



EFPIA Patients W.A.I.T. Indicator 2020 Survey

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EFPIA Patients W.A.I.T. Indicator 2020

Foreword

Improving the availability of medicines authorised in the European Union (EU) is a key priority for the European medicines regulatory network and for the pharmaceutical industry. This year's iteration of the Patients W.A.I.T. (**W**aiting to **A**ccess **I**nnovative **T**herapies) Indicator marks the 14th annual version of the largest European study into innovative medicines availability and the time to patient access.

The charts in the following report covers an broader set of countries than in previous years. In the publication, data on 34 countries (24 EU, and 10 non-EU) are included giving a full European picture of availability.

Information on the 152 innovative medicines with central-marketing authorisation between 2016 and 2019 are included within the coming pages, with a one year delay to permit countries to include these medicines on their public reimbursement list (in most instances), meaning that the data on availability is accurate as of *January 1st 2021*. This period is therefore inclusive of the first 9 months of the COVID-19 pandemic, although no significant impact is visible yet in the indicator.

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

EFPIA & the IQVIA team

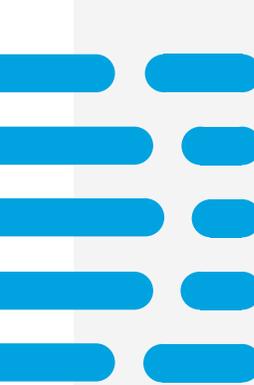


 **34**
European
countries

 **152**
innovative
medicines

 **4**
year cohort
(‘16-’19)

 Data available  Data not available / included



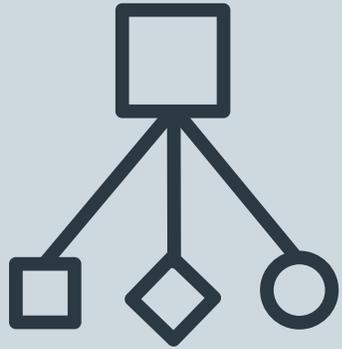
Contents

Click on hyperlinks for navigation

+ Study summary	page 3 – 5
+ Overview (all products)	page 5 – 11
+ Oncology	page 12 – 17
+ Orphan medicines	page 18 – 23
+ Non-oncology orphan medicines	page 24 – 29
+ Combination therapies	page 30 – 35
+ Appendix & detailed methodology	page 41 – 47

Core concept of “availability”

Definition of availability



In this study the term ‘**availability**’ is used throughout to permit standardised measurement across 34 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 summary

Full methodology and definitions by country are available within the appendix

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 named patient basis (individual patient basis)	
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, Russia, Serbia, Switzerland and Turkey.

Completeness: Some country associations did not submit full datasets. Countries with substantially limited datasets are: Bosnia (59% complete), Croatia (38% complete), Serbia (47% complete) and Russia (96% complete). This is noted on slides with an asterisk (*).

Average calculations: The EU averages noted throughout are averages for the 24 countries in the European Union that participate in the study (data from Cyprus, Malta, and Luxembourg is not available).

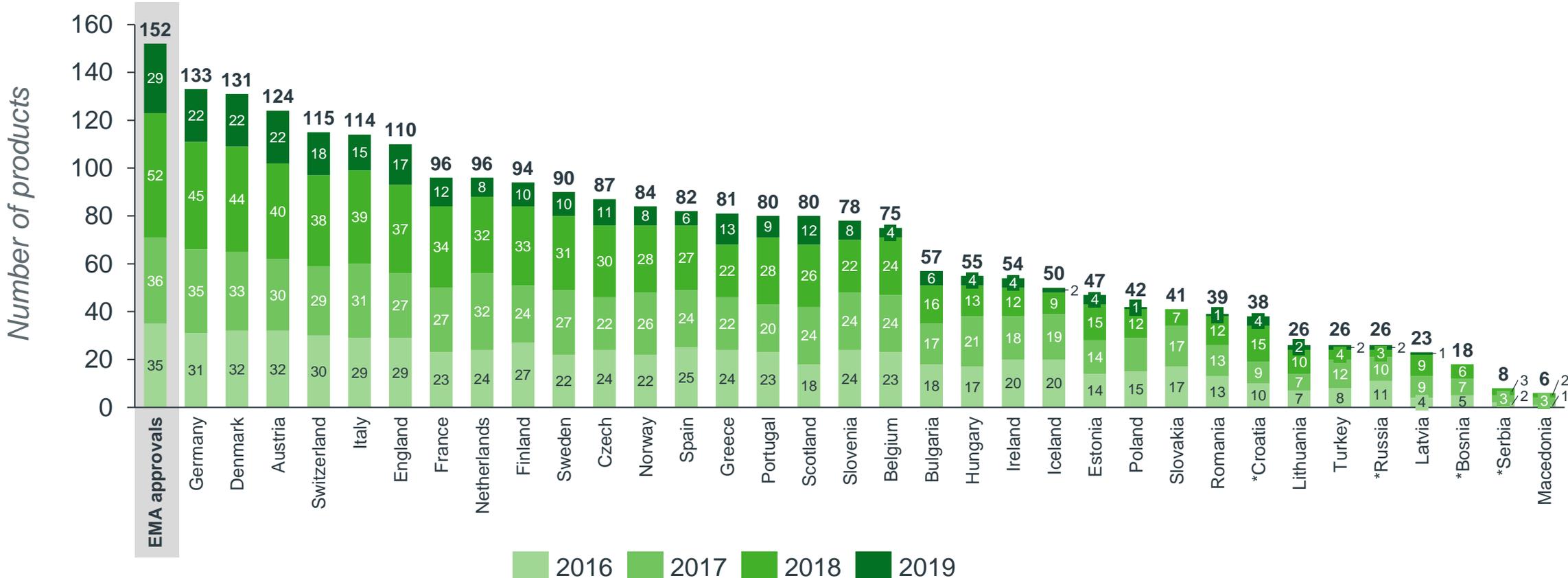
* The Patients W.A.I.T. Indicator is not a measurement of the delays as defined in the "Transparency" Directive (directive 89/105/EEC). Delays under the "Transparency" Directive reflect the number of days that national competent authorities need to make their decisions regarding price and inclusion of 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.

Overview (all products)

Availability by approval year ➤ Rate of availability ➤ Channels of availability ➤ Time to availability

Total availability by approval year (2016-2019)

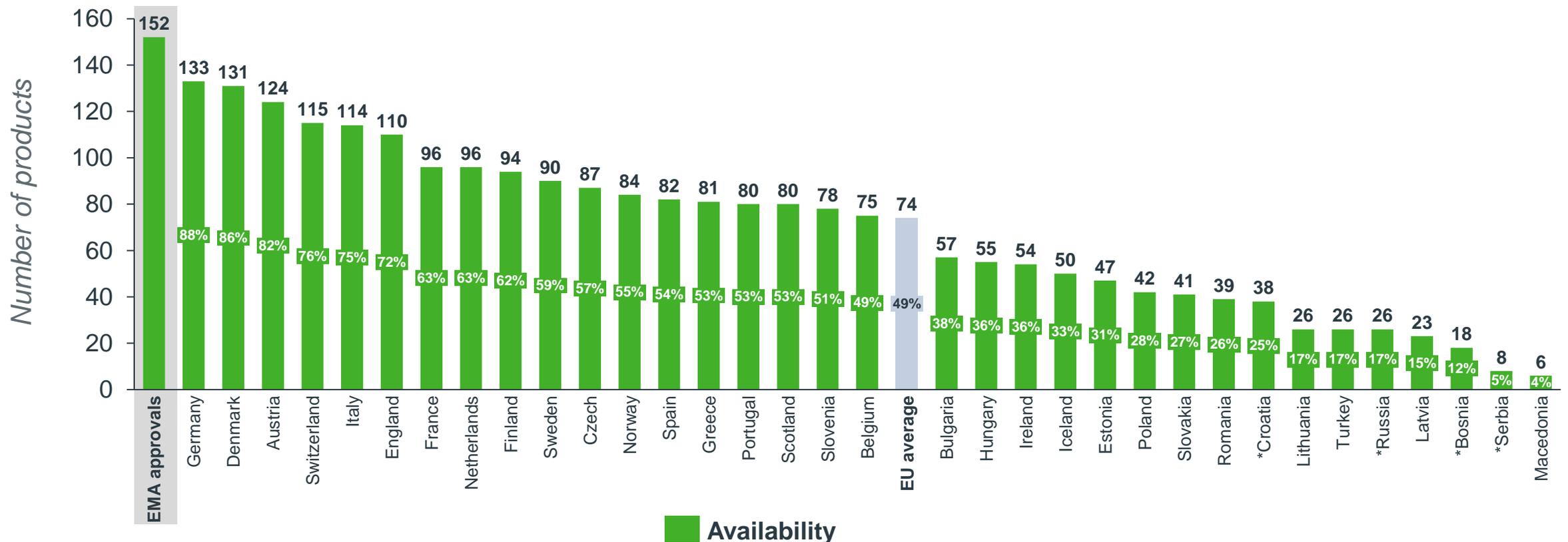
The **total of availability by approval year** is the number of medicines available to patients in European countries (for most countries this is the point at which the product gains access to the reimbursement list[†]), split by the year the product received marketing authorization in Europe.



European Union average: 74 products available (49%) (excludes data from Cyprus, Malta, and Luxembourg as these countries are not included in the study) [†]In most countries availability equates to granting of access to the reimbursement list, except in DK, FI, 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.

Rate of availability (2016-2019)

The **rate of availability**, measured by the number of medicines available to patients in European countries as of 2020. 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: 74 products available (49%) (excludes data from Cyprus, Malta, and Luxembourg as these countries are not included in the study) [†]In most countries availability equates to granting of access to the reimbursement list, except in DK, FI, 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.

Rate of availability (% , 2016 – 2019)

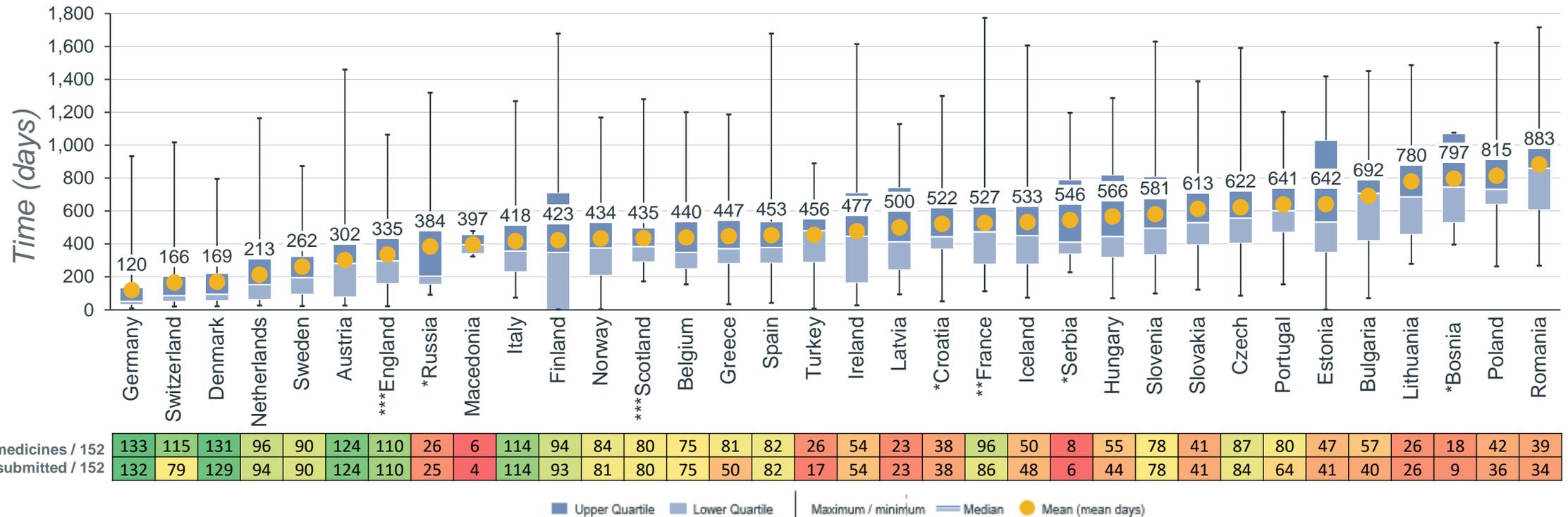
The **rate of availability** is the number of medicines available to patients in European countries (for most countries this is the point at which the product gains access to the reimbursement list[†]). This includes all medicines status to provide a complete picture of the availability of the cohort of medicines studied.



