EFPIA Patients W.A.I.T. Indicator 2023 Survey

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This year's Patients W.A.I.T. indicator covers 36 countries and includes the full EU27 countries

Indicators measure availability, limited availability and time to local authorisation dates

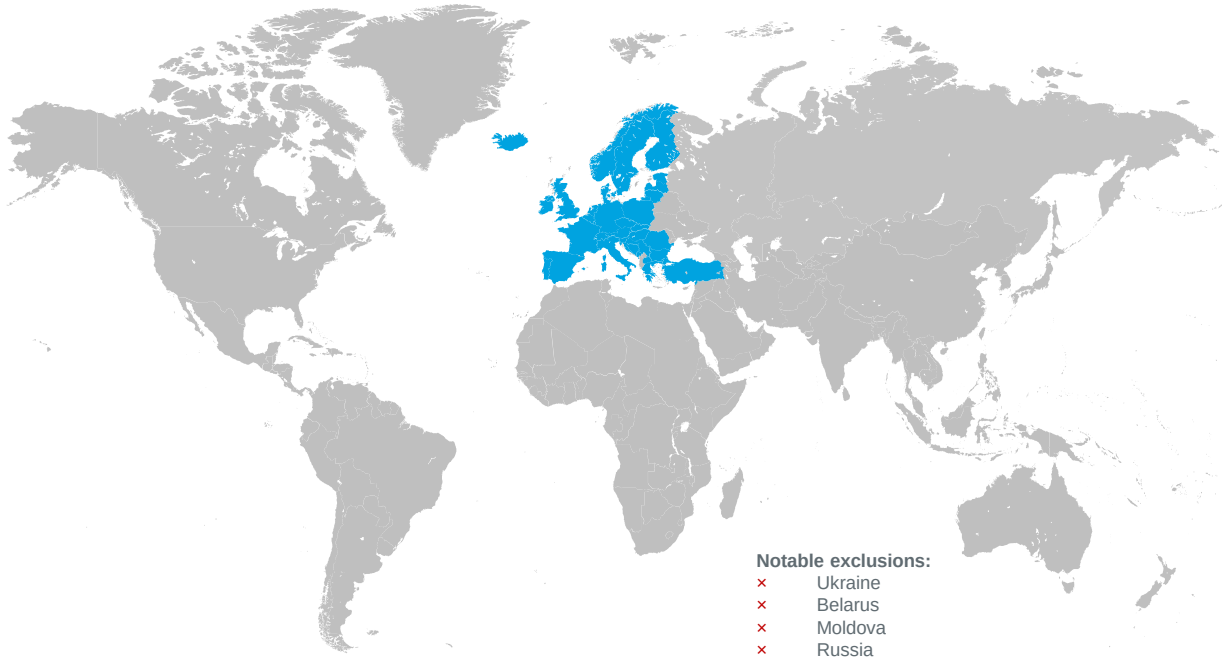
Foreword from the IQVIA project team:

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 is the largest European study into innovative medicines availability and the time to patient access.

It shows a set of Key Performance Indicators (KPIs) on the European access environment for innovative medicines across 5 cohorts of medicines (all medicines, oncology, orphan medicines, non-oncology orphan medicines, and combination therapies) to show how different segments of the market are prioritised and how the market access landscape varies.

The charts in the following report includes data on 36 countries (27 EU, and 9 non-EU), giving a full European picture of availability. Information on the 167 innovative medicines with central-marketing authorisation between 2019 and 2022 are included, with the study running on a one year delay to permit countries to include these medicines on their public reimbursement list, meaning that the data on availability is accurate as of *January 5th 2024.* This period is therefore inclusive of the COVID-19 pandemic. Although no significant impact is noted in the indicator, the continued impact on launch has been shown through other studies.

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



36 European countries

167 innovative medicines

4 year cohort ('19-'22)

2023 WAIT indicator: 7 KPIs for 5 cohorts of medicines

~43%

EU average rate of availability in 2023 vs 45% in the previous study

531

Average time for a new medicine to be available in European market is 14 days longer than the previous study

Access gap between the highest and lowest country is **84%** in the 4-year cohort, and **80%** for longer timelines

Data coverage

Full data coverage for 31 out of the 36 countries included

Study composition

Includes a fewer combination products than the previous study

Limited availability

40% of available medicines are granted limited availability

Access disparities

persist between Northern/Western and Southern/Eastern European countries

Oncology medicines

take the longest time to reimburse across all studied segments

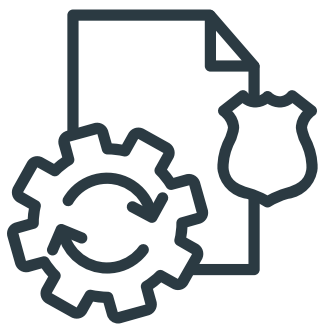
Source: EFPIA Patients WAIT indicator (2022 and 2023)

Contents

Click on hyperlinks for navigation to specific indicators

Patients W.A.I.T. survey has evolved, and is entering its 20th year

The indicator long-running, and one of the largest datasets on medicines availability in Europe



Patients W.A.I.T. stands for:

Waiting to
Access
Innovative
Therapies

EFPIA had requested that IMS Health prepare a database that can be used to analyse delays in market access for medicines in Europe. This database is issued on a 6-monthly basis, providing a benchmark analysis of time needed for pricing / reimbursement processes after MA.

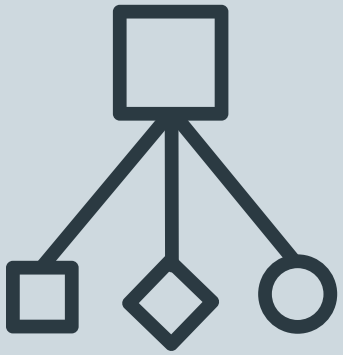
2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024

EFPIA/ CRA report on root causes

Sources include: https://www.efpia.eu/media/412416/market-access-delays-2017-final-140318.pdf; https://studylib.net/doc/7634123/patients--w.a.i.t.-indicator---report-201; https://www.efpia.eu/publications/downloads/efpia/efpia-patients-wait-indicator-2019-survey/; https://www.efpia.eu/media/602652/efpia-patient-wait-indicator-final-250521.pdf; https://www.efpia.eu/media/s4qf1eqo/efpia_patient_wait_indicator_final_report.pdf

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

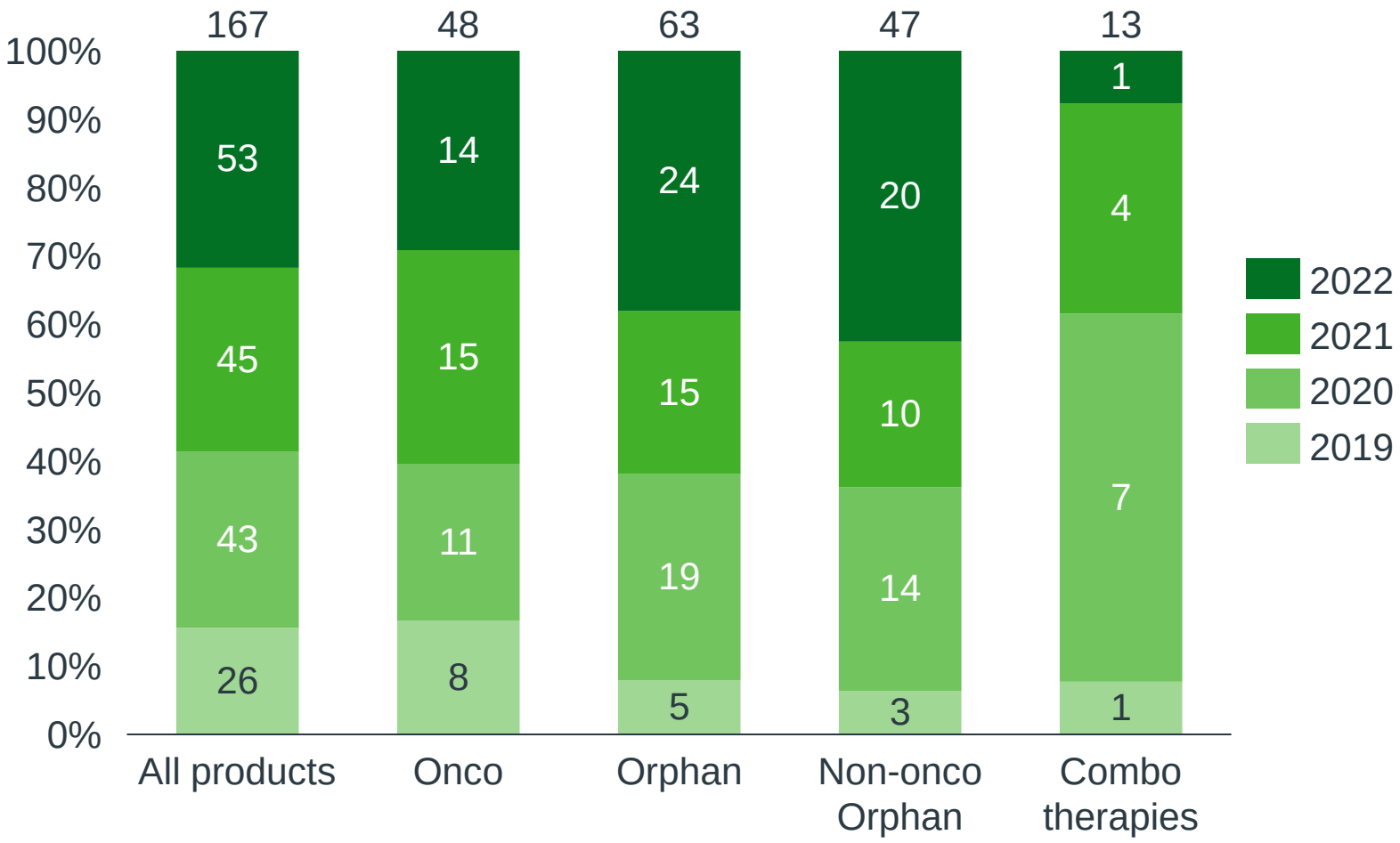
“Inclusion of a centrally-approved medicine on the public reimbursement list in a country”

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.

Study composition

By year of marketing authorisation



Definitions:

- Products with central marketing authorisation, sourced from EMA EPARs (last accessed November 2023)
- Orphan status from EMA on orphan medical products (OMP) status
- Oncology products flagged using IQVIA MIDAS Oncology market definition: L1 & L2 & V3C & Revlimid & Xgeva & Proleukin & Pomalyst
- 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

Study summary

Full methodology and definitions by country are available in the appendix of the report

Core metrics

The Patients W.A.I.T. Indicator shows 2 main metrics for new medicines (i.e. medicines including a substance not previously available in Europe) within a 4 year rolling cohort:

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

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

Availability definition

Description	Status
Full reimbursement through a national reimbursement system	Available
Full automatic reimbursement by a hospital budget (e.g. Nordic system)	
Limited reimbursement to specific subpopulations of approved indication	Available (marked LA^)
Limited reimbursement on a national named patient basis (individual patient)	
Limited reimbursement while decision is pending (where system permits)	
Availability through a special program (e.g. managed entry agreements)	
Available only within the private market at the patients 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 marketing 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 with substantially limited data sets are: Bosnia (53% complete), Croatia (63% complete), Cyprus (77% complete), and North Macedonia (66% complete). This is noted on slides with an asterisk (*). One country (Italy) submitted 98% dataset, which is not considered substantially limited.

Average calculations: The EU averages noted throughout are averages for the 27 countries in the European Union. This is the third year that Cyprus, Malta, and Luxembourg have participated in the study.

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

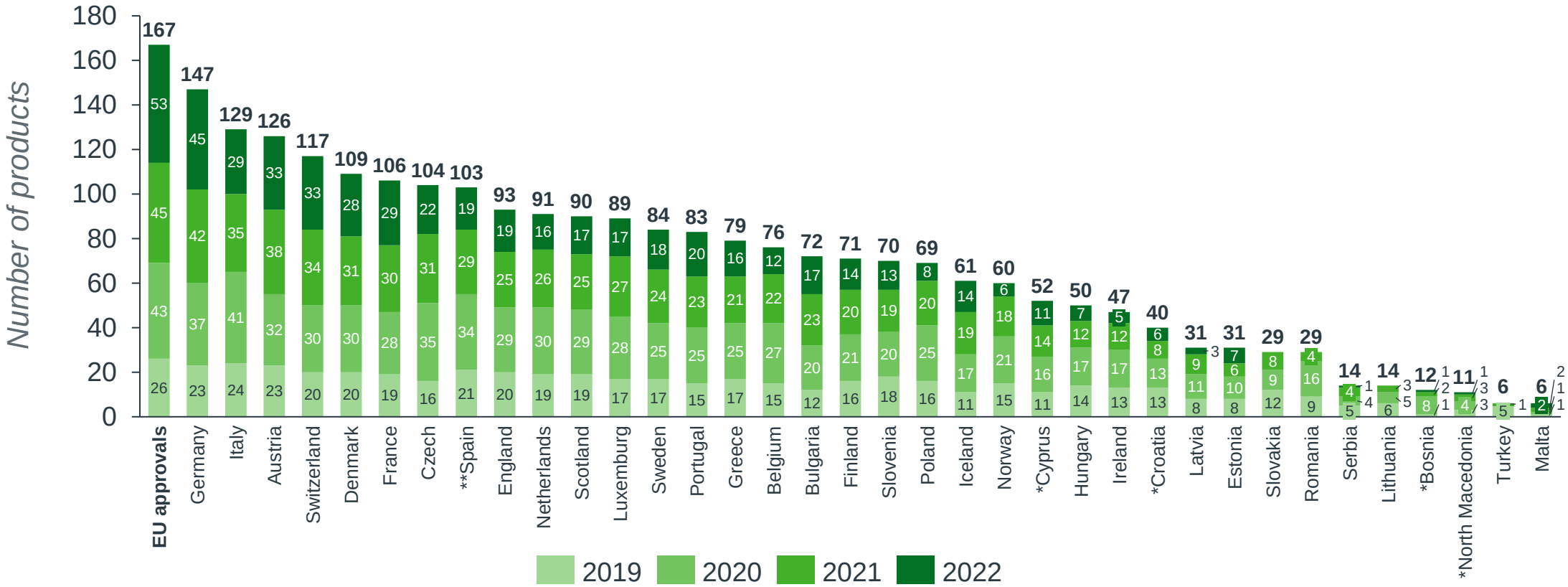
1. Overview (all products)

Indicators:

1.1. Total availability by approval year
1.2. Rate of availability
1.3. Rate of full availability
1.4. Breakdown of availability
1.5. Time from central approval to availability
1.6. Time to availability
1.7. Median time to availability

Total availability by approval year (2019-2022)

The **total availability by approval year** is the number of medicines available to patients in European countries as of 5th January 2024 (for most countries this is the point at which the product gains access to the reimbursement list†), split by the year the product received marketing authorisation in Europe.



European Union average: 72 products available (43%) †In most countries availability equates to granting of access to the reimbursement list, except in DK, FI, LU, NO, SE where some hospital products are not covered by the general reimbursement scheme. Country-specific nuances 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 (2019-2022)

The **rate of availability**, measured by the number of medicines available to patients in European countries as of 5th January 2024. For most countries this is the point at which the product gains access to the reimbursement list†, including products with limited availability.

European Union average: 72 products available (43%) †In most countries availability equates to granting of access to the reimbursement list, except in DK, FI, LU, NO, SE where some hospital products are not covered by the general reimbursement scheme. *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 full availability (%, 2019-2022)

The **rate of full availability** shows the proportion of medicines available to patients in European countries as of 5th January 2024 (for most countries this is the point at which the product gains access to the reimbursement list†) without any restrictions to the patient population, or through named patient basis schemes which have increased significantly in recent years and were not always captured in survey submissions.

