EFPIA Patients W.A.I.T. Indicator 2022 Survey

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Max Newton, *Engagement Manager, Strategic Partners (GS&AR)*
Kelsey Stoddart, *Consultant, Global Supplier & Association Relations*
Marco Travaglio, *Consultant, Global Supplier & Association Relations*
Per Troein, *VP, Strategic Partners*

This year's Patients W.A.I.T. indicator covers 37 countries, including the full EU27 countries

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

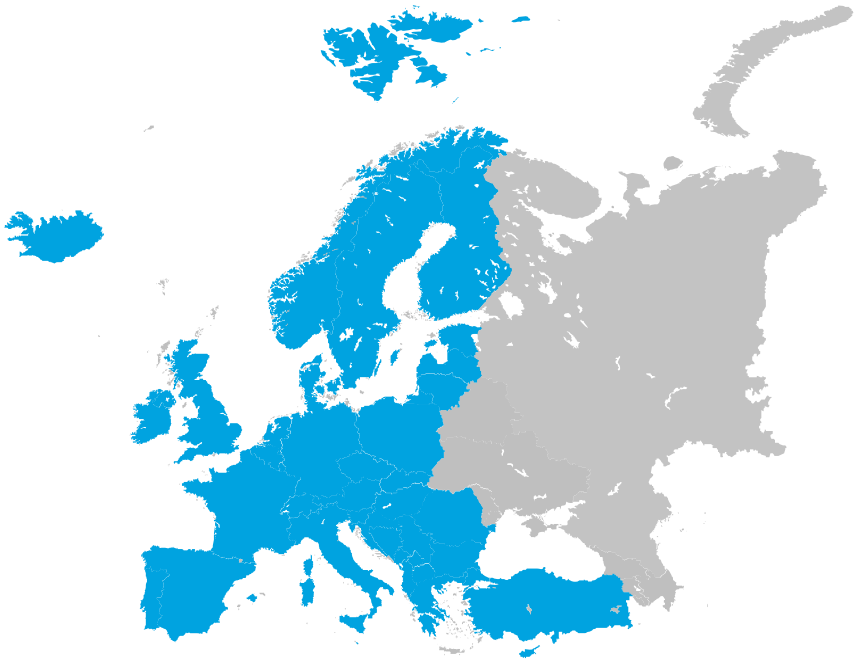
Foreword from the IQVIA project team:

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 37 countries (27 EU, and 10 non-EU), giving a full European picture of availability. Information on the 168 innovative medicines with central-marketing authorisation between 2018 and 2021 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 2023.* 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.



2022 WAIT indicator: 7 KPIs for 5 cohorts of medicines

This year's survey includes median median time to availability

~45%

EU average rate of availability in 2022 vs 47% in the previous study

517 days

Average time for a new medicine to be available in European market is 6 days longer than the previous study

Access gap between the highest and lowest country is **83%** in the 4-year cohort, and **80%** for longer timelines

<0.3%

Of products are reimbursed after longer than 4 years

Data coverage

Full data coverage for 31 out of the 37 countries included

Study composition

Includes fewer orphan and combination products than the previous study

Limited availability

1 in 3 available medicines are granted limited availability

Access disparities

persist between Northern/Western and Southern/Eastern European countries

Orphan drugs

take the longest time to reimburse across all studied segments

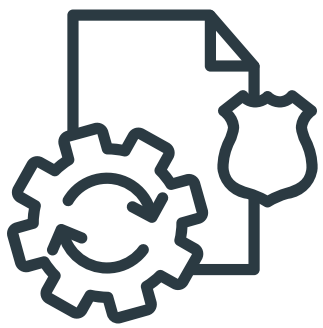
Source: EFPIA Patients WAIT indicator (2022 and 2023)

Contents

Click on hyperlinks for navigation to specific indicators

Patients W.A.I.T. survey has evolved, and is entering its 19th 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.

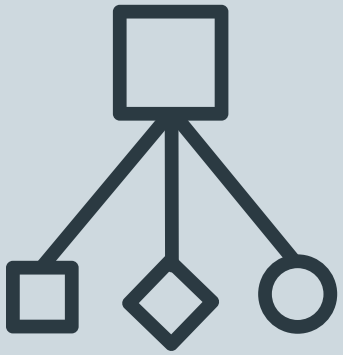
2004 2005 2006 2007 2008 2009 2010 2011 2012 2013 2014 2015 2016 2017 2018 2019 2020 2021 2022 2023

EFPIA/ CRA report on root causes

Sources include: https://www.efpia.eu/media/412416/market-access-delays-2017-final-140318.pdf; https://www.efpia.eu/media/412747/efpia-patient-wait-indicator-study-2018-results-030419.pdf 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/676539/efpia-patient-wait-indicator_update-july-2022_final.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 standarised measurement across 37 healthcare systems

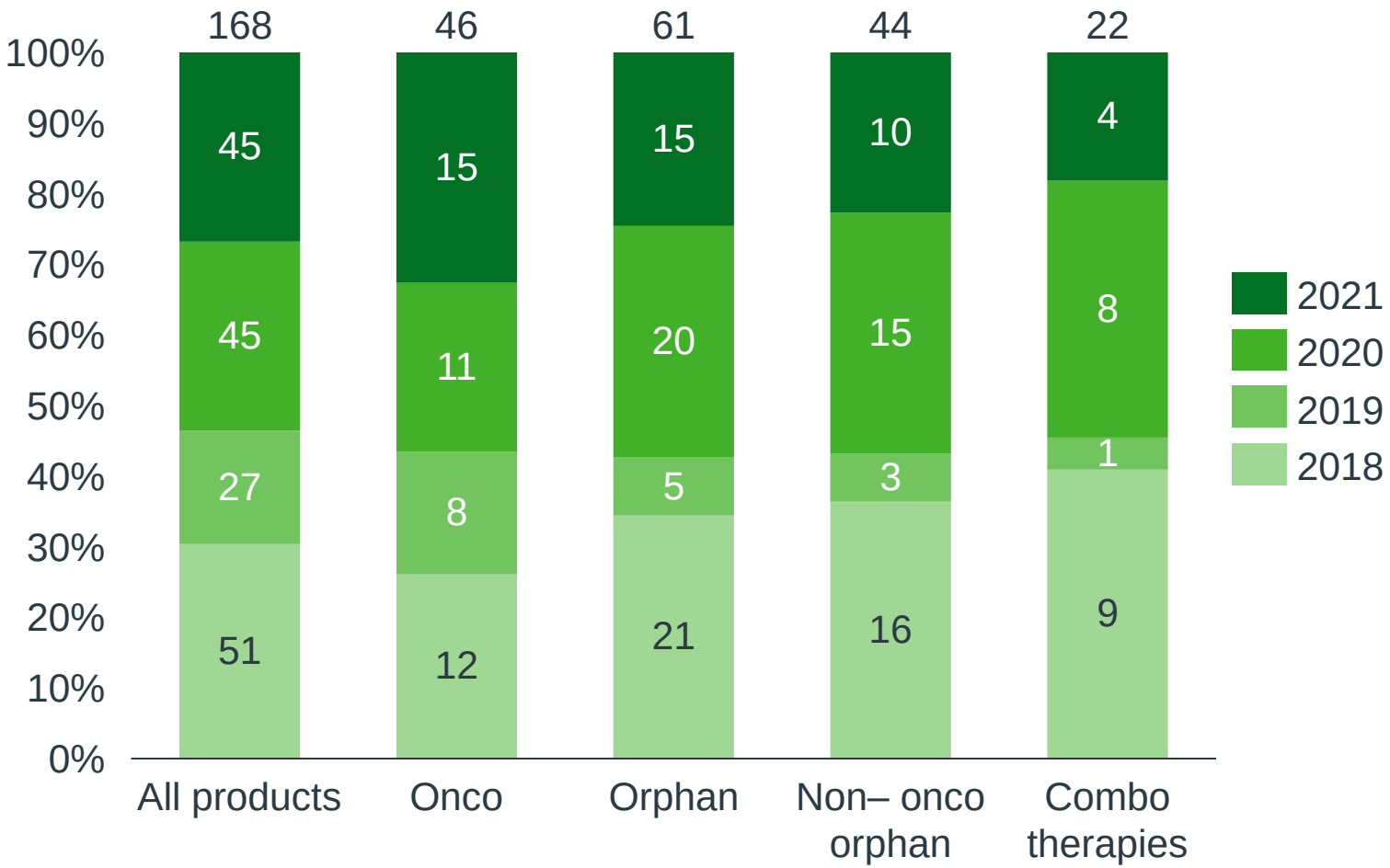
“Inclusion of a centrally-approved medicine on the public reimbursement list in a country”

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	
All products	Products with central marketing authorisation, sourced from **EMA EPARs** (last accessed November 2022)
Orphan drug	Orphan status from EMA **on orphan medical products (OMP)** status
Oncology	Oncology products flagged using **IQVIA MIDAS Oncology market** definition: L1 & L2 & V3C & Revlimid & Xgeva & Proleukin & Pomalyst
Combination products	Combination products **include any product with more than one molecule**, including branded / generic combinations in fixed doses. There are **no free-dose combinations included** within the study

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, Macedonia, Serbia, Switzerland and Turkey.

Completeness: Some country associations did not submit full datasets. Countries substantially limited data sets are: Albania (33% complete), Bosnia (49% complete), Croatia (45% complete), Cyprus (59% complete), and Macedonia (56% complete). This is noted on slides with an asterisk (*).

Average calculations: The EU averages noted throughout are averages for the 27 countries in the European Union. This is the second 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

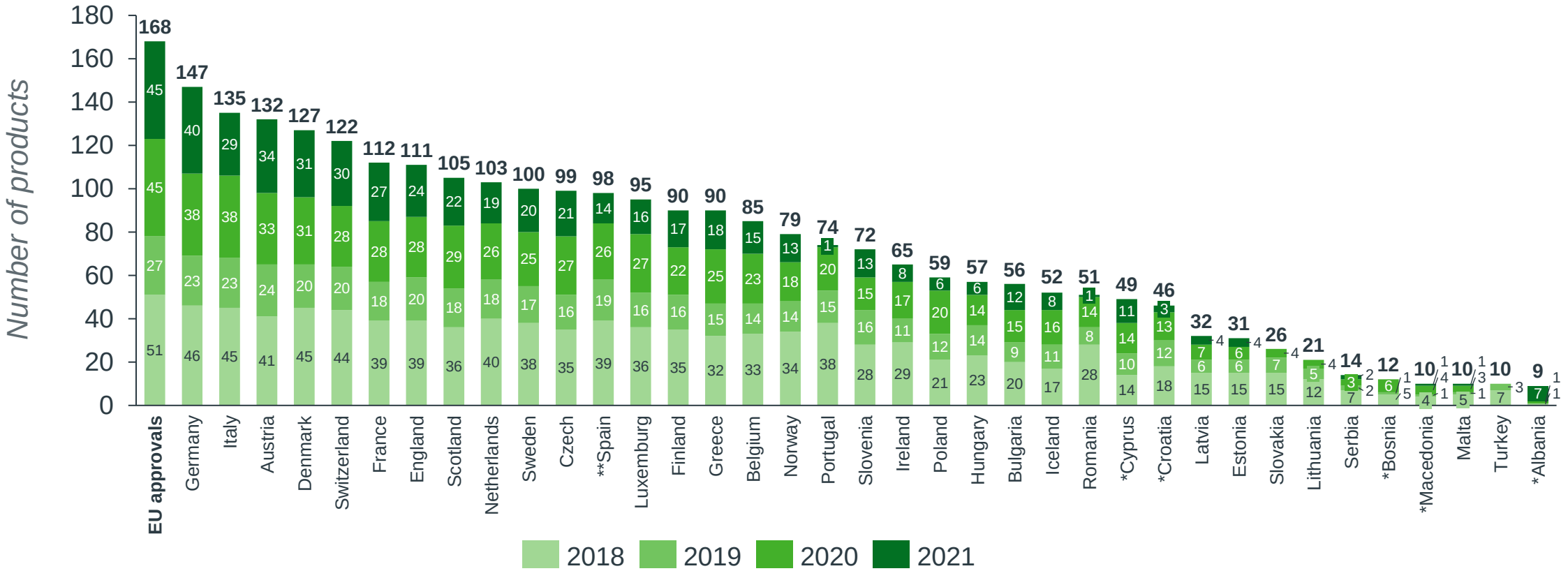
1. Overview (all products)

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 (2018-2021)

The **total availability by approval year** is the number of medicines available to patients in European countries as of 5th January 2023 (for most countries this is the point at which the product gains access to the reimbursement list†), split by the year the product received marketing authorisation in Europe.



