



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

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# Foreword

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

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

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

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

Information on the availability of 173 innovative medicines with central-marketing authorisation between 2020 and 2023 are included in the report. There is a one-year delay to permit countries to include these medicines on their public reimbursement list, meaning that the data on availability is accurate as of *January 5<sup>th</sup> 2025*.

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



## Long-running

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



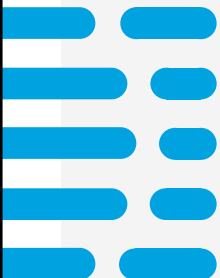
## Broad coverage

The Patients W.A.I.T. dataset covers 26 countries and 4 years of novel medicine approvals, with a historic dataset covering 10-years of data



## Widely referenced

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



# Contents

## + Background

### + The Patients W.A.I.T. indicators

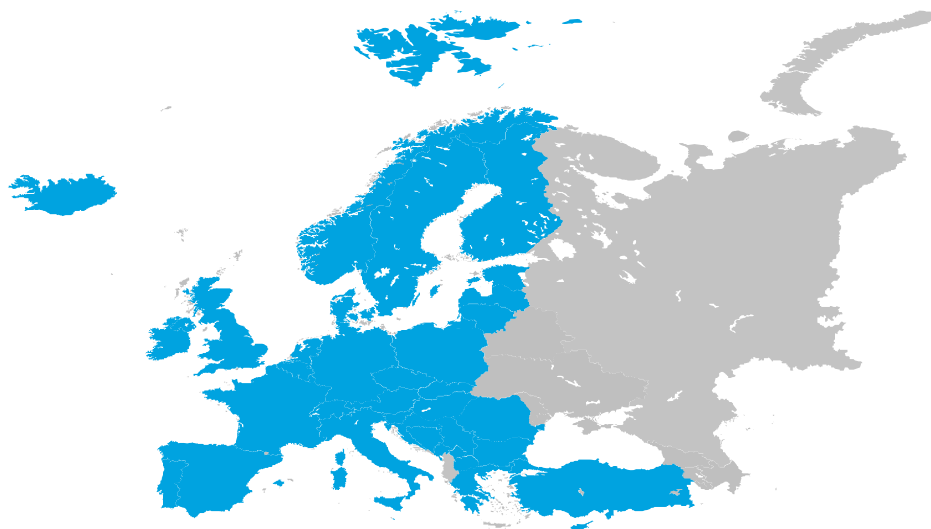
1. Overview (all products)
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5. Combination therapies
6. Historic comparisons and extended period

### + Methodology and definitions

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



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



**36**  
European  
countries



**173**  
innovative  
medicines



**4**  
year cohort  
(‘20-’23)

■ Data available   ■ Data not available / included

## Updates in 2024

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



### Additional context

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



### Reading guide

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

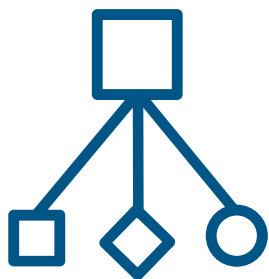


### New indicators

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

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

## *Definition of availability*



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

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

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

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

# The access landscape in Europe has continued to evolve

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

## Historic landscape (2019)



### Not available

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



### Full availability

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

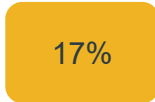


## Current landscape (2024)



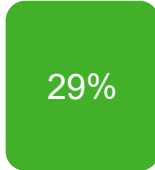
### Not available

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



### Limited availability

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



### Full availability

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

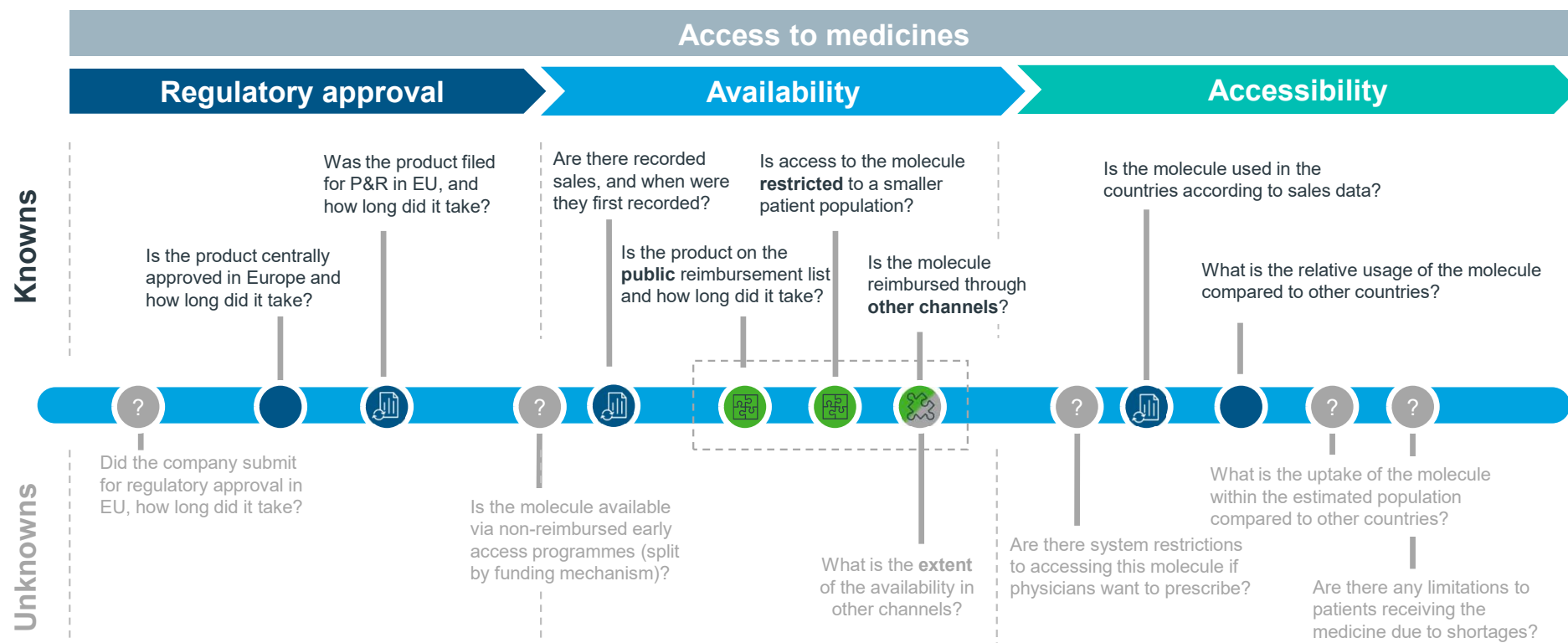


Full availability   Limited Availability   Only available privately   Not available   Data unavailable

Notes: EU averages of full / limited availability are calculated using absolute figures before determining the percentage. This approach ensures a more accurate representation by accounting for the varying number of available medicines in each EU country, thereby avoiding potential distortions that could arise from averaging individual country percentages  
Source: Historic landscape shows data from 2019 W.A.I.T. study (EU average availability for 24 countries: EU27 excl Cyprus, Luxembourg, and Malta); Current landscape shows data from 2024 W.A.I.T. study (EU average from EU27 countries)

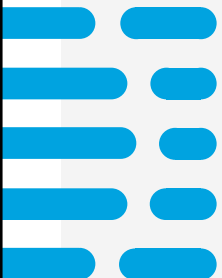
# The Patients W.A.I.T. Indicator study provides a comprehensive view of key components of access to innovative medicines

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



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

\* In cases where public reimbursement lists 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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- + Methodology and definitions

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

29%

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

17%

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

578<sub>days</sub>

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

87%

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

Source: EFPIA Patients WAIT indicator (2023 and 2024)

## Notes for consideration



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



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



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



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

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

| Patients W.A.I.T. Indicators |                                            | Purpose of the indicator                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Limitations                                                                                                                                                                                                                                             |
|------------------------------|--------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Rate of availability         | Total availability by approval year        | <ul style="list-style-type: none"> <li>› To show the availability of molecules <i>within</i> the 4-year cohort (2020-2023 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>                                                                           |



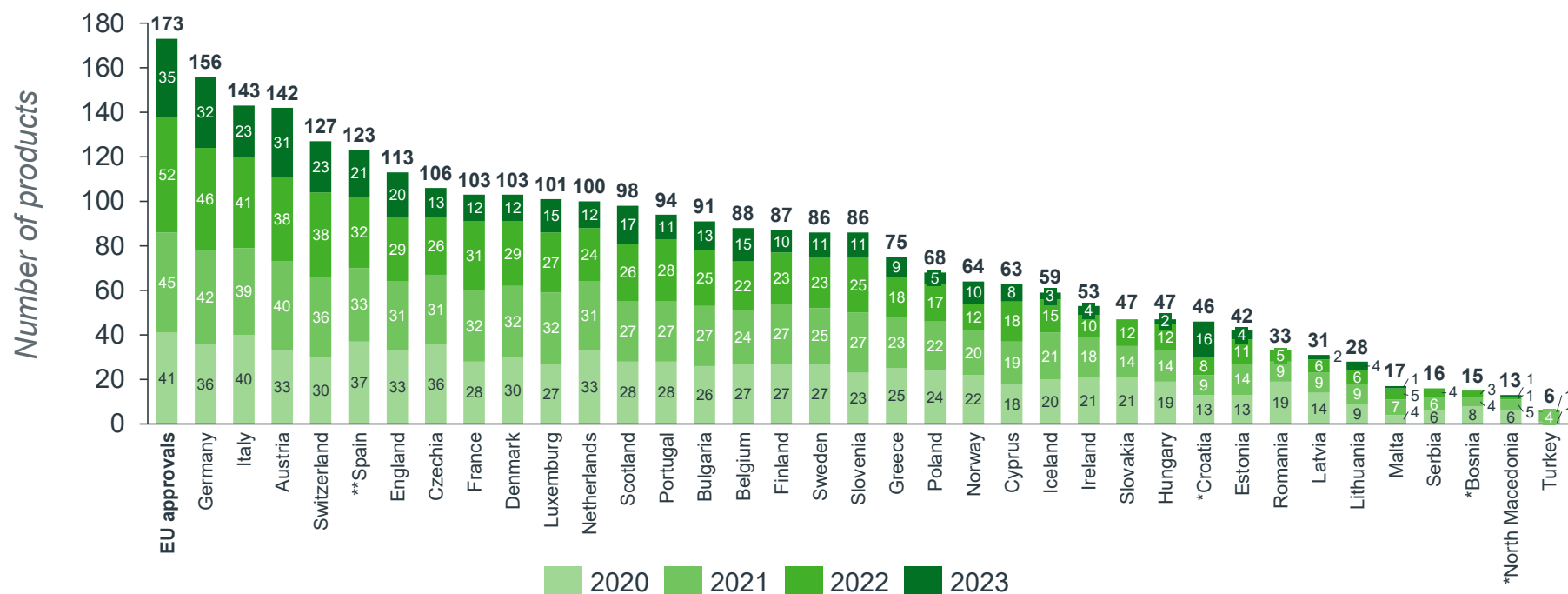
# 1. Overview (all products)

## 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 (2020-2023)

The **total availability by approval year** is the number of medicines available to patients in European countries as of 5<sup>th</sup> January 2025 (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.



European Union average: 80 products available (46%) <sup>†</sup>Country specific definitions are listed in the appendix. \*Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. \*\*In Spain, the WAIT analysis does not identify those medicinal products being accessible earlier in conformity with Spain's Royal Decree 1015/2009 relating to Medicines in Special Situations

## Rate of availability (2020-2023)

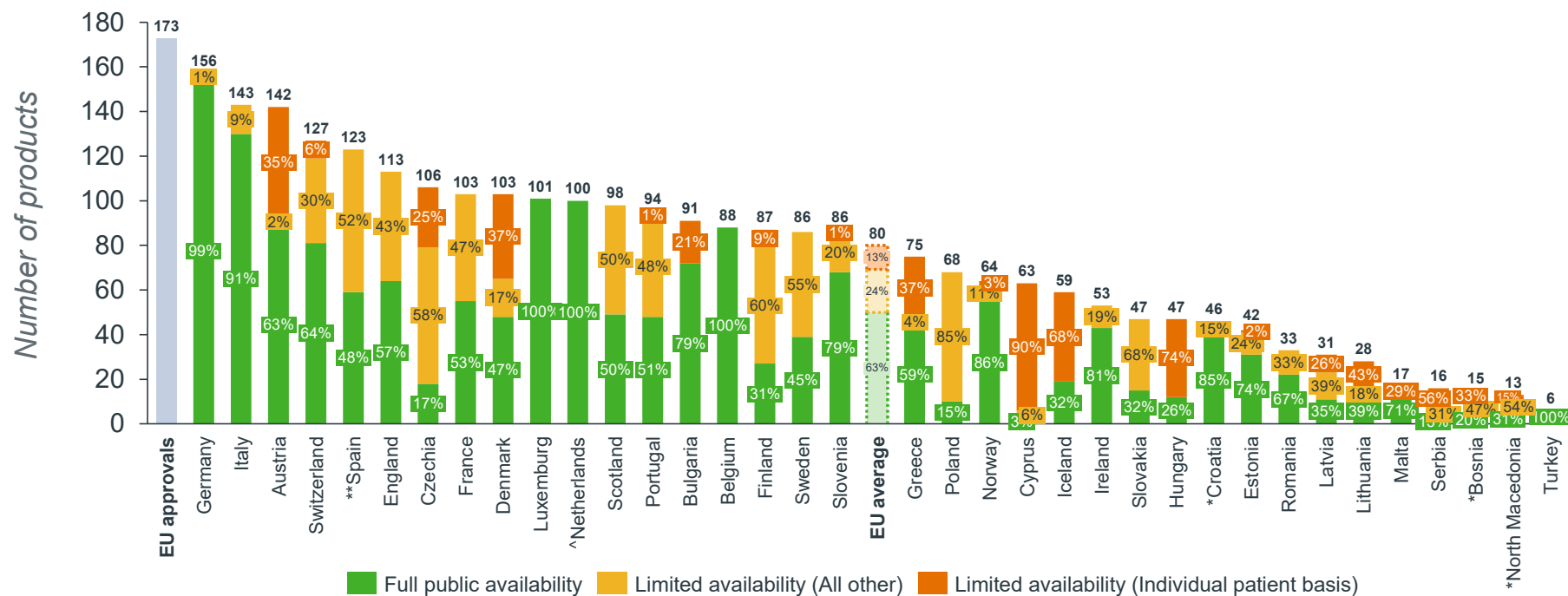
The **rate of availability**, measured by the number of medicines available to patients in European countries as of 5<sup>th</sup> January 2025. For most countries this is the point at which the product gains access to the reimbursement list<sup>†</sup>, including products with limited availability.



European Union average: 80 products available (46%) <sup>†</sup>Country specific definitions are listed in the appendix. \*Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. \*\*In Spain, the WAIT analysis does not identify those medicinal products being accessible earlier in conformity with Spain's Royal Decree 1015/2009 relating to Medicines in Special Situations.

## Breakdown of availability (2020-2023)

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

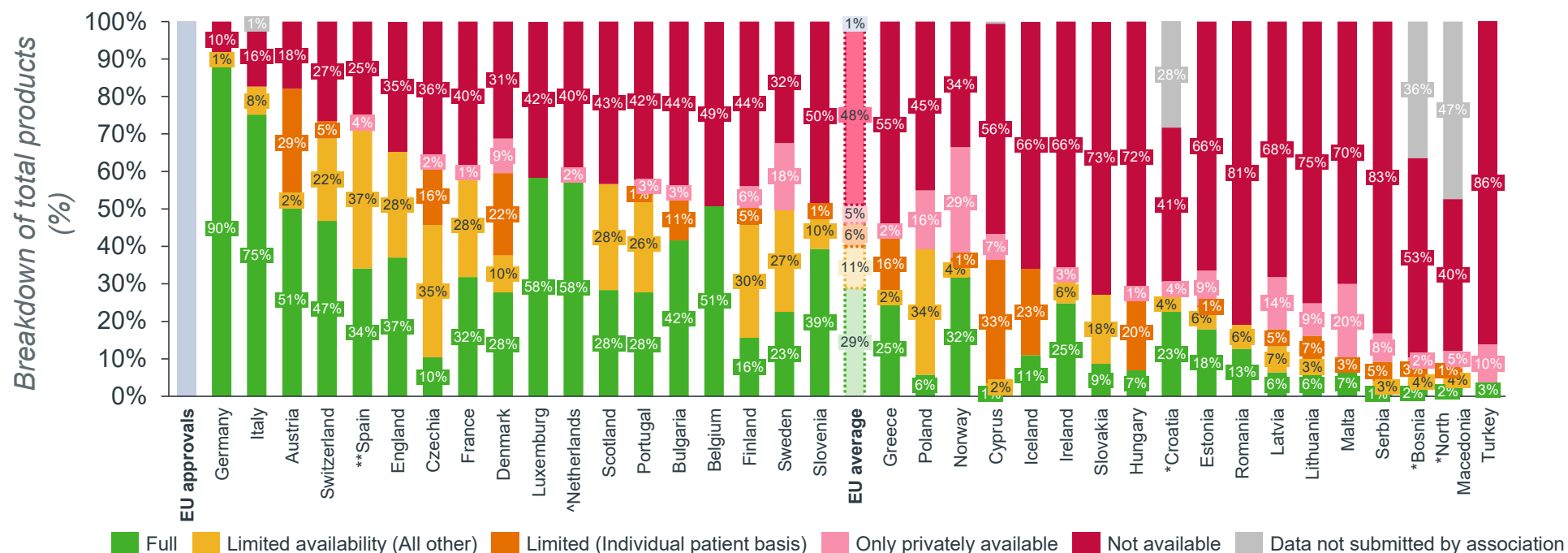


European Union average: 80 products available (46%), Limited Availability (total) (37% of available products); ^Netherlands did not submit complete information on restrictions to available medicines meaning LA\* is not captured in these countries.

<sup>†</sup>Country specific definitions are listed in the appendix. \*Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. \*\*In Spain, the WAIT analysis does not identify those medicinal products being accessible earlier in conformity with Spain's Royal Decree 1015/2009 relating to Medicines in Special Situations.

