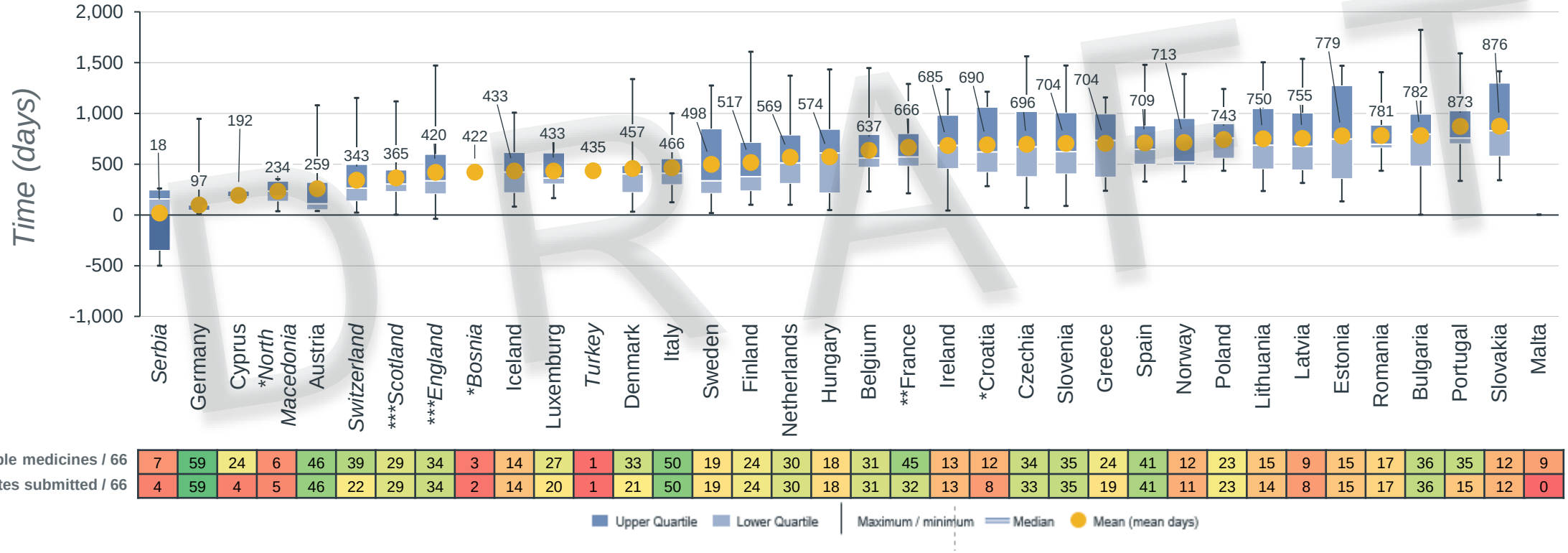
The **breakdown of total availability** is the composition of medicines available to patients in European countries as of 5th January 2025 (for most countries this is the point at which the product gains access to the reimbursement list†). This includes all medicine's status to provide a complete picture of availability.



European Union average: 28 products available (42%); Limited Availability (16% of all orphan products); ^Netherlands did not submit complete information on restrictions to available medicines meaning LA* is not captured in these countries. †Country specific definitions are listed in the appendix. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. **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

Orphan time to availability (2020-2023)

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 2025.

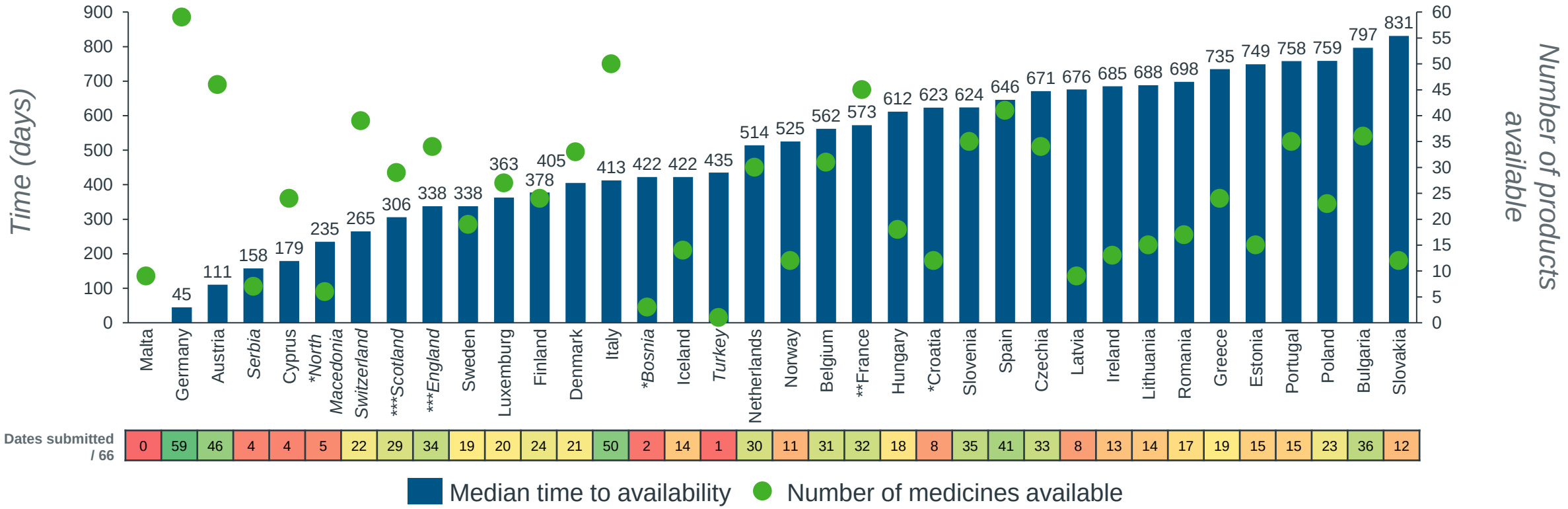


	Serbia	Germany	Cyprus	*North Macedonia	Austria	Switzerland	***Scotland	***England	*Bosnia	Iceland	Luxemburg	Turkey	Denmark	Italy	Sweden	Finland	Netherlands	Hungary	Belgium	**France	Ireland	*Croatia	Czechia	Slovenia	Greece	Spain	Norway	Poland	Lithuania	Latvia	Estonia	Romania	Bulgaria	Portugal	Slovakia	Malta
Available medicines / 66	7	59	24	6	46	39	29	34	3	14	27	1	33	50	19	24	30	18	31	45	13	12	34	35	24	41	12	23	15	9	15	17	36	35	12	9
Dates submitted / 66	4	59	4	5	46	22	29	34	2	14	20	1	21	50	19	24	30	18	31	32	13	8	33	35	19	41	11	23	14	8	15	17	36	15	12	0

European Union average: 611 days (mean) (Note: Malta is not included in EU27 average as no dates were submitted in total) †Country specific definitions are listed in the appendix. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative.; **For France, the time to availability (666 days, n=32 dates submitted) includes products under the Accès précoce system (n=2 dates submitted) for which the price negotiation process is usually longer. If one considers that products under the Accès précoce system are directly available (time to availability = 0), the average time to availability is 637 days. ***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. In this analyses, MHRA dates have been used for 2021, 2022 and 2023 products and EMA dates used for 2020 products

Orphan median time to availability (2020-2023)

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 2025.



European Union average: 555 days (median) (Note: Malta is not included in EU27 average as only 1 date was submitted in total) †Country specific definitions are listed in the appendix. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative **For France, the median time to availability (573 days, n=32 dates submitted) includes products under the Accès précoce system (n=2 dates submitted) for which the price negotiation process is usually longer. If one considers that products under the Accès précoce system are directly available (time to availability = 0), the average time to availability is 563 days ***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. In this analyses, MHRA dates have been used for 2021, 2022 and 2023 products and EMA dates used for 2020 products

Key observations

Executive summary (EU27 averages)

Measure	All products	Oncology	Orphan	Non-oncologic orphan	Combination therapy
Average rate of availability	46% (43% in 2023)	50% (52% in 2023)	42% ↑ (35% in 2023)	39% ↑ (32% in 2023)	55% (54% in 2023)
Average time to availability	578 Days ↑ (531 days in 2023)	586 Days ↑ (553 days in 2023)	611 Days ↑ (542 days in 2023)	607 Days ↑ (530 days in 2023)	553 Days ↑ (433 days in 2023)

Key Insights

Rate of availability

- The rate of availability for orphan medicines in this year's cohort is 42%, which represents a 7% improvement since last year's survey
- However, the average rate of availability for orphan medicines remains lower than the average for all products and other non-orphan segments

Time to availability

- Time to availability of orphans has significantly increased this year, and is now similar to the levels seen in the 2022 WAIT survey, however this is largely due to the changing cohort composition
- The average delay between market authorisation and patient availability for orphan drugs can be as short as 3 months in some countries or as long as 32 months (~2.5 years) in others

Metrics key:

Text colour indicates relative position versus the current (2024) EU average (*significantly worse than current EU average* / *significantly better than current EU average*)

Arrow colour indicates significant changes versus the previous (2023) 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

Malta is not included in EU27 average for time to availability as only 1 date was submitted in total