European Union average: 72 products available (43%), Limited Availability (40% of available products) Netherlands did not submit complete information on restrictions to available medicines meaning LA* is not captured in these countries. †In most countries' availability equates to granting of access to the reimbursement list, except in DK, FI, LU, NO, SE where some hospital products are not covered by the general reimbursement scheme. *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

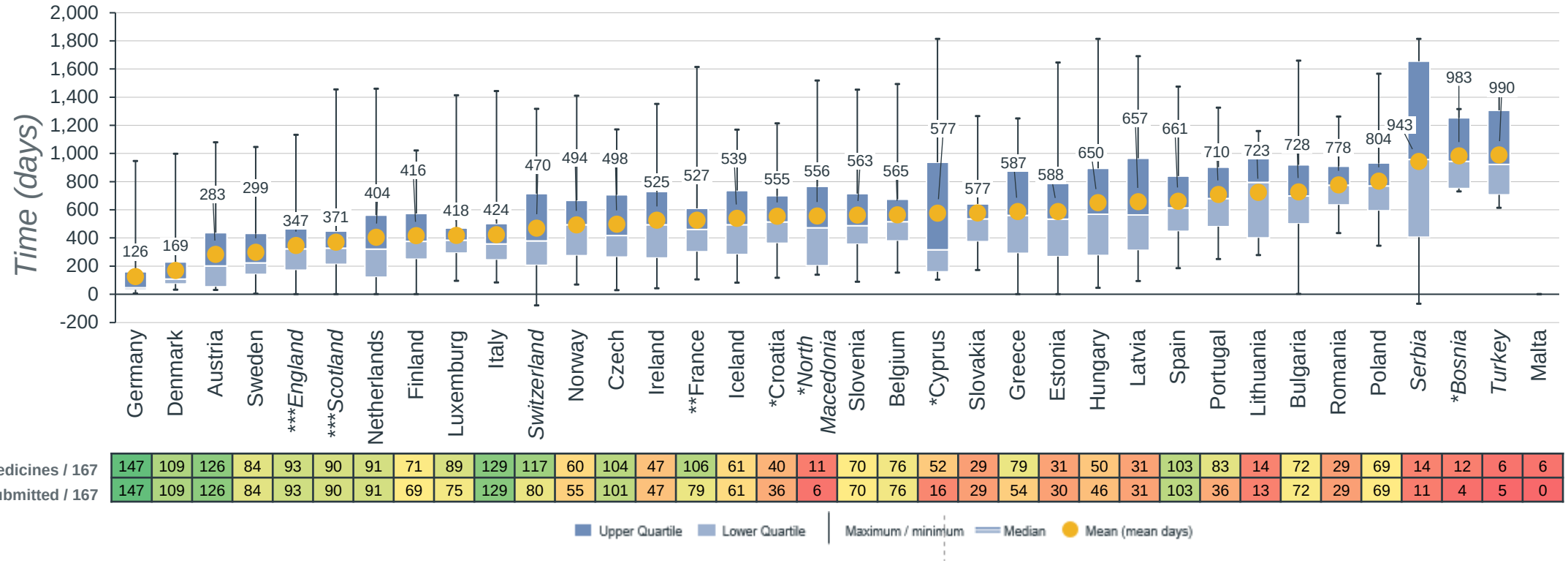
Breakdown of availability (%, 2019-2022)

The **breakdown of availability** is the composition of medicines available to patients in European countries as of 5th January 2024 (for most countries this is the point at which the product gains access to the reimbursement list†). This includes all medicine's status to provide a complete picture of the availability of the cohort studied.

European Union average: 72 products available (43%), Limited Availability (16% of all products) Netherlands did not submit complete information on restrictions to available medicines meaning LA* is not captured in these countries. †In most countries availability equates to granting of access to the reimbursement list, except in DK, FI, LU, NO, SE where some hospital products are not covered by the general reimbursement scheme. *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 (2019-2022)

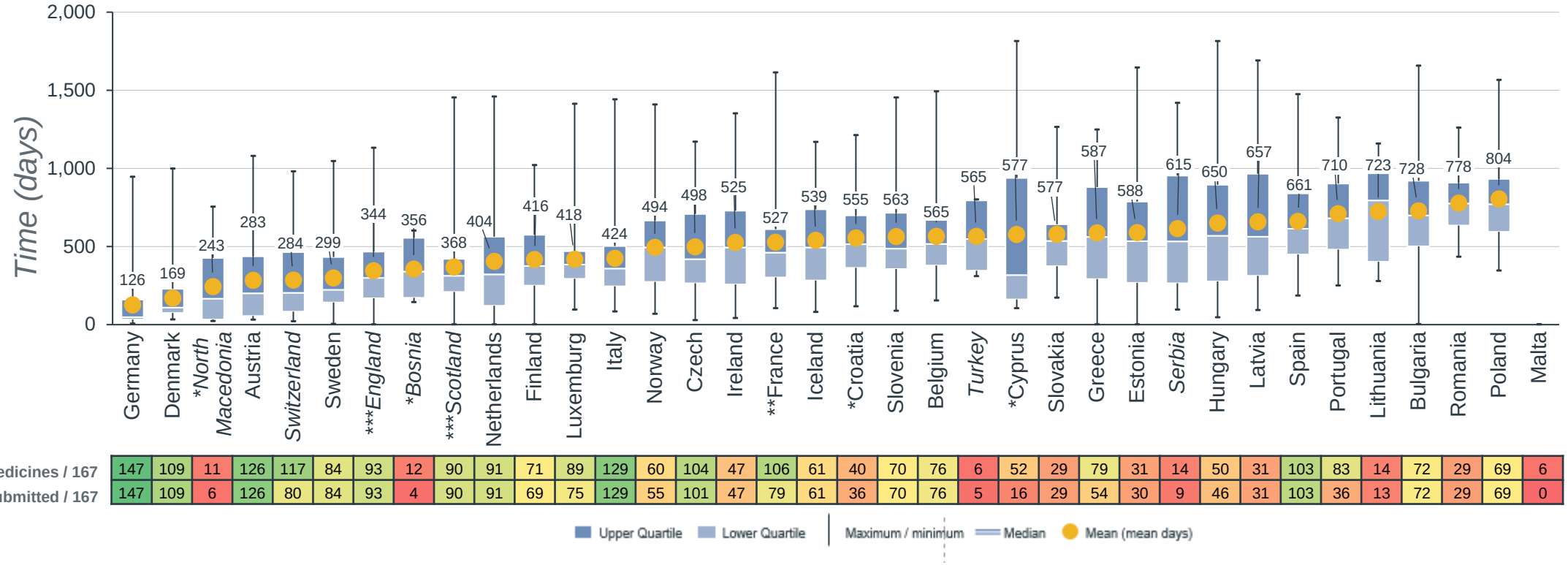
The **time from central approval to availability** is the days between marketing authorisation and the date of availability to patients in European countries (for most this is the point at which products gain access to the reimbursement list†). The marketing authorisation date is the date of central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



European Union average: 531 days (mean %) (Note: Malta is not included in EU27 average as no dates were submitted in total) †In most countries availability equates to granting of access to the reimbursement list, except in DK, FI, NO, SE where some hospital products are not covered by the general reimbursement scheme. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative **For France, the time to availability (527 days, n=79 dates submitted) includes products under the Accès précoce system (n=18 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 424 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 (2019-2022)

The **time to availability** is the days between marketing authorisation and the date of availability to patients in European countries (for most this is the point at which products gain access to the reimbursement list†). The marketing authorisation date is the date of central EU authorisation in most countries, except for countries shown in italics where local authorisation dates have been used. Data is correct to 5th January 2024.

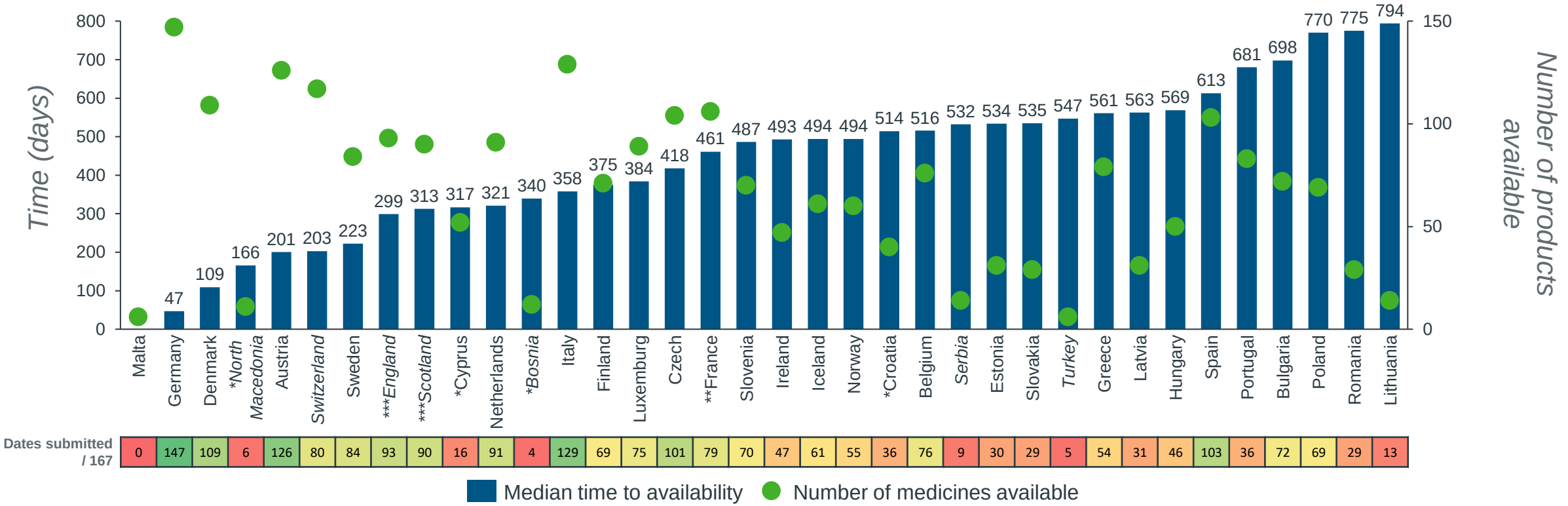


	Germany	Denmark	*North Macedonia	Austria	Switzerland	Sweden	***England	*Bosnia	***Scotland	Netherlands	Finland	Luxemburg	Italy	Norway	Czech	Ireland	**France	Iceland	*Croatia	Slovenia	Belgium	Turkey	*Cyprus	Slovakia	Greece	Estonia	Serbia	Hungary	Latvia	Spain	Portugal	Lithuania	Bulgaria	Romania	Poland	Malta
Available medicines / 167	147	109	11	126	117	84	93	12	90	91	71	89	129	60	104	47	106	61	40	70	76	6	52	29	79	31	14	50	31	103	83	14	72	29	69	6
Dates submitted / 167	147	109	6	126	80	84	93	4	90	91	69	75	129	55	101	47	79	61	36	70	76	5	16	29	54	30	9	46	31	103	36	13	72	29	69	0

European Union average: 531 days (mean %) (Note: Malta is not included in EU27 average as no dates were submitted in total) †In most countries availability equates to granting of access to the reimbursement list, except in DK, FI, NO, SE where some hospital products are not covered by the general reimbursement scheme. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative **For France, the time to availability (527 days, n=79 dates submitted) includes products under the Accès précoce system (n=18 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 424 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 products and EMA dates used for 2019-2020 products

Median time to availability (2019-2022)

The **median time to availability** is the days between marketing authorisation and the date of availability to patients in European countries (for most this is the point at which products gain access to the reimbursement list†). The marketing authorisation date is the date of central EU authorisation in most countries, except for countries shown in italics where local authorisation dates have been used. Data is correct to 5th January 2024.



European Union average: 474 days (median) (Note: Malta is not included in EU27 average as no dates were submitted in total) †In most countries availability equates to granting of access to the reimbursement list, except in DK, FI, NO, SE where some hospital products are not covered by the general reimbursement scheme. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative **For France, the median time to availability (461 days, n=79 dates submitted) includes products under the Accès précoce system (n=18 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 383 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 products and EMA dates used for 2019-2020 products

Key observations

Executive summary (EU27 averages)

Measure	All products	Oncology	Orphan	Non-oncologic orphan	Combination therapy
Average rate of availability	43% (45% in 2022)	52% (50% in 2022)	35% (39% in 2022)	32% ↓ (39% in 2022)	54% (50% in 2022)
Average time to availability	531 Days (517 days in 2022)	559 ↑ Days (526 days in 2022)	542 ↓ Days (625 days in 2022)	530 ↓ Days (626 days in 2022)	433 Days (426 days in 2022)

Key Insights

Rate of availability

- Patient access to innovative products in Europe is highly variable, with >80% variance between Northern/Western countries and Southern/Eastern European countries
- Europe's average rate of availability has marginally deteriorated versus last year

Time to availability

- The average delay from marketing authorisation to patient access can vary by a factor greater than 7x in Europe, from as little as 4 months to 31 months (~2.5 years)
- Even within a country there is a large variation in the speed of patient access to different products. Often the level of variation within a country is greater than between countries
- 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 (2023) EU average (*significantly worse than current EU average* / *significantly better than current EU average*)

Arrow colour indicates significant changes versus the previous (2021) 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 no dates were submitted in total

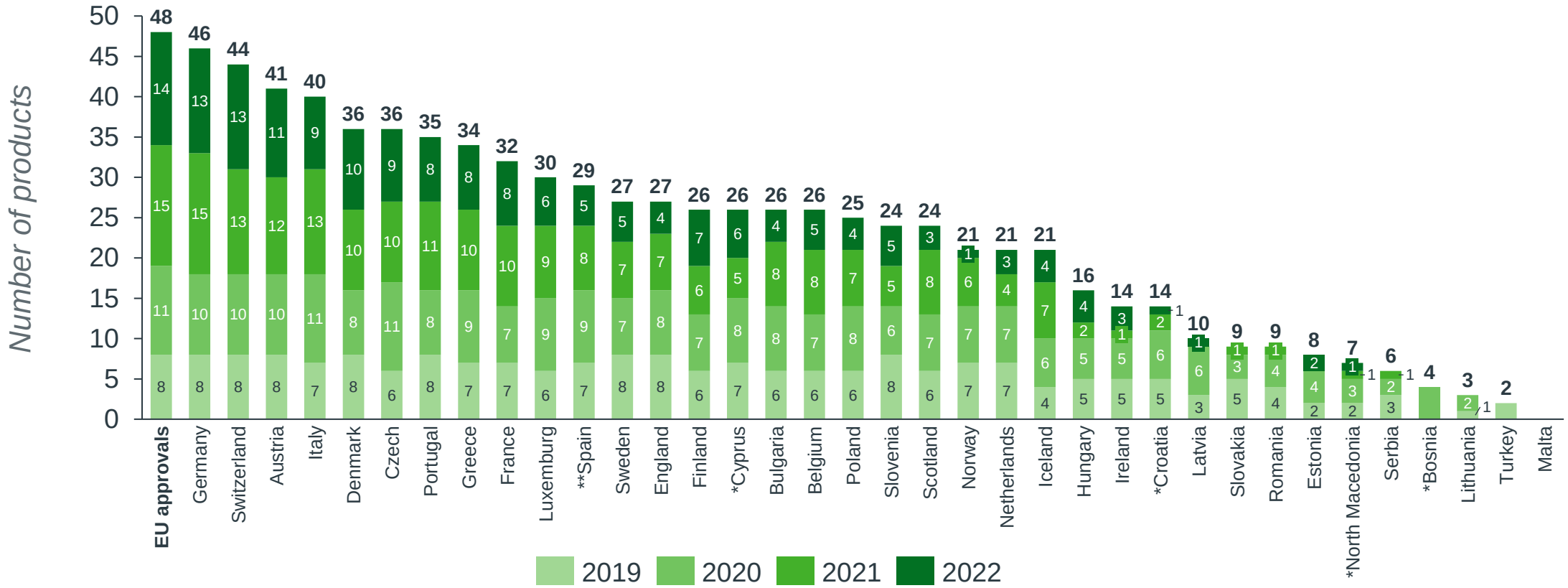
2. Oncology medicines

Indicators:

2.1. Total availability by approval year
2.2. Rate of availability
2.3. Rate of full availability
2.4. Breakdown of availability
2.5. Time to availability
2.6. Median time to availability

Oncology availability by approval year (2019-2022)

The **total availability by approval year** is the number of medicines available to patients in European countries as of 5th January 2024 (for most countries this is the point at which the product gains access to the reimbursement list†), split by the year the product received marketing authorisation in Europe.



