EFPIA Patients W.A.I.T. Indicator 2021 Survey

For use by Central & Eastern European markets, April 2022

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This year's Patients W.A.I.T. indicator has expanded to 38 countries and now includes the full EU27 countries

New indicators have been added on rate of restrictions and time to local authorisation dates

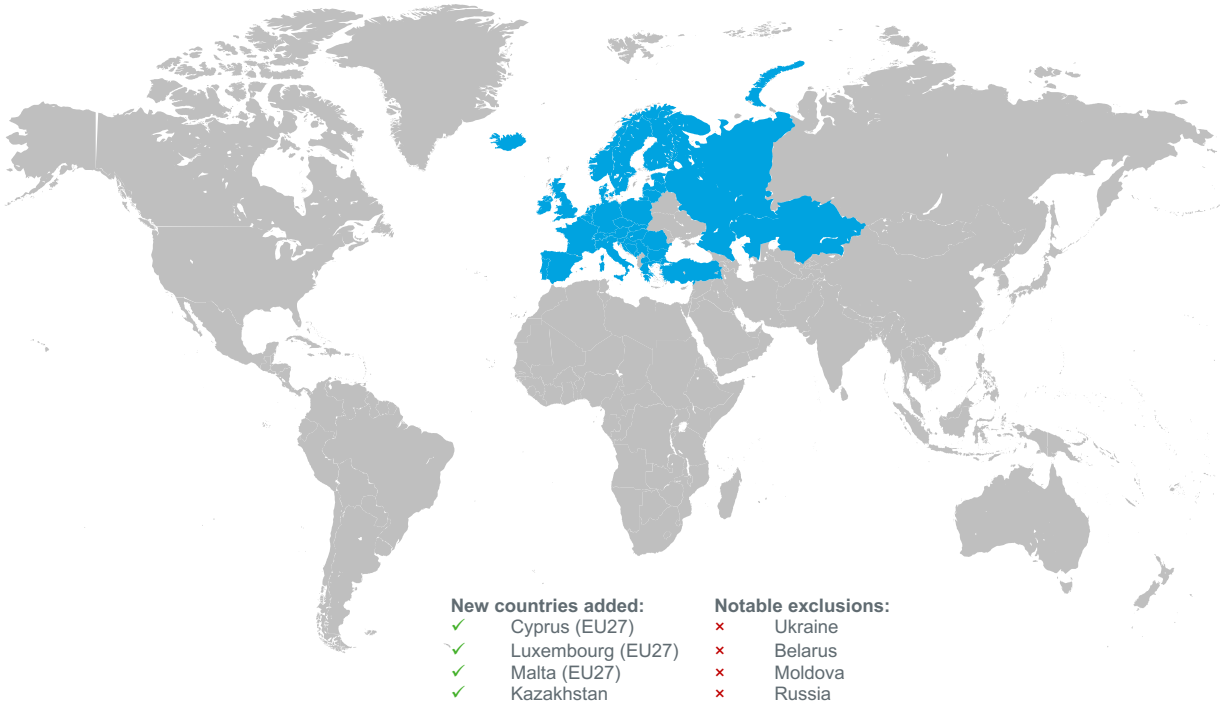
Improving the availability of medicines authorised in the European Union (EU) is a key priority for the European medicines regulatory network and for the pharmaceutical industry. This year's iteration of the Patients W.A.I.T. (**W**aiting to **A**ccess **I**nnovative **T**herapies) Indicator has been running in evolving formats since 2004 and is 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 38 countries (27 EU, and 11 non-EU) are included giving a full European picture of availability.

Information on the 160 innovative medicines with central-marketing authorisation between 2017 and 2020 are included within the coming pages, with 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 1st 2022.* This period is therefore inclusive of the COVID-19 pandemic, although no significant impact is noted in the indicator the impact on uptake has been shown through other studies.

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



38 European countries

160 innovative medicines

4 year cohort ('17-'20)

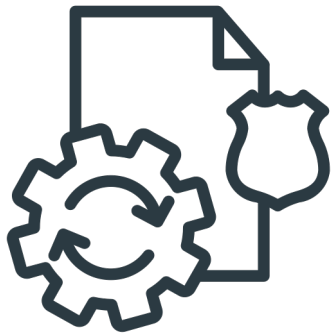
Data available | Data not available / included

Contents

Click on hyperlinks for navigation to specific indicators

Patients W.A.I.T. survey has evolved, and is entering its 18th year

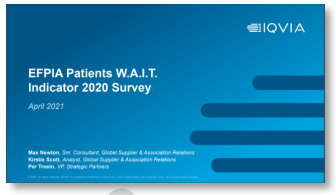
The indicator long-running, and one of the largest datasets on medicines availability in Europe



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 issued on a 6-monthly basis, providing a benchmark analysis of time needed for pricing / reimbursement processes after MA.



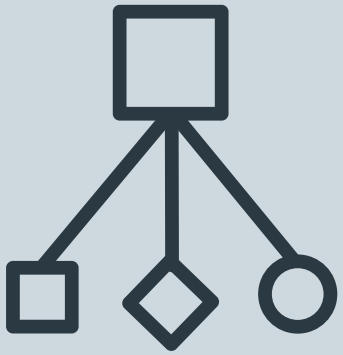
2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022

EFPIA/ CRA report on root causes

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

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 39 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 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, Kazakhstan, Macedonia, Russia, Serbia, Switzerland and Turkey.

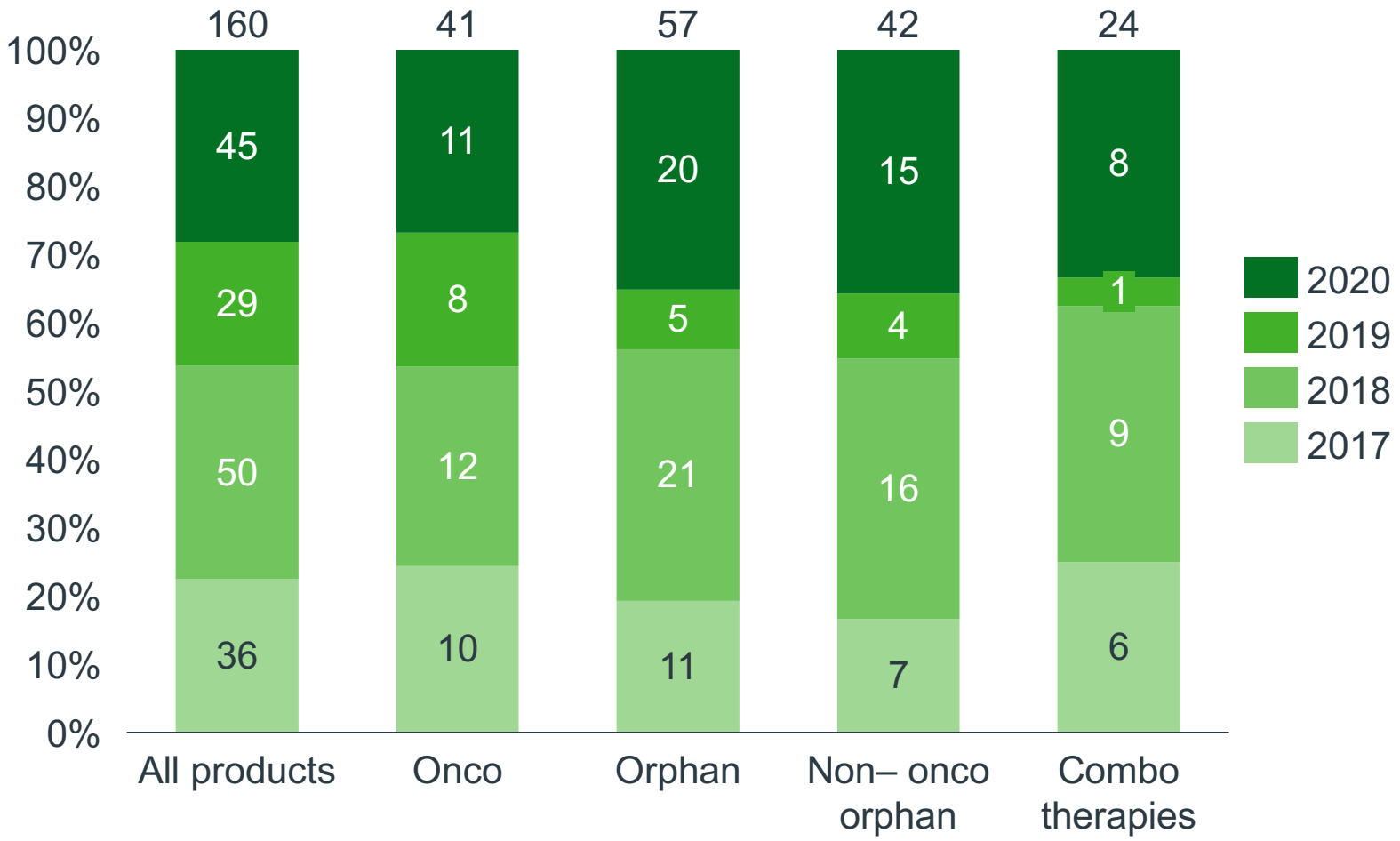
Completeness: Some country associations did not submit full datasets. Countries with substantially limited datasets are: Albania (<5% complete), Bosnia (59% complete), Croatia (34% complete), Cyprus (44% complete), Macedonia (79% complete), and Malta. This is noted on slides with an asterisk (*).

Average calculations: The EU averages noted throughout are averages for the 27 countries in the European Union. This is the first year that Cyprus, Malta, and Luxembourg have participated in the study meaning the averages use a different cohort of countries than 2020

* **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.

Study composition

By year of marketing authorisation



Definitions:

- Products with central marketing authorisation, sourced from EMA EPARs (last accessed November 2021)
- Orphan status from EMA on orphan medical products (OMP) status
- Oncology products flagged using IQVIA MIDAS Oncology market definition: L1 & L2 & V3C & Revlimid & Xgeva & Proleukin & Pomalyst
- Combination products include any product with more than one molecule, including branded / generic combinations in fixed doses.

Figures are subject to change versus previous year's due to product withdrawals

1. Overview (all products)

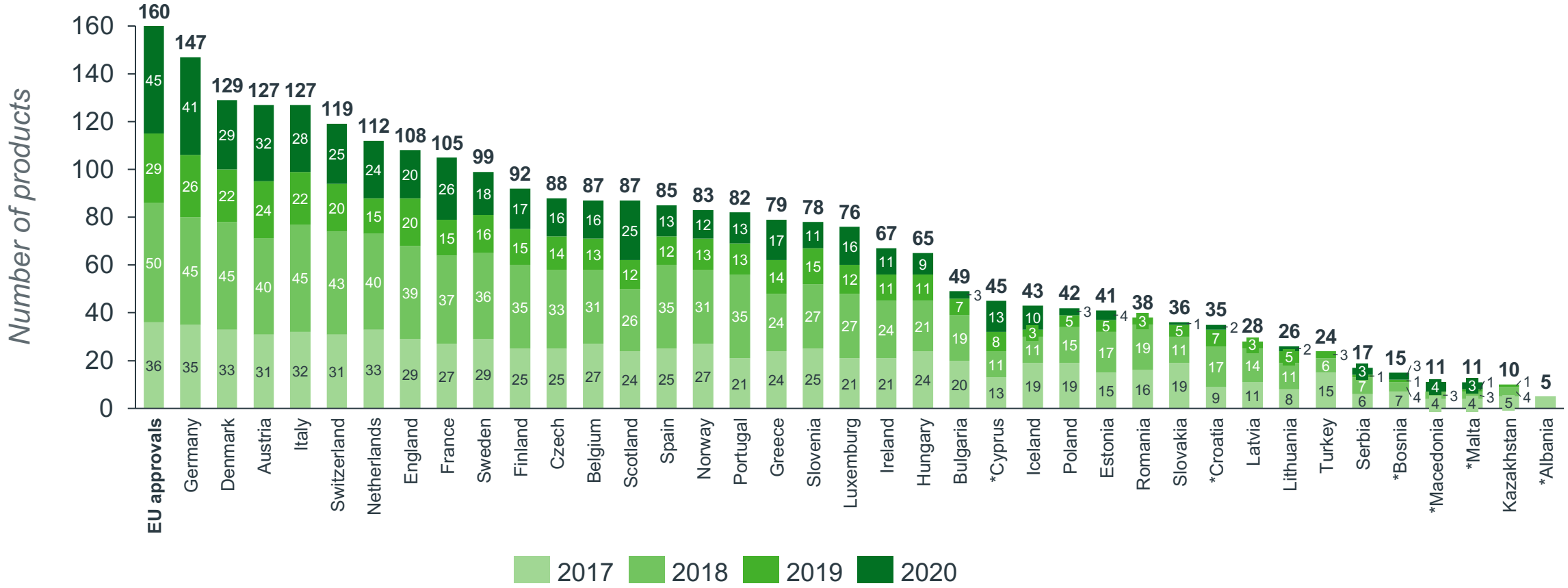
Indicators:

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 to availability
1.6. Time from central approval to availability*

**** Denotes new indicators published in 2022***

Total availability by approval year (2017-2020)

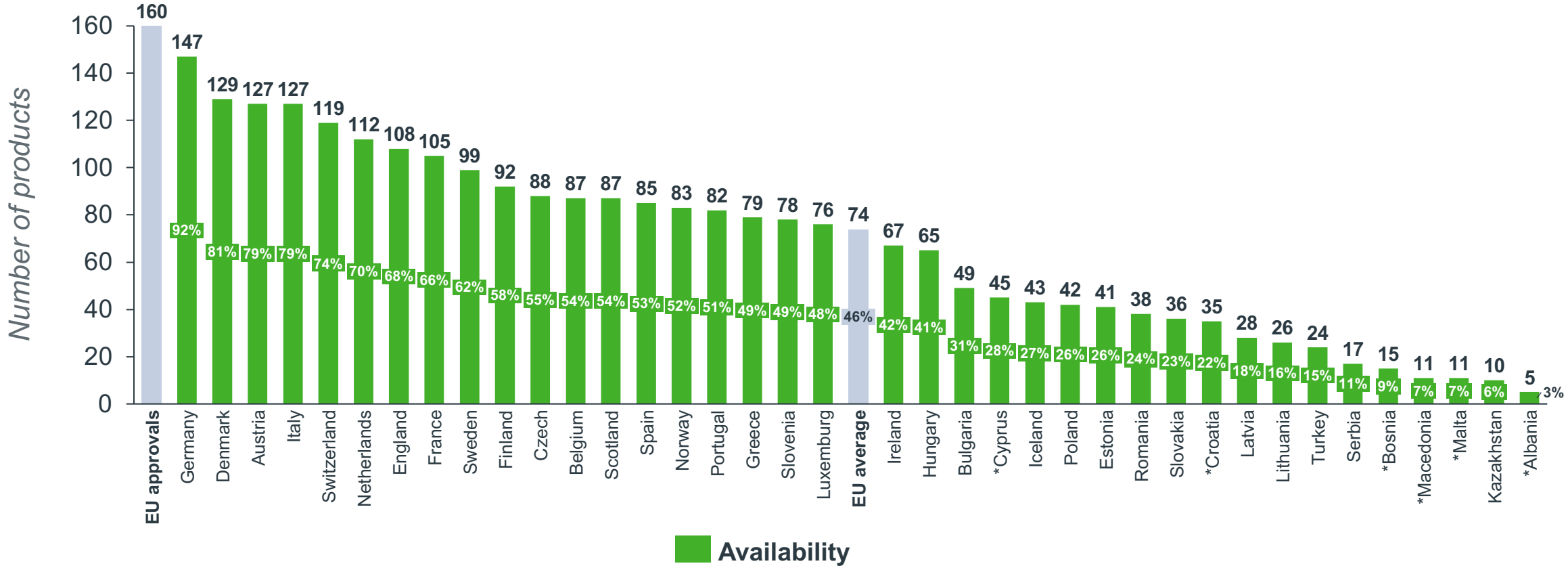
The **total availability by approval year** is the number of medicines available to patients in European countries as of 1st January 2022 (for most countries this is the point at which the product gains access to the reimbursement list†), split by the year the product received marketing authorisation in Europe.



European Union average: 74 products available (46%) †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. Country-specific nuances are listed in the appendix. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative.

Rate of availability (2017-2020)

The **rate of availability**, measured by the number of medicines available to patients in European countries as of 1st January 2022. For most countries this is the point at which the product gains access to the reimbursement list†, including products with limited availability.



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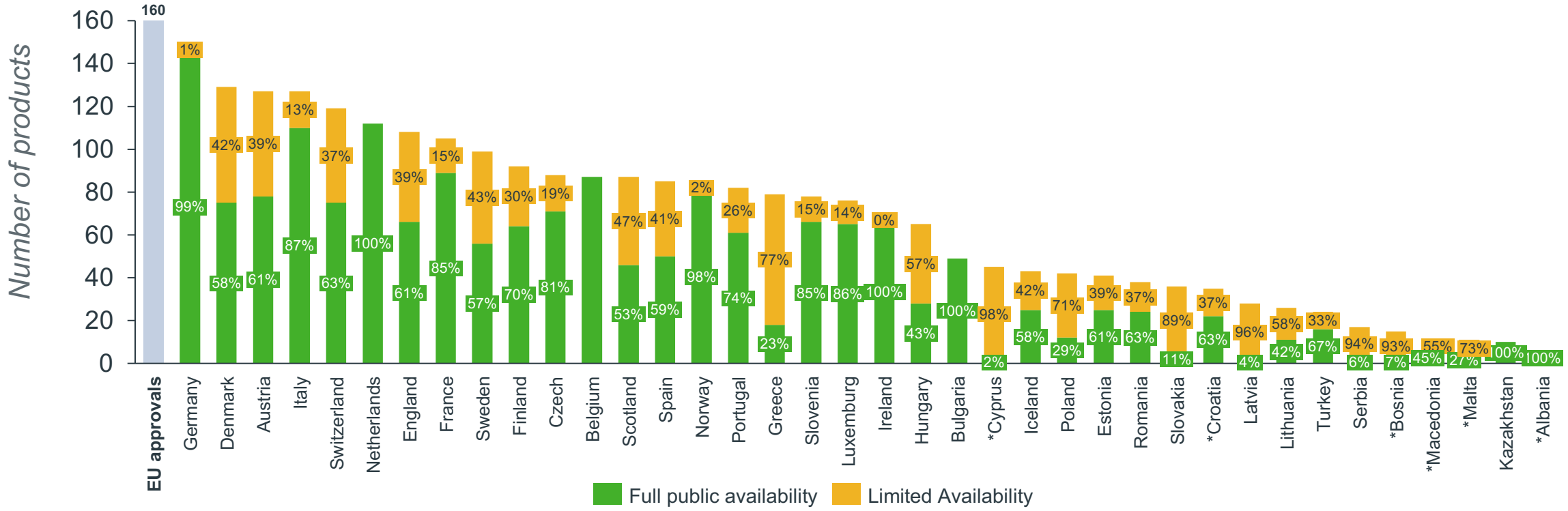
Rate of full availability (%, 2017-2020)

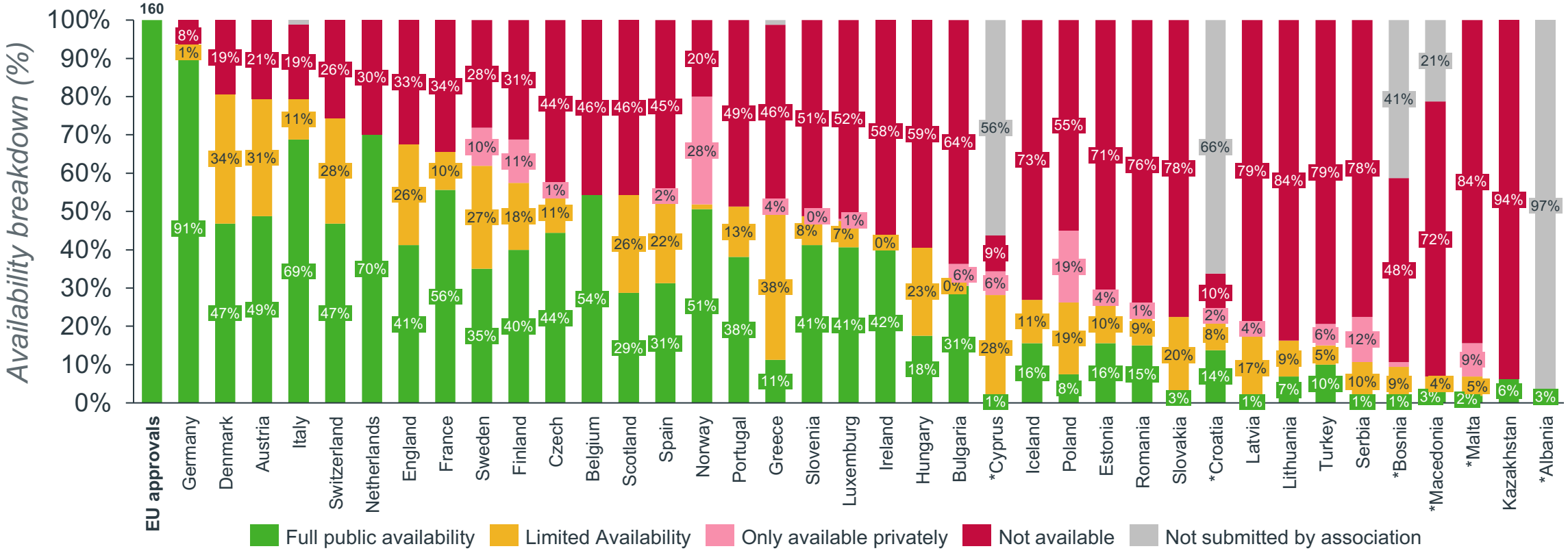
The **rate of full availability** is a new indicator which shows the proportion of medicines available to patients in European countries as of 1st January 2022 (for most countries this is the point at which the product gains access to the reimbursement list†) without any restrictions to the patient population, or through named patient basis schemes which have increased significantly in recent years and were not always captured in survey submissions.



European Union average: 74 products available (46%), Limited Availability (38% of available products) Ireland, Norway and 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, 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.

Breakdown of availability (%, 2017-2020)

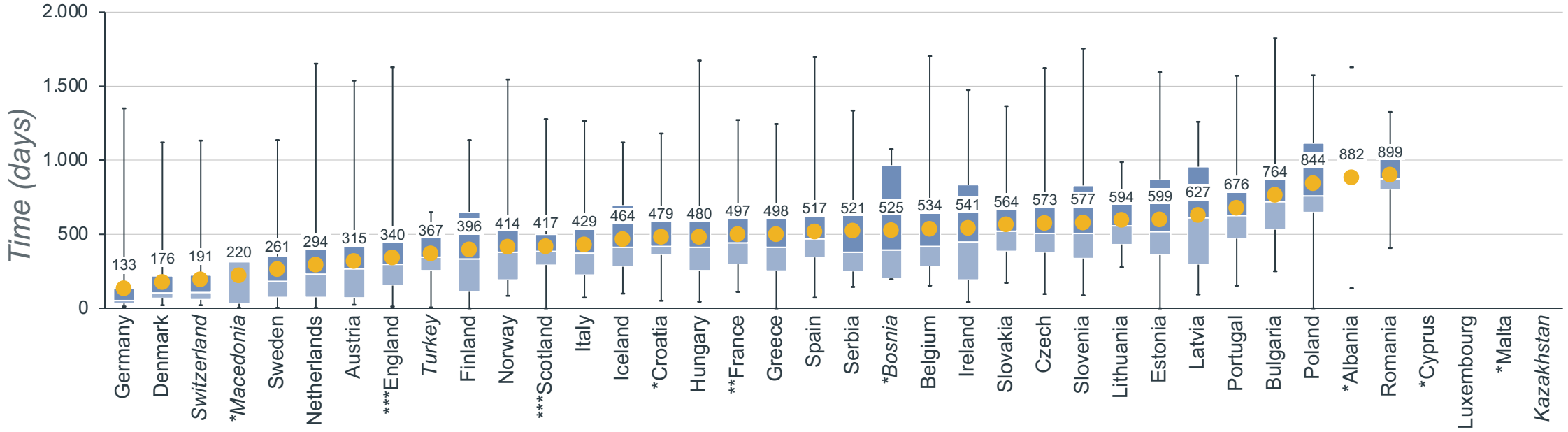
The **breakdown of availability** is the composition of medicines available to patients in European countries as of 1st January 2022 (for most countries this is the point at which the product gains access to the reimbursement list†). This includes all medicines status to provide a complete picture of the availability of the cohort studied.



European Union average: 74 products available (46%). Ireland, Norway and 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, 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 (2017-2020)

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 1st January 2022.