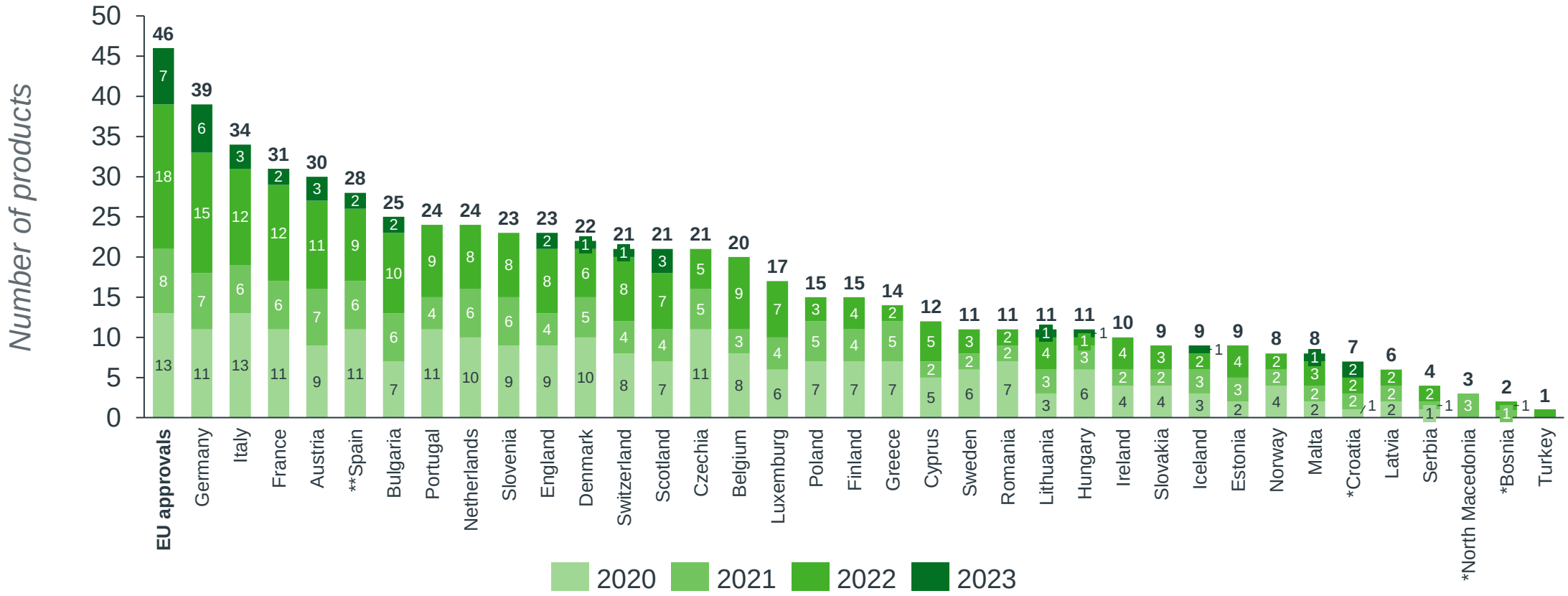
4. Non-oncology orphan medicines

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 (2020-2023)

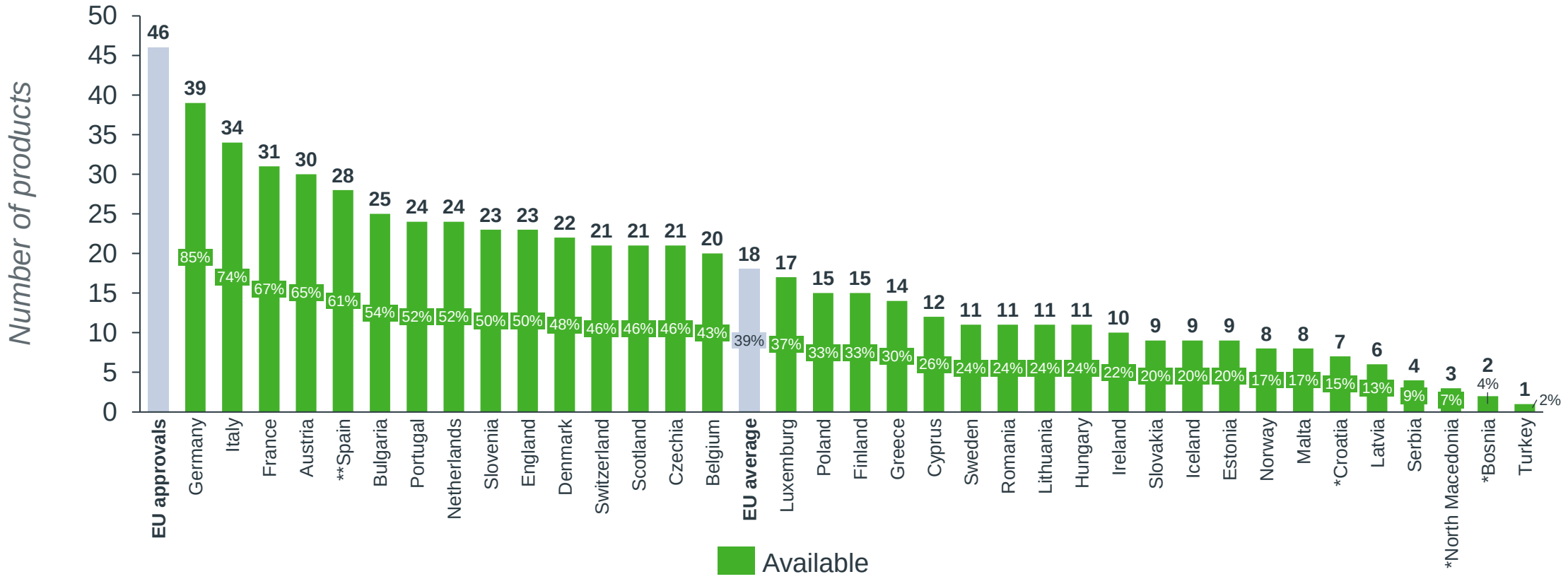
The **total availability by approval year** is the number of medicines available to patients in European countries as of 5th January 2025 (for most countries this is the point at which the product gains access to the reimbursement list†), split by the year the product received marketing authorisation in Europe.



European Union average: 18 products available (39%) †Country specific definitions are listed in the appendix. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. **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

Non-oncology orphan rate of availability (2020-2023)

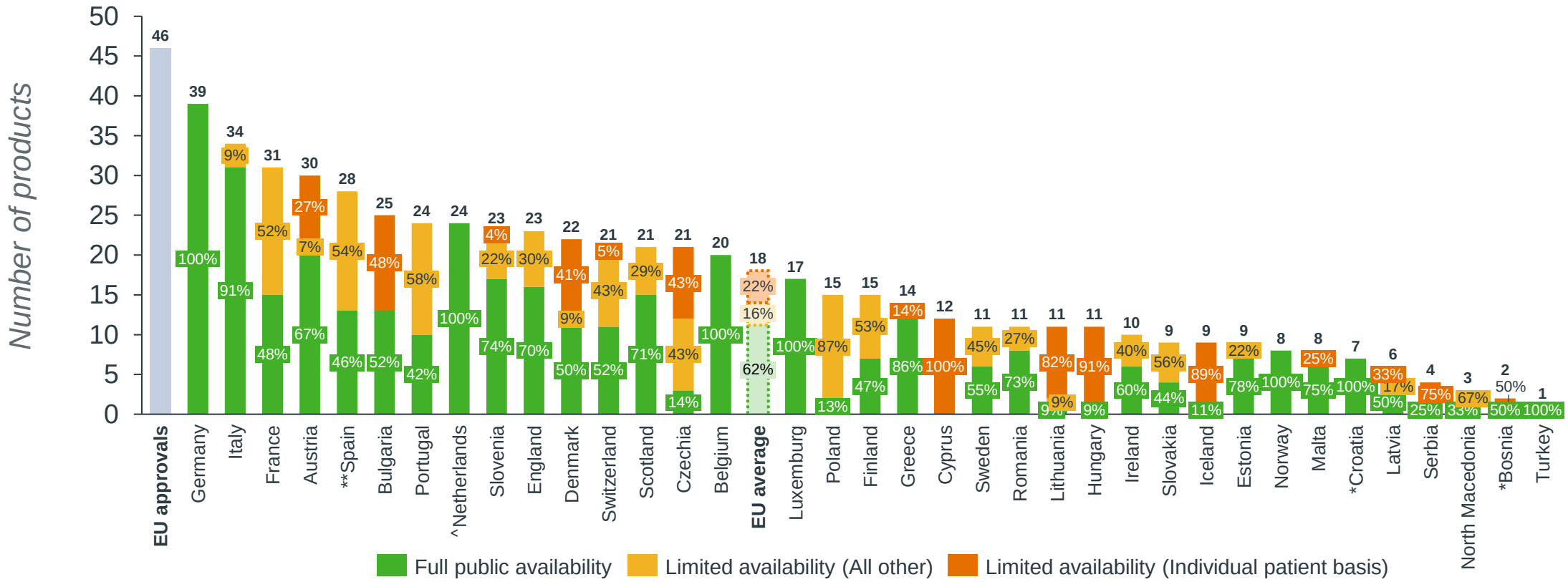
The **rate of availability**, measured by the number of medicines available to patients in European countries as of 5th January 2025. For most countries this is the point at which the product gains access to the reimbursement list†, including products with limited availability.