European Union average: 76 products available (45%) †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

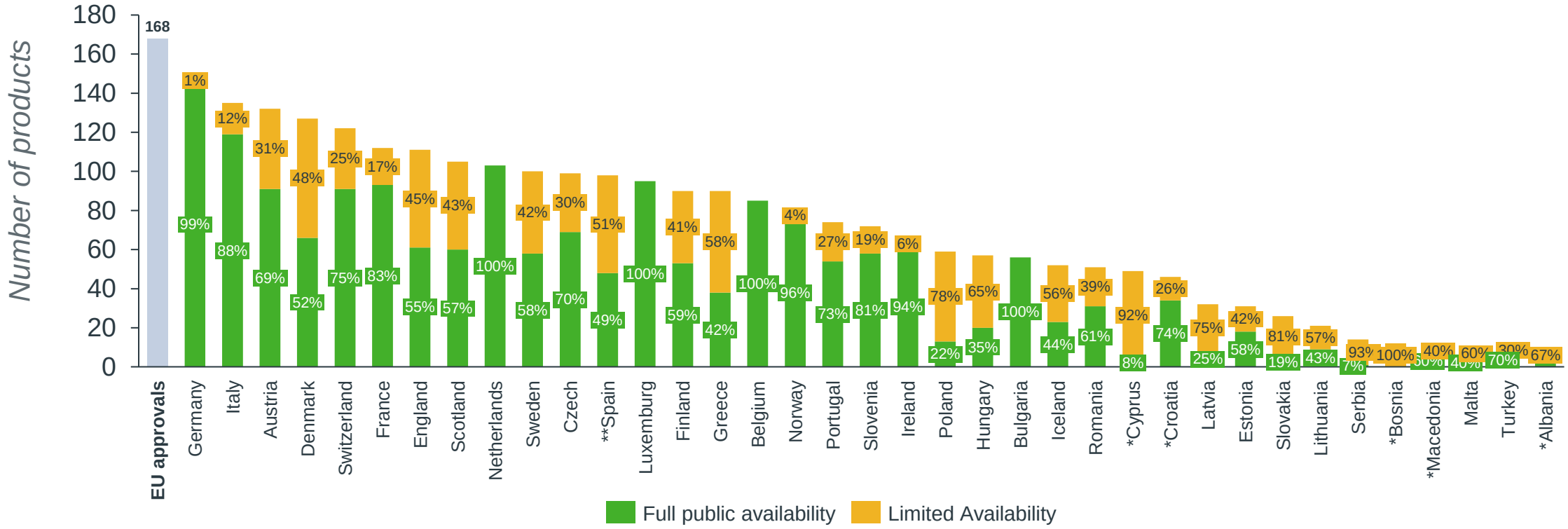
Rate of availability (2018-2021)

The **rate of availability**, measured by the number of medicines available to patients in European countries as of 5th January 2023. 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: 76 products available (45%) †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 (%, 2018-2021)

The **rate of full availability** shows the proportion of medicines available to patients in European countries as of 5th January 2023 (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: 76 products available (45%), Limited Availability (37% 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

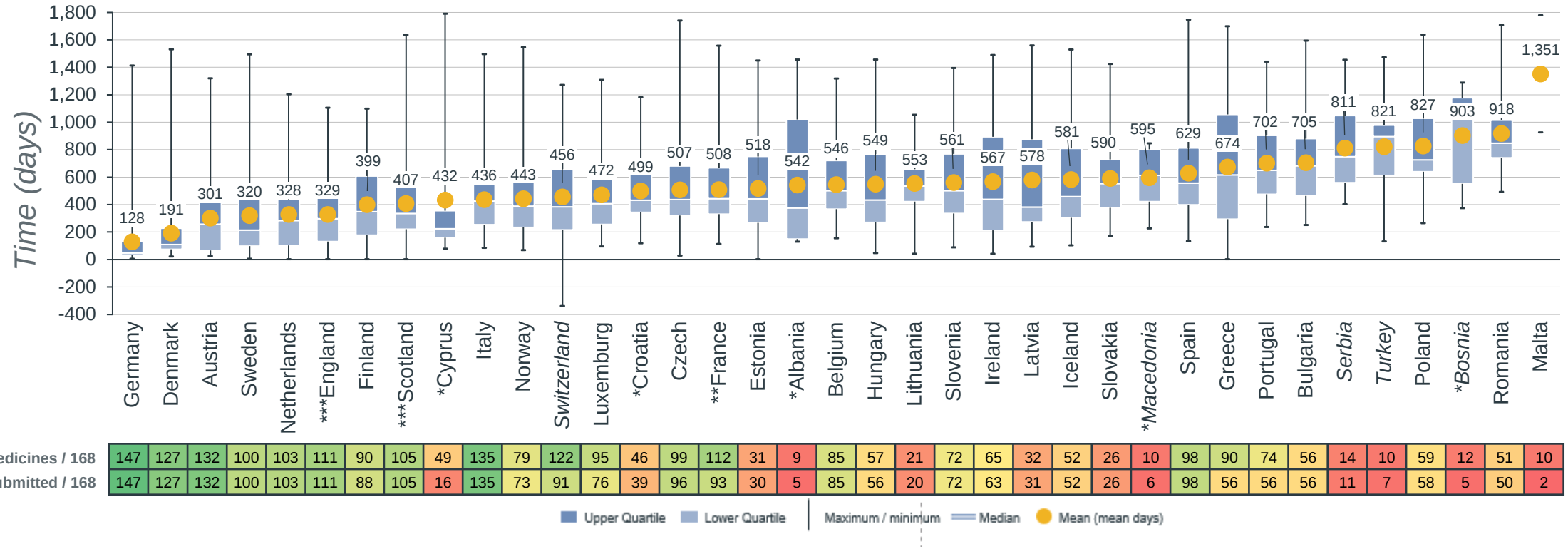
Breakdown of availability (%, 2018-2021)

The **breakdown of availability** is the composition of medicines available to patients in European countries as of 5th January 2023 (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: 76 products available (45%), Limited availability (14% 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 (2018-2021)

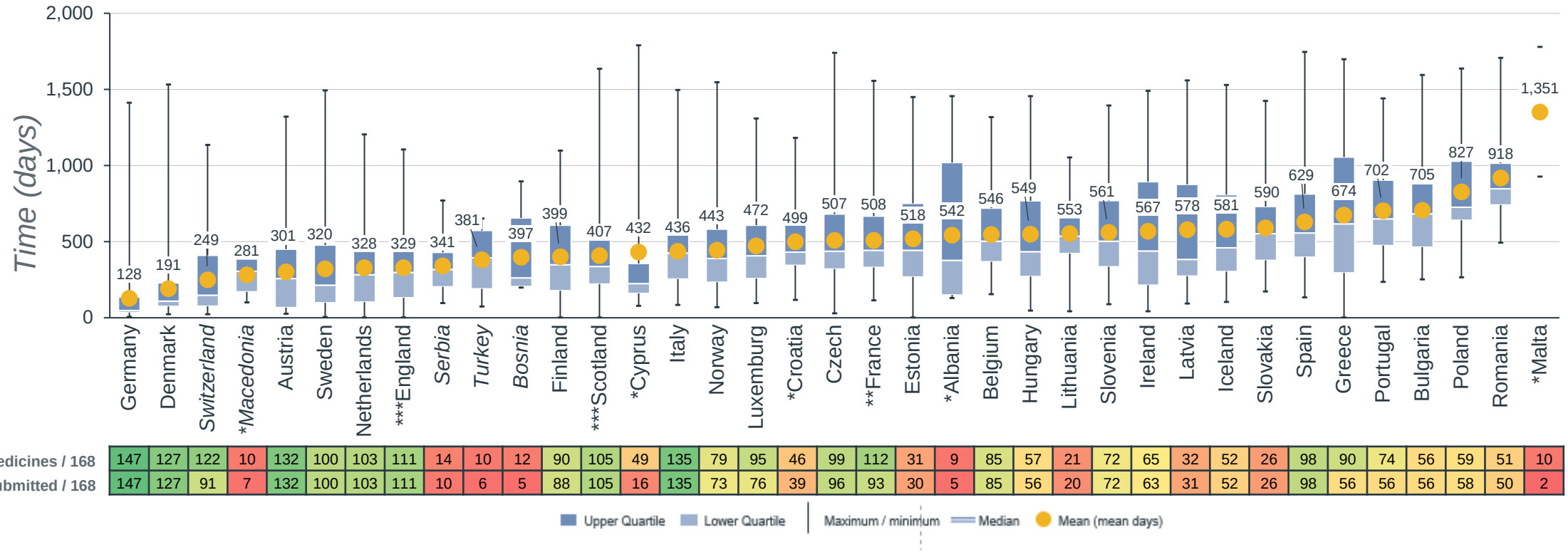
The **time from central approval to availability** is the days between marketing authorisation and the date of availability to patients in European countries (for most this is the point at which products gain access to the reimbursement list†). The marketing authorisation date is the date of central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



European Union average: 517 days (mean %) (Note: Malta is not included in EU27 average as only 2 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 (508 days, n=93 dates submitted) does not include products under the ATU system for which the price negotiation process is usually longer. ***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 (2018-2021)

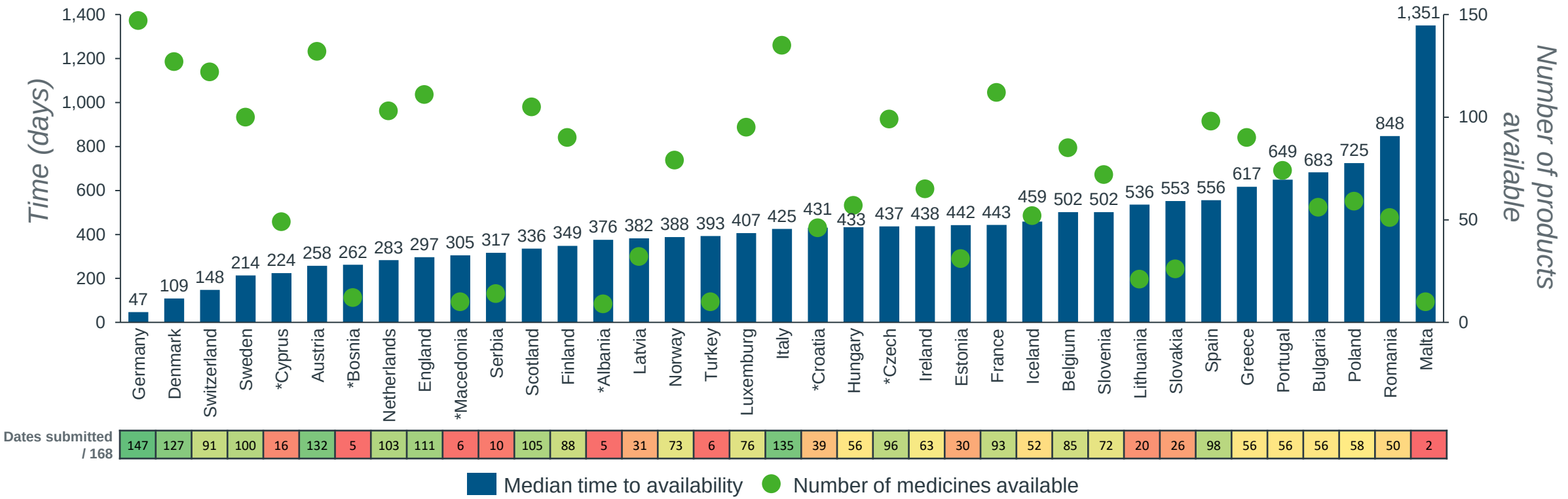
The **time to availability** is the days between marketing authorisation and the date of availability to patients in European countries (for most this is the point at which products gain access to the reimbursement list†). The marketing authorisation date is the date of central EU authorisation in most countries, except for countries shown in italics where local authorisation dates have been used. Data is correct to 5th January 2023.



European Union average: 517 days (mean %) (Note: Malta is not included in EU27 average as only 2 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 (508 days, n=93 dates submitted) does not include products under the ATU system for which the price negotiation process is usually longer. ***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.

Median time to availability (2018-2021)

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 2023.



European Union average: 442 days (median) (Note: Malta is not included in EU27 average as only 2 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 (443 days, n=93 dates submitted) does not include products under the ATU system for which the price negotiation process is usually longer. ***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.

Key observations

Executive summary (EU27 averages)

Measure	All products	Oncology	Orphan	Non-oncologic orphan	Combination therapy
Average rate of availability	45% (47% in 2021)	50% ↓ (59% in 2021)	39% (37% in 2021)	39% (35% in 2021)	50% (54% in 2021)
Average time to availability	517 Days (511 days in 2021)	526 Days (545 days in 2021)	625 Days (636 days in 2021)	626 Days ↑ (587 days in 2021)	426 Days (407 days in 2021)

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 28 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 (2022) EU average (*significantly higher than current EU average* / *significantly lower 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 only 2 dates were submitted in total

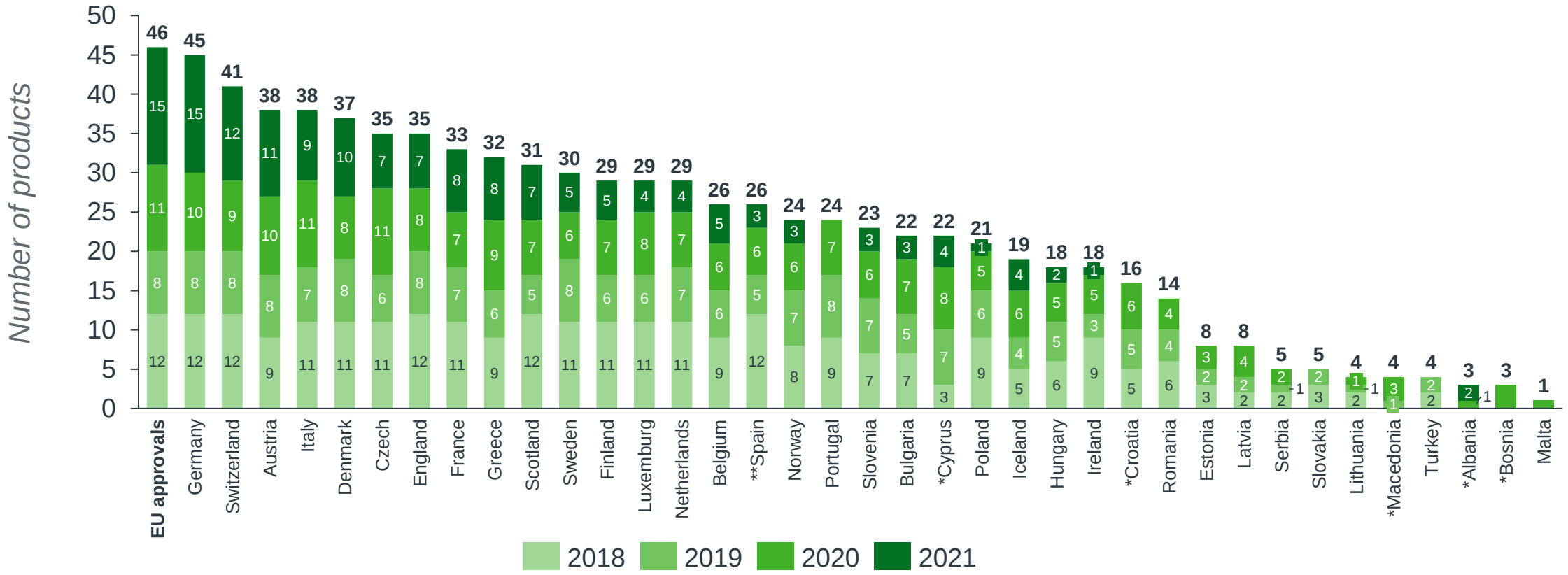
2. Oncology medicines

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 (2018-2021)

The **total availability by approval year** is the number of medicines available to patients in European countries as of 5th January 2023 (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: 23 products available (50%) †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