European Union average: 25 products available (52%) †In most countries availability equates to granting of access to the reimbursement list, except in DK, FI, LU, NO, SE where some hospital products are not covered by the general reimbursement scheme. *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

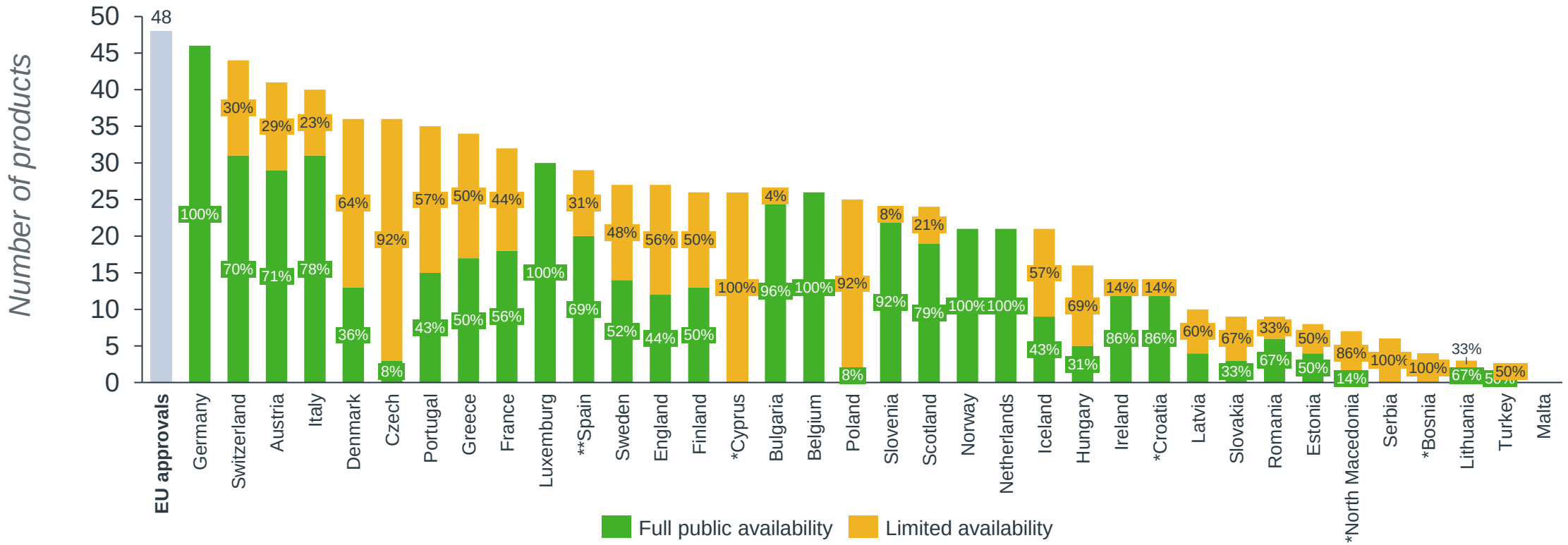
Oncology rate of availability (2019-2022)

The **rate of availability**, measured by the number of medicines available to patients in European countries as of 5th January 2024. For most countries this is the point at which the product gains access to the reimbursement list†, including products with limited availability.

European Union average: 25 products available (52%) †In most countries availability equates to granting of access to the reimbursement list, except in DK, FI, LU, NO, SE where some hospital products are not covered by the general reimbursement scheme. *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 full availability (%, 2019-2022)

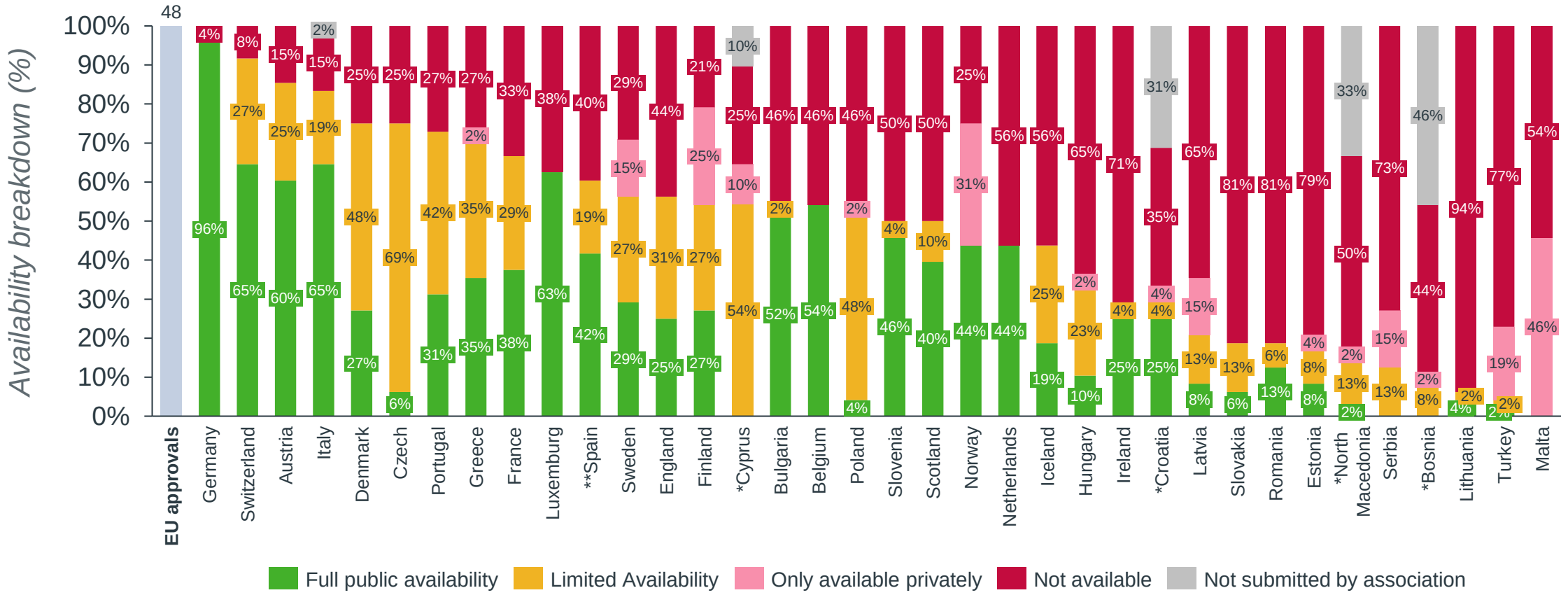
The **rate of full availability** shows the proportion of medicines available to patients in European countries as of 5th January 2024 (for most countries this is the point at which the product gains access to the reimbursement list†) without any restrictions to the patient population, or through named patient basis schemes which have increased significantly in recent years and were not always captured in survey submissions.



European Union average: 25 products available (52%), Limited availability (40% of available products). Netherlands did not submit complete information on restrictions to available medicines meaning LA* is not captured in these countries. †In most countries availability equates to granting of access to the reimbursement list, except in DK, FI, LU, NO, SE where some hospital products are not covered by the general reimbursement scheme. *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 (%, 2019-2022)

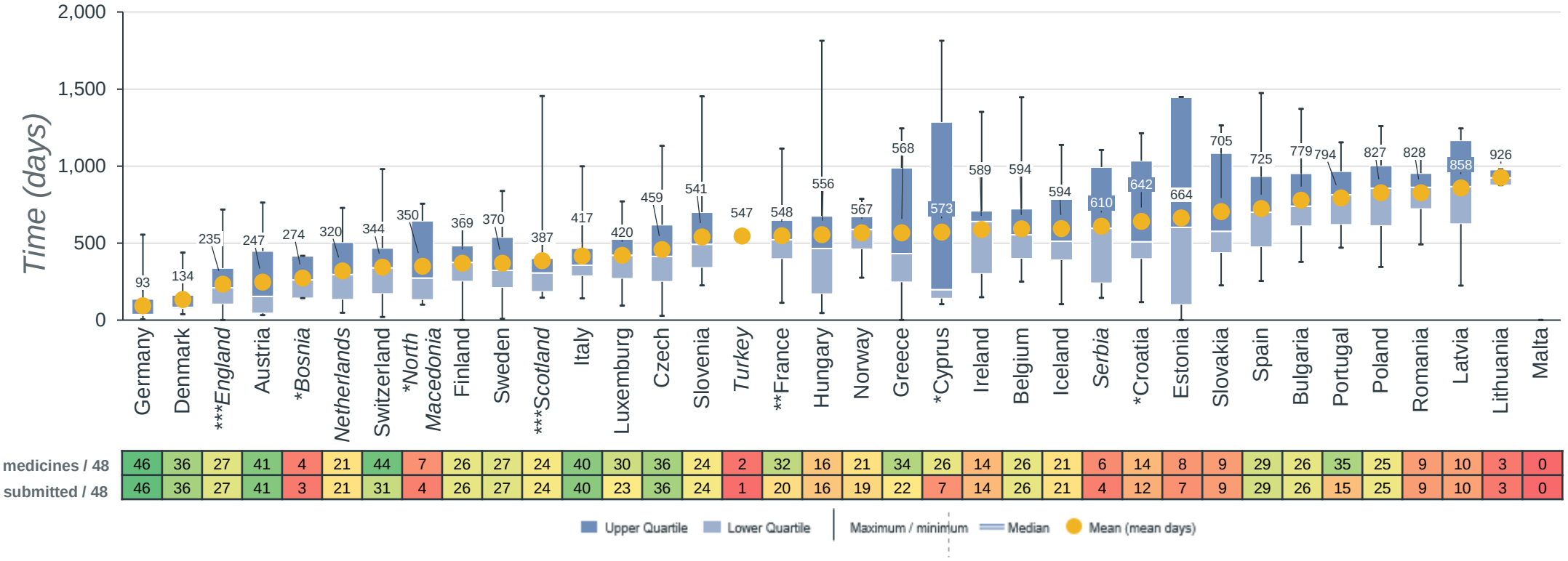
The **breakdown of availability** is the composition of medicines available to patients in European countries as of 5th January 2024 (for most countries this is the point at which the product gains access to the reimbursement list†). This includes all medicine's status to provide a complete picture of the availability of the cohort studied.



European Union average: 25 products available (52%), 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. †In most countries availability equates to granting of access to the reimbursement list, except in DK, FI, LU, NO, SE where some hospital products are not covered by the general reimbursement scheme. *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 time to availability (2019-2022)

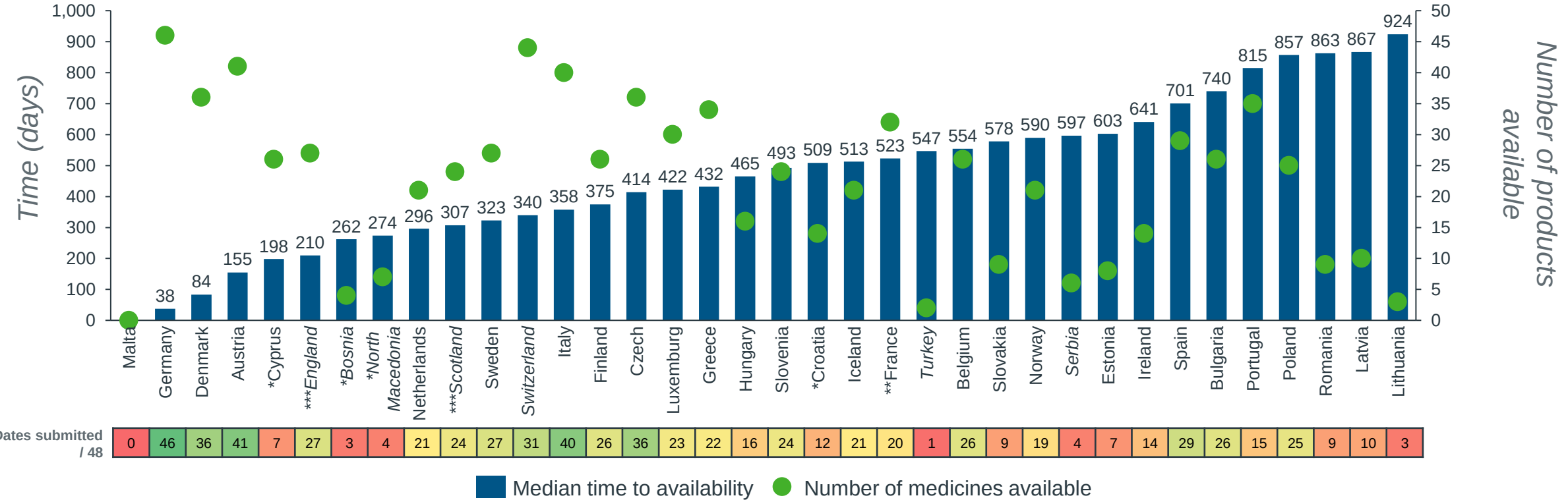
The **time to availability** is the days between marketing authorisation and the date of availability to patients in European countries (for most this is the point at which products gain access to the reimbursement list†). The marketing authorisation date is the date of central EU authorisation in most countries, except for countries shown in italics where local authorisation dates have been used. Data is correct to 5th January 2024.



European Union average: 559 days (mean) (Note: Malta is not included in EU27 average as no dates were submitted in total) †In most countries availability equates to granting of access to the reimbursement list, except in DK, FI, NO, SE where some hospital products are not covered by the general reimbursement scheme. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. unrepresentative **For France, the time to availability (548 days, n=20 dates submitted) includes products under the Accès précoce system (n=5 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 438 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 products and EMA dates used for 2019-2020 products

Oncology median time to availability (2019-2022)

The **median time to availability** is the days between marketing authorisation and the date of availability to patients in European countries (for most this is the point at which products gain access to the reimbursement list†). The marketing authorisation date is the date of central EU authorisation in most countries, except for countries shown in italics where local authorisation dates have been used. Data is correct to 5th January 2024.



European Union average: 509 days (median) †In most countries availability equates to granting of access to the reimbursement list, except in DK, FI, NO, SE where some hospital products are not covered by the general reimbursement scheme. *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=20 dates submitted) includes products under the Accès précoce system (n=5 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 443 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 products and EMA dates used for 2019-2020 products

Key observations

Executive summary (EU27 averages)

Measure	All products	Oncology	Orphan	Non-oncologic orphan	Combination therapy
Average rate of availability	43% (45% in 2022)	52% (50% in 2022)	35% (39% in 2022)	32% ↓ (39% in 2022)	54% (50% in 2022)
Average time to availability	531 Days (517 days in 2022)	559 ↑ Days (526 days in 2022)	542 ↓ Days (625 days in 2022)	530 ↓ Days (626 days in 2022)	433 Days (426 days in 2022)

Key Insights

Rate of availability

- The EU's rate of availability for oncology medicines was 9% higher than the average rate of availability for all products in 2023
- Four countries (DE, CH, AT, IT) have a rate of availability for oncology medicines higher than 80% in 2023

Time to availability

- The average delay from marketing authorisation to patient access for oncology products varies from 3 to 31 months (>2.5 years) between all countries included in the 2023 WAIT survey
- The average time to availability for oncology products is 33 days slower than comparable data published in the 2022 report

Metrics key:

Text colour indicates relative position versus the current (2023) EU average (*significantly worse than current EU average* / *significantly better than current EU average*)

Arrow colour indicates significant changes versus the previous (2021) 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 no dates were submitted in total

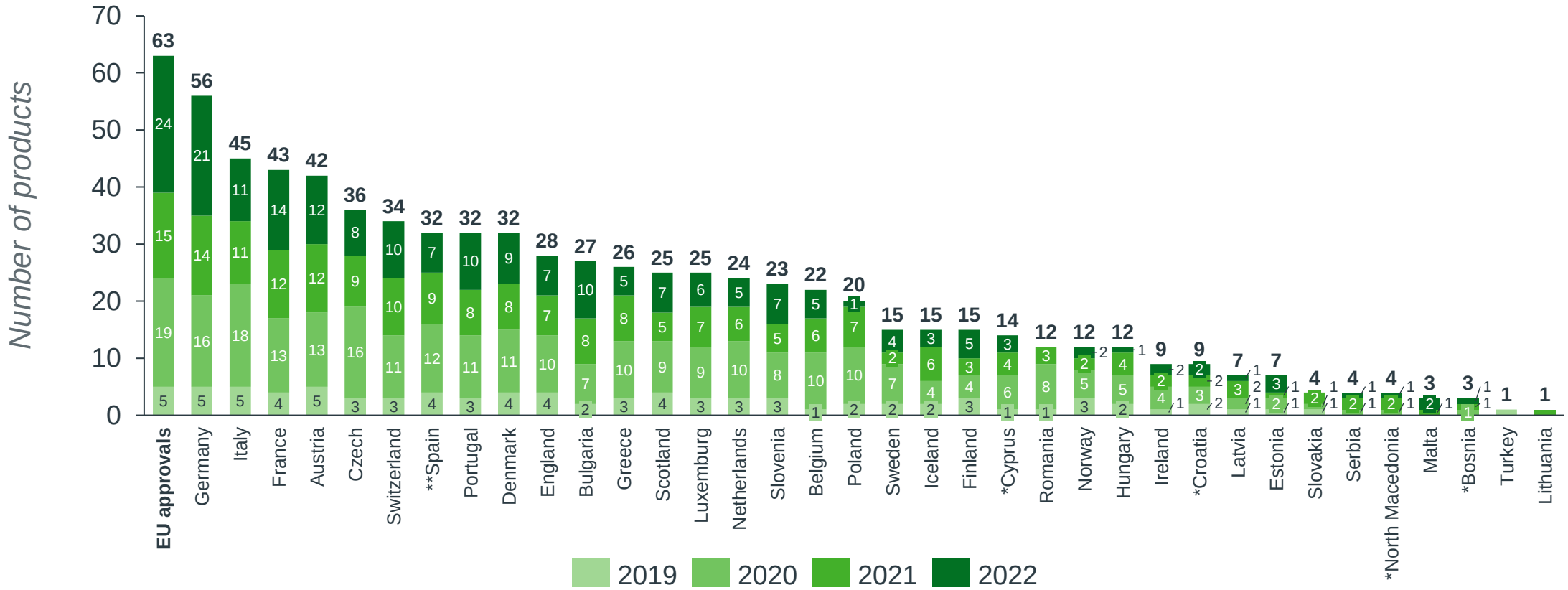
3. Orphan medicines

Indicators:

3.1. Total availability by approval year
3.2. Rate of availability
3.3. Rate of full availability
3.4. Breakdown of availability
3.5. Time to availability
3.6. Median time to availability

Orphan availability by approval year (2019-2022)

The **total availability by approval year** is the number of medicines available to patients in European countries as of 5th January 2024 (for most countries this is the point at which the product gains access to the reimbursement list†), split by the year the product received marketing authorisation in Europe.