European Union average: 74 products available (49%) (excludes data from Cyprus, Malta, and Luxembourg as these countries are not included in the study). EU averages: 12% of the study cohort is subject to limited availability; 30% of available products have limited availability across EU countries. Ireland and Norway did not submit information on restrictions to available medicines meaning LA* is not captured in these countries. As Ireland has been included in the EU average calculations, the EU average number of products with limited availability may be understated. [†]In most countries availability equates to granting of access to the reimbursement list, except in DK, FI, 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.

Time to availability (2016-2019)

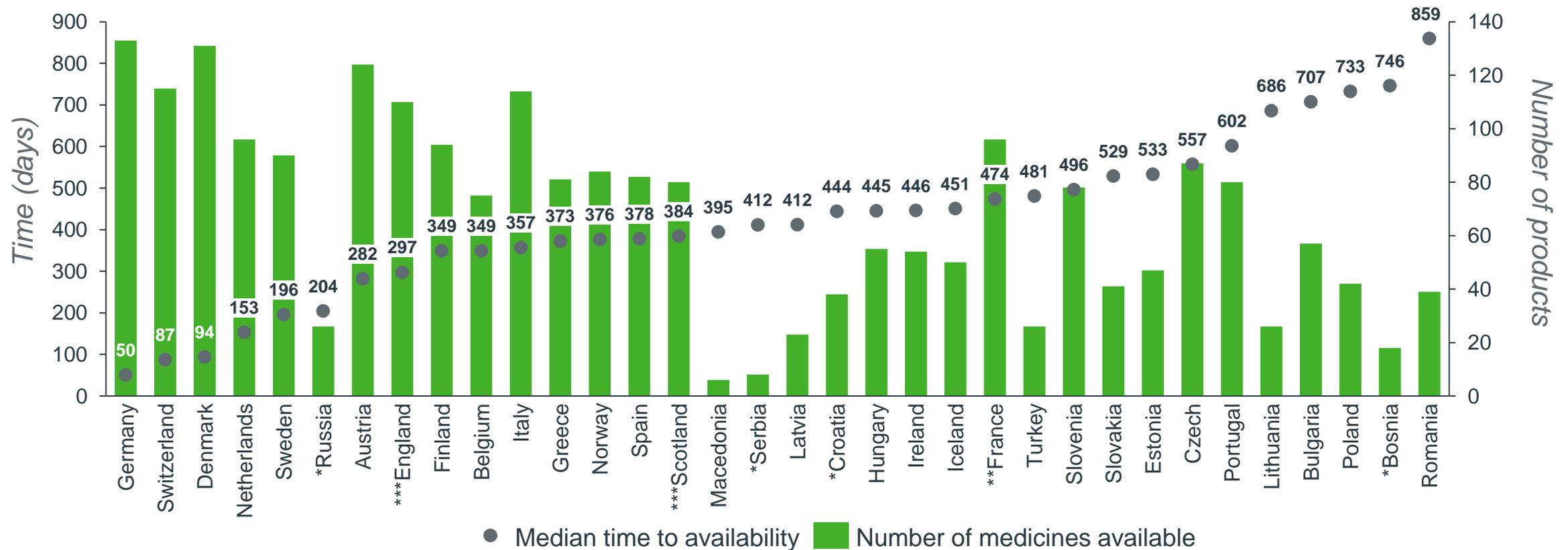
The **time to availability** (previously known as length of delay) is the days between marketing authorisation and the date of availability to patients in European countries (for most this is the point at which products gain access to the reimbursement list[†]).



European Union average: 504 days (mean %) (excludes data from Cyprus, Malta, and Luxembourg as these countries are not included in the study) [†]In most countries availability equates to granting of access to the reimbursement list, except in DK, FI, 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. **For France, the time to availability (527 days, n=86 dates submitted) includes products under the ATU system for which the price negotiation process is usually longer. If one considers that products under the ATU system are directly available (time to availability = 0), the average time to availability is 257 days. For products which do not benefit from ATU system (n=48 dates submitted), the average delay is 488 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.

Median time to availability (2016 – 2019)

The **time to availability** (previously know as length of delay) 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 †).



†In most countries patient access equates to granting of access to the reimbursement list, except for hospital products in DK, FI, NO, SE some products are not covered by the general reimbursement scheme and so this shorter delay is artificially declining the median and average; *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 reality. ***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

All products

Measure	EU average for all products	Oncology	Orphan	Non-oncology orphan	Combination therapy	Key
Rate of availability	49%	58% ↑	41% ↓	34% ↓	64% ↑	<p>Arrows indicate direction from the EU average for all products</p> <p>↑ Higher availability ↓ Lower availability</p>
Average time to availability	504 days	561 days ↑	653 days ↑	667 days ↑	411 days ↓	<p>↓ Shorter ↑ Longer</p>

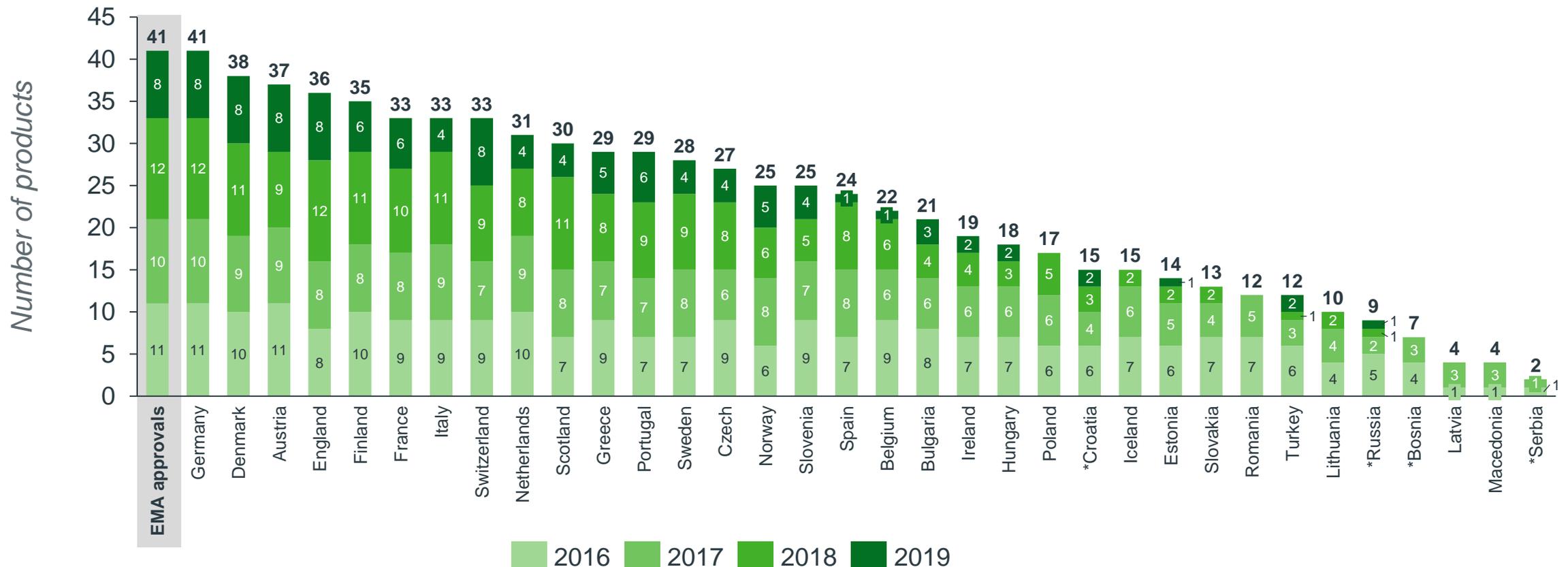
- Patient access to new medicines is highly varied across Europe, with the greatest rate of availability in Northern and Western European countries (88% in Germany) and lowest in Southern and Eastern European countries (4% in Macedonia).
- EU average availability remains at 49%, the same as last year's analysis (2019) but countries are split evenly between countries increasing and decreasing availability versus 2019.
- The average delay between market authorisation and patient access can vary by a factor greater than x7 across Europe, from as little as four months to 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 e.g. shortest versus longest delays in Finland (0 vs. 1676 days) France (112 vs. 1772 days) Spain (41 vs. 1676 days).
- Countries that follow centrally approved times can appear as outliers (e.g. Russia, Macedonia). The use of local authorisation dates in Macedonia and Serbia for the first time this year resulted in substantially faster times to availability versus the 2019 analysis (-409 days in Macedonia; -266 days in Serbia).

Oncology medicines

Availability by approval year ➤ Rate of availability ➤ Channels of availability ➤ Time to availability

Oncology availability by approval year (2016 - 2019)

The **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 in Europe.



European Union average: 24 products available (58%) (excludes data from Cyprus, Malta, and Luxembourg as these countries are not included in the study) [†]In most countries availability equates to granting of access to the reimbursement list, except in DK, FI, 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.

Oncology rate of availability (2016 - 2019)

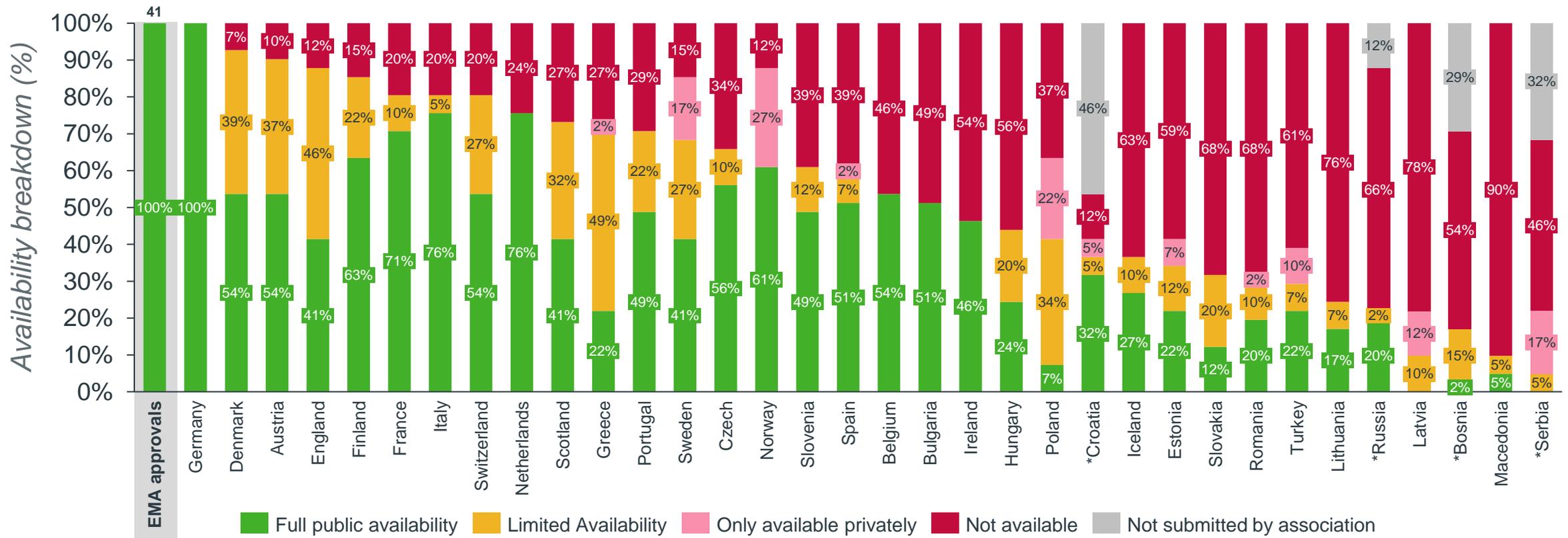
The **rate of availability**, measured by the number of medicines available to patients in European countries as of 2020. For most countries this is the point at which the product gains access to the reimbursement list[†], including products with limited availability.



European Union average: 24 products available (58%) (excludes data from Cyprus, Malta, and Luxembourg as these countries are not included in the study) [†]In most countries availability equates to granting of access to the reimbursement list, except in DK, FI, 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.

