



EFPIA Patient W.A.I.T. Indicator 2018 survey

3 April 2019

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) 3, or 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 effective marketing authorisation in non-EEA countries) 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

Introduction (2)

- The Patients W.A.I.T. Indicator gives **a snapshot** of the 2 parameters at a cut-off date (19th December 2018) – data from medicines cohorts dropping out of the reference period are not included.
- Waiting times reflected in the Patients W.A.I.T. Indicator include **any delay**, 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

Step 1 EMA list of authorisations (September 2018)

Step 2 Products in scope

- Status: Authorised, Withdrawn, Suspended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

Step 3 Remove products with an active substance which has an EMA authorisation prior to 2014

Step 4 Additional criteria for products with active substances with multiple MA's between 2014-2017

- New combination products (even those containing already approved active substances) are included
- New formulations are excluded
- New indications of already approved active substances, leading to a separate marketing authorisation only for an orphan drug are included
- Duplicates (products launched on the same date, but same company for same indication) - only one is included but both product names are added on one line

Study scope

- 121 products approved by EMA between 1st January 2015 to 31st December 2017 (excluding 4 products which were withdrawn between 2015-2017)
- The 2018 study provides an analysis of products approved between **2015-2016-2017**, for the following datasets:
 - a) **All 121 products:** 45 in 2015, 38 in 2016, 38 in 2017
 - b) **38 Orphan products:** 13 in 2015, 13 in 2016, 12 in 2017
 - c) **31 Oncology products:** 10 in 2015, 12 in 2016, 9 in 2017
 - d) **24 Combination products:** 10 in 2015, 8 in 2016, 6 in 2017
- Definitions:
 - Orphan status from EMA (September 2018)
 - Oncology products flagged using IQVIA MIDAS Oncology market definition*
 - Combination products include any product with more than one molecule
- The date of availability cut off point is 19th December 2018 (except for Estonia, Iceland, Czech Republic, Latvia, Slovakia which had a few products with a reimbursement decision on 1st January 2019)
- 30 countries included in the study

* L1&L2&V3C&Revlimid&Xgeva&Proleukin&Pomalyst

Availability and accessibility date

- 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 **accessibility 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) | Available |
| Reimbursed on an individual basis, in some cases whilst reimbursement is pending | Available (LA*) |
| Not reimbursed and only available at the patients expense | Not available |
| Pending reimbursement and only available 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**