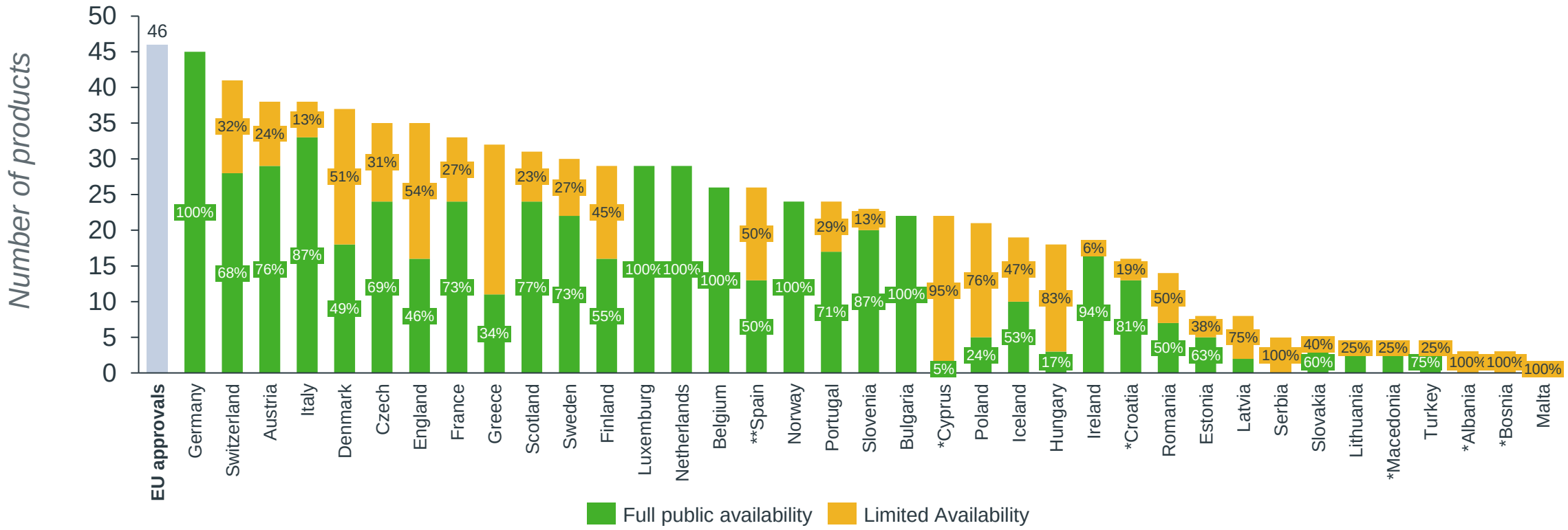
Oncology rate of availability (2018-2021)

The **rate of availability**, measured by the number of medicines available to patients in European countries as of 5th January 2023. 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: 23 products available (50%) †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 (%, 2018-2021)

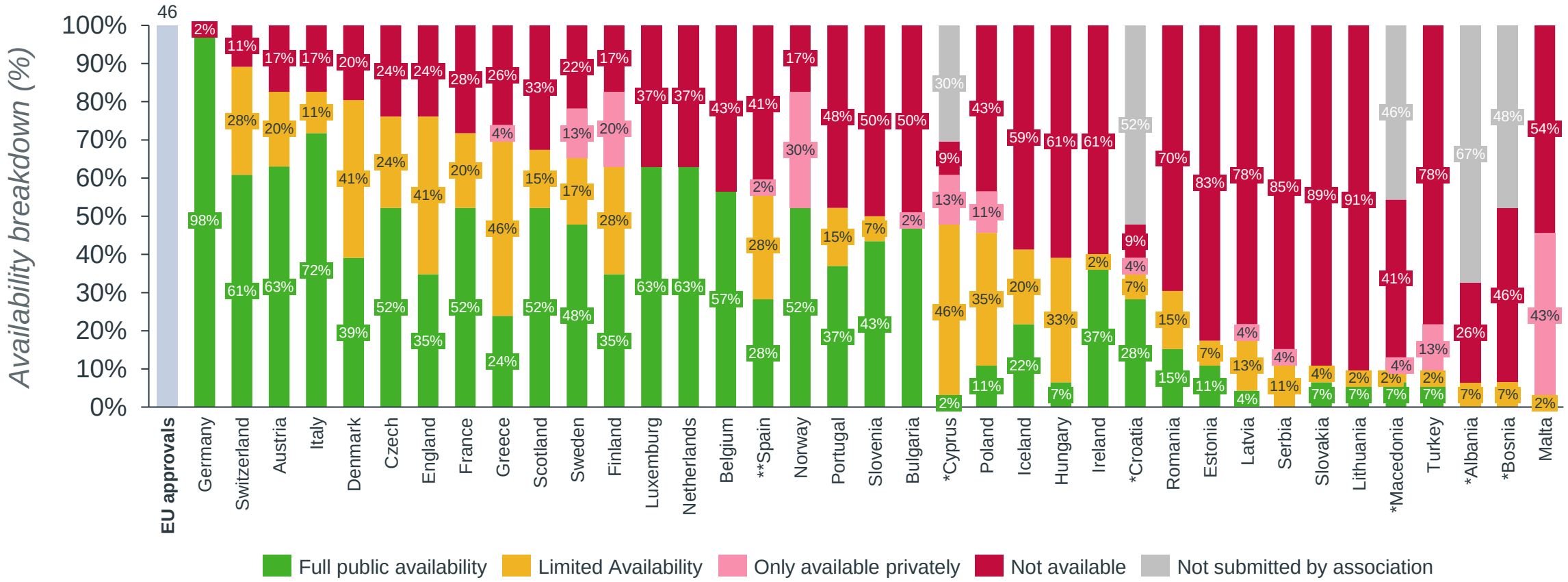
The **rate of full availability** shows the proportion of medicines available to patients in European countries as of 5th January 2023 (for most countries this is the point at which the product gains access to the reimbursement list†) without any restrictions to the patient population, or through named patient basis schemes which have increased significantly in recent years and were not always captured in survey submissions.



European Union average: 23 products available (50%), Limited availability (36% 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 (%, 2018-2021)

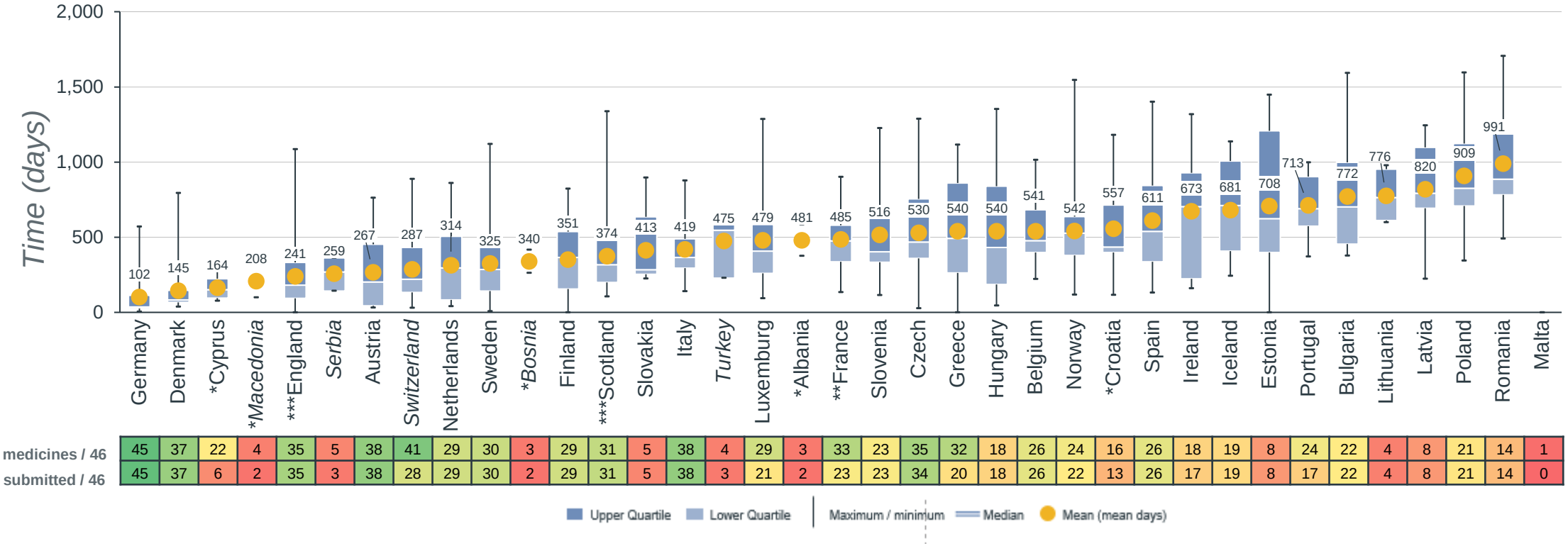
The **breakdown of availability** is the composition of medicines available to patients in European countries as of 5th January 2023 (for most countries this is the point at which the product gains access to the reimbursement list†). This includes all medicine's status to provide a complete picture of the availability of the cohort studied.



European Union average: 23 products available (50%), Limited availability (16% 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 (2018-2021)

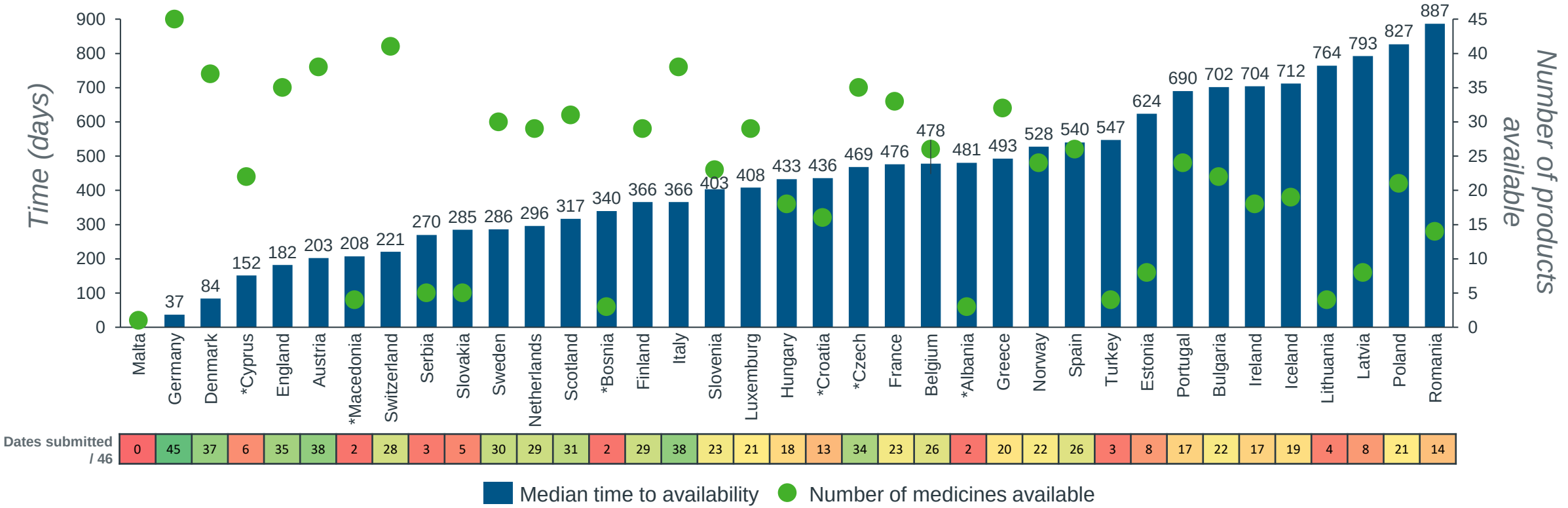
The **time to availability** is the days between marketing authorisation and the date of availability to patients in European countries (for most this is the point at which products gain access to the reimbursement list†). The marketing authorisation date is the date of central EU authorisation in most countries, except for countries shown in italics where local authorisation dates have been used. Data is correct to 5th January 2023.



European Union average: 526 days (mean) †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 (485 days, n=23 dates submitted) does not include products under the ATU system for which the price negotiation process is usually longer. ***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.

Oncology median time to availability (2018-2021)

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 2023.



European Union average: 469 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 (476 days, n=23 dates submitted) does not include products under the ATU system for which the price negotiation process is usually longer. ***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.

Key observations

Executive summary (EU27 averages)

Measure	All products	Oncology	Orphan	Non-oncologic orphan	Combination therapy
Average rate of availability	45% (47% in 2021)	50% (59% in 2021) ↓	39% (37% in 2021)	39% (35% in 2021)	50% (54% in 2021)
Average time to availability	517 Days (511 days in 2021)	526 Days (545 days in 2021)	625 Days (636 days in 2021)	626 Days (587 days in 2021) ↑	426 Days (407 days in 2021)

Metrics key:

Text colour indicates relative position versus the current (2022) EU average (*significantly higher than current EU average* / *significantly lower 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 only 2 dates were submitted in total

Key Insights

Rate of availability

- The EU's rate of availability for oncology medicines was 5% higher than the average rate of availability for all products in 2022, but has reduced compared to 2021
- For the second consecutive year, Germany is the only country to have full availability for all oncology products

Time to availability

- The average delay from marketing authorisation to patient access for oncology products varies from 3 to 30 months (>2.5 years)
- The average time to availability for oncology products is 19 days faster than in 2021

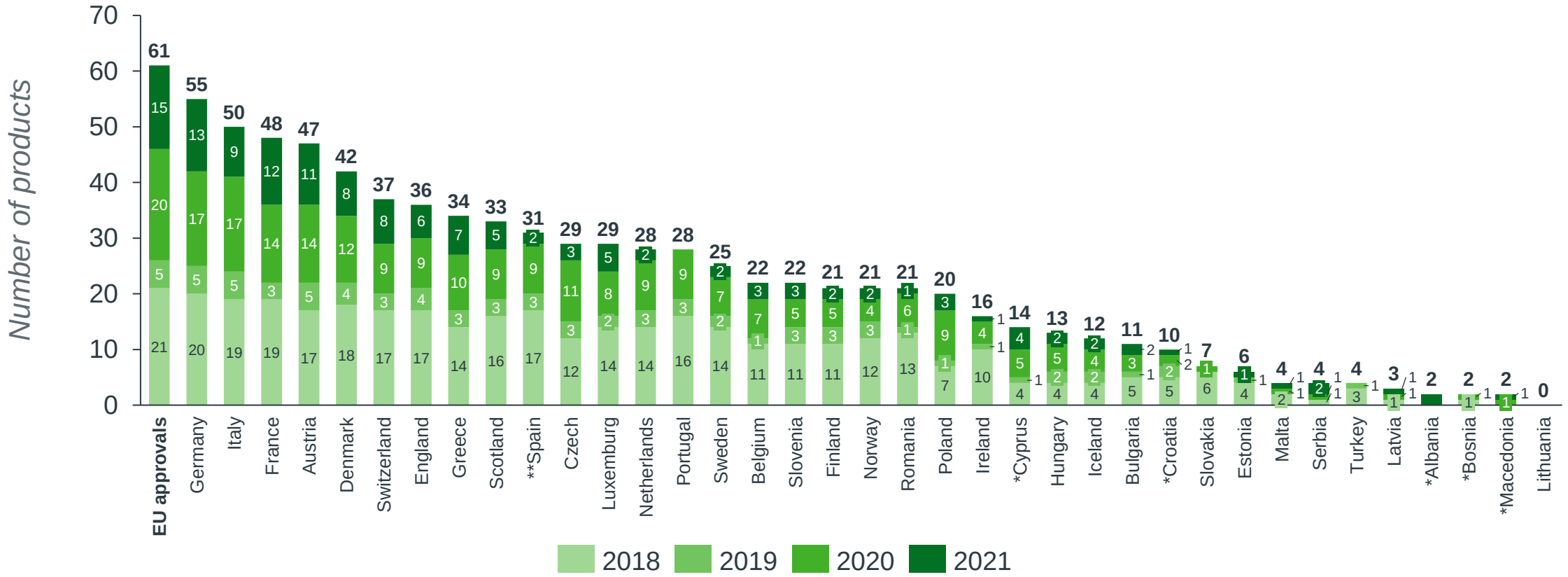
3. Orphan medicines

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 (2018-2021)

