

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

Published May 2026

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# Foreword

*Indicators measure availability, restrictions to availability and time to availability*

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

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

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

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

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



## Long-running

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



## Broad coverage

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



## Widely referenced

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

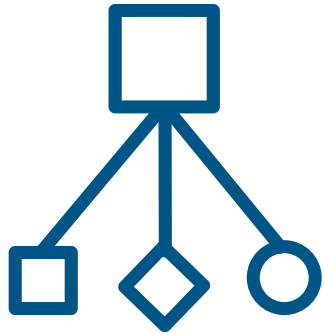


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# The study is based on the core concept of “availability”

## *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”**

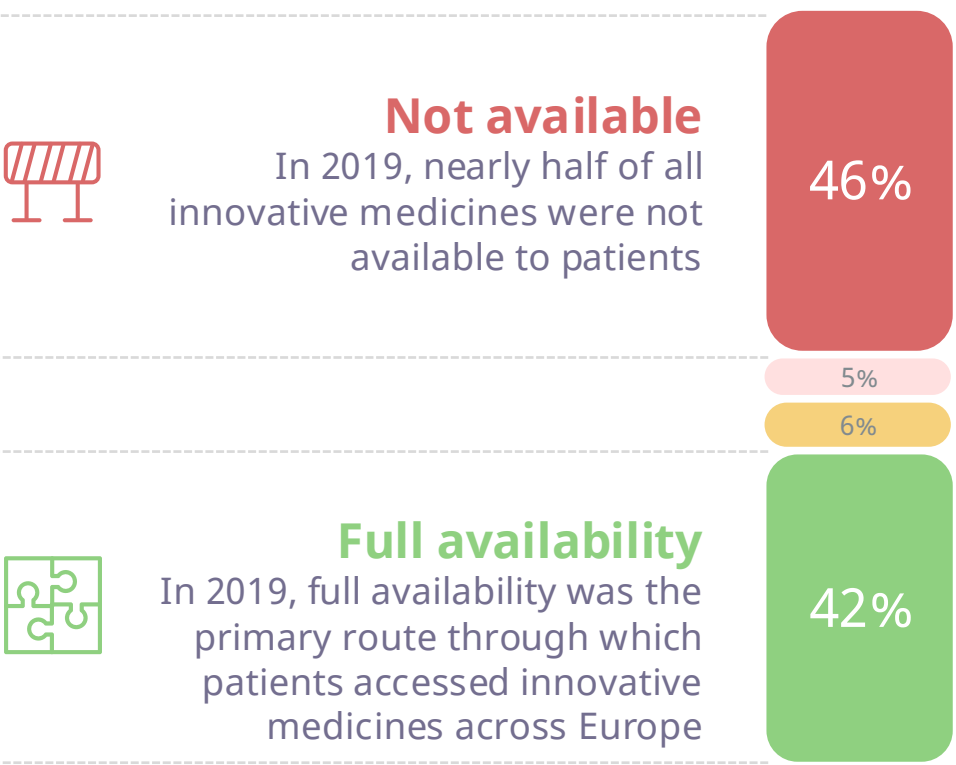
Where appropriate it takes into consideration things like managed entry agreements, line-of-therapy or formulary restrictions. However, it does not have a correlation to the use / uptake of the medicines.

**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.**

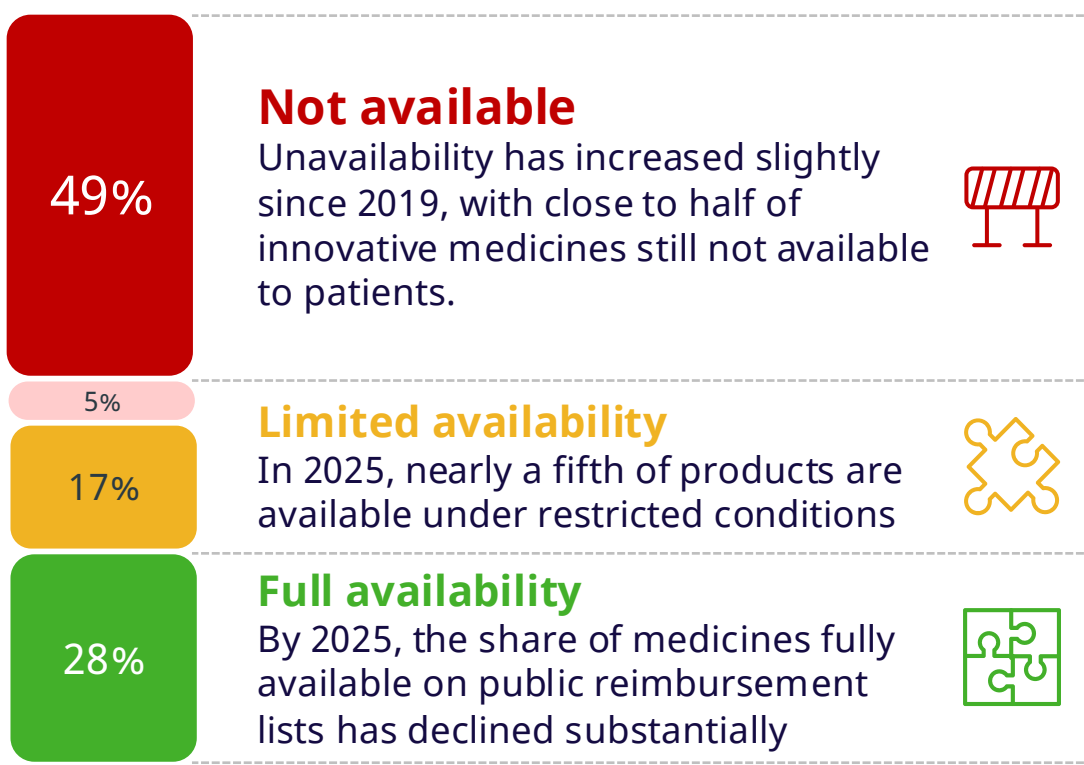
# The access landscape in Europe has continued to evolve

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

## Historic landscape (2019)



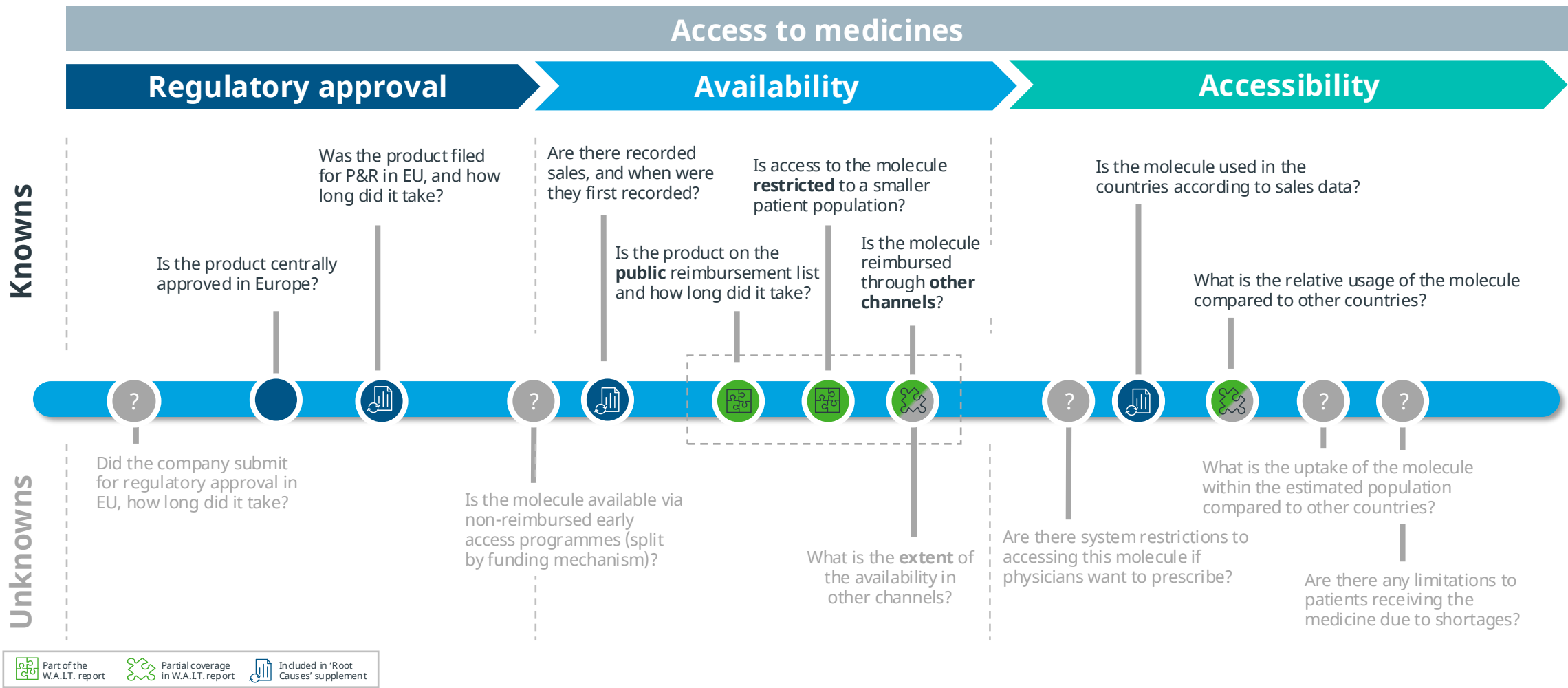
## Current landscape (2025)



Notes: EU averages of full / limited availability are calculated using absolute figures before determining the percentage. This approach ensures a more accurate representation by accounting for the varying number of available medicines in each EU country, thereby avoiding potential distortions that could arise from averaging individual country percentages. Segments total 99% due to rounding. Source: Historic landscape shows data from 2019 W.A.I.T. study (EU average availability for 24 countries: EU 27 excl Cyprus, Luxembourg, and Malta); Current landscape shows data from 2025 W.A.I.T. study (EU average from EU27 countries)

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

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



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



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

28%

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

17%

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

597<sub>days</sub>

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

88%

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

## Notes for consideration



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



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



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

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

| Patients W.A.I.T. Indicators |                                            | Purpose of the indicator                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Limitations                                                                                                                                                                                                                                             |
|------------------------------|--------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Rate of availability         | Total availability by approval year        | <ul style="list-style-type: none"> <li>› To show the availability of molecules <i>within</i> the 4-year cohort (2021-2024 approvals)</li> </ul>                                                                                                                                                                                                                                                                                                                                                                    | <ul style="list-style-type: none"> <li>- Does not show the extent to which patient populations can access novel medicines</li> </ul>                                                                                                                    |
|                              | Rate of availability                       | <ul style="list-style-type: none"> <li>› To provide an overview of patient's potential to access novel medicines</li> <li>› To be used in conjunction with '<b>Breakdown of availability</b>' KPI</li> </ul>                                                                                                                                                                                                                                                                                                       | <ul style="list-style-type: none"> <li>- Does not show the extent to which patient populations can access novel medicines</li> </ul>                                                                                                                    |
|                              | Breakdown of availability                  | <ul style="list-style-type: none"> <li>› 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)</li> </ul>                                                                                                                                                                                                                                                                               | <ul style="list-style-type: none"> <li>- Does not show a breakdown of the other types of limited availability (i.e. restricted to subpopulation, whilst decision pending, etc.)</li> </ul>                                                              |
|                              | Breakdown of total availability            | <ul style="list-style-type: none"> <li>› To provide granular insight into public, private, and non-availability of novel medicines</li> <li>› To show where data on medicine availability is not available</li> </ul>                                                                                                                                                                                                                                                                                              | <ul style="list-style-type: none"> <li>- Does not show a breakdown of the other types of limited availability (i.e. restricted to subpopulation, whilst decision pending, etc.)</li> </ul>                                                              |
| Time to availability         | Time from central approval to availability | <ul style="list-style-type: none"> <li>› To provide a consistent picture on time to availability from a standardised point in time – the European Commission's approval date</li> <li>› To show any outliers and fastest medicine's time to access, plus other statistical metrics</li> </ul>                                                                                                                                                                                                                      | <ul style="list-style-type: none"> <li>- The indicator is less representative for non-EU27 countries</li> <li>- A box and whisker plot can be complex to read all available data points</li> </ul>                                                      |
|                              | Time to availability                       | <ul style="list-style-type: none"> <li>› To provide a consistent picture of time to availability from local country authorisation dates</li> <li>› To show the impact of additional local authorisation procedures on time to availability</li> <li>› To show any outliers and fastest medicine's time to access, plus other statistical metrics</li> <li>› To be used in conjunction with '<b>Time from central approval to availability</b>' KPI to compare the impact of local regulatory procedures</li> </ul> | <ul style="list-style-type: none"> <li>- A box and whisker plot can be complex to read all available data points</li> </ul>                                                                                                                             |
|                              | Median time to availability                | <ul style="list-style-type: none"> <li>› To provide a simple metric of time to availability for international comparison</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                | <ul style="list-style-type: none"> <li>- Does not show the ability for countries to provide rapid access in rare circumstances, nor significant delays</li> <li>- Outliers can skew the median, affecting the indicator's representativeness</li> </ul> |
| Other                        | Historic comparisons and extension         | <ul style="list-style-type: none"> <li>› 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)</li> </ul>                                                                                                                                                                                                                                                                                                                    | <ul style="list-style-type: none"> <li>- The indicators only show 3 years of comparison (however, additional data exists in the public domain and can be compared)</li> </ul>                                                                           |

# 1. Overview (all products)

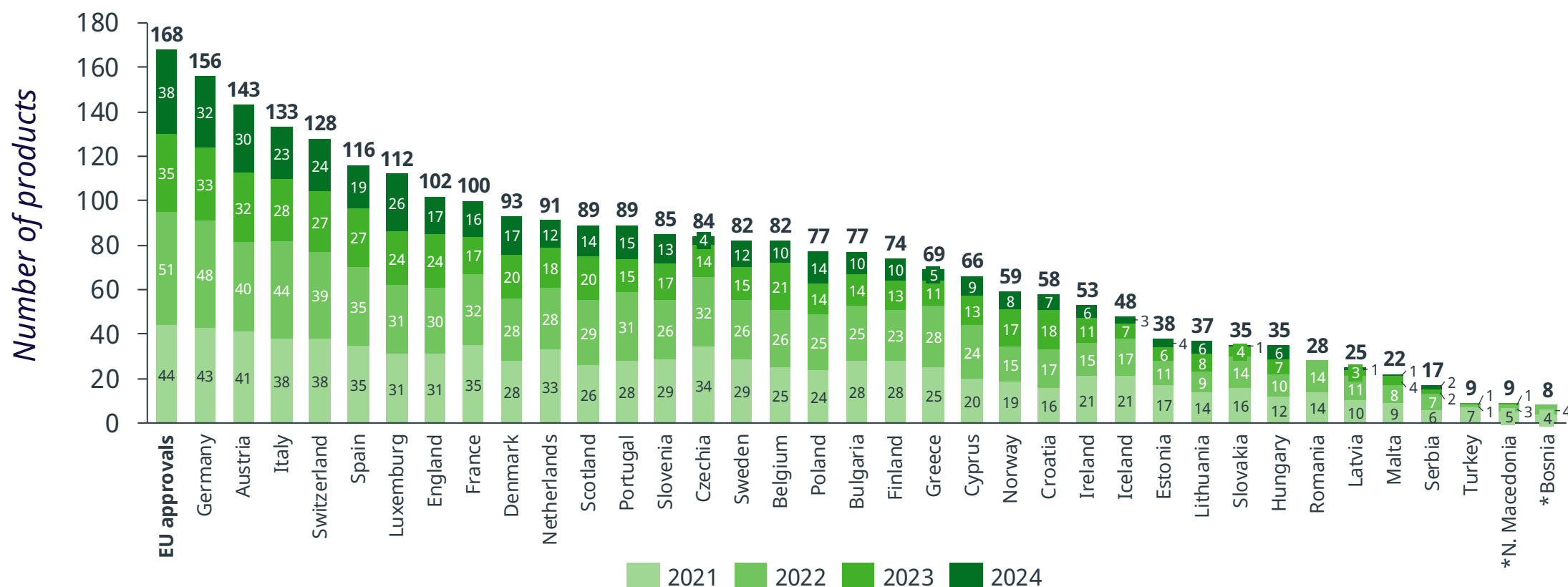
## Indicators:

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



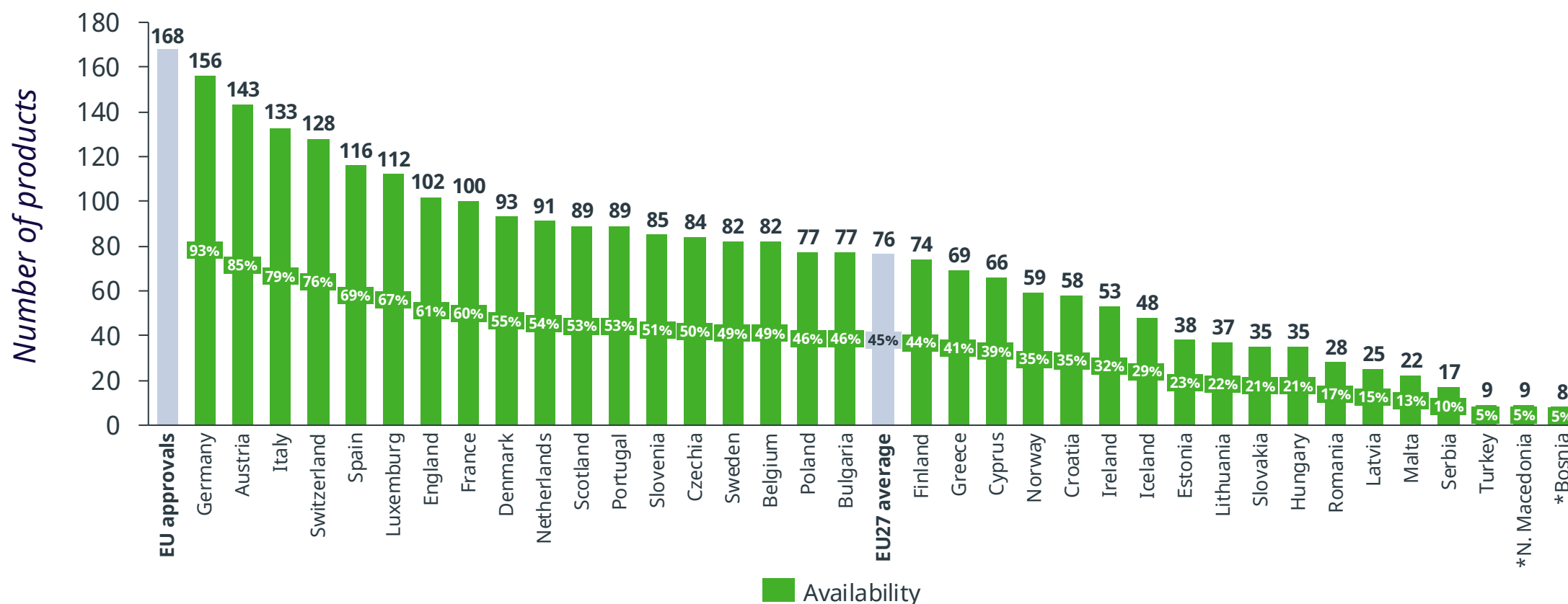
# Total availability by approval year (2021-2024)