*LA: product available for limited availability

Products with particular reimbursement conditions

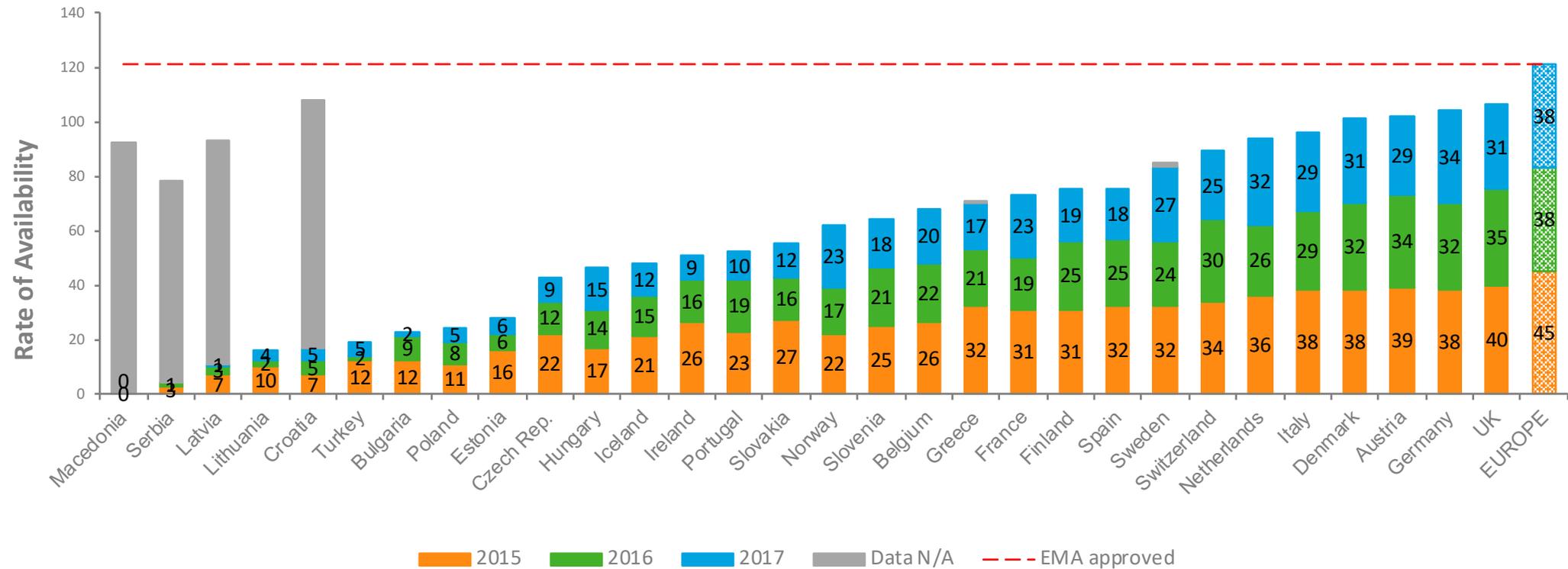
- IQVIA has differentiated between products which are reimbursed through the regular process in a country, and products with “limited availability” (LA)
- Products with LA have **special reimbursement conditions**, where reimbursement is only granted for certain patients, indications, or only through special programs (e.g. early access schemes)
- 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)* |
| Conditional reimbursement |

*Some innovative products can be made available prior to market authorization through **early access schemes** in countries. As these are not taken into account in the analysis in some countries, the average delay in these countries will be higher than in reality.

Rate of Availability

The **rate of availability**, measured by the number of medicines available to patients in European countries as of 2018: for most countries this is the point at which the product gains access to the reimbursement list*.



Data N/A- data is not provided by associations (companies have not sent data or are not members of the association)