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

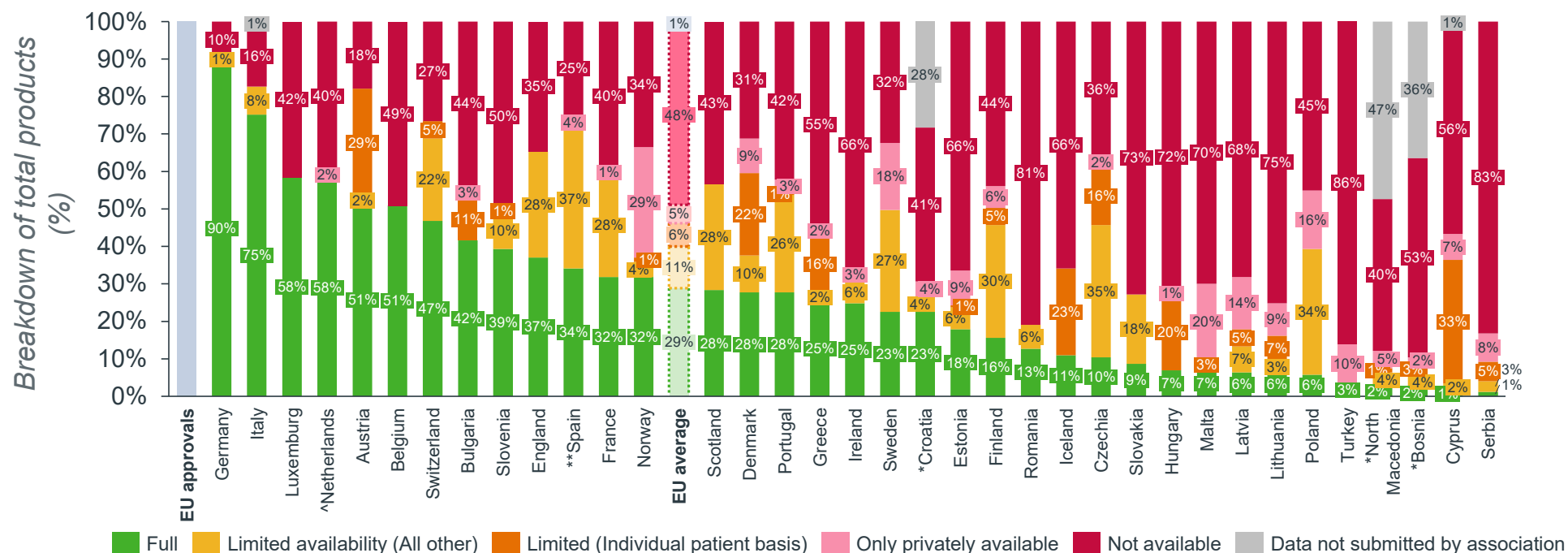
The **breakdown of total availability** is the composition of medicines available to patients in European countries as of 5<sup>th</sup> January 2025 (for most countries this is the point at which the product gains access to the reimbursement list<sup>†</sup>). This includes all medicine's status to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



European Union average: 80 products available (46%); Limited Availability (17% of all products); \*Netherlands did not submit complete information on restrictions to available medicines meaning LA\* is not captured in these countries. †Country specific definitions are listed in the appendix. \*Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. \*\*In Spain, the WAIT analysis does not identify those medicinal products being accessible earlier in conformity with Spain's Royal Decree 1015/2009 relating to Medicines in Special Situations

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

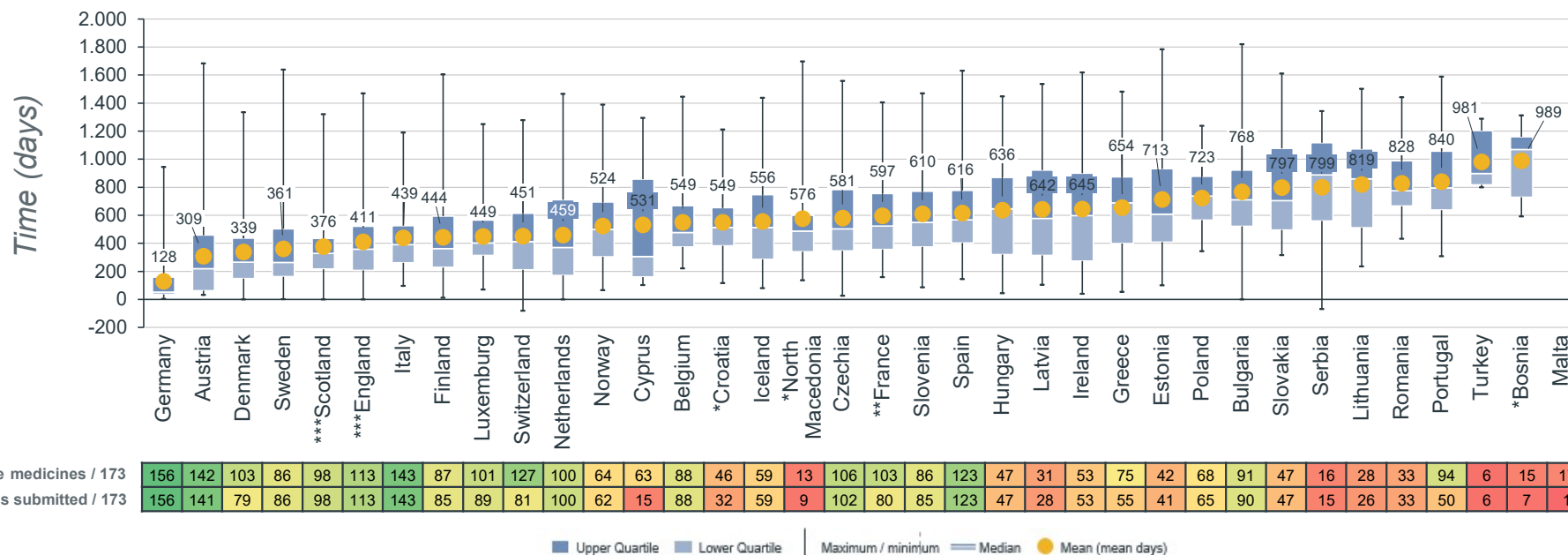
The **breakdown of total availability** is the composition of medicines available to patients in European countries as of 5<sup>th</sup> January 2025 (for most countries this is the point at which the product gains access to the reimbursement list<sup>†</sup>). This includes all medicine's status to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



European Union average: 80 products available (46%); Limited Availability (17% of all products); \*Netherlands did not submit complete information on restrictions to available medicines meaning LA\* is not captured in these countries. †Country specific definitions are listed in the appendix. \*Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. \*\*In Spain, the WAIT analysis does not identify those medicinal products being accessible earlier in conformity with Spain's Royal Decree 1015/2009 relating to Medicines in Special Situations

# Time from central approval to availability (2020-2023)

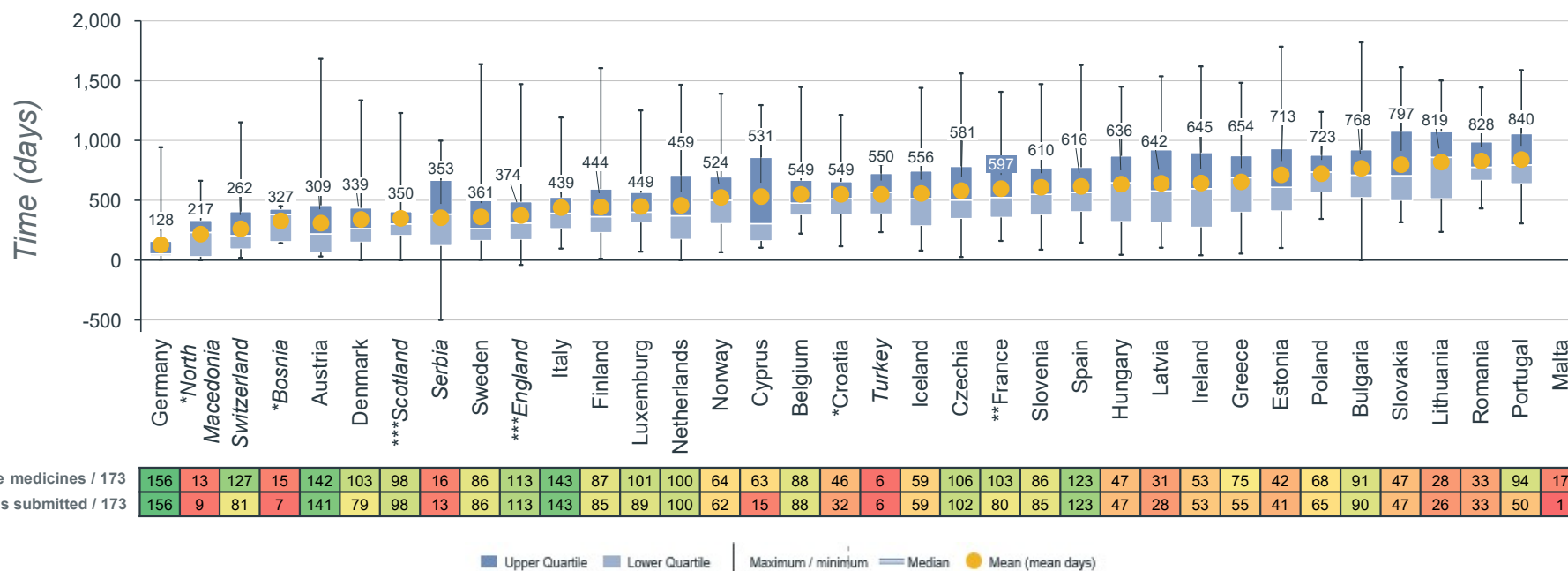
The **time from central approval to availability** is the days between marketing authorisation and the date of availability to patients in European countries (for most this is the point at which products gain access to the reimbursement list<sup>†</sup>). The marketing authorisation date is the date of central EU authorisation throughout. Data is correct to 5<sup>th</sup> January 2025.



**European Union average: 578 days (mean %)** (Note: Malta is not included in EU27 average as only 1 date was submitted in total) <sup>†</sup>Country specific definitions are listed in the appendix. \*Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative \*\*For France, the time to availability (597 days, n=80 dates submitted) includes products under the Accès précoce system (n=4 dates submitted) for which the price negotiation process is usually longer. If one considers that products under the Accès précoce system are directly available (time to availability = 0), the average time to availability is 570 days. \*\*\*In the UK, MHRA's Early Access to Medicines Scheme provides access prior to marketing authorisation but is not included within this analysis, and would reduce the overall days for a small subset of medicines.

## Time to availability (2020-2023)

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



Available medicines / 173

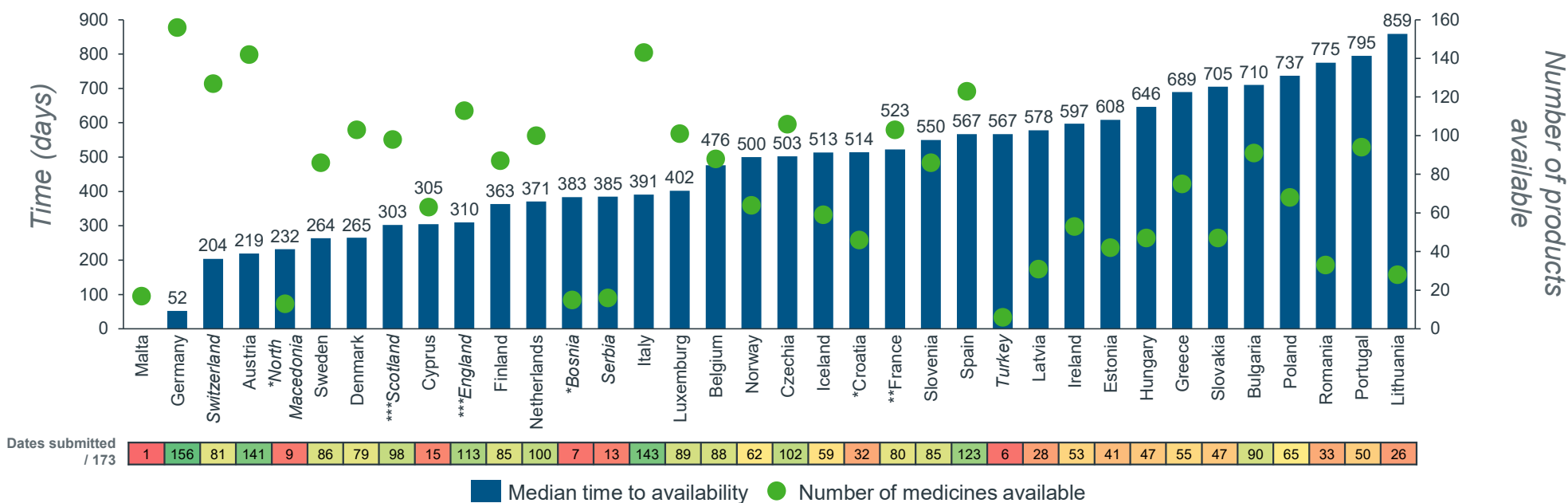
Dates submitted / 173

|     |    |     |    |     |     |    |    |    |     |     |    |     |     |    |    |    |    |   |    |     |     |    |     |    |    |    |    |    |    |    |    |    |    |    |    |
|-----|----|-----|----|-----|-----|----|----|----|-----|-----|----|-----|-----|----|----|----|----|---|----|-----|-----|----|-----|----|----|----|----|----|----|----|----|----|----|----|----|
| 156 | 13 | 127 | 15 | 142 | 103 | 98 | 16 | 86 | 113 | 143 | 87 | 101 | 100 | 64 | 63 | 88 | 46 | 6 | 59 | 106 | 103 | 86 | 123 | 47 | 31 | 53 | 75 | 42 | 68 | 91 | 47 | 28 | 33 | 94 | 17 |
| 156 | 9  | 81  | 7  | 141 | 79  | 98 | 13 | 86 | 113 | 143 | 85 | 89  | 100 | 62 | 15 | 88 | 32 | 6 | 59 | 102 | 80  | 85 | 123 | 47 | 28 | 53 | 55 | 41 | 65 | 90 | 47 | 26 | 33 | 50 | 1  |

European Union average: 578 days (mean %) (Note: Malta is not included in EU27 average as only 1 date was submitted in total)<sup>†</sup>Country specific definitions are listed in the appendix. \*Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative \*\*For France, the mean time to availability (597 days, n=80 dates submitted) includes products under the Accès précoce system (n=4 dates submitted) for which the price negotiation process is usually longer. If one considers that products under the Accès précoce system are directly available (time to availability = 0), the average time to availability is 570 days. \*\*\*In the UK, MHRA's Early Access to Medicines Scheme provides access prior to marketing authorisation but is not included within this analysis, and would reduce the overall days for a small subset of medicines. In this analyses, MHRA dates have been used for 2021, 2022 and 2023 products and EMA dates used for 2020 products

## Median time to availability (2020-2023)

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



**European Union average: 518 days (median)** (Note: Malta is not included in EU27 average as only 1 date was submitted in total) <sup>†</sup>Country specific definitions are listed in the appendix. \*Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative \*\* For France, the median time to availability (523 days, n=80 dates submitted) includes products under the Accès précoce system (n=4 dates submitted) for which the price negotiation process is usually longer. If one considers that products under the Accès précoce system are directly available (time to availability = 0), the median time to availability is 499 days. \*\*\*In the UK, MHRA's Early Access to Medicines Scheme provides access prior to marketing authorisation but is not included within this analysis, and would reduce the overall days for a small subset of medicines. In this analyses, MHRA dates have been used for 2021, 2022 and 2023 products and EMA dates used for 2020 products

# Key observations

Executive summary (EU27 averages)

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

## Key Insights

### Rate of availability

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

### Time to availability

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



### Metrics key:

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

**Arrow colour** indicates significant changes versus the previous (2023) EU average (*significant improvement versus previous year* ↑ / *significant deterioration versus prior year* ↓)

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

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



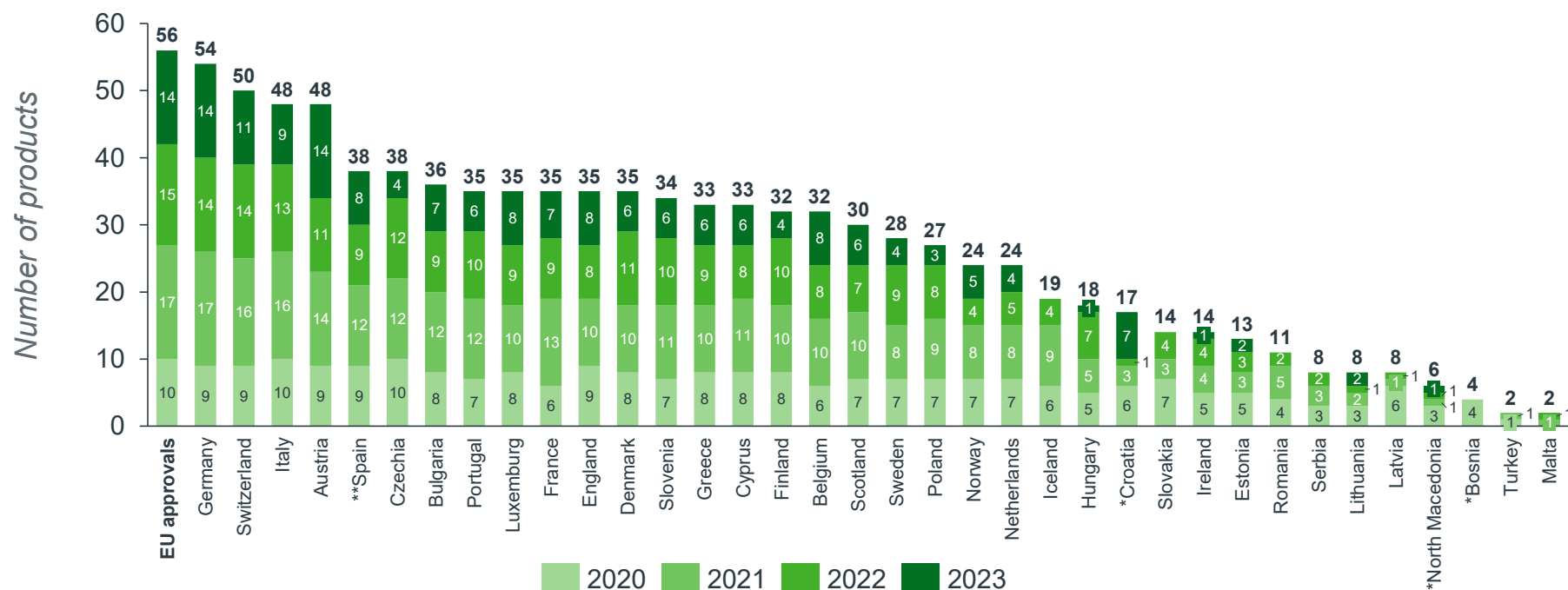
## 2. Oncology medicines

### Indicators:

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

# Oncology availability by approval year (2020-2023)

The **total availability by approval year** is the number of medicines available to patients in European countries as of 5<sup>th</sup> January 2025 (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.



