EFPIA Patients W.A.I.T. Indicator 2019 Survey

May 2020

In this study the term ‘availability’ is used throughout. The definition of ‘availability’ is as follows and should be considered when interpreting the data:

ACCESSIBILITY ON THE PUBLIC REIMBURSEMENT LIST IN A COUNTRY

This definition allows a standardised measure to compare across countries. 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.**

Introduction (1)

- “Patients W.A.I.T.” stands for *Patients Waiting to Access Innovative Therapies*. The INDICATOR provides a benchmark of the rate of availability and waiting times in European countries.

- The Patients W.A.I.T. Indicator shows, for new medicines (i.e. medicines including a substance that has not been previously available in Europe) within a (rolling) 4 year cohort:

  1. The **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

  2. The **average time between marketing authorisation and patient access**, measured by the number of days elapsing from the date of EU marketing authorisation (or Swissmedic approval in the case of Switzerland) to the day of completion of post-marketing authorisation administrative processes

- Source of information: EFPIA member associations, who either refer to information available from official sources or gather this information directly from member companies.

- Some country associations did not submit full datasets. Countries with substantially limited datasets were Bosnia (16% complete), Macedonia (26% complete), Serbia (40% complete). This is noted on each slide with an asterisk (*).

Introduction (2)

- The Patients W.A.I.T. Indicator gives **a snapshot** of the 2 parameters at a cut-off date (1st January 2020) – data from medicines cohorts dropping out of the reference period are not included.

- Waiting times reflected in the Patients W.A.I.T. Indicator includes **time to access**, whether attributable to companies or to competent authorities.

- **Rate of availability** in a country does not necessarily indicate medicine uptake. Some medicines may be available in a market with no uptake (sales or volume).

- **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.

Method for product selection

1397 > 310 > 213 > 172

EMA list

- List of all historic Marketing Authorisations for human and veterinary medicines (European Public Assessment Reports) accessed November 2019
- Human medicines only

Products in scope

- Products with EMA authorisation year: 2014, 2015, 2016, 2017, 2018
- Status: Authorised, Withdrawn, Suspended
- Non-generic; Non-biosimilar
- Include combinations (both products can have already been approved before)
- Remove ATC K, V & T*

Survey cohort (5-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 2015 - 2018

Study scope

- 172 products approved by EMA between 1st January 2015 to 31st December 2018

- The 2019 study provides an analysis of products approved between **2015-2016-2017-2018**, for the following datasets:
  a) **All 172 products:** 45 in 2015, 35 in 2016, 38 in 2017, 54 in 2018
  b) **43 Oncology products:** 10 in 2015, 10 in 2016, 11 in 2017, 12 in 2018
  c) **54 Orphan products:** 12 in 2015, 9 in 2016, 12 in 2017, 21 in 2018
  d) **39 Non-oncologic orphan products:** 9 in 2015, 7 in 2016, 7 in 2017, 16, in 2018
  e) **34 Combination products**: 10 in 2015, 8 in 2016, 6 in 2017, 10 in 2018

- Definitions:
  - Orphan status from EMA (September 2019)
  - Oncology products flagged using IQVIA MIDAS Oncology market definition*
  - Combination products include any product with more than one molecule, including branded/generic combinations

- The date of availability cut off point was 1st January 2020 (to account for Estonia, Iceland, Czech Republic, Latvia, Slovakia which had a few products with a reimbursement decision on 1st January 2020).

- 34 countries included in the study (including split of UK into England and Scotland).

Definition of Availability

- The aim of the W.A.I.T. indicator is to measure the differences in time to reimbursement across European countries
- A medicine is **available** on the market if patients can receive the medicine under a reimbursement scheme
- The **availability date** is the first date when doctors can prescribe / hospitals can administer the medicine to patients in the country, who will be able to benefit from reimbursement conditions applicable in the country (i.e. administrative procedures to be included in the positive reimbursement list have been completed, where applicable)
- IQVIA have defined a set of “rules” to determine **market availability**:

Reimbursement status of medicine	Is the medicine available?
Reimbursed through the 'normal' reimbursement system	**Available**
Automatically reimbursed or financed by a different budget (e.g. hospital) or managed entry	**Available**
Reimbursed on an individual basis, and/or to a subpopulation*, and/or in some cases whilst reimbursement is pending	**Available (LA*)**
Available only within the private market at the patients expense	**Only privately available**
Not reimbursed, or pending reimbursement (excluding availability at the patients expense)	**Not available**

In cases where a product has been categorised as “not available”, their dates will not be included in the **delay analysis;** *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. LA*: product available for limited availability

Definition of products with limited availability

- IQVIA has differentiated between products which are reimbursed through the regular process in a country, and products with “limited availability” (LA)
- Products with LA have **special reimbursement conditions**, where reimbursement is only granted for certain patients, indications, or only through special programs (e.g. early access schemes)
- Restricted or optimised recommendations may be due to either the company or HTA body
- Products which have been reimbursed with the following criteria are marked as “Available”, however have been flagged in the “Rate of Availability %” charts:

Reimbursement conditions for medicine
Restricted patient cohort (specific populations)
Individual reimbursement (case by case / named patient program)
Special programs (e.g. early access scheme)*

Definition of Availability

For most countries a product is available if it gains access to the national reimbursement list

. For countries where this differs, the definition of Availability is below:

- 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.
- Czech Republic: A medicine is available if it is on the reimbursement list, or funded through the hospital
- 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 become available straight away.
- Germany: Following marketing authorisation, prescription drugs automatically receive reimbursed status. These products are classified as available.
- Hungary: Medicines are either reimbursed through the 'normal' reimbursement system, are available through a Name Patient Program or are available but financed by the hospital budget.
- Lithuania: A medicine is available if it is on the Lithuanian market (the State Medicines Control Agency has data on the sales volume of this medicinal product)
- North Macedonia (referred to as Macedonia in the slides): The medicine is included on the positive drug list or reimbursement list. No new medicines have been included on the reimbursement list for the past 10 years.
- 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 (hospital drugs).
- Scotland: Medicines are deemed available if SMC has issued a positive recommendation. For the remaining medicines, IQVIA sales data are analysed to determine if routinely available.
- Slovakia: Primary data source used is National Health Information Center, but where not available, consumption data recorded through IQVIA is used
- Slovenia: A medicine is available if it is reimbursed through the regular system, or automatically reimbursed (e.g. all medicines for TBC)
- Sweden: A medicine is classified as available if it is currently marketed in Sweden (listed supplied FASS), and has received either: (a) a positive TLV reimbursement decision (non hospital drug), (b) a positive NT recommendation (hospital drug), (c) lacks an NT recommendation but is assessed to have a relevant level of sales based on rough estimation number patients treated in relation to the size of the patient population (hospital drug), or (d) is indicated in the treatment of a communicable disease (i.e. reimbursement decision/NT recommendation not requirement).
- 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.

Definition of Limited availability (LA)

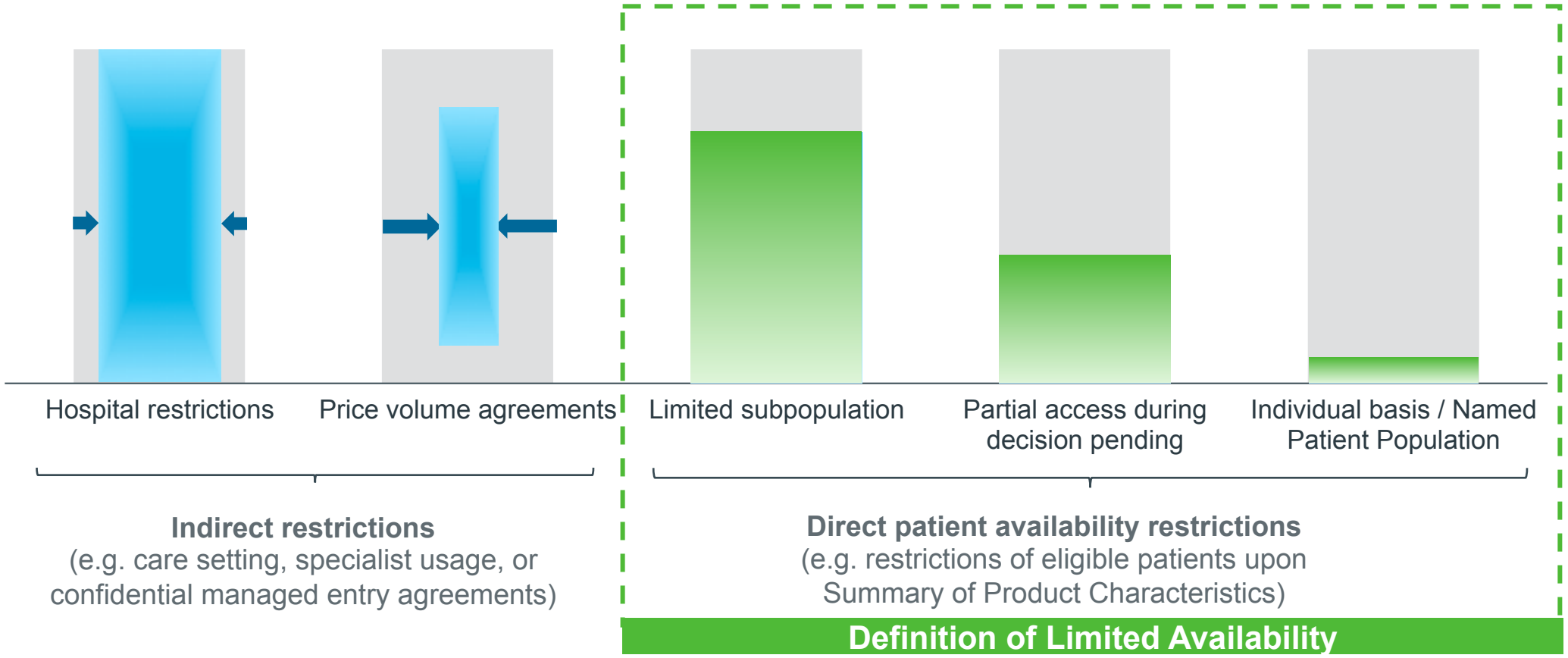
For most countries a product has limited availability if a restriction is placed upon the SmPC

For countries with specific considerations, the definition of Limited availability is below:

- Austria: Products only reimbursed on an individual basis
- Croatia: Products are available for specific patient cohorts (reimbursement guidelines outline specific criteria describing patient eligibility for treatment).
- Czech Republic: 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 licensed indication, either through an optimised NICE decision (including optimised CDF decisions) or an individual funding request
- Estonia: Only reimbursed for restricted patient cohort.
- France: Some innovative products without competitors can be made available prior to market authorisation under the system of Temporary Authorisations
- Greece: Only reimbursed for restricted patient cohort, or by 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: Only reimbursed for restricted patient cohort
- Latvia: Only available through individual reimbursement
- Lithuania: Only reimbursed for limited indications (compared to what was approved at market authorisation)
- Netherlands: Only reimbursed under certain therapeutic conditions (annex 2 on the positive reimbursement list).
- Norway: Only reimbursed for restricted patient cohort
- 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
- Scotland: Recommended for a restricted patient cohort relative to licensed indication through restricted SMC recommendation
- Serbia: Products are reimbursed with significant restrictions. Sometimes these restrictions are based on number of patients (e.g. for new generation HepC medicines, there is a cap on only 60 patients per year), sometimes on the number of indications, or there is some other limit.
- 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.