*See next slide for country specific definitions

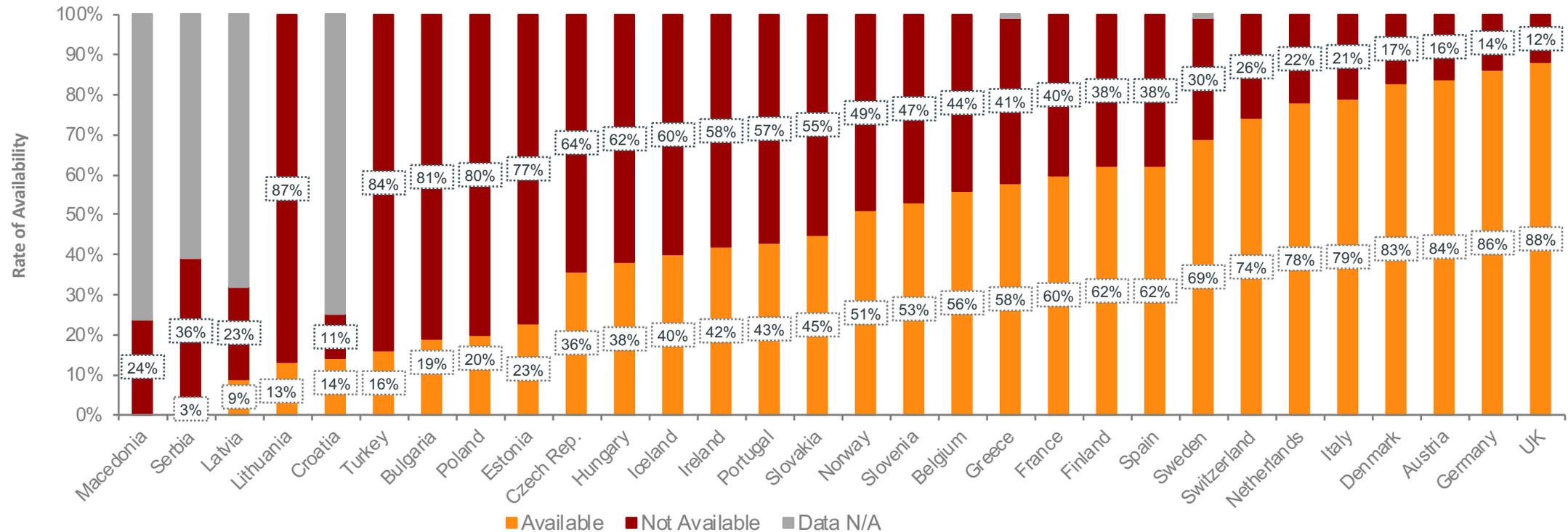
Definition of Availability

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.
- Czech Republic: A medicine is available if it is on the reimbursement list, or funded through the hospital
- 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).
- 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 either gains access to the reimbursement list or is available through a named patient scheme. Delay calculated using local market authorisation dates.
- UK: Two data sources are used- IQVIA sales data and publication of NICE opinion. IQVIA sales data is taken as the main source of information for availability; NICE opinion is used if sales aren't captured by IQVIA.

Rate of Availability (%)

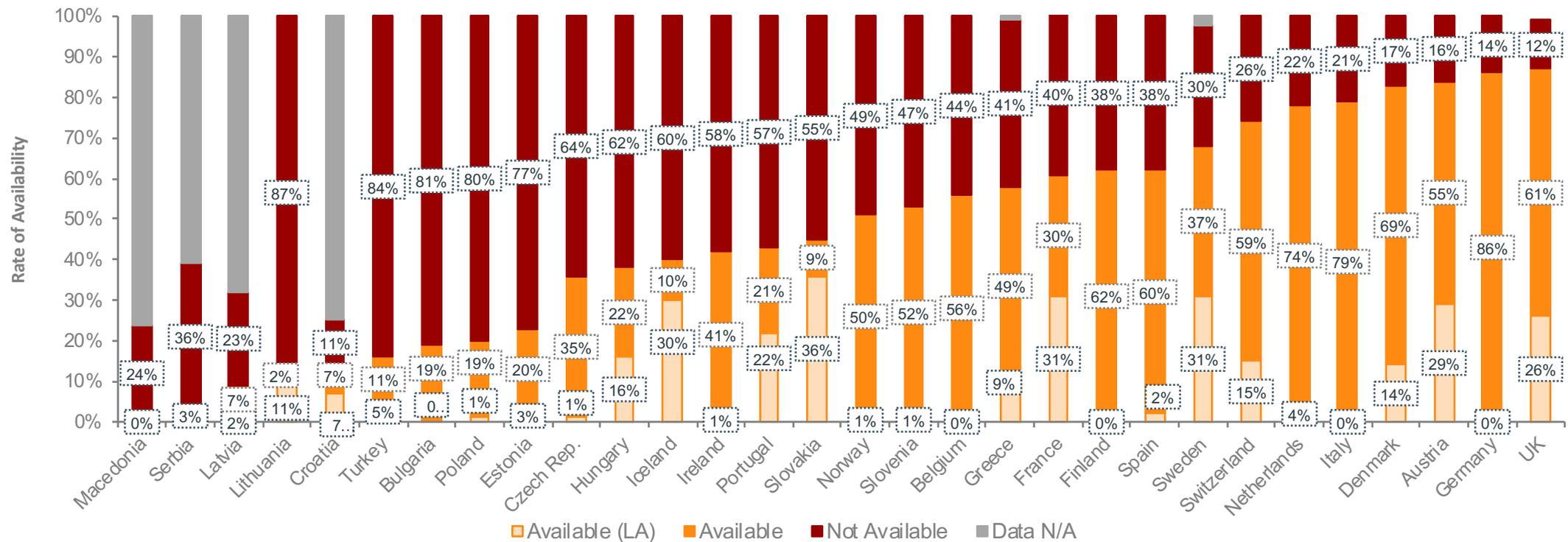
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*Available (LA) - products which have been reimbursed or are pending reimbursement, with specific conditions - see next slide for country specific definitions