European Union average: 28 products available (50%) <sup>†</sup>Country specific definitions are listed in the appendix. \*Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. \*\*In Spain, the WAIT analysis does not identify those medicinal products being accessible earlier in conformity with Spain's Royal Decree 1015/2009 relating to Medicines in Special Situations

## Oncology rate of availability (2020-2023)

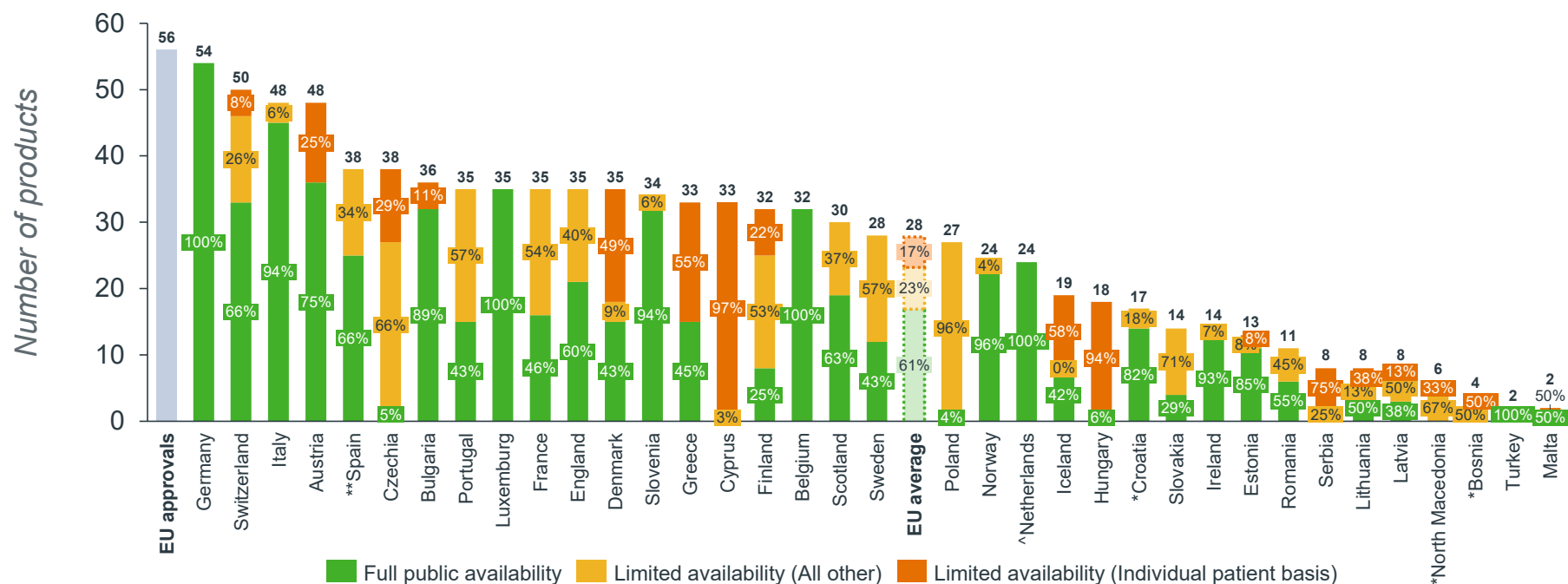
The **rate of availability**, measured by the number of medicines available to patients in European countries as of 5<sup>th</sup> January 2025. For most countries this is the point at which the product gains access to the reimbursement list<sup>†</sup>, including products with limited availability.



European Union average: 28 products available (50%) <sup>†</sup>Country specific definitions are listed in the appendix. \*Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. \*\*In Spain, the WAIT analysis does not identify those medicinal products being accessible earlier in conformity with Spain's Royal Decree 1015/2009 relating to Medicines in Special Situations

## Oncology breakdown of availability (% , 2020-2023)

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

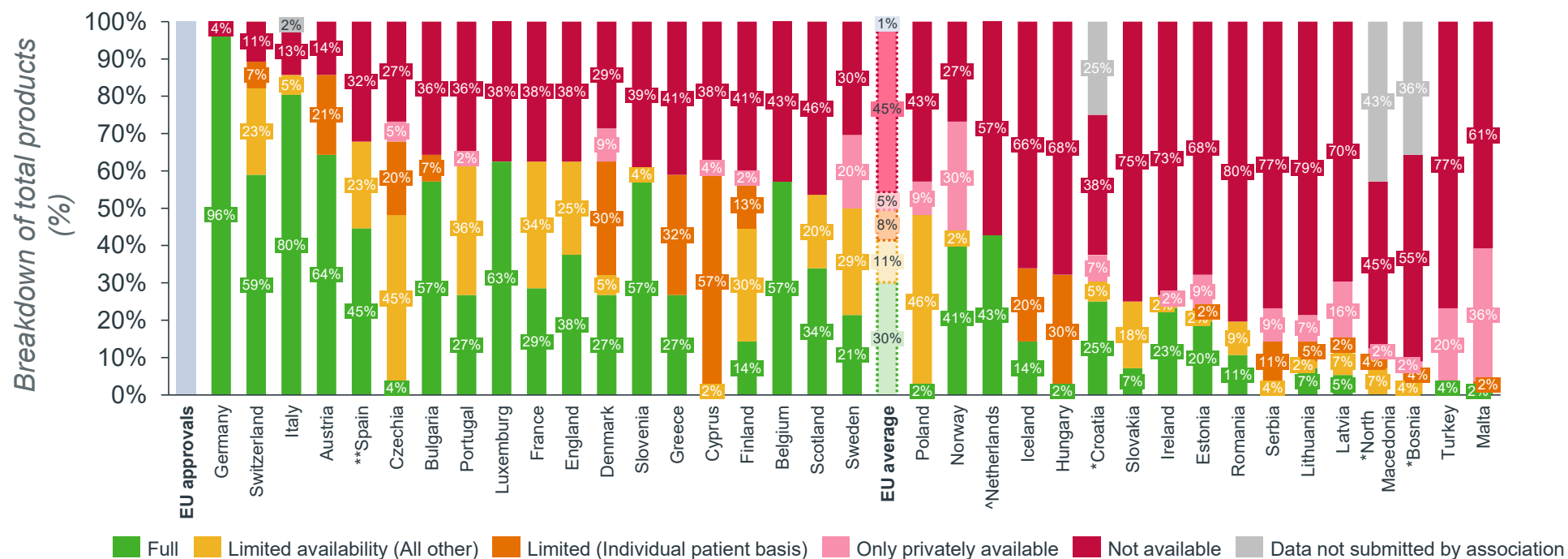


European Union average: 28 products available (50%), Limited availability (total) (40% of available products). \*Netherlands did not submit complete information on restrictions to available medicines meaning LA\* is not captured in these countries.

<sup>†</sup>Country specific definitions are listed in the appendix. \*Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. \*\*In Spain, the WAIT analysis does not identify those medicinal products being accessible earlier in conformity with Spain's Royal Decree 1015/2009 relating to Medicines in Special Situations

# Oncology breakdown of total availability (% , 2020-2023) (countries ordered by all availability)

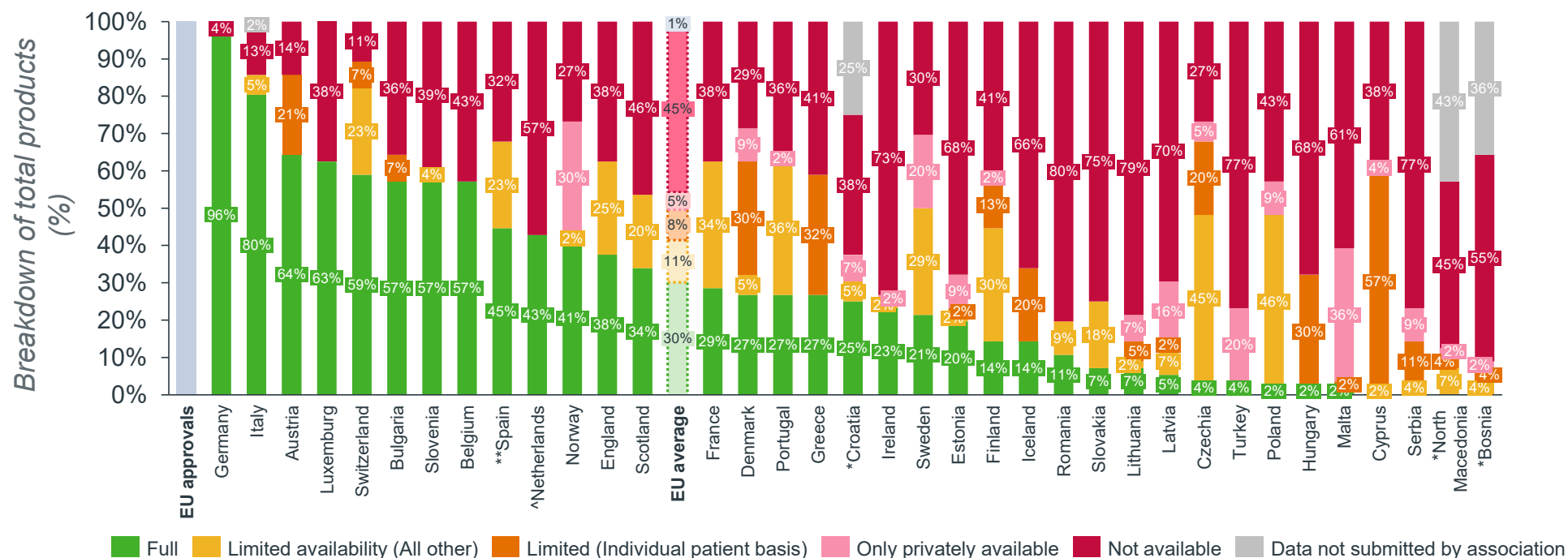
The **breakdown of total availability** is the composition of medicines available to patients in European countries as of 5<sup>th</sup> January 2025 (for most countries this is the point at which the product gains access to the reimbursement list<sup>†</sup>). This includes all medicine's status to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



European Union average: 28 products available (50%)\*; Limited Availability (19% of all oncology products); \*Netherlands did not submit complete information on restrictions to available medicines meaning LA\* is not captured in these countries. †Country specific definitions are listed in the appendix. \*Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. \*\*In Spain, the WAIT analysis does not identify those medicinal products being accessible earlier in conformity with Spain's Royal Decree 1015/2009 relating to Medicines in Special Situations. † The average rate of availability is 50%; the reason this is not represented in the chart (where segments total 49%) is due to rounding.

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

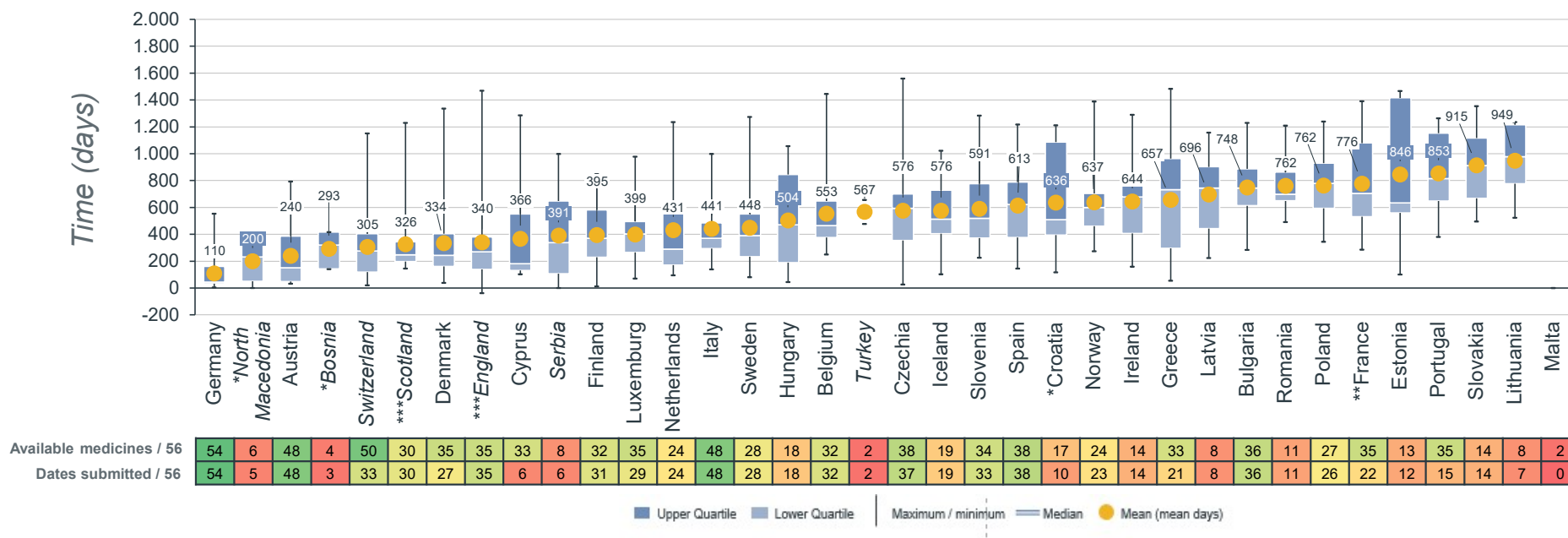
The **breakdown of total availability** is the composition of medicines available to patients in European countries as of 5<sup>th</sup> January 2025 (for most countries this is the point at which the product gains access to the reimbursement list<sup>†</sup>). This includes all medicine's status to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



European Union average: 28 products available (50%)\*; Limited Availability (19% of all oncology products); ^Netherlands did not submit complete information on restrictions to available medicines meaning LA\* is not captured in these countries. †Country specific definitions are listed in the appendix. \*Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. \*\*In Spain, the WAIT analysis does not identify those medicinal products being accessible earlier in conformity with Spain's Royal Decree 1015/2009 relating to Medicines in Special Situations. † The average rate of availability is 50%; the reason this is not represented in the chart (where segments total 49%) is due to rounding.

# Oncology time to availability (2020-2023)

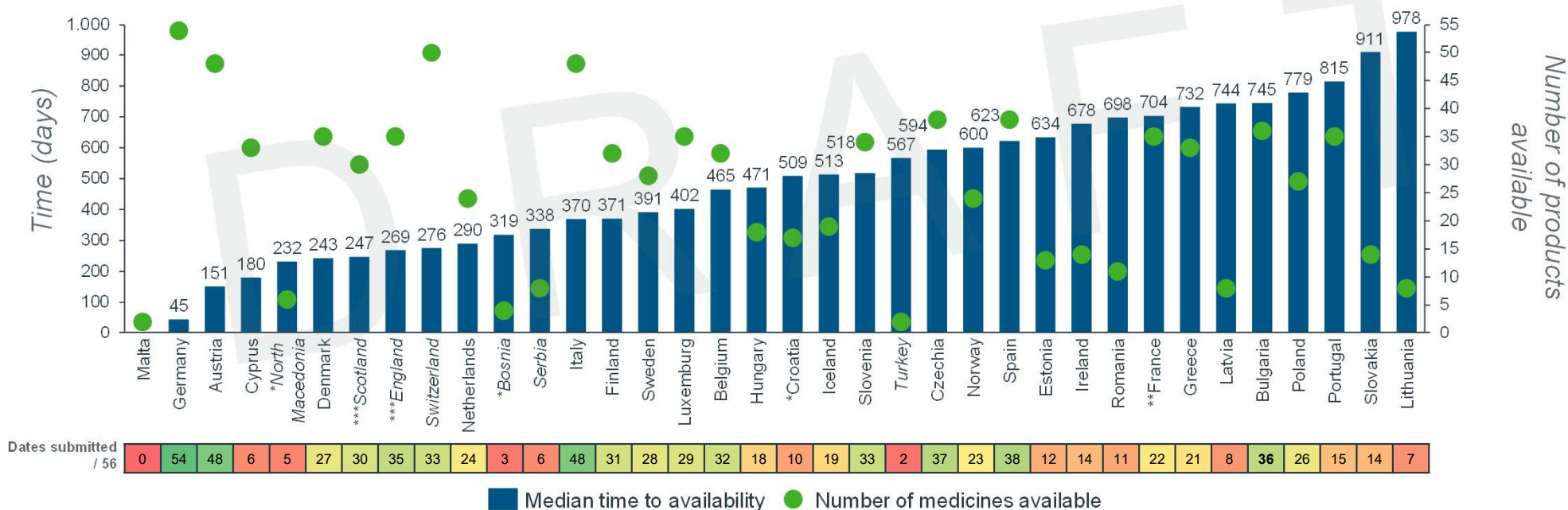
The **time to availability** is the days between marketing authorisation and the date of availability to patients in European countries (for most this is the point at which products gain access to the reimbursement list<sup>†</sup>). The marketing authorisation date is the date of central EU authorisation 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 2025.



**European Union average: 586 days (mean)** (Note: Malta is not included in EU27 average as only 1 date was submitted in total) <sup>†</sup>Country specific definitions are listed in the appendix. \*Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. \*\*For France, the mean time to availability (776 days, n=22 dates submitted) includes products under the Accès précoce system (n=1 dates submitted) for which the price negotiation process is usually longer. If one considers that products under the Accès précoce system are directly available (time to availability = 0), the average time to availability is 754 days. \*\*\*In the UK, MHRA's Early Access to Medicines Scheme provides access prior to marketing authorisation but is not included within this analysis, and would reduce the overall days for a small subset of medicines. In this analyses, MHRA dates have been used for 2021, 2022 and 2023 products and EMA dates used for 2020 products

## Oncology median time to availability (2020-2023)

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



European Union average: 540 days (median) (Note: Malta is not included in EU27 average as only 1 date was submitted in total) <sup>†</sup>Country specific definitions are listed in the appendix. \*Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative \*\*For France, the median time to availability (704 days, n=22 dates submitted) includes products under the Accès précoce system (n=1 dates submitted) for which the price negotiation process is usually longer. If one considers that products under the Accès précoce system are directly available (time to availability = 0), the median time to availability remains 704 days. \*\*\*In the UK, MHRA's Early Access to Medicines Scheme provides access prior to marketing authorisation but is not included within this analysis, and would reduce the overall days for a small subset of medicines. In this analyses, MHRA dates have been used for 2021, 2022 and 2023 products and EMA dates used for 2020 products

# Key observations

## Executive summary (EU27 averages)

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

### Key Insights

#### Rate of availability

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

#### Time to availability

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



#### Metrics key:

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

**Arrow colour** indicates significant changes versus the previous (2023) EU average (*significant improvement versus previous year* ↑ / *significant deterioration versus prior year* ↓)

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

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



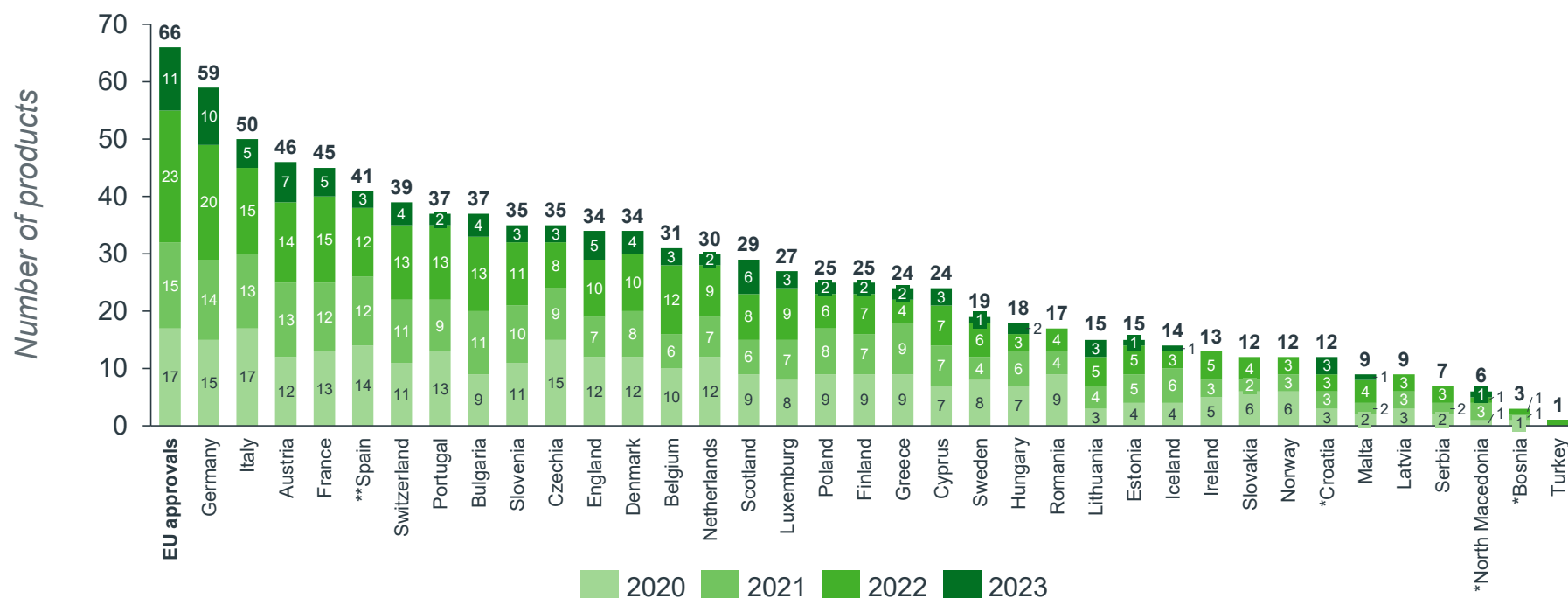
## 3. Orphan medicines

### Indicators:

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

## Orphan availability by approval year (2020-2023)

The **total availability by approval year** is the number of medicines available to patients in European countries as of 5<sup>th</sup> January 2025 (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.