Oncology rate of availability (% , 2016 – 2019)

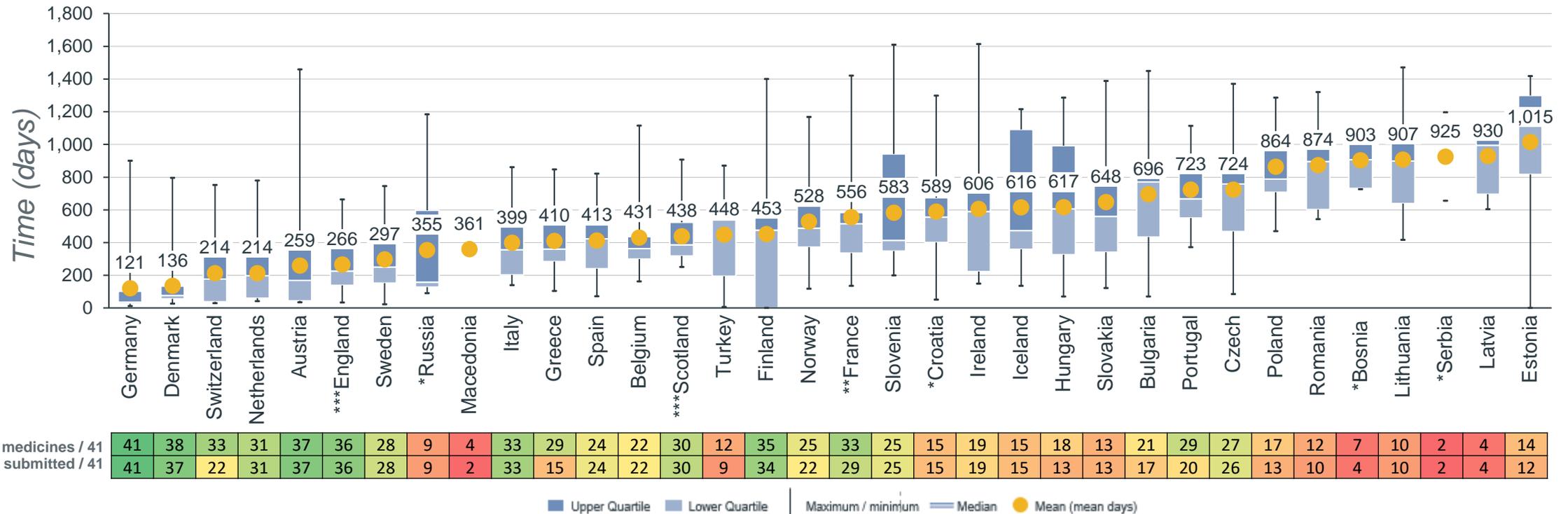
The **rate of availability** is the number of medicines available to patients in European countries (for most countries this is the point at which the product gains access to the reimbursement list[†]). This includes all medicines status to provide a complete picture of the availability of the cohort of medicines studied.



European Union average: 24 products available (58%) (excludes data from Cyprus, Malta, and Luxembourg as these countries are not included in the study) EU averages: 15% of the study cohort is subject to limited availability; 30% of available products have limited availability across EU countries. Ireland and Norway did not submit information on restrictions to available medicines meaning LA* is not captured in these countries. As Ireland has been included in the EU average calculations, the EU average number of products with limited availability may be understated. [†]In most countries availability equates to granting of access to the reimbursement list, except in DK, FI, 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.

Oncology time to availability (2016 – 2019)

The **time to availability** (previously known as length of delay) is the days between EMA 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[†]).



European Union average: 561 days (mean) (excludes data from Cyprus, Malta, and Luxembourg as these countries are not included in the study) [†]In most countries availability equates to granting of access to the reimbursement list, except in DK, FI, 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 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 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.

Key observations

Oncologics

Measure	EU average for all products	Oncology	Orphan	Non-oncology orphan	Combination therapy	Key
Rate of availability	49%	58% ↑	41% ↓	34% ↓	64% ↑	Arrows indicate direction from the EU average for all products ↑ Higher availability ↓ Lower availability
Average time to availability	504 days	561 days ↑	653 days ↑	667 days ↑	411 days ↓	↓ Shorter ↑ Longer

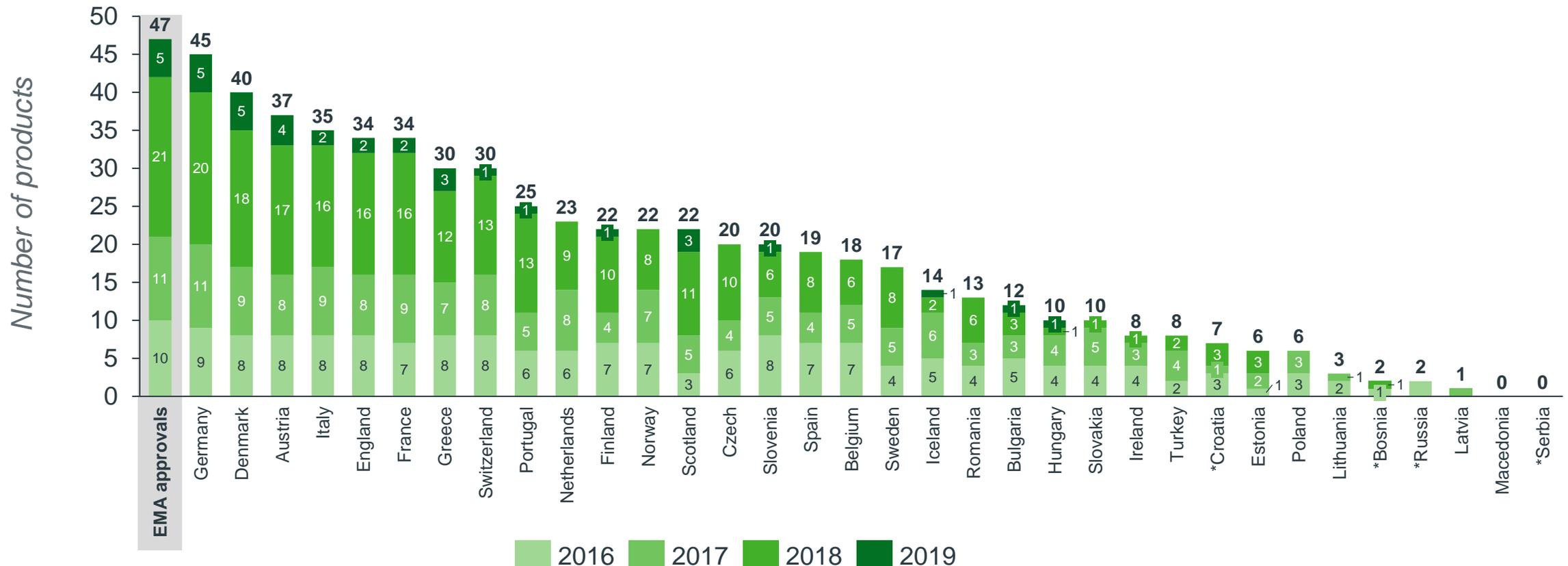
- The EU average availability is 9% higher for oncology products than all products approved, however, the average time to availability for oncology products is two months slower.
- The average delay between market authorisation and patient access for Oncology products varies from 4 months to over 2.5 years.
- 5 countries already have availability to all oncology medicines centrally approved in 2019 (Austria, Denmark, Germany, Switzerland, England), whilst others have no availability to any (e.g. Poland, Romania, Slovakia, Iceland).
- In Portugal, England, Finland, Switzerland, Norway and France the availability of oncology medicines approved in 2019 is more than 30% above the rate of availability of all approvals in 2019.
- Limited availability is prevalent within the oncology medicines with over 30% of oncology medicines having an availability restriction placed upon them in Greece (49%), England (46%), Denmark (39%), Austria (37%), Poland (34%), Scotland (32%).

Orphans medicines

Availability by approval year ➤ Rate of availability ➤ Channels of availability ➤ Time to availability

Orphan availability by approval year (2016 - 2019)

The **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 in Europe.



European Union average: 19 products available (41%) (excludes data from Cyprus, Malta, and Luxembourg as these countries are not included in the study) [†]In most countries availability equates to granting of access to the reimbursement list, except in DK, FI, 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.

Orphan rate of availability (2016 - 2019)

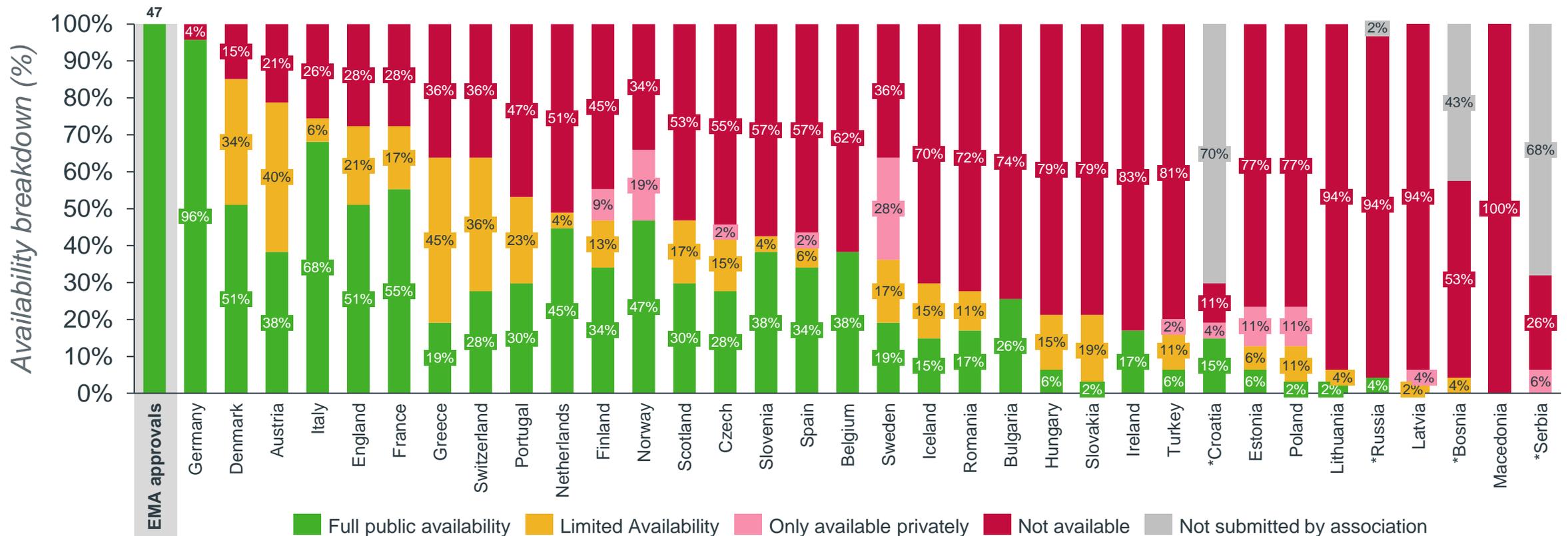
The **rate of availability**, measured by the number of medicines available to patients in European countries as of 2020. For most countries this is the point at which the product gains access to the reimbursement list[†], including products with limited availability.



European Union average: 19 products available (41%) (excludes data from Cyprus, Malta, and Luxembourg as these countries are not included in the study) [†]In most countries availability equates to granting of access to the reimbursement list, except in DK, FI, 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.