Visual of the limited availability definition

Comparable across markets and highlights major restrictions

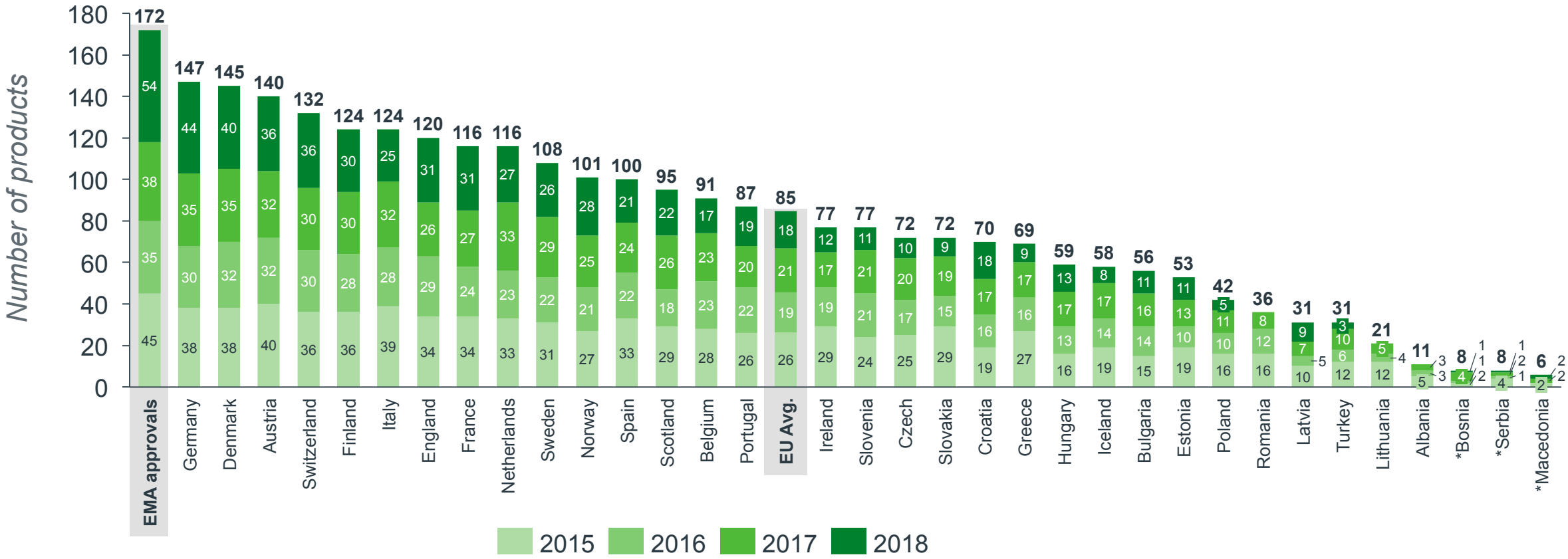


All medicines

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

Total availability by approval year (2015 - 2018)

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 in which the EMA granted marketing authorisation.

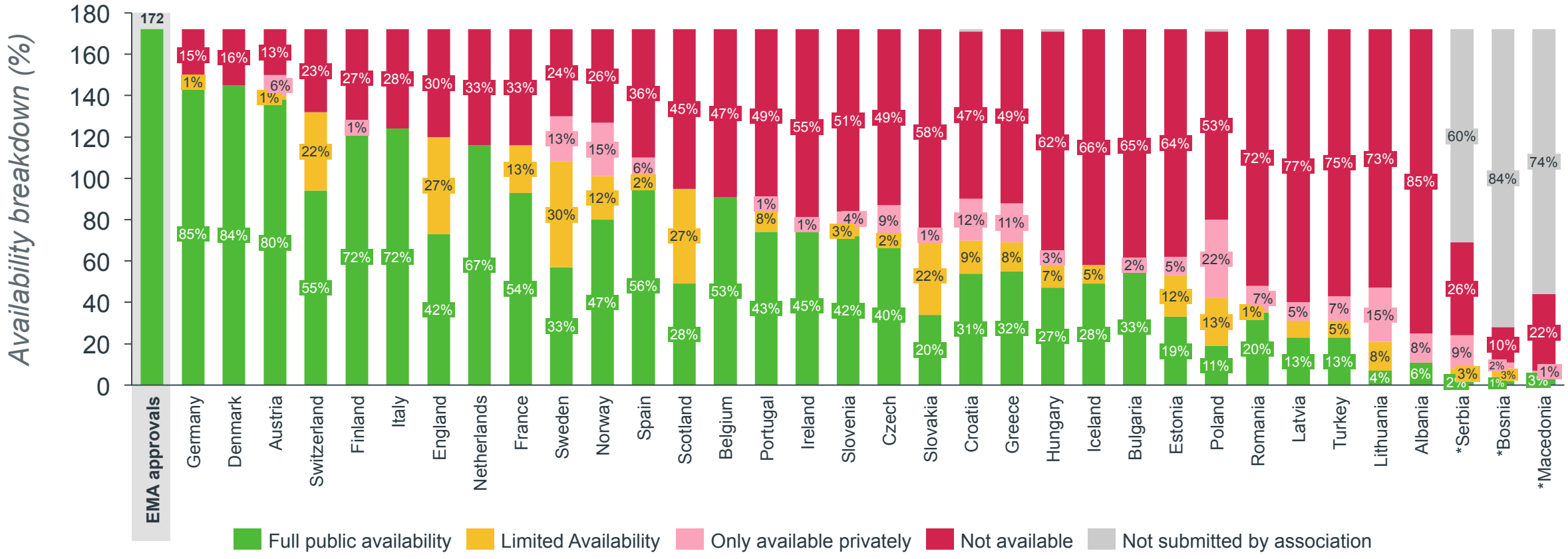


Rate of availability (2015 – 2018)

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*), inc. limited availability

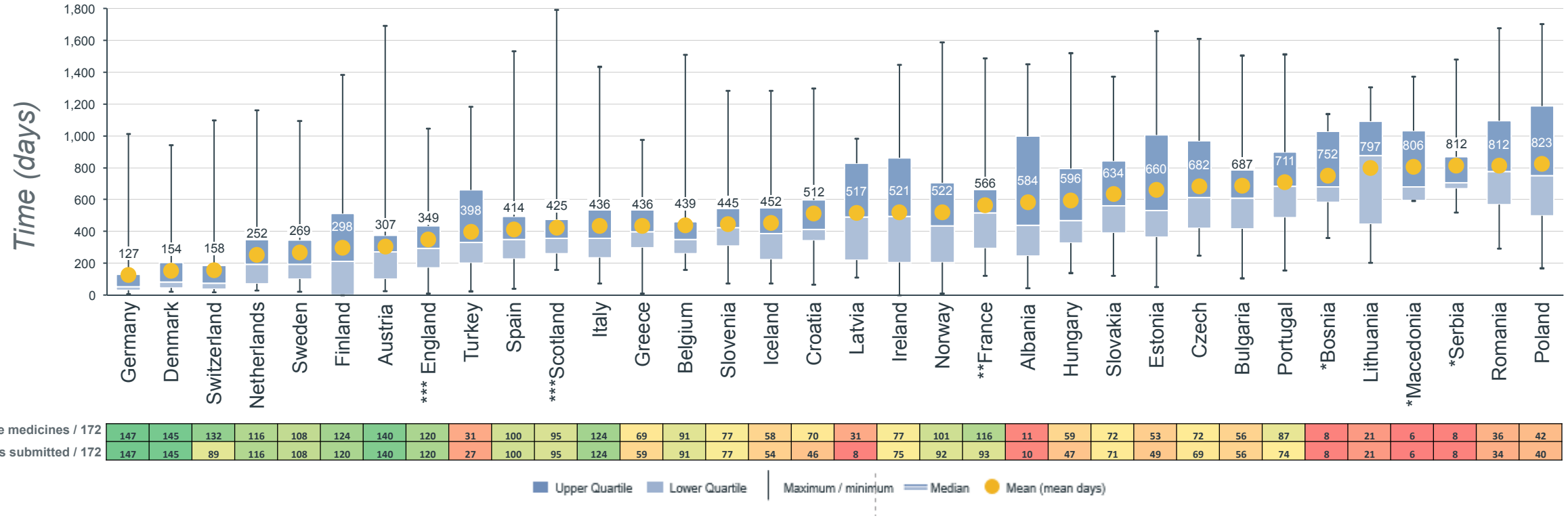
Rate of availability (%, 2015 – 2018)

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.



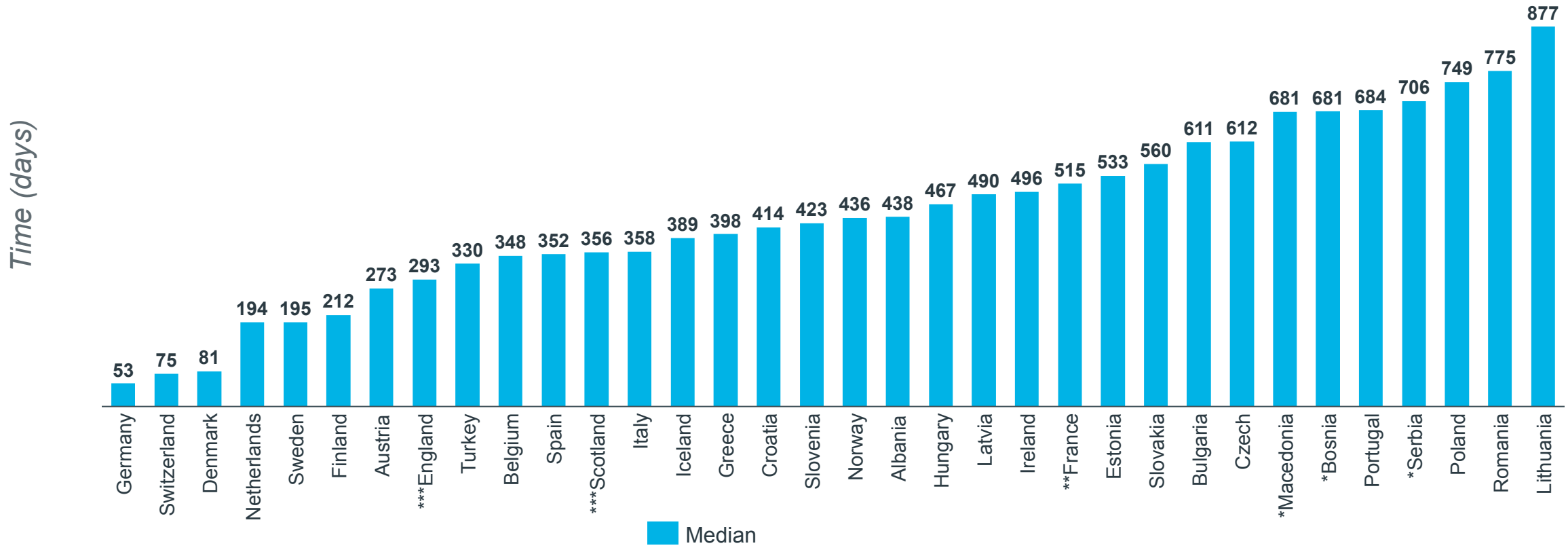
Time to availability (2015 – 2018)

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*).