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



# Rate of availability (2021-2024)

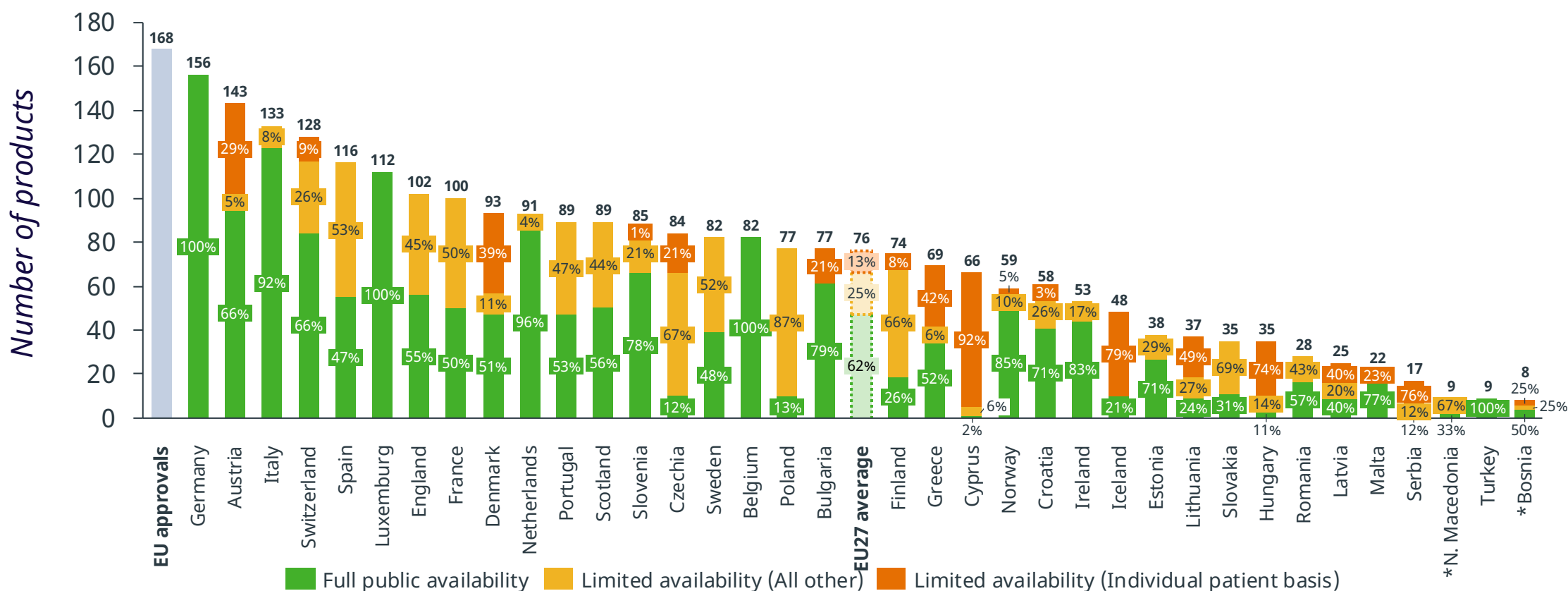
The **rate of availability**, measured by the number of medicines available to patients in European countries as of 5<sup>th</sup> January 2026. For most countries this is the point at which the product gains access to the reimbursement list<sup>†</sup>, including products with limited availability.



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

# Breakdown of availability (2021-2024)

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

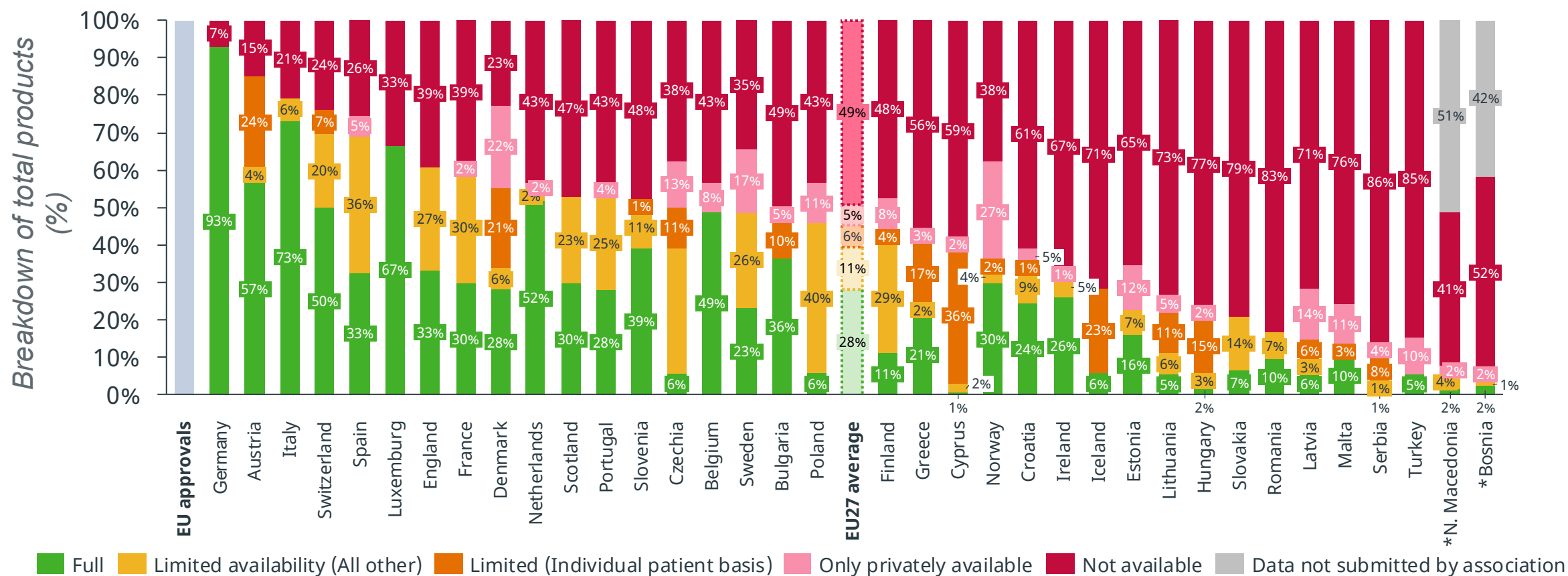


European Union average: 76 products available (45%), Limited Availability (total) (38% of available products); <sup>†</sup>Country specific definitions are listed in the appendix. Details surrounding early access schemes are provided in slide 72. \*Countries with asterisks did not complete a full dataset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

# Breakdown of total availability (% , 2021-2024)

(Countries ordered by all availability)

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

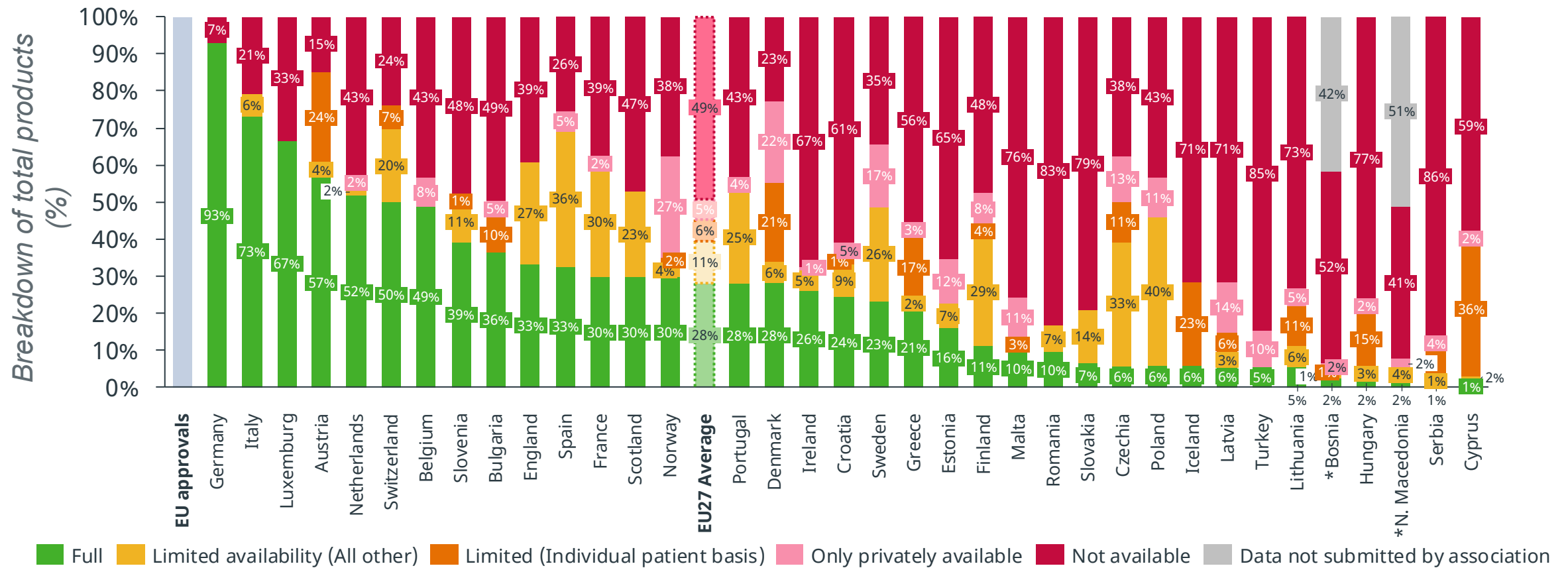


European Union average: 76 products available (45%) ; Limited Availability (17% of all products); <sup>†</sup>Country specific definitions are listed in the appendix. Details surrounding early access schemes are provided in slide 72. \*Countries with asterisks did not complete a full dataset and therefore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

# Breakdown of total availability (% , 2021-2024)

(Countries ordered by full availability)

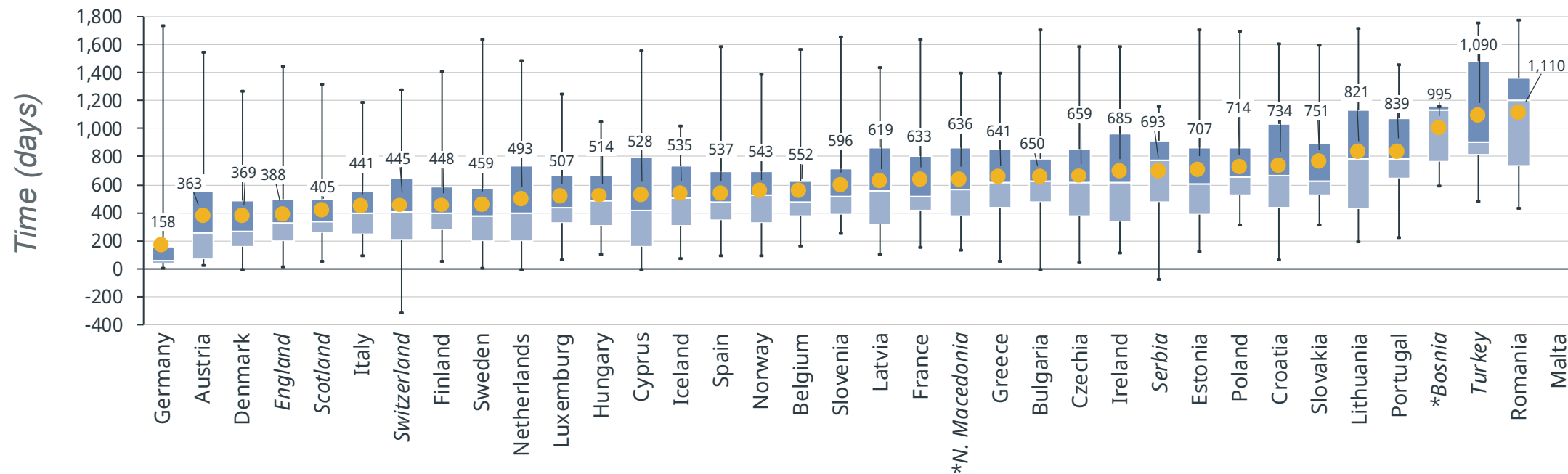
The **breakdown of total availability** is the composition of medicines available to patients in European countries as of 5<sup>th</sup> January 2026 (for most countries this is the point at which the product gains access to the reimbursement list<sup>†</sup>). This includes all medicine's status to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



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

# Time from central approval to availability (2021-2024)

The **time from central approval to availability** is the days between marketing authorisation and the date of availability to patients in European countries (for most this is the point at which products gain access to the reimbursement list<sup>†</sup>). The marketing authorisation date is the date of central EU authorisation throughout. Data is correct to 5<sup>th</sup> January 2026.



Available medicines / 168

Dates submitted / 168

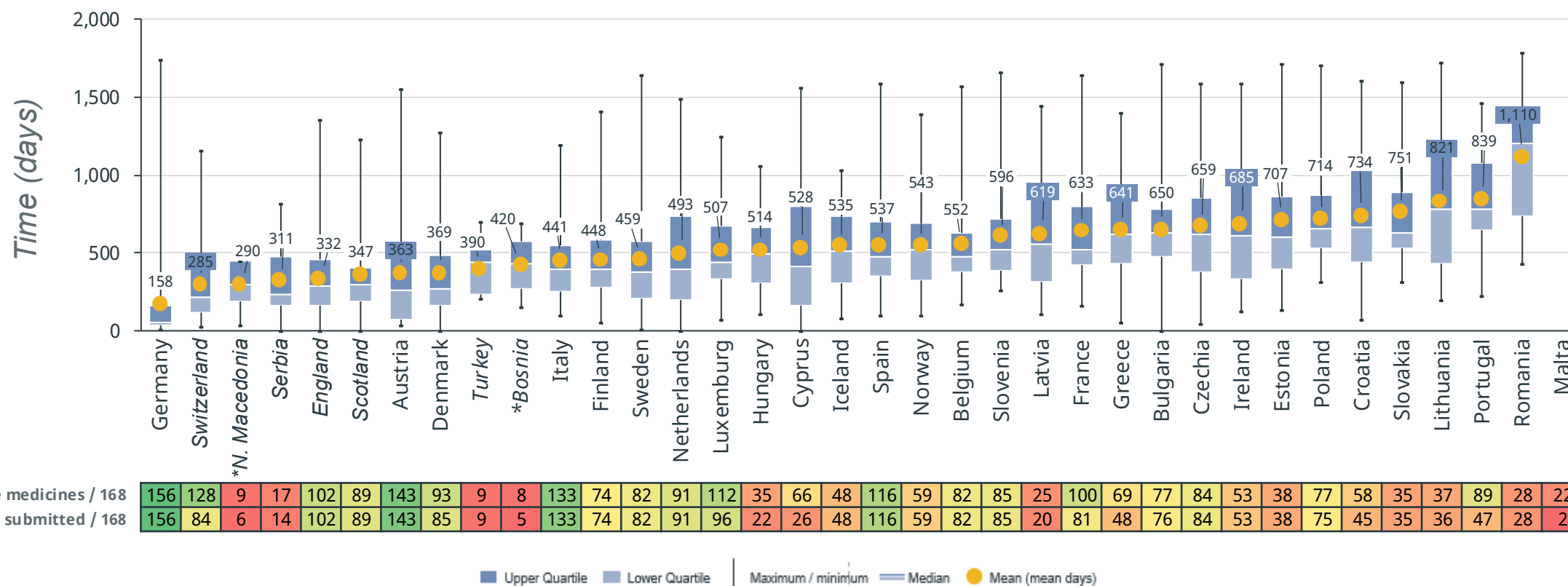
|     |     |    |     |    |     |     |    |    |    |     |    |    |    |     |    |    |    |    |    |   |    |    |    |    |    |    |    |    |    |    |    |   |   |    |    |
|-----|-----|----|-----|----|-----|-----|----|----|----|-----|----|----|----|-----|----|----|----|----|----|---|----|----|----|----|----|----|----|----|----|----|----|---|---|---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

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

**European Union average: 597 days (mean %)** <sup>†</sup>Country specific definitions are listed in the appendix. Details surrounding early access schemes are provided in slide 72. \* Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. Note: Countries with fewer than three submitted dates were excluded to avoid unreliable estimates.