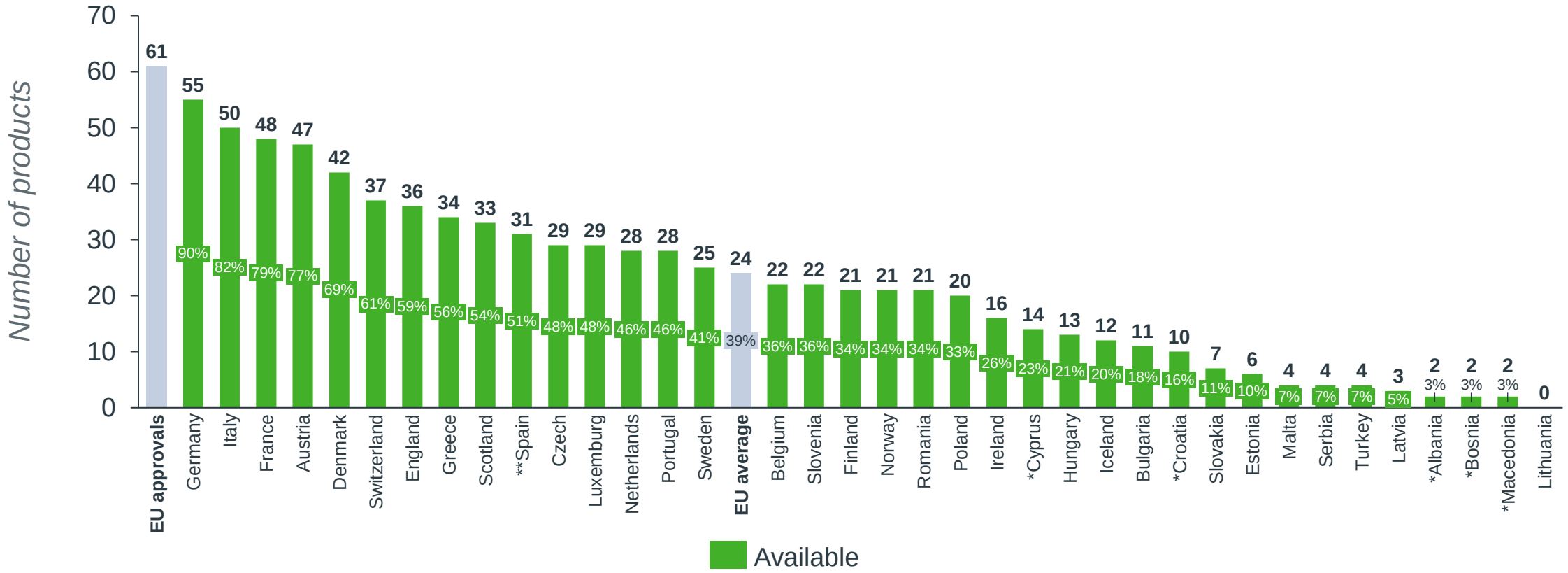
The **total availability by approval year** is the number of medicines available to patients in European countries as of 5th January 2023 (for most countries this is the point at which the product gains access to the reimbursement list†), split by the year the product received marketing authorisation in Europe.



European Union average: 24 products available (39%) †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 (2018-2021)

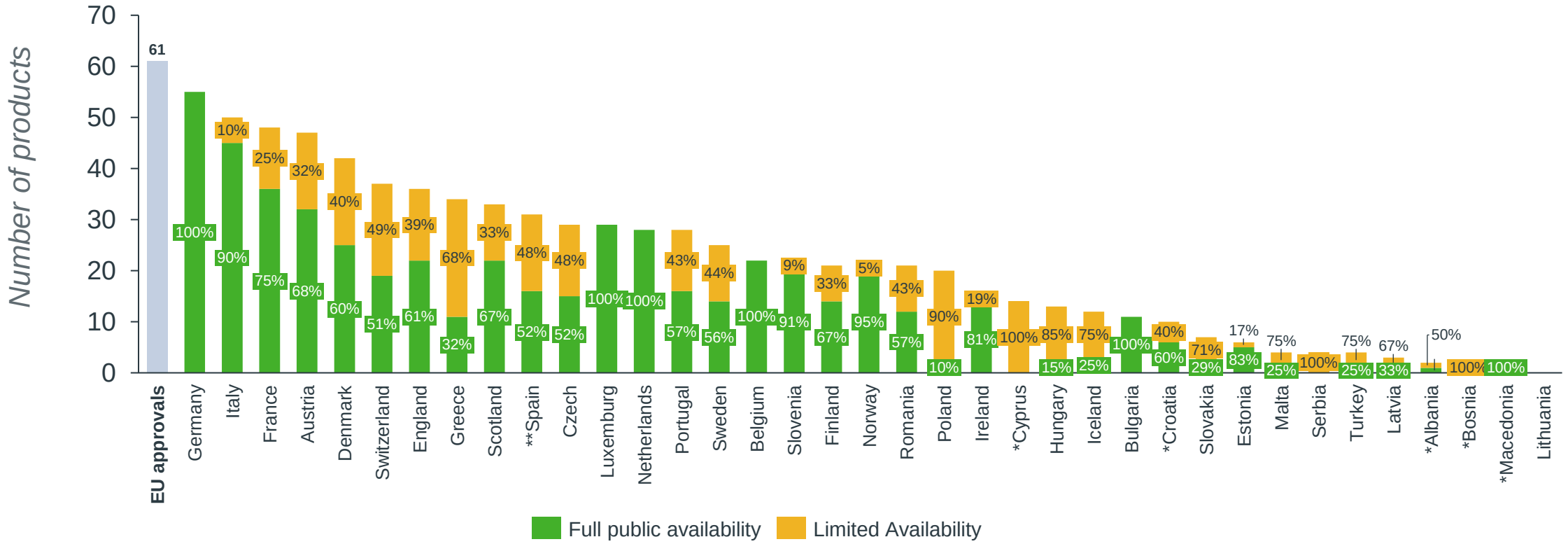
The **rate of availability**, measured by the number of medicines available to patients in European countries as of 5th January 2023. For most countries this is the point at which the product gains access to the reimbursement list†, including products with limited availability.



European Union average: 24 products available (39%) †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 (%, 2018-2021)

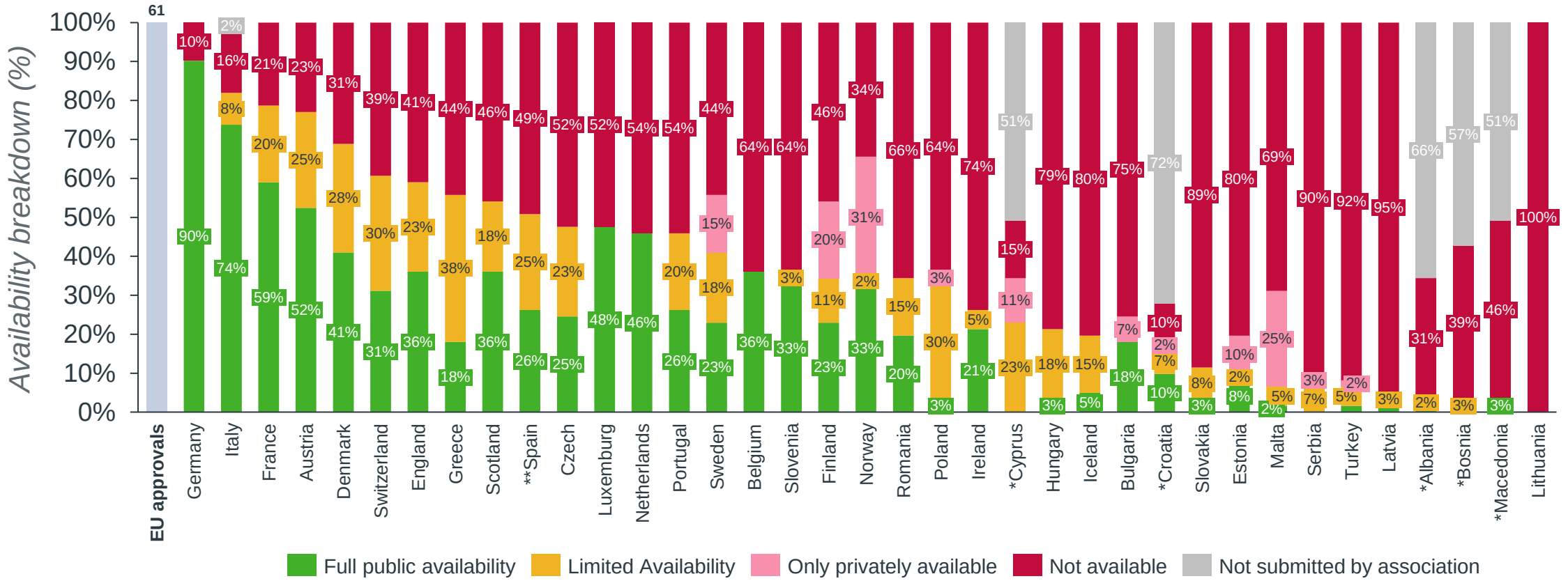
The **rate of full availability** shows the proportion of medicines available to patients in European countries as of 5th January 2023 (for most countries this is the point at which the product gains access to the reimbursement list†) without any restrictions to the patient population, or through named patient basis schemes which have increased significantly in recent years and were not always captured in survey submissions.



European Union average: 24 products available (39%), limited availability (39% 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 (%, 2018-2021)

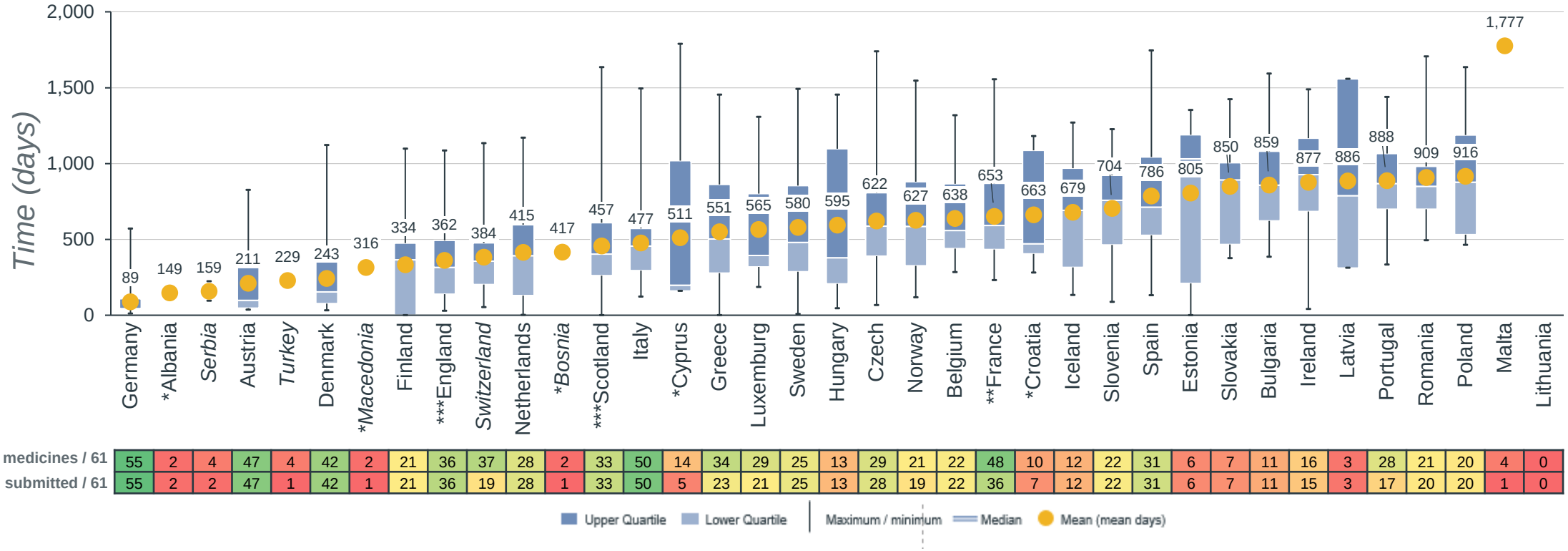
The **breakdown of availability** is the composition of medicines available to patients in European countries as of 5th January 2023 (for most countries this is the point at which the product gains access to the reimbursement list†). This includes all medicine's status to provide a complete picture of the availability of the cohort studied.



European Union average: 24 products available (39%), Limited availability (12% 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 (2018-2021)

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 2022.