	Germany	Denmark	Switzerland	*Macedonia	Sweden	Netherlands	Austria	***England	Turkey	Finland	Norway	***Scotland	Italy	Iceland	*Croatia	Hungary	**France	Greece	Spain	Serbia	*Bosnia	Belgium	Ireland	Slovakia	Czech	Slovenia	Lithuania	Estonia	Latvia	Portugal	Bulgaria	Poland	*Albania	Romania	*Cyprus	Luxembourg	*Malta	Kazakhstan
Available medicines / 160	147	129	119	11	99	112	127	108	24	92	83	87	127	43	35	65	105	79	85	17	15	87	67	36	88	78	26	41	28	82	49	42	5	38	76	45	11	10
Dates submitted / 160	146	126	75	9	99	112	127	108	16	90	80	87	127	42	32	64	90	42	85	13	9	87	67	36	87	78	25	40	28	61	49	42	2	35	0	0	0	0

European Union average: 511 days (mean %) †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 (497 days, n=105 dates submitted) includes products under the ATU system (n=44 dates submitted) 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 240 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.

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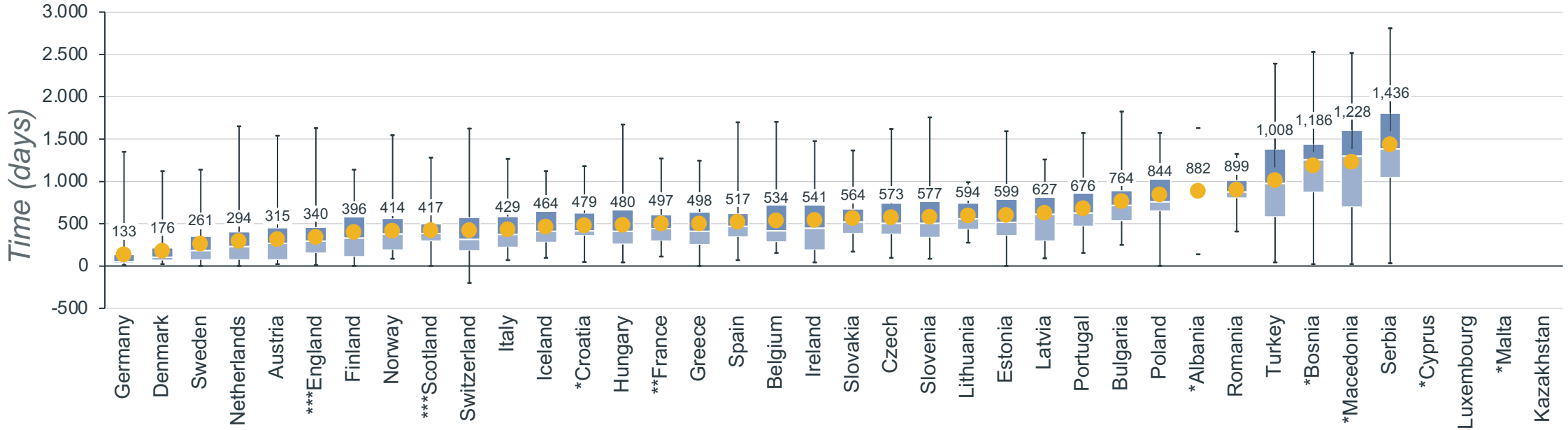
Time from central approval to availability (2017-2020)

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.



	Germany	Denmark	Sweden	Netherlands	Austria	***England	Finland	Norway	***Scotland	Switzerland	Italy	Iceland	*Croatia	Hungary	**France	Greece	Spain	Belgium	Ireland	Slovakia	Czech	Slovenia	Lithuania	Estonia	Latvia	Portugal	Bulgaria	Poland	*Albania	Romania	Turkey	*Bosnia	*Macedonia	Serbia	*Cyprus	Luxembourg	*Malta	Kazakhstan
Available medicines / 160	147	129	99	112	127	108	92	83	87	119	127	43	35	65	105	79	85	87	67	36	88	78	26	41	28	82	49	42	5	38	24	15	11	17	76	45	11	10	10
Dates submitted / 160	146	126	99	112	127	108	90	80	87	75	127	42	32	64	90	42	85	87	67	36	87	78	25	40	28	61	49	42	2	35	16	9	9	13	0	0	0	0	0

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Key observations

Executive summary

Measure	EU average for all products	Oncology	Orphan	Non-oncologic orphan	Combination therapy
Rate of availability	**46%** (49% in 2020)	55% (58% in 2020)	37% (41% in 2020)	32% (34% in 2020)	53% (64% in 2020)
Average time to availability	**511 Days** (504 days in 2020)	545 Days (561 days in 2020)	636 Days (653 days in 2020)	587 Days (667 days in 2020)	407 Days (411 days in 2020)

Summary:

- Patient access to new medicines is highly varied across Europe, with a 90% variance between Northern and Western European countries and Southern and Eastern European countries.
- EU average availability has fallen by a non-significant (<5%) versus last year's analysis, as more countries with low availability are now able to be included within the W.A.I.T. indicator
- Restrictions to the availability of medicines can change the position of countries significantly, and are increasingly present
- The average delay between market authorisation and patient access can vary by a factor greater than x7 across Europe, from as little as 4 months to 29 months (over 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 (2021) EU average (*significantly higher than current EU average* / *significantly lower than current EU average*)

Arrow colour indicates significant changes versus the previous (2020) 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

The EU averages noted throughout are averages for the 27 countries in the European Union for the first time.

2. Oncology medicines

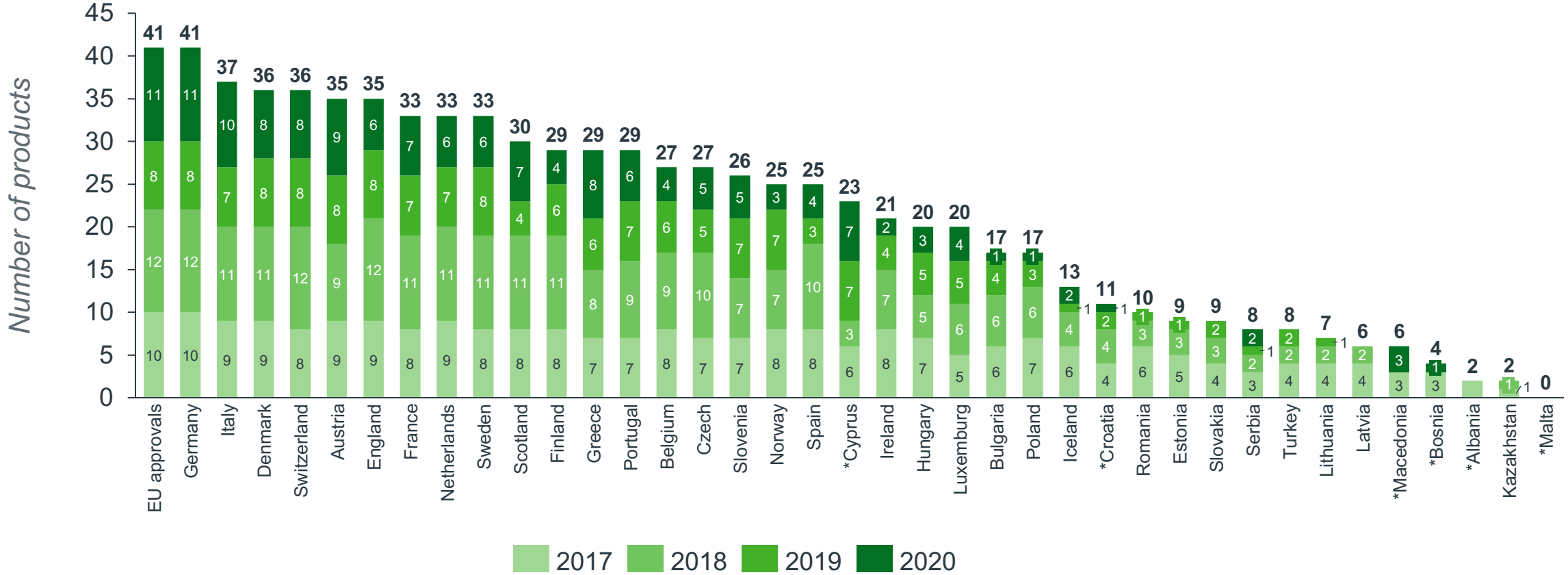
Indicators:

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

**** Denotes new indicators published in 2022***

Oncology availability by approval year (2017-2020)

The **total availability by approval year** is the number of medicines available to patients in European countries as of 1st January 2022 (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 (55%) †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 (2017-2020)

The **rate of availability**, measured by the number of medicines available to patients in European countries as of 1st January 2022. 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 (55%) †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.

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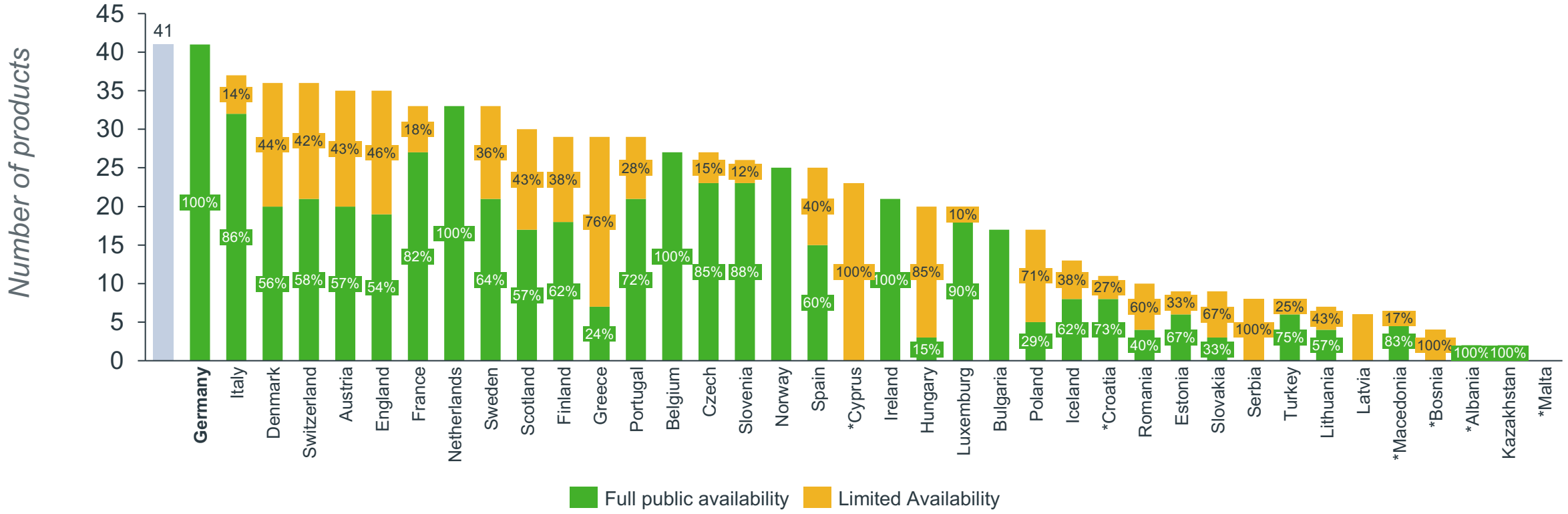
Oncology rate of full availability (%, 2017-2020)

The **rate of full availability** is a new indicator which shows the proportion of medicines available to patients in European countries as of 1st January 2022 (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 (55%), Limited availability (37% of available products). Ireland, Norway and 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, 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 breakdown of availability (%, 2017-2020)