# Time to availability (2021-2024)

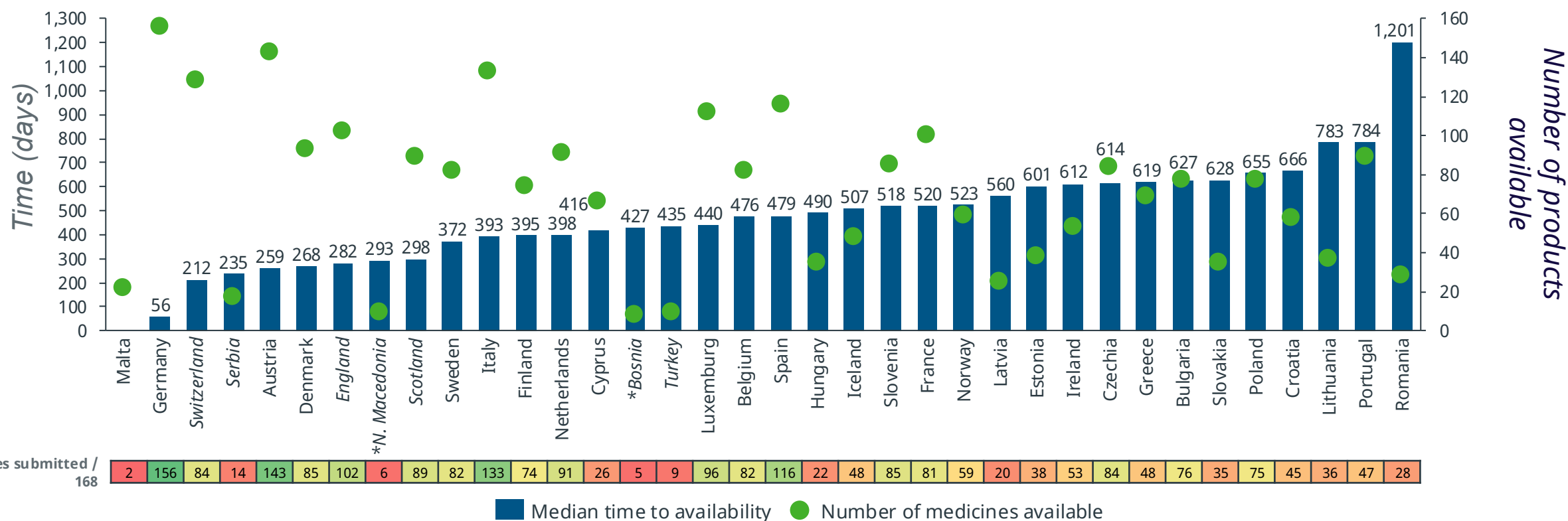
The **time to availability** is the days between marketing authorisation and the date of availability to patients in European countries (for most this is the point at which products gain access to the reimbursement list<sup>†</sup>). The marketing authorisation date is the date of central EU authorisation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



**European Union average: 597 days (mean %)** <sup>†</sup>Country specific definitions are listed in the appendix. Details surrounding early access schemes are provided in slide 72. \* Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. Note: Countries with fewer than three submitted dates were excluded to avoid unreliable estimates.

# Median time to availability (2021-2024)

The **median time to availability** is the days between marketing authorisation and the date of availability to patients in European countries (for most this is the point at which products gain access to the reimbursement list<sup>†</sup>). 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 5<sup>th</sup> January 2026.



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

# Key observations

## Executive summary (EU27 averages)

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

### Key Insights

#### Rate of availability

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

#### Time to availability

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

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



#### Metrics key:

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

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

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

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

## 2. Oncology medicines

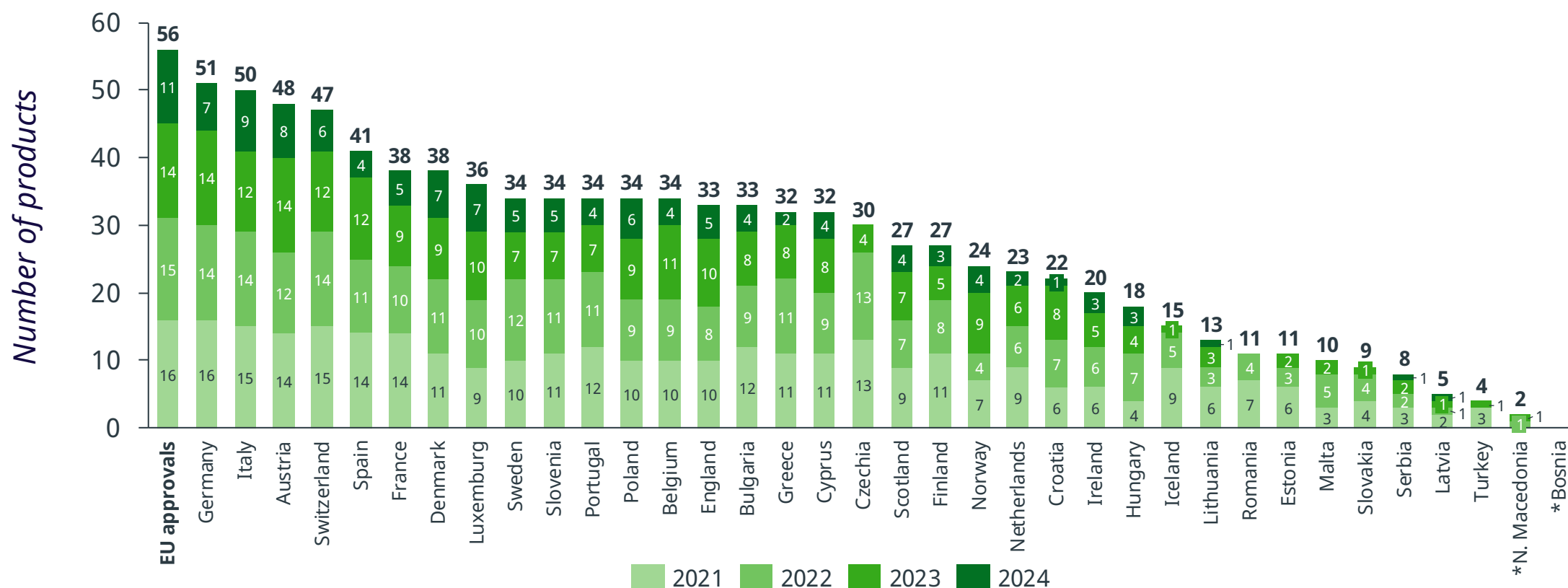
### Indicators:

- 2.1. Total availability by approval year
- 2.2. Rate of availability
- 2.3. Breakdown of availability
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- 2.7. Median time to availability
- 2.8. Key observations



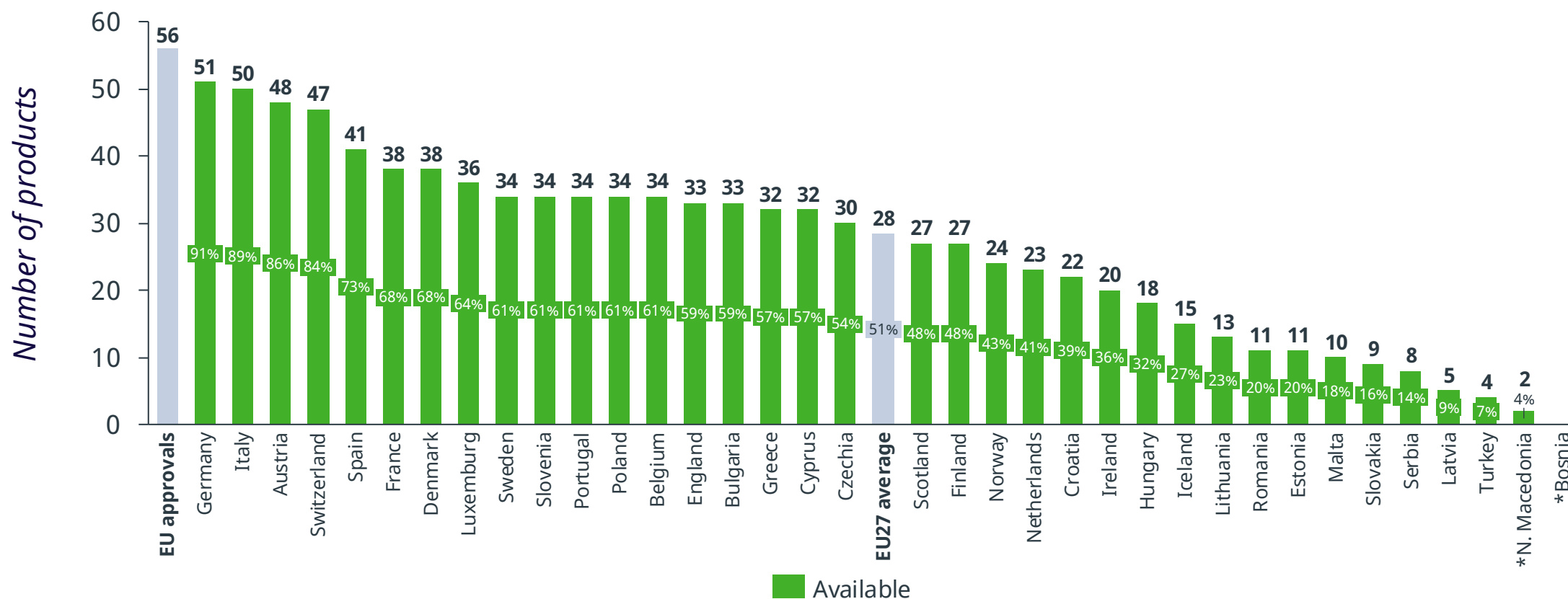
# Oncology availability by approval year (2021-2024)

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



# Oncology rate of availability (2021-2024)

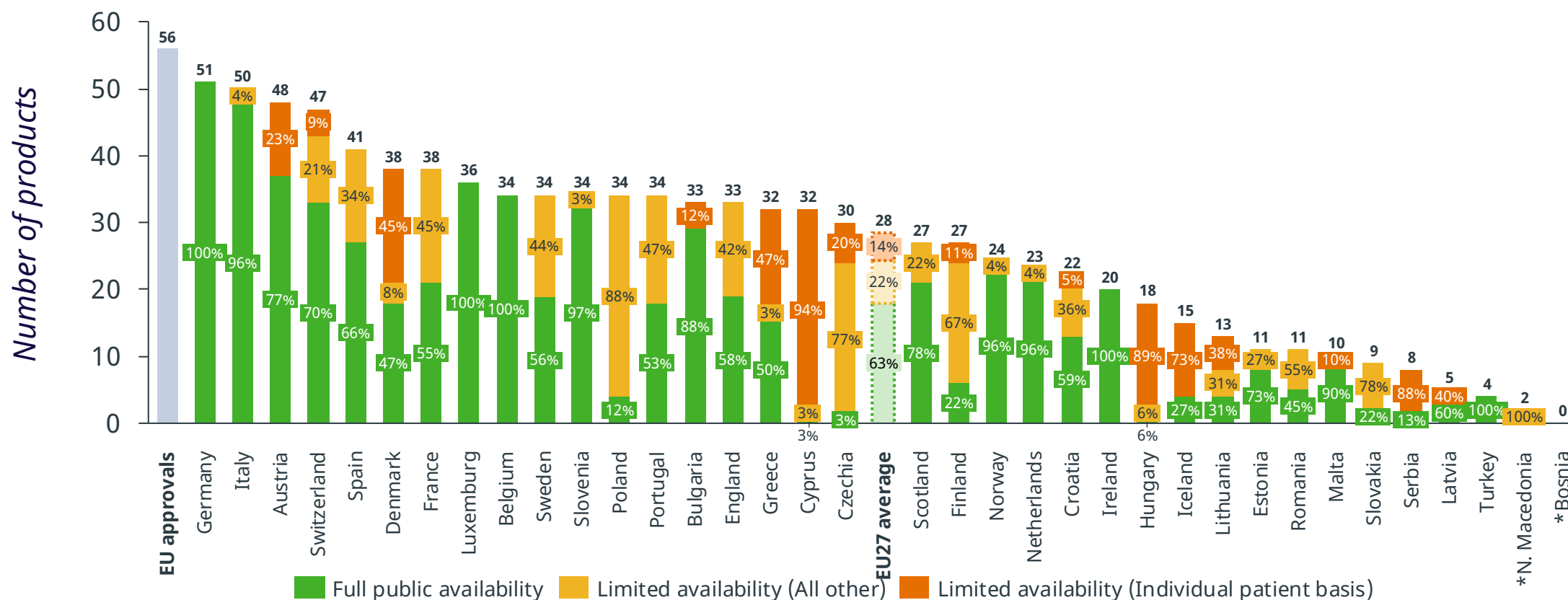
The **rate of availability**, measured by the number of medicines available to patients in European countries as of 5<sup>th</sup> January 2026. For most countries this is the point at which the product gains access to the reimbursement list<sup>†</sup>, including products with limited availability.



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

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

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

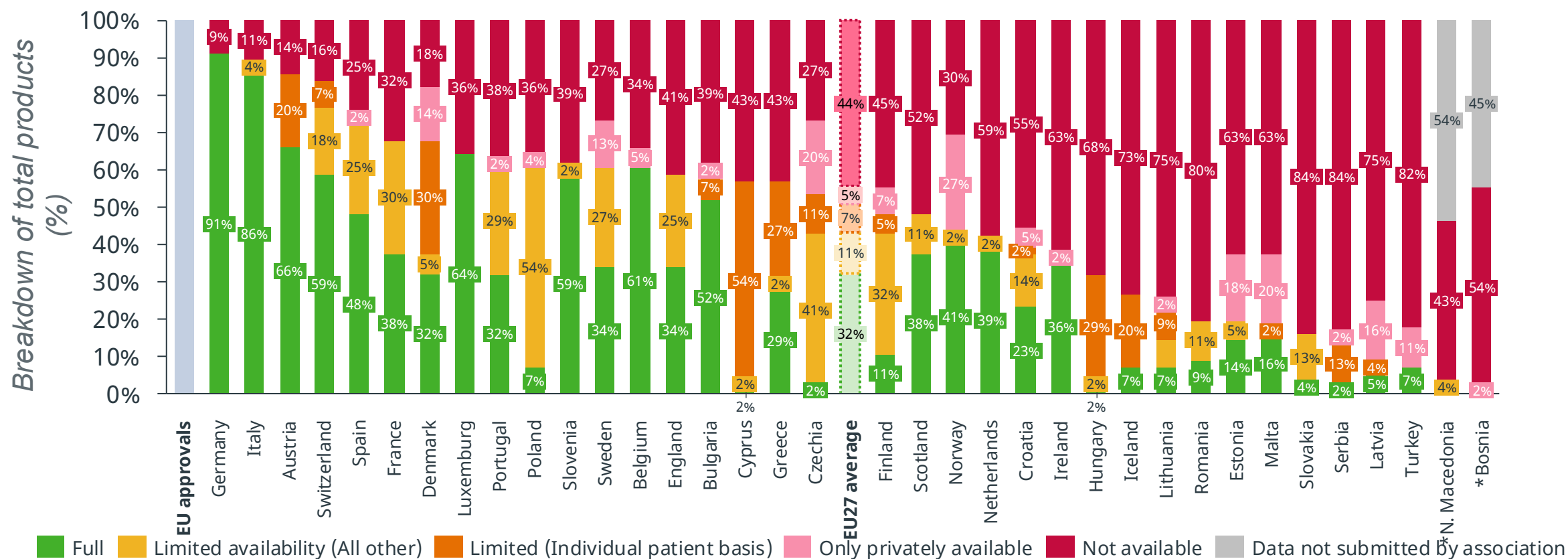


European Union average: 28 products available (51%), Limited availability (total) (36% of available products).<sup>†</sup>Country specific definitions are listed in the appendix. Details surrounding early access schemes are provided in slide 72. \*Countries with asterisks did not complete a full dataset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

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

(Countries ordered by all availability)

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

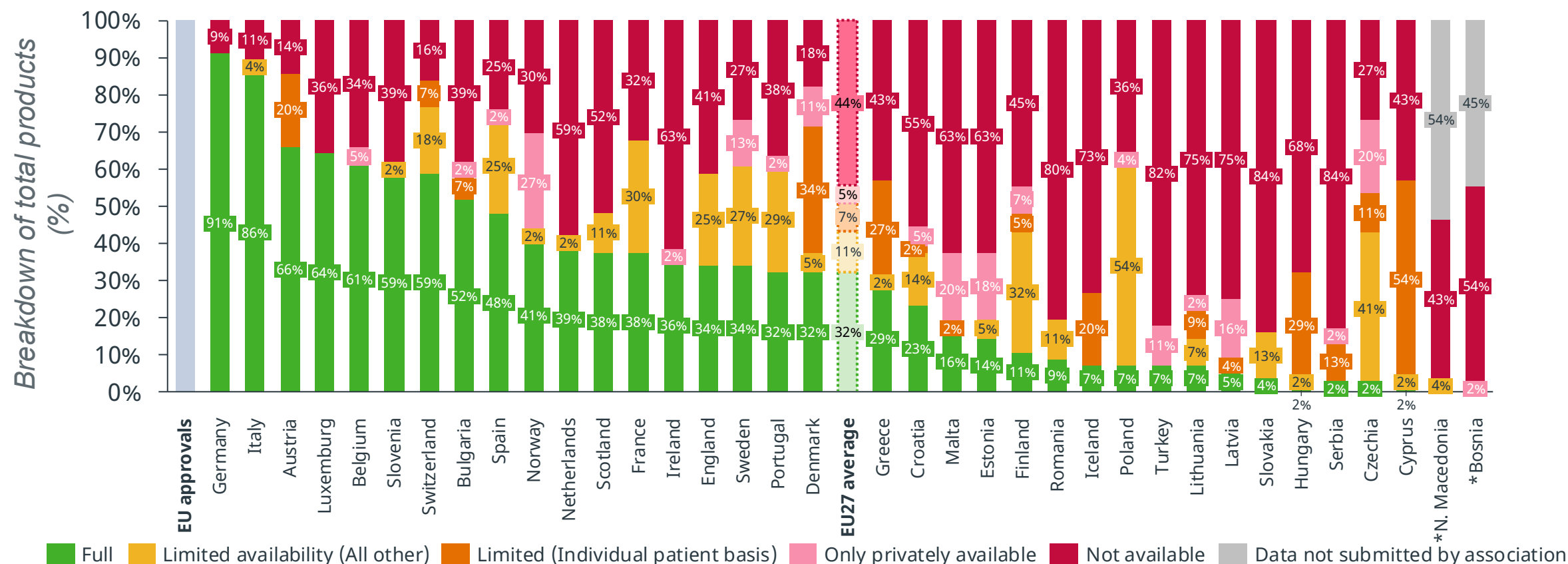


European Union average: 28 products available (51%); Limited Availability (19% of all oncology products)<sup>1</sup>; <sup>†</sup>Country specific definitions are listed in the appendix. Details surrounding early access schemes are provided in slide 72. \*Countries with asterisks did not complete a full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

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

(Countries ordered by full availability)