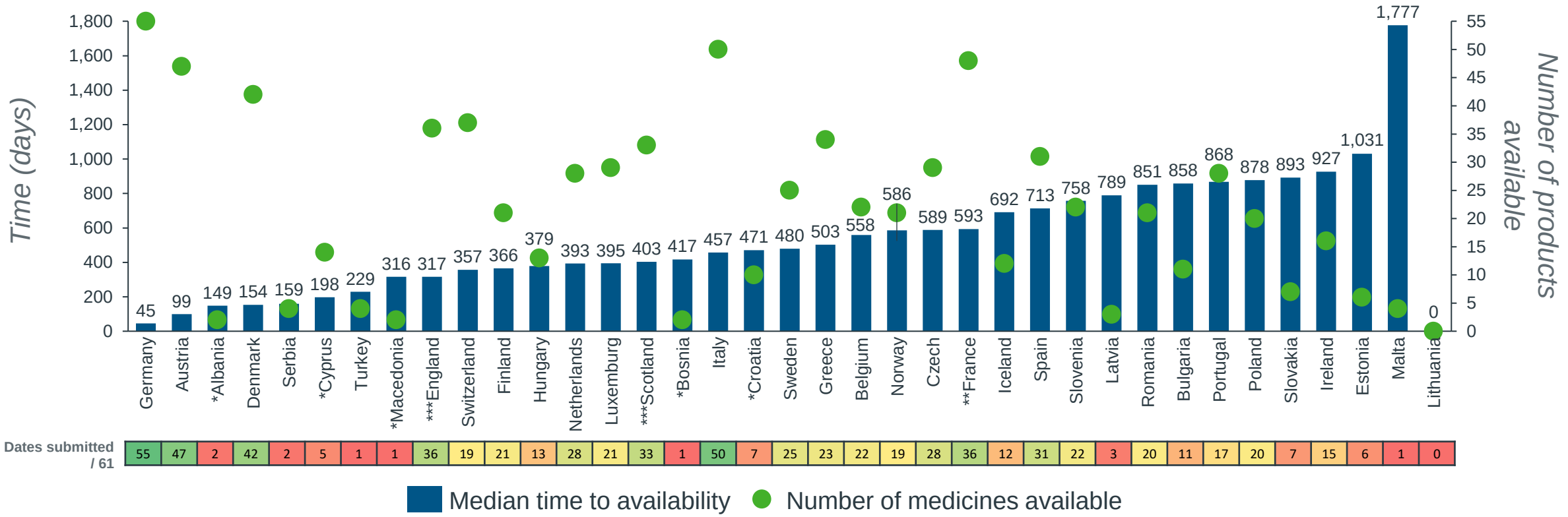


	Germany	*Albania	Serbia	Austria	Turkey	Denmark	*Macedonia	Finland	***England	Switzerland	Netherlands	*Bosnia	***Scotland	Italy	*Cyprus	Greece	Luxemburg	Sweden	Hungary	Czech	Norway	Belgium	**France	*Croatia	Iceland	Slovenia	Spain	Estonia	Slovakia	Bulgaria	Ireland	Latvia	Portugal	Romania	Poland	Malta	Lithuania
Available medicines / 61	55	2	4	47	4	42	2	21	36	37	28	2	33	50	14	34	29	25	13	29	21	22	48	10	12	22	31	6	7	11	16	3	28	21	20	4	0
Dates submitted / 61	55	2	2	47	1	42	1	21	36	19	28	1	33	50	5	23	21	25	13	28	19	22	36	7	12	22	31	6	7	11	15	3	17	20	20	1	0

European Union average: 625 days (mean) (Note: Malta is not included in EU27 average as only 2 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 (653 days, n=36 dates submitted) does not include products under the ATU system for which the price negotiation process is usually longer. ***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.

Orphan median time to availability (2018-2021)

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 2023.



European Union average: 548 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 (589 days, n=36 dates submitted) does not include products under the ATU system for which the price negotiation process is usually longer. ***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.

Key observations

Executive summary (EU27 averages)

Measure	All products	Oncology	Orphan	Non-oncologic orphan	Combination therapy
Average rate of availability	45% (47% in 2021)	50% (59% in 2021) ↓	39% (37% in 2021)	39% (35% in 2021)	50% (54% in 2021)
Average time to availability	517 Days (511 days in 2021)	526 Days (545 days in 2021)	625 Days (636 days in 2021)	626 Days (587 days in 2021) ↑	426 Days (407 days in 2021)

Key Insights

Rate of availability

- Average rate of availability for orphan medicines is 6% lower than the average for all products
- In CEE countries, the rate of availability for orphan drugs is 11%, which represents a 10% decline since last year's survey and a 20% decline since 2018

Time to availability

- The average time to availability for orphan products is nearly 4 months slower than the average for all products
- 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 (2022) EU average (*significantly higher than current EU average* / *significantly lower 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 only 2 dates were submitted in total

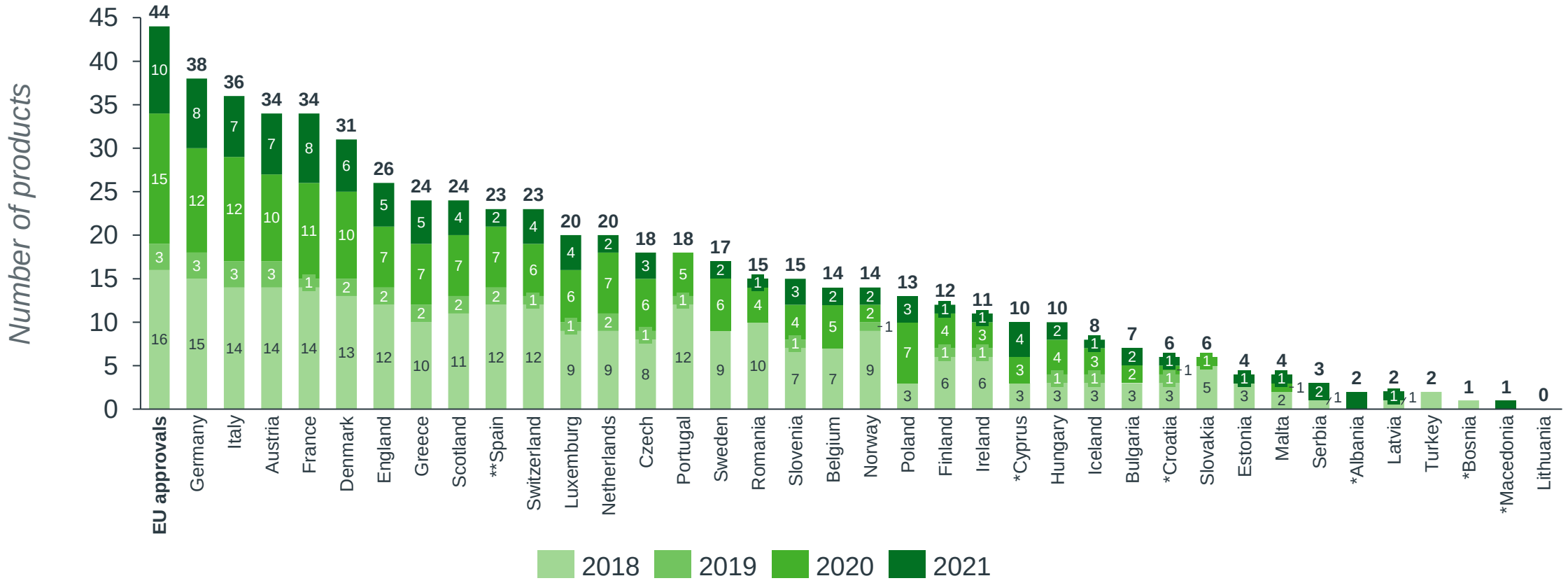
4. Non-oncology orphan medicines

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 (2018-2021)

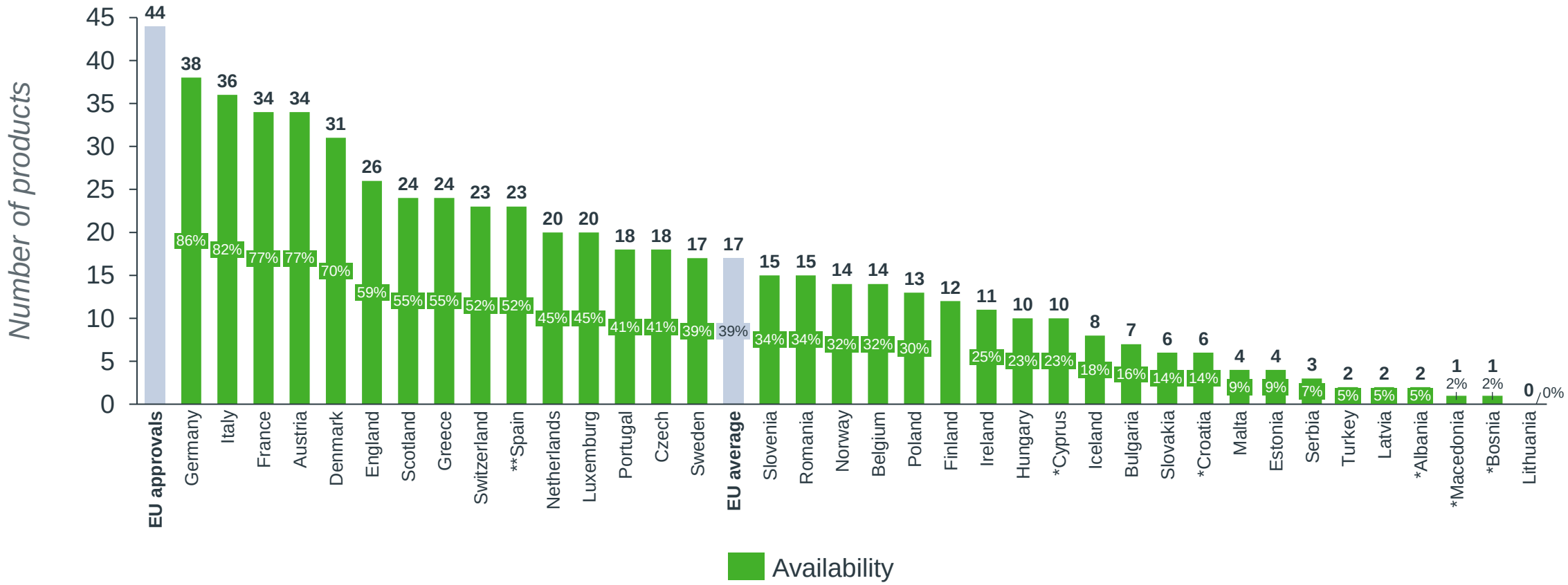
The **total availability by approval year** is the number of medicines available to patients in European countries as of 5th January 2023 (for most countries this is the point at which the product gains access to the reimbursement list†), split by the year the product received marketing authorisation in Europe.



European Union average: 17 products available (39%) †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 (2018-2021)

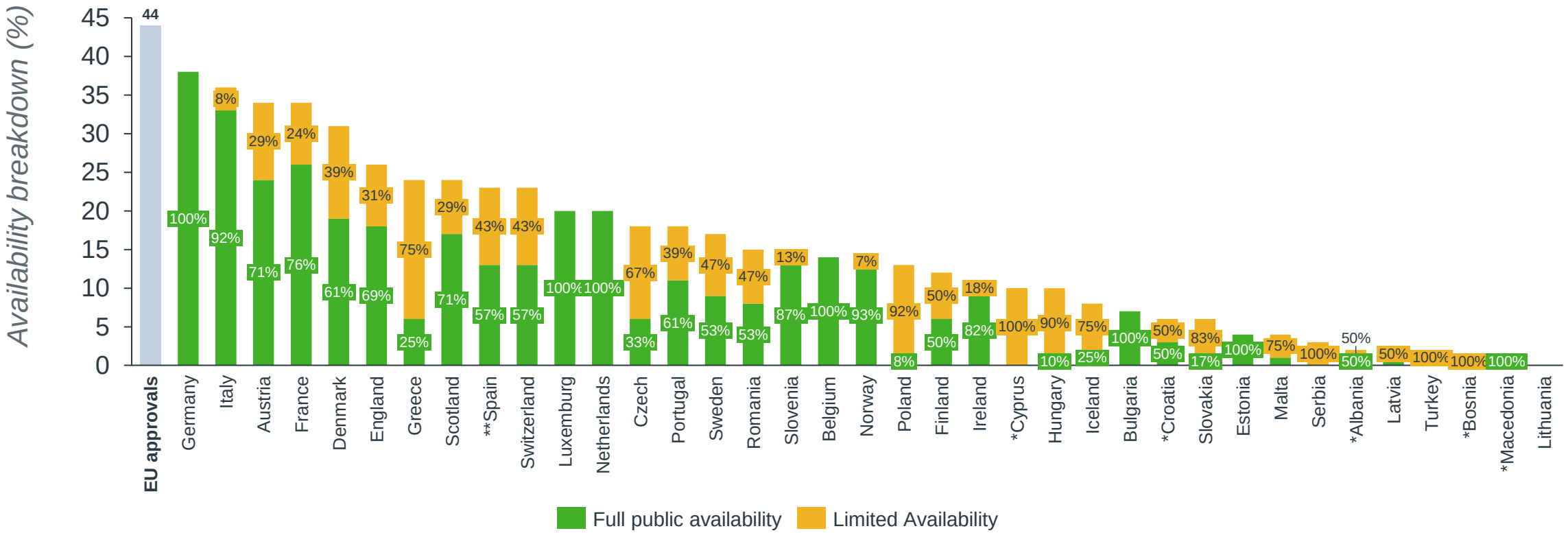
The **rate of availability**, measured by the number of medicines available to patients in European countries as of 5th January 2023. For most countries this is the point at which the product gains access to the reimbursement list†, including products with limited availability.