European Union average: 18 products available (39%) †Country specific definitions are listed in the appendix. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. **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

Non-oncology orphan breakdown of availability (%, 2020-2023)

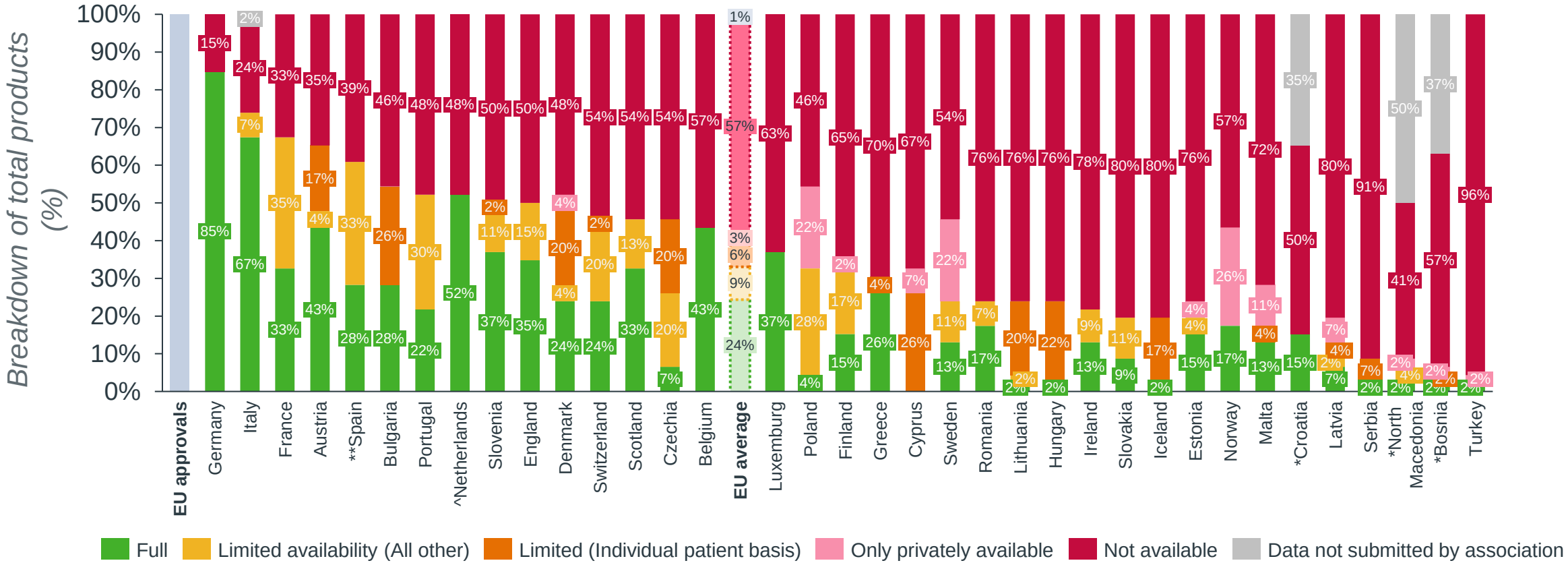
The **breakdown of availability** shows the proportion of medicines available to patients in European countries as of 5th January 2025 (for most countries this is the point at which the product gains access to the reimbursement list†) with full availability, via individual patient schemes, or with other restrictions.



European Union average: 18 products available (39%), Limited availability (total) (38% of available products) ^Netherlands did not submit complete information on restrictions to available medicines meaning LA* is not captured in these countries. †Country specific definitions are listed in the appendix. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. **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

Non-oncology orphan breakdown of total availability (%, 2020-2023) *(countries ordered by all availability)*

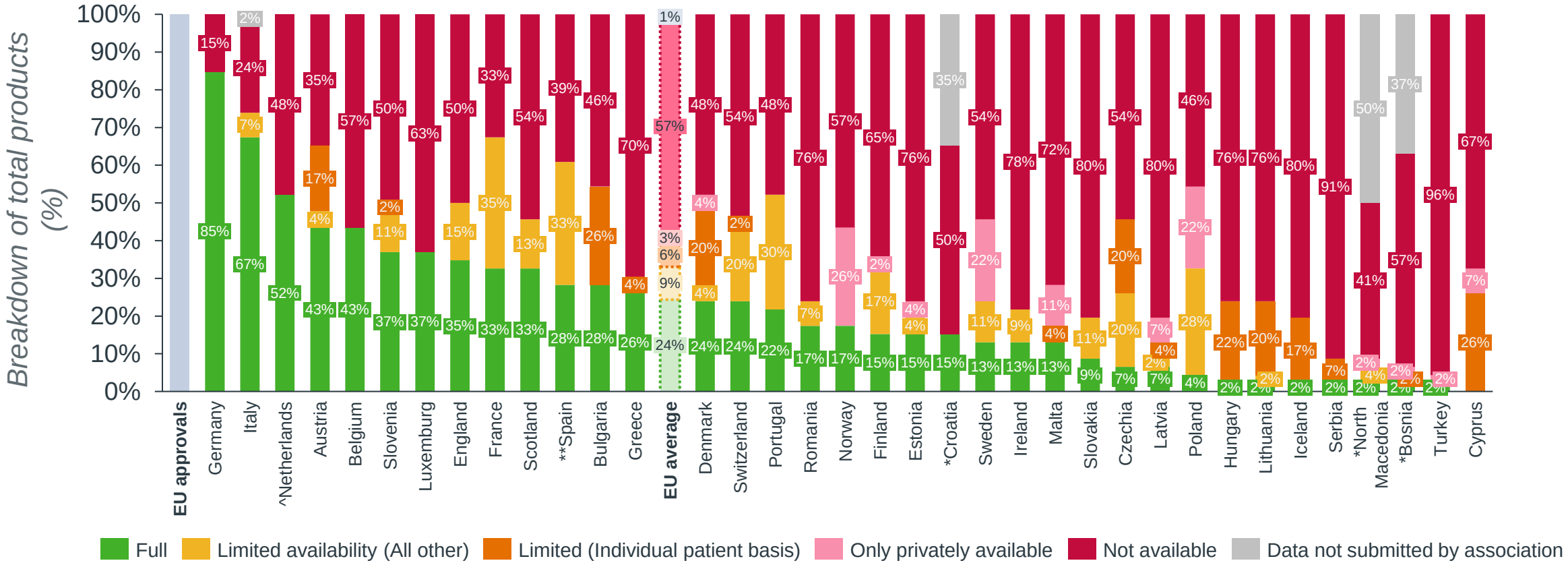
The **breakdown of total availability** is the composition of medicines available to patients in European countries as of 5th January 2025 (for most countries this is the point at which the product gains access to the reimbursement list†). This includes all medicine's status to provide a complete picture of availability.



European Union average: 18 products available (39%); Limited Availability (15% of all non-onco orphan products); ^Netherlands did not submit complete information on restrictions to available medicines meaning LA* is not captured in these countries.
†Country specific definitions are listed in the appendix. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. **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

Non-oncology orphan breakdown of total availability (%, 2020-2023) *(countries ordered by full availability)*

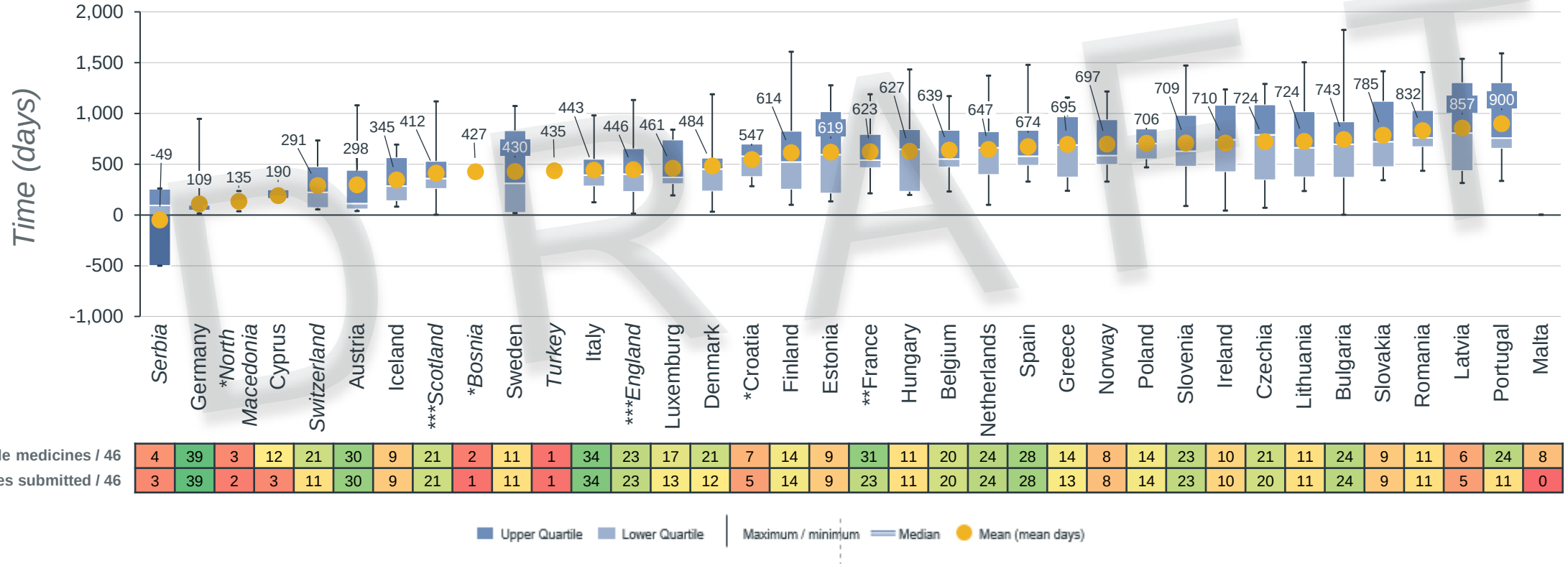
The **breakdown of total availability** is the composition of medicines available to patients in European countries as of 5th January 2025 (for most countries this is the point at which the product gains access to the reimbursement list†). This includes all medicine's status to provide a complete picture of availability.



European Union average: 18 products available (39%); Limited Availability (15% of all non-onco orphan products); ^Netherlands did not submit complete information on restrictions to available medicines meaning LA* is not captured in these countries. †Country specific definitions are listed in the appendix. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. **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

Non-oncology orphan time to availability (2020-2023)

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 2025.