European Union average: 22 products available (35%) †In most countries availability equates to granting of access to the reimbursement list, except in DK, FI, LU, NO, SE where some hospital products are not covered by the general reimbursement scheme. *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

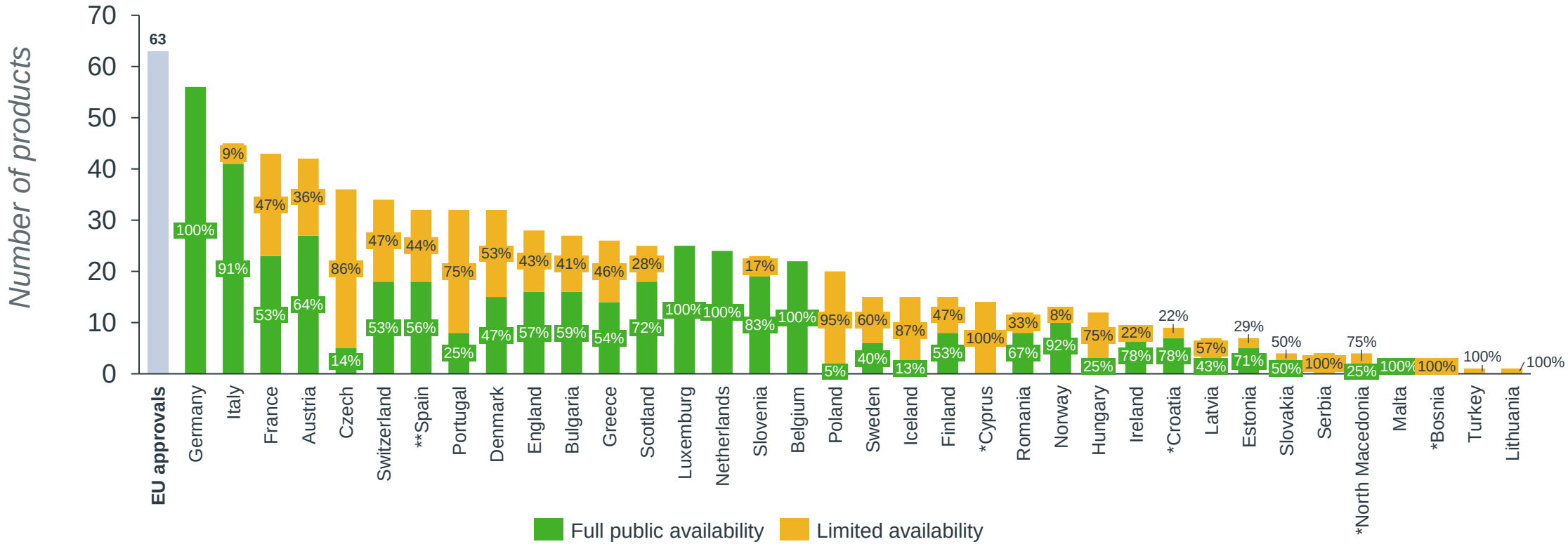
Orphan rate of availability (2019-2022)

The **rate of availability**, measured by the number of medicines available to patients in European countries as of 5th January 2024. For most countries this is the point at which the product gains access to the reimbursement list†, including products with limited availability.

European Union average: 22 products available (35%) †In most countries availability equates to granting of access to the reimbursement list, except in DK, FI, LU, NO, SE where some hospital products are not covered by the general reimbursement scheme. *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 full availability (%, 2019-2022)

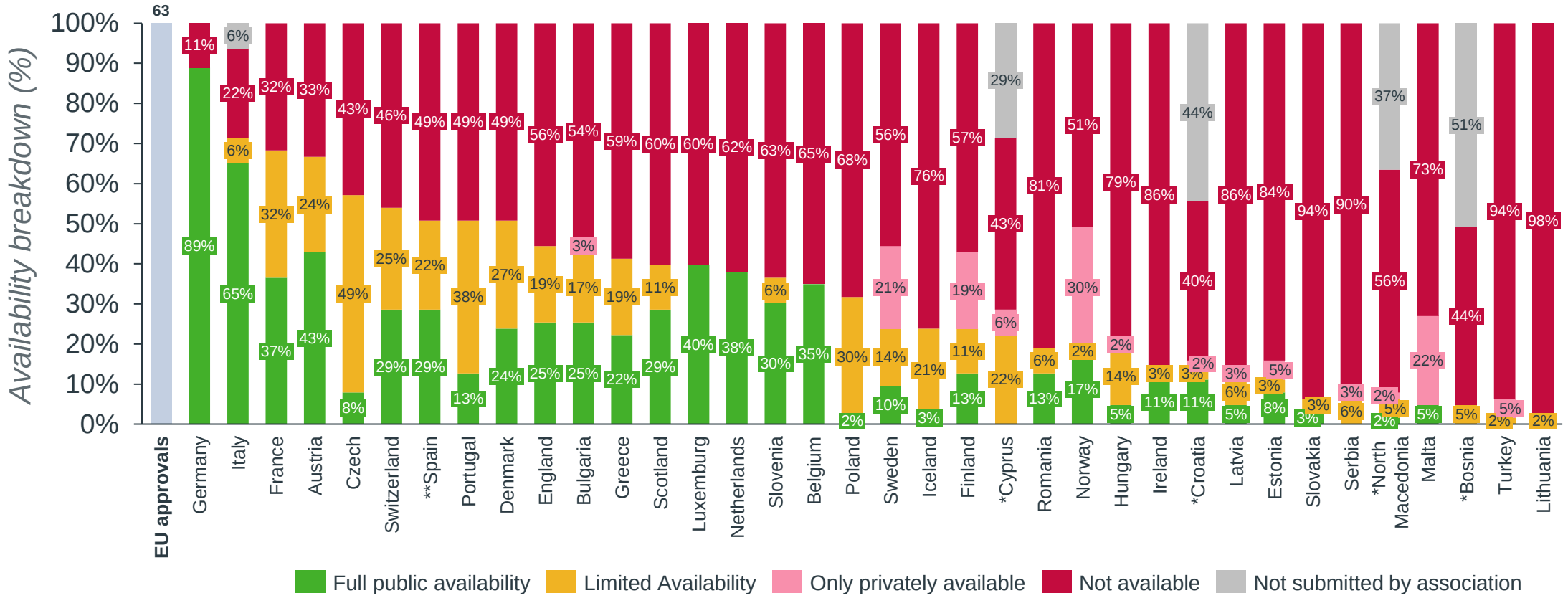
The **rate of full availability** shows the proportion of medicines available to patients in European countries as of 5th January 2024 (for most countries this is the point at which the product gains access to the reimbursement list†) without any restrictions to the patient population, or through named patient basis schemes which have increased significantly in recent years and were not always captured in survey submissions.



European Union average: 22 products available (35%), Limited availability (42% of available products). Netherlands did not submit complete information on restrictions to available medicines meaning LA* is not captured in these countries. †In most countries availability equates to granting of access to the reimbursement list, except in DK, FI, LU, NO, SE where some hospital products are not covered by the general reimbursement scheme. *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 (%, 2019-2022)

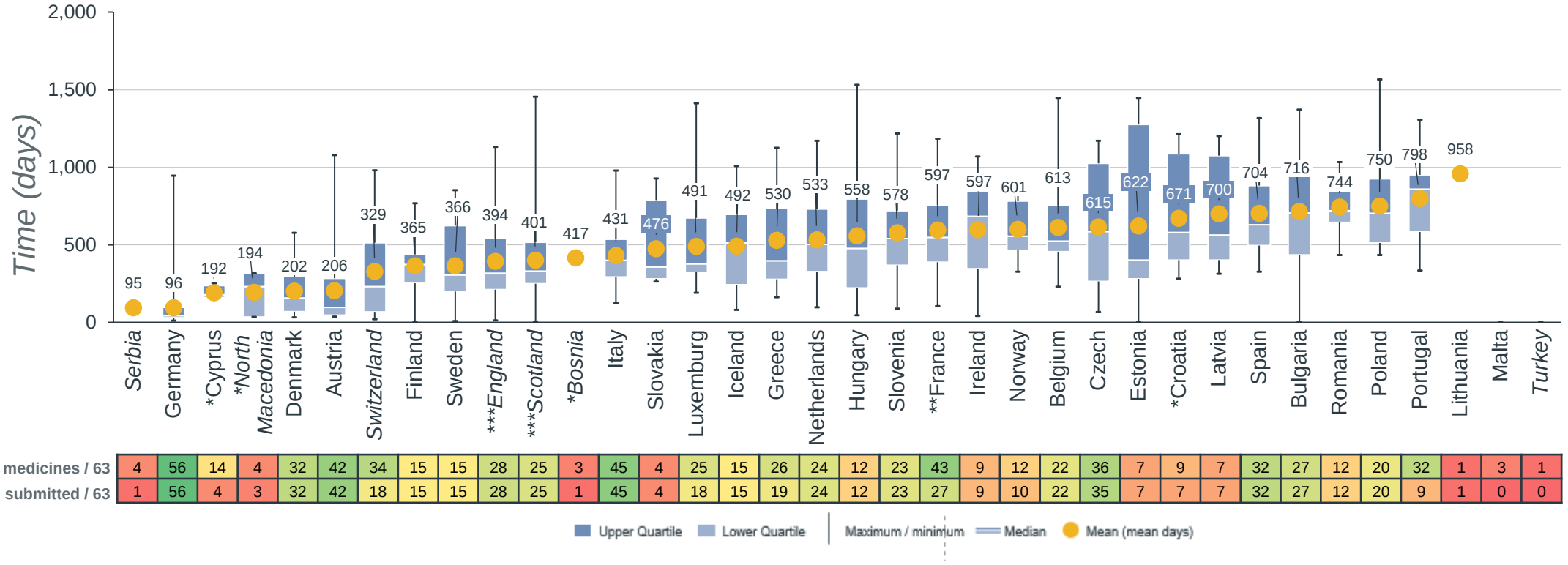
The **breakdown of availability** is the composition of medicines available to patients in European countries as of 5th January 2024 (for most countries this is the point at which the product gains access to the reimbursement list†). This includes all medicine's status to provide a complete picture of the availability of the cohort studied.



European Union average: 22 products available (35%), Limited availability (13% of all orphan products). Netherlands did not submit complete information on restrictions to available medicines meaning LA* is not captured in these countries. †In most countries availability equates to granting of access to the reimbursement list, except in DK, FI, LU, NO, SE where some hospital products are not covered by the general reimbursement scheme. *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 (2019-2022)

The **time to availability** is the days between marketing authorisation and the date of availability to patients in European countries (for most this is the point at which products gain access to the reimbursement list†). The marketing authorisation date is the date of central EU authorisation in most countries, except for countries shown in italics where local authorisation dates have been used. Data is correct to 5th January 2024.

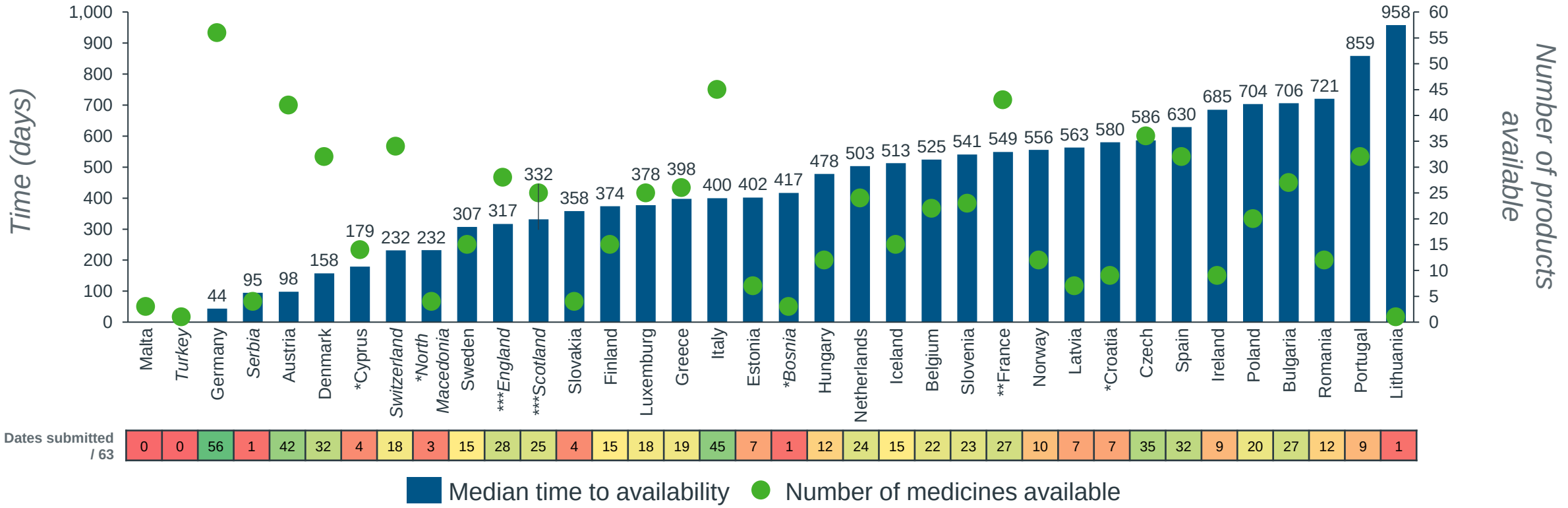


	Serbia	Germany	*Cyprus	*North Macedonia	Denmark	Austria	Switzerland	Finland	Sweden	***England	***Scotland	*Bosnia	Italy	Slovakia	Luxemburg	Iceland	Greece	Netherlands	Hungary	Slovenia	**France	Ireland	Norway	Belgium	Czech	Estonia	*Croatia	Latvia	Spain	Bulgaria	Romania	Poland	Portugal	Lithuania	Malta	Turkey
Available medicines / 63	4	56	14	4	32	42	34	15	15	28	25	3	45	4	25	15	26	24	12	23	43	9	12	22	36	7	9	7	32	27	12	20	32	1	3	1
Dates submitted / 63	1	56	4	3	32	42	18	15	15	28	25	1	45	4	18	15	19	24	12	23	27	9	10	22	35	7	7	7	32	27	12	20	9	1	0	0

European Union average: 542 days (mean) (Note: Malta is not included in EU27 average as no dates were submitted in total) †In most countries availability equates to granting of access to the reimbursement list, except in DK, FI, NO, SE where some hospital products are not covered by the general reimbursement scheme. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative.; **For France, the time to availability (597 days, n=27 dates submitted) includes products under the Accès précoce system (n=11 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 420 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 products and EMA dates used for 2019-2020 products

Orphan median time to availability (2019-2022)

The **median time to availability** is the days between marketing authorisation and the date of availability to patients in European countries (for most this is the point at which products gain access to the reimbursement list†). The marketing authorisation date is the date of central EU authorisation in most countries, except for countries shown in italics where local authorisation dates have been used. Data is correct to 5th January 2024.