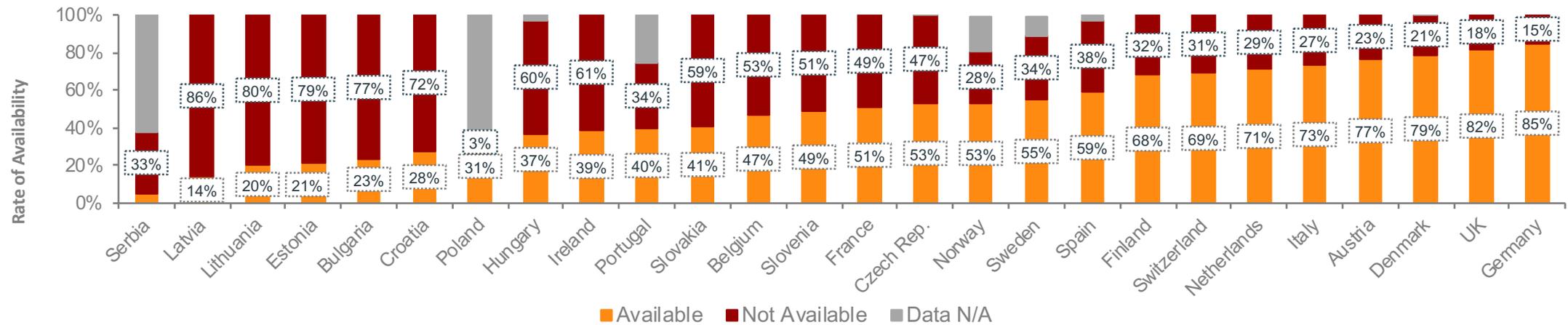
Definition of Available with special reimbursement conditions

- 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.
- 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
- 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.
- UK: England, Scotland and Wales do not limit reimbursement for medicines for specific groups of patients relative to license. But following a health technology appraisal by the national appraisal body (National Institute of health and Clinical Evidence, Scottish Medicines Committee, All Wales Medicines Strategy Group) recommended usage of medicines may be restricted to a subgroup of patients relative to the scope of the license under consideration.

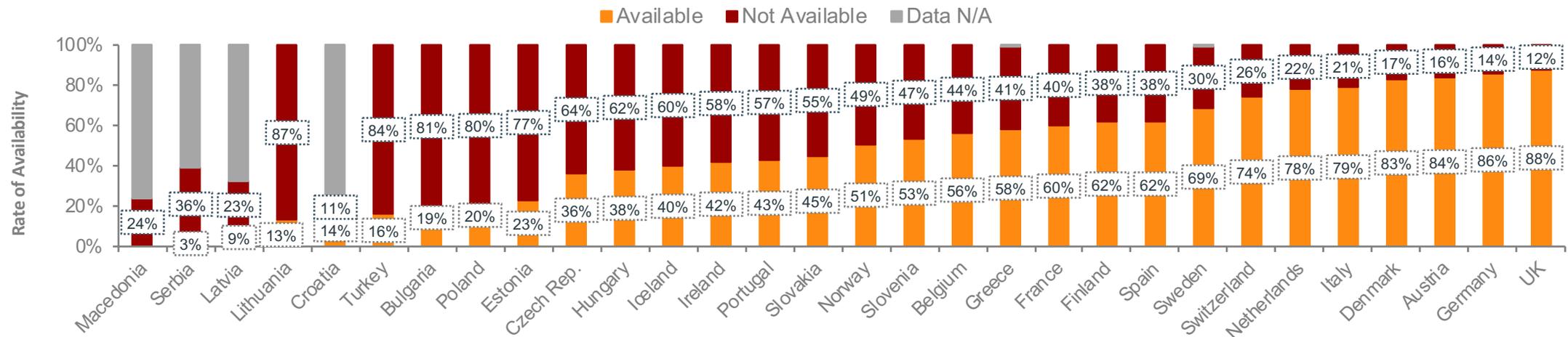
Rate of Availability (%)