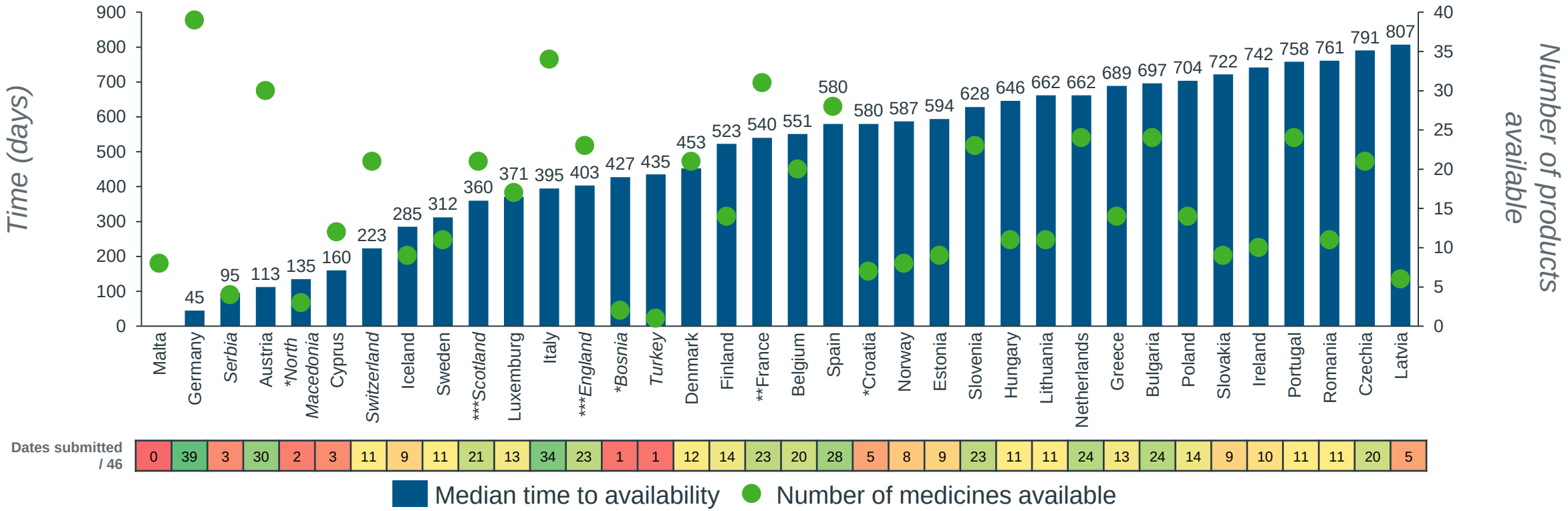
	Serbia	Germany	*North Macedonia	Cyprus	Switzerland	Austria	Iceland	***Scotland	*Bosnia	Sweden	Turkey	Italy	***England	Luxemburg	Denmark	*Croatia	Finland	Estonia	**France	Hungary	Belgium	Netherlands	Spain	Greece	Norway	Poland	Slovenia	Ireland	Czechia	Lithuania	Bulgaria	Slovakia	Romania	Latvia	Portugal	Malta
Available medicines / 46	4	39	3	12	21	30	9	21	2	11	1	34	23	17	21	7	14	9	31	11	20	24	28	14	8	14	23	10	21	11	24	9	11	6	24	8
Dates submitted / 46	3	39	2	3	11	30	9	21	1	11	1	34	23	13	12	5	14	9	23	11	20	24	28	13	8	14	23	10	20	11	24	9	11	5	11	0

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

European Union average: 607 days (mean) (Note: Malta is not included in EU27 average as only 1 date was submitted in total) †Country specific definitions are listed in the appendix. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. **For France, the time to availability (623 days, n=23 dates submitted) includes products under the Accès précoce system (n=2 dates submitted) for which the price negotiation process is usually longer. If one considers that products under the Accès précoce system are directly available (time to availability = 0), the average time to availability is 583 days. ***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. In this analyses, MHRA dates have been used for 2021, 2022 and 2023 products and EMA dates used for 2020 products

Non-oncology orphan median time to availability (2020-2023)

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 2025.



European Union average: 557 days (median) (Note: Malta is not included in EU27 average as only 1 date was submitted in total) †Country specific definitions are listed in the appendix. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative . **For France, the median time to availability (540 days, n=23 dates submitted) includes products under the Accès précoce system (n=2 dates submitted) for which the price negotiation process is usually longer. If one considers that products under the Accès précoce system are directly available (time to availability = 0), the median time to availability is 527 days. ***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. In this analyses, MHRA dates have been used for 2021, 2022 and 2023 products and EMA dates used for 2020 products

Key observations

Executive summary (EU27 averages)

Measure	All products	Oncology	Orphan	Non-oncologic orphan	Combination therapy
Average rate of availability	46% (43% in 2023)	50% (52% in 2023)	42% (35% in 2023) ↑	39% (32% in 2023) ↑	55% (54% in 2023)
Average time to availability	578 Days (531 days in 2023) ↑	586 Days (553 days in 2023) ↑	611 Days (542 days in 2023) ↑	607 Days (530 days in 2023) ↑	553 Days (433 days in 2023) ↑

Key Insights

Rate of availability

- The rate of availability for non-oncologic orphan medicines in this year's cohort is 39%, which represents a 7% improvement since last year's survey and is in line with 2022 levels
- However, the average rate of availability for non-oncologic orphan medicines remains lower than the average for all products and other non-orphan segments

Time to availability

- Time to availability of non-oncologic orphans has significantly increased this year, and is now similar to the levels seen in the 2022 WAIT survey, however this is largely due to the changing cohort composition
- The average delay between market authorisation and patient availability for orphan drugs can be as short as 3 months in some countries or as long as 32 months (~2.5 years) in others

Metrics key:

Text colour indicates relative position versus the current (2024) EU average (*significantly worse than current EU average* / *significantly better than current EU average*)

Arrow colour indicates significant changes versus the previous (2023) 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

Malta is not included in EU27 average for time to availability as only 1 date was submitted in total

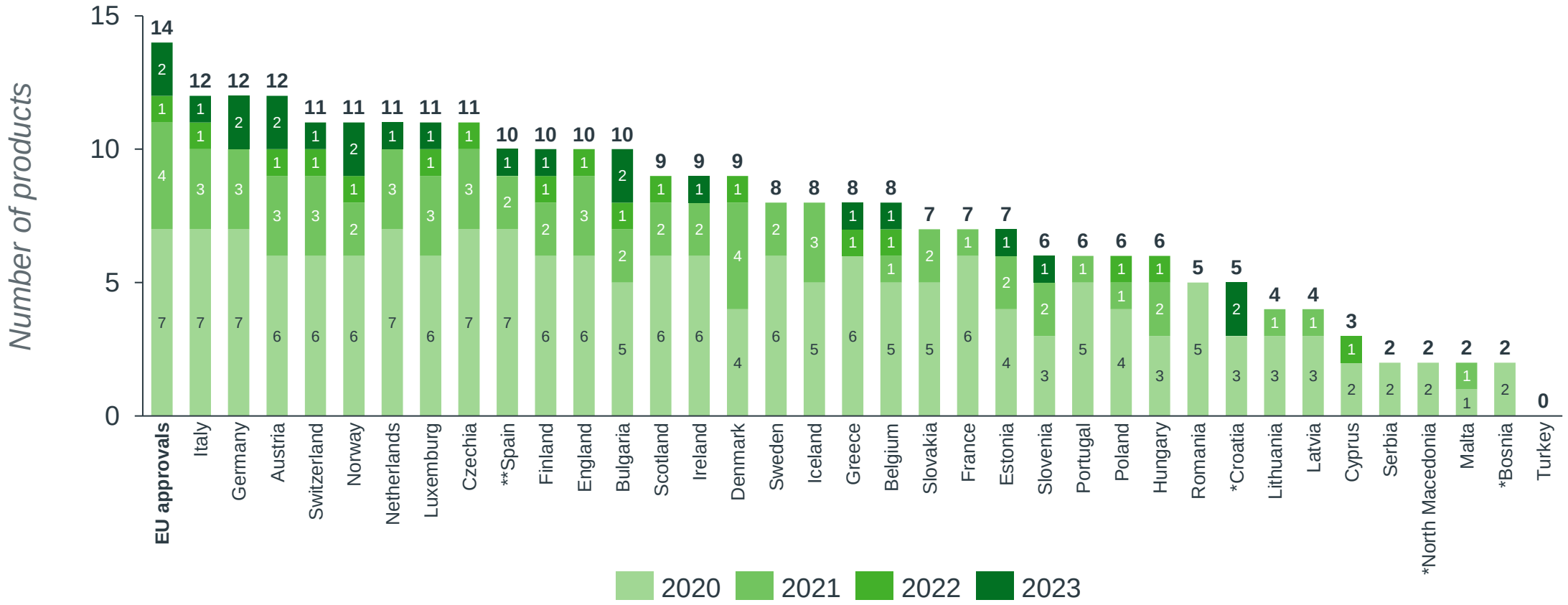
5. Combination therapies

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 (2020-2023)

The **total availability by approval year** is the number of fixed dose combination medicines available to patients in European countries as of 5th January 2025 (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: 8 products available (55%) Combination products can include innovative branded / generic combinations. †Country specific definitions are listed in the appendix. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. **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

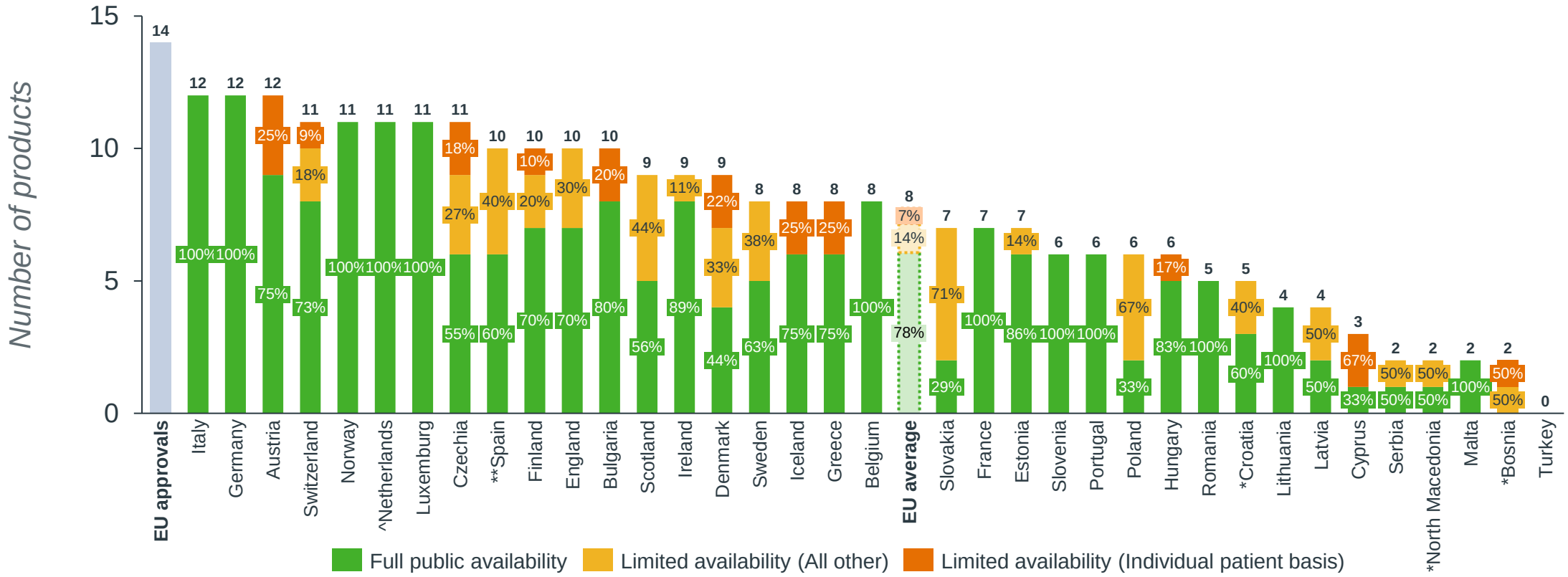
Combination therapies rate of availability (2020-2023)