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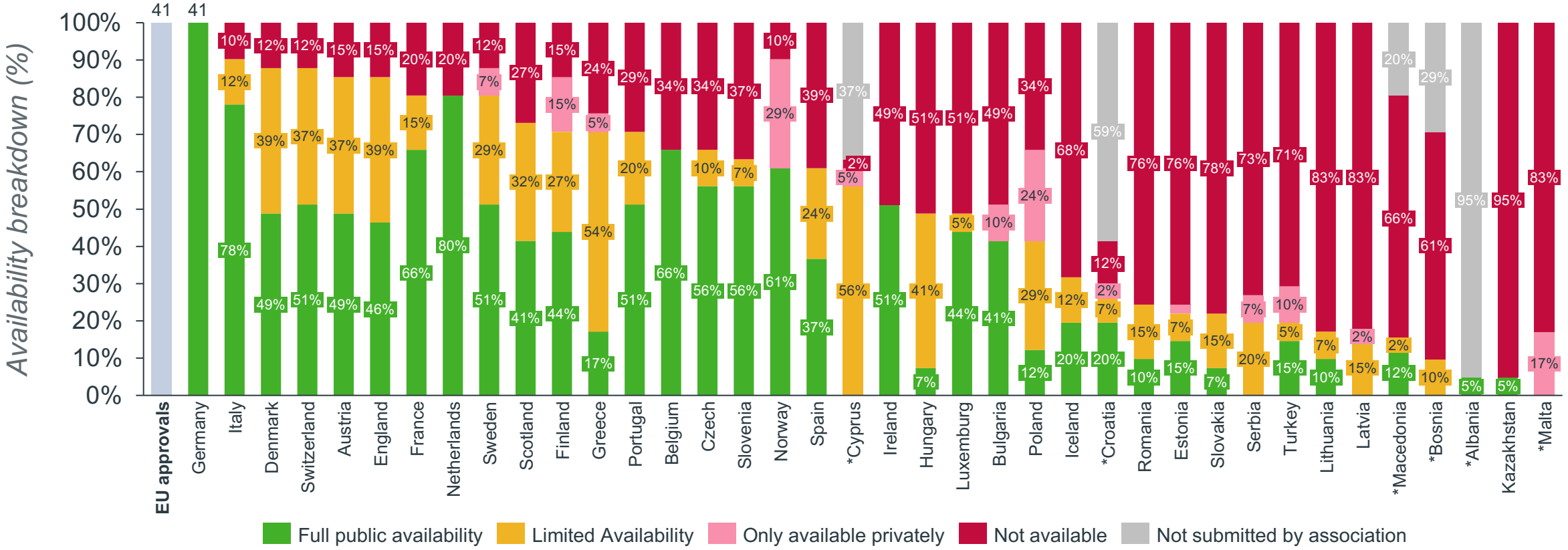

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Oncology time to availability (2017-2020)

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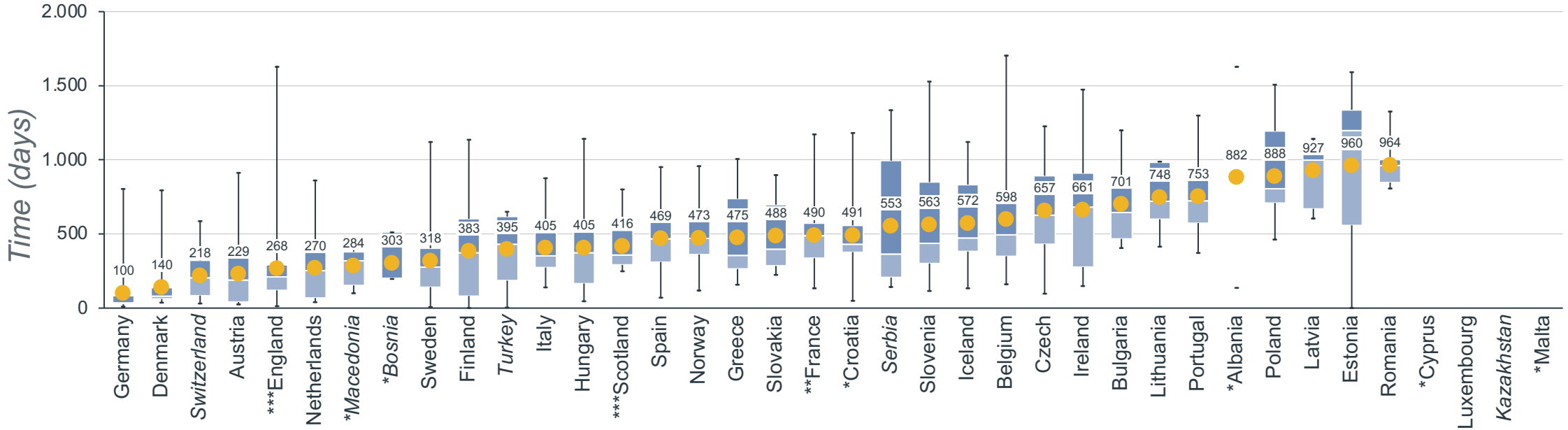

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Available medicines / 41	41	36	36	35	35	33	6	4	33	29	8	37	20	30	25	25	29	9	33	11	8	26	13	27	27	21	17	7	29	2	17	6	9	10	23	20	2	0
Dates submitted / 41	41	36	21	35	35	33	4	3	33	29	6	37	20	30	25	22	13	9	27	11	5	26	13	27	27	21	17	7	21	2	17	6	9	9	0	0	0	0

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

European Union average: 545 days (mean) †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.

IQVIA

Key observations

Executive summary

Measure	EU average for all products	Oncology	Orphan	Non-oncologic orphan	Combination therapy
Rate of availability	**46%** (49% in 2020)	55% (58% in 2020)	37% (41% in 2020)	32% (34% in 2020)	53% (64% in 2020)
Average time to availability	**511 Days** (504 days in 2020)	545 Days (561 days in 2020)	636 Days (653 days in 2020)	587 Days (667 days in 2020)	407 Days (411 days in 2020)

Summary:

- The EU average availability is 9% higher for oncology products than all products approved, however, the average time to availability for oncology products is 1 month slower which is an improvement from 2020.
- The average delay between market authorisation and patient access for Oncology products varies from 3 months to over 31 months (>2.5 years).
- Only Germany has availability to all of the most recent year's oncology medicines, versus 5 countries for 2019 (Austria, Denmark, Germany, Switzerland, England) whilst others have no availability to any
- In many markets 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 highest in this section of the W.A.I.T indicator, although it is noted that restrictions are in different markets are not always equivalent between countries

Metrics key:

Text colour indicates relative position versus the current (2021) EU average (*significantly higher than current EU average* / *significantly lower than current EU average*)

Arrow colour indicates significant changes versus the previous (2020) 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

The EU averages noted throughout are averages for the 27 countries in the European Union for the first time.

3. Orphans medicines

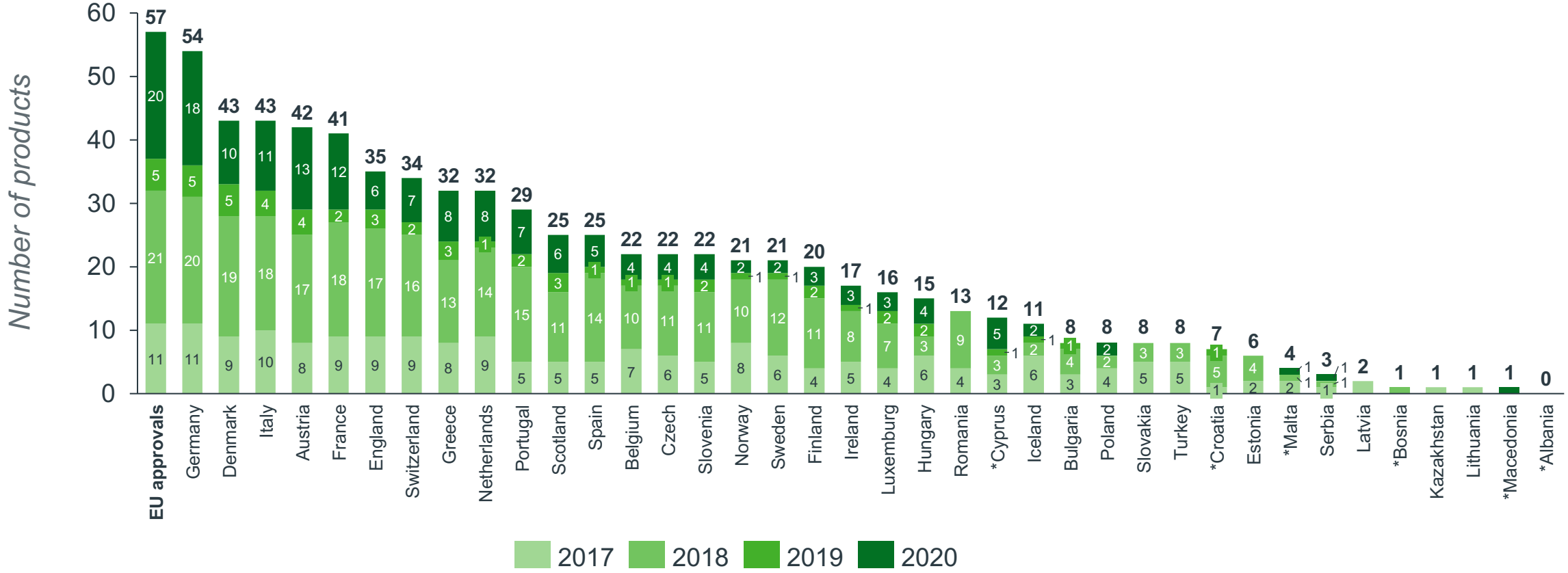
Indicators:

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

**** Denotes new indicators published in 2022***

Orphan availability by approval year (2017-2020)

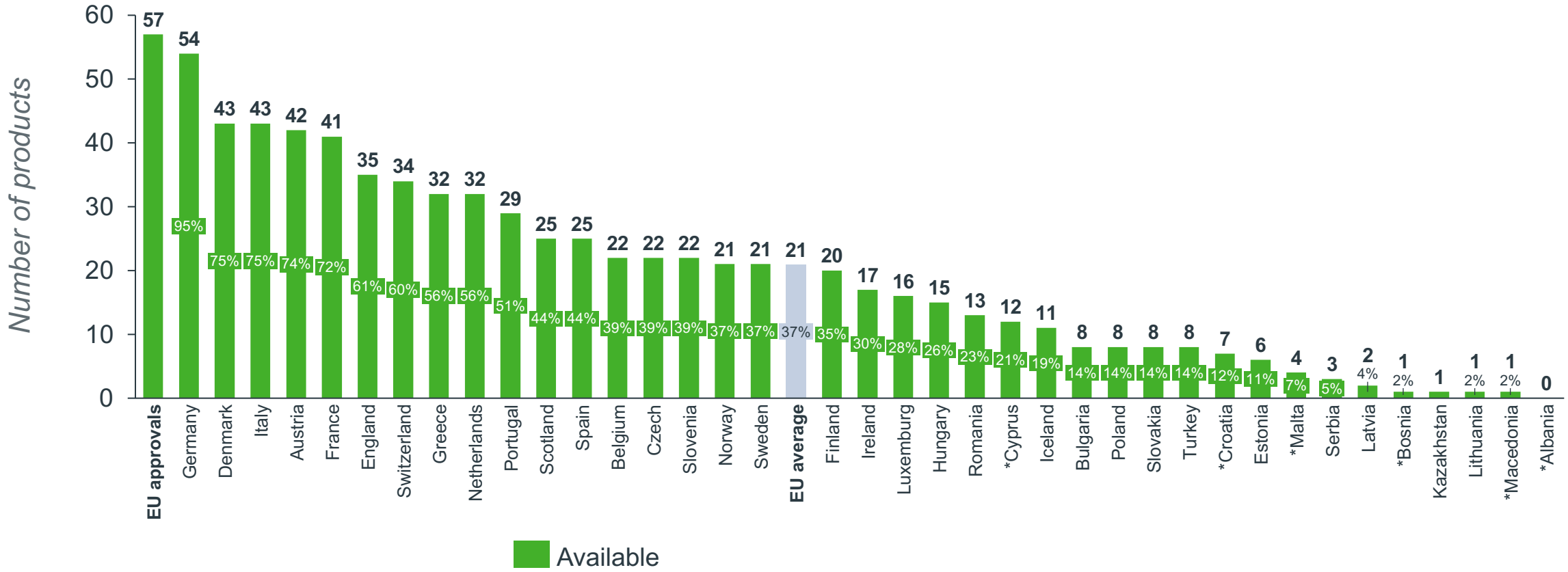
The **total availability by approval year** is the number of medicines available to patients in European countries as of 1st January 2022 (for most countries this is the point at which the product gains access to the reimbursement list†), split by the year the product received marketing authorisation in Europe.