The **rate of availability**, measured by the number of medicines available to patients in European countries as of 2018, compared to the rate of availability in the 2017 W.A.I.T. indicator study

2017 study
(2014-2016)



2018 study
(2015-2017)

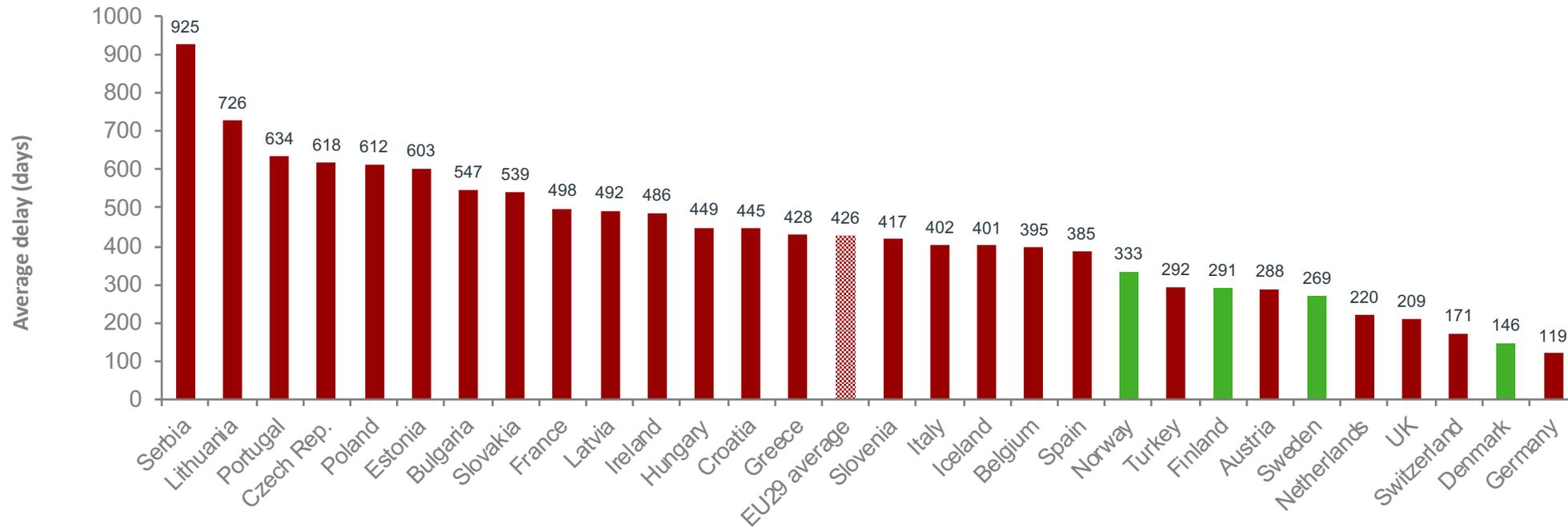


Data N/A- data is not provided by associations (companies have not sent data or are not members of the association)

Note: there are differences in country scope and methodology for product selection between the 2017 and 2018 studies (26 countries included in 2017 study; 30 countries in 2018 study)

Length of market access delays (average)

The **average time between marketing authorisation and patient access** - the number of days elapsing from the date of EU marketing authorisation (or effective marketing authorisation in non-EEA countries) to the day of completion of post-marketing authorisation administrative processes