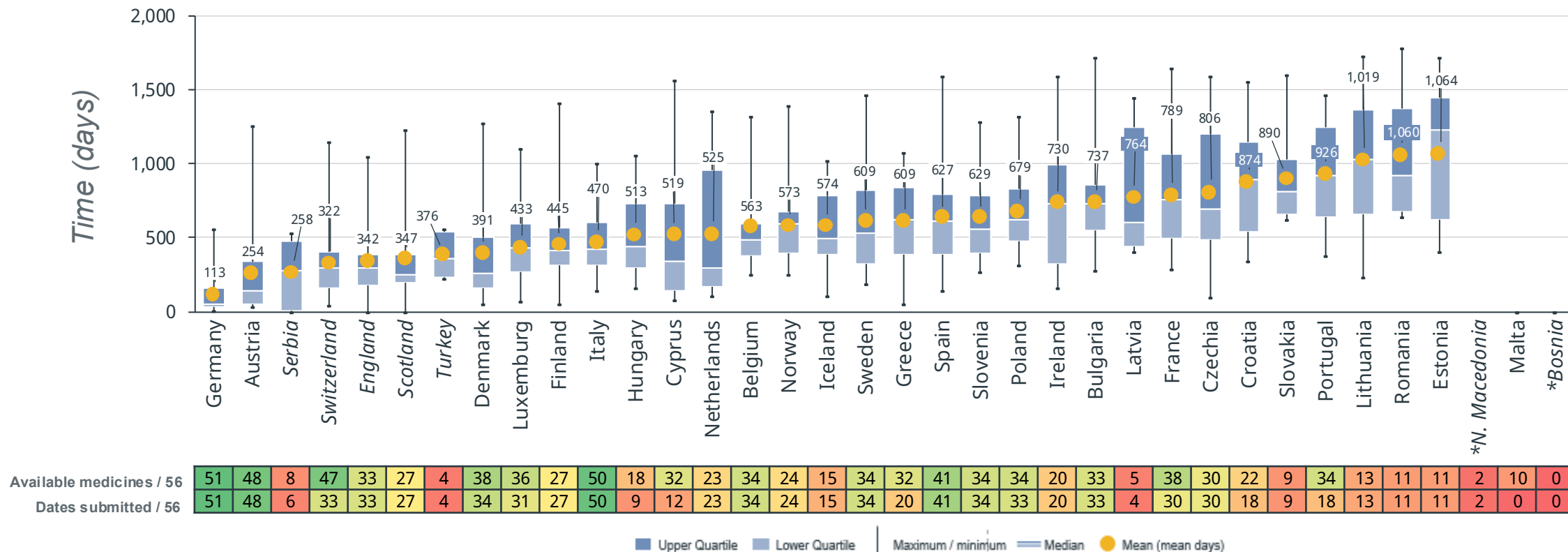
The **breakdown of total availability** is the composition of medicines available to patients in European countries as of 5<sup>th</sup> January 2026 (for most countries this is the point at which the product gains access to the reimbursement list<sup>†</sup>). This includes all medicine's status to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



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

# Oncology time to availability (2021-2024)

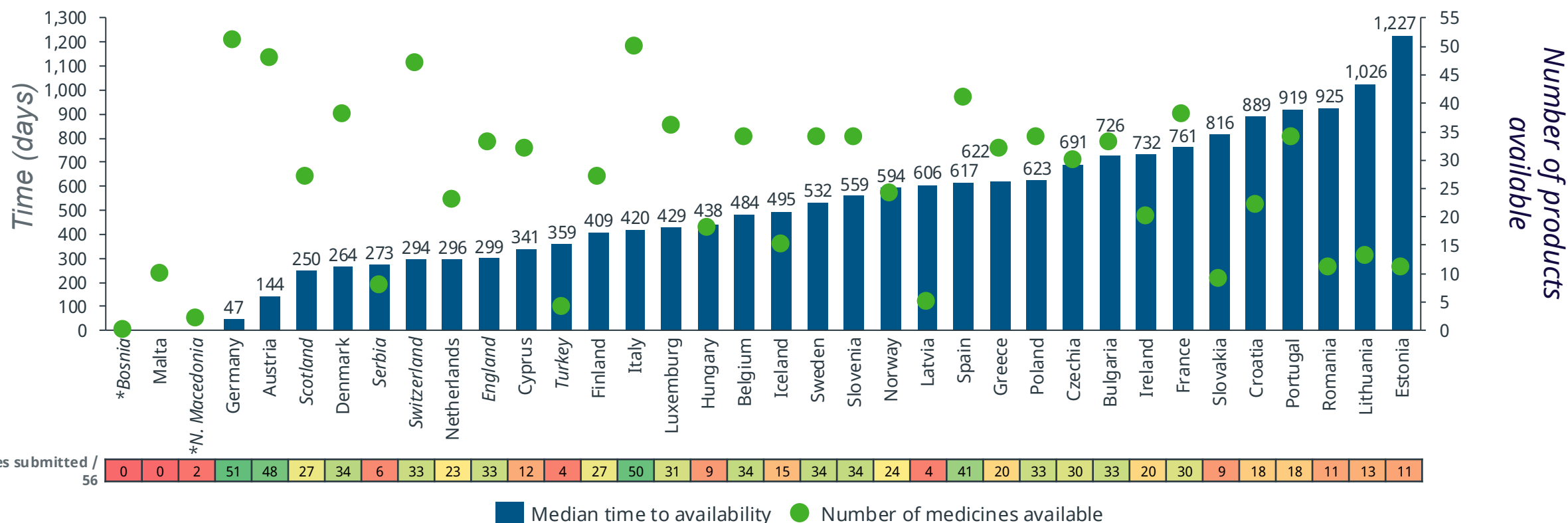
The **time to availability** is the days between marketing authorisation and the date of availability to patients in European countries (for most this is the point at which products gain access to the reimbursement list<sup>†</sup>). The marketing authorisation date is the date of central EU authorisation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



**European Union average: 655 days (mean)** <sup>†</sup>Country specific definitions are listed in the appendix. Details surrounding early access schemes are provided in slide 72. \* Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. Note: Countries with fewer than three submitted dates were excluded to avoid unreliable estimates.

# Oncology median time to availability (2021-2024)

The **median time to availability** is the days between marketing authorisation and the date of availability to patients in European countries (for most this is the point at which products gain access to the reimbursement list<sup>†</sup>). 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 5<sup>th</sup> January 2026.



# Key observations

## Executive summary (EU27 averages)

| Measure                      | All products                   | Oncology                       | Orphan                         | Non-oncologic orphan           | Combination therapy            |
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| Average time to availability | 597 Days<br>(578 days in 2024) | 655 Days<br>(586 days in 2024) | 614 Days<br>(611 days in 2024) | 595 Days<br>(607 days in 2024) | 553 Days<br>(553 days in 2024) |

### Key Insights

#### Rate of availability

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

#### Time to availability

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

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



#### Metrics key:

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

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

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

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

## 3. Orphan medicines

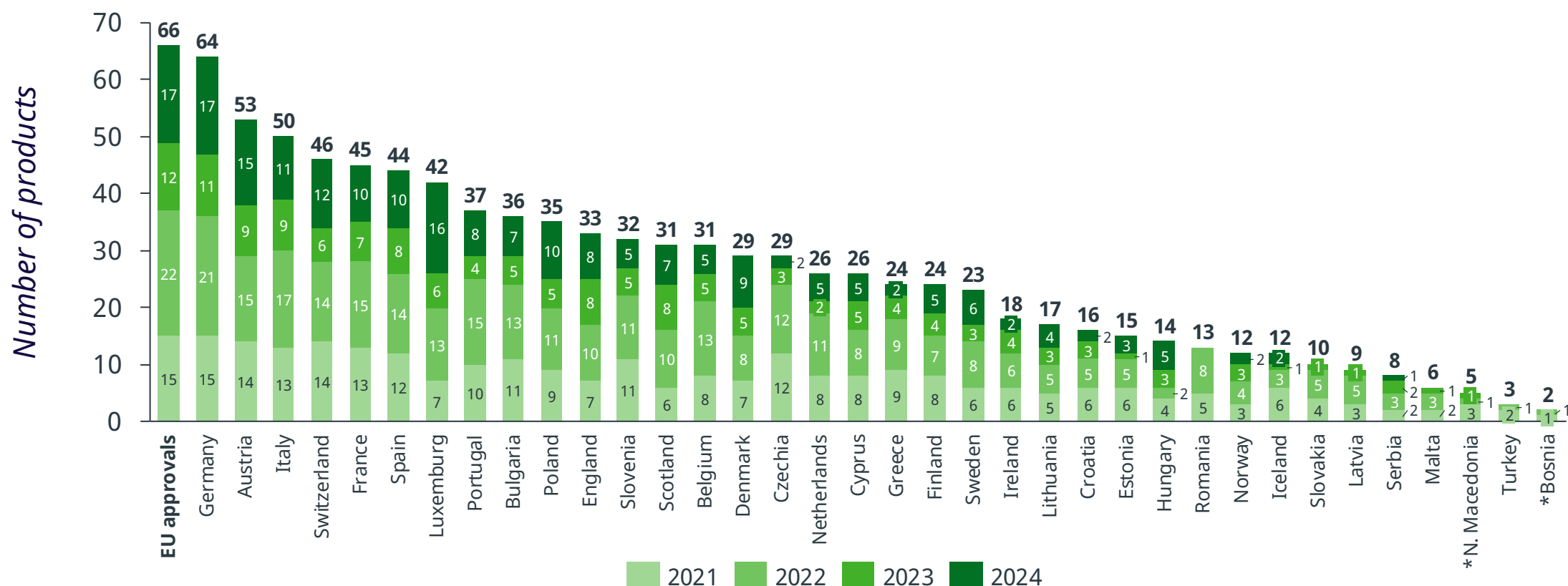
### Indicators:

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



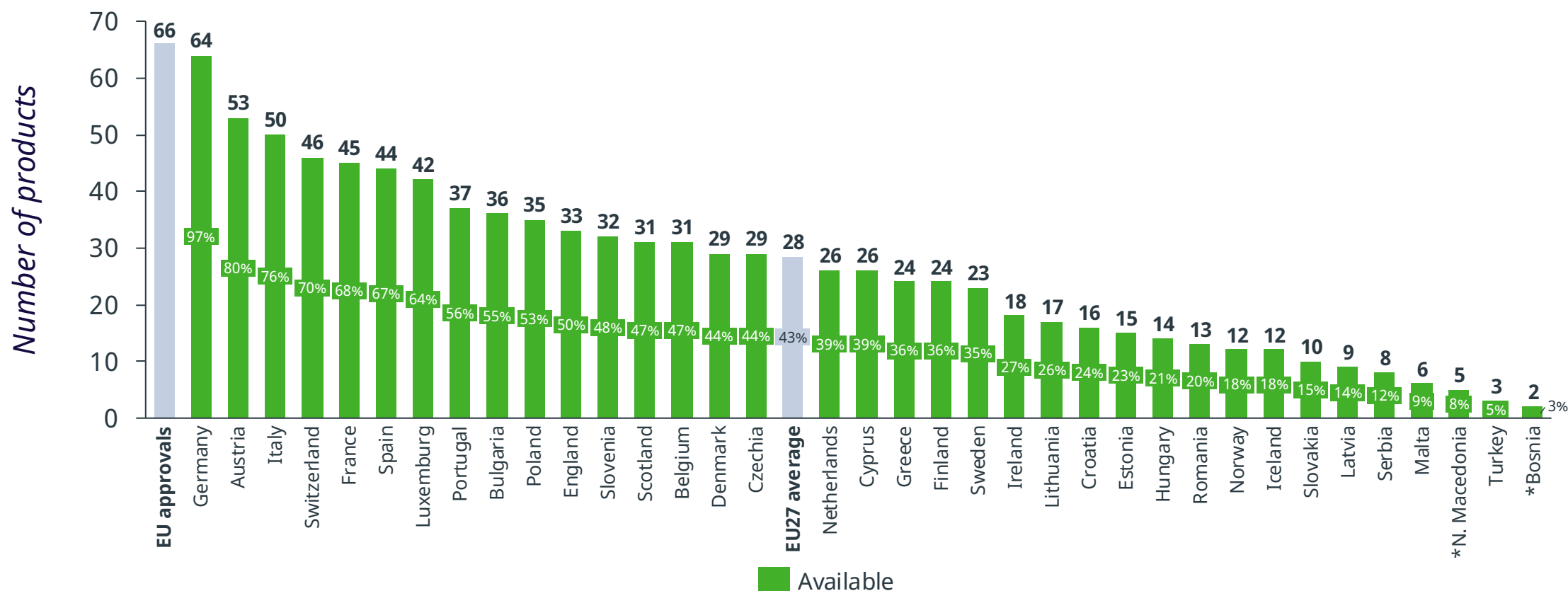
# Orphan availability by approval year (2021-2024)

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



# Orphan rate of availability (2021-2024)

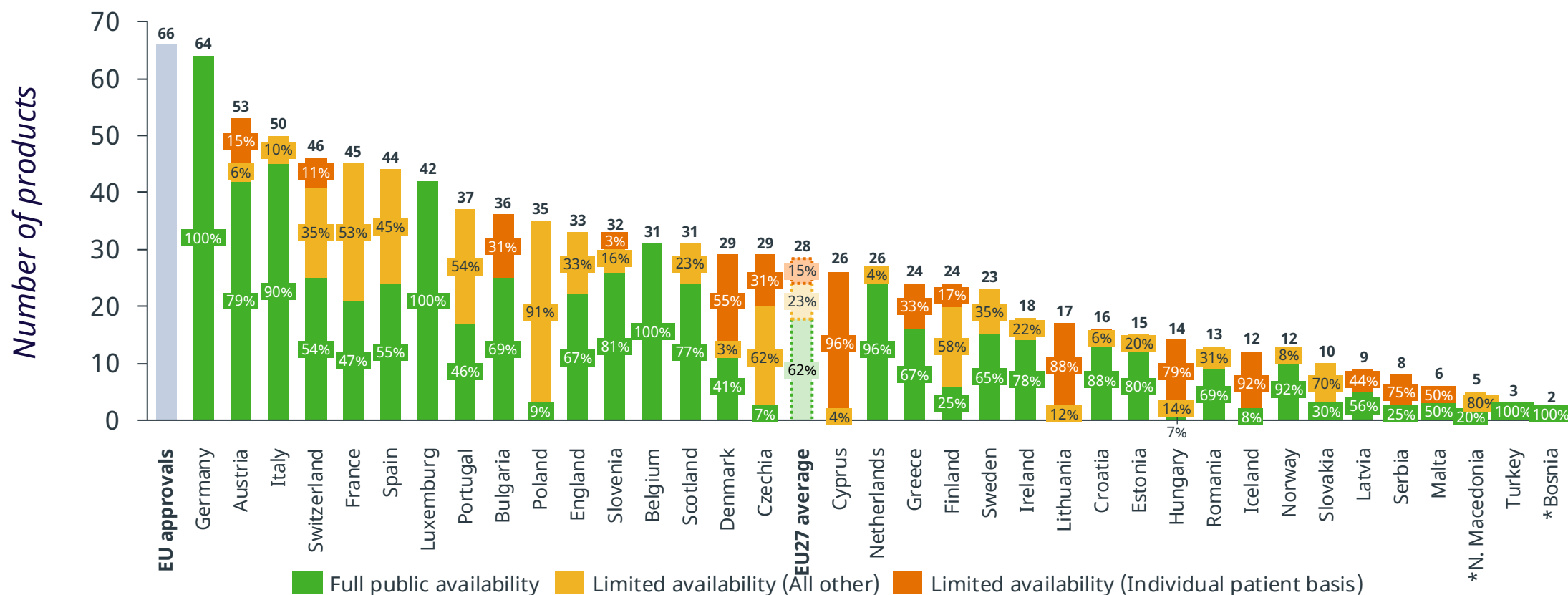
The **rate of availability**, measured by the number of medicines available to patients in European countries as of 5<sup>th</sup> January 2026. For most countries this is the point at which the product gains access to the reimbursement list<sup>†</sup>, including products with limited availability.



European Union average: 28 products available (43%) <sup>†</sup>Country specific definitions are listed in the appendix. Details surrounding early access schemes are provided in slide 72. \* Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative.