European Union average: 21 products available (37%) †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 (2017-2020)

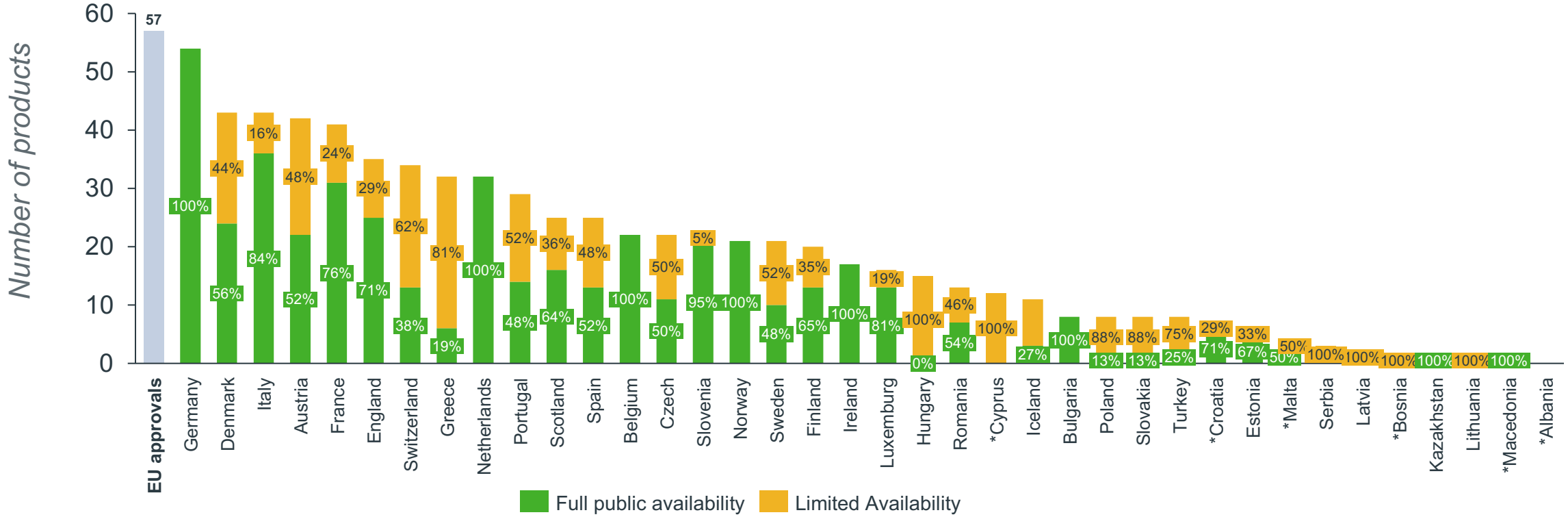
The **rate of availability**, measured by the number of medicines available to patients in European countries as of 1st January 2022. For most countries this is the point at which the product gains access to the reimbursement list†, including products with limited availability.



European Union average: 21 products available (37%) †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 full availability (%, 2017-2020)

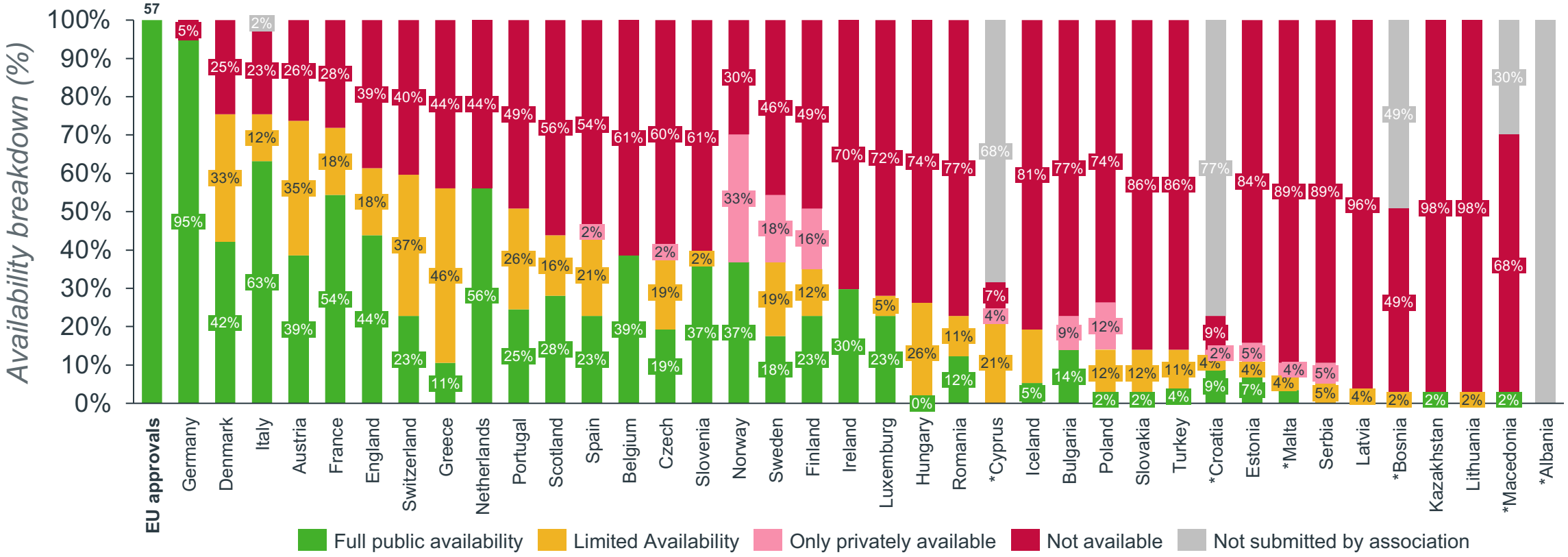
The **rate of full availability** is a new indicator which shows the proportion of medicines available to patients in European countries as of 1st January 2022 (for most countries this is the point at which the product gains access to the reimbursement list†) without any restrictions to the patient population, or through named patient basis schemes which have increased significantly in recent years and were not always captured in survey submissions.



European Union average: 21 products available (37%), limited availability (45% of available products). Ireland, Norway and 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, 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 (%, 2017-2020)

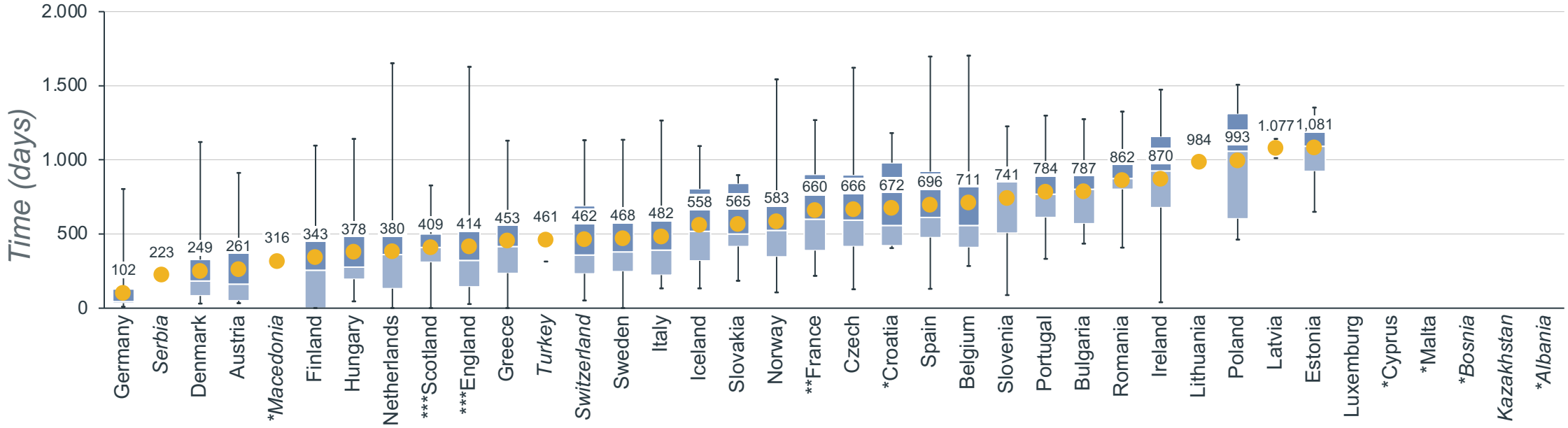
The **breakdown of availability** is the composition of medicines available to patients in European countries as of 1st January 2022 (for most countries this is the point at which the product gains access to the reimbursement list†). This includes all medicines status to provide a complete picture of the availability of the cohort studied.



European Union average: 21 products available (37%) Ireland, Norway and 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, 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 (2017-2020)

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 1st January 2022.



	Germany	Serbia	Denmark	Austria	*Macedonia	Finland	Hungary	Netherlands	***Scotland	***England	Greece	Turkey	Switzerland	Sweden	Italy	Iceland	Slovakia	Norway	**France	Czech	*Croatia	Spain	Belgium	Slovenia	Portugal	Bulgaria	Romania	Ireland	Lithuania	Poland	Latvia	Estonia	Luxemburg	*Cyprus	*Malta	*Bosnia	Kazakhstan	*Albania
Available medicines / 57	54	3	43	42	1	20	15	32	25	35	32	8	34	21	43	11	8	21	41	22	7	25	22	22	29	8	13	17	1	8	2	6	16	12	4	1	1	0
Dates submitted / 57	54	1	42	42	1	20	15	32	25	35	19	2	13	21	43	11	8	21	31	22	5	25	22	22	14	8	12	17	1	8	2	6	0	0	0	0	0	0

European Union average: 636 days (mean) †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.

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Key observations

Executive summary

Measure	EU average for all products	Oncology	Orphan	Non-oncologic orphan	Combination therapy
Rate of availability	**46%** (49% in 2020)	55% (58% in 2020)	37% (41% in 2020)	32% (34% in 2020)	53% (64% in 2020)
Average time to availability	**511 Days** (504 days in 2020)	545 Days (561 days in 2020)	636 Days (653 days in 2020)	587 Days (667 days in 2020)	407 Days (411 days in 2020)

Summary:

- EU average availability is 9% lower for orphans than for all products approved and average time to availability is 4 months slower, although improve has occurred this is a non-significant improvement
- The incoming cohort of innovative orphans (centrally approved in 2019) is much larger than previous years
- Many countries have not made orphan medicines available in 2020 or in 2019, making 2-years of delays in some cases.
- 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 although many more still have unknown status and are yet to be available
- In ~80% of the countries, the rate of availability is lower for Orphan drugs compared to all products approved between 2017-20.

Metrics key:

Text colour indicates relative position versus the current (2021) EU average (*significantly higher than current EU average* / *significantly lower than current EU average*)

Arrow colour indicates significant changes versus the previous (2020) 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

The EU averages noted throughout are averages for the 27 countries in the European Union for the first time.

4. Non-oncology orphan medicines

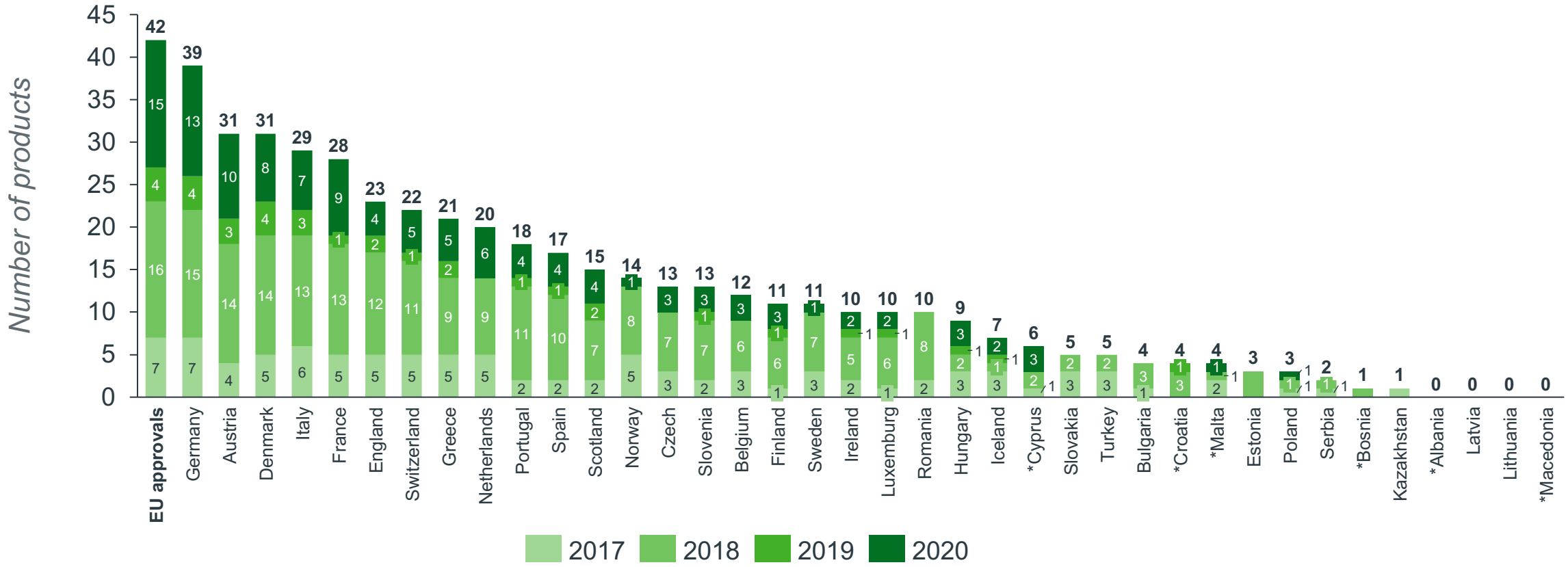
Indicators:

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

**** Denotes new indicators published in 2022***

Non-oncology orphan availability by approval year (2017-2020)

The **total availability by approval year** is the number of medicines available to patients in European countries as of 1st January 2022 (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: 13 products available (32%) †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.