Median time to availability (2015 – 2018)

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*).

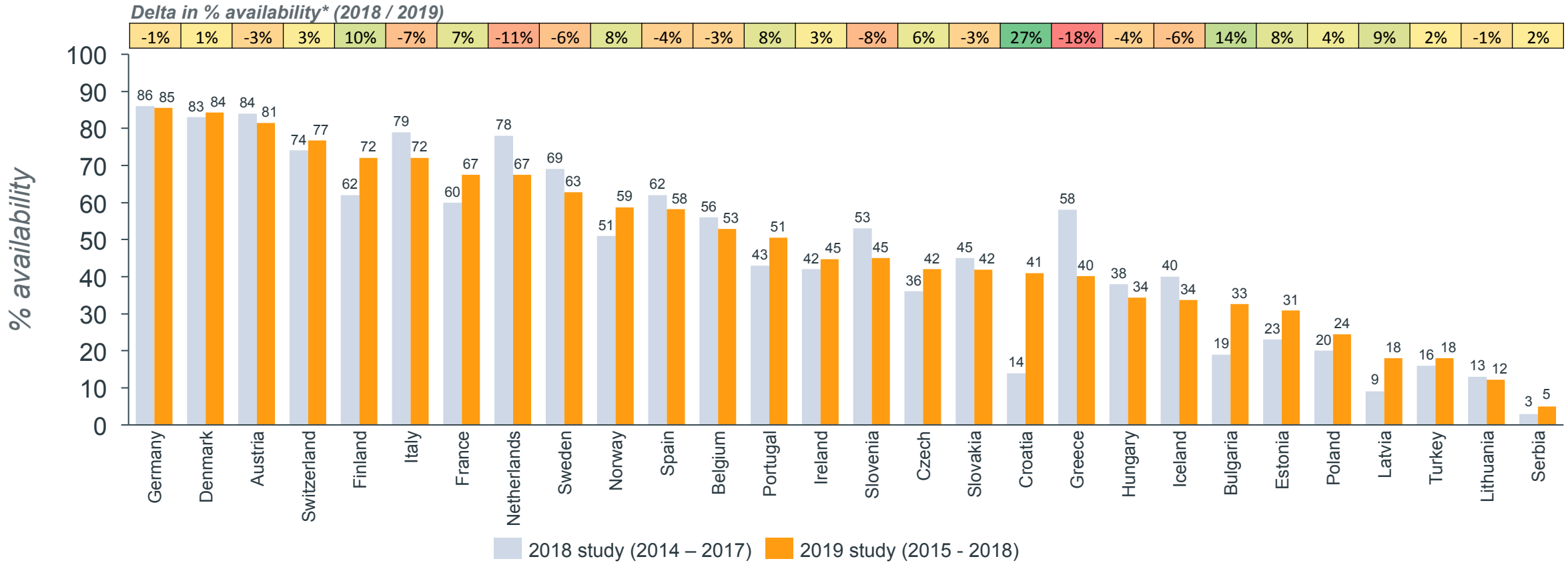


All medicines study comparison

Rate of availability 2018 vs 2019 W.A.I.T study ❯ Time to availability 2018 vs 2019 W.A.I.T study

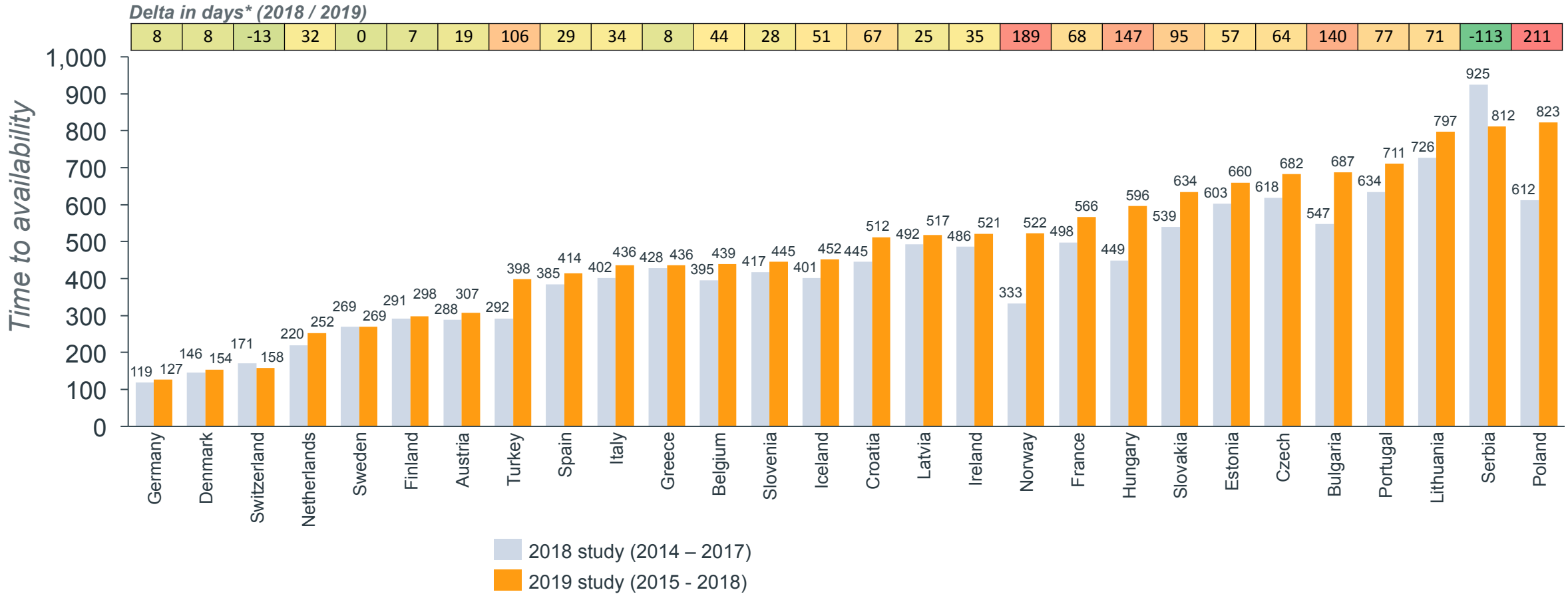
Comparison of availability (2018 study vs 2019 study)

The **rate of availability**, measured by the number of medicines available to patients in European countries as of 2019, compared to the rate of availability in the 2018 W.A.I.T. indicator study



Comparison of time to availability (2018 study vs 2019 study)

The **time to availability** (previously know as length of delay) is the days between EMA marketing authorisation and the date of availability to patients compared to the rate of availability in the 2018 W.A.I.T. indicator study



Key observations

All medicines

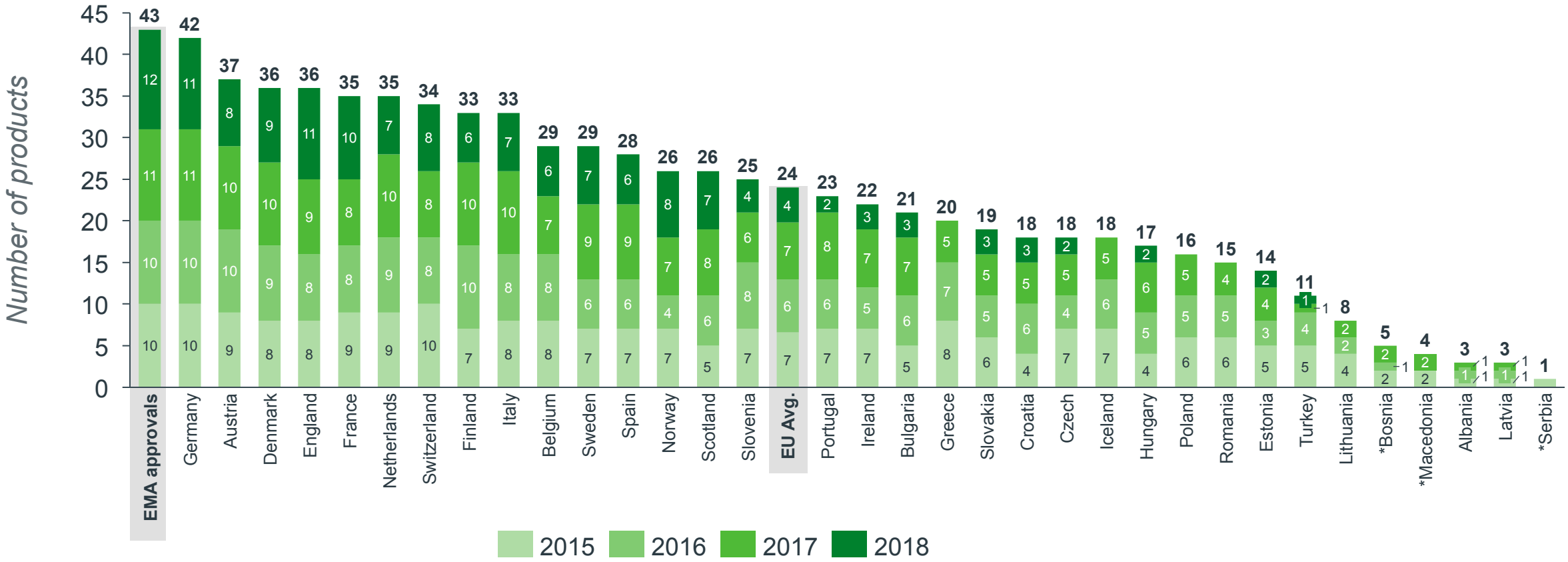
- **Patient access to new medicines is highly varied across Europe**, with the greatest rate of availability in Northern and Western European countries and lowest in Southern and Eastern European countries.
- In some countries, up to 30% of products are available and reimbursed but with specific conditions.
- The average delay between market authorisation and patient access can **vary by a factor greater than x 6 across Europe**, with patients in Northern /Western Europe accessing new products 100 - 350 days after market authorisation and patients mainly in Southern/ Eastern Europe between 600-850 days.
- **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 Scotland (159 vs. 1789 days), Austria (24 vs. 1689 days) and Estonia (52 vs. 1657 days).
- **Comparison to 2018 W.A.I.T. indicator study**: of the countries overlapping both analyses, 54% countries have a higher rate of availability, although 93% countries have a longer delay in the 2019 study.

Oncology medicines

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

Oncology availability by approval year (2015 - 2018)

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 in which the EMA granted marketing authorisation.