Orphan rate of availability (% , 2016 – 2019)

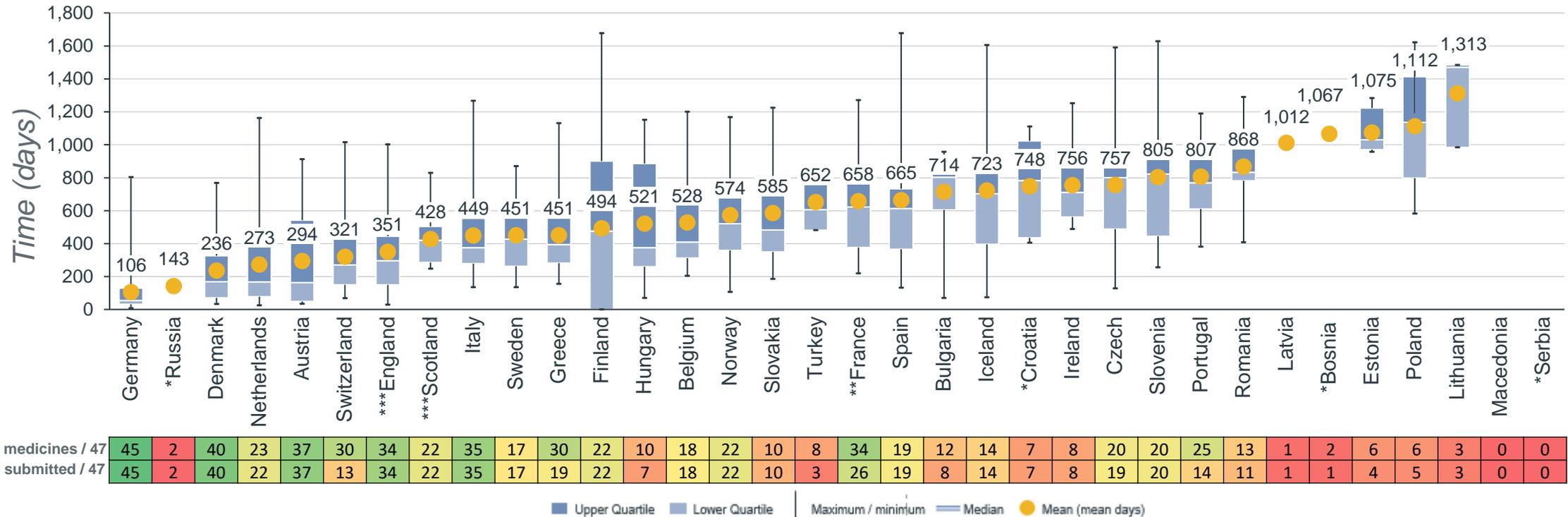
The **rate of availability** is the number of medicines available to patients in European countries (for most countries this is the point at which the product gains access to the reimbursement list[†]). This includes all medicines status to provide a complete picture of the availability of the cohort of medicines studied.



European Union average: 19 products (41%) (excludes data from Cyprus, Malta, and Luxembourg as these countries are not included in the study); EU averages: 12% of the study cohort is subject to limited availability; 37% of available products have limited availability across EU countries. Ireland and Norway did not submit information on restrictions to available medicines meaning LA* is not captured in these countries. As Ireland has been included in the EU average calculations, the EU average number of products with limited availability may be understated. [†]In most countries availability equates to granting of access to the reimbursement list, except in DK, FI, 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.

Orphan time to availability (2016 – 2019)

The **time to availability** (previously know as length of delay) is the days between EMA 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[†]).



European Union average: 653 days (mean) (excludes data from Cyprus, Malta, and Luxembourg as these countries are not included in the study) [†]In most countries availability equates to granting of access to the reimbursement list, except in DK, FI, 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 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 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.

Key observations

Orphan medicines

Measure	EU average for all products	Oncology	Orphan	Non-oncology orphan	Combination therapy	Key
Rate of availability	49%	58%	41%	34%	64%	Arrows indicate direction from the EU average for all products Higher availability Lower availability
Average time to availability	504 days	561 days	653 days	667 days	411 days	Shorter Longer

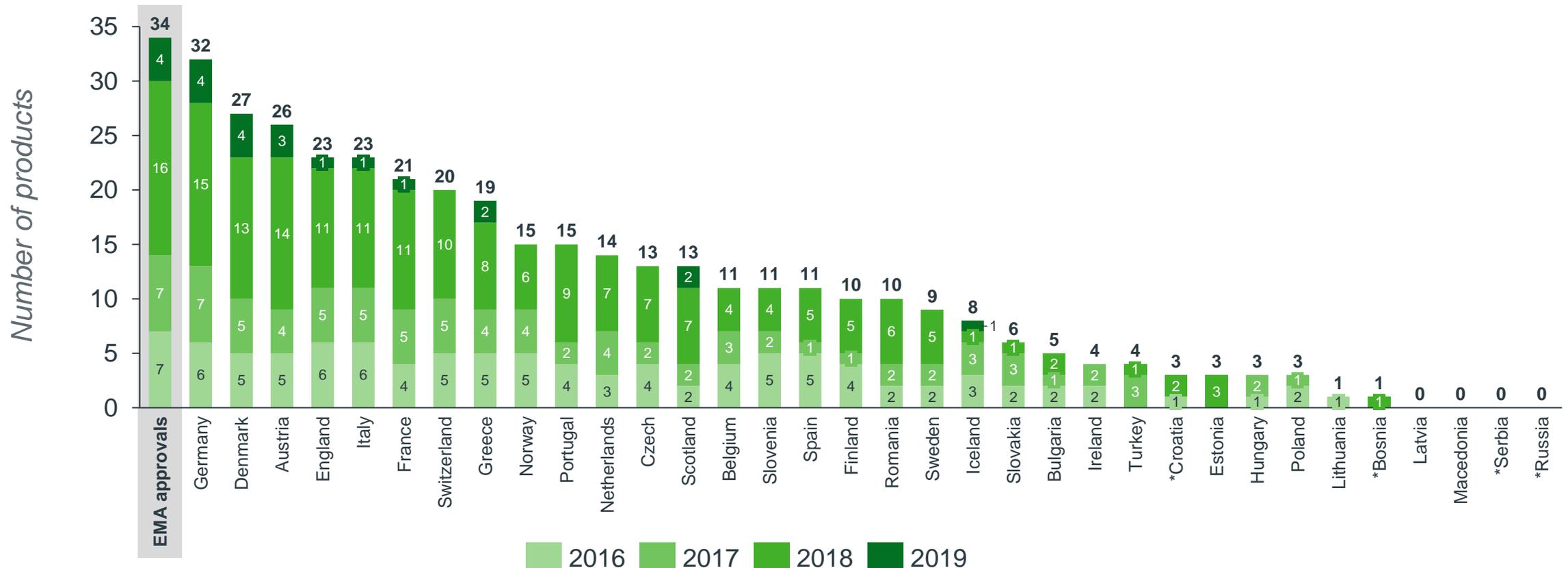
- EU average availability is 8% lower for orphans than for all products approved and average time to availability is 5 months slower.
- The incoming cohort of innovative orphans (centrally approved in 2019) is much smaller than previous years (5 versus 12 in the outgoing cohort [2015], or 21 in 2018).
- Over half of the countries studied have not made any orphans approved in 2019 available.
- The average delay between market authorisation and patient availability for Orphan drugs can be as short as 3.5 months in some countries or as long as 3.6 years.
- All countries have an orphan product that has taken more than 2 years to become available (except Russia, which is an outlier as it has a sample size of 2 and uses local approval dates).
- In ~80% of the countries, the rate of availability is lower for Orphan drugs compared to all products approved between 2016-2019.
- Only in Greece, France, Germany, Romania and Portugal is the rate of orphan availability higher than all products approved 2016 – 2019.

Non-oncology orphans medicines

Availability by approval year ➤ Rate of availability ➤ Channels of availability ➤ Time to availability

Non-oncology orphan availability by approval year (2016 - 2019)

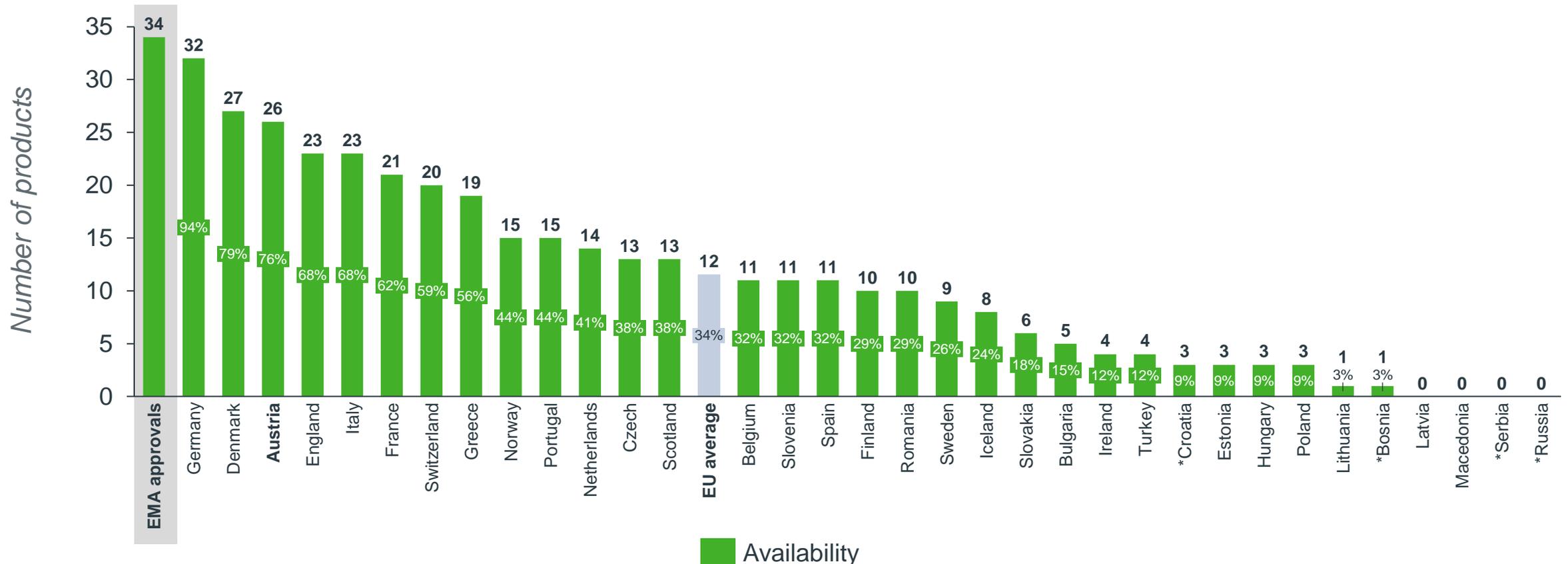
The **total of availability by approval year** is the number of medicines available to patients in European countries (for most countries this is the point at which the product gains access to the reimbursement list[†]), split by the year the product received marketing authorization in Europe.



European Union average: 12 products available (34%) (excludes data from Cyprus, Malta, and Luxembourg as these countries are not included in the study) [†]In most countries availability equates to granting of access to the reimbursement list, except in DK, FI, 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.

Non-oncology orphan rate of availability (2016 - 2019)

The **rate of availability**, measured by the number of medicines available to patients in European countries as of 2020. 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: 12 products available (34%) (excludes data from Cyprus, Malta, and Luxembourg as these countries are not included in the study) [†]In most countries availability equates to granting of access to the reimbursement list, except in DK, FI, 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.

Non-oncology orphan rate of availability (% , 2016 – 2019)

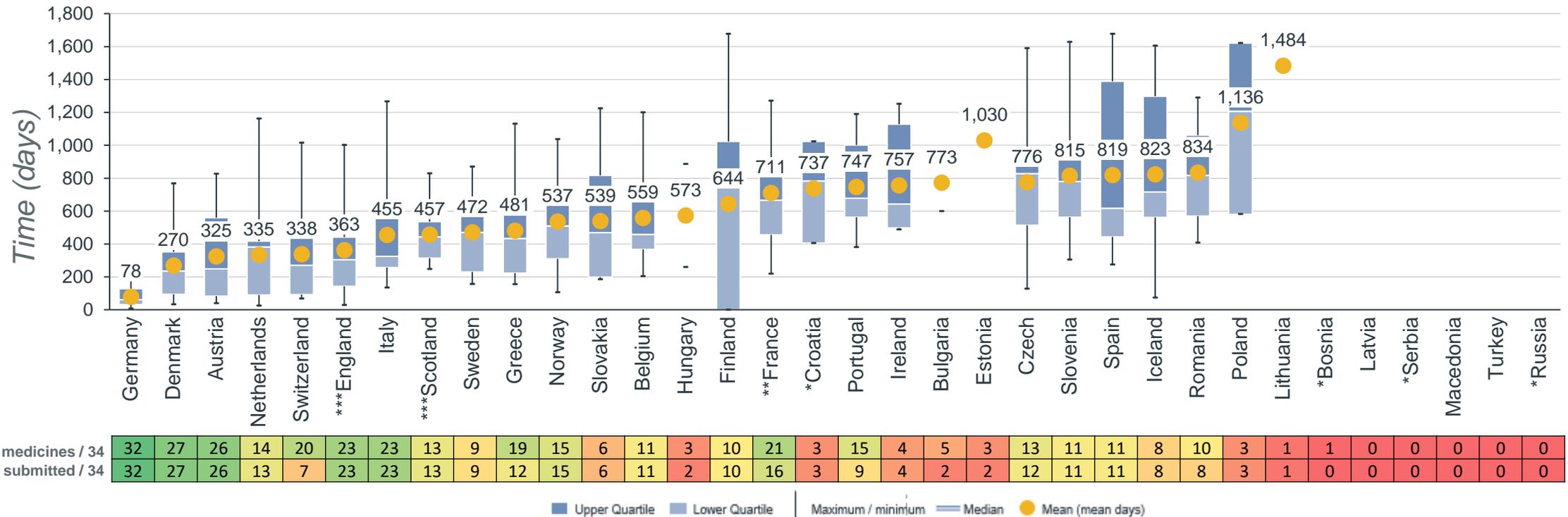
The **rate of availability** is the number of medicines available to patients in European countries (for most countries this is the point at which the product gains access to the reimbursement list[†]). This includes all medicines status to provide a complete picture of the availability of the cohort of medicines studied.