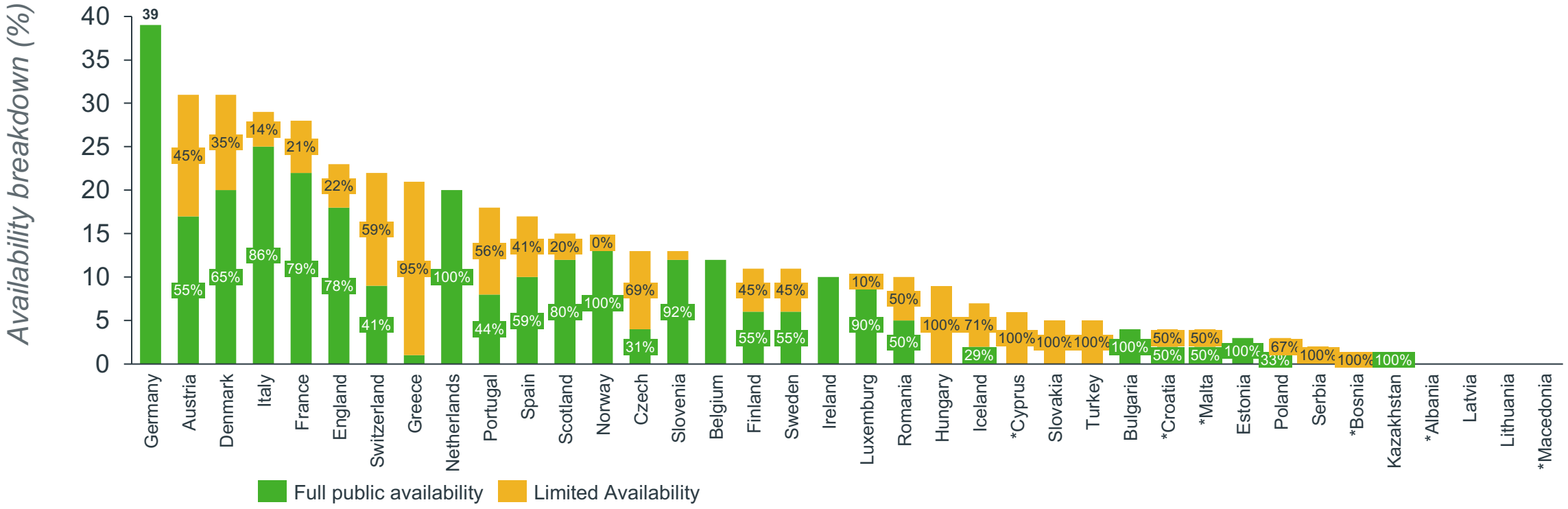
Non-oncology orphan rate of availability (2017-2020)

The **rate of availability**, measured by the number of medicines available to patients in European countries as of 1st January 2022. 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: 13 products available (32%) †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 full availability (%, 2017-2020)

The **rate of full availability** is a new indicator which shows the proportion of medicines available to patients in European countries as of 1st January 2022 (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: 13 products available (32%), limited availability (40% of available products) Ireland, Norway and 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, 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.

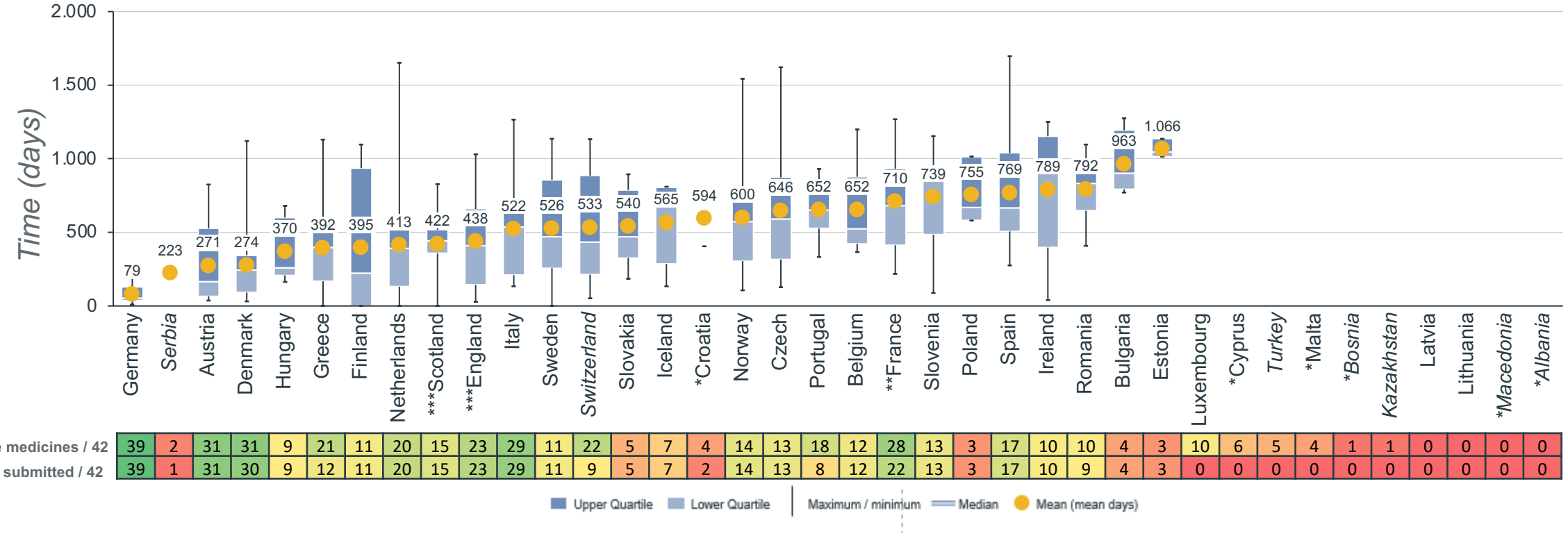
Non-oncology orphan breakdown of availability (%, 2017-2020)

The **breakdown of availability** is the composition of medicines available to patients in European countries as of 1st January 2022 (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 studied.

European Union average: 13 products available (32%) Ireland, Norway and 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, 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 (2017-2020)

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 1st January 2022.



	Germany	Serbia	Austria	Denmark	Hungary	Greece	Finland	Netherlands	***Scotland	***England	Italy	Sweden	Switzerland	Slovakia	Iceland	*Croatia	Norway	Czech	Portugal	Belgium	**France	Slovenia	Poland	Spain	Ireland	Romania	Bulgaria	Estonia	Luxembourg	*Cyprus	Turkey	*Malta	*Bosnia	Kazakhstan	Latvia	Lithuania	*Macedonia	*Albania
Available medicines / 42	39	2	31	31	9	21	11	20	15	23	29	11	22	5	7	4	14	13	18	12	28	13	3	17	10	10	4	3	10	6	5	4	1	1	0	0	0	0
Dates submitted / 42	39	1	31	30	9	12	11	20	15	23	29	11	9	5	7	2	14	13	8	12	22	13	3	17	10	9	4	3	0	0	0	0	0	0	0	0	0	0

European Union average: 587 days (mean) †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.

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Key observations

Executive summary

Measure	EU average for all products	Oncology	Orphan	Non-oncologic orphan	Combination therapy
Rate of availability	**46%** (49% in 2020)	55% (58% in 2020)	37% (41% in 2020)	32% (34% in 2020)	53% (64% in 2020)
Average time to availability	**511 Days** (504 days in 2020)	545 Days (561 days in 2020)	636 Days (653 days in 2020)	587 Days (667 days in 2020)	407 Days (411 days in 2020)

Summary:

- The non-oncology orphans represent generally poorly understood conditions (e.g. metabolic disorders)
- EU average availability is 14% lower for non-oncology orphans than for all orphan products
- The segment has the slowest average time to availability of the studied segments, but has had a notable improvement versus the previous study and is now faster (for those available products) than the average orphan reimbursement process
- In over 90% of the countries, the rate of availability for non-oncology orphan drugs is lower than for all orphan medicinal products approved
- 25% of countries studies do not have availability to any non-oncology orphan drugs approved in 2020
- 30% of countries studied have availability to less than 10% of the non-oncology orphan drugs approved between 2017 - 2020

Metrics key:

Text colour indicates relative position versus the current (2021) EU average (*significantly higher than current EU average* / *significantly lower than current EU average*)

Arrow colour indicates significant changes versus the previous (2020) 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

The EU averages noted throughout are averages for the 27 countries in the European Union for the first time.

5. Combination therapies

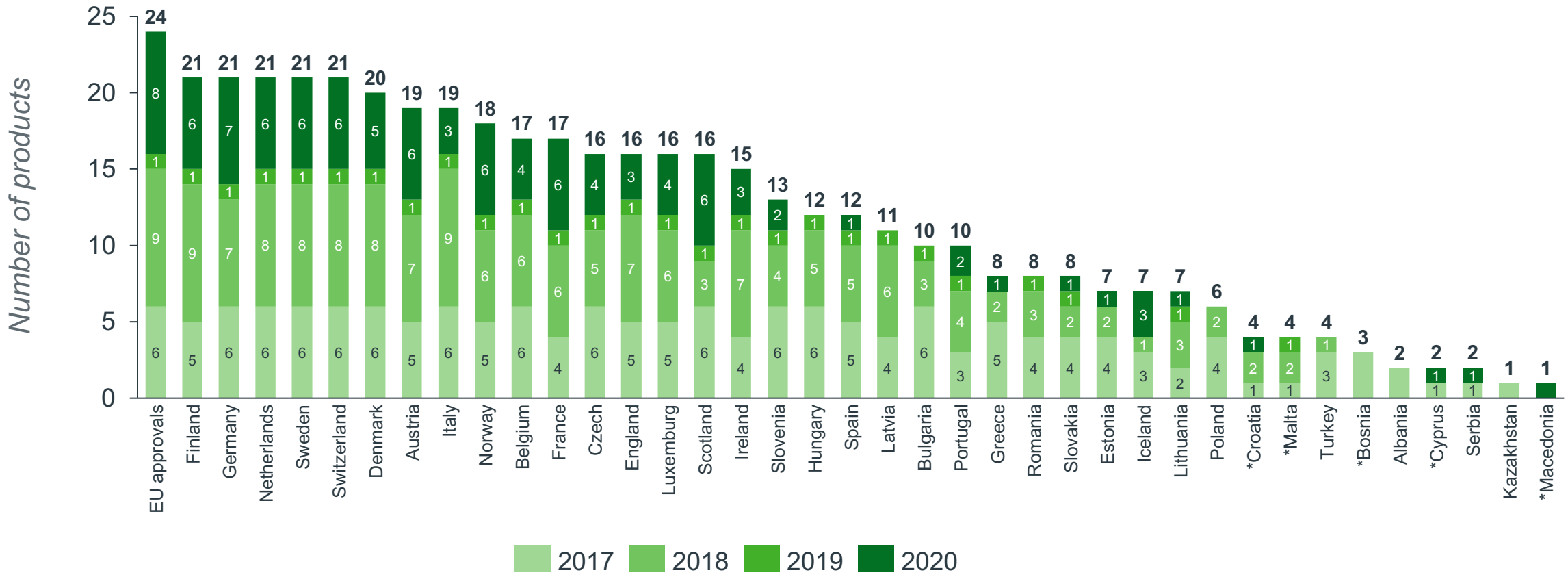
Indicators:

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

**** Denotes new indicators published in 2022***

Combination therapies availability by approval year (2017-2020)

The **total availability by approval year** is the number of medicines available to patients in European countries as of 1st January 2022 (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: 13 products available (53%); 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 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 (2017-2020)

The **rate of availability**, measured by the number of medicines available to patients in European countries as of 1st January 2022. 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: 13 products available (53%) 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 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.