European Union average: 488 days (median) †In most countries availability equates to granting of access to the reimbursement list, except in DK, FI, NO, SE where some hospital products are not covered by the general reimbursement scheme. *Countries with asterisks did not complete a full dataset and therefore availability may be **For France, the median time to availability (549 days, n=27 dates submitted) includes products under the Accès précoce system (n=11 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 445 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 products and EMA dates used for 2019-2020 products

Key observations

Executive summary (EU27 averages)

Measure	All products	Oncology	Orphan	Non-oncologic orphan	Combination therapy
Average rate of availability	43% (45% in 2022)	52% (50% in 2022)	35% (39% in 2022)	32% ↓ (39% in 2022)	54% (50% in 2022)
Average time to availability	531 Days (517 days in 2022)	559 ↑ Days (526 days in 2022)	542 ↓ Days (625 days in 2022)	530 ↓ Days (626 days in 2022)	433 Days (426 days in 2022)

Key Insights

Rate of availability

- Average rate of availability for orphan medicines is 8% lower than the average for all products
- The rate of availability for orphan medicines in 2023 is 35%, which represents a 4% decline since last year's survey

Time to availability

- The average time to availability for orphan products is significantly faster than last year's study, which reflects a change in product 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 2.5 years for others

Metrics key:

Text colour indicates relative position versus the current (2023) EU average (*significantly worse than current EU average* / *significantly better than current EU average*)

Arrow colour indicates significant changes versus the previous (2021) 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 no dates were submitted in total

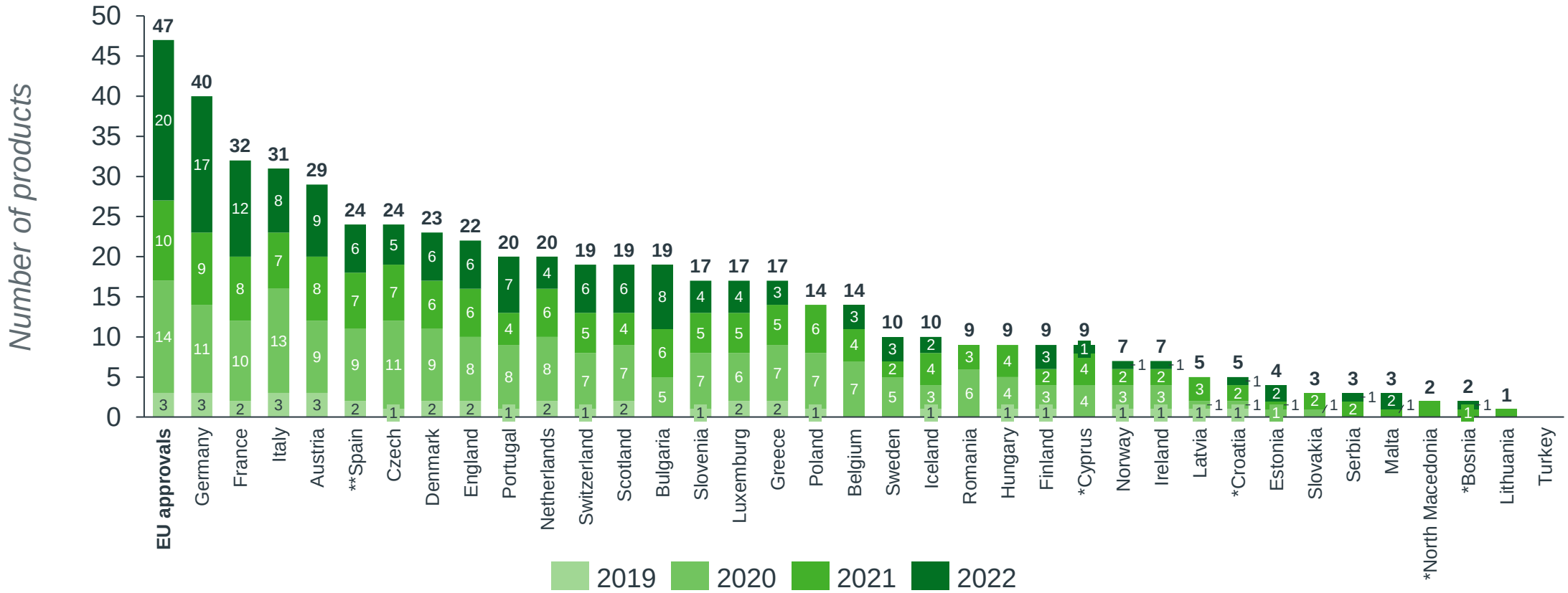
4. Non-oncology orphan medicines

Indicators:

4.1. Total availability by approval year
4.2. Rate of availability
4.3. Rate of full availability
4.4. Breakdown of availability
4.5. Time to availability
4.6. Median time to availability

Non-oncology orphan availability by approval year (2019-2022)

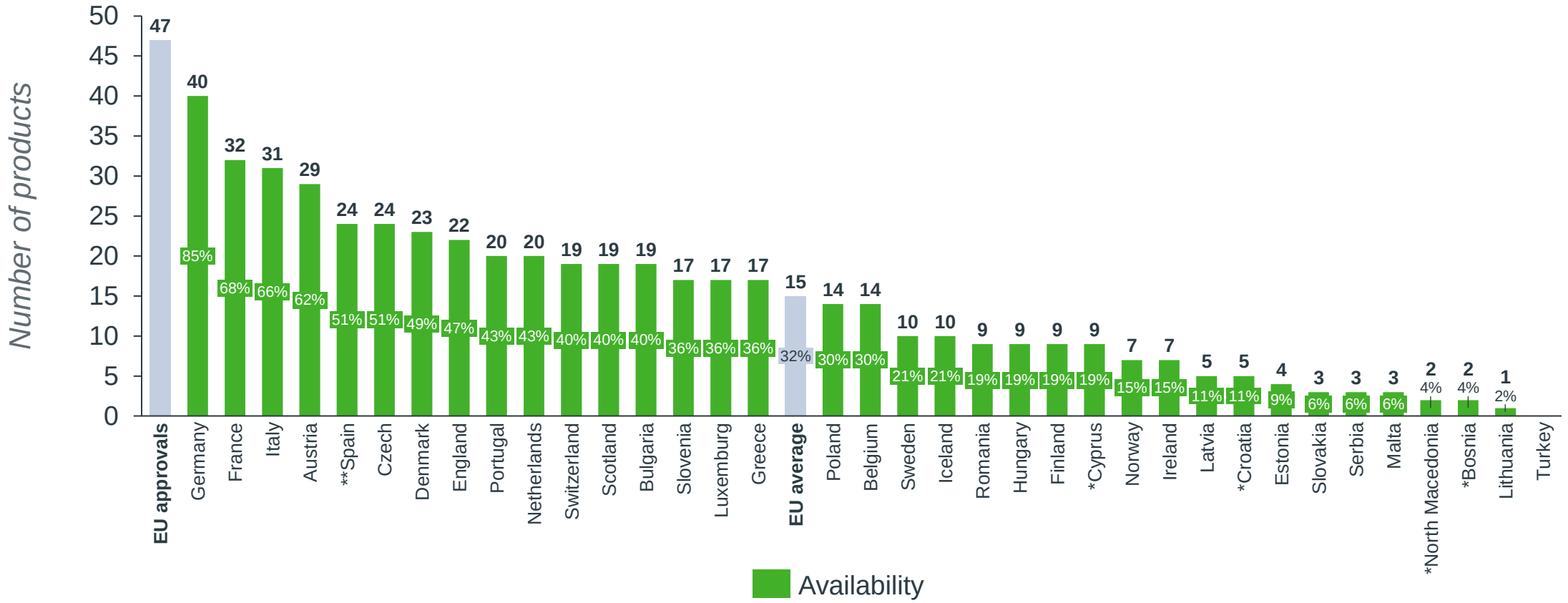
The **total availability by approval year** is the number of medicines available to patients in European countries as of 5th January 2024 (for most countries this is the point at which the product gains access to the reimbursement list†), split by the year the product received marketing authorisation in Europe.



European Union average: 15 products available (32%) †In most countries availability equates to granting of access to the reimbursement list, except in DK, FI, LU, NO, SE where some hospital products are not covered by the general reimbursement scheme. *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 (2019-2022)

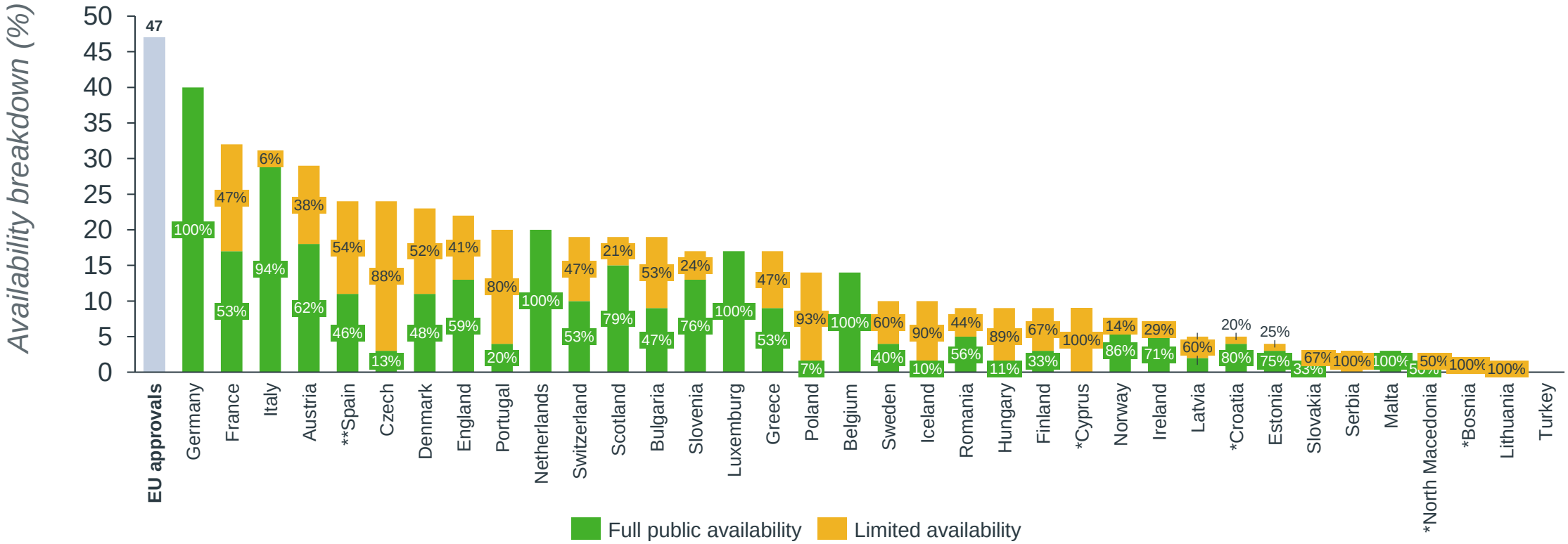
The **rate of availability**, measured by the number of medicines available to patients in European countries as of 5th January 2024. For most countries this is the point at which the product gains access to the reimbursement list†, including products with limited availability.



European Union average: 15 products available (32%) †In most countries availability equates to granting of access to the reimbursement list, except in DK, FI, LU, NO, SE where some hospital products are not covered by the general reimbursement scheme. *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 full availability (%, 2019-2022)

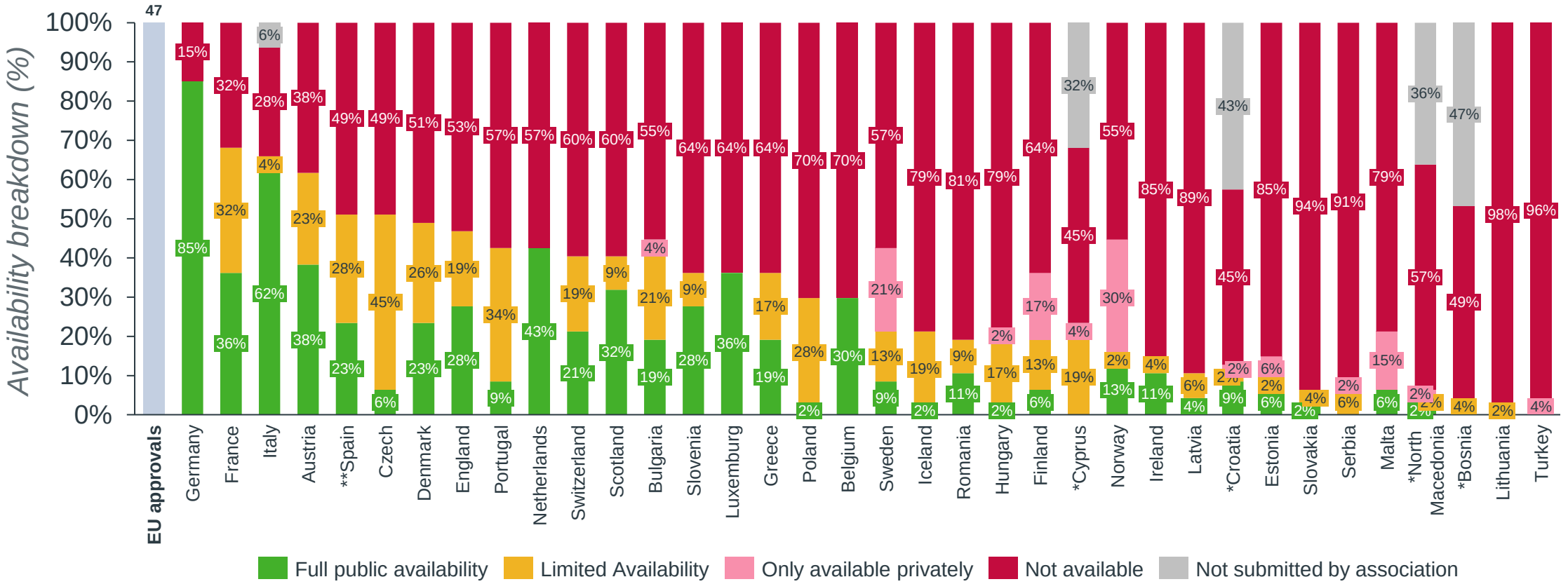
The **rate of full availability** shows the proportion of medicines available to patients in European countries as of 5th January 2024 (for most countries this is the point at which the product gains access to the reimbursement list†) without any restrictions to the patient population, or through named patient basis schemes which have increased significantly in recent years and were not always captured in survey submissions.