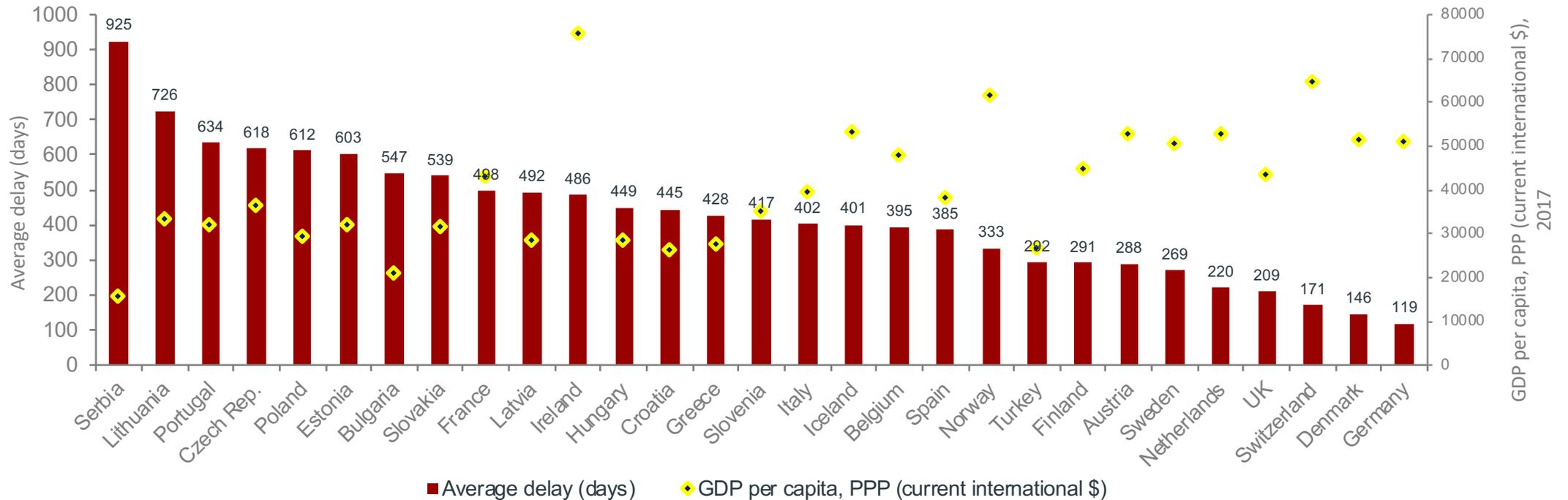


In most countries patient access equates to granting of access to the reimbursement list, except for hospital products in DK, FI, NO, SE where some products are not covered by the general reimbursement scheme and so this shorter delay is artificially declining the median and average.

- 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 is higher than in reality.
- Average of 29 European countries in the analysis (excludes Macedonia)

Length of market access delays (average)

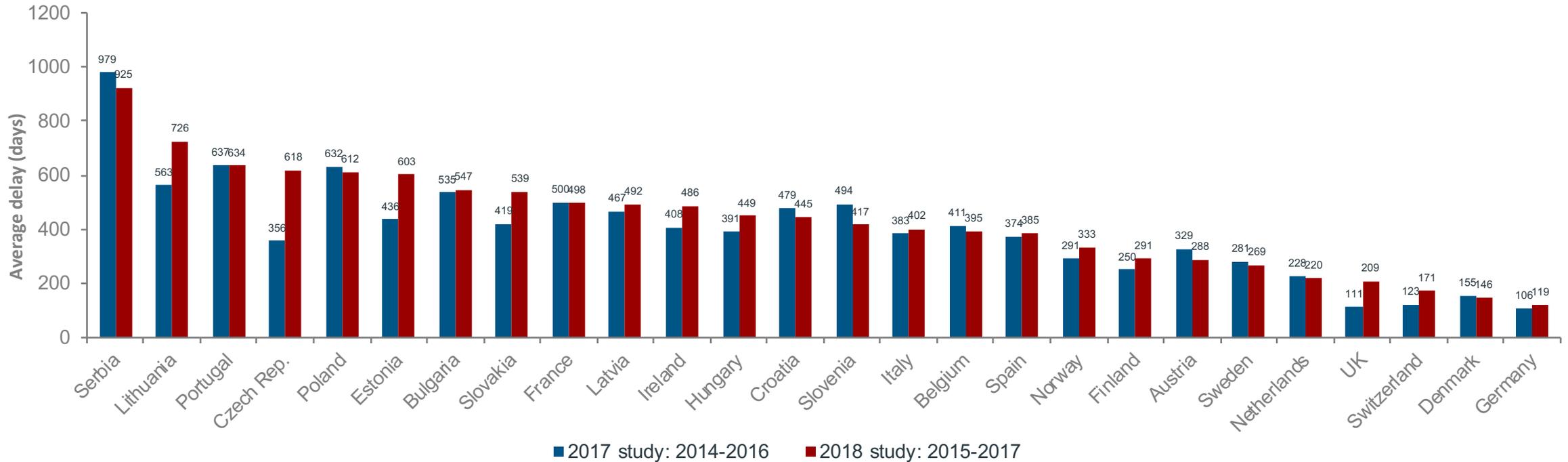
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Source: GDP per capita, PPP (current international \$), 2017 - World Development Indicators, World Bank