European Union average: 17 products available (39%) †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 (%, 2018-2021)

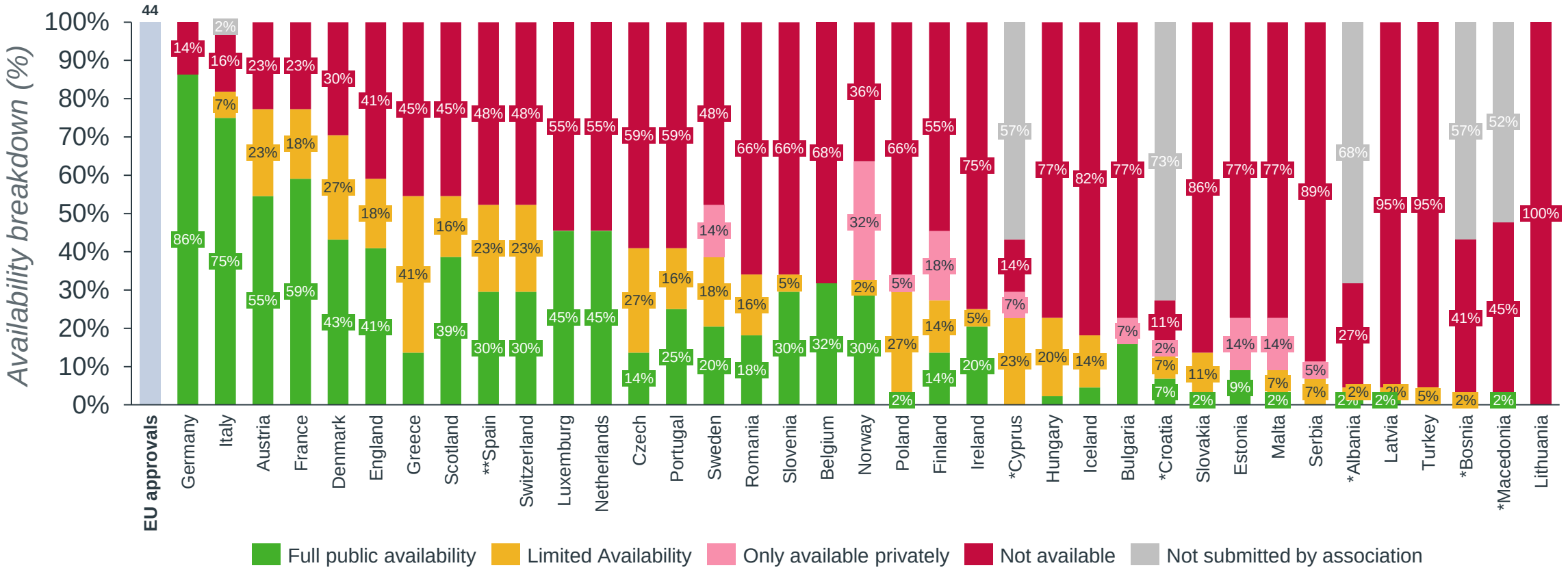
The **rate of full availability** shows the proportion of medicines available to patients in European countries as of 5th January 2023 (for most countries this is the point at which the product gains access to the reimbursement list†) without any restrictions to the patient population, or through named patient basis schemes which have increased significantly in recent years and were not always captured in survey submissions.



European Union average: 17 products available (39%), 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

Non-oncology orphan breakdown of availability (%, 2018-2021)

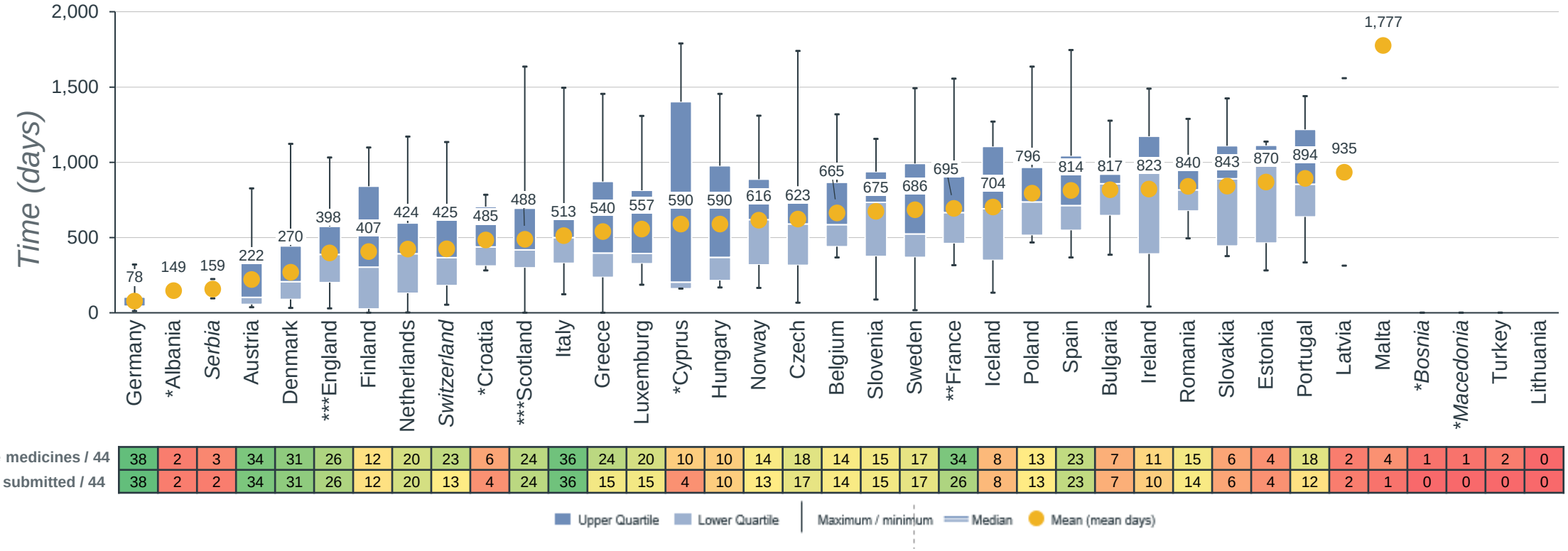
The **breakdown of availability** is the composition of medicines available to patients in European countries as of 5th January 2023 (for most countries this is the point at which the product gains access to the reimbursement list†). This includes all medicine's status to provide a complete picture of the availability of the cohort studied.



European Union average: 17 products available (39%), Limited availability (12% 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 (2018-2021)

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 2023.



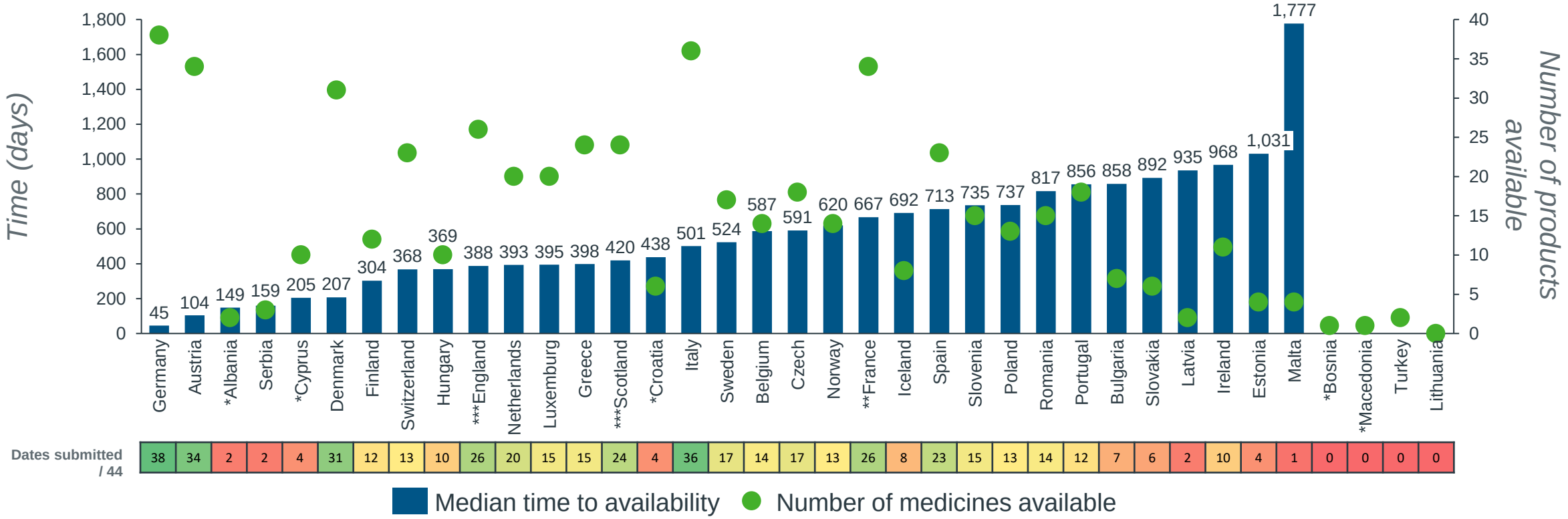
	Germany	*Albania	Serbia	Austria	Denmark	***England	Finland	Netherlands	Switzerland	*Croatia	***Scotland	Italy	Greece	Luxemburg	*Cyprus	Hungary	Norway	Czech	Belgium	Slovenia	Sweden	**France	Iceland	Poland	Spain	Bulgaria	Ireland	Romania	Slovakia	Estonia	Portugal	Latvia	Malta	*Bosnia	*Macedonia	Turkey	Lithuania
Available medicines / 44	38	2	3	34	31	26	12	20	23	6	24	36	24	20	10	10	14	18	14	15	17	34	8	13	23	7	11	15	6	4	18	2	4	1	1	2	0
Dates submitted / 44	38	2	2	34	31	26	12	20	13	4	24	36	15	15	4	10	13	17	14	15	17	26	8	13	23	7	10	14	6	4	12	2	1	0	0	0	0

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

European Union average: 626 days (mean) (Note: Malta is not included in EU27 average as only 2 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 (695 days, n=26 dates submitted) does not include products under the ATU system for which the price negotiation process is usually longer. ***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.

Non-oncology orphan median time to availability (2018-2021)

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 2023.



European Union average: 571 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 (667 days, n=26 dates submitted) does not include products under the ATU system for which the price negotiation process is usually longer. ***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.

Key observations

Executive summary (EU27 averages)

Measure	All products	Oncology	Orphan	Non-oncologic orphan	Combination therapy
Average rate of availability	45% (47% in 2021)	50% (59% in 2021) ↓	39% (37% in 2021)	39% (35% in 2021)	50% (54% in 2021)
Average time to availability	517 Days (511 days in 2021)	526 Days (545 days in 2021)	625 Days (636 days in 2021)	626 Days (587 days in 2021) ↑	426 Days (407 days in 2021)

Key Insights

Rate of availability

- Average rate of availability for non-oncology orphan medicines is 6% lower than the average for all products
- Nearly a quarter of countries studied had access to less than 10% of all non-oncology orphan products that received central approval in 2021

Time to availability

- The average time to availability for non-oncology orphan products is nearly 4 months slower than the average for all products, making it the segment with the slowest 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 (2022) EU average (*significantly higher than current EU average* / *significantly lower 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 only 2 dates were submitted in total

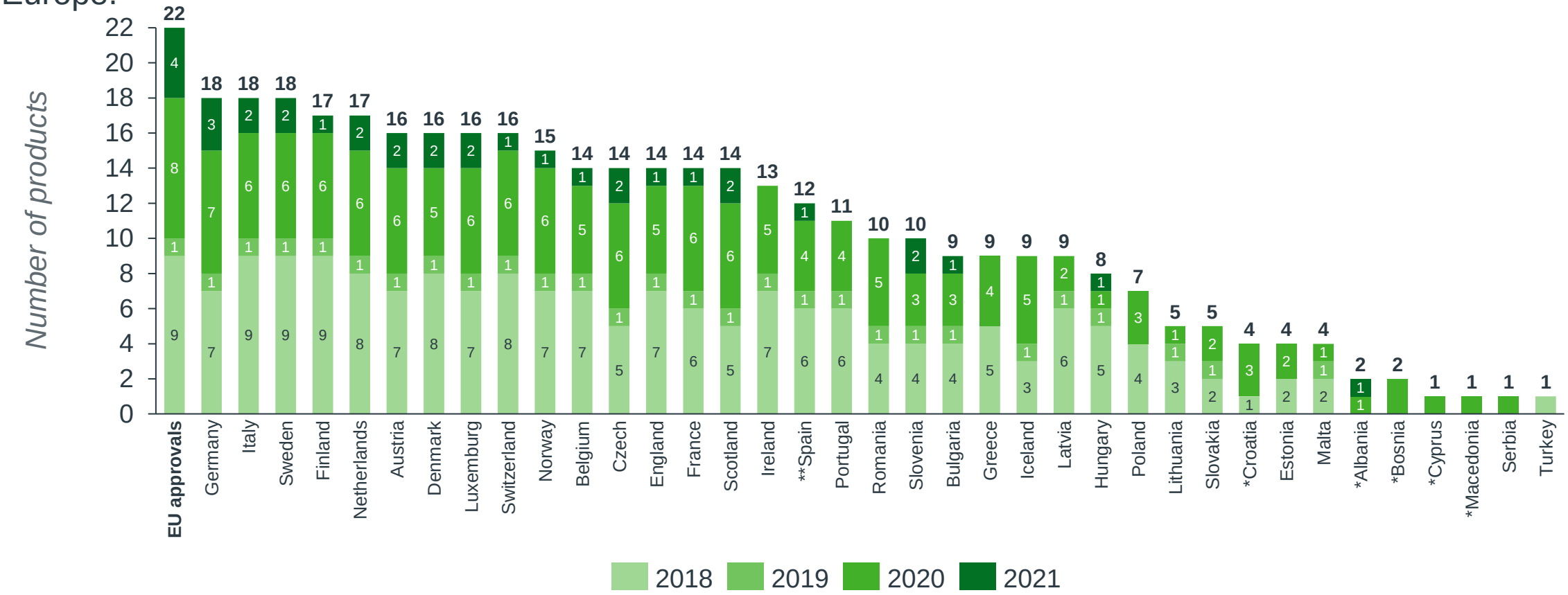
5. Combination therapies

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 (2018-2021)

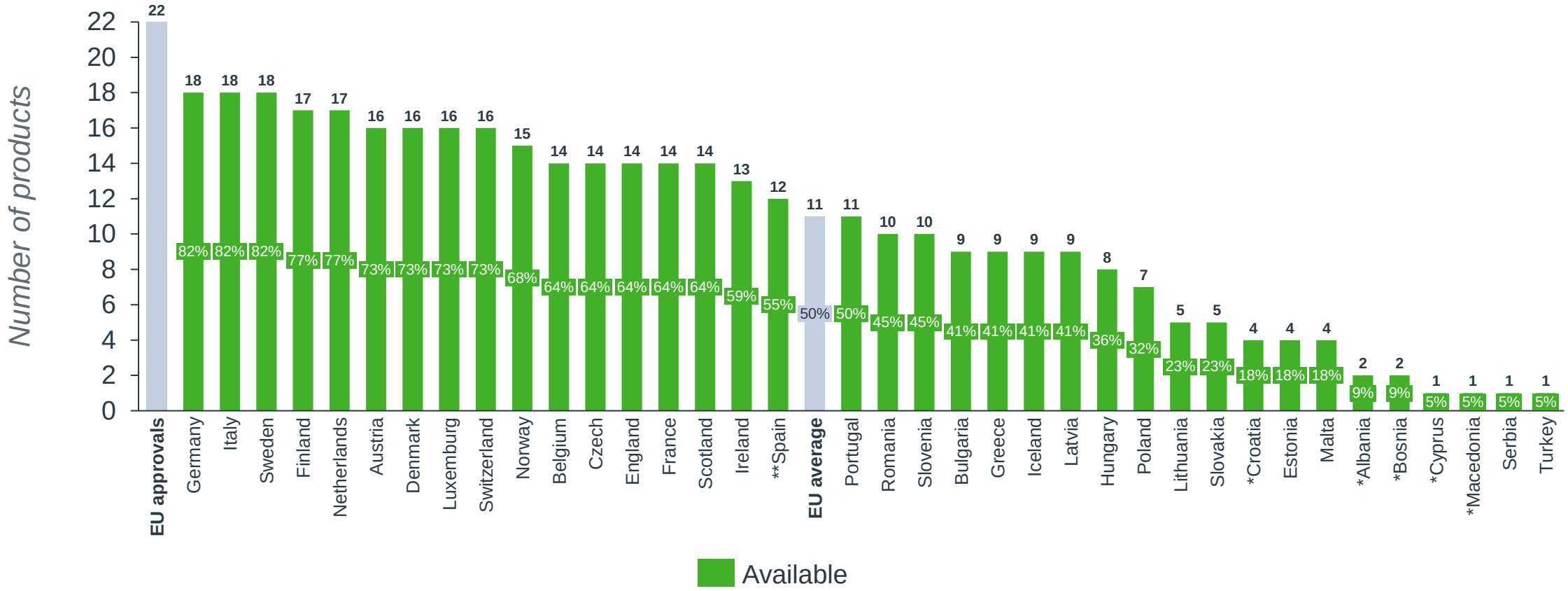
The **total availability by approval year** is the number of fixed dose combination medicines available to patients in European countries as of 5th January 2023 (for most countries this is the point at which the product gains access to the reimbursement list†), split by the year the product received marketing authorisation in Europe.