Oncology rate of Availability (2015 - 2018)

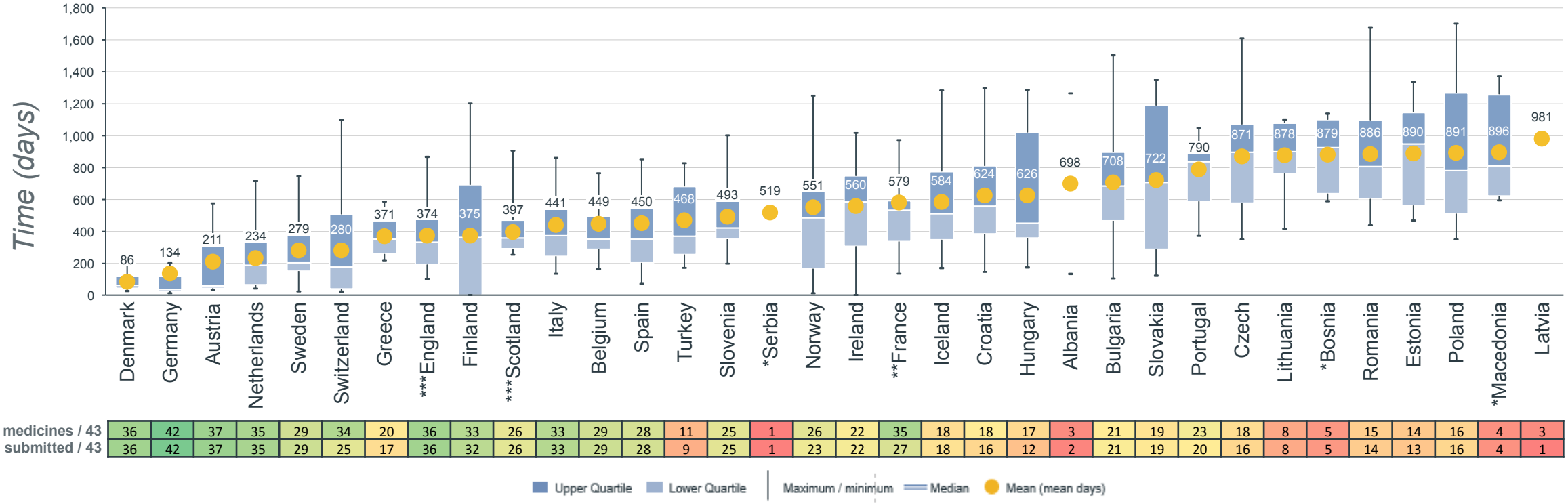
The **rate of availability**, measured by the number of medicines available to patients in European countries as of 2019: for most countries this is the point at which the product gains access to the reimbursement list, inc. limited availability

Oncology rate of availability (%, 2015 – 2018)

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.

Oncology time to availability (2015 – 2018)

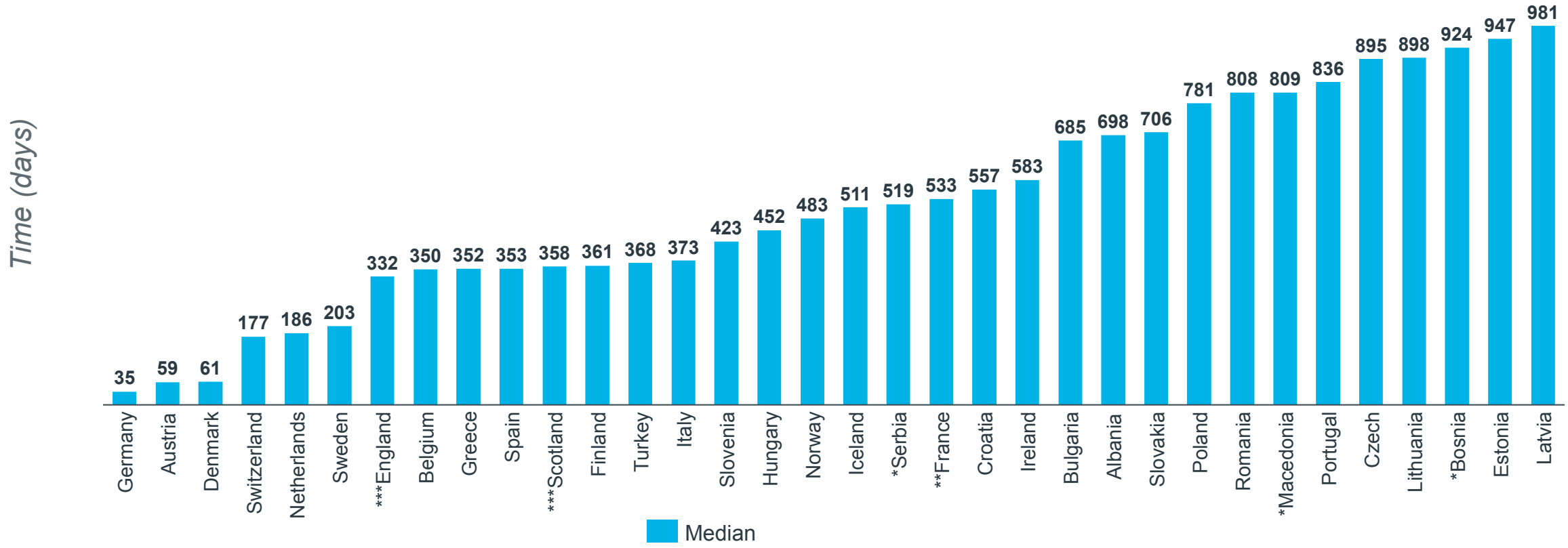
The **time to availability** (previously know as length of delay) is the days between EMA marketing authorisation and the date of availability to patients in European countries (for most this is the point at which products gain access to the reimbursement list*).



	Denmark	Germany	Austria	Netherlands	Sweden	Switzerland	Greece	***England	Finland	***Scotland	Italy	Belgium	Spain	Turkey	Slovenia	*Serbia	Norway	Ireland	**France	Iceland	Croatia	Hungary	Albania	Bulgaria	Slovakia	Portugal	Czech	Lithuania	*Bosnia	Romania	Estonia	Poland	*Macedonia	Latvia
Available medicines / 43	36	42	37	35	29	34	20	36	33	26	33	29	28	11	25	1	26	22	35	18	18	17	3	21	19	23	18	8	5	15	14	16	4	3
Dates submitted / 43	36	42	37	35	29	25	17	36	32	26	33	29	28	9	25	1	23	22	27	18	16	12	2	21	19	20	16	8	5	14	13	16	4	1

Oncology median time to availability (2015 – 2018)

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*).



Key observations

Oncology medicines

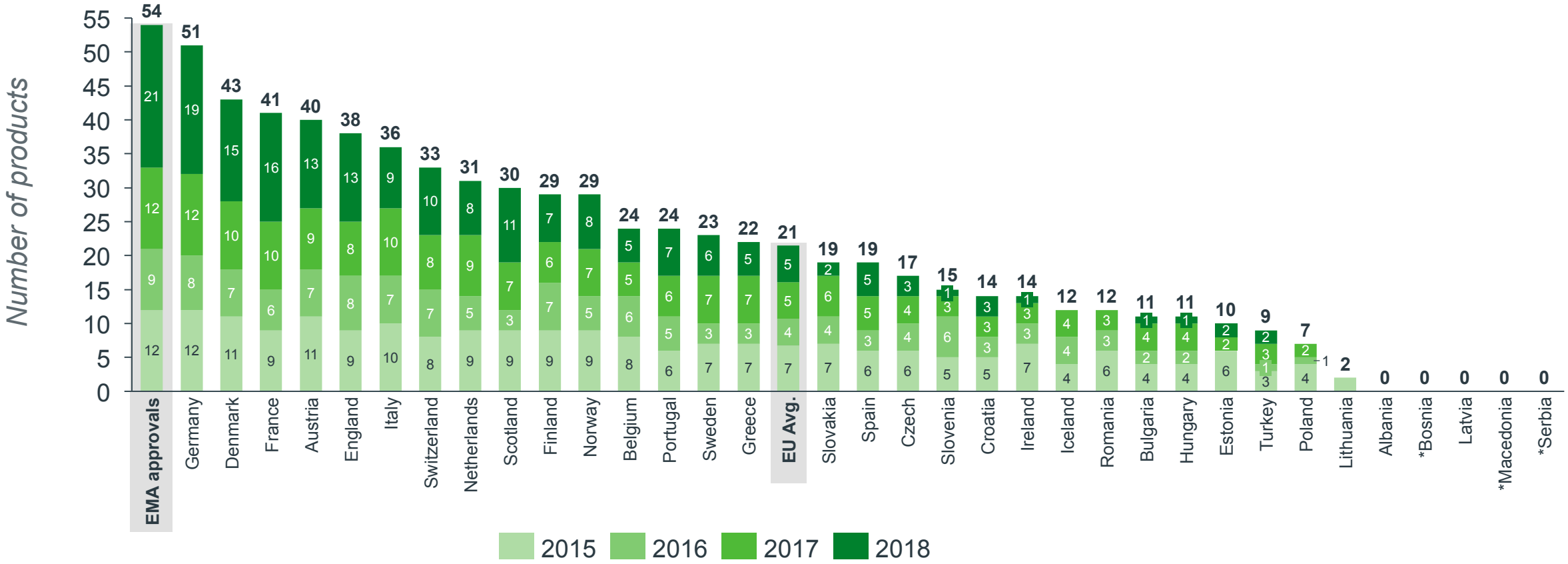
- Patient access to new Oncology medicines is highly varied across Europe, with the greatest rate of availability in Northern and Western European countries.
- In 88% of the countries, the rate of availability is **higher for Oncology products** compared to all products approved between 2015-2018
- In Germany, France, England, Netherlands, Belgium, Bulgaria, and Romania, the availability of oncology medicines in more than 10% above the rate of all medicines approvals.
- Limited availability is prevalent within the oncology medicines with over 20% of oncology medicines having a restriction placed upon them after SmPC in England (40%), Sweden (26%), Scotland, (21%), and Poland (21%)
- The average delay between market authorisation and patient access for Oncology products varies 2.5 months to over 2.5 years

Orphans medicines

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

Orphan availability by approval year (2015 - 2018)

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 in which the EMA granted marketing authorisation.



Orphan rate of availability (2015 - 2018)

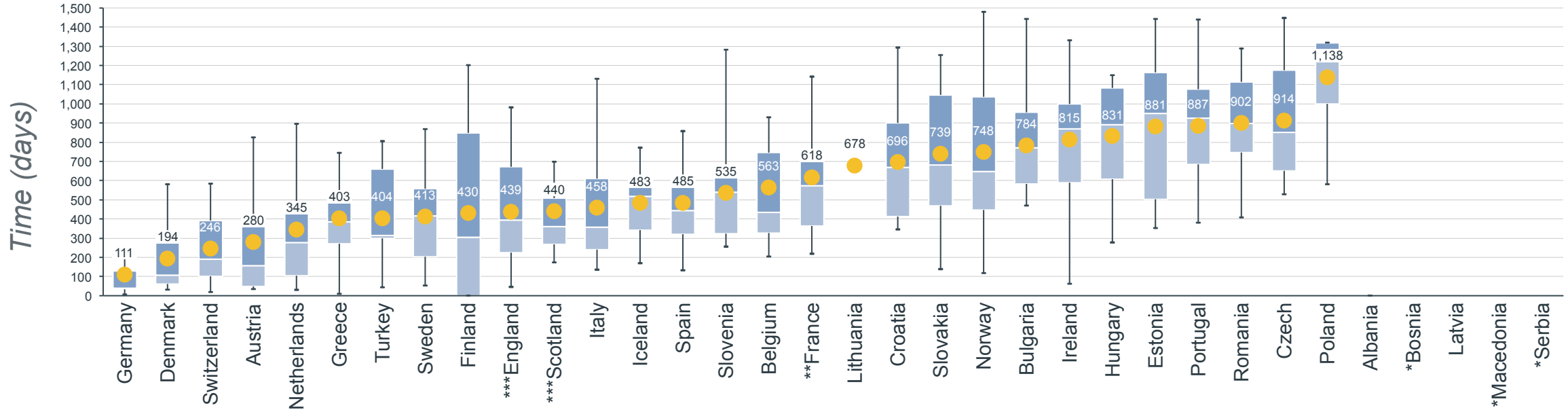
The **rate of availability**, measured by the number of medicines available to patients in European countries as of 2019: for most countries this is the point at which the product gains access to the reimbursement list, inc. limited availability

Orphan rate of availability (%, 2015 – 2018)

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.