European Union average: 28 products available (42%) <sup>†</sup>Country specific definitions are listed in the appendix. \*Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. \*\*In Spain, the WAIT analysis does not identify those medicinal products being accessible earlier in conformity with Spain's Royal Decree 1015/2009 relating to Medicines in Special Situations

## Orphan rate of availability (2020-2023)

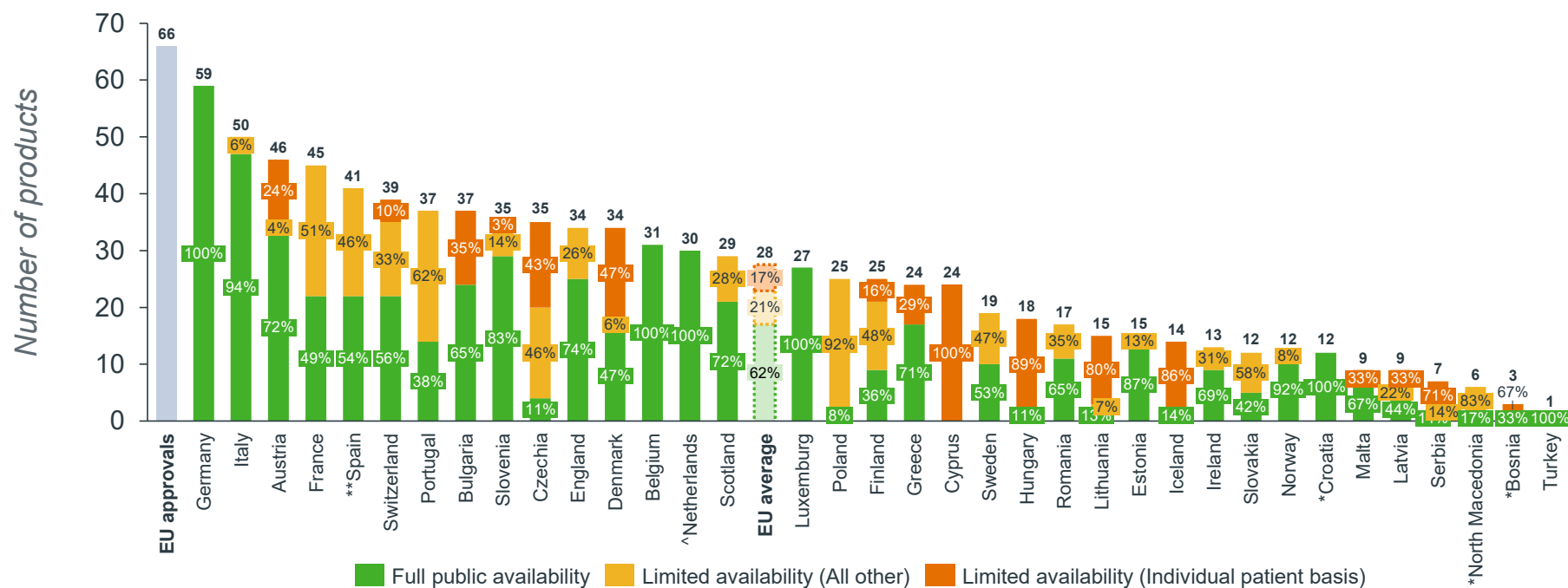
The **rate of availability**, measured by the number of medicines available to patients in European countries as of 5<sup>th</sup> January 2025. For most countries this is the point at which the product gains access to the reimbursement list<sup>†</sup>, including products with limited availability.



European Union average: 28 products available (42%) <sup>†</sup>Country specific definitions are listed in the appendix. <sup>\*</sup>Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. <sup>\*\*</sup>In Spain, the WAIT analysis does not identify those medicinal products being accessible earlier in conformity with Spain's Royal Decree 1015/2009 relating to Medicines in Special Situations

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

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

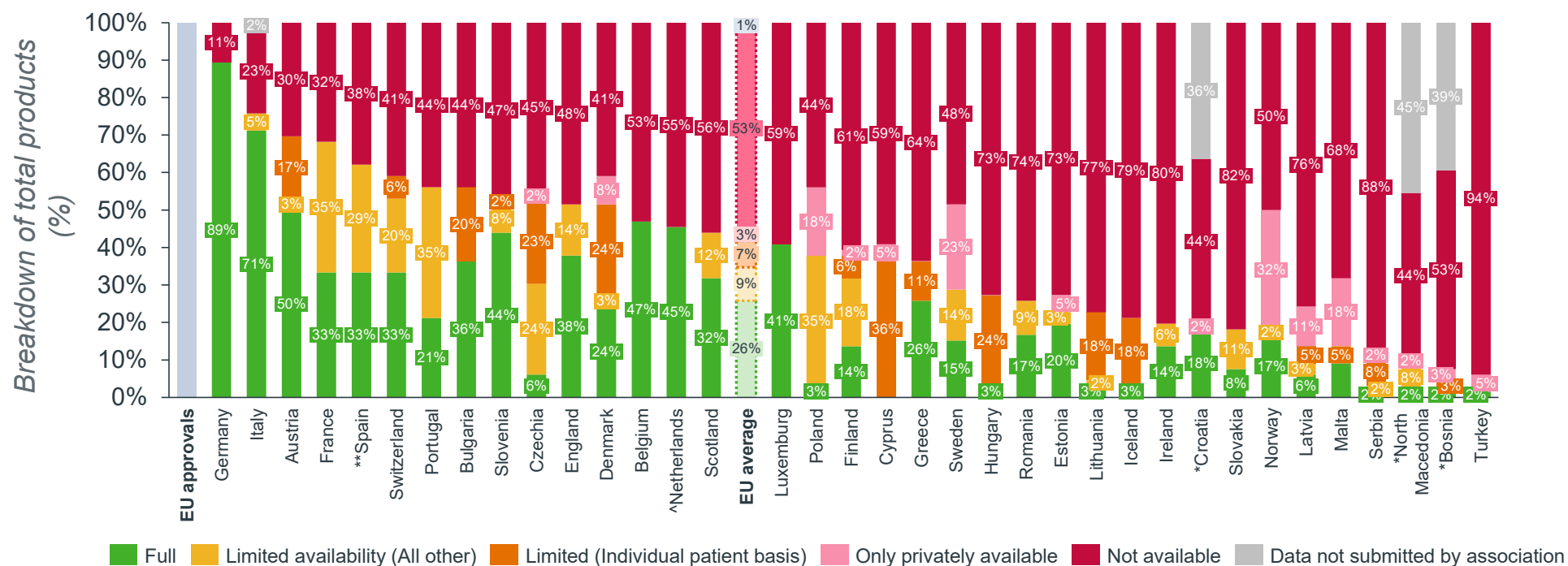


European Union average: 28 products available (42%), Limited availability (total) (38% of available products). \*Netherlands did not submit complete information on restrictions to available medicines meaning LA\* is not captured in these countries.

<sup>†</sup>Country specific definitions are listed in the appendix. \*Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. \*\*In Spain, the WAIT analysis does not identify those medicinal products being accessible earlier in conformity with Spain's Royal Decree 1015/2009 relating to Medicines in Special Situations

# Orphan breakdown of total availability (% , 2020-2023) (countries ordered by all availability)

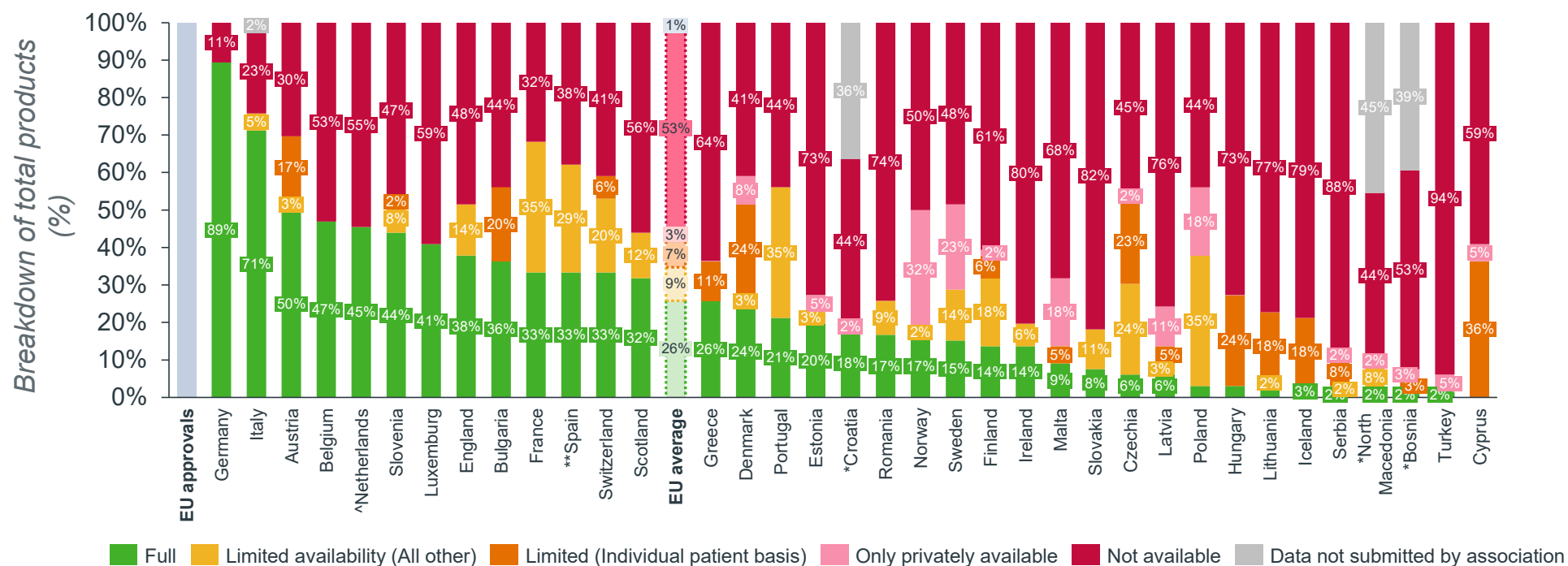
The **breakdown of total availability** is the composition of medicines available to patients in European countries as of 5<sup>th</sup> January 2025 (for most countries this is the point at which the product gains access to the reimbursement list<sup>†</sup>). This includes all medicine's status to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



European Union average: 28 products available (42%); Limited Availability (16% of all orphan products); \*Netherlands did not submit complete information on restrictions to available medicines meaning LA\* is not captured in these countries. †Country specific definitions are listed in the appendix. \*Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. \*\*In Spain, the WAIT analysis does not identify those medicinal products being accessible earlier in conformity with Spain's Royal Decree 1015/2009 relating to Medicines in Special Situations

# Orphan breakdown of total availability (% , 2020-2023) (countries ordered by full availability)

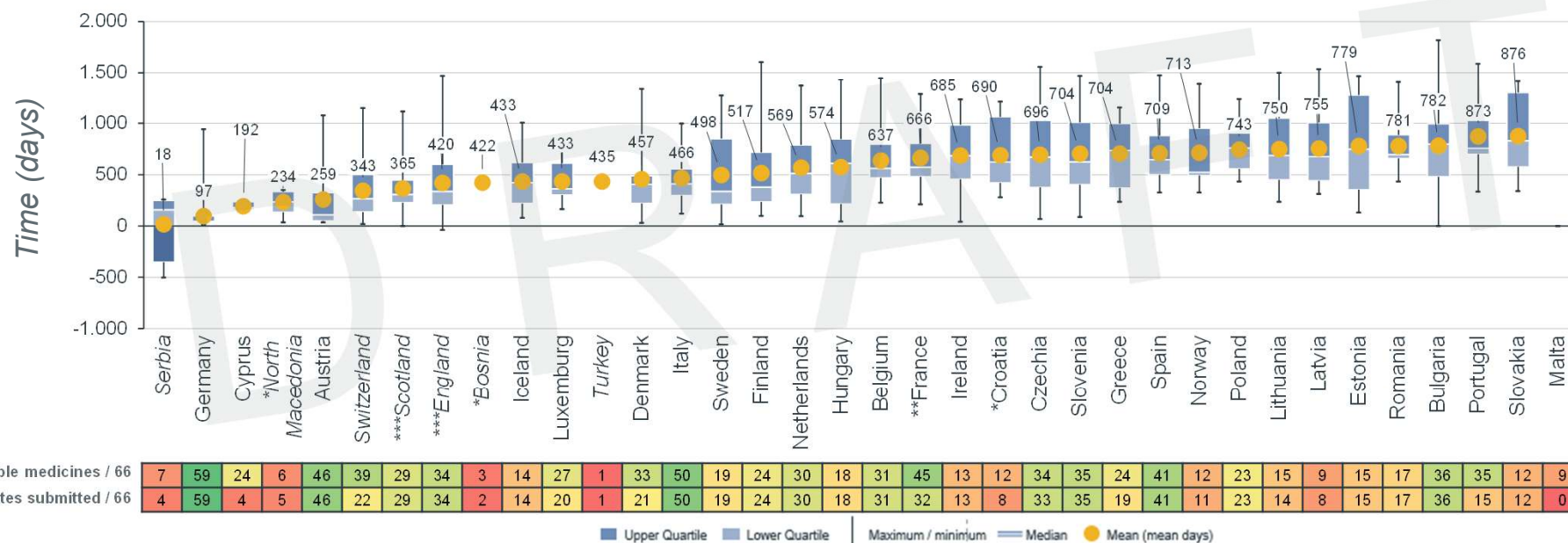
The **breakdown of total availability** is the composition of medicines available to patients in European countries as of 5<sup>th</sup> January 2025 (for most countries this is the point at which the product gains access to the reimbursement list<sup>†</sup>). This includes all medicine's status to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



European Union average: 28 products available (42%); Limited Availability (16% of all orphan products); \*Netherlands did not submit complete information on restrictions to available medicines meaning LA\* is not captured in these countries. †Country specific definitions are listed in the appendix. \*Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. \*\*In Spain, the WAIT analysis does not identify those medicinal products being accessible earlier in conformity with Spain's Royal Decree 1015/2009 relating to Medicines in Special Situations

## Orphan time to availability (2020-2023)

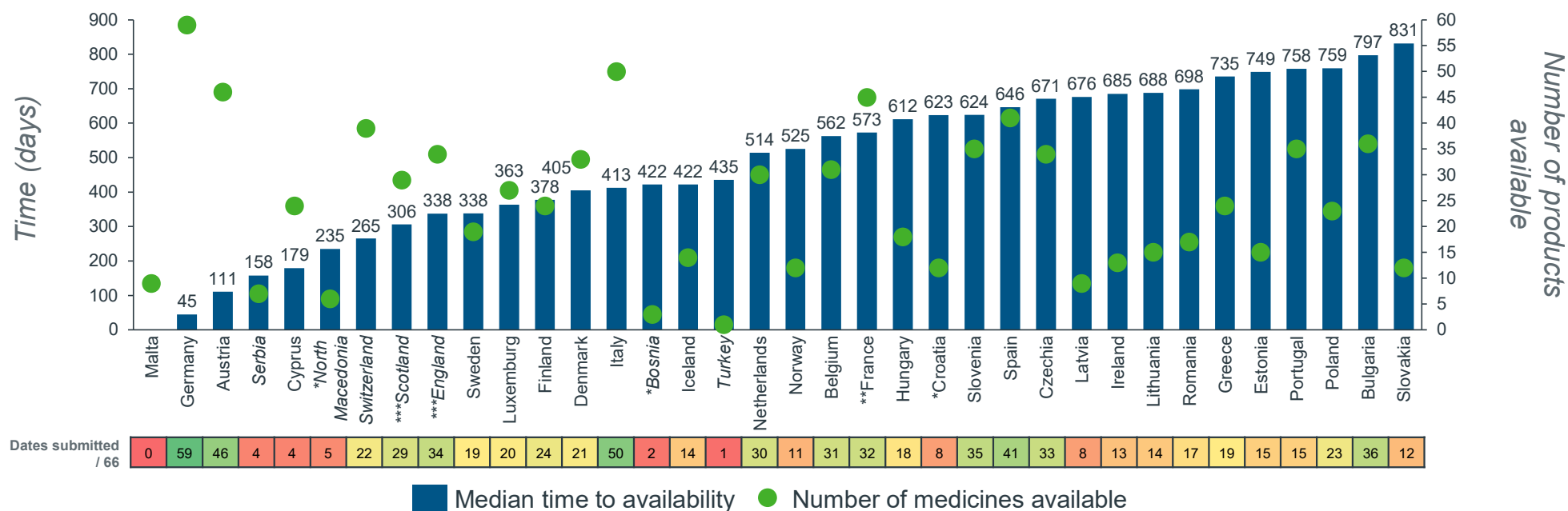
The **time to availability** is the days between marketing authorisation and the date of availability to patients in European countries (for most this is the point at which products gain access to the reimbursement list<sup>†</sup>). The marketing authorisation date is the date of central EU authorisation 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 2025.