European Union average: 12 products available (34%) (excludes data from Cyprus, Malta, and Luxembourg as these countries are not included in the study). EU averages: 10% of the study cohort is subject to limited availability; 30% of available products have limited availability across EU countries. Ireland and Norway did not submit information on restrictions to available medicines meaning LA* is not captured in these countries. As Ireland has been included in the EU average calculations, the EU average number of products with limited availability may be understated. [†]In most countries availability equates to granting of access to the reimbursement list, except in DK, FI, 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.

Non-oncology orphan time to availability (2016 – 2019)

The **time to availability** (previously know as length of delay) is the days between EMA 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[†]).



European Union average: 667 days (mean) (excludes data from Cyprus, Malta, and Luxembourg as these countries are not included in the study) [†]In most countries availability equates to granting of access to the reimbursement list, except in DK, FI, 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 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 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.

Key observations

Non-oncologic orphan medicines

Measure	EU average for all products	Oncology	Orphan	Non-oncology orphan	Combination therapy	Key
Rate of availability	49%	58% ↑	41% ↓	34% ↓	64% ↑	Arrows indicate direction from the EU average for all products ↑ Higher availability ↓ Lower availability
Average time to availability	504 days	561 days ↑	653 days ↑	667 days ↑	411 days ↓	↓ Shorter ↑ Longer

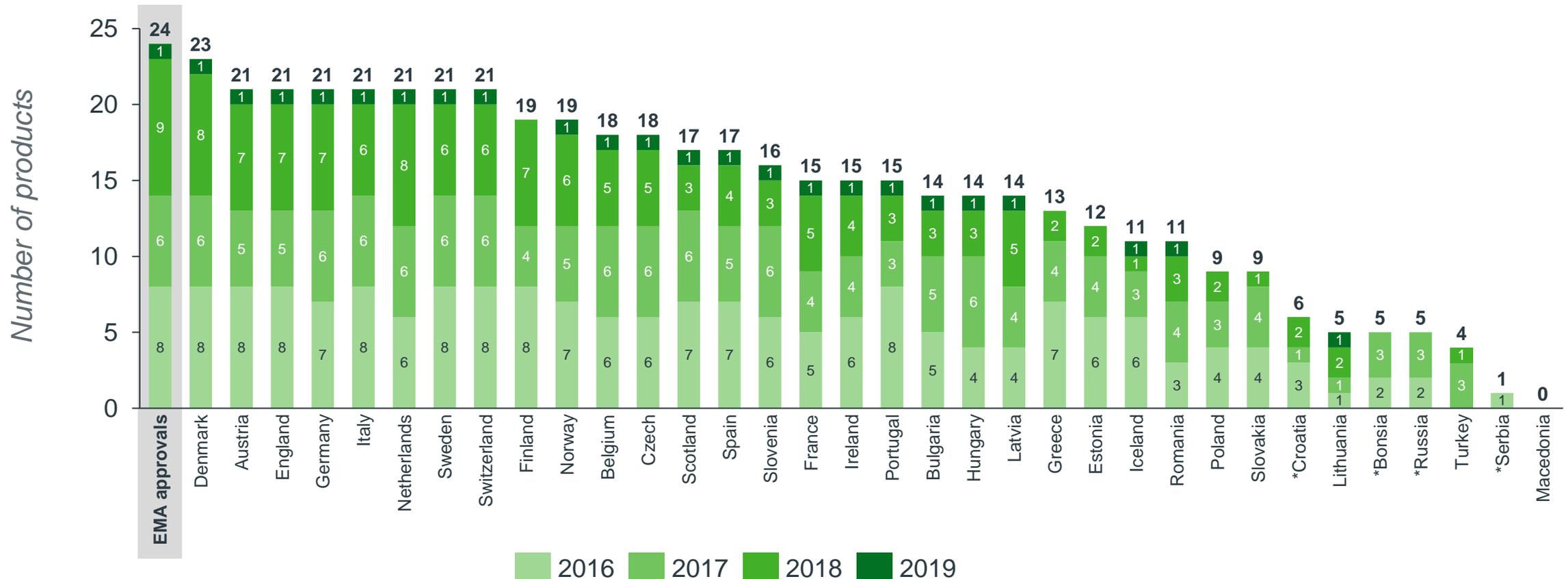
- The non-oncology orphans represent generally poorly understood conditions (e.g. metabolic disorders).
- EU average availability is 7% lower for non-oncology orphans than for all orphan products, and has the slowest average time to availability of the studied segments (nominally slower than the orphan segment).
- In over 90% of the countries, the rate of availability for non-oncology orphan drugs is lower than for all orphan medicinal products approved between 2016-2019.
- The increased availability of orphans compared to non-oncology orphans is more than 10% in some countries (Finland, Hungary, Bulgaria, France) but is small in others (e.g. 2% in Germany and Austria).
- Three quarters of countries studied do not have availability to any non-oncology orphan drugs approved in 2019.
- 30% of countries studied have availability to less than 10% of the non-oncology orphan drugs approved between 2016 and 2019.

Combination therapies

Availability by approval year ➤ Rate of availability ➤ Channels of availability ➤ Time to availability

Combination therapies availability by approval year (2016 - 2019)

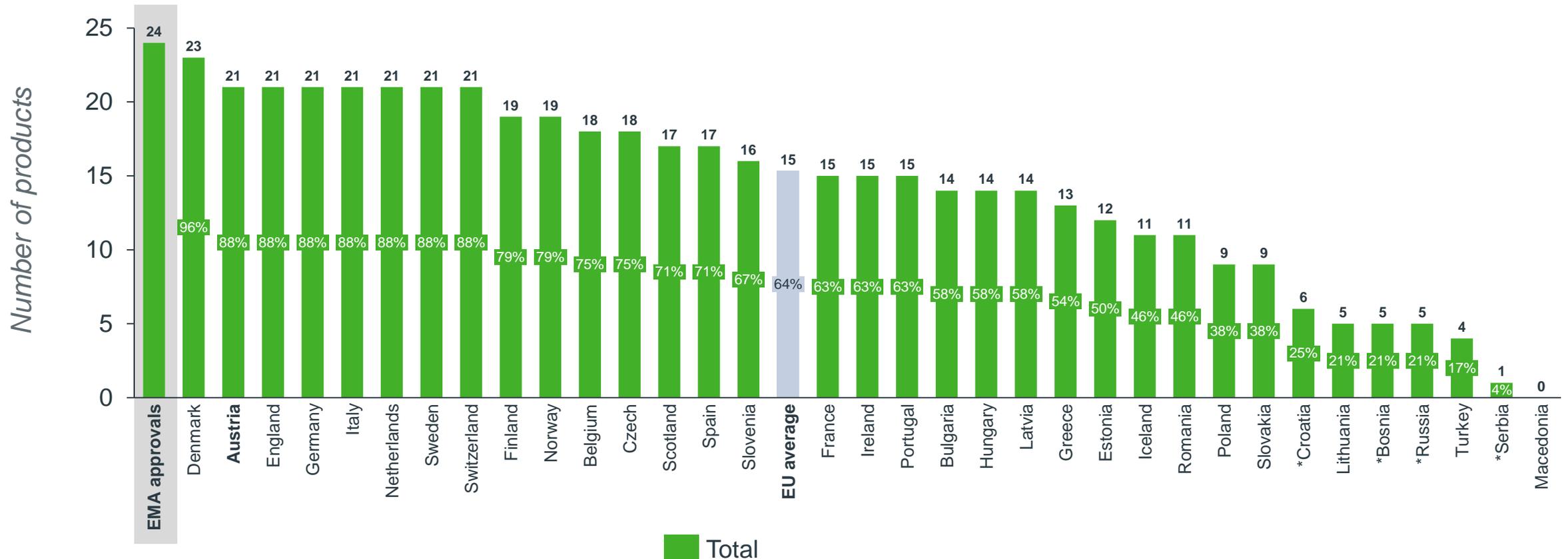
The **total of availability by approval year** is the number of medicines available to patients in European countries (for most countries this is the point at which the product gains access to the reimbursement list[†]), split by the year the product received marketing authorization in Europe.



European Union average: 15 products available (64%) (excludes data from Cyprus, Malta, and Luxembourg as these countries are not included in the study) [†]In most countries availability equates to granting of access to the reimbursement list, except in DK, FI, 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.

Combination therapies rate of availability (2016 - 2019)

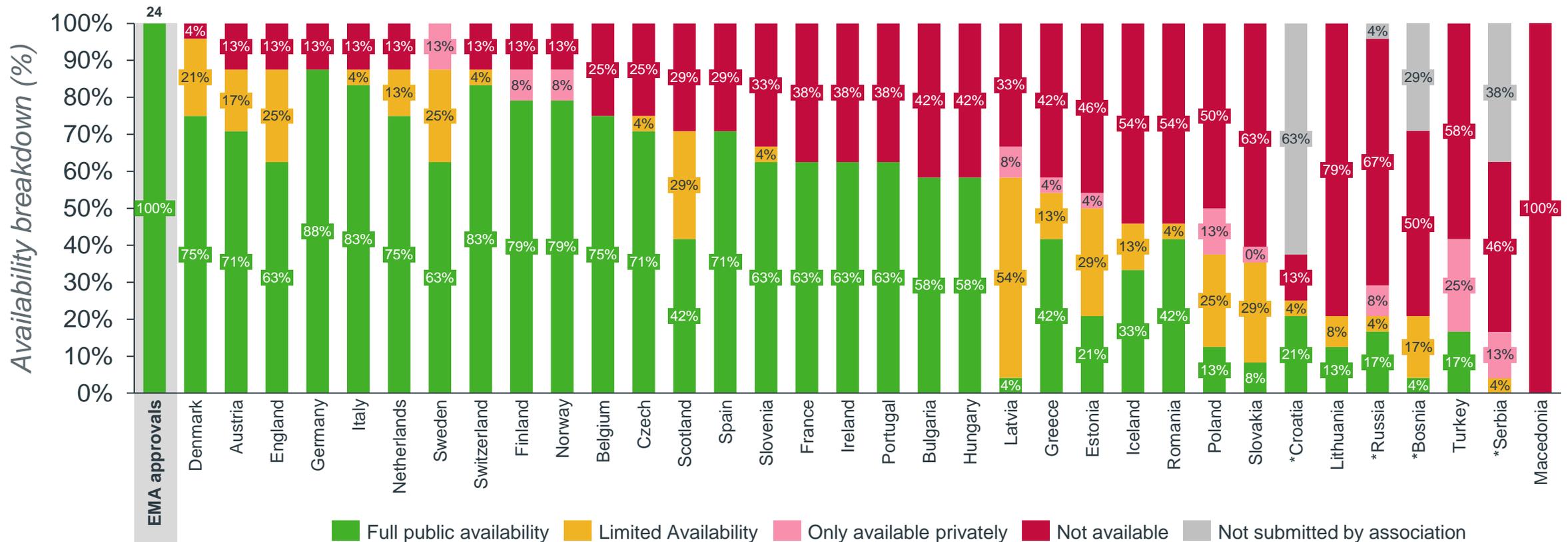
The **rate of availability**, measured by the number of medicines available to patients in European countries as of 2020. For most countries this is the point at which the product gains access to the reimbursement list†, including products with limited availability.