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

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

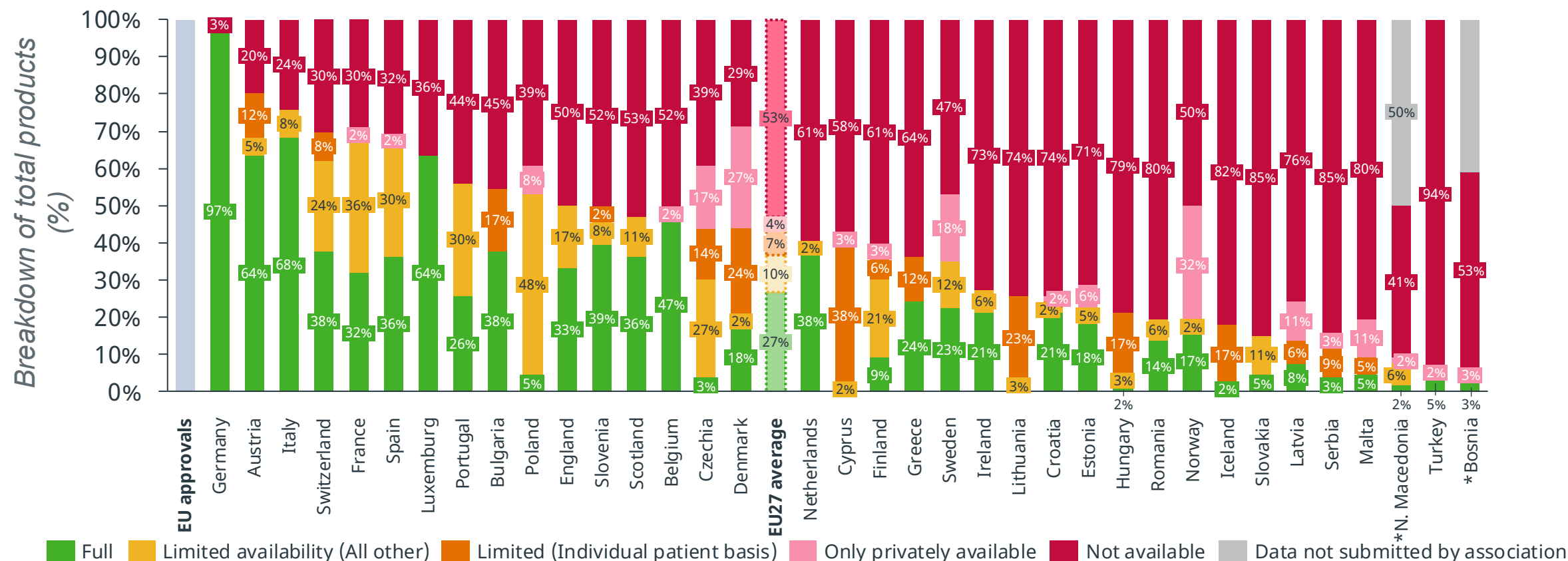


**European Union average: 28 products available (43%), Limited availability (total) (38% of available products).**<sup>†</sup>Country specific definitions are listed in the appendix. Details surrounding early access schemes are provided in slide 72. \*Countries with asterisks did not complete a full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

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

(Countries ordered by all availability)

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

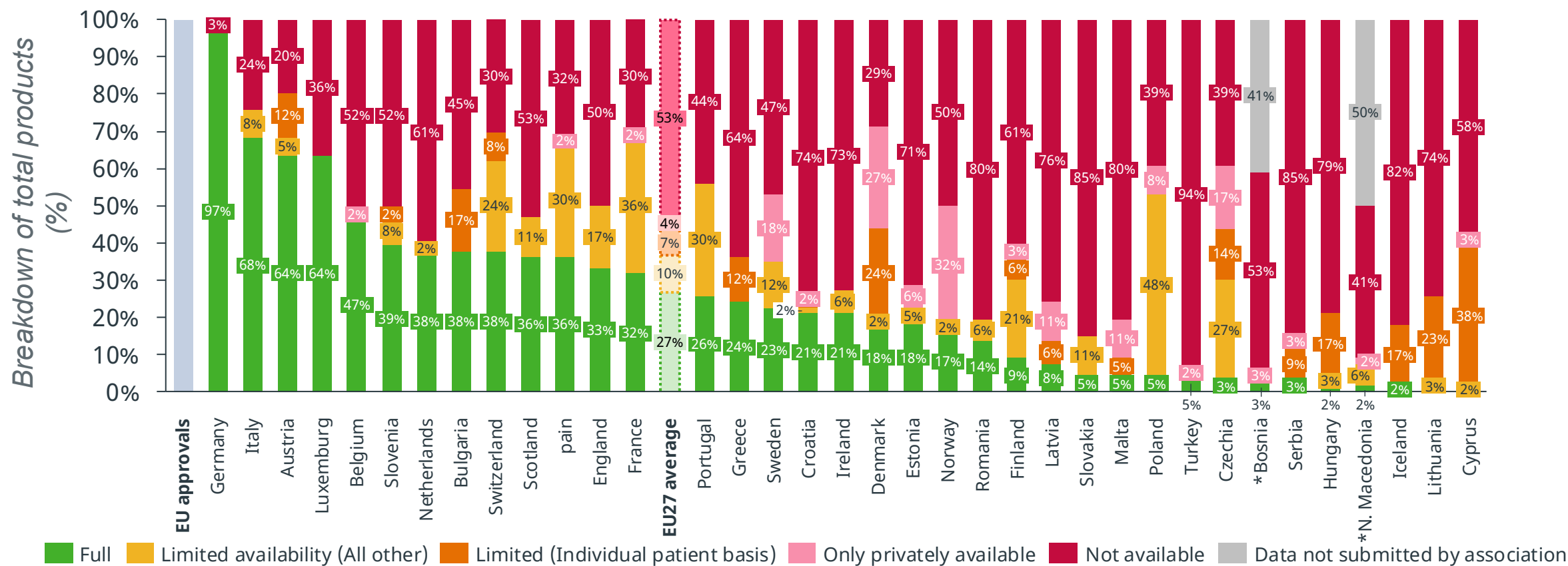


European Union average: 28 products available (43%); Limited Availability (16% of all orphan products) <sup>†</sup>; <sup>†</sup>Country specific definitions are listed in the appendix. Details surrounding early access schemes are provided in slide 72. \*Countries with asterisks did not complete a full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

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

(Countries ordered by full availability)

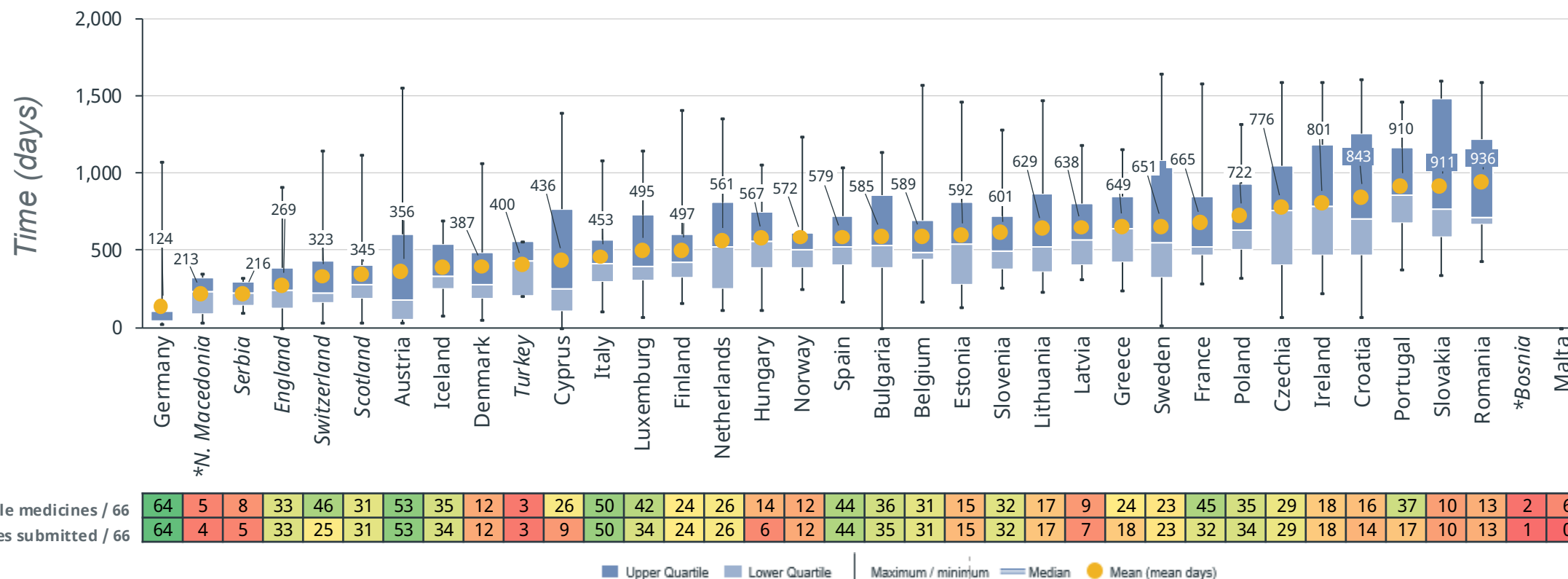
The **breakdown of total availability** is the composition of medicines available to patients in European countries as of 5<sup>th</sup> January 2026 (for most countries this is the point at which the product gains access to the reimbursement list<sup>†</sup>). This includes all medicine's status to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



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

# Orphan time to availability (2021-2024)

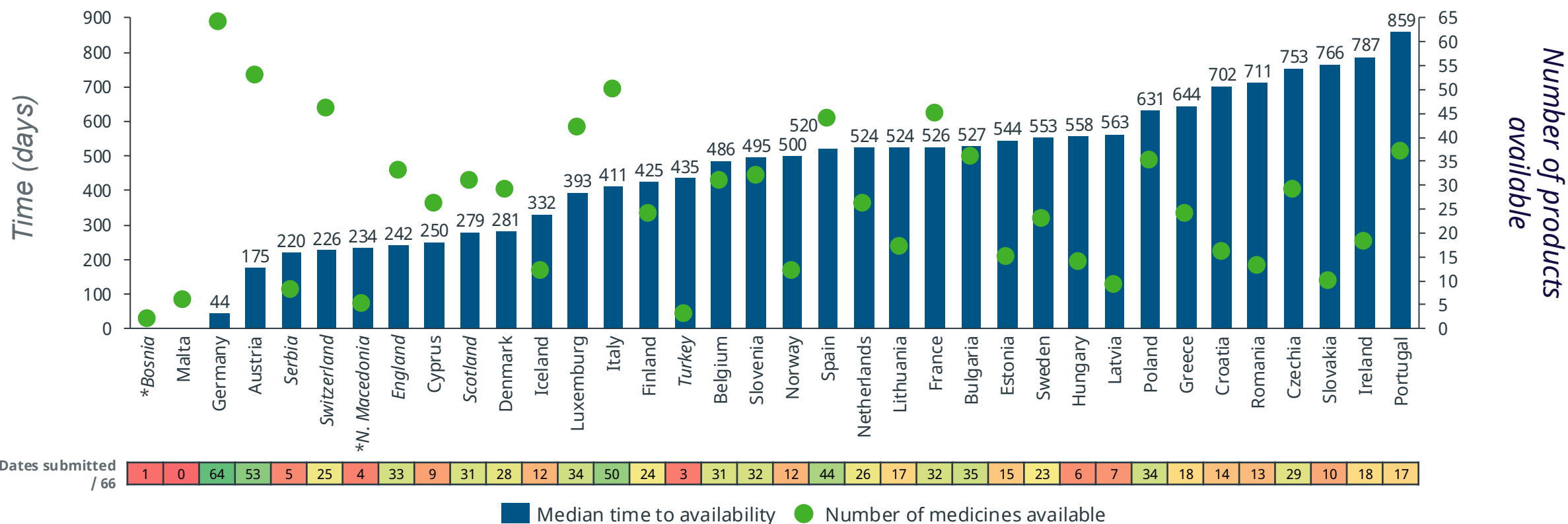
The **time to availability** is the days between marketing authorisation and the date of availability to patients in European countries (for most this is the point at which products gain access to the reimbursement list<sup>†</sup>). The marketing authorisation date is the date of central EU authorisation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



**European Union average: 614 days (mean)** <sup>†</sup>Country specific definitions are listed in the appendix. Details surrounding early access schemes are provided in slide 72. \* Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. Note: Countries with fewer than three submitted dates were excluded to avoid unreliable estimates.

# Orphan median time to availability (2021-2024)

The **median time to availability** is the days between marketing authorisation and the date of availability to patients in European countries (for most this is the point at which products gain access to the reimbursement list<sup>†</sup>). 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 5<sup>th</sup> January 2026.



# Key observations

## Executive summary (EU27 averages)

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

### Key Insights

#### Rate of availability

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

#### Time to availability

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

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



#### Metrics key:

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

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

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

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

## 4. Non-oncology orphan medicines

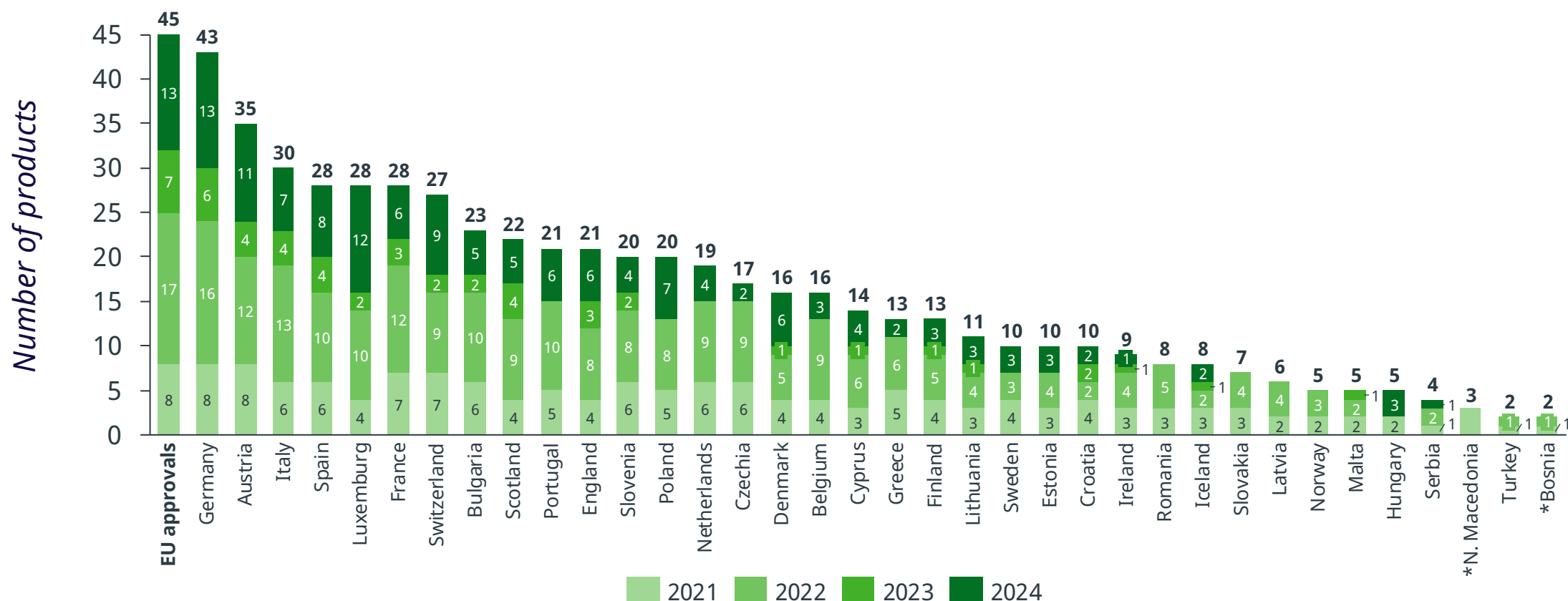
### Indicators:

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



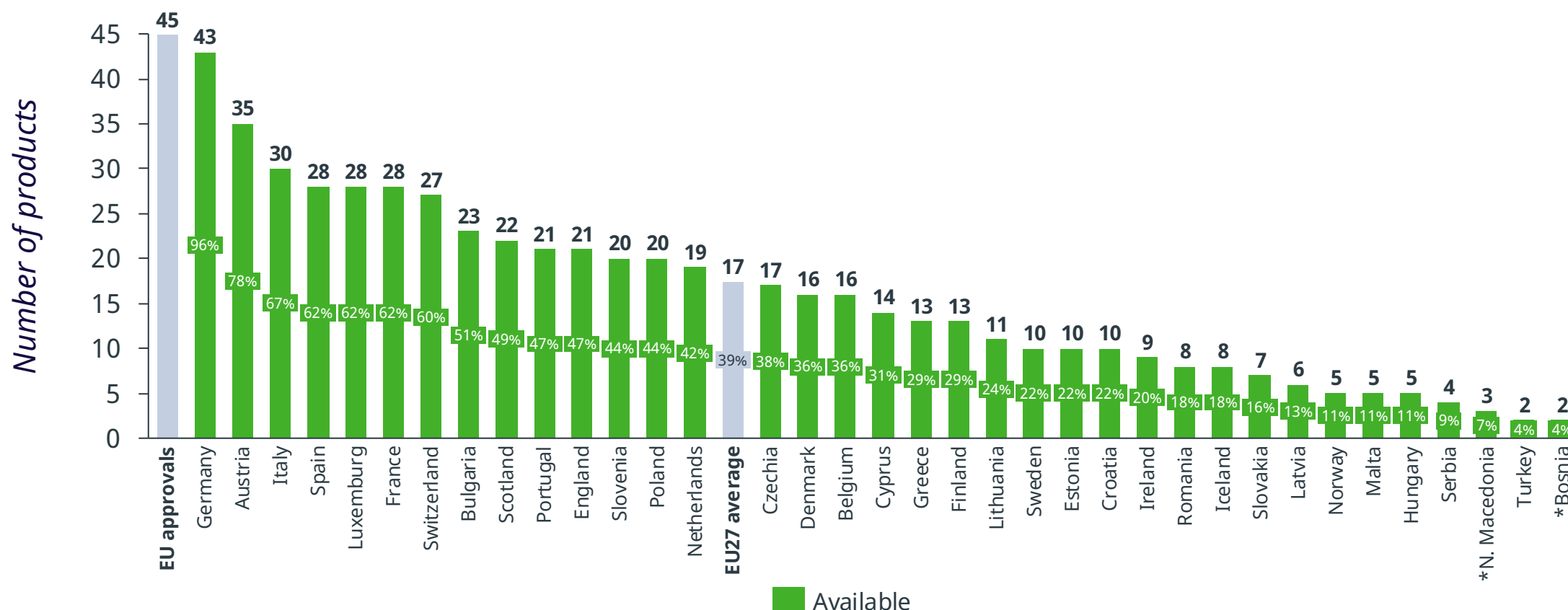
# Non-oncology orphan availability by approval year (2021-2024)

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



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

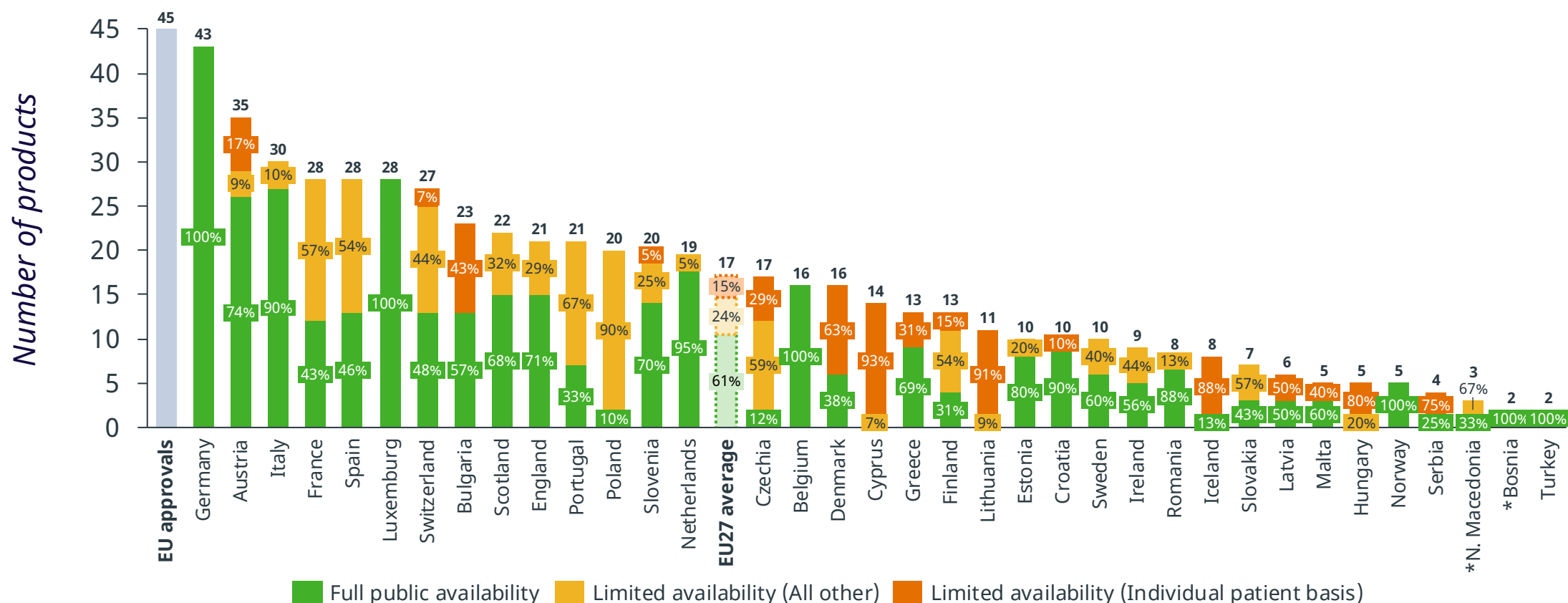
The **rate of availability**, measured by the number of medicines available to patients in European countries as of 5<sup>th</sup> January 2026. For most countries this is the point at which the product gains access to the reimbursement list<sup>†</sup>, including products with limited availability.