**European Union average: 611 days (mean)** (Note: Malta is not included in EU27 average as no dates were submitted in total) <sup>†</sup>Country specific definitions are listed in the appendix. \*Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative.; \*\*For France, the time to availability (666 days, n=32 dates submitted) includes products under the Accès précoce system (n=2 dates submitted) for which the price negotiation process is usually longer. If one considers that products under the Accès précoce system are directly available (time to availability = 0), the average time to availability is 637 days. \*\*\*In the UK, MHRA's Early Access to Medicines Scheme provides access prior to marketing authorisation but is not included within this analysis, and would reduce the overall days for a small subset of medicines. In this analyses, MHRA dates have been used for 2021, 2022 and 2023 products and EMA dates used for 2020 products

## Orphan median time to availability (2020-2023)

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



**European Union average: 555 days (median)** (Note: Malta is not included in EU27 average as only 1 date was submitted in total) <sup>†</sup>Country specific definitions are listed in the appendix. \*Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative \*\*For France, the median time to availability (573 days, n=32 dates submitted) includes products under the Accès précoce system (n=2 dates submitted) for which the price negotiation process is usually longer. If one considers that products under the Accès précoce system are directly available (time to availability = 0), the average time to availability is 563 days \*\*\*In the UK, MHRA's Early Access to Medicines Scheme provides access prior to marketing authorisation but is not included within this analysis, and would reduce the overall days for a small subset of medicines. In this analyses, MHRA dates have been used for 2021, 2022 and 2023 products and EMA dates used for 2020 products

# Key observations

## Executive summary (EU27 averages)

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

## Key Insights

### Rate of availability

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

### Time to availability

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



### Metrics key:

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

**Arrow colour** indicates significant changes versus the previous (2023) EU average (*significant improvement versus previous year* ↑ / *significant deterioration versus prior year* ↓)

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

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



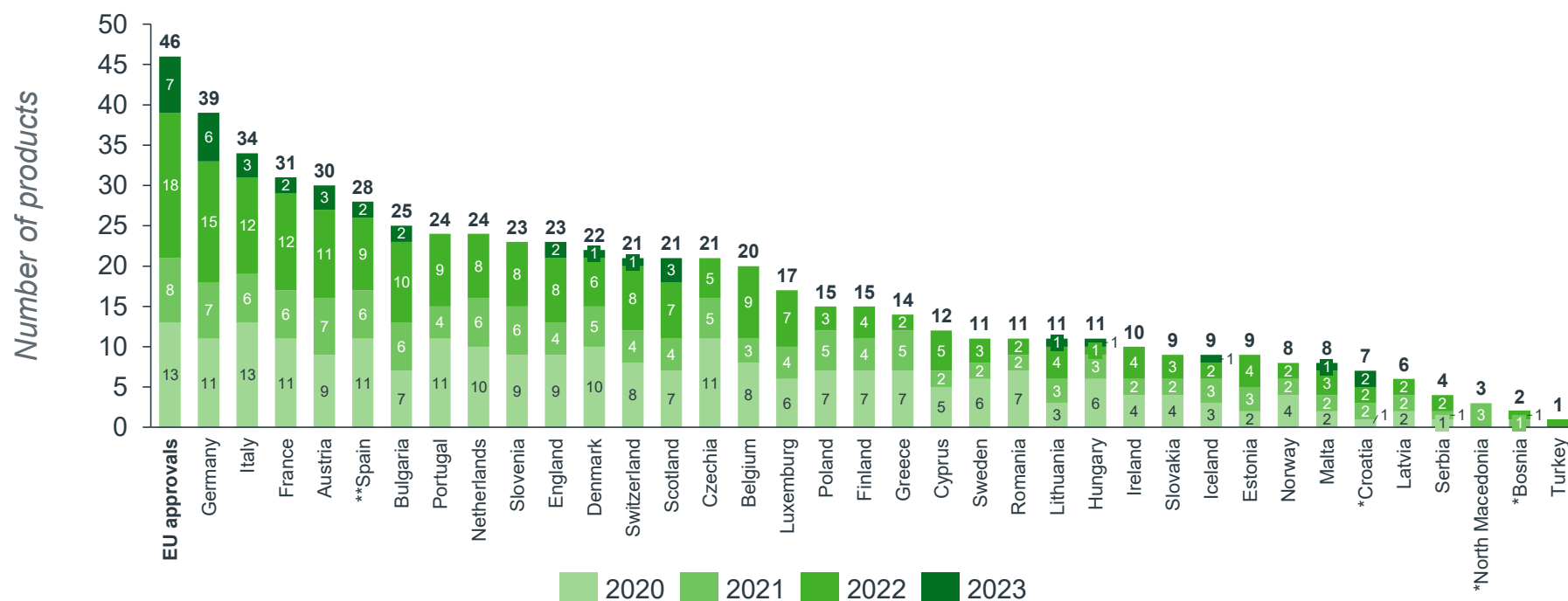
## 4. Non-oncology orphan medicines

### Indicators:

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

## Non-oncology orphan availability by approval year (2020-2023)

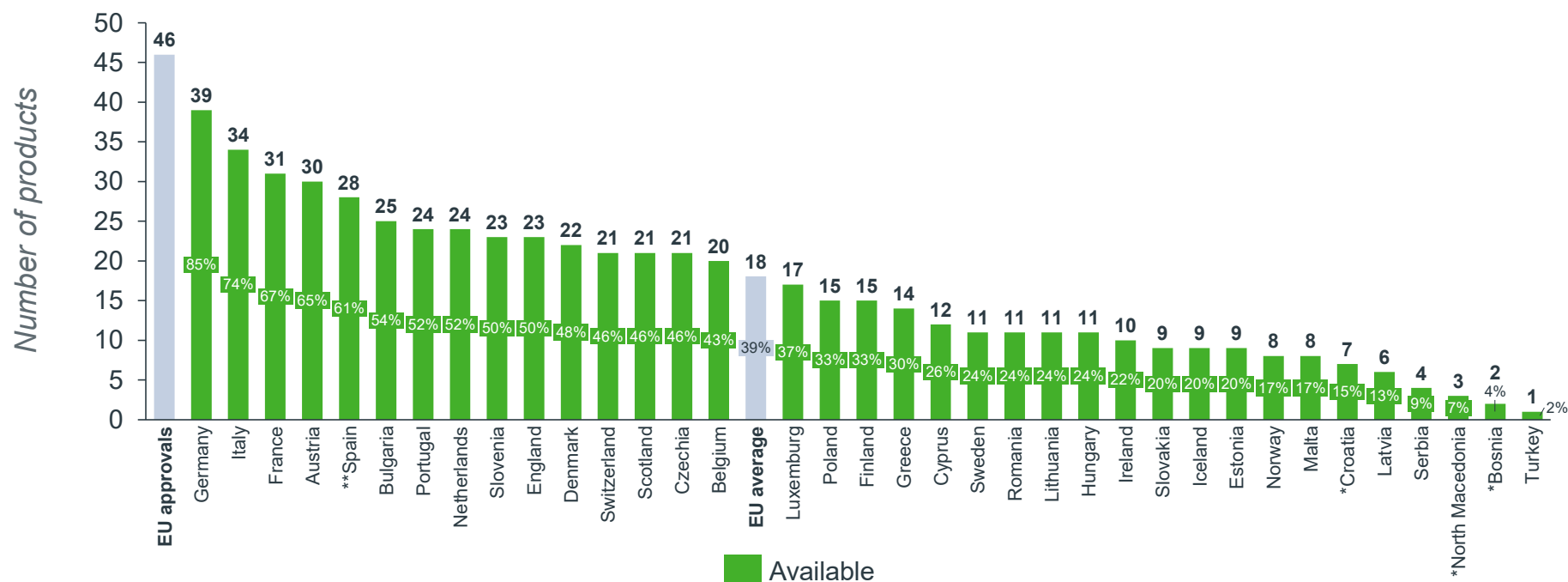
The **total availability by approval year** is the number of medicines available to patients in European countries as of 5<sup>th</sup> January 2025 (for most countries this is the point at which the product gains access to the reimbursement list<sup>†</sup>), split by the year the product received marketing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



European Union average: 18 products available (39%) <sup>†</sup>Country specific definitions are listed in the appendix. \*Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. \*\*In Spain, the WAIT analysis does not identify those medicinal products being accessible earlier in conformity with Spain's Royal Decree 1015/2009 relating to Medicines in Special Situations

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

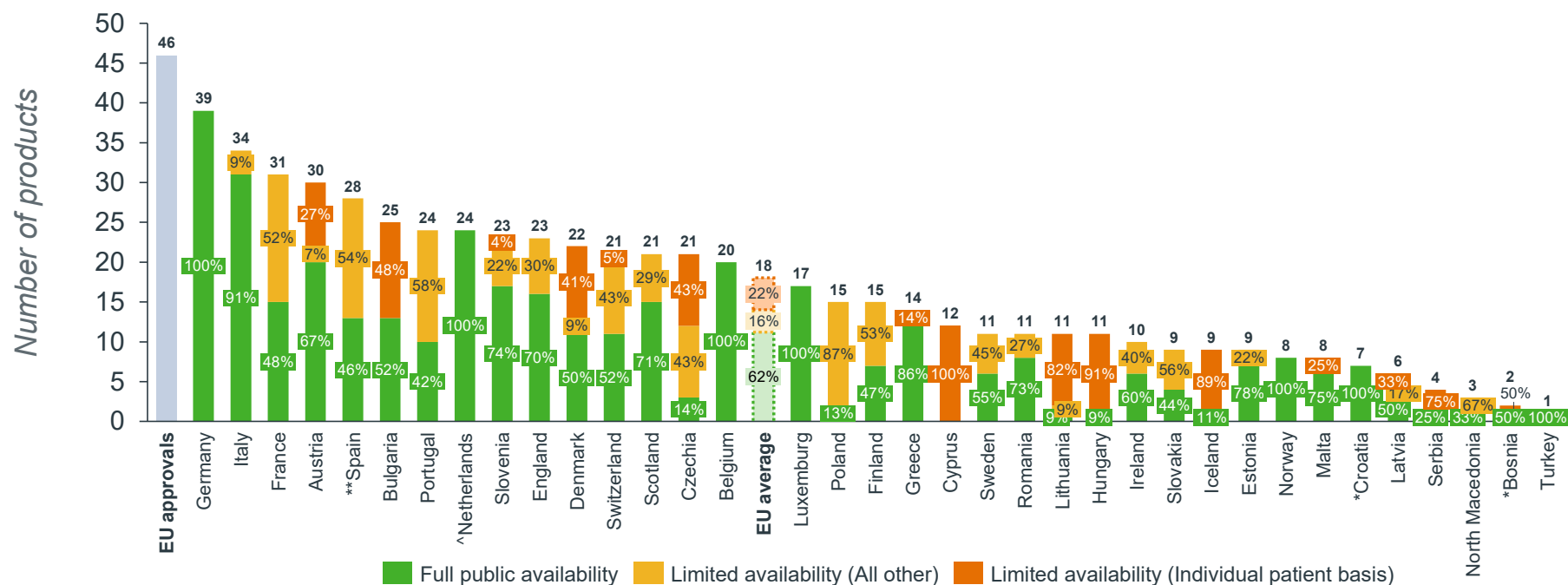
The **rate of availability**, measured by the number of medicines available to patients in European countries as of 5<sup>th</sup> January 2025. For most countries this is the point at which the product gains access to the reimbursement list<sup>†</sup>, including products with limited availability.



European Union average: 18 products available (39%) <sup>†</sup>Country specific definitions are listed in the appendix. \*Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. \*\*In Spain, the WAIT analysis does not identify those medicinal products being accessible earlier in conformity with Spain's Royal Decree 1015/2009 relating to Medicines in Special Situations

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

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

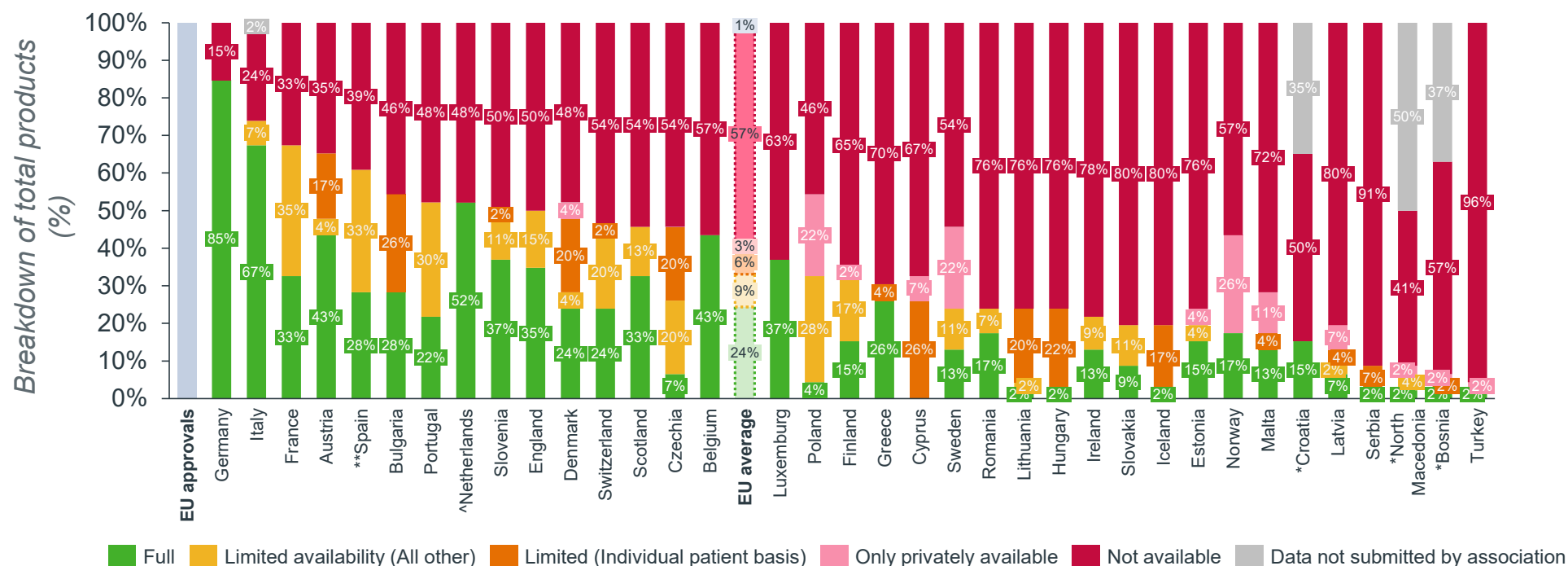


European Union average: 18 products available (39%), Limited availability (total) (38% of available products) \*Netherlands did not submit complete information on restrictions to available medicines meaning LA\* is not captured in these countries. †Country specific definitions are listed in the appendix. \*Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. \*\*In Spain, the WAIT analysis does not identify those medicinal products being accessible earlier in conformity with Spain's Royal Decree 1015/2009 relating to Medicines in Special Situations

# Non-oncology orphan breakdown of total availability

## (%, 2020-2023) *(countries ordered by all availability)*

The **breakdown of total availability** is the composition of medicines available to patients in European countries as of 5<sup>th</sup> January 2025 (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.



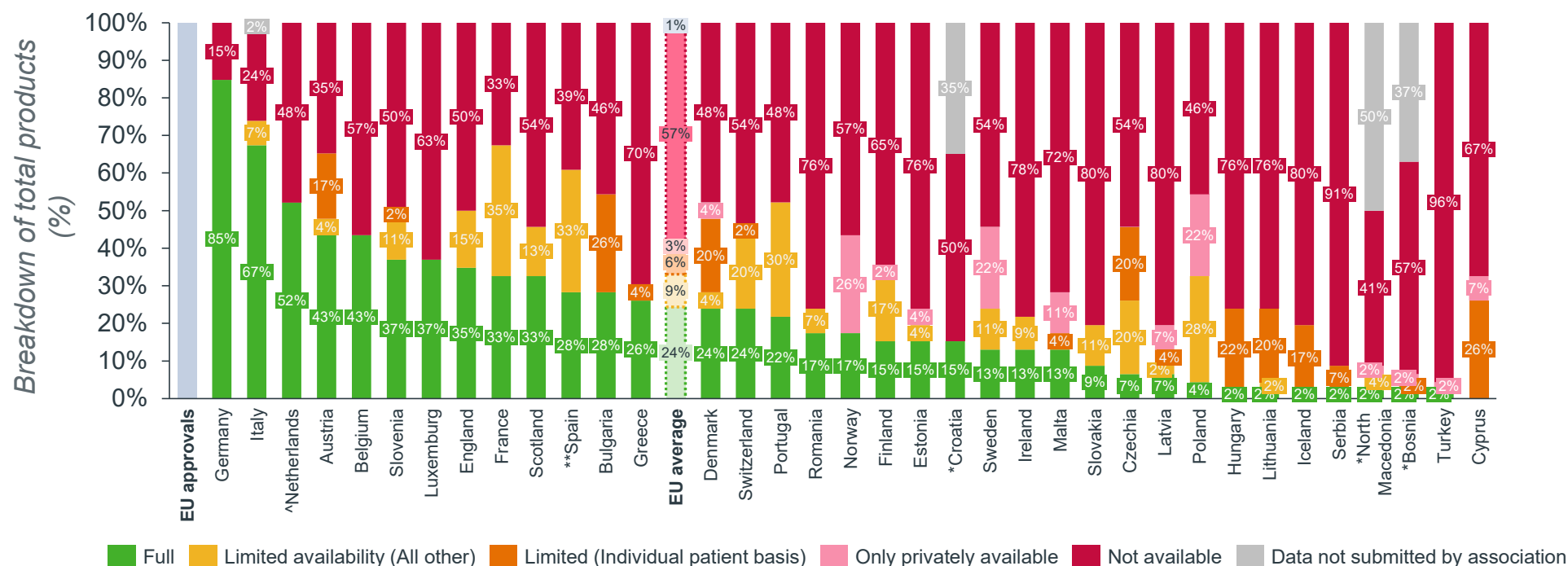
European Union average: 18 products available (39%); Limited Availability (15% of all non-onco orphan products); ^Netherlands did not submit complete information on restrictions to available medicines meaning LA\* is not captured in these countries.

<sup>†</sup>Country specific definitions are listed in the appendix. \*Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. \*\*In Spain, the WAIT analysis does not identify those medicinal products being accessible earlier in conformity with Spain's Royal Decree 1015/2009 relating to Medicines in Special Situations

# Non-oncology orphan breakdown of total availability

## (%, 2020-2023) *(countries ordered by full availability)*

The **breakdown of total availability** is the composition of medicines available to patients in European countries as of 5<sup>th</sup> January 2025 (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.

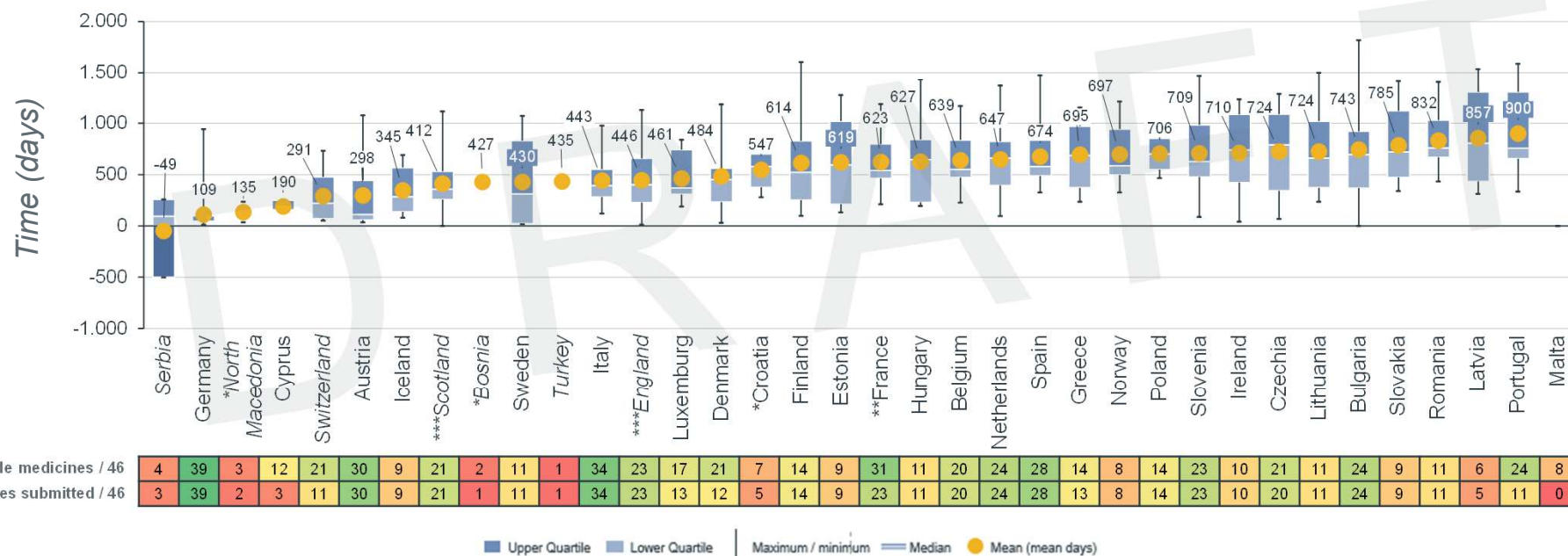


European Union average: 18 products available (39%); Limited Availability (15% of all non-onco orphan products); \*Netherlands did not submit complete information on restrictions to available medicines meaning LA\* is not captured in these countries.