Orphan time to availability (2015 – 2018)

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*).

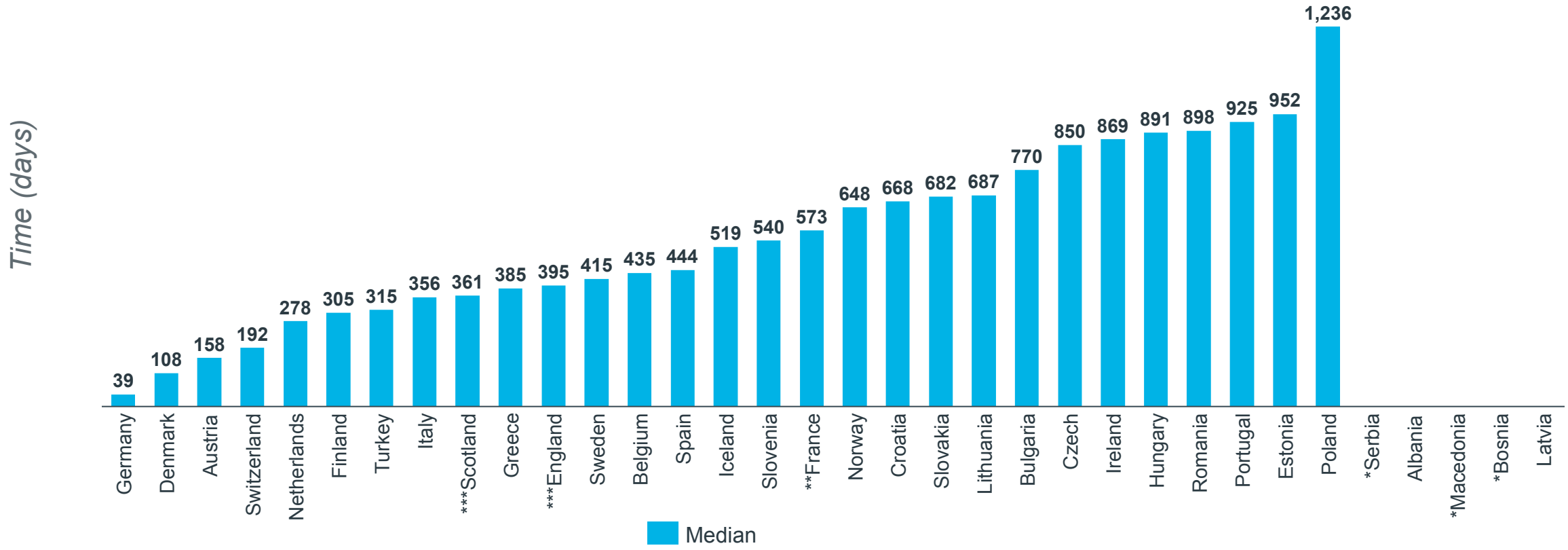


	Germany	Denmark	Switzerland	Austria	Netherlands	Greece	Turkey	Sweden	Finland	***England	***Scotland	Italy	Iceland	Spain	Slovenia	Belgium	**France	Lithuania	Croatia	Slovakia	Norway	Bulgaria	Ireland	Hungary	Estonia	Portugal	Romania	Czech	Poland	Albania	*Bosnia	Latvia	*Macedonia	*Serbia
Available medicines / 54	51	43	33	40	31	22	9	23	29	38	30	36	12	19	15	24	41	2	14	19	29	11	14	11	10	24	12	17	7	0	0	0	0	0
Dates submitted / 54	51	43	12	40	31	18	7	23	28	38	30	36	11	19	15	24	22	2	8	19	27	11	13	6	8	14	12	14	6	0	0	0	0	0

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

Orphan median time to availability (2015 – 2018)

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*).



Key observations

Orphan drugs

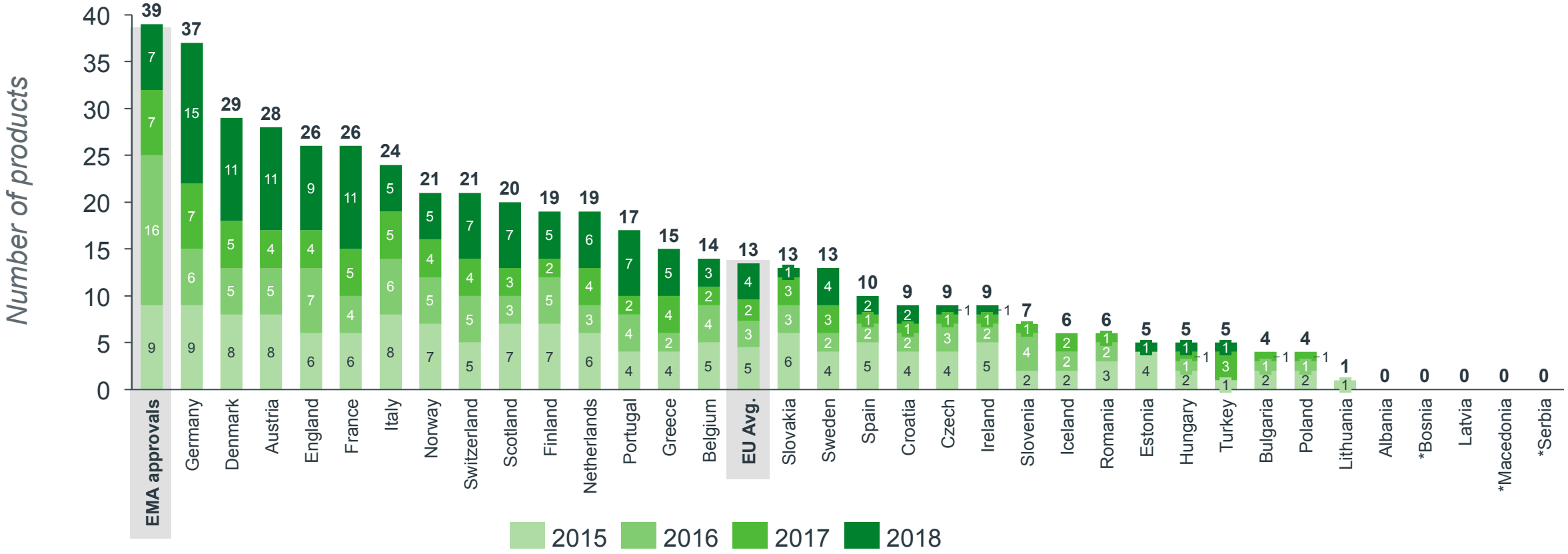
- Patient access to new Orphan medicines is highly varied across Europe, with the greatest rate of availability in Northern and Western European countries.
- In over 80% of the countries, the rate of availability **is lower for Orphan drugs** compared to all products approved between 2015-2018
- Only in Germany, England, Switzerland, Greece, and France is the rate of orphan medicines availability higher than all products approved 2015 - 2018
- Almost 80% of the countries have a **longer average delay** to EMA authorisation for Orphan drugs compared to all products approved 2015-2017
- The average delay between market authorisation and patient access for Orphan drugs is between 3.7 months to 3.2 years
- **15% of all countries studied do not have access to any of the orphan medicines** approved between 2015 and 2018

Non-oncology orphans medicines

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

Non-oncology orphan availability by approval year (2015 - 2018)

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 in which the EMA granted marketing authorisation.

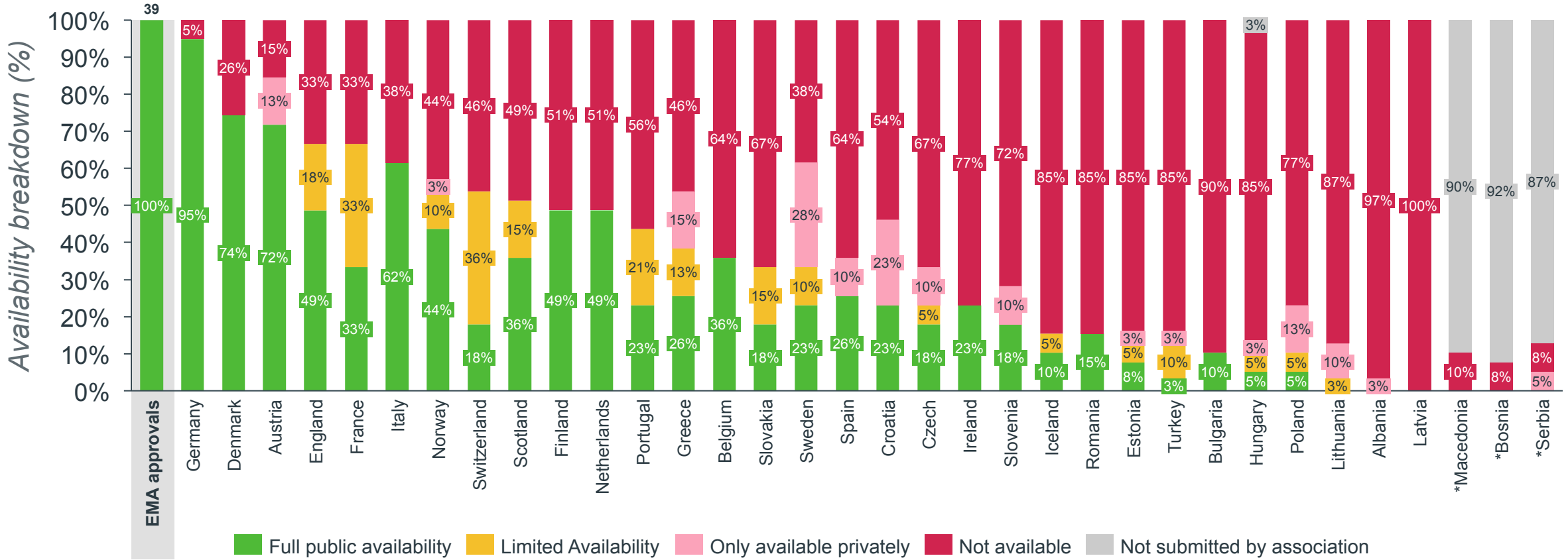


Non-oncology orphan rate of availability (2015 - 2018)

The **rate of availability**, measured by the number of medicines available to patients in European countries as of 2019: for most countries this is the point at which the product gains access to the reimbursement list, inc. limited availability.