European Union average: 15 products available (32%). Limited availability (46% of available products) Netherlands did not submit complete information on restrictions to available medicines meaning LA* is not captured in these countries. †In most countries availability equates to granting of access to the reimbursement list, except in DK, FI, LU, NO, SE where some hospital products are not covered by the general reimbursement scheme. *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 (%, 2019-2022)

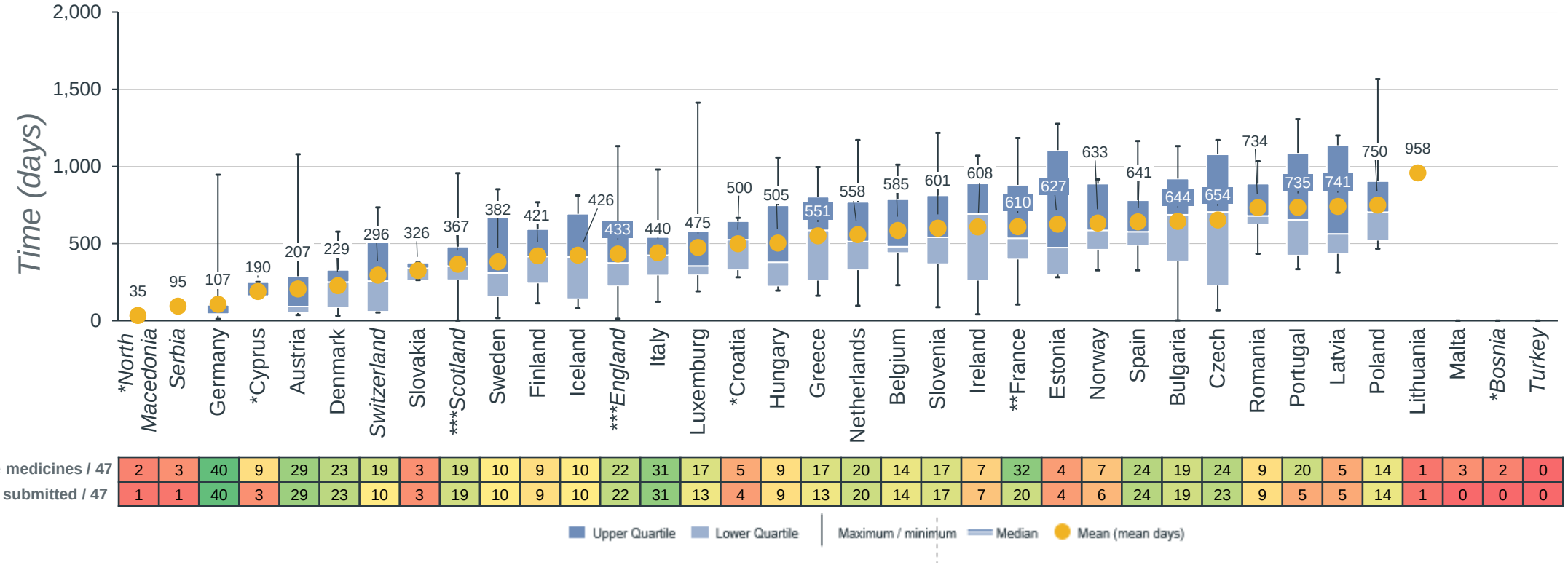
The **breakdown of availability** is the composition of medicines available to patients in European countries as of 5th January 2024 (for most countries this is the point at which the product gains access to the reimbursement list†). This includes all medicine's status to provide a complete picture of the availability of the cohort studied.



European Union average: 15 products available (32%), Limited availability (13% of all non-onc orphan products). Netherlands did not submit complete information on restrictions to available medicines meaning LA* is not captured in these countries. †In most countries availability equates to granting of access to the reimbursement list, except in DK, FI, LU, NO, SE where some hospital products are not covered by the general reimbursement scheme. *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 (2019-2022)

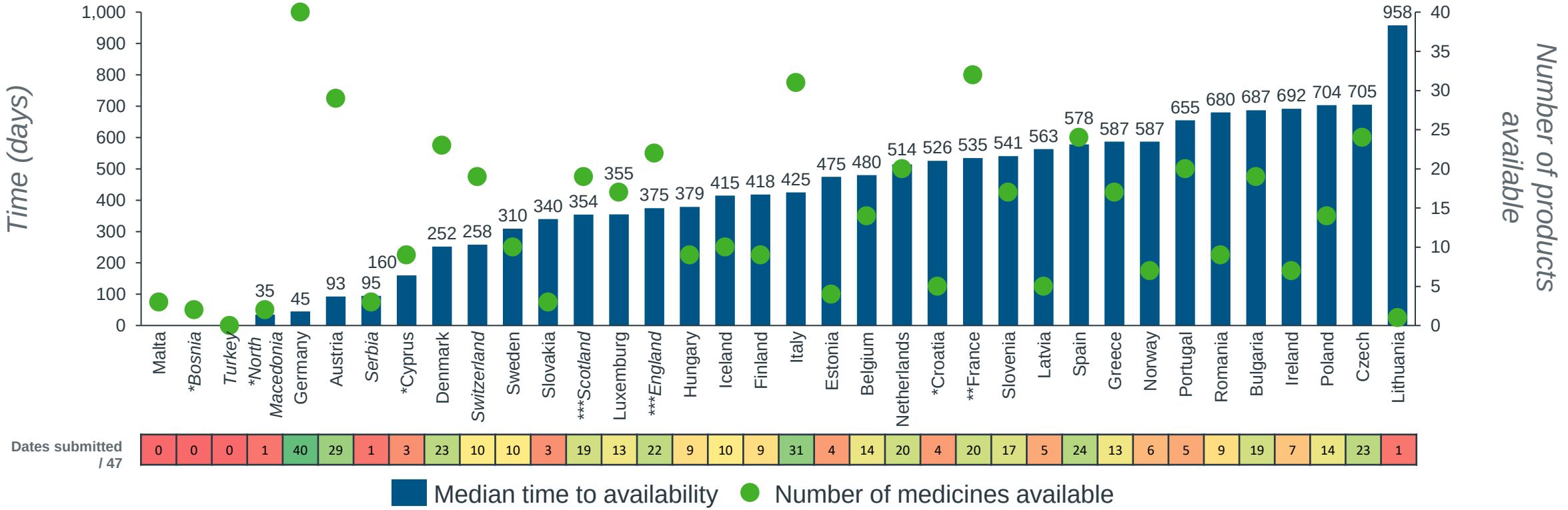
The **time to availability** is the days between marketing authorisation and the date of availability to patients in European countries (for most this is the point at which products gain access to the reimbursement list†). The marketing authorisation date is the date of central EU authorisation in most countries, except for countries shown in italics where local authorisation dates have been used. Data is correct to 5th January 2024.



European Union average: 530 days (mean) (Note: Malta is not included in EU27 average as no dates were submitted in total) †In most countries availability equates to granting of access to the reimbursement list, except in DK, FI, NO, SE where some hospital products are not covered by the general reimbursement scheme. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative, **For France, the time to availability (610 days, n=20 dates submitted) includes products under the Accès précoce system (n=10 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 401 day. ***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 products and EMA dates used for 2019-2020 products

Non-oncology orphan median time to availability (2019-2022)

The **median time to availability** is the days between marketing authorisation and the date of availability to patients in European countries (for most this is the point at which products gain access to the reimbursement list†). The marketing authorisation date is the date of central EU authorisation in most countries, except for countries shown in italics where local authorisation dates have been used. Data is correct to 5th January 2024.



European Union average: 487 days (median) †In most countries availability equates to granting of access to the reimbursement list, except in DK, FI, NO, SE where some hospital products are not covered by the general reimbursement scheme. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative **For France, the median time to availability (535 days, n=20 dates submitted) includes products under the Accès précoce system (n=10 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 382 day. ***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 products and EMA dates used for 2019-2020 products

Key observations

Executive summary (EU27 averages)

Measure	All products	Oncology	Orphan	Non-oncologic orphan	Combination therapy
Average rate of availability	43% (45% in 2022)	52% (50% in 2022)	35% (39% in 2022)	32% ↓ (39% in 2022)	54% (50% in 2022)
Average time to availability	531 Days (517 days in 2022)	559 ↑ Days (526 days in 2022)	542 ↓ Days (625 days in 2022)	530 ↓ Days (626 days in 2022)	433 Days (426 days in 2022)

Key Insights

Rate of availability

- Average rate of availability for non-oncology orphan medicines is 11% lower than the average for all products
- The rate of availability for non-oncology orphan medicines in 2023 is 32%, which represents a 7% decline since last year's survey

Time to availability

- The average time to availability for non-oncology orphan products is in line with the average for all products, making it one of the segments with the fastest time to availability
- Europe's time to availability for non-oncology orphan drugs can vary from less than 3 months to over 31 months

Metrics key:

Text colour indicates relative position versus the current (2023) EU average (*significantly worse than current EU average* / *significantly better than current EU average*)

Arrow colour indicates significant changes versus the previous (2021) 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 no dates were submitted in total

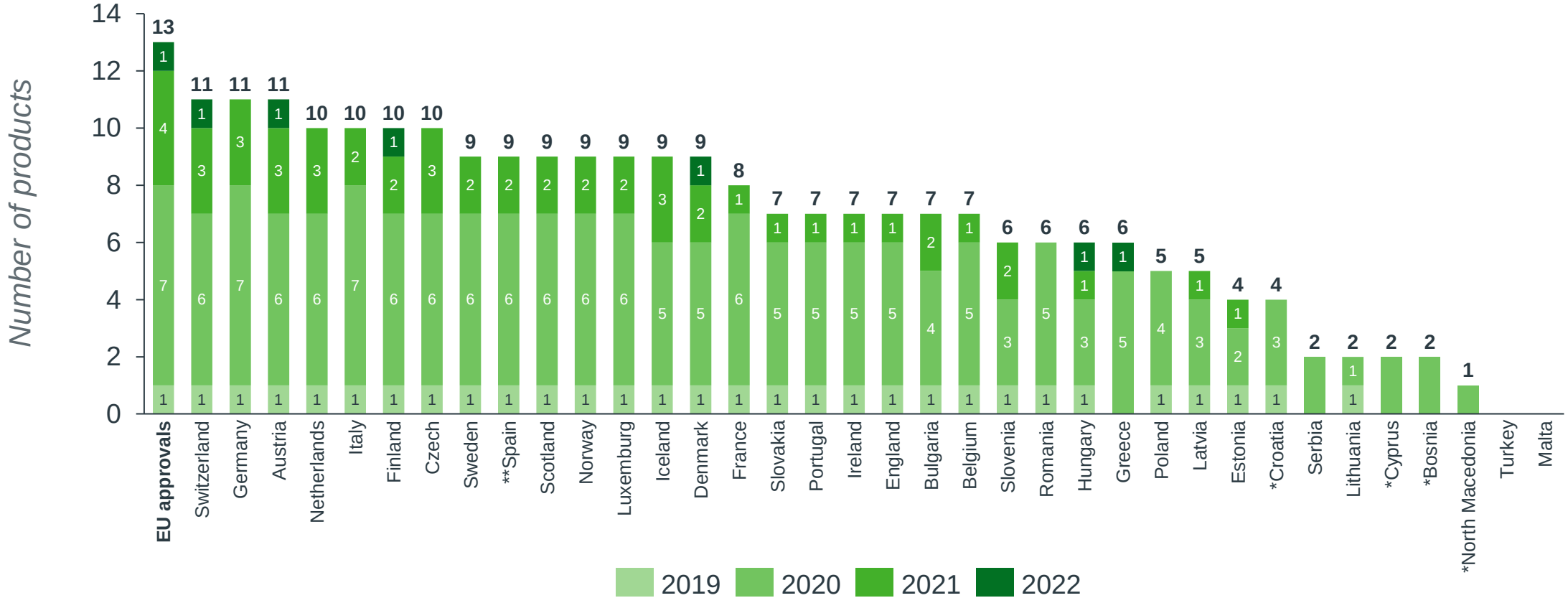
5. Combination therapies

Indicators:

5.1. Total availability by approval year
5.2. Rate of availability
5.3. Rate of full availability
5.4. Breakdown of availability
5.5. Time to availability
5.6. Median time to availability

Combination therapies availability by approval year (2019-2022)

The **total availability by approval year** is the number of fixed dose combination medicines available to patients in European countries as of 5th January 2024 (for most countries this is the point at which the product gains access to the reimbursement list†), split by the year the product received marketing authorisation in Europe.



European Union average: 7 products available (54%) Combination products can include innovative branded / generic combinations. †In most countries availability equates to granting of access to the reimbursement list, except in DK, FI, LU, NO, SE where some hospital products are not covered by the general reimbursement scheme. *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

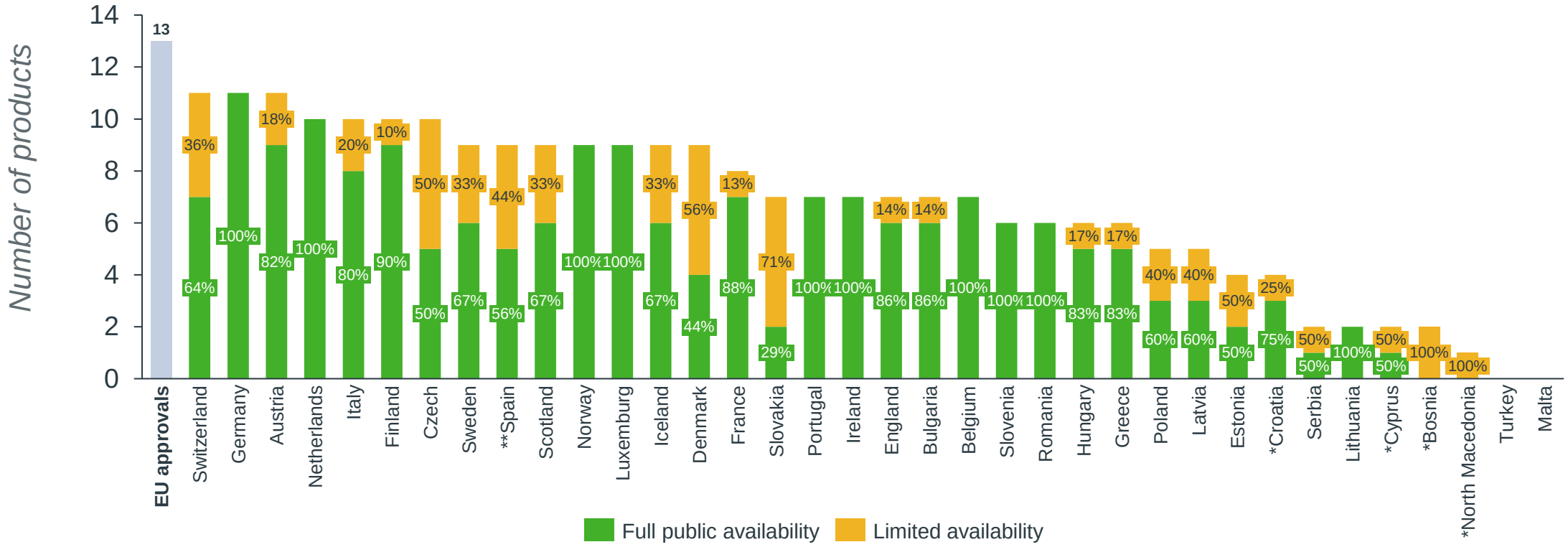
Combination therapies rate of availability (2019-2022)

The **rate of availability**, measured by the number of fixed dose combination medicines available to patients in European countries as of 5th January 2024. For most countries this is the point at which the product gains access to the reimbursement list†, including products with limited availability.

European Union average: 7 products available (54%) Combination products can include innovative branded / generic combinations; †In most countries availability equates to granting of access to the reimbursement list, except in DK, FI, LU, NO, SE where some hospital products are not covered by the general reimbursement scheme. *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 full availability (%, 2019-2022)

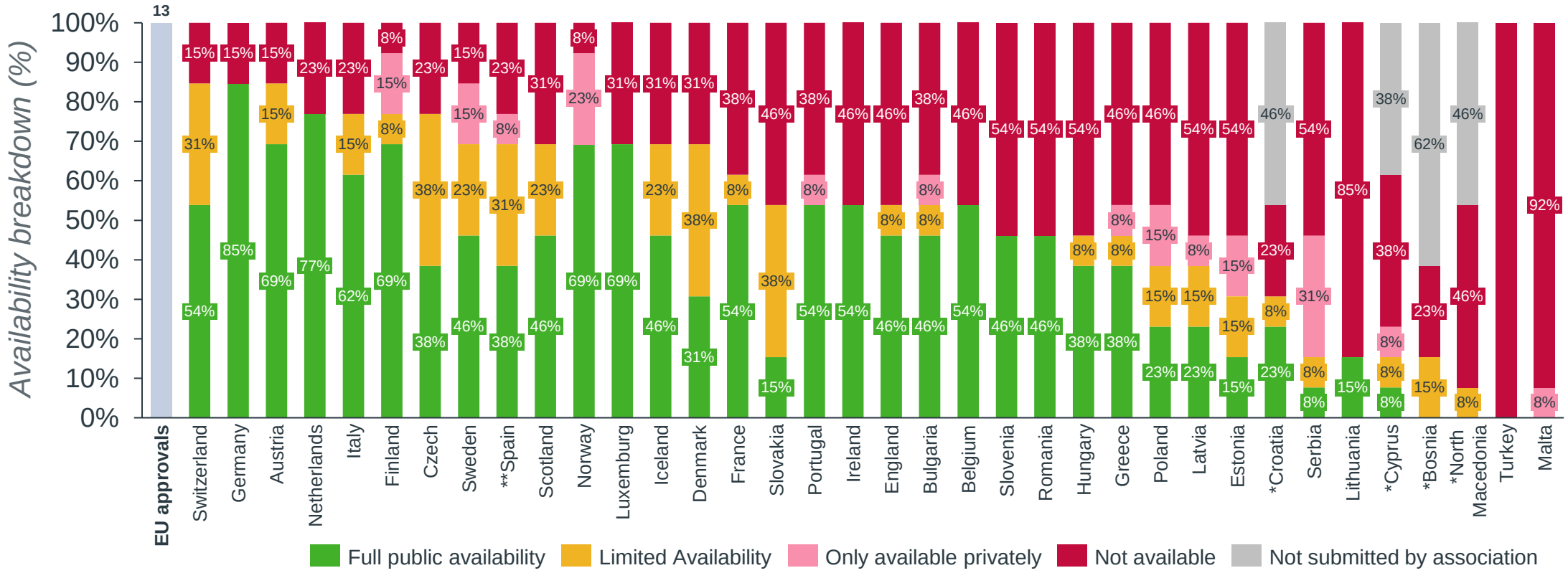
The **rate of full availability** shows the proportion of fixed dose combination medicines available to patients in European countries as of 5th January 2024 (for most countries this is the point at which the product gains access to the reimbursement list†) without any restrictions to the patient population, or through named patient basis schemes which have increased significantly in recent years and were not always captured in survey submissions.