European Union average: 11 products available (50%) 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 (2018-2021)

The **rate of availability**, measured by the number of fixed dose combination medicines available to patients in European countries as of 5th January 2023. 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: 11 products available (50%) 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 (%, 2018-2021)

The **rate of full availability** shows the proportion of fixed dose combination medicines available to patients in European countries as of 5th January 2023 (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: 11 products available (50%), limited availability (27% 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

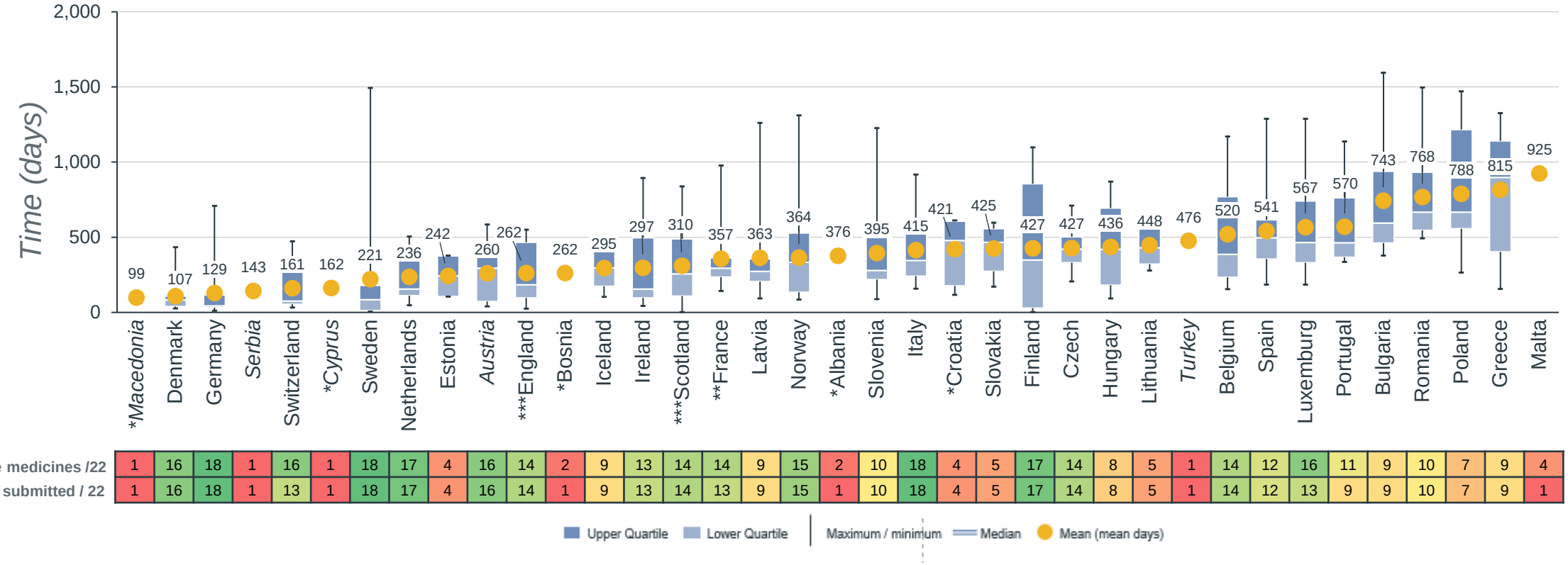
Combination therapies breakdown of availability (%, 2018-2021)

The **breakdown of availability** is the composition of fixed dose combination medicines available to patients in European countries as of 5th January 2023 (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: 11 products available (50%) , Limited availability (9% 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 (2018-2021)

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 2022.



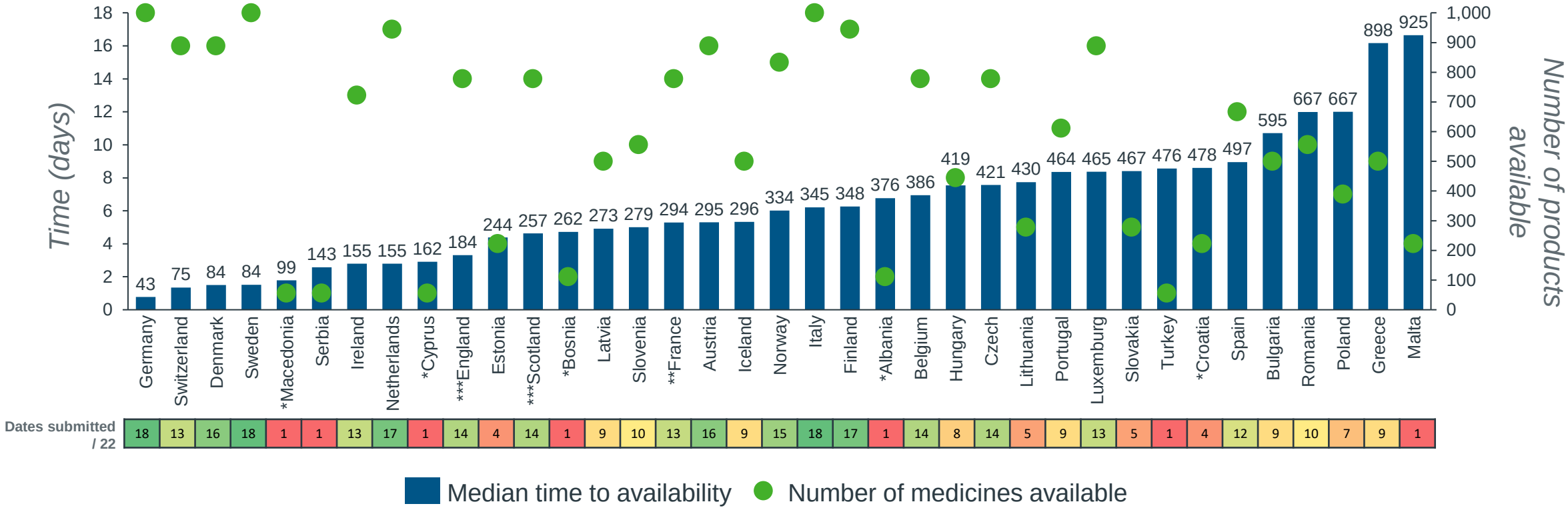
Available medicines /22	1	16	18	1	16	1	18	17	4	16	14	2	9	13	14	14	9	15	2	10	18	4	5	17	14	8	5	1	14	12	16	11	9	10	7	9	4
Dates submitted / 22	1	16	18	1	13	1	18	17	4	16	14	1	9	13	14	13	9	15	1	10	18	4	5	17	14	8	5	1	14	12	13	9	9	10	7	9	1

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

European Union average: 426 days (mean) (Note: Malta is not included in EU27 average as only 2 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, the time to availability (357 days, n=13 dates submitted) does not include products under the ATU system for which the price negotiation process is usually longer. ***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.

Combination median time to availability (2018-2021)

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 2023.



European Union average: 370 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 (294 days, n=13 dates submitted) does not include products under the ATU system for which the price negotiation process is usually longer. ***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.

Key observations

Executive summary (EU27 averages)

Measure	All products	Oncology	Orphan	Non-oncologic orphan	Combination therapy
Average rate of availability	45% (47% in 2021)	50% ↓ (59% in 2021)	39% (37% in 2021)	39% (35% in 2021)	50% (54% in 2021)
Average time to availability	517 Days (511 days in 2021)	526 Days (545 days in 2021)	625 Days (636 days in 2021)	626 ↑ Days (587 days in 2021)	426 Days (407 days in 2021)

Key Insights

Rate of availability

- Average rate of availability for combination therapies is 5% higher than the average for all products
- The rate of availability for combination therapies remains broadly consistent with the previous study, despite the lower number of central approvals (50% decline)

Time to availability

- The time to availability for combination therapies is the fastest across all segments, with an average of ~14 months vs ~17 months for all products
- For nearly 80% of all countries, the time to availability of combination therapies is less than 16 months

Metrics key:

Text colour indicates relative position versus the current (2022) EU average (*significantly higher than current EU average* / *significantly lower 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 only 2 dates were submitted in total

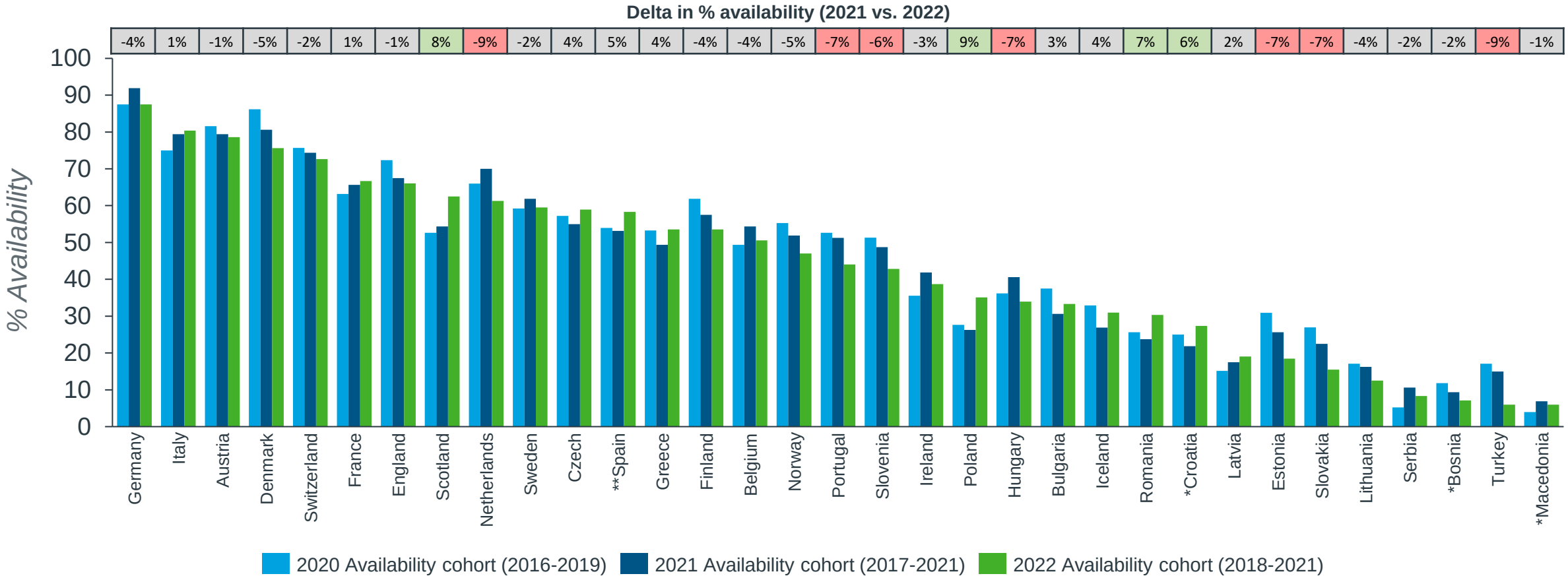
6. Historic comparisons and extension

Indicators:

6.1. Comparison of availability versus prior studies (2020 – 2022)
6.2. Comparison of time to availability versus prior studies (2020 – 2022)
6.3. Extended period total availability by approval year (2014 – 2021)

Comparison of rate of availability (2020 study – 2022 study)

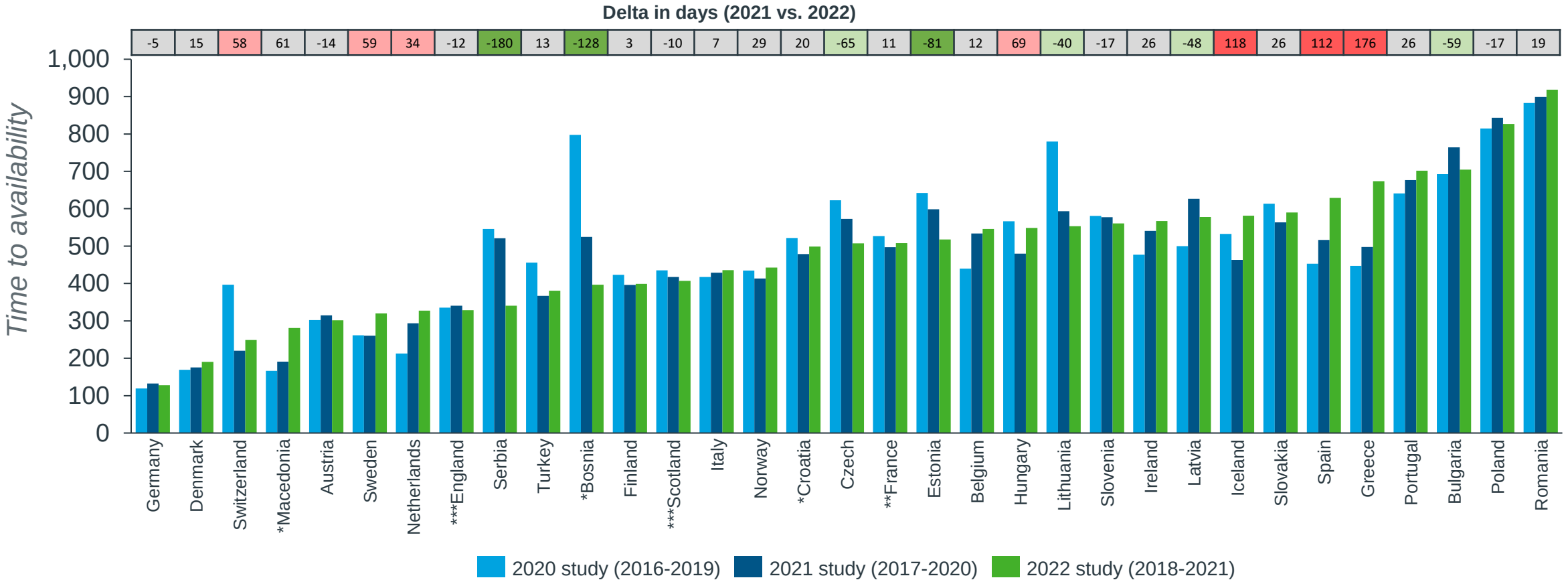
The **comparison of rate of availability**†, measured by the number of medicines available to patients in European countries as of 5th January 2023, compared to the rate of availability in previous (comparable) studies. Figures are based on the historic statistics published in the indicators, and major 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 (2020 study – 2022 study)