European Union average: 15 products available (64%) (excludes data from Cyprus, Malta, and Luxembourg as these countries are not included in the study) †In most countries availability equates to granting of access to the reimbursement list, except in DK, FI, 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.

Combination therapies rate of availability (% , 2016 – 2019)

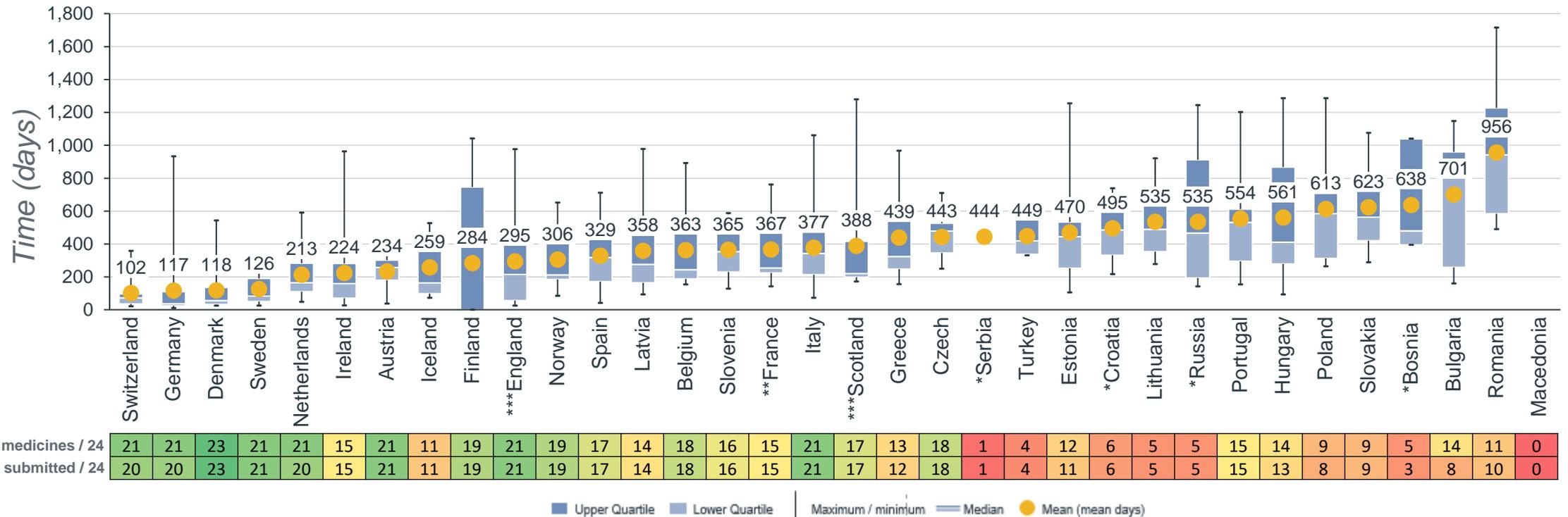
The **rate of availability** is the number of medicines available to patients in European countries (for most countries this is the point at which the product gains access to the reimbursement list[†]). This includes all medicines status to provide a complete picture of the availability of the cohort of medicines studied.



European Union average: 15 products available (64%) (excludes data from Cyprus, Malta, and Luxembourg as these countries are not included in the study); EU averages: 11% of the study cohort is subject to limited availability; 20% of available products have limited availability across EU countries. Ireland and Norway did not submit information on restrictions to available medicines meaning LA* is not captured in these countries. As Ireland has been included in the EU average calculations, the EU average number of products with limited availability may be understated. [†]In most countries availability equates to granting of access to the reimbursement list, except in DK, FI, 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.

Combination therapies time to availability (2016 – 2019)

The **time to availability** (previously know as length of delay) is the days between EMA 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[†]).



European Union average: 411 days (mean) (excludes data from Cyprus, Malta, and Luxembourg as these countries are not included in the study) [†]In most countries availability equates to granting of access to the reimbursement list, except in DK, FI, 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 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.

Key observations

Combination therapies

Measure	EU average for all products	Oncology	Orphan	Non-oncology orphan	Combination therapy	Key
Rate of availability	49%	58% ↑	41% ↓	34% ↓	64% ↑	Arrows indicate direction from the EU average for all products ↑ Higher availability ↓ Lower availability
Average time to availability	504 days	561 days ↑	653 days ↑	667 days ↑	411 days ↓	↓ Shorter ↑ Longer

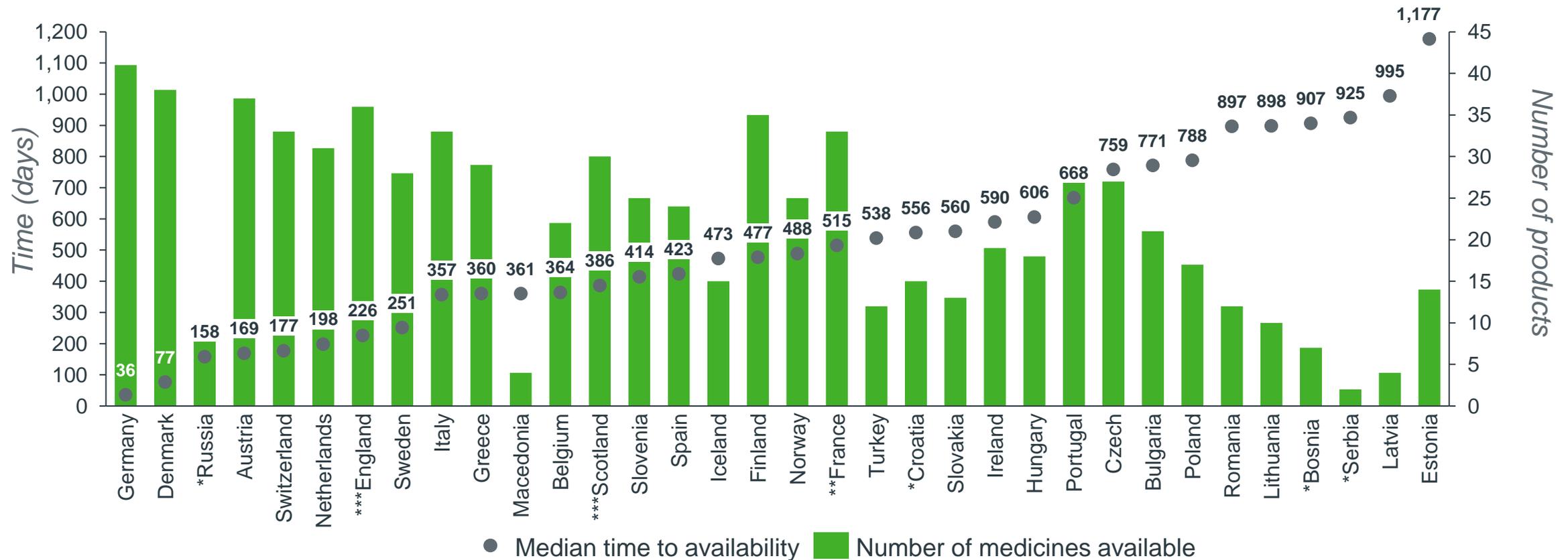
- EU average availability is 15% higher for combination therapies than for all products.
- Combination therapies is the only segment where average time to availability is faster than the average time to availability for all products (3 months faster).
- Only one innovative combination therapy was centrally approved in 2019 and added to the incoming cohort [2019], compared to 10 in the outgoing cohort [2015].
- In over 80% of countries, the rate of availability is higher for combination products compared to all products approved between 2016-2019.
- 85% of the countries have a shorter average delay for combination drugs compared to all products approved 2016-2019.

Appendix and detailed methodology

Comparison versus prior studies ➤ Extended data period ➤ Study cohort ➤ Country specific definitions

Oncology median time to availability (2016 – 2019)

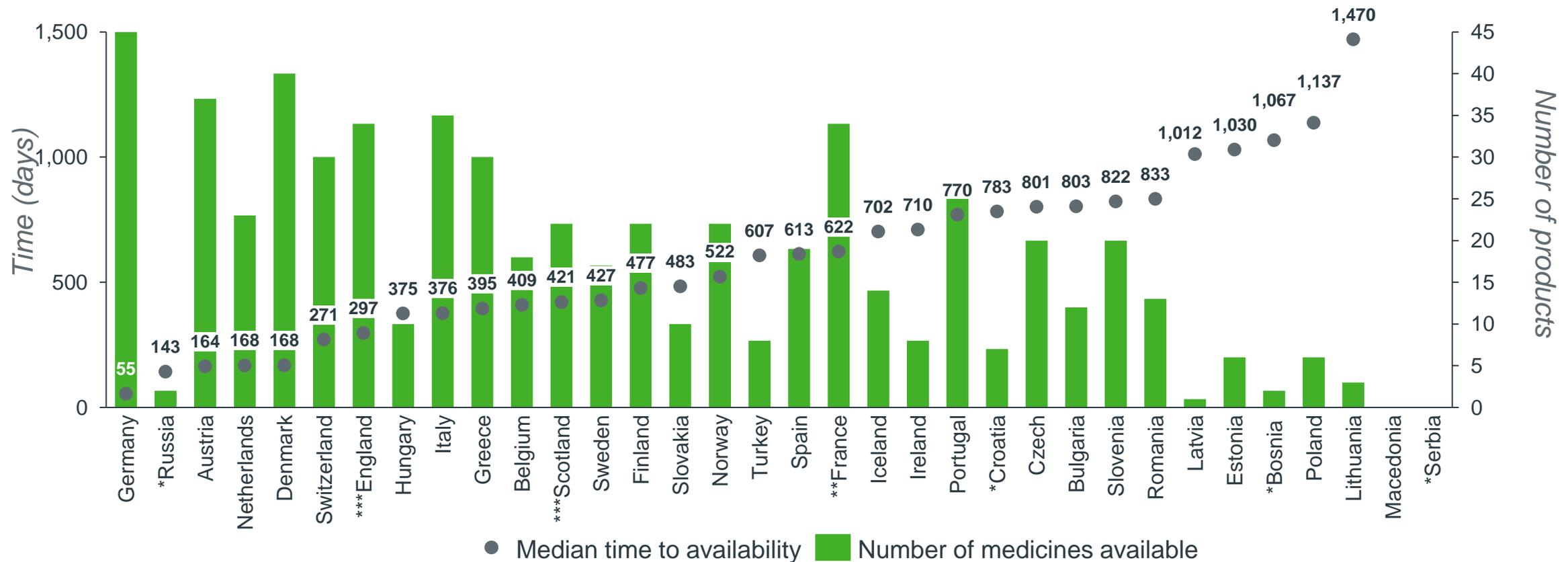
The **time to availability** (previously known as length of delay) is the days between marketing authorisation and the date of availability to patients in European countries (for most this is the point at which products gain access to the reimbursement list †).