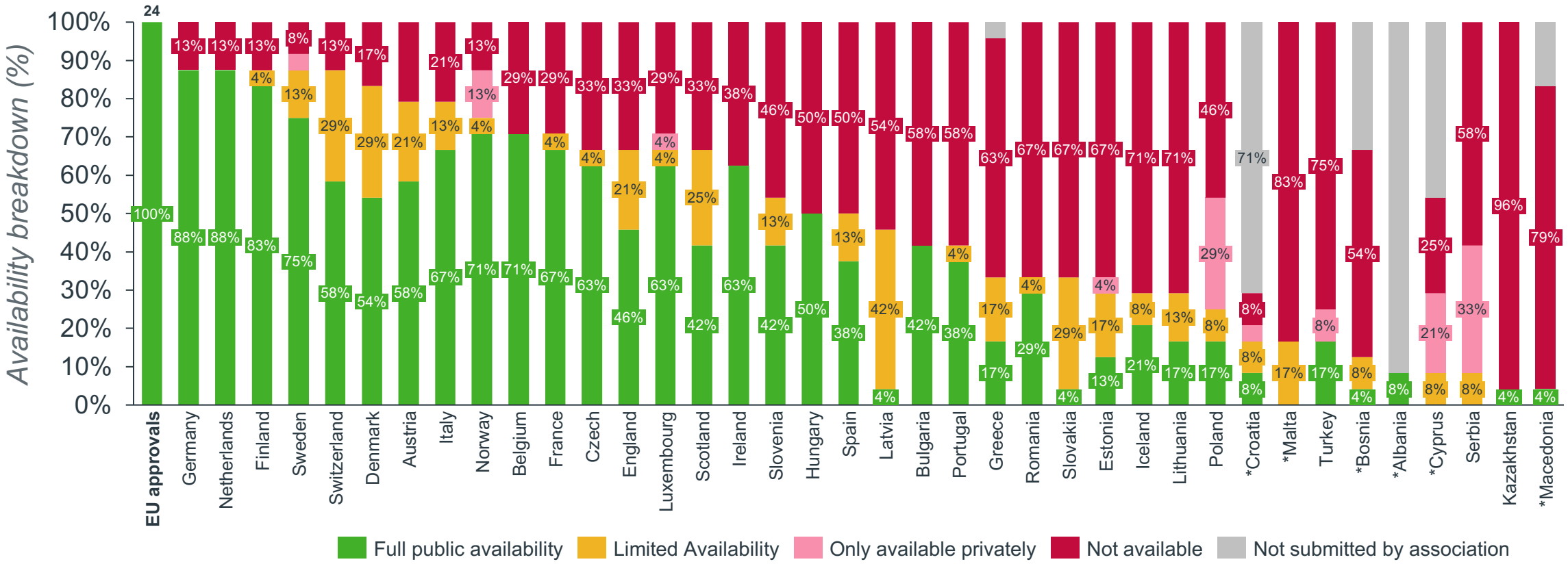
Combination therapies rate of full availability (%, 2017-2020)

The **rate of full availability** is a new indicator which shows the proportion of medicines available to patients in European countries as of 1st January 2022 (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: 13 products available (53%), limited availability (30% of available products). Combination products can include innovative branded / generic combinations; Ireland, Norway and 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, 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 breakdown of availability (%, 2017-2020)

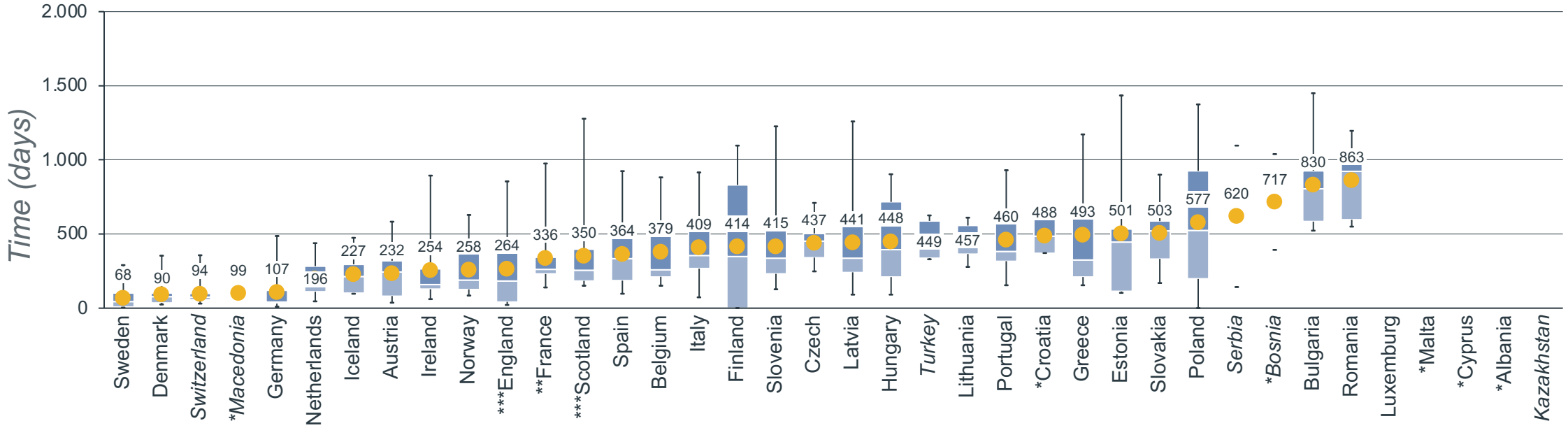
The **breakdown of availability** is the composition of medicines available to patients in European countries as of 1st January 2022 (for most countries this is the point at which the product gains access to the reimbursement list†). This includes all medicines status to provide a complete picture of the availability of the cohort studied.



European Union average: 13 products available (53%) Combination products can include innovative branded / generic combinations; Ireland, Norway and 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, 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 (2017-2020)

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 1st January 2022.



	Sweden	Denmark	Switzerland	*Macedonia	Germany	Netherlands	Iceland	Austria	Ireland	Norway	***England	**France	***Scotland	Spain	Belgium	Italy	Finland	Slovenia	Czech	Latvia	Hungary	Turkey	Lithuania	Portugal	*Croatia	Greece	Estonia	Slovakia	Poland	Serbia	*Bosnia	Bulgaria	Romania	Luxemburg	*Malta	*Cyprus	*Albania	Kazakhstan
Available medicines / 24	21	20	21	1	21	21	7	19	15	18	16	17	16	12	17	19	21	13	16	11	12	4	7	10	4	8	7	8	6	2	3	10	8	16	4	2	2	1
Dates submitted / 24	21	20	14	1	21	21	7	19	15	18	16	16	16	12	17	19	20	13	16	11	12	4	7	9	4	7	7	8	6	2	2	10	7	0	0	0	0	0

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

European Union average: 407 days (mean) 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 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.

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Key observations

Executive summary

Measure	EU average for all products	Oncology	Orphan	Non-oncologic orphan	Combination therapy
Rate of availability	**46%** (49% in 2020)	55% (58% in 2020)	37% (41% in 2020)	32% (34% in 2020)	53% (64% in 2020)
Average time to availability	**511 Days** (504 days in 2020)	545 Days (561 days in 2020)	636 Days (653 days in 2020)	587 Days (667 days in 2020)	407 Days (411 days in 2020)

Summary:

- EU average availability is 7% higher for combination therapies than for all products.
- Combination therapies have experienced a significant reduction in their rate of availability versus the previous study which can be attributed to the fact that only 1 combination therapy was centrally approved in 2019, versus 8 in 2020
- 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).
- 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.

Metrics key:

Text colour indicates relative position versus the current (2021) EU average (*significantly higher than current EU average* / *significantly lower than current EU average*)

Arrow colour indicates significant changes versus the previous (2020) 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

The EU averages noted throughout are averages for the 27 countries in the European Union for the first time.

6. Historic comparisons and extension

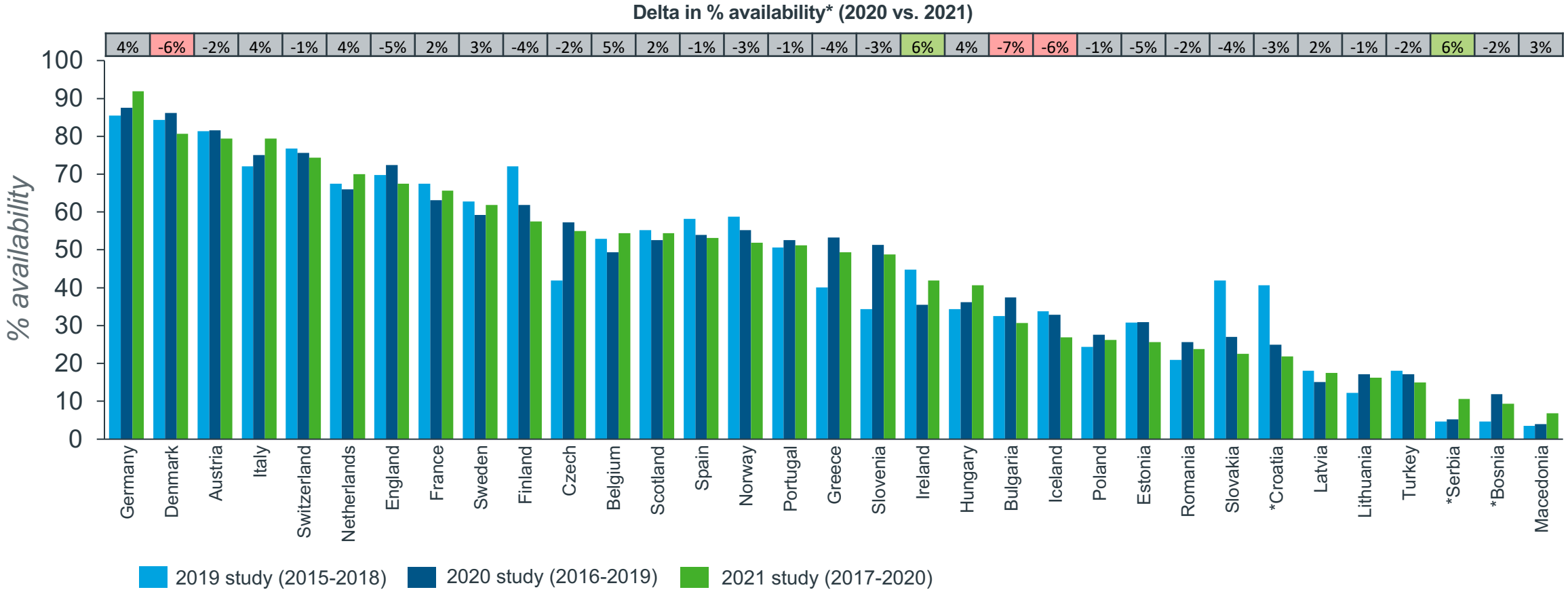
Indicators:

6.1. Comparison of availability versus prior years (2019 - 2021)
6.2 Comparison of time to availability versus prior years (2019 - 2021)
6.3 Extended period total availability by approval year (2014 – 2020)
6.4 Extended period rate of full availability (2014 – 2020)

**** Denotes new indicators published in 2022***

Comparison of rate of availability

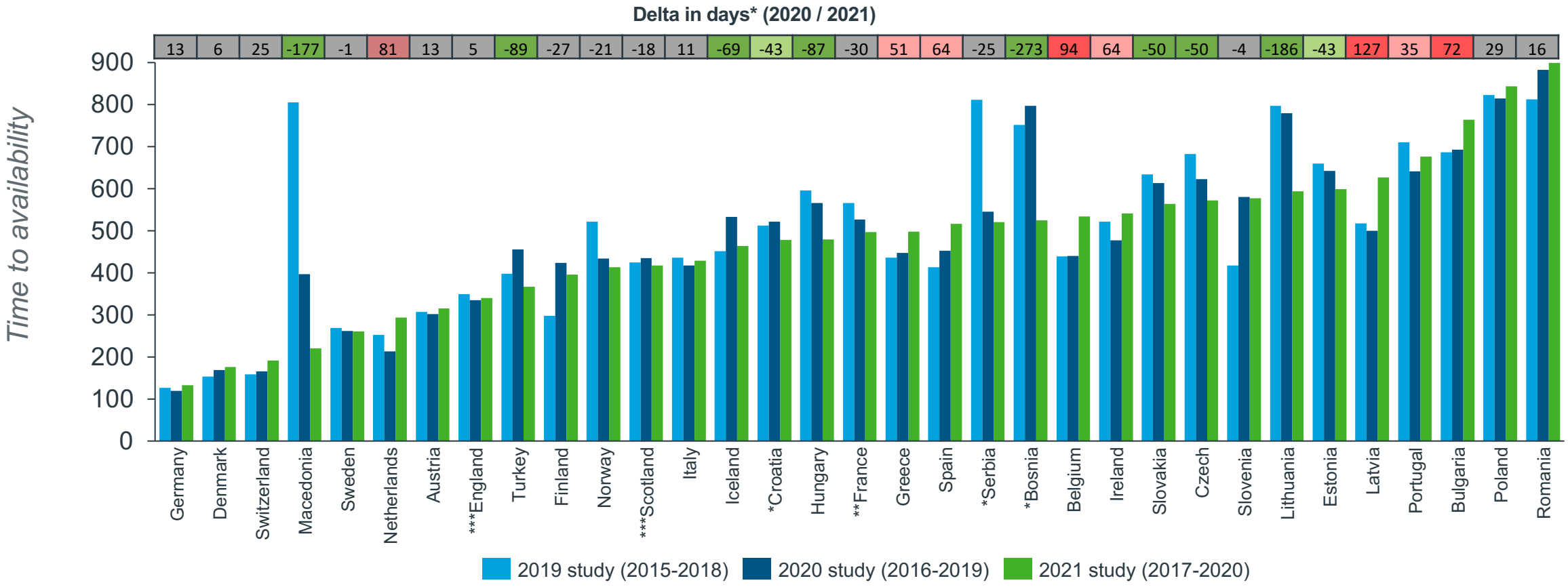
The **comparison of rate of availability**†, measured by the number of medicines available to patients in European countries as of 1st January 2022, compared to the rate of availability in previous (comparable) studies. Figures are based on the historic statistics published in the indicators, and major changes are often due to improved reporting.