The **rate of availability**, measured by the number of fixed dose combination medicines available to patients in European countries as of 5th January 2025. 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: 8 products available (55%) Combination products can include innovative branded / generic combinations; †Country specific definitions are listed in the appendix.. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. **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

Combination therapies breakdown of availability (%, 2020-2023)

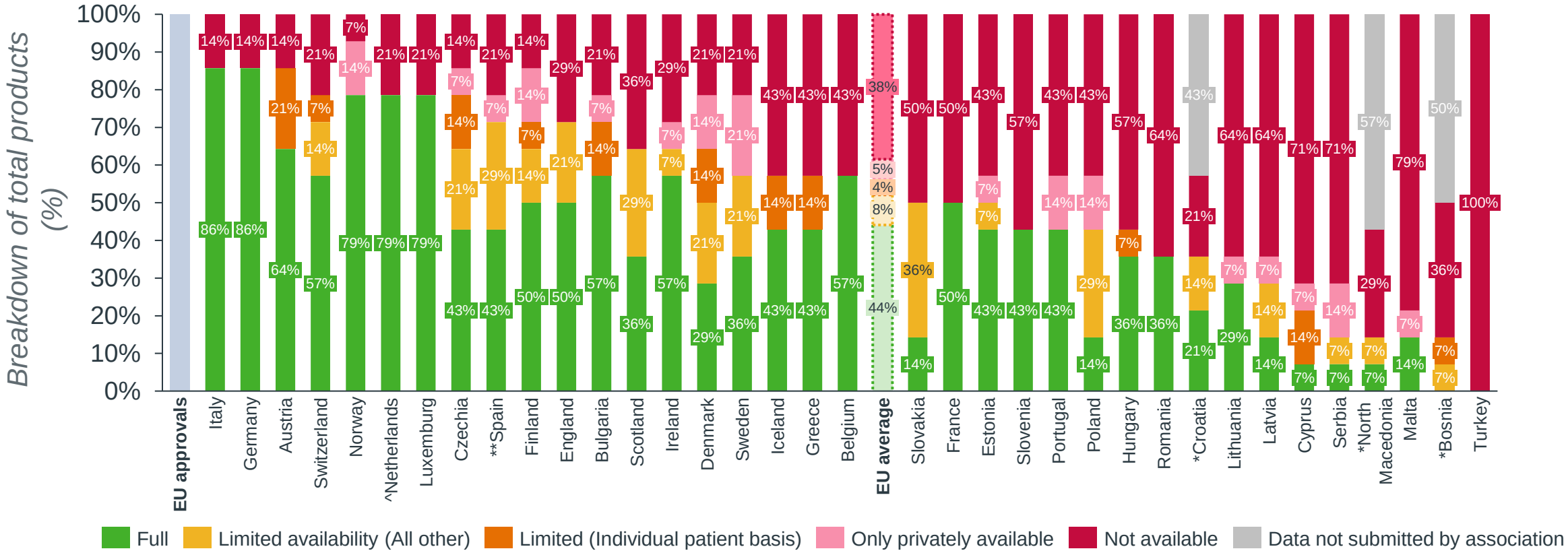
The **breakdown of availability** shows the proportion of medicines available to patients in European countries as of 5th January 2025 (for most countries this is the point at which the product gains access to the reimbursement list†) with full availability, via individual patient schemes, or with other restrictions.



European Union average: 8 products available (55%), limited availability (total) (21% of available products). Combination products can include innovative branded / generic combinations; ^Netherlands did not submit complete information on restrictions to available medicines meaning LA* is not captured in these countries †Country specific definitions are listed in the appendix. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. **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

Combination therapies breakdown of total availability (%, 2020-2023) *(countries ordered by all availability)*

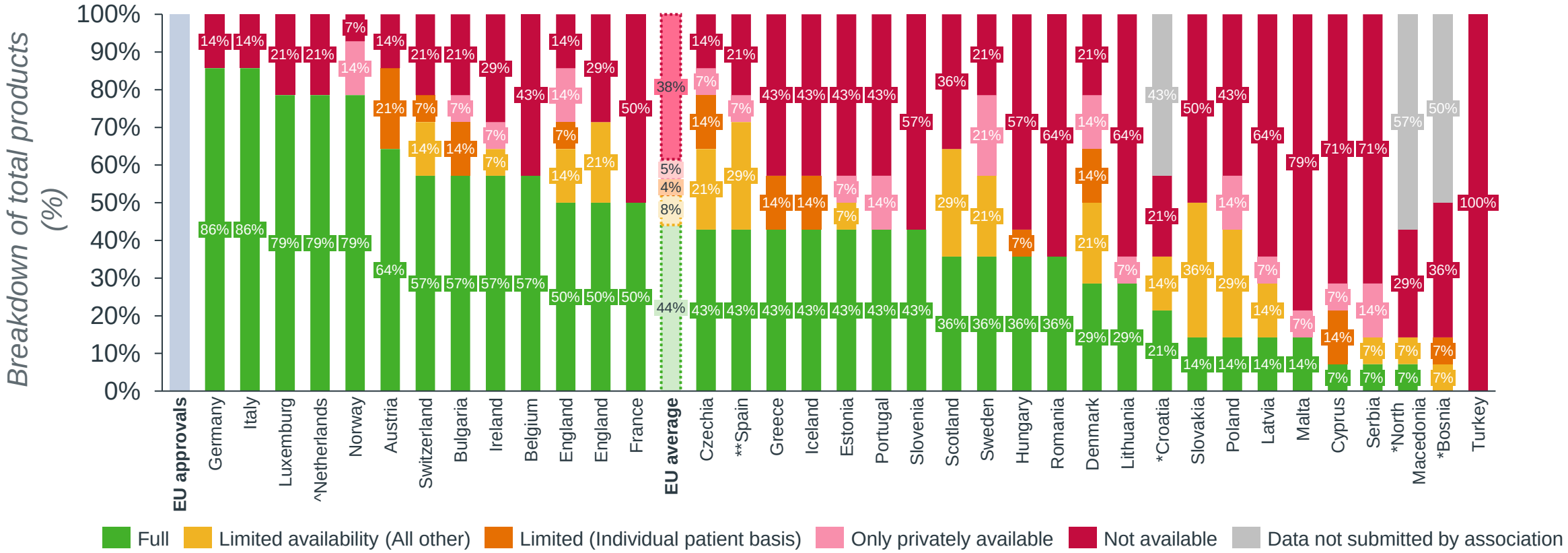
The **breakdown of total availability** is the composition of medicines available to patients in European countries as of 5th January 2025 (for most countries this is the point at which the product gains access to the reimbursement list†). This includes all medicine's status to provide a complete picture of availability.



European Union average: 8 products available (55%); Limited Availability (12% of all combination therapies); Combination products can include innovative branded / generic combinations; ^Netherlands did not submit complete information on restrictions to available medicines meaning LA* is not captured in these countries. †Country specific definitions are listed in the appendix. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. **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

Combination therapies breakdown of total availability (%, 2020-2023) *(countries ordered by full availability)*

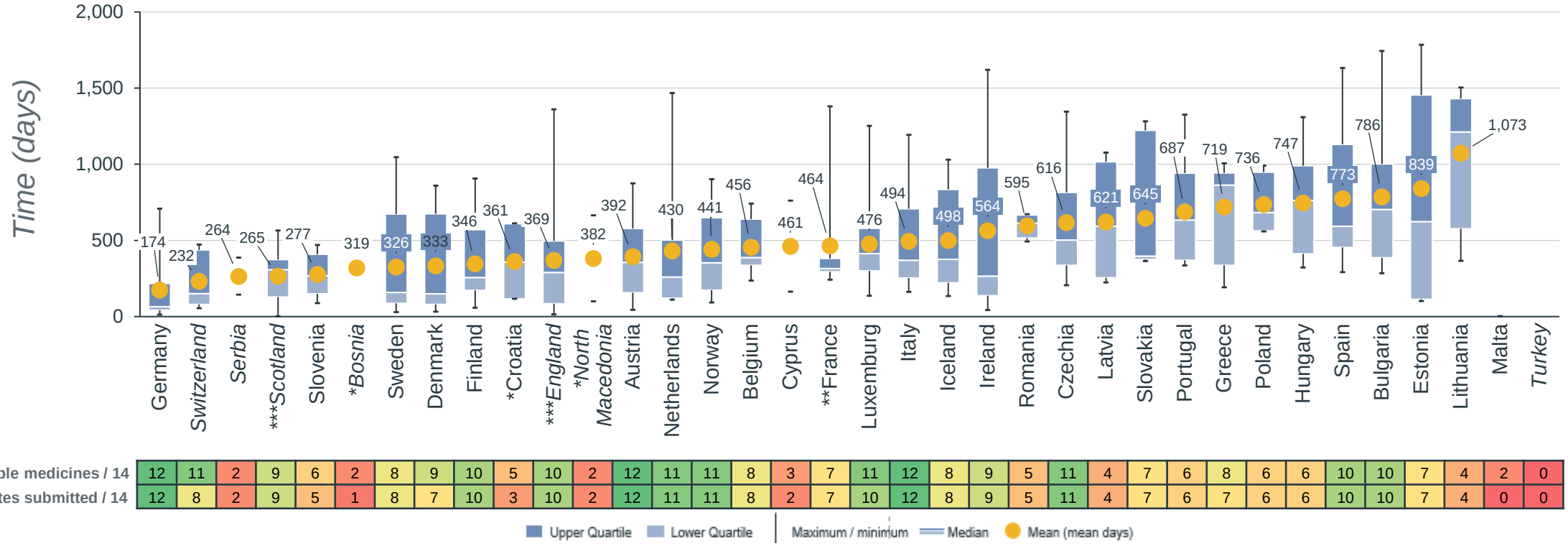
The **breakdown of total availability** is the composition of medicines available to patients in European countries as of 5th January 2025 (for most countries this is the point at which the product gains access to the reimbursement list†). This includes all medicine's status to provide a complete picture of availability.