<sup>†</sup>Country specific definitions are listed in the appendix. \*Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. \*\*In Spain, the WAIT analysis does not identify those medicinal products being accessible earlier in conformity with Spain's Royal Decree 1015/2009 relating to Medicines in Special Situations

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

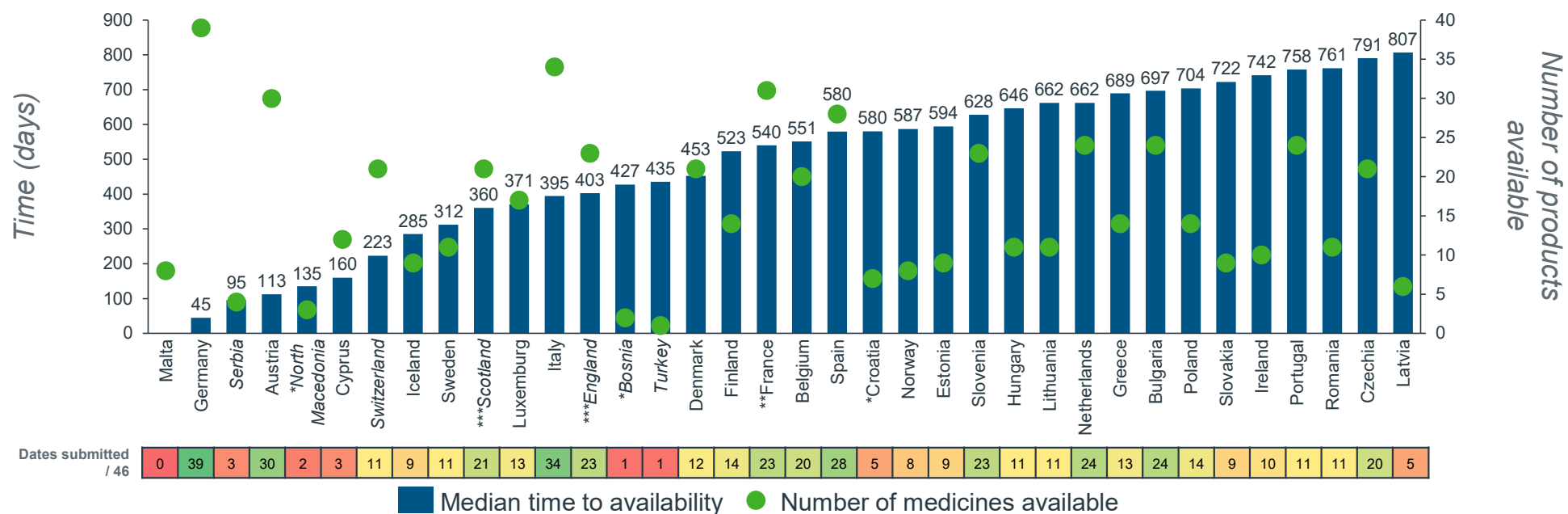
The **time to availability** is the days between marketing authorisation and the date of availability to patients in European countries (for most this is the point at which products gain access to the reimbursement list<sup>†</sup>). The marketing authorisation date is the date of central EU authorisation 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 2025.



**European Union average: 607 days (mean)** (Note: Malta is not included in EU27 average as only 1 date was submitted in total) <sup>†</sup>Country specific definitions are listed in the appendix. \*Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. \*\*For France, the time to availability (623 days, n=23 dates submitted) includes products under the Accès précoce system (n=2 dates submitted) for which the price negotiation process is usually longer. If one considers that products under the Accès précoce system are directly available (time to availability = 0), the average time to availability is 593 days. \*\*\*In the UK, MHRA's Early Access to Medicines Scheme provides access prior to marketing authorisation but is not included within this analysis, and would reduce the overall days for a small subset of medicines. In this analyses, MHRA dates have been used for 2021, 2022 and 2023 products and EMA dates used for 2020 products

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

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



European Union average: 557 days (median) (Note: Malta is not included in EU27 average as only 1 date was submitted in total) <sup>†</sup>Country specific definitions are listed in the appendix. \*Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. \*\*For France, the median time to availability (540 days, n=23 dates submitted) includes products under the Accès précoce system (n=2 dates submitted) for which the price negotiation process is usually longer. If one considers that products under the Accès précoce system are directly available (time to availability = 0), the median time to availability is 527 days. \*\*\*In the UK, MHRA's Early Access to Medicines Scheme provides access prior to marketing authorisation but is not included within this analysis, and would reduce the overall days for a small subset of medicines. In this analyses, MHRA dates have been used for 2021, 2022 and 2023 products and EMA dates used for 2020 products

# Key observations

## Executive summary (EU27 averages)

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

## Key Insights

### Rate of availability

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

### Time to availability

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



### Metrics key:

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

**Arrow colour** indicates significant changes versus the previous (2023) EU average (*significant improvement versus previous year* ↑ / *significant deterioration versus prior year* ↓)

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

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



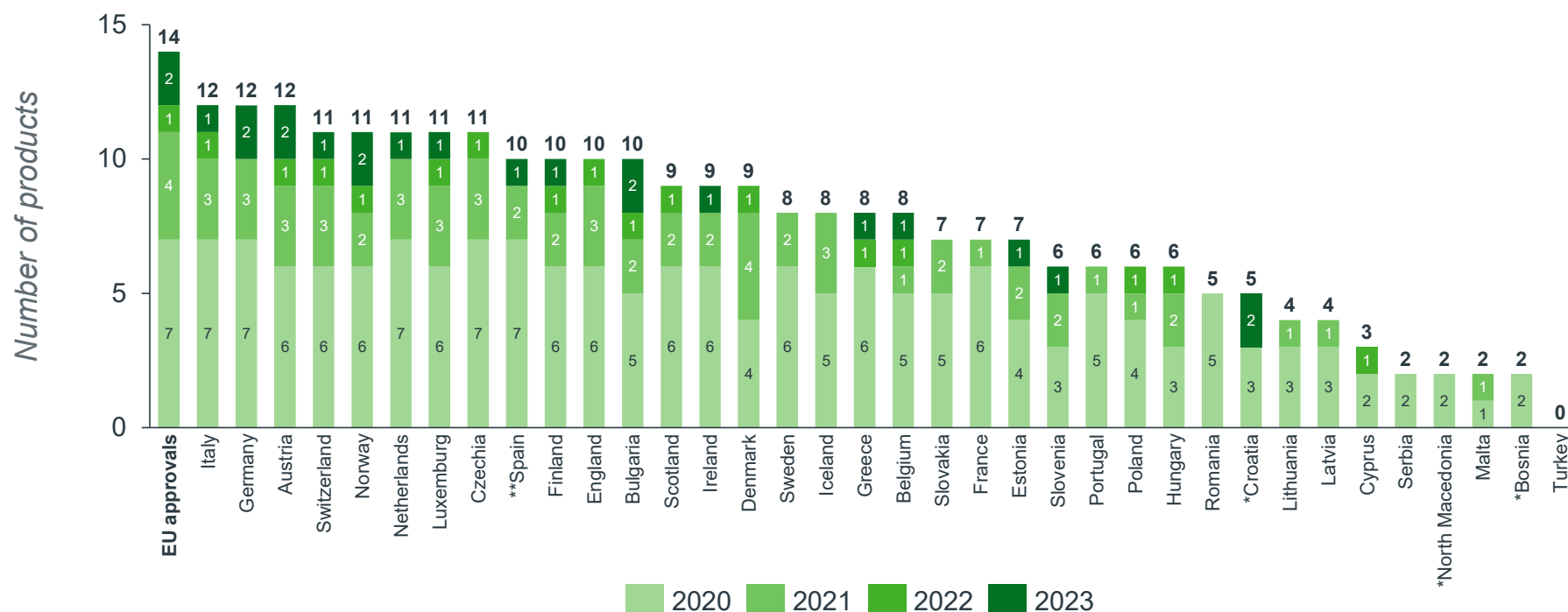
## 5. Combination therapies

### Indicators:

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

## Combination therapies availability by approval year (2020-2023)

The **total availability by approval year** is the number of fixed dose combination medicines available to patients in European countries as of 5<sup>th</sup> January 2025 (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.



European Union average: 8 products available (55%) Combination products can include innovative branded / generic combinations. <sup>†</sup>Country specific definitions are listed in the appendix. \*Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. \*\*In Spain, the WAIT analysis does not identify those medicinal products being accessible earlier in conformity with Spain's Royal Decree 1015/2009 relating to Medicines in Special Situations

## Combination therapies rate of availability (2020-2023)

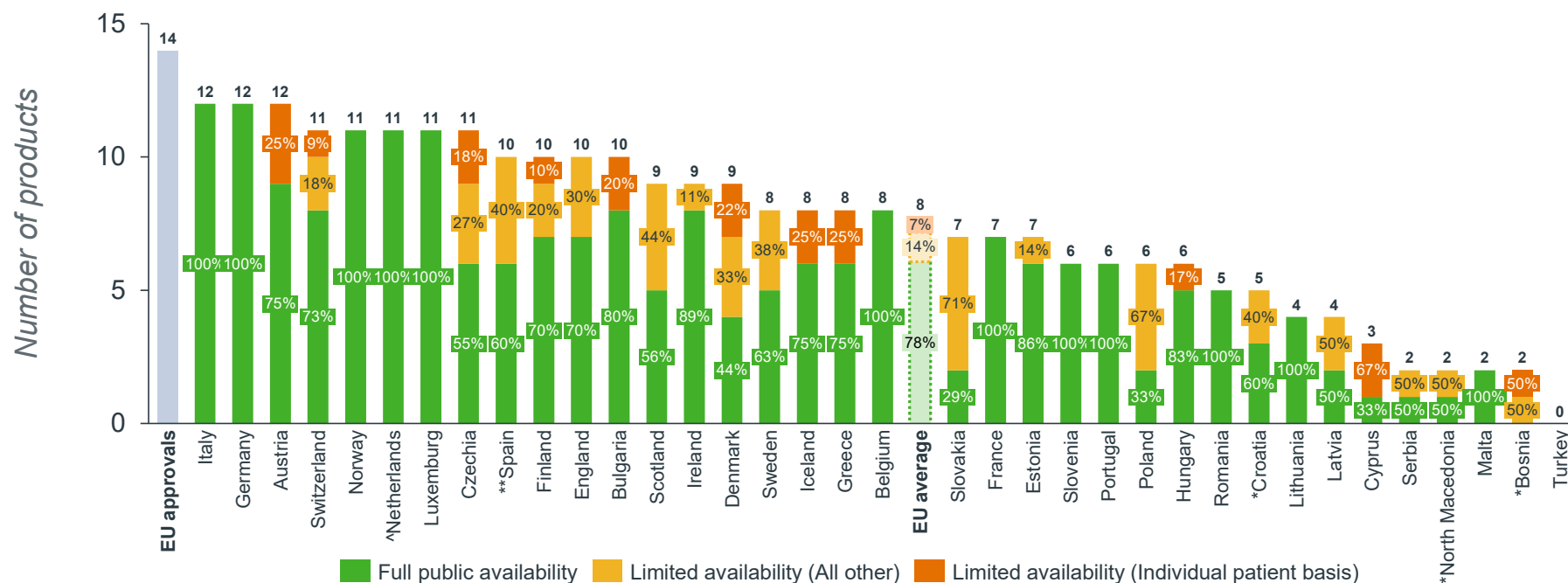
The **rate of availability**, measured by the number of fixed dose combination medicines available to patients in European countries as of 5<sup>th</sup> January 2025. For most countries this is the point at which the product gains access to the reimbursement list<sup>†</sup>, including products with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



European Union average: 8 products available (55%) Combination products can include innovative branded / generic combinations; <sup>†</sup>Country specific definitions are listed in the appendix.. \*Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. \*\*In Spain, the WAIT analysis does not identify those medicinal products being accessible earlier in conformity with Spain's Royal Decree 1015/2009 relating to Medicines in Special Situations

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

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

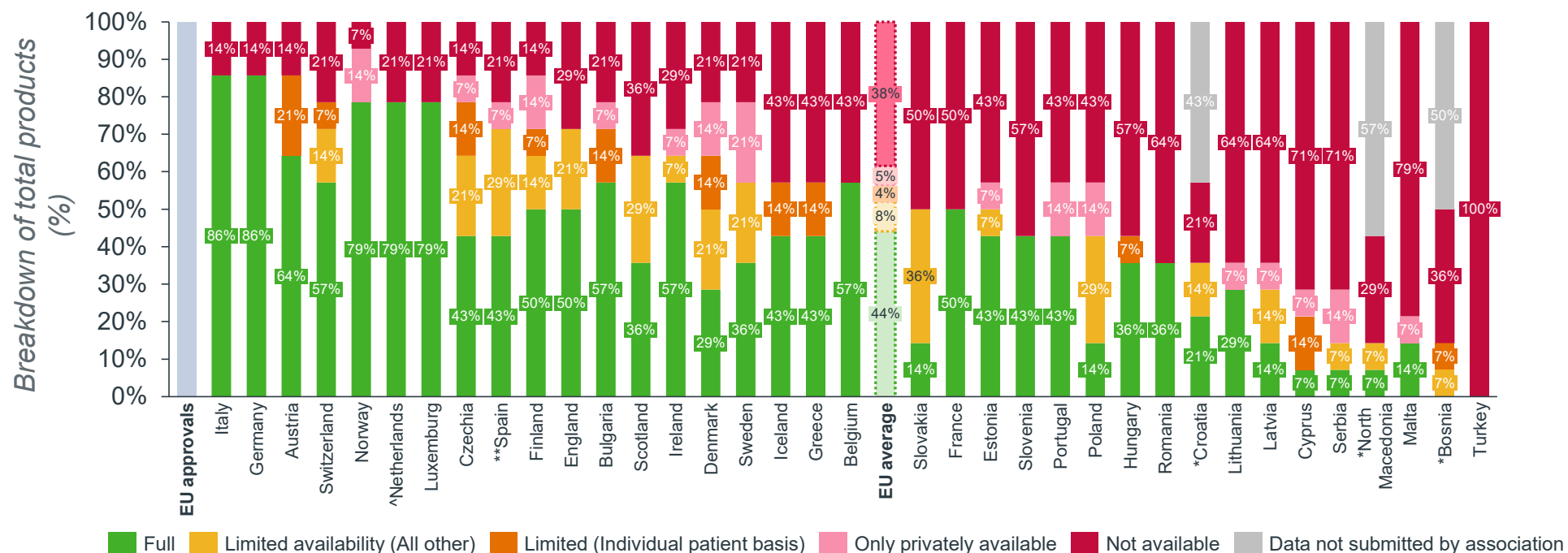


European Union average: 8 products available (55%), limited availability (total) (21% of available products). Combination products can include innovative branded / generic combinations; \*Netherlands did not submit complete information on restrictions to available medicines meaning LA\* is not captured in these countries<sup>†</sup>Country specific definitions are listed in the appendix. \*Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. \*\*In Spain, the WAIT analysis does not identify those medicinal products being accessible earlier in conformity with Spain's Royal Decree 1015/2009 relating to Medicines in Special Situations

# Combination therapies breakdown of total availability

## (%, 2020-2023) *(countries ordered by all availability)*

The **breakdown of total availability** is the composition of medicines available to patients in European countries as of 5<sup>th</sup> January 2025 (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.