European Union average: 7 products available (54%), Limited availability (22% 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.†In most countries availability equates to granting of access to the reimbursement list, except in DK, FI, LU, NO, SE where some hospital products are not covered by the general reimbursement scheme. *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 (%, 2019-2022)

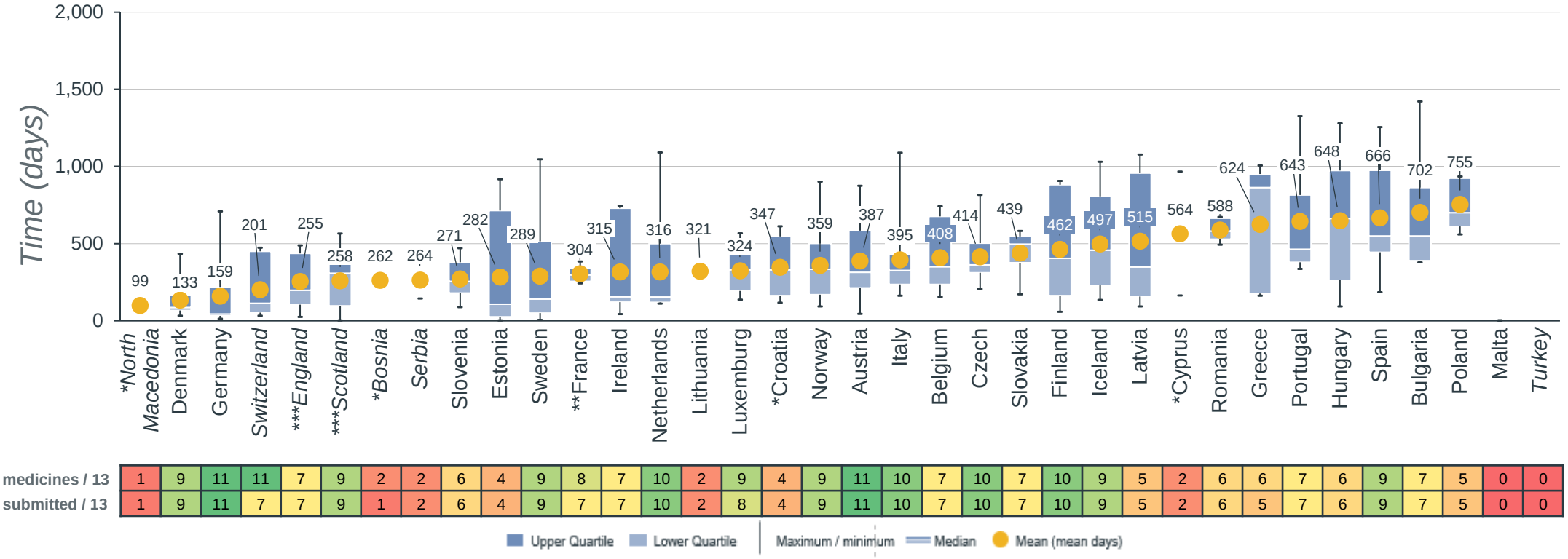
The **breakdown of availability** is the composition of fixed dose combination medicines available to patients in European countries as of 5th January 2024 (for most countries this is the point at which the product gains access to the reimbursement list†). This includes all medicine's status to provide a complete picture of the availability of the cohort studied.



European Union average: 7 products available (54%), Limited availability (11% of all 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.†In most countries availability equates to granting of access to the reimbursement list, except in DK, FI, LU, NO, SE where some hospital products are not covered by the general reimbursement scheme. *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 (2019-2022)

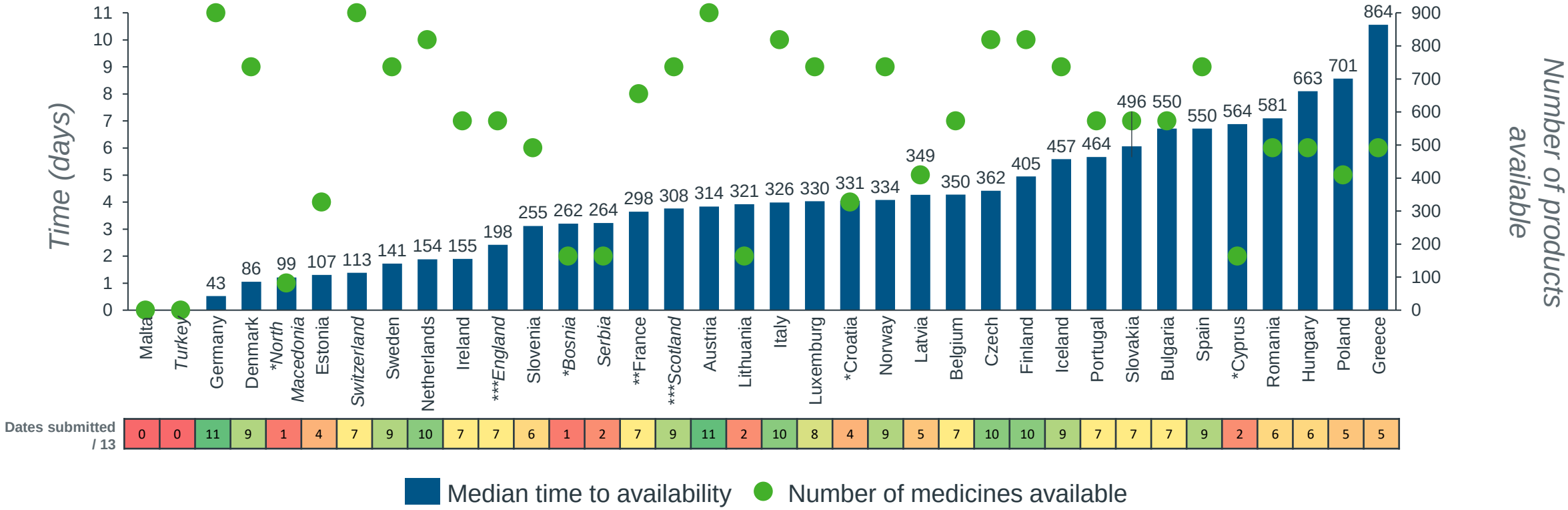
The **time to availability** is the days between marketing authorisation and the date of availability of fixed dose combination medicines to patients in European countries (for most this is the point at which products gain access to the reimbursement list†). The marketing authorisation date is the date of central EU authorisation in most countries, except for countries shown in italics where local authorisation dates have been used. Data is correct to 5th January 2024.



European Union average: 433 days (mean) (Note: Malta is not included in EU27 average as no dates were submitted in total) Combination products can include innovative branded / generic combinations; †In most countries availability equates to granting of access to the reimbursement list, except in DK, FI, NO, SE where some hospital products are not covered by the general reimbursement scheme. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. **For France, no combination therapy was approved via 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 products and EMA dates used for 2019-2020 products

Combination median time to availability (2019-2022)

The **median time to availability** is the days between marketing authorisation and the date of availability to patients in European countries (for most this is the point at which products gain access to the reimbursement list†). The marketing authorisation date is the date of central EU authorisation in most countries, except for countries shown in italics where local authorisation dates have been used. Data is correct to 5th January 2024.



European Union average: 375 days (median) †In most countries availability equates to granting of access to the reimbursement list, except in DK, FI, NO, SE where some hospital products are not covered by the general reimbursement scheme. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative **For France, no combination therapy was approved via 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 products and EMA dates used for 2019-2020 products

Key observations

Executive summary (EU27 averages)

Measure	All products	Oncology	Orphan	Non-oncologic orphan	Combination therapy
Average rate of availability	43% (45% in 2022)	52% (50% in 2022)	35% (39% in 2022)	32% ↓ (39% in 2022)	54% (50% in 2022)
Average time to availability	531 Days (517 days in 2022)	559 ↑ Days (526 days in 2022)	542 ↓ Days (625 days in 2022)	530 ↓ Days (626 days in 2022)	433 Days (426 days in 2022)

Key Insights

Rate of availability

- Average rate of availability for combination therapies is 11% higher than the average for all products
- The rate of availability for combination therapies is 4% higher than the previous study, despite the lower number of central approvals in this year's survey

Time to availability

- The time to availability for combination therapies is the fastest across all segments, with an average of ~14 months in Europe vs ~18 months for all products
- For over half of the countries included in this year's WAIT survey, the time to availability of combination therapies is less than 13 months

Metrics key:

Text colour indicates relative position versus the current (2023) EU average (*significantly worse than current EU average* / *significantly better than current EU average*)

Arrow colour indicates significant changes versus the previous (2021) 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 no dates were submitted in total

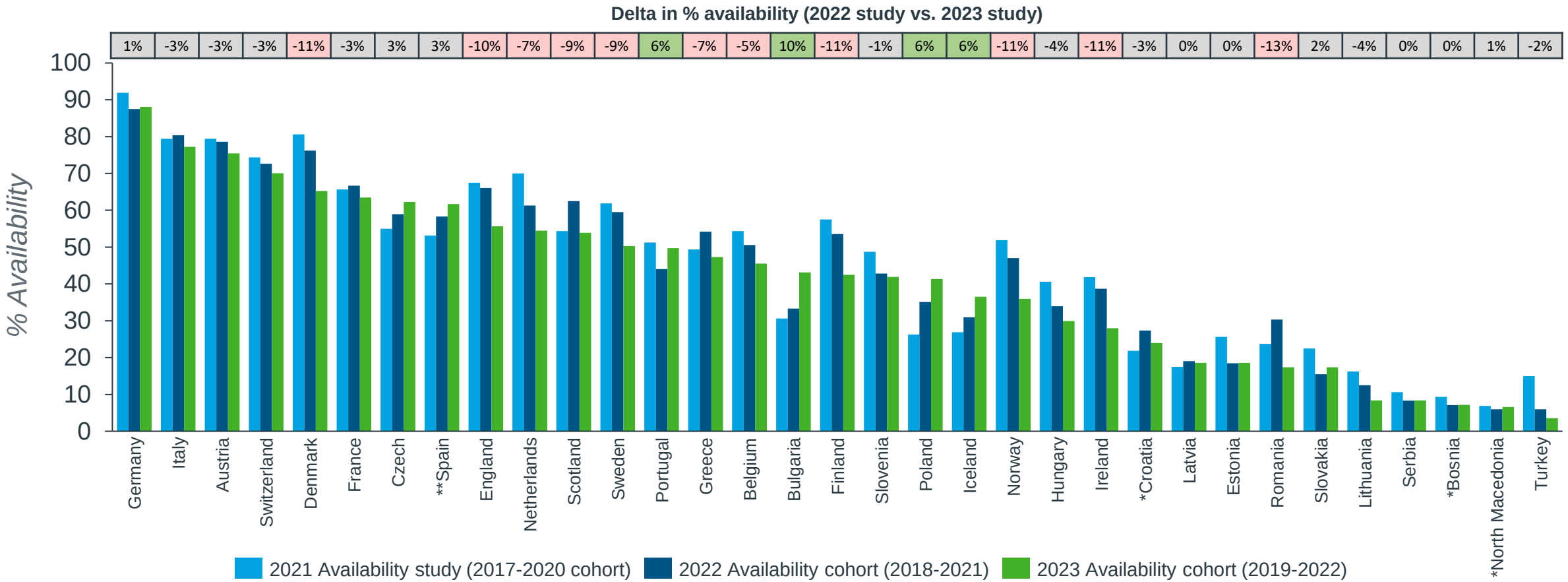
6. Historic comparisons and extended period

Indicators:

6.1. Comparison of availability versus prior studies (2021 – 2023)
6.2. Comparison of time to availability versus prior studies (2021 – 2023)
6.3. Extended period total availability by approval year (2014 – 2022)

Comparison of rate of availability (2021 study – 2023 study)

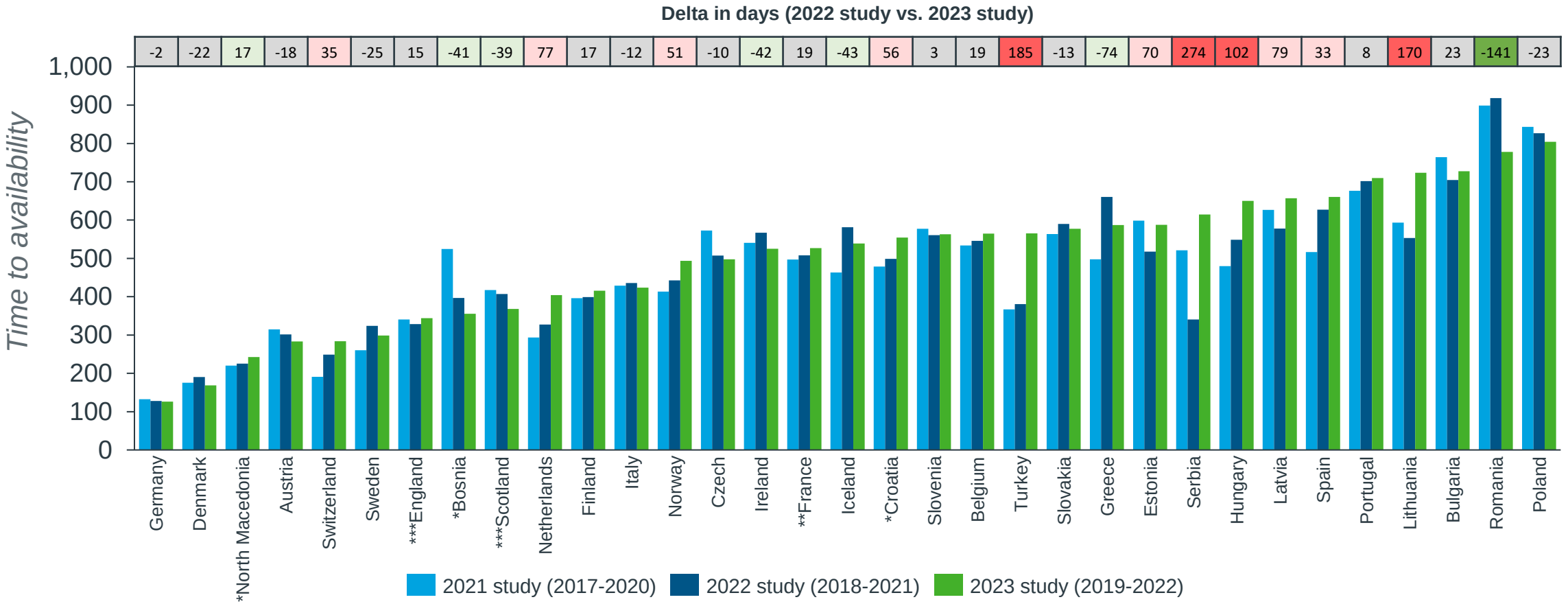
The **comparison of rate of availability**†, measured by the number of medicines available to patients in European countries as of 5th January 2024, compared to the rate of availability in previous (comparable) studies. Figures are based on the historic statistics published in the indicators, and major changes are often due to improved reporting.