Increases of <=5% are not considered to be statistically significant and are therefore highlighted in grey. Note: *Discrepancies between the graph and delta are due to rounding; Netherlands has retrospectively corrected 2020 data in 2021; †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

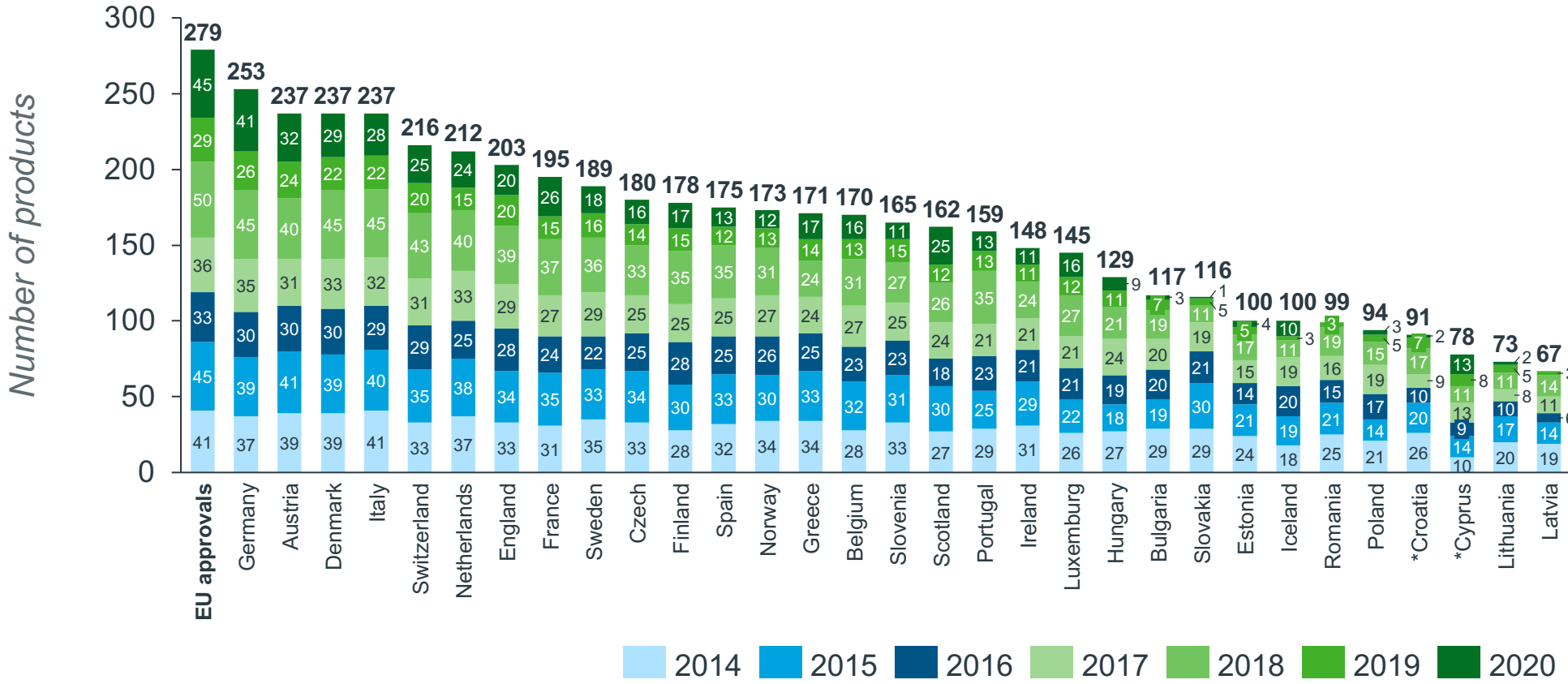
The **comparison of time to availability** (previously know as length of delay) is the days between marketing authorisation and the date of availability to patients compared to previous comparable studies. Figures are based on the historic statistics published in the indicators, and major changes are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



Increases of <=5% are not considered to be statistically significant and are therefore highlighted in grey. 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.

Extended period total availability by approval year (2014-2020)

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: 150 products available (63%) †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.

Extended period rate of availability (2014-2020)

The **extended period 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. 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: 150 products available (54%) †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.

Appendix and detailed methodology

Method and data availability

Process for product selection

1575 〉 **384** 〉 **284** 〉 **160**

EMA list

- List of all historic Marketing Authorisations for human and veterinary medicines (European Public Assessment Reports) accessed November 2021
- Human medicines only

Products in scope

- Products with authorisation year: 2014, 2015, 2016, 2017, 2018, 2019, 2020
- 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 (7-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 2017 – 2020
- Exclude products that are recently withdrawn prior to analysis (5)

*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: 2017-2020 approvals (n=160)

Adakveo	Cystadrops	Juluca	Obiltoxaximab SFL	Rydapt	Ultomiris
Adynovi	Daurismo	Jyseleca	Ocrevus	Sarclisa	Vaborem
Afstyla	Delstrigo	Kaftrio	Olumiant	Segluromet	Vemlidy
Aimovig	Doptelet	Kevzara	Onpattro	Skyrizi	Verkazia
Ajovy	Dovato	Kisqali	Oxervate	Spherox	Verzenios
Alecensa	Dovprela	Kymriah	Oxlumo	Spinraza	Veyvondi
Alofisel	Dupixent	Kyntheum	Ozempic	Spravato	Vitrakvi
Alunbrig	Emgality	Lamzede	Palynziq	Steglatro	Vizimpro
Amglidia	Enerzair Breezhaler / Zimbus Breezhaler	Ledaga	Phesgo	Steglujan	Vocabria
Arikayce liposomal	Epidyolex	Leqvio	Pifeltro	Suliqua	Vosevi
Atectura Breezhaler / Bemrist Breezhaler	Erleada	Libmeldy	Piqray	Sunosi	Vyxeos liposomal
Ayvakyt	Evenity	Libtayo	Polivy	Symkevi	Waylivra
Baqsimi	Fasenra	Lorviqua	Poteligeo	Symtuza	Xeljanz
Bavencio	Fetcroja	Luxturna	Prevymis	Takhzyro	Xenleta
Beovu	Fintepla	Maviret	Quofenix	Talzenna	Xerava
Besponsa	Fotivda	Mayzent	Reagila	Tavlesse	Xermelo
Besremi	Giapreza	Mektovi	Reblozyl	Tecartus	Xospata
Bevespi Aerosphere	Givlaari	Mepsevii	Recarbrio	Tecentriq	Yescarta
Biktarvy	Hemlibra			Tegsedi	Zejula
Blenrep	Hepcludex	Myalepta	Rekambys	Tookad	Zeposia
Braftovi	Idefirix	Mylotarg	Rhokiinsa	Trecondi	Zinplava
Brineura	Ilumetri	Namuscla	Rinvoq	*Trelegy Ellipta	Zolgensma
Cablivi	Imfinzi	Natpar	Rizmoic	Tremfya	Zynquista
Calquence	Intrarosa	Nerlynx	Rozlytrek	Trepulmix	Zynrelef
Chenodeoxycholic acid Leadiant	Isturisa	Nilemdo	Rubraca	Trimbow	Zynteglo
Crysvita	Jivi	Nubeqa	Rxulti	Trixeo Aerosphere	
Cuprior	Jorveza	Nustendi	Rybelsus	Trogarzo	

*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: 2017-2020 approvals

Oncologics (n=41)

Alecensa	Poteligeo
Alunbrig	Rozlytrek
Ayvakyt	Rubraca
Bavencio	Rydapt
Besponsa	Sarclisa
Blenrep	Talzenna
Braftovi	Tecartus
Calquence	Tecentriq
Daurismo	Tookad
Erleada	Trecondi
Fotivda	Verzenios
Imfinzi	Vitrakvi
Kisqali	Vizimpro
Kymriah	Vyxeos liposomal
Ledaga	Xospata
Libtayo	Yescarta
Lorviqua	Zejula
Mektovi	
Mylotarg	
Nerlynx	
Nubeqa	
Phesgo	
Piqray	
Polivy	

Orphans (n=57)

Adakveo	Mylotarg
Alofisel	Namuscla
Amglidia	Natpar
Arikayce liposomal	Obiltoxaximab SFL
Ayvakyt	Onpattro
Besponsa	Oxervate
Blenrep	Oxlumo
Brineura	Palynziq
Cablivi	Polivy
Chenodeoxycholic acid Leadiant	Poteligeo
Crysvita	Prevymis
Cystadrops	Reblozyl
Daurismo	Rydapt
Dovprela	Spinraza
Epidyolex	Symkevi
Fintepla	Takhzyro
Givlaari	Tecartus
Hepcludex	Tegsedi
Idefirix	Trepulmix
Isturisa	Verkazia
Jorveza	Vyxeos liposomal
Kaftrio	Waylivra
Kymriah	Xermelo
Lamzede	Xospata
Ledaga	Yescarta
Libmeldy	Zejula
Luxturna	Zolgensma
Mepsevii	Zynteglo
Myalepta	

Non-oncologic orphans (n=42)

Adakveo	Natpar
Alofisel	Obiltoxaximab SFL
Amglidia	Onpattro
Arikayce liposomal	Oxervate
Brineura	Oxlumo
Cablivi	Palynziq
Chenodeoxycholic acid Leadiant	Prevymis
Crysvita	Reblozyl
Cystadrops	Spinraza
Dovprela	Symkevi
Epidyolex	Takhzyro
Fintepla	Tegsedi
Givlaari	Trepulmix
Hepcludex	Verkazia
Idefirix	Waylivra
Isturisa	Xermelo
Jorveza	Zolgensma
Kaftrio	Zynteglo
Lamzede	
Libmeldy	
Luxturna	
Mepsevii	
Myalepta	
Namuscla	

Combination therapies (n=24)

Atectura Breezhaler / Bemrist Breezhaler
Bevespi Aerosphere
Biktarvy
Delstrigo
Dovato
Enerzair Breezhaler / Zimbus Breezhaler
Juluca
Maviret
Nustendi
Phesgo
Recarbrio
Segluromet
Steglujan
Suliqua
Symkevi
Symtuza
*Trelegy Ellipta
Trimbow
Trixeo Aerosphere
Vaborem
Vocabria
Vosevi
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 for the same company 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	Medicine is available if either (1) reimbursed within the SmPC, without any restrictions (e.g. any physician can prescribe)
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 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
Italy	A product is available if it has received reimbursement status
Kazakhstan	Accessibility on the public reimbursement list
Latvia	Accessibility on the public reimbursement list
Lithuania	Accessibility on the public reimbursement list
Luxembourg	Accessibility on the public reimbursement list
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
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 for individual patients on a named patient basis
Czech	Reimbursement is only granted for individual patients on a named patient basis or there is limited reimbursement while a decision is pending.
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 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	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)
Luxembourg	There are no restrictions on availability
Kazakhstan	Not applicable; no medicines are listed as limited 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	Reimbursement is only granted for specific subpopulations of the approved indications. Note: Association was unable to report limitations to availability for the full dataset.
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.
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
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
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	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 + 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	For available reimbursement drugs with a TLV decision: date of TLV decision; For available hospital drugs with an NT recommendation: date of NT recommendation; For available hospital drugs lacking an NT recommendation and not part of managed national introduction: date of marketing in Sweden (supplied in FASS); For available medicines indicated in communicable diseases: 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”

Notes: Luxembourg, Malta, Cyprus and Kazakhstan are not included in the time to availability analysis due to lack of data

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