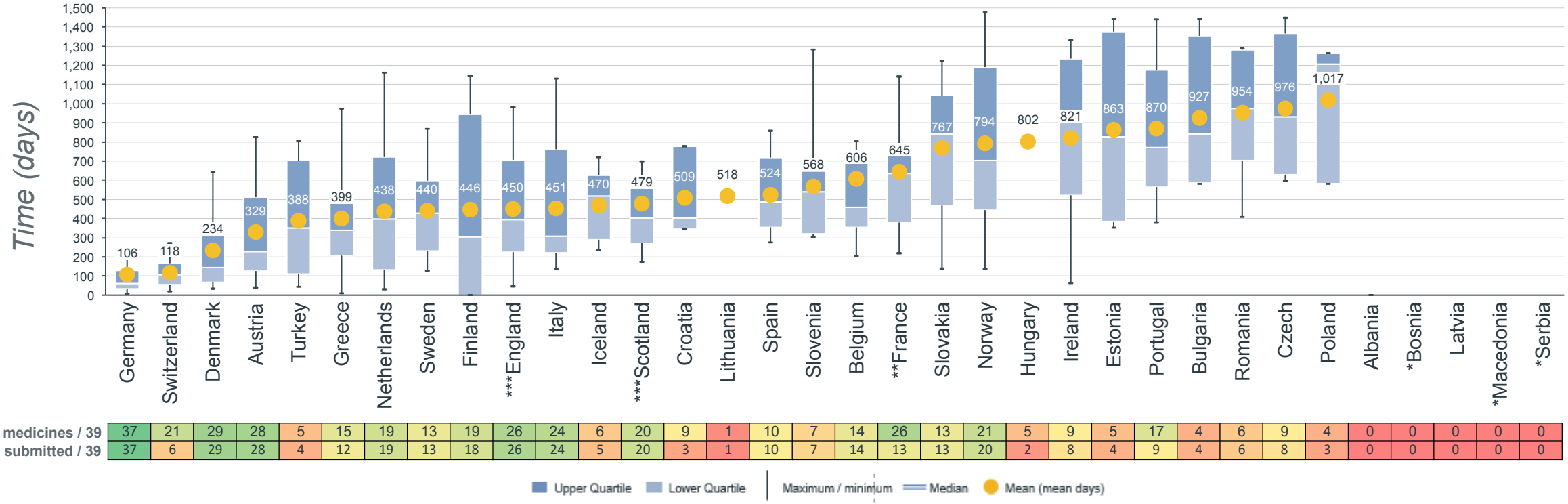
Non-oncology orphan rate of availability (%, 2015 – 2018)

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.



Non-oncology orphan time to availability (2015 – 2018)

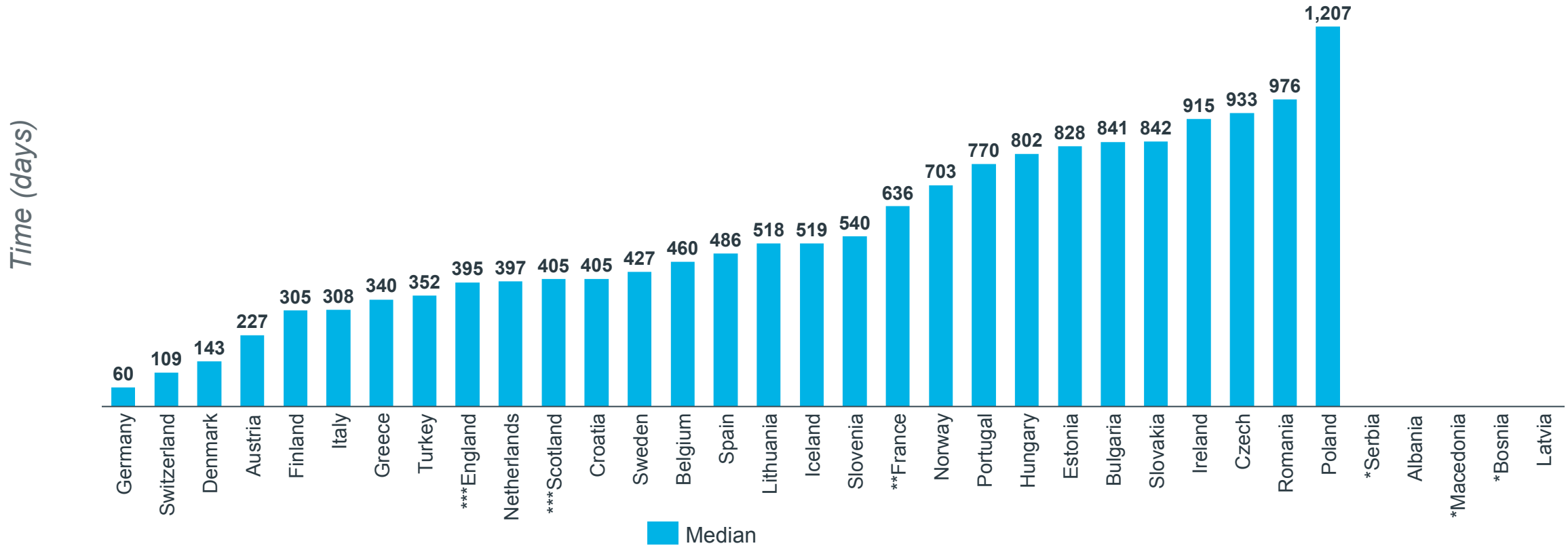
The **time to availability** (previously know as length of delay) is the days between EMA marketing authorisation and the date of availability to patients in European countries (for most this is the point at which products gain access to the reimbursement list*).



	Germany	Switzerland	Denmark	Austria	Turkey	Greece	Netherlands	Sweden	Finland	***England	Italy	Iceland	***Scotland	Croatia	Lithuania	Spain	Slovenia	Belgium	**France	Slovakia	Norway	Hungary	Ireland	Estonia	Portugal	Bulgaria	Romania	Czech	Poland	Albania	*Bosnia	Latvia	*Macedonia	*Serbia
Available medicines / 39	37	21	29	28	5	15	19	13	19	26	24	6	20	9	1	10	7	14	26	13	21	5	9	5	17	4	6	9	4	0	0	0	0	0
Dates submitted / 39	37	6	29	28	4	12	19	13	18	26	24	5	20	3	1	10	7	14	13	13	20	2	8	4	9	4	6	8	3	0	0	0	0	0

Non-oncologic orphan median time to availability (2015 – 2018)

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*).



Key observations

Non-oncology orphan drugs

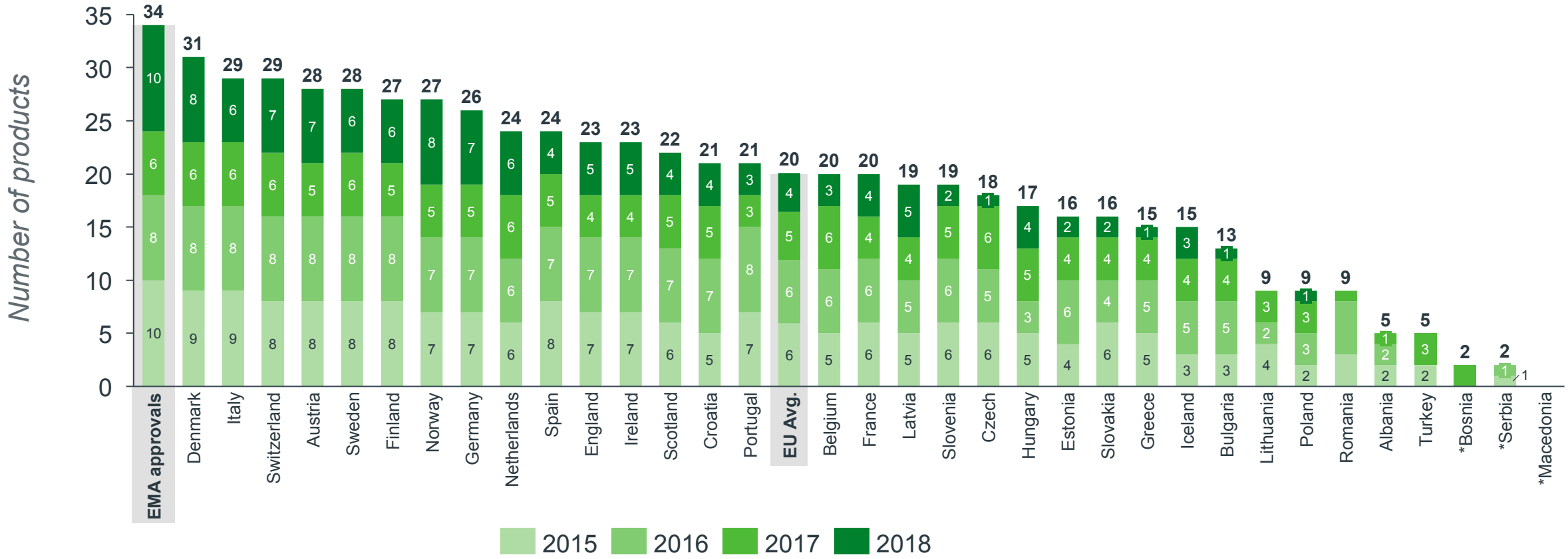
- Patient access to new Orphan medicines is generally low across Europe versus other segments, with the greatest rate of availability in Northern and Western European countries.
- In 95% of the countries, the rate of availability **is lower for non-oncology orphan drugs** compared to all orphan medicinal products approved between 2015-2018
- Only in Germany, and Norway is the rate of non-oncology orphan medicines availability equivalent to all orphan medicinal products approved 2015 - 2018
- The average delay between market authorisation and patient access for Orphan drugs is between 3.7 months to 2.8 years
- **15% of all countries studied do not have access to any of the non-oncology orphan medicines** approved between 2015 and 2018