European Union average: 8 products available (55%); Limited Availability (12% of all combination therapies); Combination products can include innovative branded / generic combinations; ^Netherlands did not submit complete information on restrictions to available medicines meaning LA* is not captured in these countries. †Country specific definitions are listed in the appendix. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. **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

Combination therapies time to availability (2020-2023)

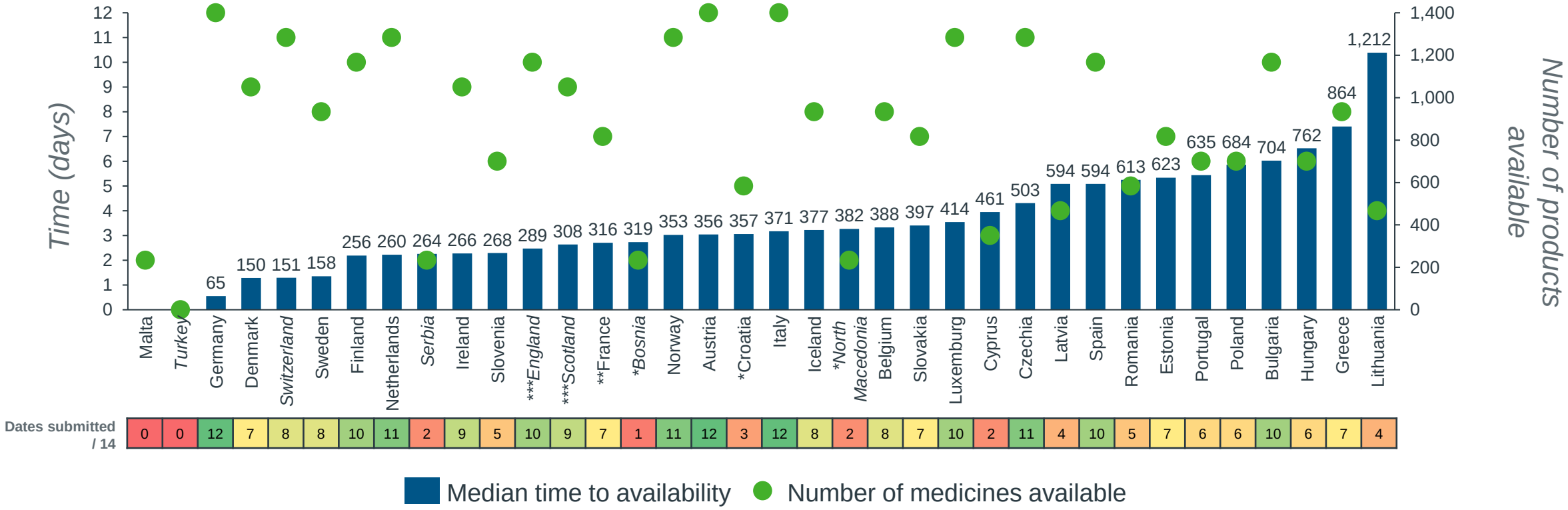
The **time to availability** is the days between marketing authorisation and the date of availability of fixed dose combination medicines to patients in European countries (for most this is the point at which products gain access to the reimbursement list†). The marketing authorisation date is the date 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 2025.



European Union average: 553 days (mean) (Note: Malta is not included in EU27 average as only 1 date was submitted in total) Combination products can include innovative branded / generic combinations; †Country specific definitions are listed in the appendix. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. **For France, the time to availability (464 days, n=7 dates submitted) includes products under the Accès précoce system (n=2 dates submitted) for which the price negotiation process is usually longer. No combination therapy fell under the Accès précoce system. ***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. In this analyses, MHRA dates have been used for 2021, 2022 and 2023 products and EMA dates used for 2020 products

Combination median time to availability (2020-2023)

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 2025.



European Union average: 471 days (median) (Note: Malta is not included in EU27 average as only 1 date was submitted in total) †Country specific definitions are listed in the appendix. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative **For France, the time to availability (464 days, n=7 dates submitted) includes products under the Accès précoce system (n=2 dates submitted) for which the price negotiation process is usually longer. No combination therapy fell under the Accès précoce system. ***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. In this analyses, MHRA dates have been used for 2021, 2022 and 2023 products and EMA dates used for 2020 products

Key observations

Executive summary (EU27 averages)

Measure	All products	Oncology	Orphan	Non-oncologic orphan	Combination therapy
Average rate of availability	46% (43% in 2023)	50% (52% in 2023)	42% (35% in 2023) ↑	39% (32% in 2023) ↑	55% (54% in 2023)
Average time to availability	578 Days (531 days in 2023) ↑	586 Days (553 days in 2023) ↑	611 Days (542 days in 2023) ↑	607 Days (530 days in 2023) ↑	553 Days (433 days in 2023) ↑

Key Insights

Rate of availability

- Average rate of availability for combination therapies is 9% higher than the average for all products, however nearly 80% of the products included in this survey were authorised before 2022
- The rate of availability for combination therapies is 1% higher than the previous study, despite a similar number of central approvals in this year's survey

Time to availability

- The time to availability for combination therapies continues to be the fastest across all segments, however the gap with all products is now narrower (1 month vs 4 months) compared to last year
- For over half of the countries included in this year's WAIT survey, the time to availability for combination therapies is less than 13 months

Metrics key:

Text colour indicates relative position versus the current (2024) EU average (*significantly worse than current EU average* / *significantly better than current EU average*)

Arrow colour indicates significant changes versus the previous (2023) 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

Malta is not included in EU27 average for time to availability as only 1 date was submitted in total

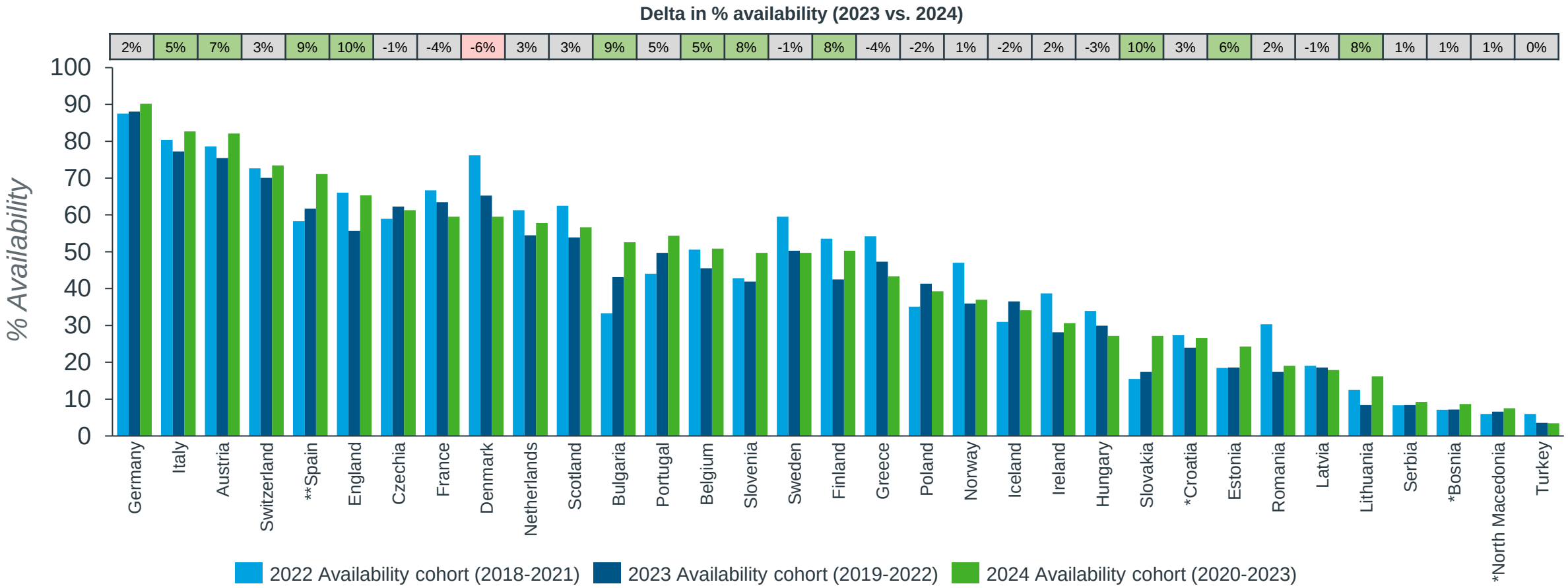
6. Historic comparisons and extension

Indicators:

6.1. Comparison of availability versus prior studies (2022 – 2024)
6.2. Comparison of time to availability versus prior studies (2022 – 2024)
6.3. Extended period of total availability (2014 – 2023)

Comparison of rate of availability (2022 study – 2024 study)