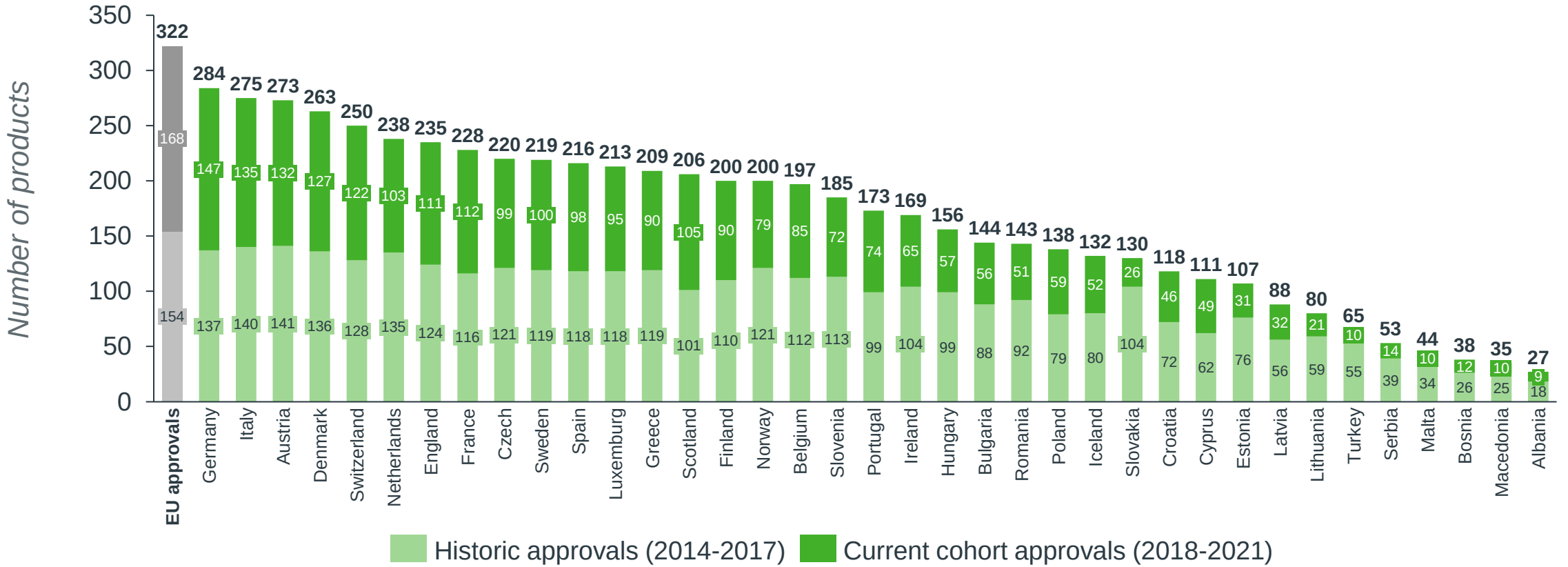
The **comparison of time to availability** (previously know as length of delay) is the days between marketing authorisation and the date of availability to patients compared to previous comparable studies. Figures are based on the historic statistics published in the indicators, and major changes are 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. **In France, some innovative products without competitors can be made available prior to market authorisation under the system of Temporary Authorisations. As these are not taken into account in the analysis, the average for France would be lower. ***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.

Extended period total availability by approval year (2014-2021)

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: 179 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

1683 〉 **399** 〉 **231** 〉 **168**

EMA list

- List of all historic Marketing Authorisations for human and veterinary medicines (European Public Assessment Reports) accessed November 2022
- Human medicines only

Products in scope

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

Survey cohort (8-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 2018 – 2021
- Exclude products that are recently withdrawn prior to analysis (2)

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

Products included in the study: 2018-2021 approvals (n=168)

Abecma	Copiktra	Ilumetri	Myalepta	Rekambys	Trecondi
Adakveo	Crysvita	Imcivree	Mylotarg	Retsevmo	Trepulmix
Adtralza	Daurismo	Imfinzi	Namuscla	Rhokiinsa	Trixeo Aerosphere
Adynovi	Delstrigo	Inrebic	Nerlynx	Rinvoq	Trodelvy
Aimovig	Doptelet	Intrarosa	Nexpovio	Rizmoic	Trogarzo
Ajovy	Dovato	Isturisa	Nilemdo	Roclanda	Tukysa
Alofisel	Dovprela	Jemperli	Nubeqa	Rozlytrek	Ultomiris
Alunbrig	Drovelis/Lydisilka	Jivi	Nustendi	Rubraca	Vaborem
Amglidia	Elzonris	Jorveza	Obiltoxaximab SFL	Rukobia	Vazkepa
Arikayce liposomal	Emgality	Juluca	Ocrevus	Rxulti	Verkazia
Artesunate Amivas	Enerzair Breezhaler / Zimbus Breezhaler	Jyseleca	Onpattro	Rybelsus	Verquvo
Aspaveli	Enhertu	Kaftrio	Ontozry	Rybrevant	Verzenios
Atectura Breezhaler / Bemrist Breezhaler	Enspryng	Kesimpta	Orladeyo	Ryeqo	Veyvondi
Ayvakyt	Epidyolex	Kigabeq	Oxlumo	Sarclisa	Vitrakvi
Baqsimi	Erleada	Klisyri	Ozempic	Segluromet	Vizimpro
Beovu	Evenity	Koselugo	Palynziq	Sibnayal	Vocabria
Besremi	Evkeeza	Kymriah	Pemazyre	Skyrizi	Voxzogo
Bevespi Aerosphere	Evrenzo	Lamzede	Phesgo	Sogroya	Vumerity
Biktarvy	Evrysdi	Leqvio	Pifeltro	Spravato	Vyxeos liposomal
Bimzelx	Fasenra	Libmeldy	Piqray	Steglatro	Waylivra
Blenrep	Fetcroja	Libtayo	Polivy	Steglujan	Xenleta
Braftovi	Fintepla	Lorviqua	Ponvory	Sunosi	Xerava
Brukinsa	Gavreto	Luxturna	Poteligeo	Symkevi	Xofluza
Byfavo	Giapreza	Mayzent	Prevymis	Takhzyro	Xospata
Bylvay	Givlaari	Mektovi	Qinlock	Talzenna	Yescarta
Cablivi	Hemlibra	Mepsevii	Quofenix	Tavlesse	Zeposia
Calquence	Hepcludex	Minjuvi	Reblozyl	Tecartus	Zolgensma
Cibinqo	Idefirix	Mulpleo	Recarbrio	Tegsedi	Zynrelef

* 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: 2018-2021 approvals

Oncologics (n=46)

Abecma	Pemazyre
Alunbrig	Pemazyre
Ayvakyt	Phesgo
Blenrep	Phesgo
Braftovi	Piqray
Brukinsa	Polivy
Calquence	Poteligeo
Copiktra	Qinlock
Daurismo	Retsevmo
Elzonris	Rozlytrek
Enhertu	Rubraca
Erleada	Rybrevant
Gavreto	Sarclisa
Imfinzi	Talzenna
Jemperli	Tecartus
Kymriah	Trecondi
Libtayo	Trodelvy
Lorviqua	Tukysa
Mektovi	Verzenios
Minjuvi	Vitrakvi
Mylotarg	Vizimpro
Nerlynx	Vyxeos liposomal
Nexpovio	Xospata
Nubeqa	Yescarta

Orphans (n=61)

Abecma	Luxturna
Adakveo	Mepsevii
Alofisel	Minjuvi
Amglidia	Myalepta
Arikayce liposomal	Mylotarg
Artesunate Amivas	Namuscla
Aspaveli	Obiltoxaximab SFL
Ayvakyt	Onpattro
Blenrep	Oxlumo
Bylvay	Palynziq
Cablivi	Pemazyre
Crysvita	Polivy
Daurismo	Poteligeo
Dovprela	Prevymis
Elzonris	Qinlock
Enspryng	Reblozyl
Epidyolex	Sogroya
Evrysdi	Symkevi
Fintepla	Takhzyro
Givlaari	Tecartus
Hepcludex	Tegsedi
Idefirix	Trecondi
Imcivree	Trepulmix
Inrebic	Verkazia
Isturisa	Voxzogo
Jorveza	Vyxeos liposomal
Kaftrio	Waylivra
Koselugo	Xospata
Kymriah	Yescarta
Lamzede	Zolgensma
Libmeldy	

Non-oncologic orphans (n=44)

Adakveo	Libmeldy
Alofisel	Luxturna
Amglidia	Mepsevii
Arikayce liposomal	Myalepta
Artesunate Amivas	Namuscla
Aspaveli	Obiltoxaximab SFL
Bylvay	Onpattro
Cablivi	Oxlumo
Crysvita	Palynziq
Dovprela (previously Pretomanid FGK)	Prevymis
Enspryng	Reblozyl
Epidyolex	Sogroya
Evrysdi	Symkevi
Fintepla	Takhzyro
Givlaari	Tegsedi
Hepcludex	Trepulmix
Idefirix	Verkazia
Imcivree	Voxzogo
Inrebic	Waylivra
Isturisa	Zolgensma
Jorveza	
Kaftrio	
Koselugo	
Lamzede	

Combination therapies (n=22)

Atectura Breezhaler / Bemrist Breezhaler
Bevespi Aerosphere
Biktarvy
Delstrigo
Dovato
Drovelis/Lydisilka
Enerzair Breezhaler / Zimbus Breezhaler
Juluca
Kaftrio
Nustendi
Phesgo
Recarbrio
Roclanda
Ryeqo
Segluromet
Sibnayal
Steglujan
Symkevi
Trixeo Aerosphere
Vaborem
Vyxeos liposomal
Zynrelef

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
Albania	Accessibility on the public reimbursement list
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	Reimbursed without restriction; any physician can prescribe
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 reimbursed (pharmacy products). Hospital products might need an appraisal from COHERE (Council of Choices in Healthcare in Finland) before hospital uptake
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)
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 medicine has received a positive reimbursement decision by NoMA (out-patient drugs); or the Decision Forum (System of New Methods) has approved reimbursement of a hospital product.
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	Accessibility on the public reimbursement list
Sweden	A medicine is classified as available if it was marketed in Sweden as of December 21st 2021 (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 has 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
Albania	Reimbursement is only granted for specific subpopulations of the approved indications.
Austria	Products outside reimbursement system (EKO), but reimbursed on individual pre-approval (No Box)
Bulgaria	No products are reported to have limited availability
Belgium	There are no restrictions on availability meaning medicines are reimbursable in all approved patient populations
Bosnia	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.
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 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	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	Only available through individual reimbursement
Lithuania	Only reimbursed for limited indications (compared to what was approved at market authorisation)
Luxembourg	There are no restrictions on availability
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 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
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	Only reimbursed for restricted patient cohort
Sweden	Only reimbursed for restricted patient cohort
Switzerland	For products pending reimbursement, patients have restricted reimbursement access. Such restricted access includes 'individual reimbursement' regulated by Art. 71a-b of KVV ordinance.
Turkey	Products only available through a "Named Patient Scheme". These medicines do not require TITCK (Turkish Medical Agency) approval but are reimbursed.

Country specific definitions of the availability date

Country	Definition of the availability date
Albania	The first date of availability on the public reimbursement list
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
Czech	The first date of availability on the public reimbursement list
Cyprus	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 most hospital products, the date of availability is the marketing authorization date, however, some products undergo evaluation in which case the availability date is considered to be the 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
Malta	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
Luxemburg	The first date of availability on the public reimbursement list (liste positive) which is updated each month and shared by the Health National Fund (CNS – Caisse Nationale de Santé). When the medicine is for hospitals and not on the positive list, the date of availability provided by the members were reported.
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.
Netherlands	The first date of availability on the public reimbursement list
Norway	The first date of availability on the public reimbursement list; or for hospital products, the date of the positive decision in Decision Forum
Poland	The first date of availability on the public reimbursement list, except for HIV / haemophilia drugs (financed by state budget) where availability date is date of publication of tender results or date of first order received from companies.
Portugal	The first date of availability on the public reimbursement list
Romania	Date of publication of government decision (for medicines that don't need therapeutic protocols elaboration or update) or therapeutic protocols (for the majority of medicines) in the Official Journal.
Scotland*	For medicines with a positive SMC recommendation, the accessibility date is the date of published guidance. For remaining medicines, IQVIA sales data is analysed to determine month of routine availability.
Serbia	The first date of availability on the public reimbursement list
Slovakia	The first date of availability on the public reimbursement list (published on monthly basis)
Slovenia	The first date of availability on the public reimbursement list
Spain	The first date of availability on the public reimbursement list
Sweden	For medicines indicated For diseases included in the communicable disease program: date of marketing in Sweden (supplied in FASS); For nationally reimbursed prescription medicines with a TLV decision: date of TLV decision; For nationally reimbursed hospital drugs with an NT-recommendation: date of NT recommendation; For nationally reimbursed hospital medicines lacking an NT-recommendation and not part of national managed introduction: date of marketing in Sweden (supplied in FASS)
Switzerland	The first date of inclusion in the specialties 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”

*Notable change to definition versus previous study

Contact details

General queries:
Francois Bouvy, EFPIA
francois.bouvy@efpia.eu

Additional analysis:
Max Newton, IQVIA
maximilian.newton@iqvia.com

Country-specific insights:
Local pharma industry associations