Combination therapies

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

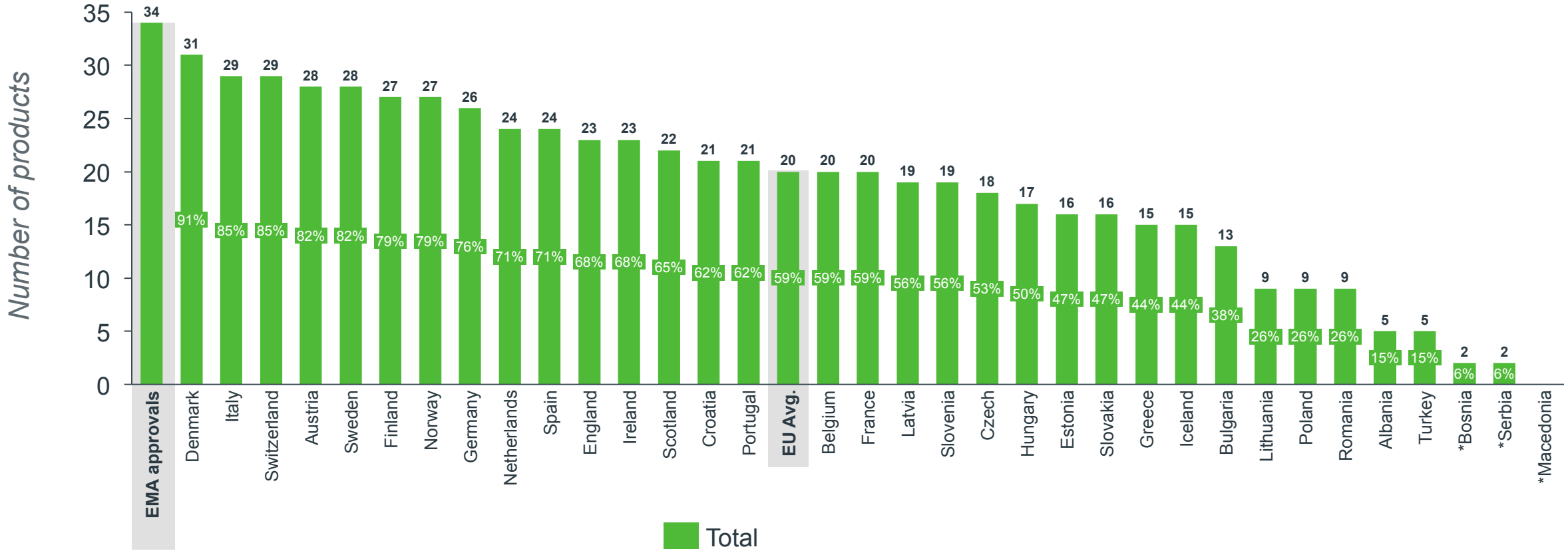
Combination therapies availability by approval year (2015 - 2018)

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 in which the EMA granted marketing authorisation.



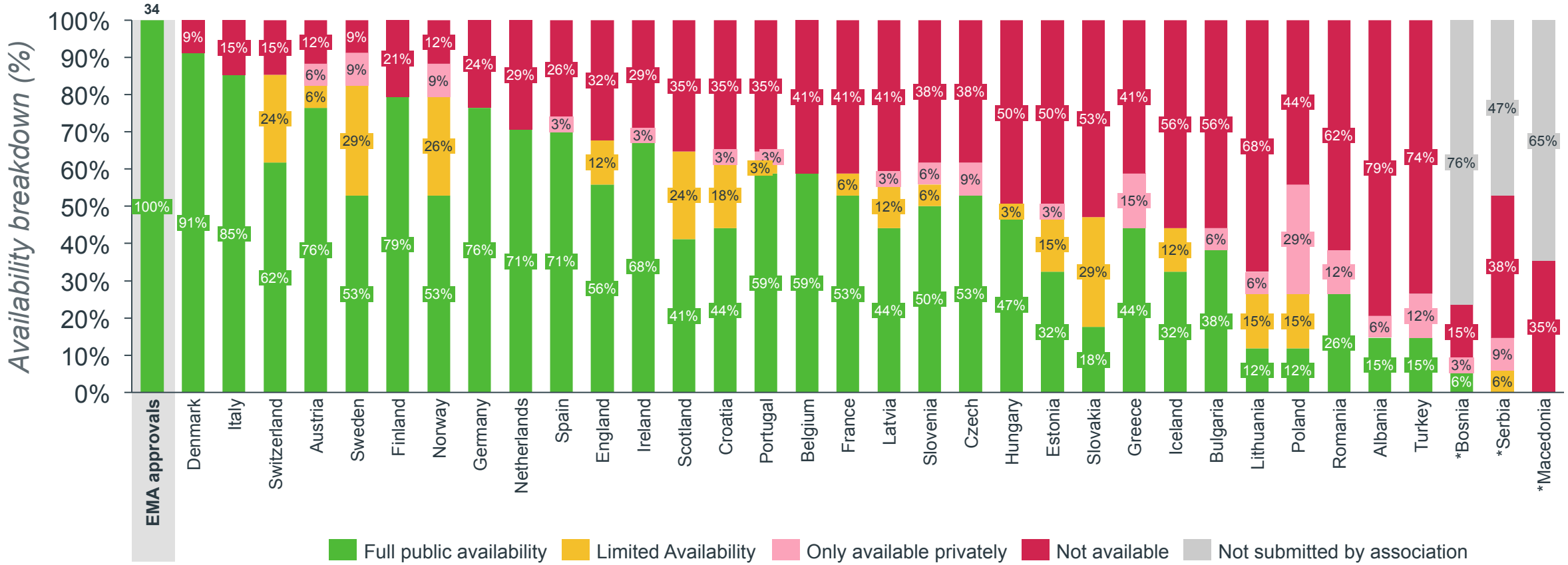
Combination therapies rate of availability (2015 - 2018)

The **rate of availability**, measured by the number of medicines available to patients in European countries as of 2019: for most countries this is the point at which the product gains access to the reimbursement list, inc. limited availability.



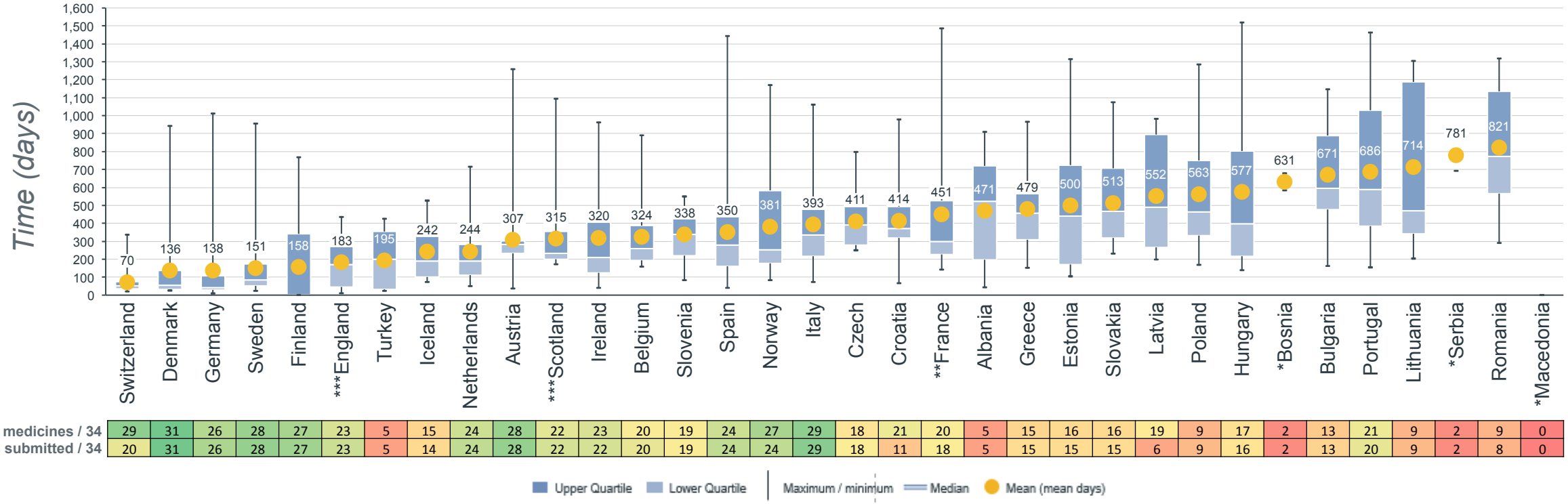
Combination therapies rate of availability (%, 2015 – 2018)

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.



Combination therapies time to availability (2015 – 2018)

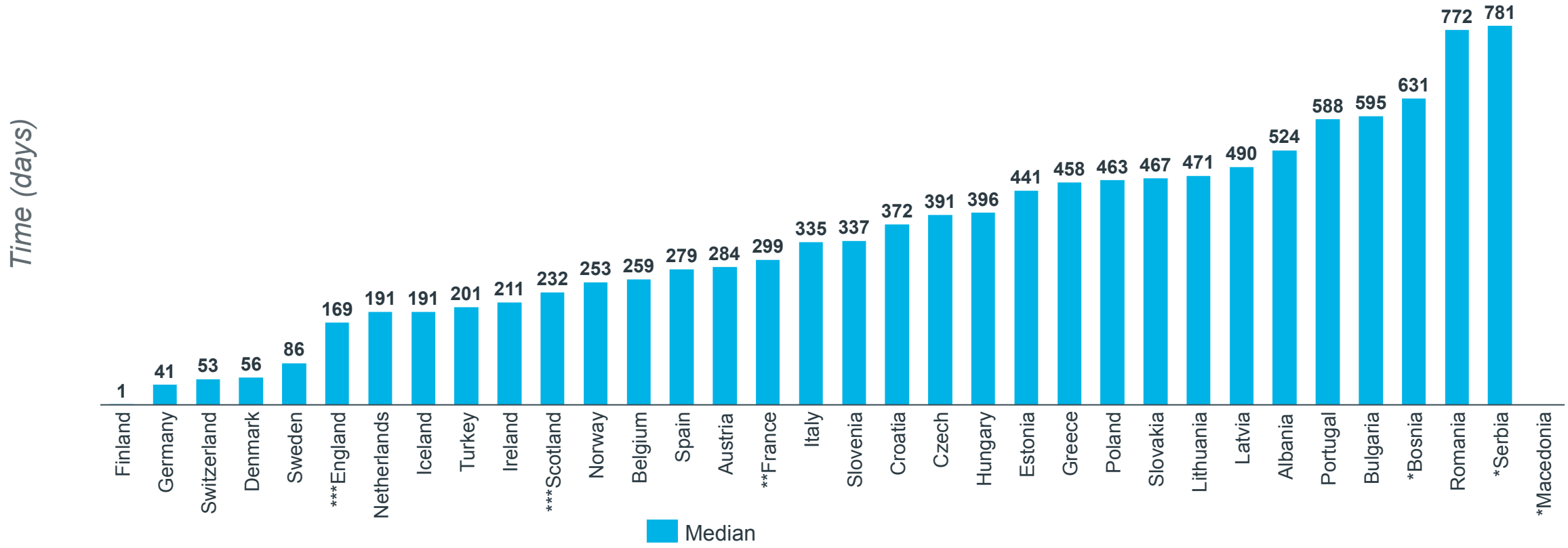
The **time to availability** (previously know as length of delay) is the days between EMA marketing authorisation and the date of availability to patients in European countries (for most this is the point at which products gain access to the reimbursement list*).



	Switzerland	Denmark	Germany	Sweden	Finland	***England	Turkey	Iceland	Netherlands	Austria	***Scotland	Ireland	Belgium	Slovenia	Spain	Norway	Italy	Czech	Croatia	**France	Albania	Greece	Estonia	Slovakia	Latvia	Poland	Hungary	*Bosnia	Bulgaria	Portugal	Lithuania	*Serbia	Romania	*Macedonia
Available medicines / 34	29	31	26	28	27	23	5	15	24	28	22	23	20	19	24	27	29	18	21	20	5	15	16	16	19	9	17	2	13	21	9	2	9	0
Dates submitted / 34	20	31	26	28	27	23	5	14	24	28	22	22	20	19	24	24	29	18	11	18	5	15	15	15	6	9	16	2	13	20	9	2	8	0

Combination therapy median time to availability (2015 – 2018)

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*).