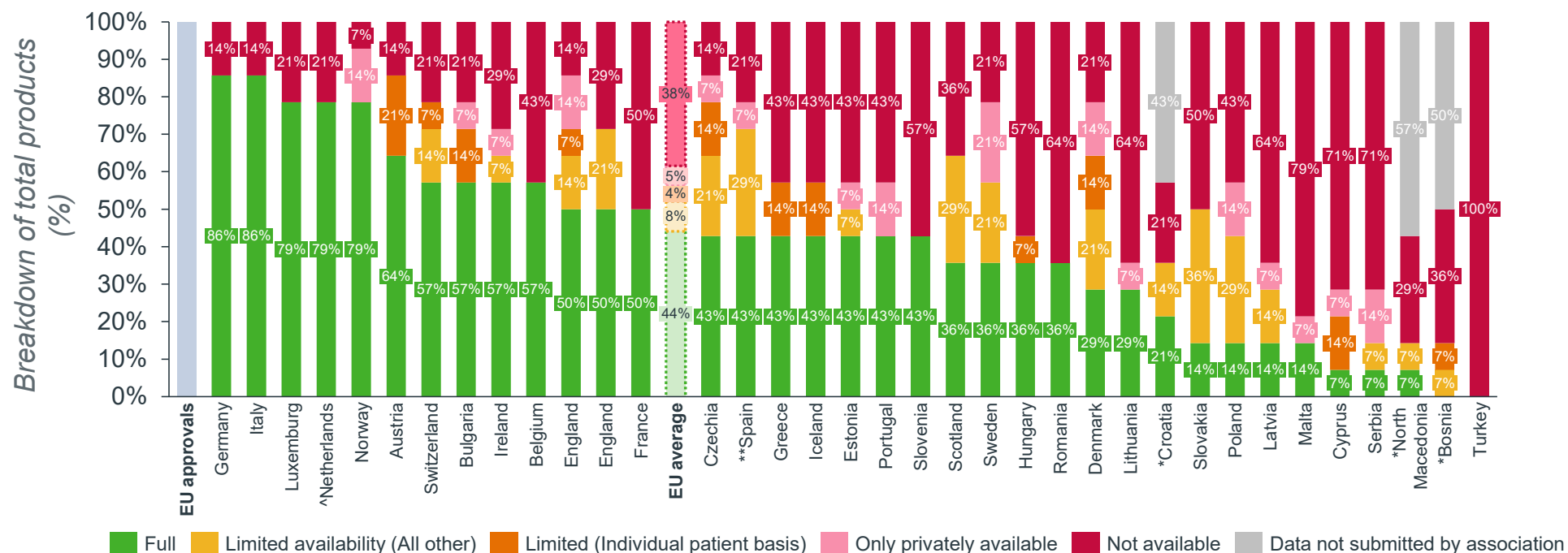


European Union average: 8 products available (55%); Limited Availability (12% of all combination therapies); Combination products can include innovative branded / generic combinations; \*Netherlands did not submit complete information on restrictions to available medicines meaning LA\* is not captured in these countries. †Country specific definitions are listed in the appendix. \*Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. \*\*In Spain, the WAIT analysis does not identify those medicinal products being accessible earlier in conformity with Spain's Royal Decree 1015/2009 relating to Medicines in Special Situations

# Combination therapies breakdown of total availability

## (%, 2020-2023) *(countries ordered by full availability)*

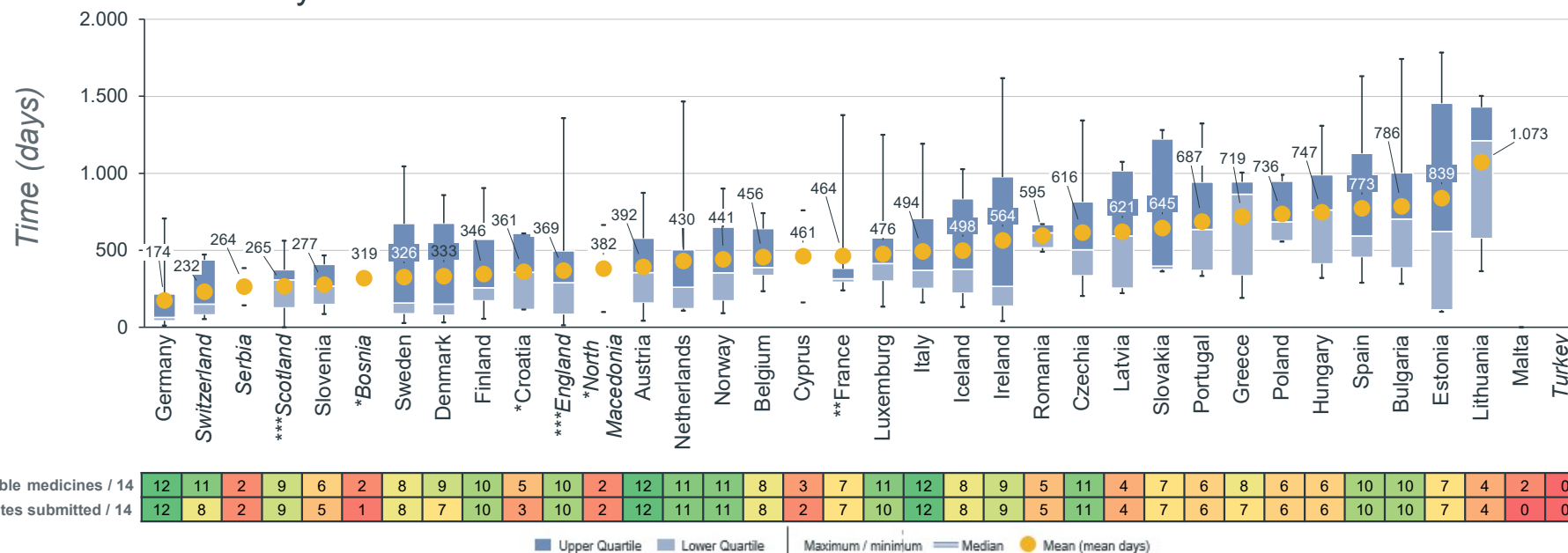
The **breakdown of total availability** is the composition of medicines available to patients in European countries as of 5<sup>th</sup> January 2025 (for most countries this is the point at which the product gains access to the reimbursement list<sup>†</sup>). This includes all medicine's status to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



European Union average: 8 products available (55%); Limited Availability (12% of all combination therapies); Combination products can include innovative branded / generic combinations; \*Netherlands did not submit complete information on restrictions to available medicines meaning LA\* is not captured in these countries. †Country specific definitions are listed in the appendix. \*Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. \*\*In Spain, the WAIT analysis does not identify those medicinal products being accessible earlier in conformity with Spain's Royal Decree 1015/2009 relating to Medicines in Special Situations

# Combination therapies time to availability (2020-2023)

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

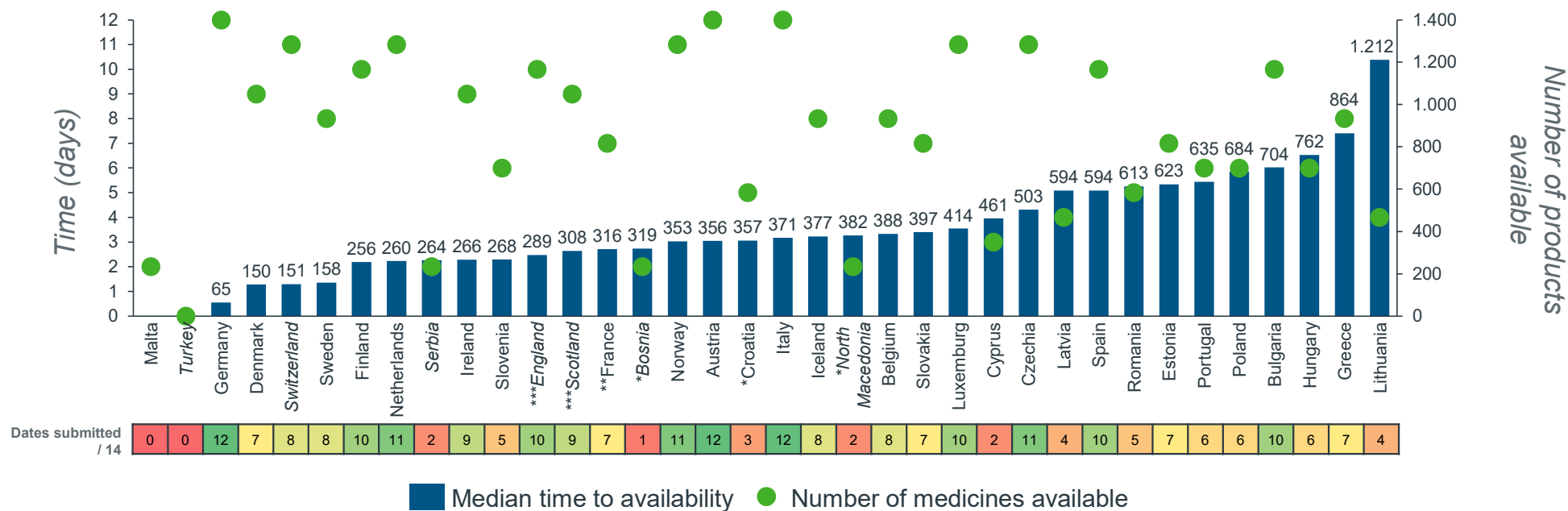


European Union average: 553 days (mean) (Note: Malta is not included in EU27 average as only 1 date was submitted in total) Combination products can include innovative branded / generic combinations; <sup>†</sup>Country specific definitions are listed in the appendix.

\*Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. \*\*For France, the time to availability (464 days, n=7 dates submitted) includes products under the Accès précoce system (n=2 dates submitted) for which the price negotiation process is usually longer. No combination therapy fell under the Accès précoce system. \*\*\*In the UK, MHRA's Early Access to Medicines Scheme provides access prior to marketing authorisation but is not included within this analysis, and would reduce the overall days for a small subset of medicines. In this analyses, MHRA dates have been used for 2021, 2022 and 2023 products and EMA dates used for 2020 products

## Combination median time to availability (2020-2023)

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



**European Union average: 471 days (median)** (Note: Malta is not included in EU27 average as only 1 date was submitted in total) <sup>†</sup>Country specific definitions are listed in the appendix. \*Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative \*\*For France, the time to availability (464 days, n=7 dates submitted) includes products under the Accès précoce system (n=2 dates submitted) for which the price negotiation process is usually longer. No combination therapy fell under the Accès précoce system. \*\*\*In the UK, MHRA's Early Access to Medicines Scheme provides access prior to marketing authorisation but is not included within this analysis, and would reduce the overall days for a small subset of medicines. In this analyses, MHRA dates have been used for 2021, 2022 and 2023 products and EMA dates used for 2020 products

# Key observations

## Executive summary (EU27 averages)

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



### Metrics key:

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

**Arrow colour** indicates significant changes versus the previous (2023) EU average (*significant improvement versus previous year* ↑ / *significant deterioration versus prior year* ↓)

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

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

## Key Insights

### Rate of availability

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

### Time to availability

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



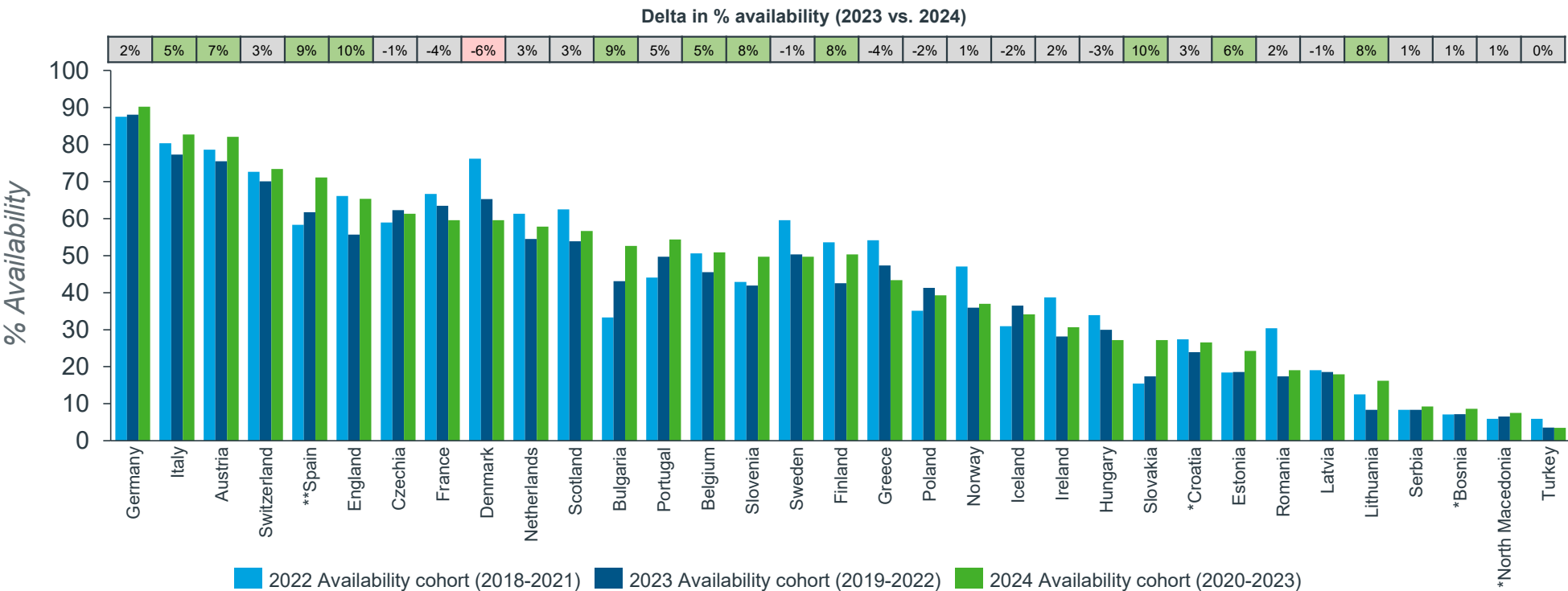
## 6. Historic comparisons and extension

### Indicators:

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

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

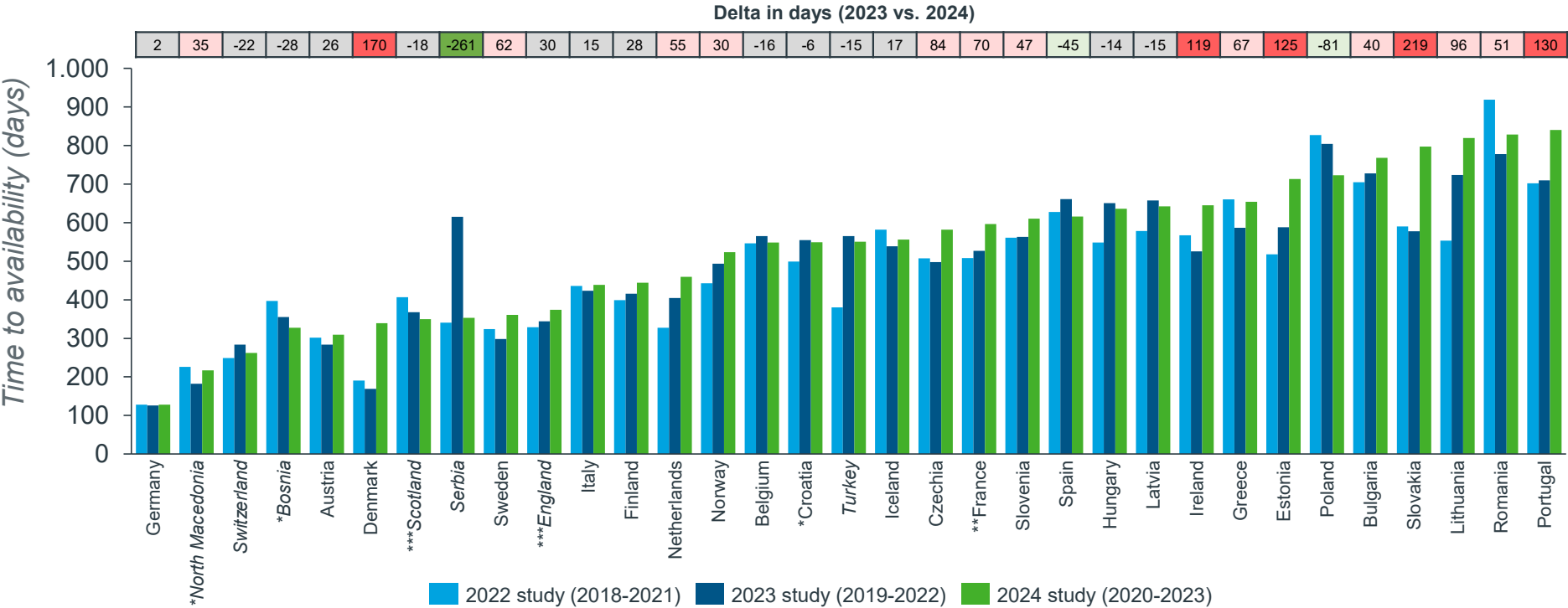
The **comparison of rate of availability**<sup>†</sup>, measured by the number of medicines available to patients in European countries as of 5<sup>th</sup> January 2025, compared to the rate of availability in previous (comparable) studies. Figures are based on the historic statistics published in the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



Increases of <=5% are not considered to be statistically significant and are therefore highlighted in grey. Note: Netherlands has retrospectively corrected 2020 data; <sup>†</sup>Country specific definitions are listed in the appendix. \*Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. \*\*In Spain, the WAIT analysis does not identify those medicinal products being accessible earlier in conformity with Spain's Royal Decree 1015/2009 relating to Medicines in Special Situations. Differences in availability rates between years may appear as 0% due to rounding. This rounding effect can result in minor discrepancies that do not reflect significant changes.

# Comparison of time to availability (2022 study – 2024 study)

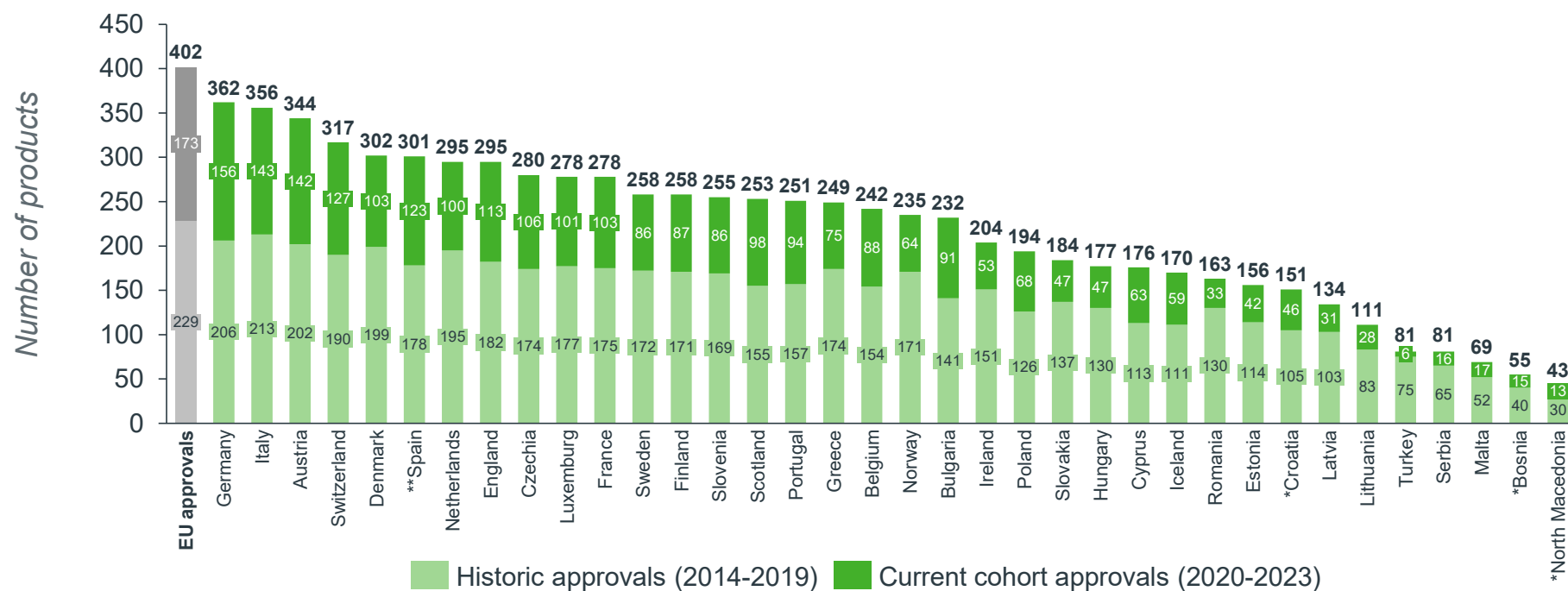
The **comparison of time to availability** is the days between marketing authorisation and the date of availability to patients compared to previous comparable studies. Figures are based on the historic statistics published in the indicators.



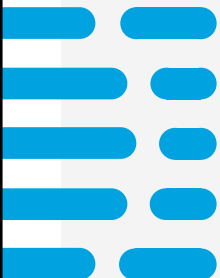
Changes of <=30 days are not considered to be statistically significant and are therefore highlighted in grey. The marketing authorisation date is the date of central EU authorisation in most countries, except for countries shown in italics where local authorisation dates have been used; \*Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. \*\*For France, status of Accès précoce products TBC. \*\*\*In the UK, MHRA's Early Access to Medicines Scheme provides access prior to marketing authorisation but is not included within this analysis, and would reduce the overall days for a small subset of medicines. In this analyses, MHRA dates have been used for 2021-2023 products and EMA dates used for 2020 products. Differences in availability rates between years may appear as 0% due to rounding. This rounding effect can result in minor discrepancies that do not reflect significant changes.