†In most countries patient access equates to granting of access to the reimbursement list, except for hospital products in DK, FI, NO, SE some products are not covered by the general reimbursement scheme and so this shorter delay is artificially declining the median and average; *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 reality. ***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 (2016 – 2019)

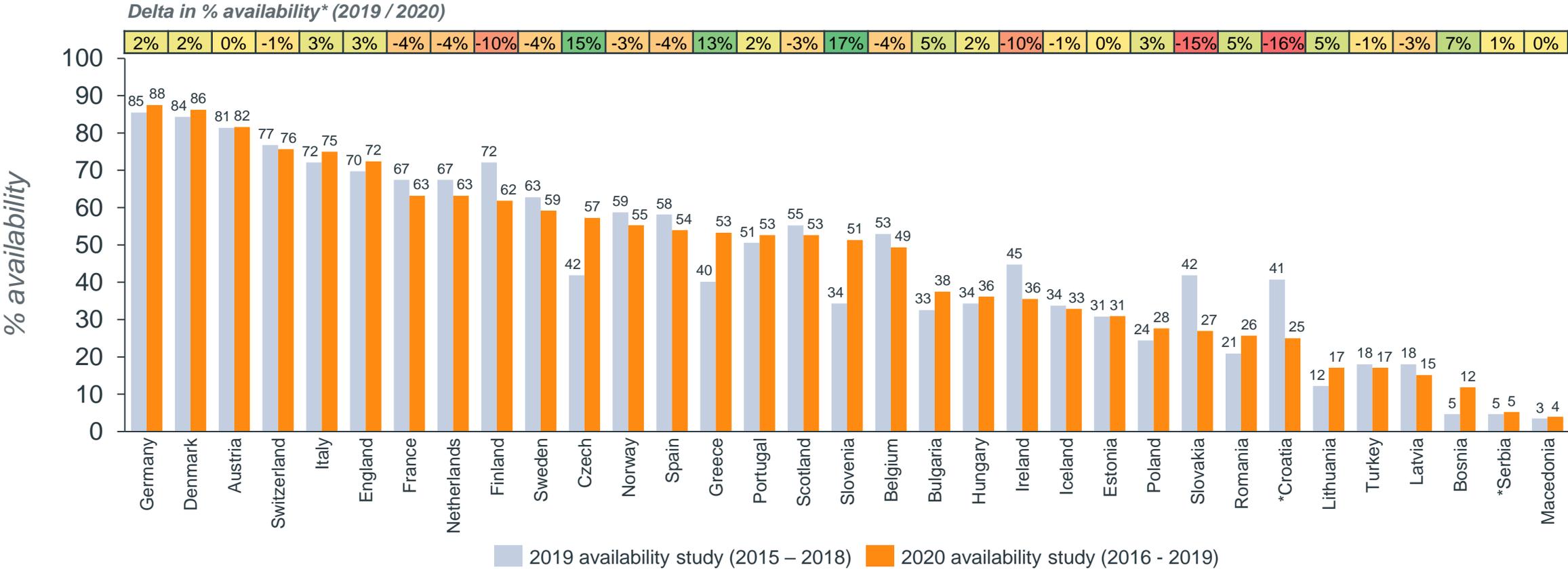
The **time to availability** (previously know as length of delay) is the days between marketing authorisation and the date of availability to patients in European countries (for most this is the point at which products gain access to the reimbursement list †).



†In most countries patient access equates to granting of access to the reimbursement list, except for hospital products in DK, FI, NO, SE some products are not covered by the general reimbursement scheme and so this shorter delay is artificially declining the median and average; *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 reality. ***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

Comparison of availability (2019 study vs 2020 study)

The **rate of availability**[†], measured by the number of medicines available to patients in European countries as of 2020, compared to the rate of availability in the 2019 W.A.I.T. indicator study.



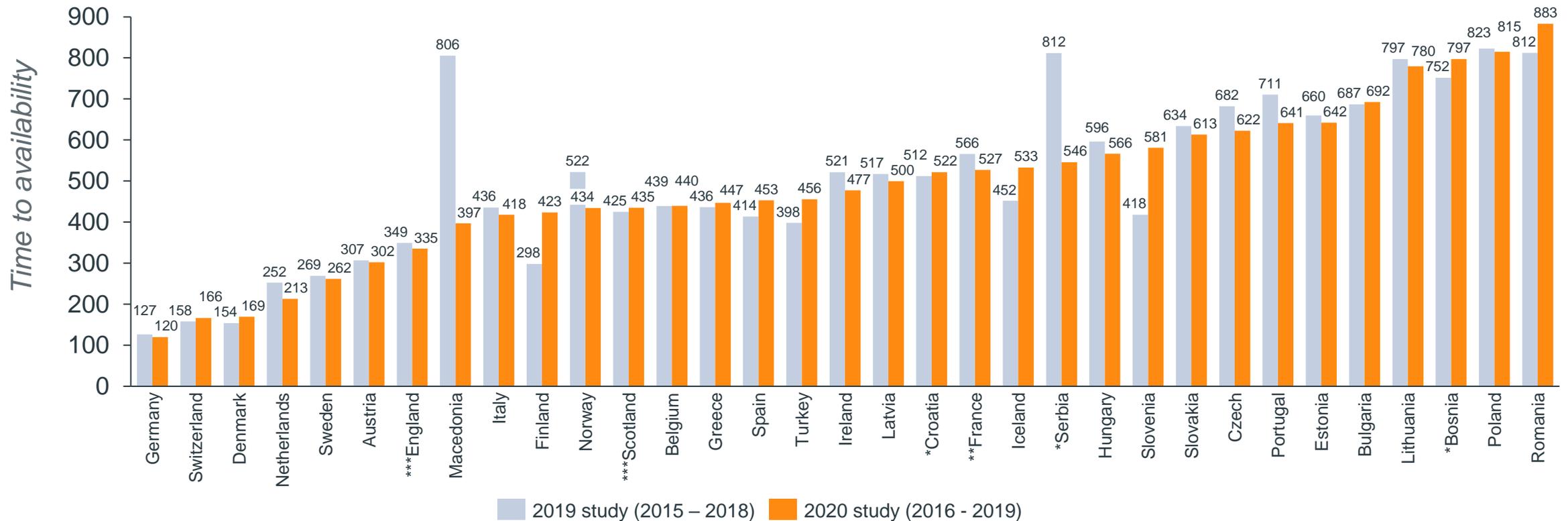
Note: *Discrepancies between the graph and delta are due to rounding; †In most countries availability equates to granting of access to the reimbursement list, except in DK, FI, NO, SE some hospital products are not covered by the general reimbursement scheme. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative.

Comparison of time to availability (2019 study vs 2020 study)

The **time to availability** (previously know as length of delay) is the days between marketing authorisation and the date of availability to patients compared to the time to availability in the 2019 W.A.I.T. indicator study.

Delta in days* (2019 / 2020)

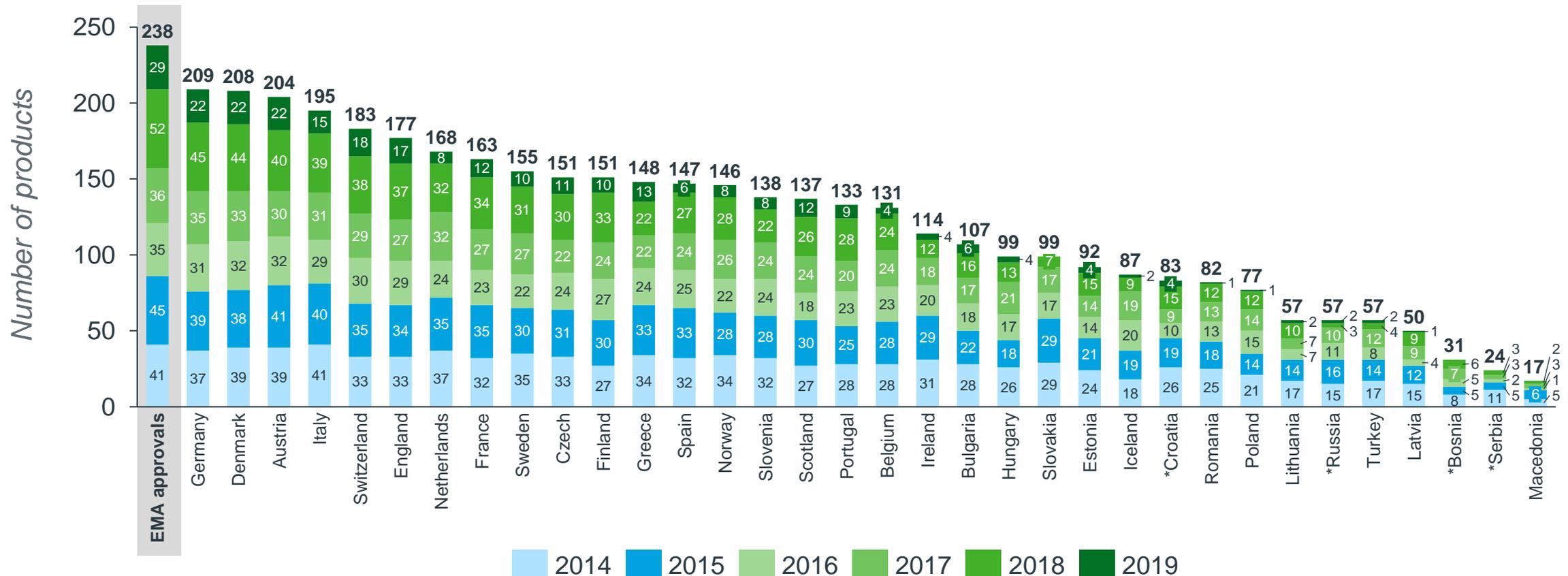
-7	8	16	-40	-7	-4	-14	-409	-18	125	-88	10	1	11	39	58	-44	-18	9	-39	81	-266	-30	163	-21	-60	-70	-18	6	-17	46	-8	71
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Note: Discrepancies between the graph and delta are due to rounding; *Countries with asterisks did not complete a full dataset and therefore 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.

Total availability by approval year (2014-2019)

The **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 in Europe.



European Union average: 132 products available (55%) (excludes data from Cyprus, Malta, and Luxembourg as these countries are not included in the study) [†]In most countries availability equates to granting of access to the reimbursement list, except in DK, FI, 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.

Rate of availability (2014-2019)

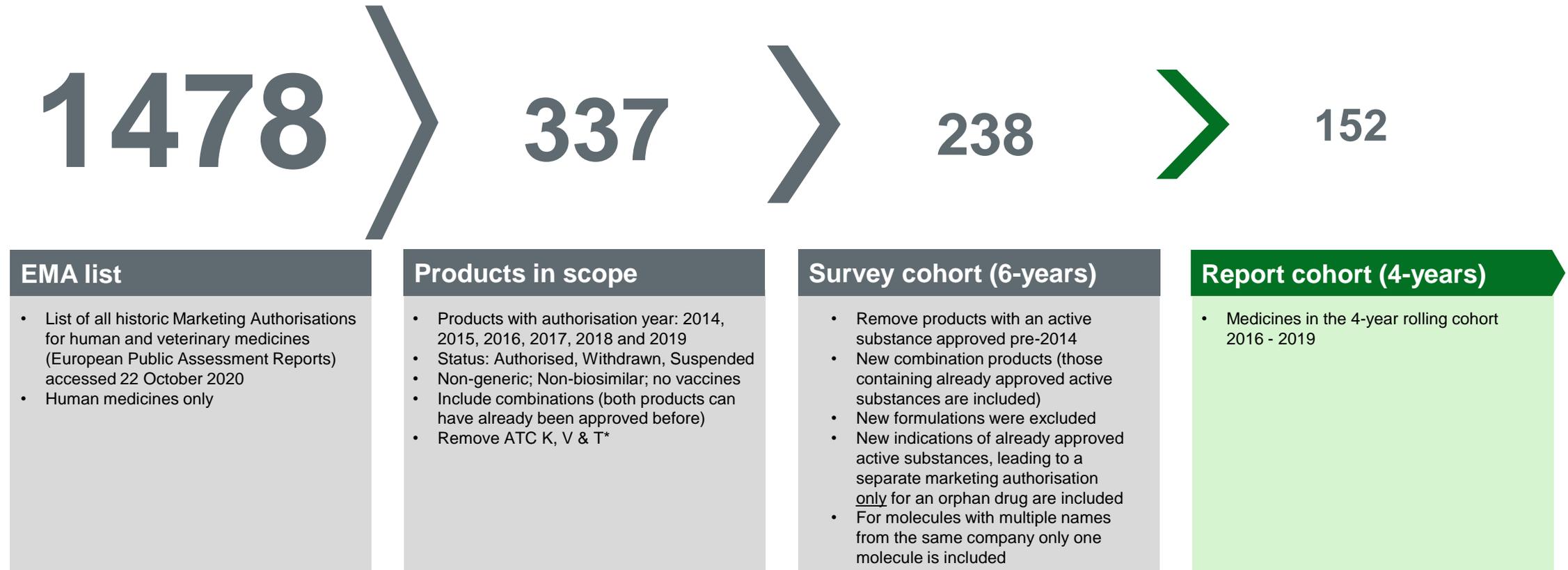
The **rate of availability**, measured by the number of medicines available to patients in European countries as of 2020. For most countries this is the point at which the product gains access to the reimbursement list[†], including products with limited availability.