Key observations

Combination therapies

- Patient access to new combination medicines is highly varied across Europe
- Over 40% of these combinations are for HIV or Hep-C, two products are Oncology combinations
- In 82% of the countries, the rate of availability is **higher for combination products** compared to all products approved between 2015-2018
- Over 75% of the countries have a **shorter average delay** to EMA authorisation for combination drugs compared to all products approved 2015-2018
- The average delay between market authorisation and patient access for combination therapies is between 4.7 months to 2.2 years

Appendix

5-year rolling cohort: 2014-2018

Study scope

- 213 products approved by EMA between 1st January 2014 to 31st December 2018

- The 2019 study provides an analysis of products approved between **2014-2015-2016-2017-2018**, for the following dataset:
  a) **All 213 products:** 41 in 2014, 45 in 2015, 35 in 2016, 38 in 2017, 54 in 2018
  b) **52 Oncology products:** 9 in 2014,10 in 2015, 10 in 2016, 11 in 2017, 12 in 2018
  c) **66 Orphan products:** 12 in 2014, 12 in 2015, 9 in 2016, 12 in 2017, 21 in 2018
  d) **44 Combination products**: 10 in 2014, 10 in 2015, 8 in 2016, 6 in 2017, 10 in 2018

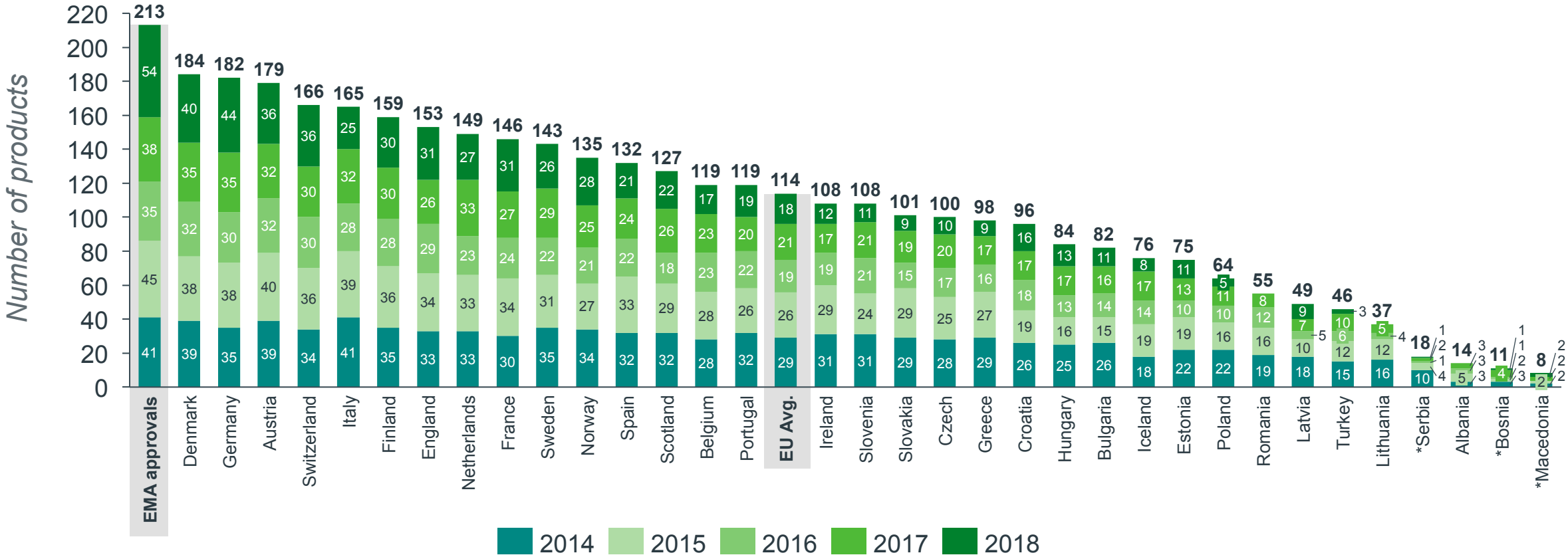
- Definitions:
  - Orphan status from EMA (September 2019)
  - Oncology products flagged using IQVIA MIDAS Oncology market definition*
  - Combination products include any product with more than one molecule, including branded/generic combinations

- The date of availability cut off point was 1st January 2020 (to account for Estonia, Iceland, Czech Republic, Latvia, Slovakia which had a few products with a reimbursement decision on 1st January 2020).

- 34 countries included in the study (including split of UK into England and Scotland).

Total availability by approval year (2014 - 2018)

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 in which the EMA granted marketing authorisation.



Rate of availability (2014 – 2018)

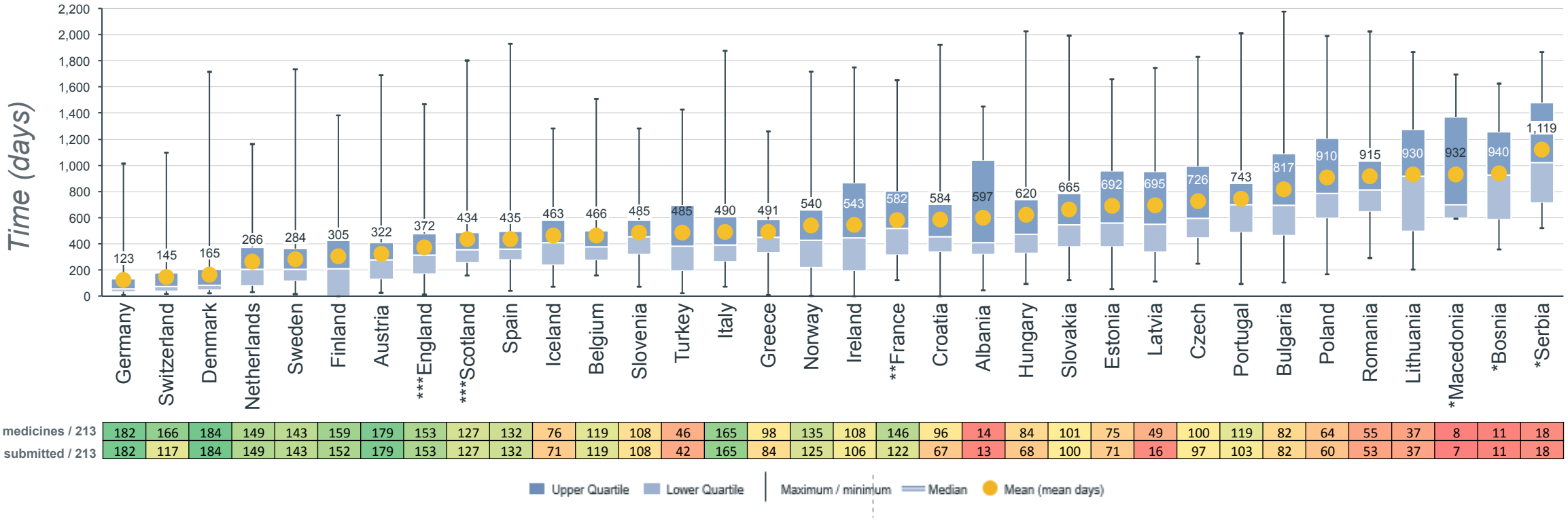
The **rate of availability** is the number of medicines available to patients in European countries (for most countries this is the point at which the product gains access to the reimbursement list*), inc. limited availability

Rate of availability (%, 2014 – 2018)

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.

Time to availability (2014 – 2018)

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*).

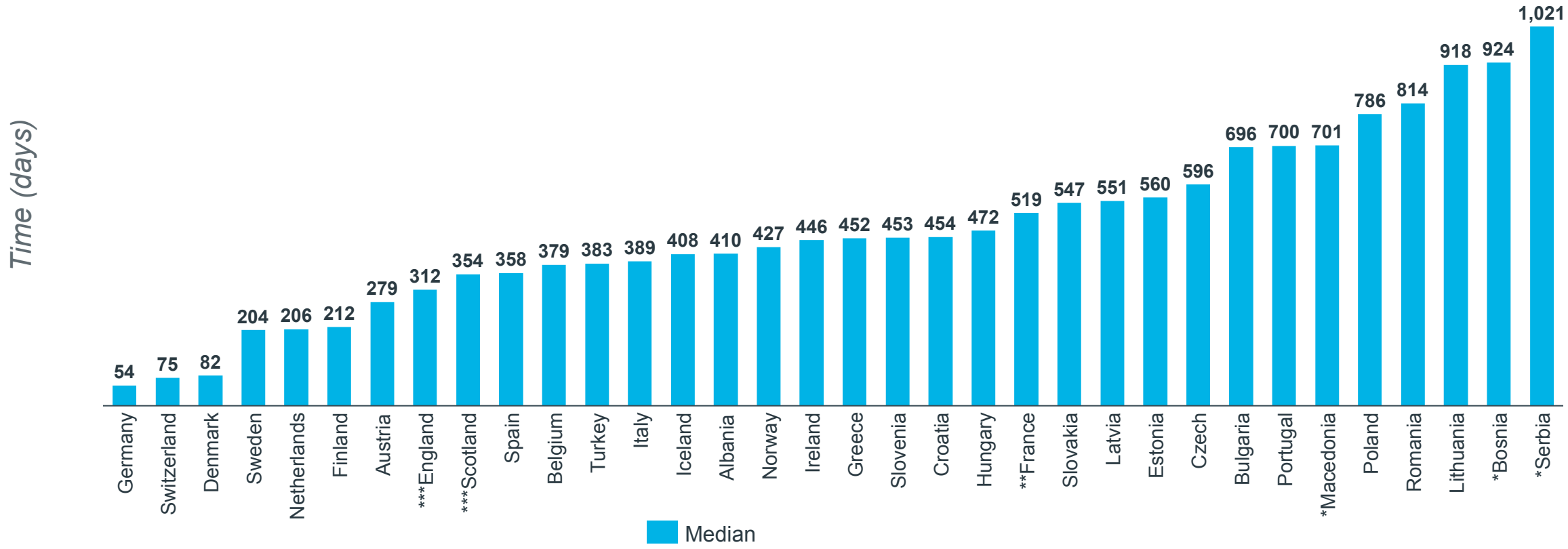


	Germany	Switzerland	Denmark	Netherlands	Sweden	Finland	Austria	***England	***Scotland	Spain	Iceland	Belgium	Slovenia	Turkey	Italy	Greece	Norway	Ireland	**France	Croatia	Albania	Hungary	Slovakia	Estonia	Latvia	Czech	Portugal	Bulgaria	Poland	Romania	Lithuania	*Macedonia	*Bosnia	*Serbia
Available medicines / 213	182	166	184	149	143	159	179	153	127	132	76	119	108	46	165	98	135	108	146	96	14	84	101	75	49	100	119	82	64	55	37	8	11	18
Dates submitted / 213	182	117	184	149	143	152	179	153	127	132	71	119	108	42	165	84	125	106	122	67	13	68	100	71	16	97	103	82	60	53	37	7	11	18

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

Median time to availability (2014 – 2018)

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*).



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Country-specific insights:
Local Associations