**European Union average: 17 products available (39%)** <sup>†</sup>Country specific definitions are listed in the appendix. Details surrounding early access schemes are provided in slide 72. \* Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative.

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

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

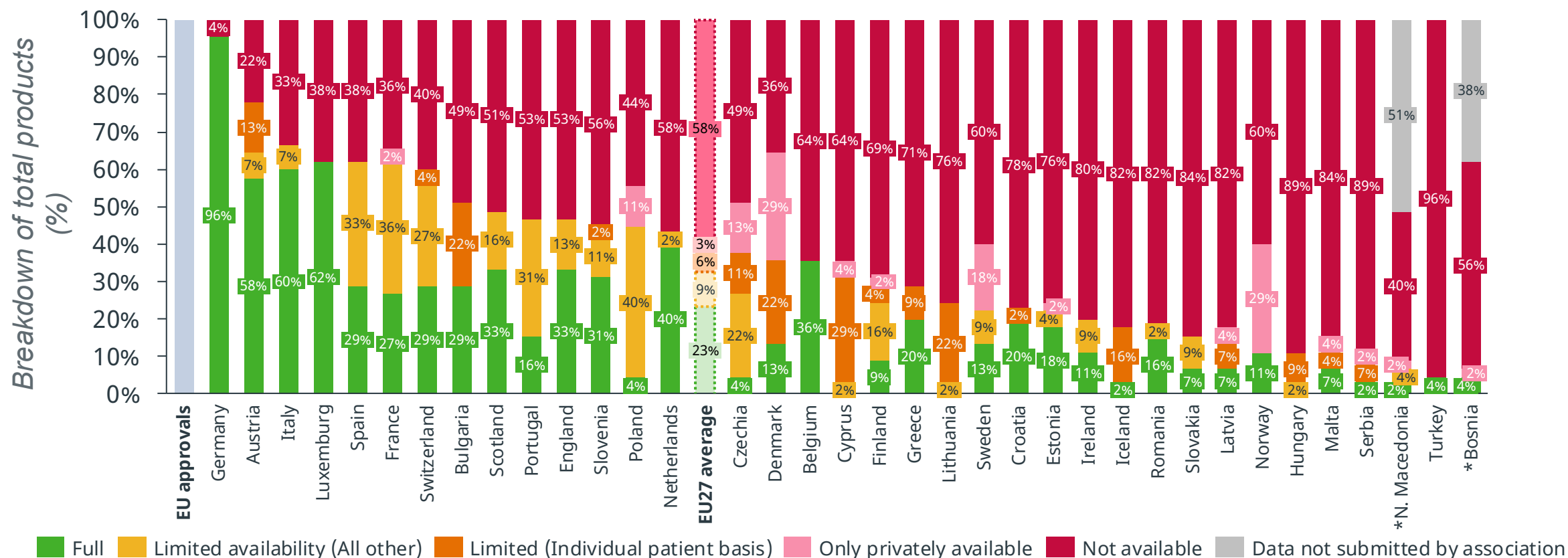


European Union average: 17 products available (39%), Limited availability (total) (39% of available products) <sup>†</sup>Country specific definitions and early access schemes are listed in the appendix.

\*Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. <sup>†</sup> The average rate of limited availability is 39%; the reason this is not represented in the chart (where segments total 40%) is due to rounding.

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

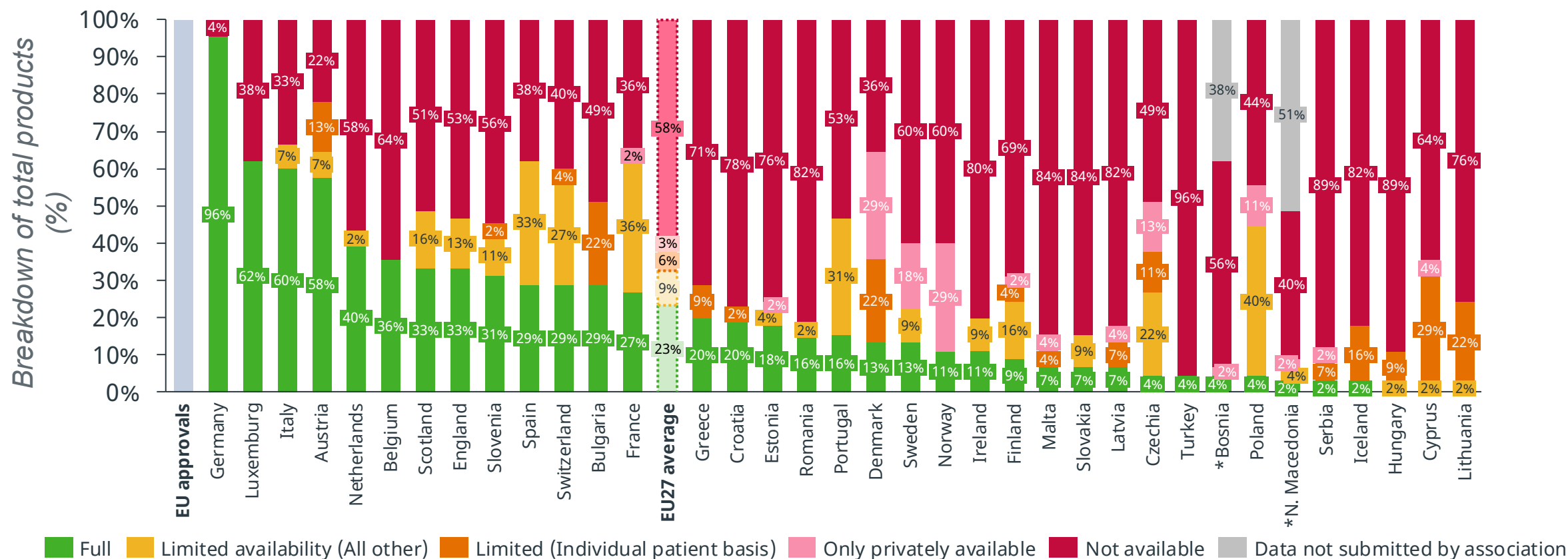
The **breakdown of total availability** is the composition of medicines available to patients in European countries as of 5<sup>th</sup> January 2026 (for most countries this is the point at which the product gains access to the reimbursement list<sup>†</sup>). This includes all medicine's status to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



European Union average: 17 products available (39%); Limited Availability (15% of all non-onco orphan products)<sup>1</sup>; <sup>†</sup>Country specific definitions are listed in the appendix. Details surrounding early access schemes are provided in slide 72. \*Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. <sup>1</sup> The average rate of availability is 39%; the reason this is not represented in the chart (where segments total 38%) is due to rounding.

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

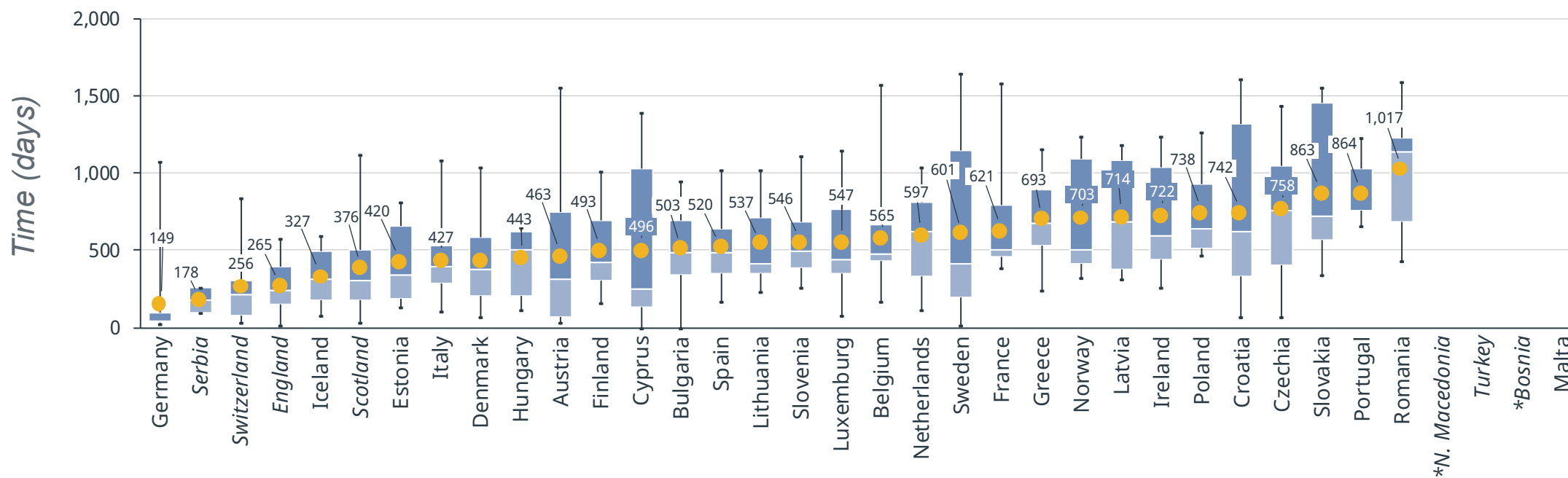
The **breakdown of total availability** is the composition of medicines available to patients in European countries as of 5<sup>th</sup> January 2026 (for most countries this is the point at which the product gains access to the reimbursement list<sup>†</sup>). This includes all medicine's status to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



European Union average: 17 products available (39%); Limited Availability (15% of all non-onco orphan products)<sup>1</sup>; <sup>†</sup>Country specific definitions are listed in the appendix. Details surrounding early access schemes are provided in slide 72. \*Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. <sup>1</sup> The average rate of availability is 39%; the reason this is not represented in the chart (where segments total 38%) is due to rounding.

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

The **time to availability** is the days between marketing authorisation and the date of availability to patients in European countries (for most this is the point at which products gain access to the reimbursement list<sup>†</sup>). 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 5<sup>th</sup> January 2026.



\*N. Macedonia

Available medicines / 45

Dates submitted / 45

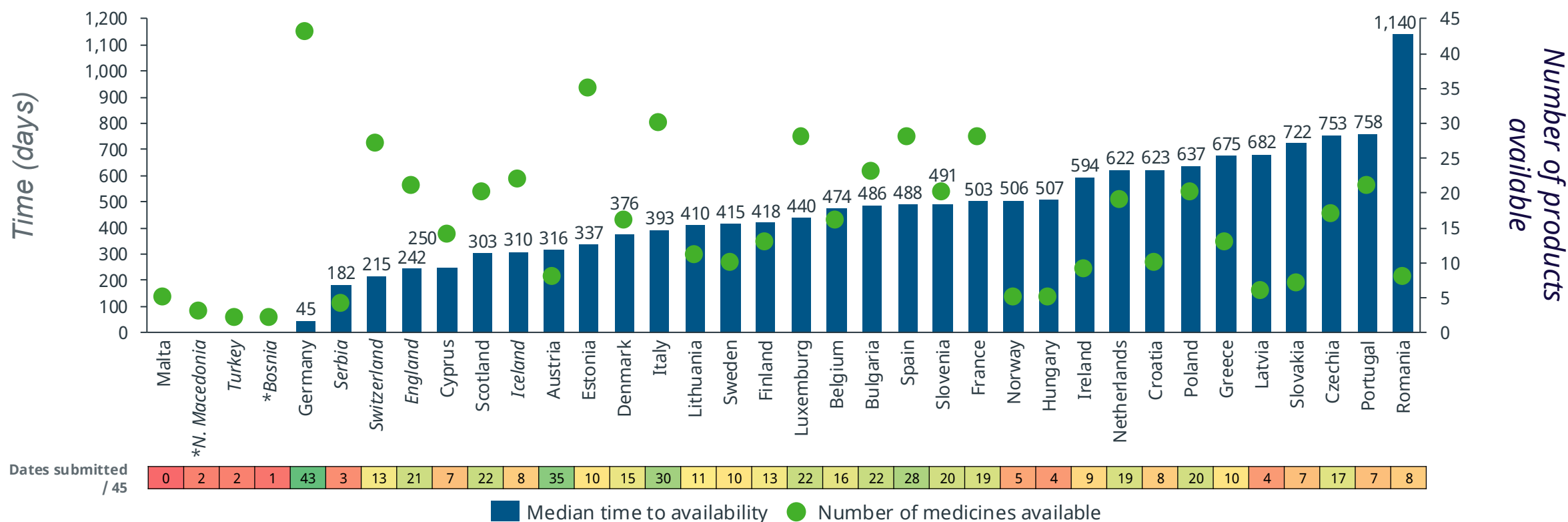
|    |   |    |    |   |    |    |    |    |   |    |    |    |    |    |    |    |    |    |    |    |    |    |   |   |   |    |    |    |   |    |   |   |   |   |   |
|----|---|----|----|---|----|----|----|----|---|----|----|----|----|----|----|----|----|----|----|----|----|----|---|---|---|----|----|----|---|----|---|---|---|---|---|
| 43 | 4 | 27 | 21 | 8 | 22 | 20 | 10 | 30 | 5 | 35 | 13 | 14 | 23 | 28 | 11 | 20 | 28 | 16 | 19 | 10 | 28 | 13 | 5 | 6 | 9 | 20 | 10 | 17 | 7 | 21 | 8 | 3 | 2 | 2 | 5 |
| 43 | 3 | 13 | 21 | 8 | 22 | 19 | 10 | 30 | 4 | 35 | 13 | 7  | 22 | 28 | 11 | 20 | 22 | 16 | 19 | 10 | 19 | 10 | 5 | 4 | 9 | 20 | 8  | 17 | 7 | 7  | 8 | 2 | 2 | 1 | 0 |

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

**European Union average: 595 days (mean)** <sup>†</sup>Country specific definitions are listed in the appendix. Details surrounding early access schemes are provided in slide 72. \* Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. Note: Countries with fewer than three submitted dates were excluded to avoid unreliable estimates.

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

The **median time to availability** is the days between marketing authorisation and the date of availability to patients in European countries (for most this is the point at which products gain access to the reimbursement list<sup>†</sup>). 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 5<sup>th</sup> January 2026.