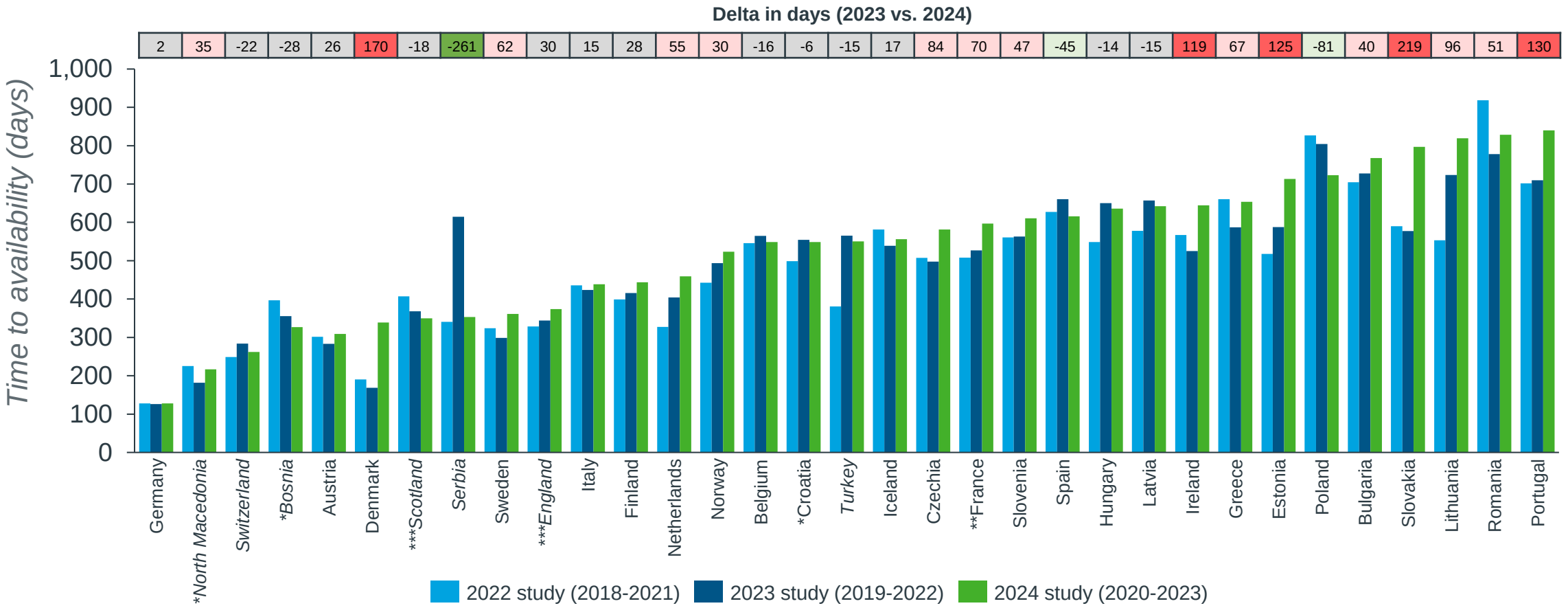
The **comparison of rate of availability**†, measured by the number of medicines available to patients in European countries as of 5th January 2025, compared to the rate of availability in previous (comparable) studies. Figures are based on the historic statistics published in the indicators.



Increases of <=5% are not considered to be statistically significant and are therefore highlighted in grey. Note: Netherlands has retrospectively corrected 2020 data; †Country specific definitions are listed in the appendix. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. **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. 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 (2022 study – 2024 study)

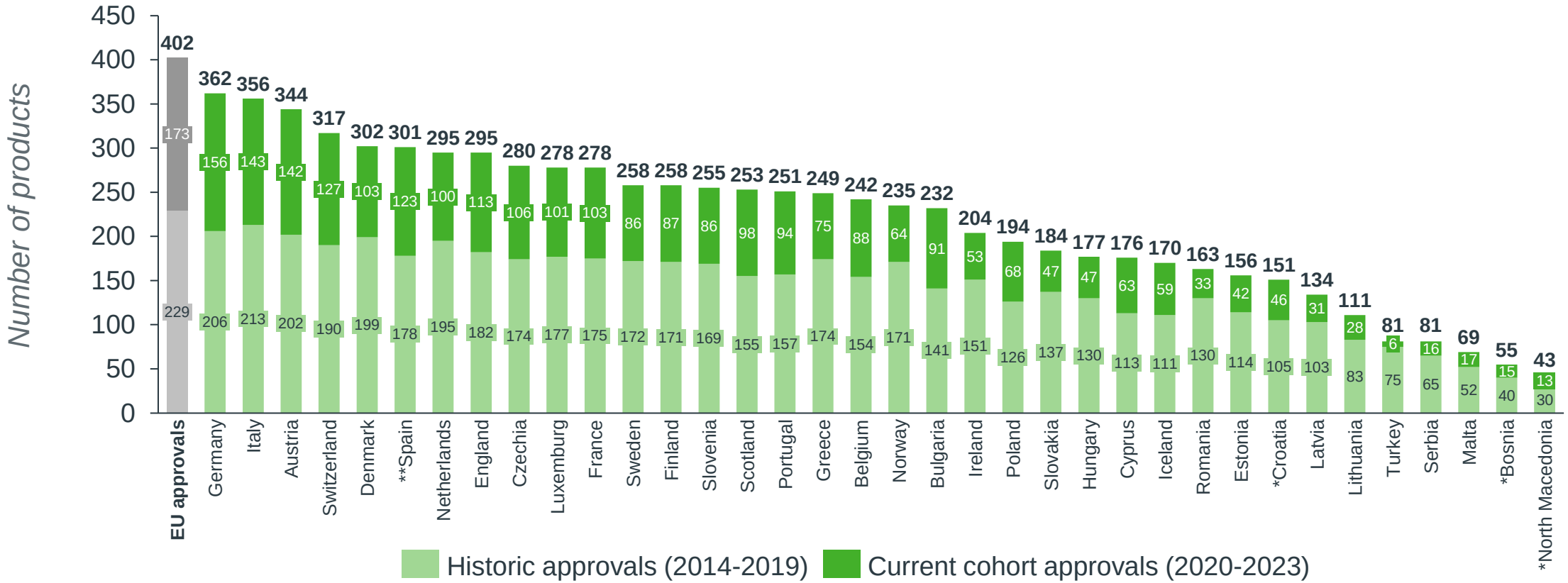
The **comparison of time to availability** is the days between marketing authorisation and the date of availability to patients compared to previous comparable studies. Figures are based on the historic statistics published in the indicators.



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; *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. **For France, status of Accès précoce products TBC. ***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. In this analyses, MHRA dates have been used for 2021-2023 products and EMA dates used for 2020 products. 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.

Extended period of total availability (2014-2023)

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: 232 products available (58%) †Country specific definitions are listed in the appendix. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. **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

Note: National Associations perform checks on historic products on a best-effort basis, although it has been noted that status changes do not often occur.

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 (64% complete), Croatia (72% complete), and North Macedonia (53% 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 (Malta is not included in EU27 average for time to availability as only 1 date was submitted in total). 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

2234 〉 **583** 〉 **402** 〉 **173**

EMA list

- List of all historic Marketing Authorisations for human and veterinary medicines (European Public Assessment Reports) accessed November 2024
- Human medicines only

Products in scope

- Products with authorisation year: 2014, 2015, 2016, 2017, 2018, 2019, 2020, 2021, 2022, 2023
- 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**

Full data cohort (10-years)

- 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

Report cohort (4-years)

- Medicines in the 4-year rolling cohort 2020 – 2023^
- Exclude products that have been withdrawn prior to analysis

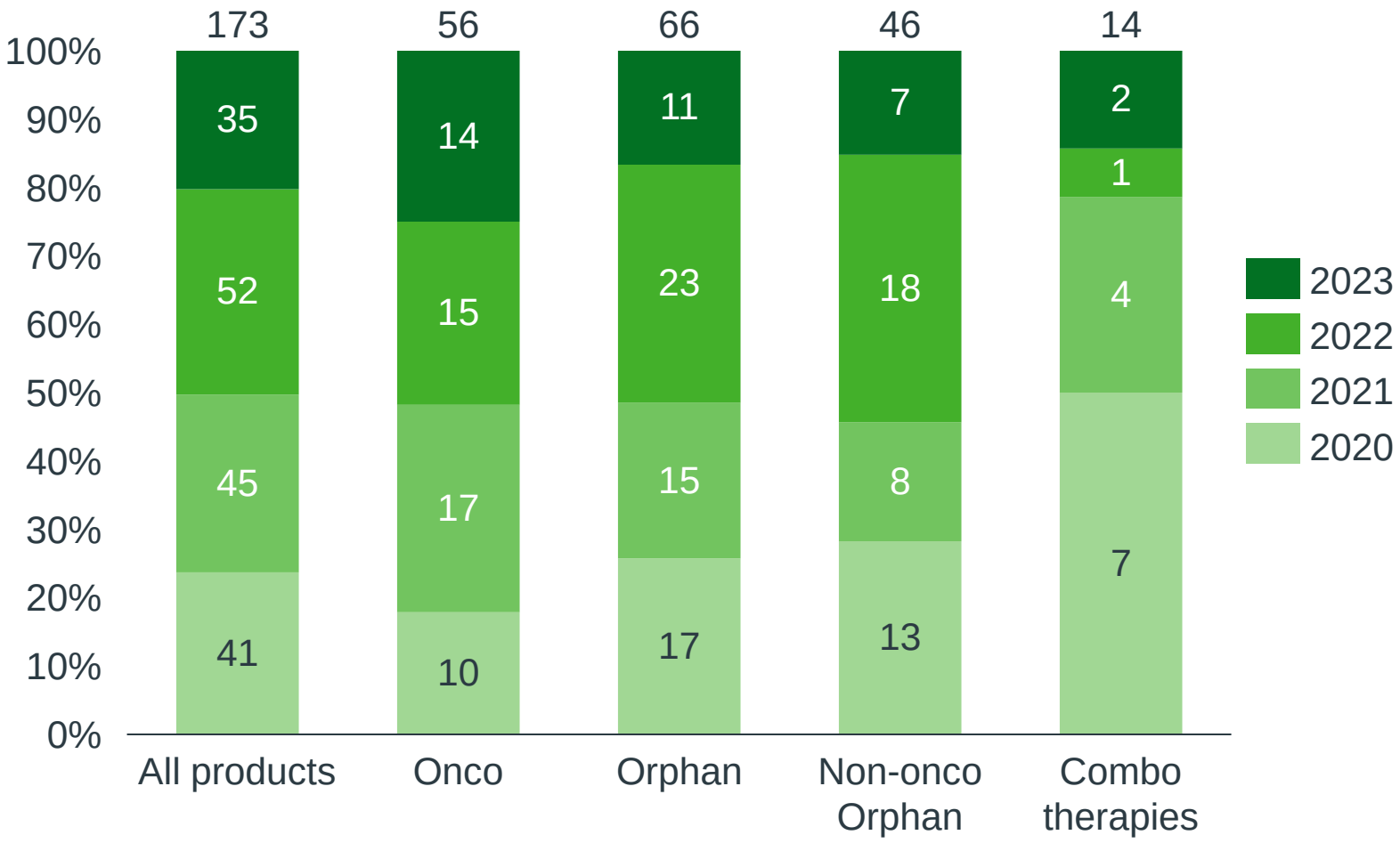
* Removal ATC class exclusions: K = Hospital Solutions; V = Various, T = Diagnostics; Oncology definition used throughout = L1 & L2 & L3B1 & V3C & Proleukin