European Union average: 132 products available (55%) (excludes data from Cyprus, Malta, and Luxembourg as these countries are not included in the study) [†]In most countries availability equates to granting of access to the reimbursement list, except in DK, FI, 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.

Method and data availability

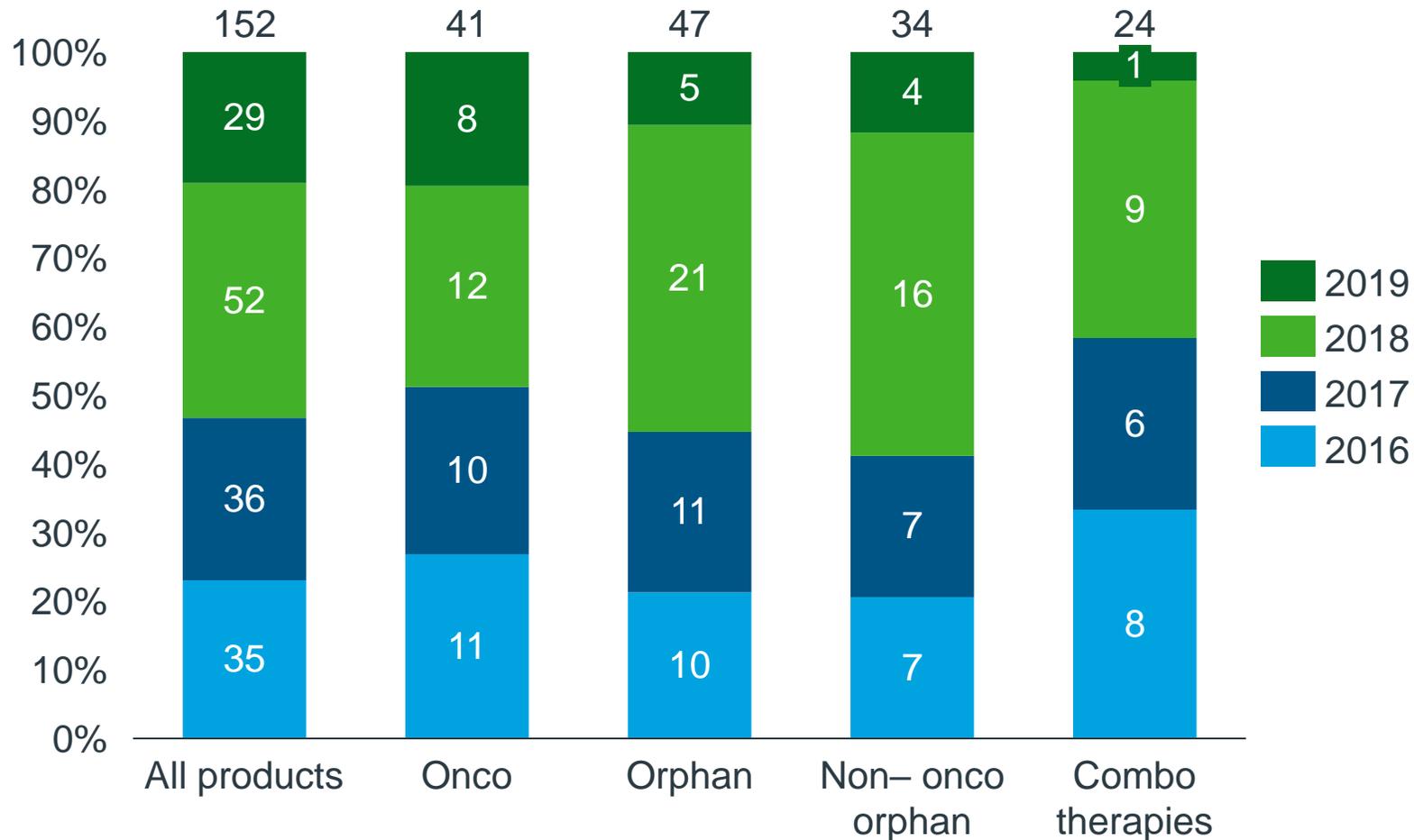
Process for product selection



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

Study composition

By year of marketing authorisation



Definitions:

- Products with central marketing authorisation, sourced from EMA EPARs (last accessed December 2020)
- 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

Products included in the study: 2016-2019 approvals (n=152)

Adynovi	Darzalex	Jorveza	Olumiant	Spectrila	Vemlidy
Afstyla	Delstrigo	Juluca	Oncaspar	Spherox	Venclyxto
Aimovig	Descovy	Kevzara	Ongentys	Spinraza	Verkazia
Ajovy	Doptelet	Kigabeg	Onivyde pegylated liposomal	Spravato	Verzenio
Alecensa	Dovato	Kisqali	Onpattro	Steglatro	Veyvondi
Alofisel	Dupixent	Kymriah	Oxervate	Steglujan	Vitrakvi
Alpivab	Emgality	Kyntheum	Ozempic	Strimvelis	Vizimpro
Alprolix	Empliciti	Lamzede	Palynziq	Suliqua	Vosevi
Alunbrig	Epclusa	Ledaga	Parsabiv	Symkevi	Vyxeos liposomal
Amglidia	Epidyolex	Libtayo	Pifeltro	Symtuza	Wakix
Baqsimi	Episalvan	Lonsurf	Portrazza	Tagrisso	Waylivra
Bavencio	Erleada	Lorviqua	Poteligeo	Takhzyro	Xeljanz
Besponsa	Evenity	Luxturna	Prevymis	Taltz	Xerava
Besremi	Fasenra	Maviret	Qtern	Talzenna	Xermelo
Bevespi Aerosphere	Feraccru	Mektovi	Quofenix	Tecentriq	Xospata
Biktarvy	Fotivda	Mepsevii	Reagila	Tegsedi	Yescarta
Braftovi	Galafold	Mulpleo	Refixia	Tookad	Zavicefta
Brineura	Giapreza	Myalepta	Rekovelte	Trecondi	Zejula
Briviact	Glyxambi	Mylotarg	Rhokiinsa	*Trelegy Ellipta	Zepatier
Cablivi	Hemlibra	Namuscla	Rinvoq	Tremfya	Zinplava
Chenodeoxycholic acid Leadiant	Ibrance	Natpar	Rizmoic	Trimbow	Zynquista
Cinquaero	Idelvion	Nerlynx	Rubraca	Trogarzo	Zynteglo
Coagadex	Ilumetri	Ninlaro	Rxulti	Truberzi	
Crysvita	Imfinzi	Ocaliva	Rydapt	Ultomiris	
Cuprior	Intrarosa	Ocrevus	Segluromet	Uptravi	
Cystadrops	Jivi	Odefsey	Skyrizi	Vaborem	

*Trelegy Ellipta and Elebrato Ellipta are considered as one product as there are multiple authorisations for the same active substance combination for the same company on the same date

Products included in the study by segment: 2016-2019 approvals

Oncologics (n=41)

Alecensa	Poteligeo
Alunbrig	Rubraca
Bavencio	Rydapt
Besponsa	Spectrila
Braftovi	Tagrisso
Darzalex	Talzenna
Empliciti	Tecentriq
Erleada	Tookad
Fotivda	Trecondi
Ibrance	Venclyxto
Imfinzi	Verzenio
Kisqali	Vitrakvi
Kymriah	Vizimpro
Ledaga	Vyxeos liposomal
Libtayo	Xospata
Lonsurf	Yescarta
Lorviqua	Zejula
Mektovi	
Mylotarg	
Nerlynx	
Ninlaro	
Oncaspar	
Onivyde pegylated liposomal	
Portrazza	

Orphans (n=47)

Alofisel	Ninlaro
Alprolix	Ocaliva
	Onivyde pegylated liposomal
Amglicia	Onpattro
Besponsa	Oxervate
Brineura	Palynziq
Cablivi	
Chenodeoxycholic acid Leadiant	Poteligeo
Coagadex	Prevymis
Crysvita	Rydapt
Cystadrops	Spinraza
Darzalex	Strimvelis
Epidyolex	Symkevi
Galafold	Takhzyro
Idelvion	Tegsedi
Jorveza	Verkazia
Kymriah	Vyxeos liposomal
Lamzede	Wakix
Ledaga	Waylivra
Luxturna	Xermelo
Mepsevii	Xospata
Myalepta	Yescarta
Mylotarg	Zejula
Namuscla	Zynteglo
Natpar	

Non-oncologic orphans (n=34)

Alofisel	Spinraza
Alprolix	Strimvelis
Amglicia	Symkevi
Brineura	Takhzyro
Cablivi	Tegsedi
Chenodeoxycholic acid Leadiant	Verkazia
Coagadex	Wakix
Crysvita	Waylivra
Cystadrops	Xermelo
Epidyolex	Zynteglo
Galafold	
Idelvion	
Jorveza	
Lamzede	
Luxturna	
Mepsevii	
Myalepta	
Namuscla	
Natpar	
Ocaliva	
Onpattro	
Oxervate	
Palynziq	
Prevymis	

Combination therapies (n=24)

Bevespi Aerosphere
Biktarvy
Delstrigo
Descovy
Dovato
Epclusa
Glyxambi
Juluca
Lonsurf
Maviret
Odefsey
Qtern
Segluromet
Steglujan
Suliqua
Symkevi
Symtuza
*Trelegy Ellipta
Trimbow
Vaborem
Vosevi
Vyxeos liposomal
Zavicefta
Zepatier

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
Czech	A medicine is available if it is on the reimbursement list, or funded through the hospital
Denmark	Accessibility on the public reimbursement list
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 reimbursement system, are available through a Name Patient Program or are financed by the hospital budget.
Iceland	Accessibility on the public reimbursement list
Ireland	Accessibility on the public reimbursement list
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
Macedonia	Product is available via specially allocated budget for all eligible patients
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 for New Technologies has recommended the introduction of the new drug into hospitals.
Poland	In most cases a medicine is available if it gains access to the reimbursement list, however, some medicines are financed via an alternative financial source (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.
Russia	Inclusion on the Essential Drug 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 22nd 2020 (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 but had a non-negligible level of sales (estimated to be recurrent and representative of more than single patients) during the first ten months of 2020.
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 only reimbursed on an individual basis
Bulgaria	No products are reported to have limited availability
Belgium	There are no restrictions on availability
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).
Czech	Product is only reimbursed for limited indications (compared to what was approved at market authorisation)
Denmark	Products which don't automatically receive public reimbursement, however, the patient can obtain an individual reimbursement if the doctors apply on their behalf.
England	Recommended for a restricted patient cohort relative to licenced indication, either through an optimised NICE decision (including optimised CDF decisions) or an individual funding request.
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 system of Temporary Use Authorisations
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 pending reimbursement decision or has not been reimbursed, but is available through a Name Patient Program.
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	Association was unable to report on limitations to availability
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
Latvia	Only available through individual reimbursement
Lithuania	Only reimbursed for limited indications (compared to what was approved at market authorisation)
Macedonia	Product is available via specially allocated budget for limited number of patients
Netherlands	Only reimbursed under certain therapeutic conditions (annex 2 on the positive reimbursement list).
Norway	Association was unable to report on limitations to availability
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.
Russia	Medicines included in regional reimbursement channels
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-d 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
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 1 st 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
Denmark	The medicine gained market approval by the Danish Medicines Agency and a price noted in medicinpriser.dk.
England	For medicines with a positive NICE recommendation, the accessibility date is the date of published guidance (cancer medicines) or date of published guidance + 90 days (non-cancer medicines). Cancer medicines benefit from earlier funding. For the remaining medicines, the 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
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
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	Almost all availability dates are found on public lists, with a few exceptions for some of the oldest medicines in the survey which became available on an individual basis without a formal decision.
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	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.
Russia	The date of availability is considered to be the first date of availability on the public reimbursement list or the first month of sales of reimbursement /hospital channel according to IQVIA's sales database.
Scotland	For medicines with a positive SMC recommendation, the accessibility date is the date of published guidance + 90 days. 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	The first date of a positive TLV decision or NT recommendation for available reimbursement or hospital drugs, or YY-MM-15 for hospital drugs where no NT recommendation had been made but the medicine was assessed to have relevant IQVIA sales; or whichever occurred first of YY-MM-15 or the first date of a positive TLV decision/NT recommendation for medicines indicated for treatment of communicable diseases according to The Communicable Diseases Act (2004:168).
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"



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