Increases of <=5% are not considered to be statistically significant and are therefore highlighted in grey. Note: Netherlands has retrospectively corrected 2020 data; †In most countries availability equates to granting of access to the reimbursement list, except in DK, FI, LU, NO, SE some hospital products are not covered by the general reimbursement scheme. *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

Comparison of time to availability (2021 study – 2023 study)

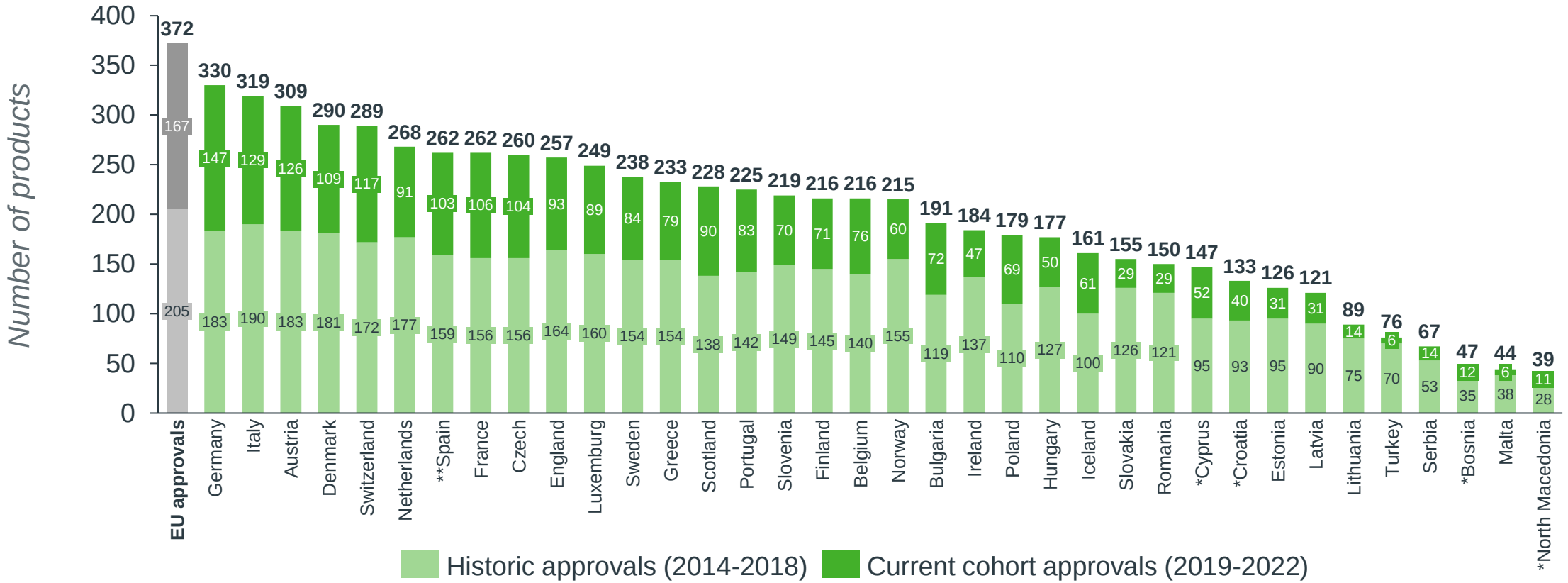
The **comparison of time to availability** (previously know as length of delay) is the days between marketing authorisation and the date of availability to patients compared to previous comparable studies. Figures are based on the historic statistics published in the indicators, and major changes are often due to improved reporting.



Changes of <=30 days are not considered to be statistically significant and are therefore highlighted in grey. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. **For France, the time to availability (527 days, n=79 dates submitted) includes products under the Accès précoce system (n=18 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 424 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 products and EMA dates used for 2019-2020 products

Extended period total availability by approval year (2014-2022)

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



European Union average: 207 products available (56%) †In most countries availability equates to granting of access to the reimbursement list, except in DK, FI, LU, NO, SE some hospital products are not covered by the general reimbursement scheme.
*Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative.
Note: National Associations perform checks on historic products on a best efforts basis, although it has been noted that status changes do not often occur.

Appendix and detailed methodology

Method and data availability

Process for product selection

1758 〉 **489** 〉 **372** 〉 **167**

EMA list

- List of all historic Marketing Authorisations for human and veterinary medicines (European Public Assessment Reports) accessed November 2023
- Human medicines only

Products in scope

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

Survey cohort (9-years)

- Remove 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 2019 – 2022^
- Exclude products that are recently withdrawn prior to analysis (3)

^ Note: Products included in the WAIT indicator are aligned with products included in EFPIA Access Hurdles Portal (except biosimilar products, which are included in the Portal and excluded in WAIT indicator)
* Removal ATC class exclusions: K = Hospital Solutions; V = Various, T = Diagnostics; Oncology definition used throughout = L1&L2&V3C&Revlimid&Xgeva&Proleukin&Pomalyst
** 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.

Products included in the study: 2019-2022 approvals (n=167)

Abecma	Eladynos	Kesimpta	Opdualag	Rukobia	Tukysa
Adtralza	Elzonris	Kimmtrak	Orgovyx	Rybelsus	Ultomiris
Ajovy	Enerzair Breezhaler / Zimbus Breezhaler	Kinpeygo	Orladeyo	Rybrevant	Uplizna
Amvuttra	Enhertu	Klisyri	Oxbryta	Ryeqo	Upstaza
Arikayce liposomal	Enjaymo	Koselugo	Oxlumo	Saphnelo	Vabysmo
Artesunate Amivas	Enspryng	Leqvio	Padcev	Sarclisa	Vazkepa
Aspaveli	Epidyolex	Libmeldy	Palynziq	Scemblix	Verquvo
Atectura Breezhaler / Bemrist Breezhaler	Erleada	Libtayo	Pemazyre	Sibnayal	Vitrakvi
Ayvakyt	Evenity	Livmarli	Phesgo	Skyrizi	Vizimpro
Baqsimi	Evkeeza	Livtencity	Piqray	Skytrofa	Vocabria
Beovu	Evrenzo	Lorviqua	Pluvicto	Sogroya	Voraxaze
Besremi	Evrysdi	Lumykras	Polivy	Spevigo	Voxzogo
Bimzelx	Fetcroja	Lunsumio	Ponvory	Spravato	Vumerity
Blenrep	Filsuvez	Lupkynis	Pyrukynd	Sunlenca	Vydura
Breyanzi	Fintepla	Mayzent	Qinlock	Sunosi	Vyepti
Brukinsa	Gavreto	Minjuvi	Quofenix	Tabrecta	Vyvgart
Byfavo	Giapreza	Mounjaro	Quviviq	Talzenna	Waylivra
Bylvay	Givlaari	Mulpleo	Rayvow	Tavlesse	Wegovy
Calquence	Hepcludex	Mycapssa	Reblozyl	Tavneos	Xenleta
Carvykti	Idefirix	Nexpovio	Recarbrio	Tecartus	Xenpozyme
Cibinqo	Imcivree	Nexviadyme	Rekambys	Tecovirimat SIGA	Xofluza
Copiktra	Inrebic	Ngenla	Retsevmo	Tecvayli	Xospata
Daurismo	Isturisa	Nilemdo	Rhokiinsa	Tepmetko	Yselty
Doptelet	Jemperli	Nubeqa	Rinvoq	Tezspire	Zeposia
Dovato	Jyseleca	Nulibry	Rizmoic	Trecondi	Zokinvy
Dovprela (previously Pretomanid FGK)	Kaftrio	Nustendi	Roclanda	Trepulmix	Zolgensma
Drovelis/Lydisilka	Kapruvia	Obiltoxaximab SFL	Roctavian	Trixeo Aerosphere	Zynlonta
Ebvallo	Kerendia	Ontozry	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 by segment: 2019-2022 approvals

Oncologics (n=48)

Zynlonta	Pemazyre
Pluvicto	Retsevmo
Opdualag	Tukysa
Scemblix	Enhertu
Tecvayli	Elzonris
Tabrecta	Phesgo
Lunsumio	Tecartus
Carvykti	Calquence
Orgovyx	Ayvakyt
Padcev	Blenrep
Breyanzi	Rozlytrek
Kimmtrak	Piqray
Tepmetko	Daurismo
Lumykras	Sarclisa
Rybrevant	Nubeqa
Brukinsa	Polivy
Trodelvy	Xospata
Gavreto	Vitrakvi
Qinlock	Libtayo
Minjuvi	Talzenna
Abecma	Trecondi
Copiktra	Lorviqua
Jemperli	Vizimpro
Nexpovio	Erleada

Orphans (n=63)

Ebvallo	Enspryng
Livmarli	Koselugo
Mycapssa	Sogroya
Enjaymo	Evrysdi
Livtencity	Pemazyre
Pyrukynd	Inrebic
Nulibry	Elzonris
Amvuttra	Fintepla
Scemblix	Libmeldy
Roctavian	Tecartus
Vyvgart	Oxlumo
Zokinvy	Obiltoxaximab SFL
Upstaza	Arikayce liposomal
Kinpeygo	Ayvakyt
Xenpozyme	Blenrep
Filsuvez	Idefirix
Lunsumio	Kaftrio
Carvykti	Dovprela
Kimmtrak	Hepcludex
Oxbryta	Daurismo
Ngenla	Reblozyl
Tavneos	Zolgensma
Skytrofa	Trepulmix
Voraxaze	Givlaari
Aspaveli	Polivy
Artesunate Amivas	Isturisa
Qinlock	Xospata
Minjuvi	Epidyolex
Voxzogo	Trecondi
Abecma	Palynziq
Bylvay	Waylivra
Imcivree	

Non-oncologic orphans (n=47)

Ebvallo	Imcivree
Livmarli	Enspryng
Mycapssa	Koselugo
Enjaymo	Sogroya
Livtencity	Evrysdi
Pyrukynd	Inrebic
Nulibry	Fintepla
Amvuttra	Libmeldy
Roctavian	Oxlumo
Vyvgart	Obiltoxaximab SFL
Zokinvy	Arikayce liposomal
Upstaza	Idefirix
Kinpeygo	Kaftrio
Xenpozyme	Dovprela
Filsuvez	Hepcludex
Oxbryta	Reblozyl
Ngenla	Zolgensma
Tavneos	Trepulmix
Skytrofa	Givlaari
Voraxaze	Isturisa
Aspaveli	Epidyolex
Artesunate Amivas	Palynziq
Voxzogo	Waylivra
Bylvay	

Combination therapies (n=13)

Opdualag
Ryeqo
Drovelis/Lydisilka
Sibnayal
Roclanda
Phesgo
Trixeo Aerosphere
Kaftrio
Enerzair Breezhaler / Zimbus Breezhaler
Atectura Breezhaler / Bemrist Breezhaler
Nustendi
Recarbrio
Dovato

Notes: Segments are not mutually exclusive; *Trelegy Ellipta and Elebrato Ellipta are considered as one product 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
Czech	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	Products that are accessible in Denmark and available for public reimbursement
England	Medicines are deemed available if NICE has issued a positive recommendation. 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	A pharmacy product is available if it is on a national reimbursement list. Hospital products need an appraisal for COHERE (Council of Choices in Healthcare in Finland) or from the National Assessment Network coordinated by FinCCHTA (Finnish Coordinating Center for HTA).
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)
North Macedonia	Product is available via specially allocated budget for all eligible patients
Malta	Accessibility on the public reimbursement list
Netherlands	Accessibility on the public reimbursement list
Norway	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	Availability according to the National Health Information Center. For remaining medicines, IQVIA sales data is used.
Slovenia	A medicine is available if it is reimbursed through the regular system, or automatically reimbursed
Spain	Medicines are deemed available if SMC has issued a positive recommendation. For the remaining medicines, IQVIA sales data are analysed to determine if routinely available.
Sweden	A medicine is classified as available (nationally reimbursed) if it was marketed in Sweden as of December 21st 2023 (listed as supplied in FASS), and: Is indicated for a disease included in the communicable disease program, or Had received a positive TLV decision (prescribed drugs), or - Had received a positive recommendation from the New Therapies (NT) Council (hospital drugs), or - Had not received an NT-recommendation and is not part of national managed introduction (hospital drugs)
Switzerland	The medicine gained market approval by Swissmedic. Delay calculated using local market authorisation dates.
Turkey	A medicine is available if it gains access to the reimbursement list.

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	No products are reported to have limited availability
Bosnia	There are no restrictions on availability meaning medicines are reimbursable in all approved patient populations
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	Reimbursment is only granted, on an indivitual name patient basis or for specifi subpopulations of the approved indications.
Czech	Reimbursed only if: (a) prescribed by specific speciality of physician; (b) specific setting (e.g. Centers of excellence) (c) hospital product only
Denmark	Products that have received a partial recommendation or are not recommended by the Danish Medicines Council as well as products that have received conditional reimbursement or individual reimbursement by The Reimbursement Committee.
England	Recommended for a restricted patient cohort relative to licensed indication, either: (a) through an optimised NICE decision (including optmised CDF decisions) or an individual funding request. (b) where at least one indication is recommended for use but either optmised, not recommended, or no decision reached to date for another indication.
Estonia	Only reimbursed for restricted patient cohort.
Finland	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.
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	There are no restrictions on availability
North Macedonia	Product is available via specially allocated budget for limited number of patients
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).
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	Drugs included in the reimbursement list have some limitation (prescription limitation, indication limitation and limitation based on prior insurance company approval), or are reimbursed for individual patients
Slovenia	Only reimbursed for restricted patient cohort
Spain	Recommended for a resticted patient cohort relative to licensed indication by SMC using their HTA process (through submission or resubmission).
Sweden	Only reimbursed for restricted patient cohort
Switzerland	For products pending reimbursement, patients have restricted reimbursement access. Such restricted access includes 'individual reimbursement' regulated by Art. 71a-b of KVV ordinance.
Turkey	Products only available through a "Named Patient Scheme". These medicines do not require TITCK (Turkish Medical Agency) approval but are reimbursed.

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	The first date of availability on the public reimbursement list available on the website of the payer INAMI-RIZIV : https://ondpanon.riziv.fgov.be/SSPWebApplicationPublic/fr/Public/ProductSearch
Bosnia	The first date of availability on the public reimbursement list
Bulgaria	In general, new innovative products are eligible for reimbursement as of 1st January following the year they have been included in PDL, however there are nuances and exceptions.
Croatia	The first date of availability on the public reimbursement list
Cyprus	The first date of availability on the public reimbursement list
Czech	The first date of availability on the public reimbursement list
Denmark	Products are available when they have been marketed on the Danish pharmaceutical market and a price has been listed on Medicinpriser.dk.
England	For medicines with a positive NICE recommendation, the accessibility date is the date of publication of the Final Draft Guidance produced by NICE (oncology medicines), or date of published guidance + 90 days (non-oncology medicines). Oncology medicines benefit from earlier funding. For the remaining medicines, IQVIA sales data is analysed to determine month of routine availability.
Estonia	Availability date of reimbursement list and date of inclusion to the health service list or state project tender decision time.
Finland	Availability for reimbursed products is the date of Pharmaceutical Pricing Board approval. For hospital products, the date of availability is the COHERE appraisal date OR the National Assessment Network appraisal date.
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 first date of availability on the public reimbursement list
Luxembourg	The date of the decision to include the medicine into 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.
Malta	The first date of availability on the public reimbursement list
Netherlands	The first date of availability on the public reimbursement list; or for hospital products, the date of the positive decision in Decision Forum
Norway	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.
Poland	The first date of availability on the public reimbursement list
Portugal	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.
Romania	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.
Scotland	The first date of availability on the public reimbursement list
Serbia	The first date of availability on the public reimbursement list (published on monthly basis)
Slovakia	The first date of availability on the public reimbursement list
Slovenia	For medicines with a positive SMC recommendation, the accessibility date is the date of published guidance. For the remaining medicines, the IQVIA sale data is analysed to determine month of routine availability.
Spain	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)
Sweden	For medicines indicated For diseases included in the communicable disease program: date of marketing in Sweden (supplied in FASS); For nationally reimbursed prescription medicines with a TLV decision: date of TLV decision; For nationally reimbursed hospital drugs with an NT-recommendation: date of NT recommendation; For nationally reimbursed hospital medicines lacking an NT-recommendation and not part of national managed introduction: date of marketing in Sweden (supplied in FASS)
Switzerland	The date of full availability is the first date of availability on the public reimbursement list; the date of limited availability is the first date of availability on the list of products reimbursed through “Named Patient Scheme”

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