** 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 2024)
- 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: 2020-2023 approvals (n=173)

Abecma	Eladynos	Kaftrio	Nustendi	Rukobia	Tukysa
Adtralza	Elfabrio	Kapruvia	Omvoh	Rybelsus	Uplizna
Agamree	Elrexfio	Kerendia	Ontozry	Rybrevant	Upstaza
Akeega	Elzonris	Kesimpta	Opdualag	Ryeqo	Vabysmo
Amvuttra	Enerzair Breezhaler / Zimbus Breezhaler	Kimmtrak	Opfolda	Saphnelo	Vafseo
Aquipta	Enhertu	Kinpeygo	Orgovyx	Sarclisa	Vanflyta
Arikayce liposomal	Enjaymo	Klisyri	Orladeyo	Scemblix	Vazkepa
Artesunate Amivas	Enspryng	Koselugo	Orserdu	Sibnayal	Veoza
Aspaveli	Evkeeza	Leqvio	Oxlumo	Skytrofa	Verquvo
Atectura Breezhaler	Evrenzo	Libmeldy	Padcev	Sogroya	Vocabria
Ayvakyt	Evrysdi	Litfulo	Pemazyre	Sotyktu	Voraxaze
Beovu	Fetcroja	Livmarli	Phesgo	Spevigo	Voxzogo
Bimzelx	Filsuvez	Livtencity	Piqray	Sunlenca	Vumerity
Breyanzi	Finlee	Loargys	Pluvicto	Sunosi	Vydura
Briumvi	Fintepla	Lumykras	Polivy	Tabrecta	Vyepti
Brukinsa	Gavreto	Lunsumio	Pombiliti	Talvey	Vyvgart
Byfavo	Givlaari	Lupkynis	Ponvory	Tavlesse	Wegovy
Bylvay	Hemgenix	Lyfnua	Pyrukynd	Tavneos	Xenleta
Calquence	Hepcludex	Lytgobi	Qinlock	Tecartus	Xenpozyme
Camzyos	Hyftor	Mayzent	Quviviq	Tecovirimat SIGA	Xofluza
Carvykti	Idefirix	Minjuvi	Rayvow	Tecvayli	Yorvipath
Cibinqo	Imcivree	Mounjaro	Reblozyl	Tepkinly	Yselty
Columvi	Imjudo	Mycapssa	Recarbrio	Tepmetko	Zeposia
Copiktra	Inaqovi	Nexpovio	Rekambys	Tevimbra	Zilbrysq
Daurismo	Inrebic	Nexviadyme	Retsevmo	Tezspire	Zokinvy
Dovprela	Isturisa	Ngenla	Rezzayo	Tibsovo	Zolgensma
Drovelis/Lydisilka*	Jaypirca	Nilemdo	Roclanda	Trepulmix	Ztalmy
Ebglyss	Jemperli	Nubeqa	Roctavian	Trixeo Aerosphere	Zynlonta
Ebvallo	Jyseleca	Nulibry	Rozlytrek	Trodelvy	

* 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: 2020-2023 approvals (n=173)

Oncologics (n=56)

Abecma	Nubeqa
Akeega	Opdualag
Ayvakyt	Orgovyx
Breyanzi	Orserdu
Brukinsa	Padcev
Calquence	Pemazyre
Carvykti	Phesgo
Columvi	Piqray
Copiktra	Pluvicto
Daurismo	Polivy
Ebvallo	Qinlock
Elrexfio	Retsevmo
Elzonris	Rozlytrek
Enhertu	Rybrevant
Finlee	Sarclisa
Gavreto	Scemblix
Imjudo	Tabrecta
Inaqovi	Talvey
Inrebic	Tecartus
Jaypirca	Tecvayli
Jemperli	Tepkinly
Kimmtrak	Tepmetko
Koselugo	Tevimbra
Lumykras	Tibsovo
Lunsumio	Trodelvy
Lytgobi	Tukysa
Minjuvi	Vanflyta
Nexpovio	Zynlonta

Orphans (n=66)

Abecma	Livmarli
Agamree	Livtencity
Amvuttra	Loargys
Arikayce liposomal	Lunsumio
Artesunate Amivas	Minjuvi
Aspaveli	Mycapssa
Ayvakyt	Ngenla
Bylvay	Nulibry
Carvykti	Oxlumo
Columvi	Pemazyre
Daurismo	Polivy
Dovprela	Pyrukynd
Ebvallo	Qinlock
Elzonris	Reblozyl
Enjaymo	Rezzayo
Enspryng	Roctavian
Evrysdi	Scemblix
Filsuvez	Skytrofa
Finlee	Sogroya
Fintepla	Talvey
Givlaari	Tavneos
Hemgenix	Tecartus
Hepcludex	Tibsovo
Hyftor	Trepulmix
Idefirix	Upstaza
Imcivree	Voraxaze
Inrebic	Voxzogo
Isturisa	Vyvgart
Kaftrio	Xenpozyme
Kimmtrak	Yorvipath
Kinpeygo	Zokinvy
Koselugo	Zolgensma
Libmeldy	Ztalmy

Non-oncologic orphans (n=46)

Agamree	Livtencity
Amvuttra	Loargys
Arikayce liposomal	Mycapssa
Artesunate Amivas	Ngenla
Aspaveli	Nulibry
Bylvay	Oxlumo
Dovprela	Pyrukynd
Enjaymo	Reblozyl
Enspryng	Rezzayo
Evrysdi	Roctavian
Filsuvez	Skytrofa
Fintepla	Sogroya
Givlaari	Tavneos
Hemgenix	Trepulmix
Hepcludex	Upstaza
Hyftor	Voraxaze
Idefirix	Voxzogo
Imcivree	Vyvgart
Isturisa	Xenpozyme
Kaftrio	Yorvipath
Kinpeygo	Zokinvy
Libmeldy	Zolgensma
Livmarli	Ztalmy

Combination therapies (n=14)

Akeega	Opdualag
Atectura Breezhaler	Phesgo
Drovelis/Lydisilka*	Recarbrio
Enerzair Breezhaler / Zimbus Breezhaler	Roclanda
Inaqovi	Ryeqo
Kaftrio	Sibnayal
Nustendi	Trixeo Aerosphere

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	***REFINED*** 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/partial recommendation from the Danish Medicines Council.
England	***REFINED*** 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, COHERE or FINCCHTA. For the remaining medicines hospital formulary decisions and sales data is analysed to determine if product is 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	Accessibility on the public reimbursement list (retail drugs); or product D and H commercialized medicines (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)
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: 1) Reimbursement list valid from January 1st 2025 or 2) DRG list for drugs used during hospitalization for 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 20st 2024 (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	***REFINED*** The medicine gained market approval by Swissmedic. Delay calculated using local market authorisation and dates from admission into the specialty list.
Turkey	***REFINED*** 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

Country	Definition of limited availability
Austria	Products outside reimbursement system (EKO), but reimbursed on individual pre-approval (No Box)
Belgium	***REFINED*** 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	***REFINED*** 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 products with individual access as well as products that have received conditional reimbursement or single reimbursement by the Danish Medicines Agency.
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*** Product is recommended for a restricted use relative to licenced indication(s), either 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 limitation or is regional.
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	***REFINED*** 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)
Serbia	Products are reimbursed with significant restrictions on the number of patients (e.g. for new generation HepC medicines, there is a cap on only 60 patients per year) or number of indications
Slovakia	***REFINED*** Drugs included in the reimbursement list have some limitations (prescription limitation defining specialist that can prescribe the drug) or indication limitation (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	***REFINED*** 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

Country	Definition of the availability date
Austria	The first date of availability on the public reimbursement list or Austrian Pharmacies list
Belgium	***REFINED*** 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	***REFINED*** The first date of availability on the public reimbursement list. If not reimbursed, date of first availability on the market.
Denmark	***REFINED*** 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	***REFINED*** 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*** Date of availability is the first day of reimbursement after HILAs positive decision, or when national contract becomes valid after COHERE's or FINCCHTA's recommendation, or for the remaining medicines, when regular sales is recorded.
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	The first date of availability on the public reimbursement list
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	***REFINED*** 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.
Serbia	The first date of availability on the public reimbursement list
Slovakia	***REFINED*** The first date of availability on the reimbursement list (published on monthly basis) or in DRG list for hospital only drugs (published annualy starting January st and valid for the rest 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	***REFINED*** 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	***REFINED*** 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”

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