# Key observations

## Executive summary (EU27 averages)

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

### Key Insights

#### Rate of availability

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

#### Time to availability

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

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



#### Metrics key:

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

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

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

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

## 5. Combination therapies

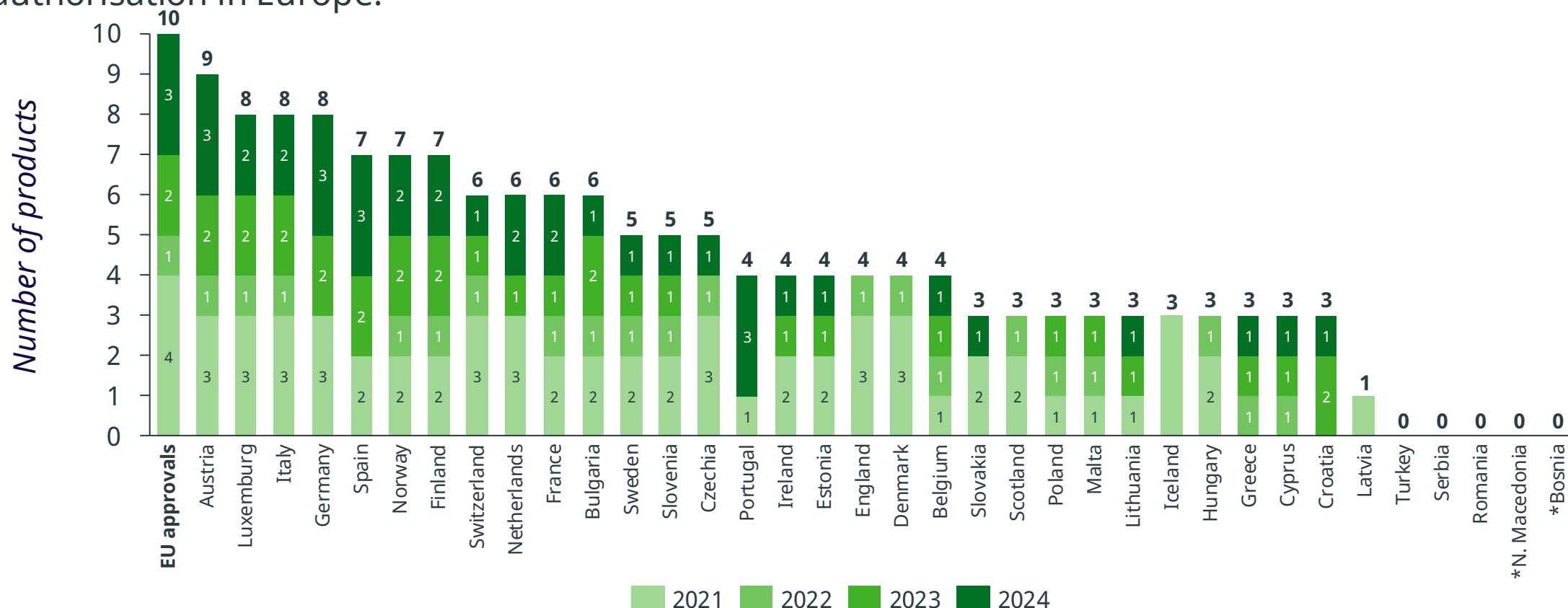
### Indicators:

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



# Combination therapies availability by approval year (2021-2024)

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



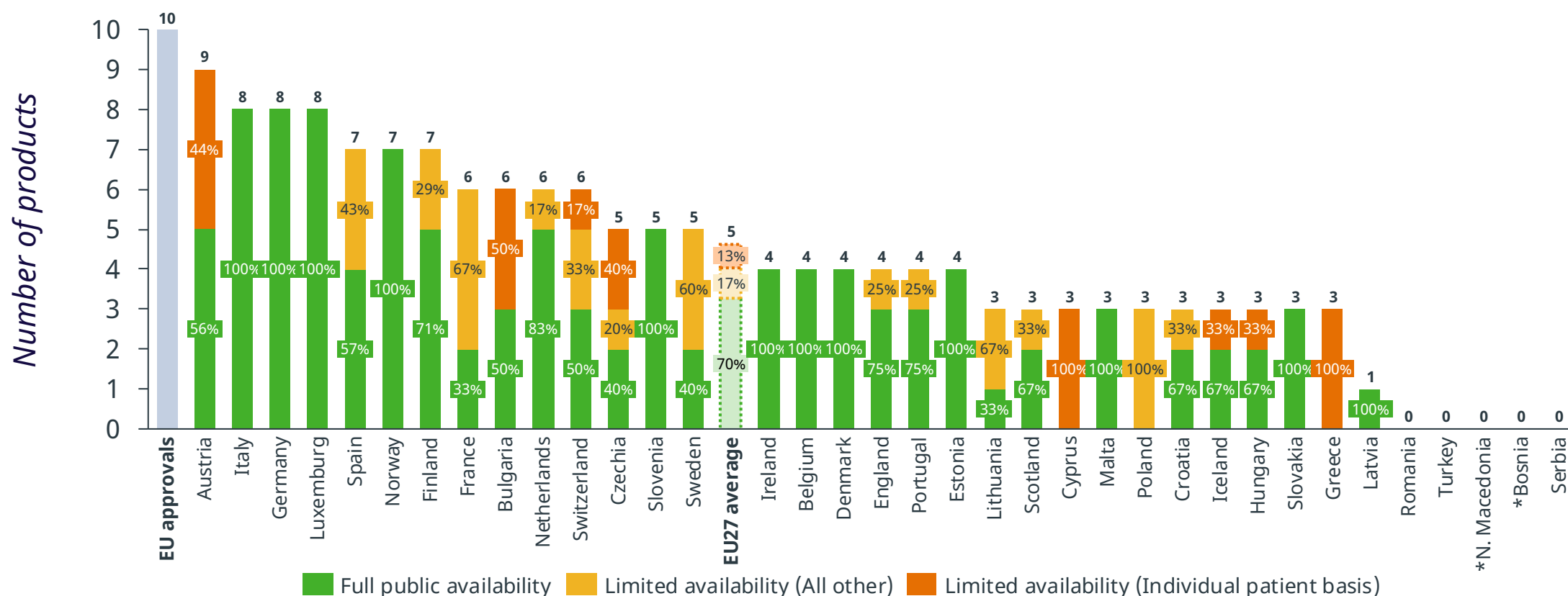
# Combination therapies rate of availability (2021-2024)

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



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

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

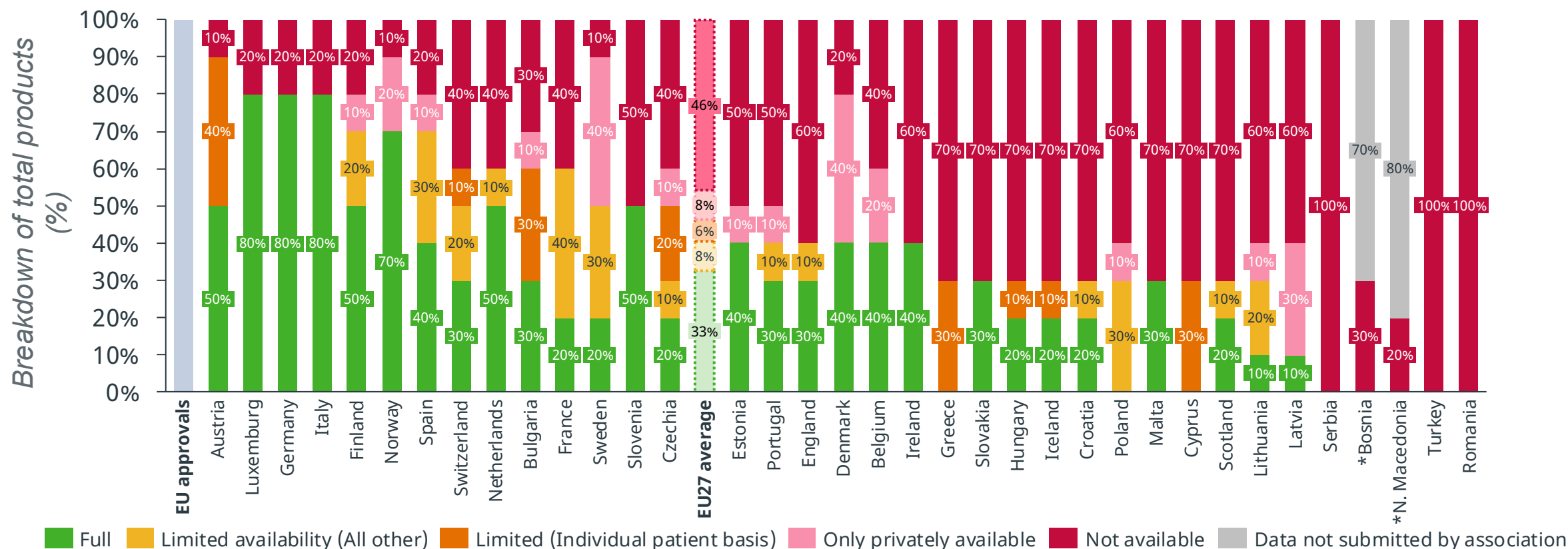


**European Union average: 5 products available (48%), limited availability (total) (30% of available products).** Combination products can include innovative branded / generic combinations;

<sup>†</sup>Country specific definitions are listed in the appendix. Details surrounding early access schemes are provided in slide 72. \* Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative.

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

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

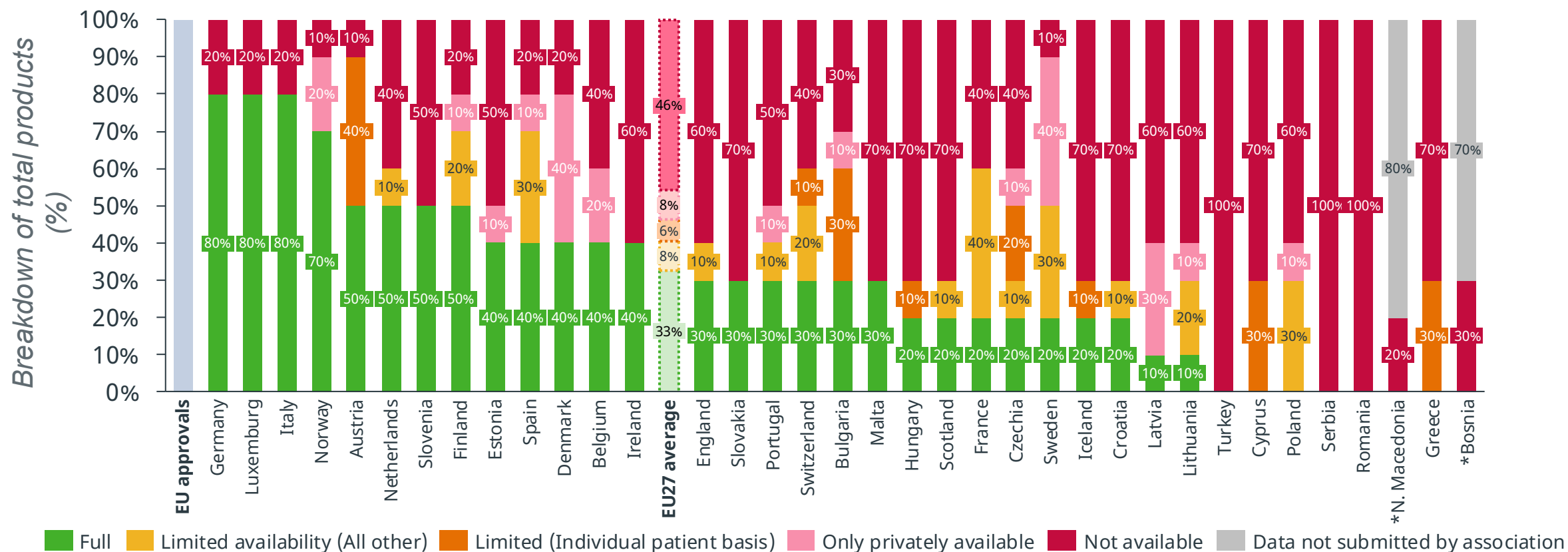


European Union average: 5 products available (48%); Limited Availability (14% of all combination therapies) <sup>1</sup>; Combination products can include innovative branded / generic combinations;

<sup>†</sup>Country specific definitions are listed in the appendix. Details surrounding early access schemes are provided in slide 72. \* Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. <sup>1</sup> The average rate of availability is 48%; the reason this is not represented in the chart (where segments total 47%) is due to rounding.

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

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

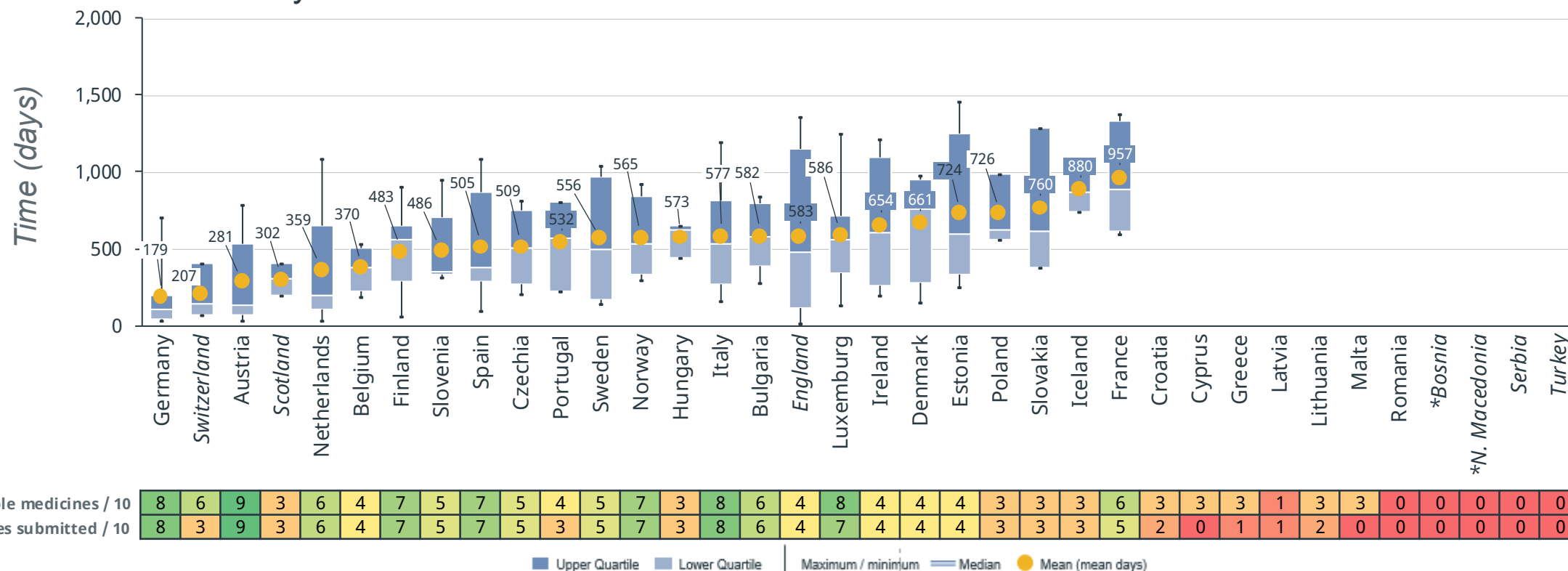


**European Union average: 5 products available (48%); Limited Availability (14% of all combination therapies)** <sup>1</sup>; Combination products can include innovative branded / generic combinations;

<sup>†</sup>Country specific definitions are listed in the appendix. Details surrounding early access schemes are provided in slide 72. \* Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. <sup>1</sup> The average rate of availability is 48%; the reason this is not represented in the chart (where segments total 47%) is due to rounding.

# Combination therapies time to availability (2021-2024)

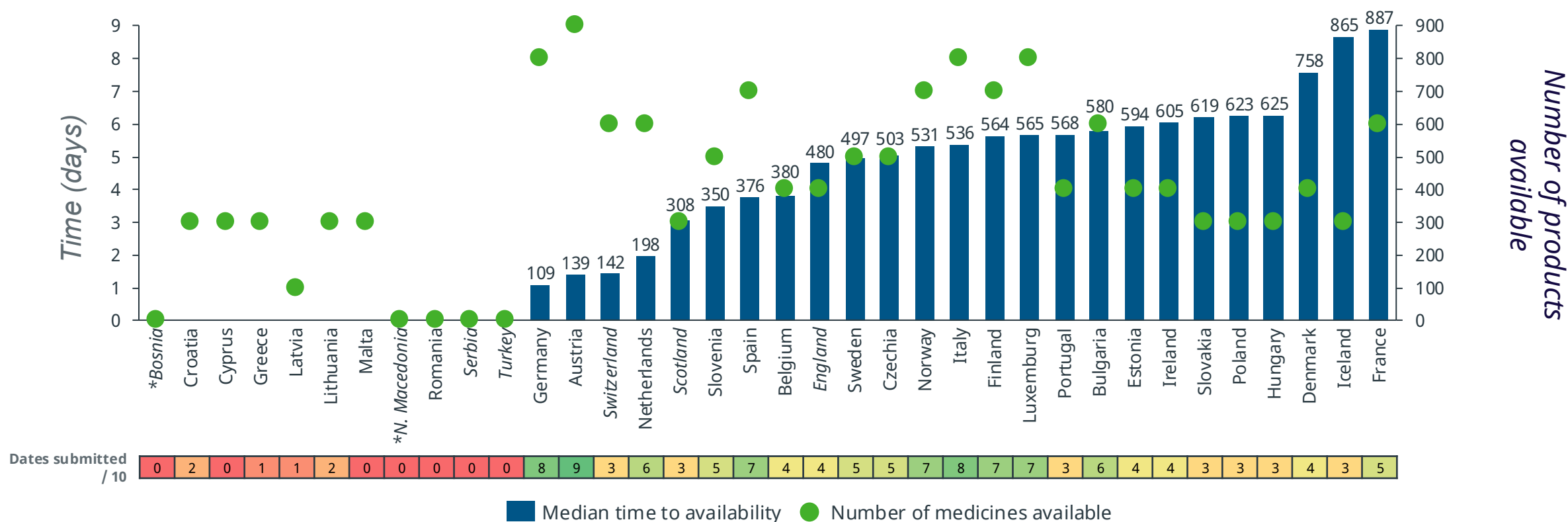
The **time to availability** is the days between marketing authorisation and the date of availability of fixed dose combination medicines to patients in European countries (for most this is the point at which products gain access to the reimbursement list<sup>†</sup>). The marketing authorisation date 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 5<sup>th</sup> January 2026.



**European Union average: 553 days (mean)** Combination products can include innovative branded / generic combinations; <sup>†</sup>Country specific definitions are listed in the appendix. Details surrounding early access schemes are provided in slide 72. \*Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. Note: Countries with fewer than three submitted dates were excluded to avoid unreliable estimates.

# Combination median time to availability (2021-2024)

The **median time to availability** is the days between marketing authorisation and the date of availability to patients in European countries (for most this is the point at which products gain access to the reimbursement list<sup>†</sup>). 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 5<sup>th</sup> January 2026.



**European Union average: 504 days (median)** <sup>†</sup>Country specific definitions are listed in the appendix. Details surrounding early access schemes are provided in slide 72. \* Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. Note: Countries with fewer than three submitted dates were excluded to avoid unreliable estimates.