## Extended period of total availability (2014-2023)

The **extended period of total availability** is the number of medicines available to patients in European countries (for most countries this is the point at which the product gains access to the reimbursement list<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: 232 products available (58%) <sup>†</sup>Country specific definitions are listed in the appendix. \*Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. \*\*In Spain, the WAIT analysis does not identify those medicinal products being accessible earlier in conformity with Spain's Royal Decree 1015/2009 relating to Medicines in Special Situations  
Note: National Associations perform checks on historic products on a best-effort basis, although it has been noted that status changes do not often occur.



# Contents

## + Background

### + The Patients W.A.I.T. indicators

1. Overview (all products)
2. Oncology
3. Orphan medicines
4. Non-oncology orphan medicines
5. Combination therapies
6. Historic comparisons and extended period

## + 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 (64% complete), Croatia (72% complete), and North Macedonia (53% complete). This is noted on slides with an asterisk (\*).

**Average calculations:** The EU averages noted throughout are for the 27 countries in the European Union (Malta is not included in EU27 average for time to availability as only 1 date was submitted in total). EU averages of full / limited availability are calculated using absolute figures before determining the percentage. This approach ensures a more accurate representation by accounting for the varying number of available medicines in each EU country, thereby avoiding potential distortions that could arise from averaging individual country percentages

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

# Method and data availability

## Process for product selection



### EMA list

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

### Products in scope

- Products with authorisation year: 2014, 2015, 2016, 2017, 2018, 2019, 2020, 2021, 2022, 2023
- Status: Authorised
- Non-generic; Non-biosimilar; no vaccines
- Include combinations (both products can have already been approved before)
- Remove ATC K & T\*
- Exclude specific ATC V products\*\*

### Full data cohort (10-years)

- Removed products with an active substance approved pre-2014
- New combination products (those containing already approved active substances are included)
- New formulations were excluded
- New indications of already approved active substances, leading to a separate marketing authorisation only for an orphan drug are included
- For molecules with multiple names from the same company only one molecule is included

### Report cohort (4-years)

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

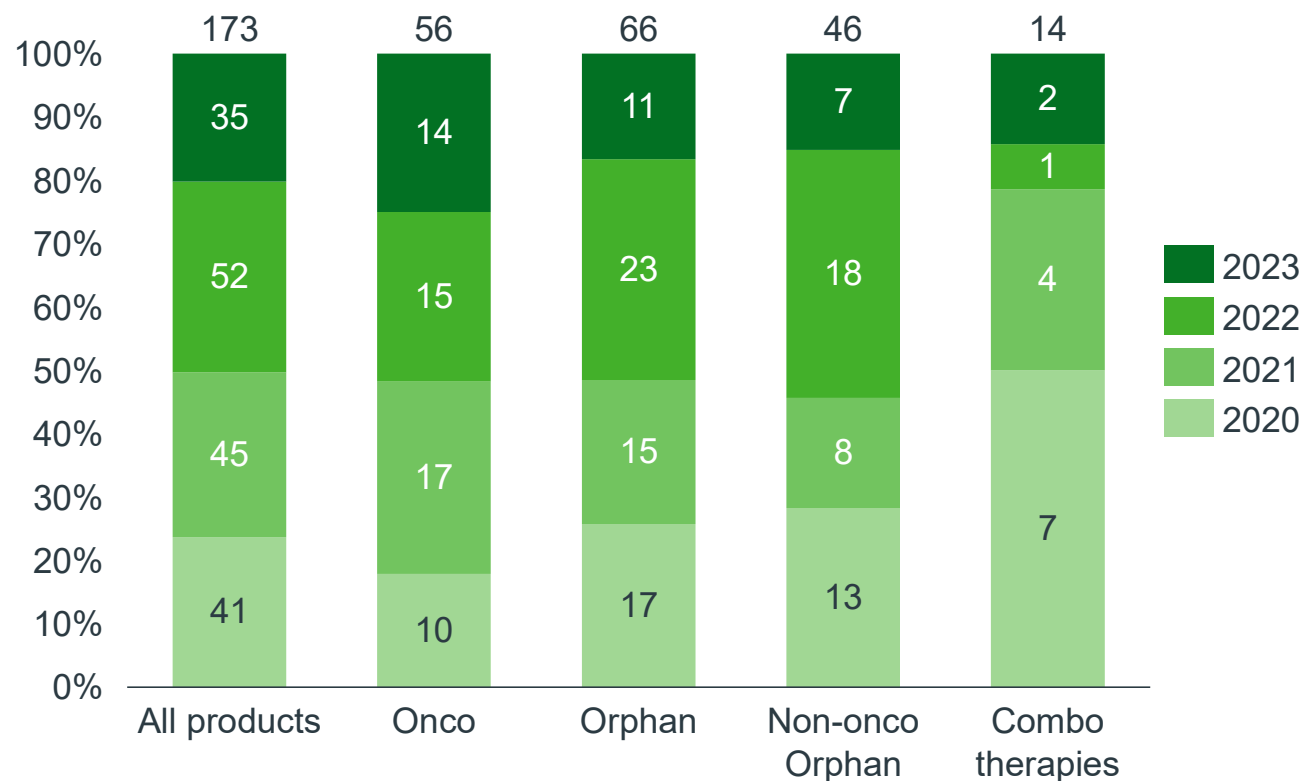
\* Removal ATC class exclusions: K = Hospital Solutions; V = Various, T = Diagnostics; Oncology definition used throughout = L1 & L2 & L3B1 & V3C & Proleukin

\*\* In previous years, all products within ATC-V class have been excluded from the WAIT indicator; However, the criteria has been adapted to exclude ATC-V products that are allergens, diagnostic agents, general nutrients, contrast media, diagnostic radiopharmaceuticals, surgical dressings, and all other non-therapeutic products; Other new innovative therapeutics that are classified within ATC-V should be considered for inclusion.

<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 2024)
- Orphan status from EMA on orphan medical products (OMP) status
- Oncology products flagged using IQVIA MIDAS Oncology market definition: L1 & L2 & L3B1 & V3C & Proleukin
- Combination products include any product with more than one molecule, including branded / generic combinations in fixed doses.

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

## Products included in the study: 2020-2023 approvals (n=173)

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

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

# Products included in the study: 2020-2023 approvals (n=173)

## Oncologics (n=56)

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

## Orphans (n=66)

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

## Non-oncologic orphans (n=46)

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

## Combination therapies (n=14)

|                       |                   |
|-----------------------|-------------------|
| Akeega                | Opdualag          |
| Aectura Breezhaler    | Phesgo            |
| Drovelis/Lydisilka*   | Recarbrio         |
| Enerzair Breezhaler / |                   |
| Zimbus Breezhaler     | Roclanda          |
| Inaqovi               | Ryeqo             |
| Kaftrio               | Sibnaya           |
| Nustendi              | Trixeo Aerosphere |

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

# Country specific definitions of products with availability

| Country         | Definition of availability                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Austria         | A medicine is available if it is included in the reimbursement system (EKO) or available through the Austrian pharmacies list                                                                                                                                                                                                                                                                                                                                                                                               |
| Belgium         | Medicine is available if it is listed on the official website of INAMI-RIZIV as a definitive reimbursement or as a temporary reimbursement (code T) under a Managed Entry Agreement                                                                                                                                                                                                                                                                                                                                         |
| Bosnia          | Accessibility on the public reimbursement list                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| Bulgaria        | Accessibility on the public reimbursement list                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| Croatia         | Accessibility on the public reimbursement list                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| Cyprus          | Accessibility on the public reimbursement list                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| Czechia         | <b>*REFINED*</b> 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/partial recommendation from the Danish Medicines Council.                                                                                                                                                                                                                                                                                              |
| England         | <b>*REFINED*</b> 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, COHERE or FINCCHTA. For the remaining medicines hospital formulary decisions and sales data is analysed to determine if product is routinely available through hospital budget.                                                                                                                                                                                                                                                |
| France          | Accessibility on the public reimbursement list                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| Germany         | Following marketing authorisation, prescription drugs automatically receive reimbursed status                                                                                                                                                                                                                                                                                                                                                                                                                               |
| Greece          | Accessibility on the public reimbursement list                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| Hungary         | Medicines are either reimbursed through the indication linked reimbursement system, or available by special finance system (item based) or financed by hospital budget                                                                                                                                                                                                                                                                                                                                                      |
| Iceland         | Accessibility on the public reimbursement list                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| Ireland         | Accessibility on the public reimbursement list, through a hospital setting or other public scheme                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Italy           | A product is available if it has received reimbursement status                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| Latvia          | Accessibility on the public reimbursement list                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| Lithuania       | Accessibility on the public reimbursement list                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| Luxembourg      | Accessibility on the public reimbursement list (retail drugs); or product D and H commercialized medicines (hospital drugs)                                                                                                                                                                                                                                                                                                                                                                                                 |
| Malta           | Accessibility on the public reimbursement list                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| Netherlands     | Accessibility on the public reimbursement list                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| North Macedonia | Product is available via specially allocated budget for all eligible patients                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| Norway          | <b>*REFINED*</b> The medicines has received a positive reimbursement decision by NoMA (out-patient drugs), or the Decision Forum (hospital products)                                                                                                                                                                                                                                                                                                                                                                        |
| Poland          | In most cases a medicine is available if it gains access to the reimbursement list; some medicines are financed via state budget and the date of accessibility would be the date of tender results published by governmental payers.                                                                                                                                                                                                                                                                                        |
| Portugal        | Accessibility on the public reimbursement list                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| Romania         | For 98% of reimbursed medicines, accessibility is considered to be at therapeutic protocol publication (as the HCP cannot prescribe the product until the therapeutic protocols are published). For the remaining 2% of reimbursed medicines that don't need therapeutic protocols, accessibility is after publication in the reimbursement list.                                                                                                                                                                           |
| Scotland        | Medicines are deemed available if SMC has issued a positive HTA recommendation. For the remaining medicines, IQVIA sales data are analysed to determine if routinely available.                                                                                                                                                                                                                                                                                                                                             |
| Serbia          | Accessibility on the public reimbursement list                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| Slovakia        | <b>*REFINED*</b> Availability according: 1) Reimbursement list valid from January 1st 2025 or 2) DRG list for drugs used during hospitalization for hospital only products.                                                                                                                                                                                                                                                                                                                                                 |
| Slovenia        | A medicine is available if it is reimbursed through the regular system, or automatically reimbursed                                                                                                                                                                                                                                                                                                                                                                                                                         |
| Spain           | Accessibility on the public reimbursement list                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| Sweden          | <b>*REFINED*</b> A medicine is classified as available (nationally reimbursed) if it was marketed in Sweden as of December 20th 2024 (listed as supplied in FASS), and: Is indicated for a disease included in the communicable disease program, or Had received a positive TLV decision (prescribed drugs), or - Had received a positive recommendation from the New Therapies (NT) Council (hospital drugs), or - Had not received an NT-recommendation and is not part of national managed introduction (hospital drugs) |
| Switzerland     | <b>*REFINED*</b> The medicine gained market approval by Swissmedic. Delay calculated using local market authorisation and dates from admission into the specialty list.                                                                                                                                                                                                                                                                                                                                                     |
| Turkey          | <b>*REFINED*</b> A medicine is available if it gains access to the reimbursement list (SSI HIC Annex 4/A).                                                                                                                                                                                                                                                                                                                                                                                                                  |

# Country specific definitions of products with limited availability

| Country         | Definition of limited availability                                                                                                                                                                                                                                                                                                                                                            |
|-----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Austria         | Products outside reimbursement system (EKO), but reimbursed on individual pre-approval (No Box)                                                                                                                                                                                                                                                                                               |
| Belgium         | <b>*REFINED*</b> 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         | <b>*REFINED*</b> 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 products with individual access as well as products that have received conditional reimbursement or single reimbursement by the Danish Medicines Agency.                                                                                    |
| England         | Recommended for a restricted patient cohort relative to licenced 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> Product is recommended for a restricted use relative to licenced indication(s), either a) HILA has granted reimbursement as restricted; b) COHERE's or FINCCHTA's recommendation is restricted for certain subpopulations / indications / named patient use; or if hospital procurement decision includes limitation or is regional.                                         |
| France          | Some innovative products without competitors can be made available prior to market authorisation under the Early Access program.                                                                                                                                                                                                                                                              |
| Germany         | There are no restrictions on availability meaning drugs are reimbursable in all patient populations.                                                                                                                                                                                                                                                                                          |
| Greece          | Only reimbursed for restricted patient cohorts, or case by case reimbursement if the responsible committee judges its use necessary.                                                                                                                                                                                                                                                          |
| Hungary         | Medicine is available through a Name Patient Program (access depends on application for individual use)                                                                                                                                                                                                                                                                                       |
| Iceland         | Products are available to the patients with full reimbursement, but only through individual reimbursement, which can be applied for on individual basis by the patient's doctor.                                                                                                                                                                                                              |
| Ireland         | Subject to Managed Access Protocol                                                                                                                                                                                                                                                                                                                                                            |
| Italy           | A product has limited availability if it has not received the reimbursement status (decision is pending) but it is dispensed, generally, via hospital for a specific subpopulation, subject to medical advice. It is not at patient's expense                                                                                                                                                 |
| Latvia          | Limited reimbursement to specific subpopulations of the approved indications; individual reimbursement (limited reimbursement on the named patient basis)                                                                                                                                                                                                                                     |
| Lithuania       | Only reimbursed for limited indications (compared to what was approved at market authorisation)                                                                                                                                                                                                                                                                                               |
| Luxembourg      | <b>*REFINED*</b> A medicine is indicated for a specific population of patients who meet clearly defined criteria, such as contraindications to standard treatments, medical precautions, or personal preferences. Access to the medicine requires documented evidence in the patient's medical record confirming their eligibility at the time of the request for reimbursement or treatment. |
| Malta           | Limited availability means on a named patient basis or similar or at times approved on a named patient basis for subpopulations.                                                                                                                                                                                                                                                              |
| Netherlands     | Only reimbursed under certain therapeutic conditions (annex 2 on the positive reimbursement list).                                                                                                                                                                                                                                                                                            |
| North Macedonia | Product is available via specially allocated budget for limited number of patients                                                                                                                                                                                                                                                                                                            |
| Norway          | The Association has only information on limited availability for specific subpopulation of the approved indication. We have no access to public information on limited availability to individual patients (named patient basis), or a group of patients while decision is pending                                                                                                            |
| Poland          | Only reimbursed for limited indications (compared to what was approved at market authorisation)                                                                                                                                                                                                                                                                                               |
| Portugal        | Product is only available on a patient by patient basis and after an Exceptional Authorisation has been granted, usually while public financing decision is pending (i.e., during the assessment process)                                                                                                                                                                                     |
| Romania         | Reimbursement is only granted for specific subpopulations of the approved indications, for individual patients on a named patient basis or there is limited reimbursement while a decision is pending. Limited availability refers also to MEA.                                                                                                                                               |
| Scotland        | Recommended for a restricted patient cohort relative to licenced indication by SMC using their HTA process (through submission or resubmission)                                                                                                                                                                                                                                               |
| Serbia          | Products are reimbursed with significant restrictions on the number of patients (e.g. for new generation HepC medicines, there is a cap on only 60 patients per year) or number of indications                                                                                                                                                                                                |
| Slovakia        | <b>*REFINED*</b> Drugs included in the reimbursement list have some limitations (prescription limitation defining specialist that can prescribe the drug) or indication limitation (specification of the reimbursed subpopulation).                                                                                                                                                           |
| Slovenia        | Only reimbursed for restricted patient cohort                                                                                                                                                                                                                                                                                                                                                 |
| Spain           | Only reimbursed for restricted patient cohort                                                                                                                                                                                                                                                                                                                                                 |
| Sweden          | Only reimbursed for restricted patient cohort                                                                                                                                                                                                                                                                                                                                                 |
| Switzerland     | For products pending reimbursement, patients have restricted reimbursement access. Such restricted access includes 'individual reimbursement' regulated by Art. 71a-b of KVV ordinance..                                                                                                                                                                                                      |
| Turkey          | <b>*REFINED*</b> Products only available through a "Named Patient Scheme". These medicines do not require TITCK (Turkish Medical Agency) approval but are reimbursed (SSI HIC Annex 4/C).                                                                                                                                                                                                     |

# Country specific definitions of the availability date

| Country         | Definition of the availability date                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-----------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Austria         | The first date of availability on the public reimbursement list or Austrian Pharmacies list                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Belgium         | <b>*REFINED*</b> The first date of availability on the public reimbursement list available on the website of the payer INAMI-RIZIV: <a href="https://webappsa.riziv-inami.fgov.be/ssp/ProductSearch">https://webappsa.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         | <b>*REFINED*</b> The first date of availability on the public reimbursement list. If not reimbursed, date of first availability on the market.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Denmark         | <b>*REFINED*</b> 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         | <b>*REFINED*</b> 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> Date of availability is the first day of reimbursement after HILAs positive decision, or when national contract becomes valid after COHERE's or FINCCHTA's recommendation, or for the remaining medicines, when regular sales is recorded.                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| France          | The first date of availability on the public reimbursement list                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Germany         | Date of market entry listed in the LauerTaxe                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| Greece          | The first date of availability on the public reimbursement list                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Hungary         | The date when the therapy is available for the first patient. This is the earliest date that the therapy is available on the public reimbursement list or the date the first patient received the therapy in Named Patient Program.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Iceland         | The first date of availability on the public reimbursement list                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Ireland         | The first date of availability on the public reimbursement list                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Italy           | The first date of availability on the public reimbursement list                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Latvia          | The first date of availability on the public reimbursement list                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Lithuania       | The date of the decision to include the medicine into the public reimbursement list                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Luxembourg      | The first date of availability on the public reimbursement list                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Malta           | The first date of availability on the public reimbursement list                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Netherlands     | The first date of availability on the public reimbursement list                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| North Macedonia | The Positive Drug List has not been revised for more than 10 years. Therefore, availability dates are provided on a case by case basis.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| Norway          | <b>*REFINED*</b> The first date of availability on the public reimbursement list; or for hospital products, the date of the positive decision in Decision Forum                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Poland          | The first date of availability on the public reimbursement list, except for HIV / haemophilia drugs (financed by state budget) where availability date is date of publication of tender results or date of first order received from companies.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Portugal        | The first date of availability on the public reimbursement list                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Romania         | Date of publication of government decision (for medicines that don't need therapeutic protocols elaboration or update) or therapeutic protocols (for the majority of medicines) in the Official Journal.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| Scotland        | For medicines with a positive SMC recommendation, the accessibility date is the date of published guidance. For remaining medicines, IQVIA sales data is analysed to determine month of routine availability.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Serbia          | The first date of availability on the public reimbursement list                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Slovakia        | <b>*REFINED*</b> The first date of availability on the reimbursement list (published on monthly basis) or in DRG list for hospital only drugs (published annually starting January 1 <sup>st</sup> and valid for the rest of the respective year).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Slovenia        | The first date of availability on the public reimbursement list                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Spain           | The first date of availability on the public reimbursement list                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Sweden          | <b>*REFINED*</b> 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     | <b>*REFINED*</b> 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"                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |

# Contact details

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## Country-specific insights:

Local pharma industry associations