# Key observations

Executive summary (EU27 averages)

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



### Metrics key:

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

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

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

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

## Key Insights

|                      |                                                                                                                                                                                                                                                                                                                                                 |
|----------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Rate of availability | <ul style="list-style-type: none"><li>At EU level, combination therapies sit marginally above the overall average in terms of availability.</li><li>Cautious interpretation is suggested as this segment includes very few products, making results sensitive to individual observations.</li></ul>                                             |
| Time to availability | <ul style="list-style-type: none"><li>Time to availability for combination therapies remains broadly similar to the previous year, and significantly shorter than the overall average.</li><li>As with availability, findings should be interpreted with caution, reflecting the limited number of products included in this segment.</li></ul> |

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

## 6. Historic comparisons and extension

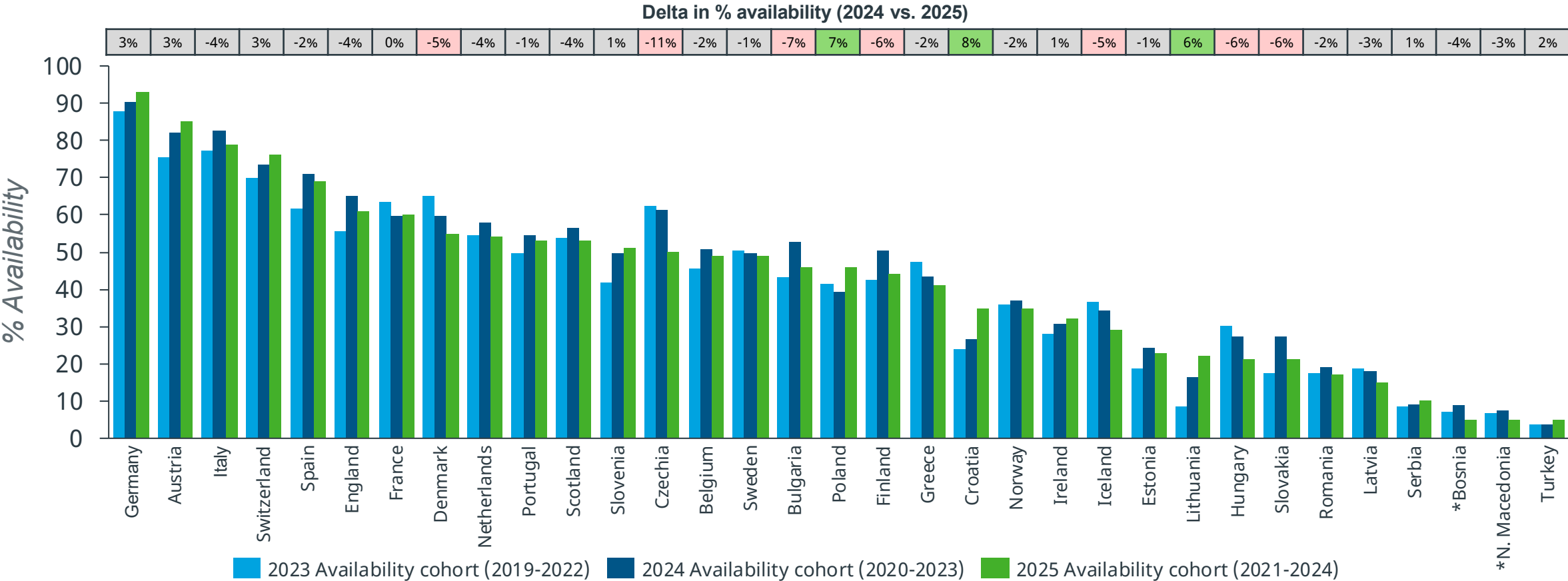
### Indicators:

- 6.1. Comparison of availability versus prior studies (2023 – 2025)
- 6.2. Extended period of total availability (2014 – 2024)



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

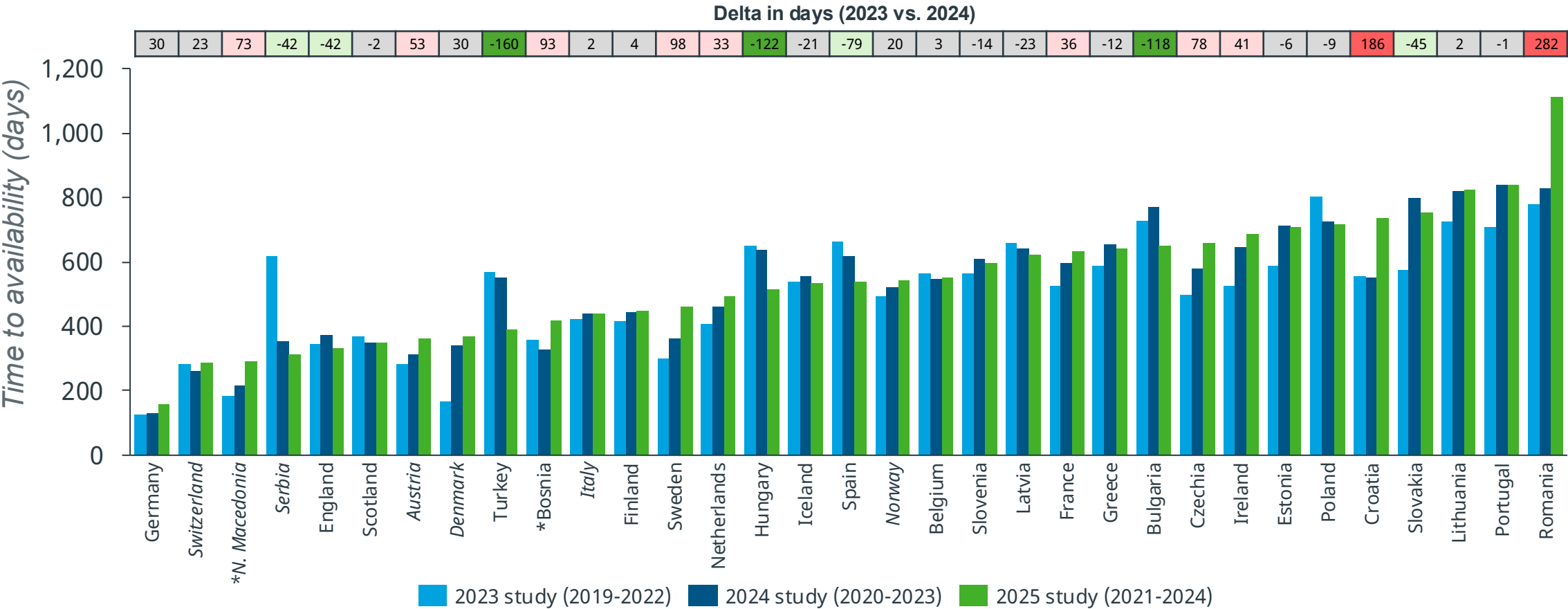
The **comparison of rate of availability**<sup>†</sup>, measured by the number of medicines available to patients in European countries as of 5<sup>th</sup> January 2026, compared to the rate of availability in previous (comparable) studies. Figures are based on the historic statistics published in the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



Increases of <=5% are not considered to be statistically significant and are therefore highlighted in grey. Italy, England and Croatia have deltas of <5% but are listed as 5% here due to rounding. Note: Netherlands has retrospectively corrected 2020 data; <sup>†</sup>Country specific definitions are listed in the appendix. Details surrounding early access schemes are provided in slide 72. \* Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. Differences in availability rates between years may appear as 0% due to rounding. This rounding effect can result in minor discrepancies that do not reflect significant changes.

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

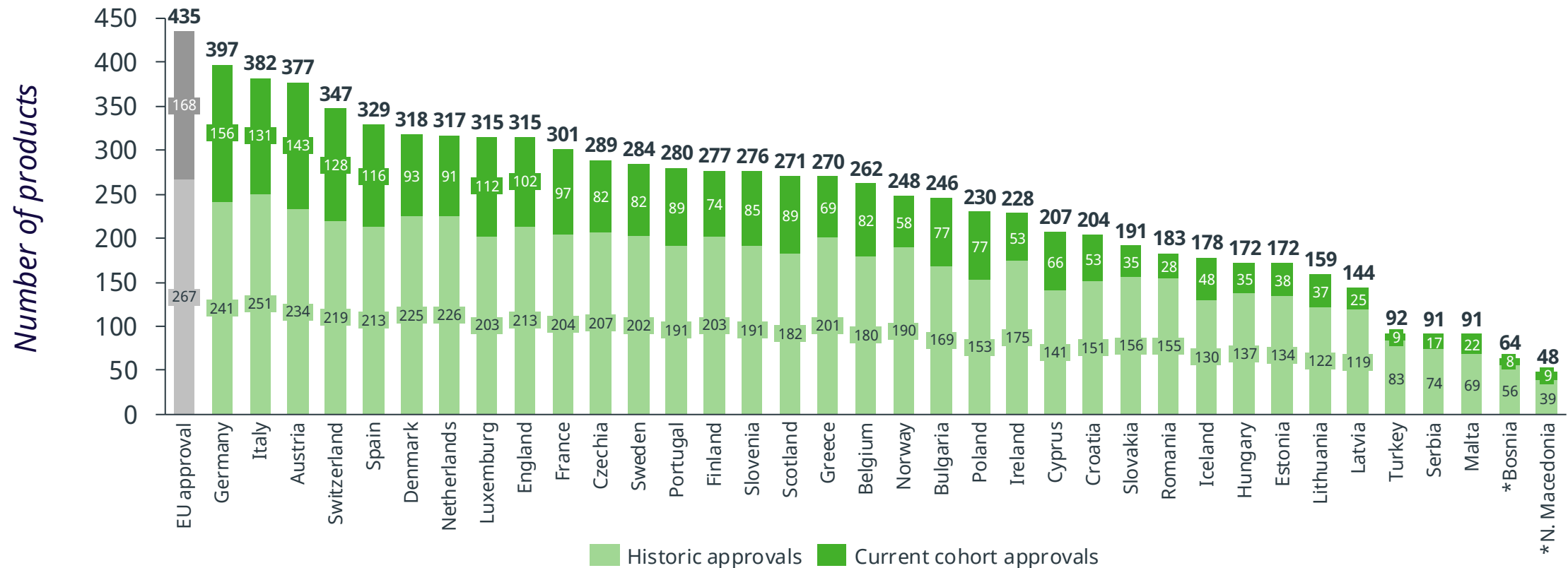
The **comparison of time to availability** is the days between marketing authorisation and the date of availability to patients compared to previous comparable studies. Figures are based on the historic statistics published in the indicators.



Changes of <=30 days are not considered to be statistically significant and are therefore highlighted in grey. The marketing authorisation date is the date of central EU authorisation in most countries, except for countries shown in italics where local authorisation dates have been used; \*Country specific definitions are listed in the appendix. Details surrounding early access schemes are provided in slide 72. \* Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative.

# Extended period of total availability (2014-2024)

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



European Union average: 256 products available (59%) <sup>†</sup>Country specific definitions are listed in the appendix. Details surrounding early access schemes are provided in slide 72. \* Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative.



# Contents

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- **Methodology and definitions**

# 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 <sup>^</sup> )  |
| Limited reimbursement while decision is pending (where system permits)  |                                      |
| Availability through a special program (e.g. managed entry agreements)  |                                      |
| Limited reimbursement on a named patient basis (individual patient)     | Available (Individual patient basis) |
| Available only within the private market at the patient's expense       | Only privately available             |
| Not reimbursed, or not reimbursed while awaiting decision               | Not available                        |

## Notes and caveats

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

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

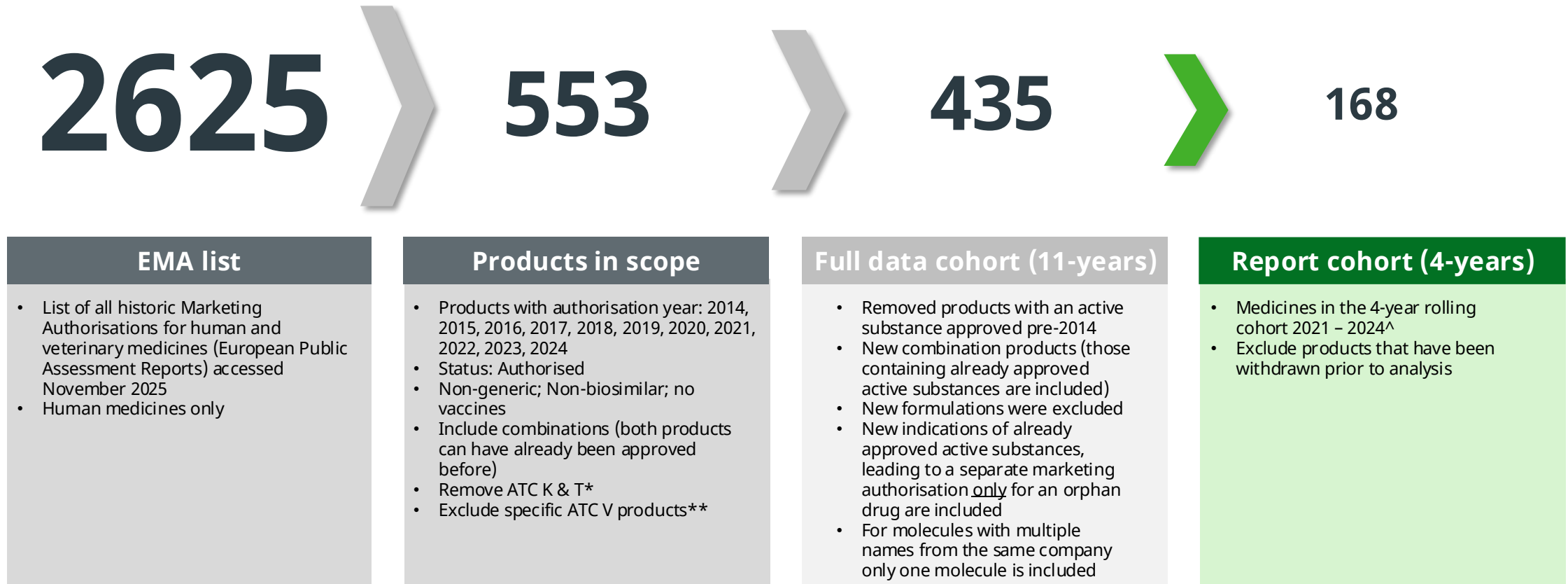
**Completeness:** Some country associations did not submit full datasets. Countries substantially limited data sets are: Bosnia (42% complete) and North Macedonia (51% complete). This is noted on slides with an asterisk (\*).

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

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

# Method and data availability

## *Process for product selection*



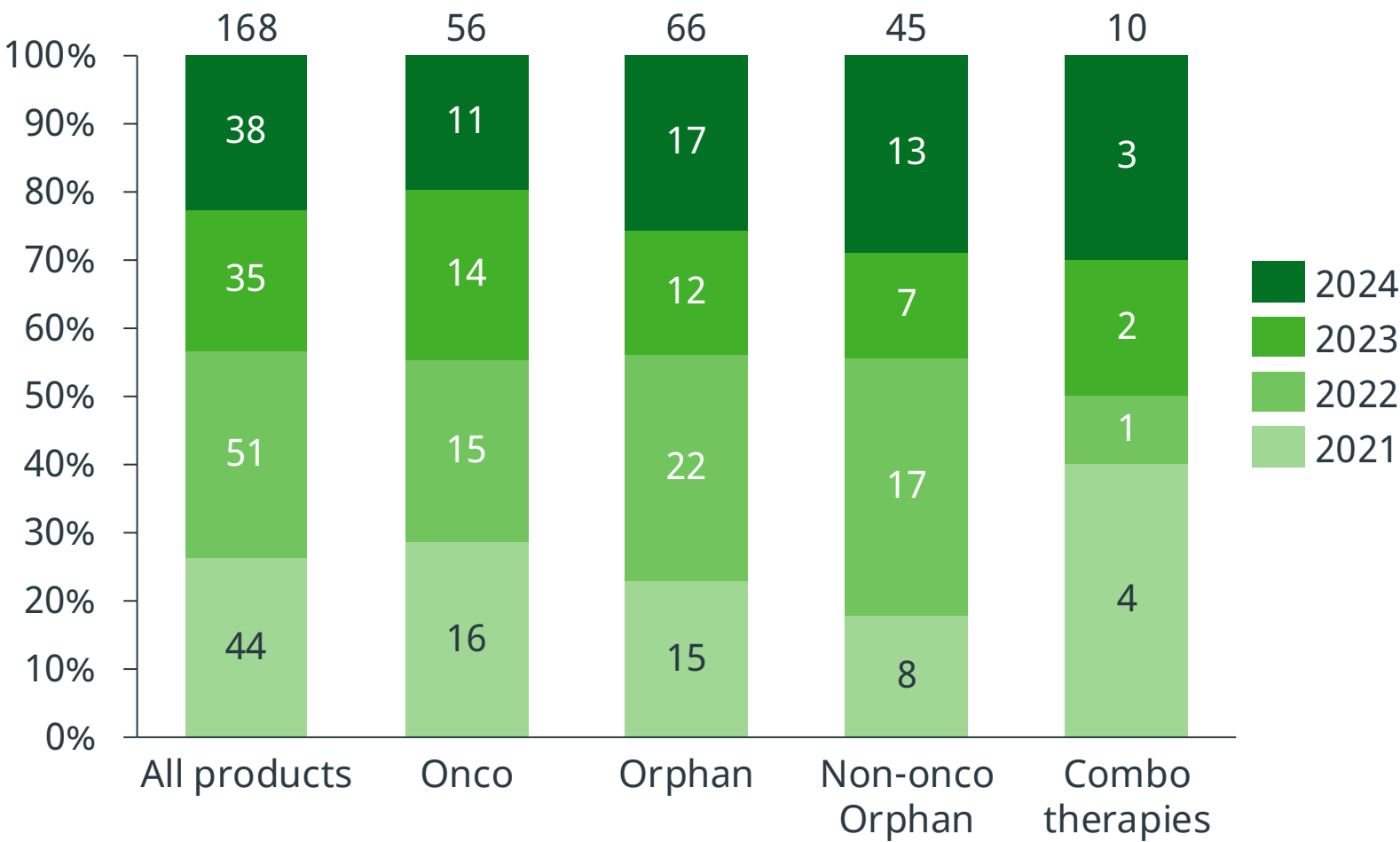
\* Removal ATC class exclusions: K = Hospital Solutions; V = Various, T = Diagnostics; Oncology definition used throughout = L1 & L2 & L3B1 & V3C & Proleukin

\*\* 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.

<sup>^</sup> Note: Products included in the WAIT indicator are aligned with products included in EFPIA Access Hurdles Portal

# Study composition and category definitions

*By year of marketing authorisation*



## Definitions:

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

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

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

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

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

## Oncologics (n=56)

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

## Orphans (n=66)

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

## Non-oncologic orphans (n=45)

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

## Combination therapies (n=10)

|                    |          |
|--------------------|----------|
| Akeega             | Opdualag |
| Drovelis/Lydisilka | Roclanda |
| Emblaveo           | Ryeqo    |
| Exblifep           | Sibnaya  |
| Inaqovi            | Yuvanci  |

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

# Country specific definitions of products with availability

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

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

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

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

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

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

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

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

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

# Country specific early access schemes

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

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



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### Country-specific insights:

Local pharma industry associations