Length of market access delays (average)

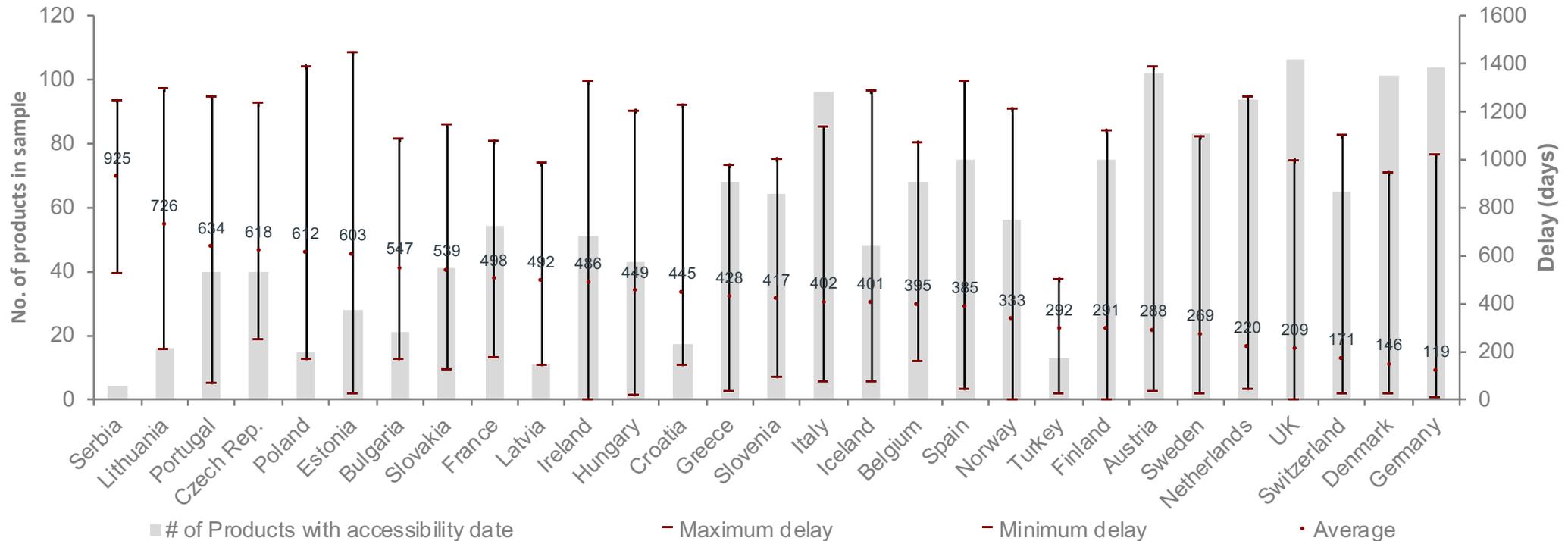
The **average time between marketing authorisation and patient access** - compared to the average delay in the 2017 W.A.I.T. indicator study



Note: there are differences in methodology for product selection between the 2017 and 2018 studies; chart only shows countries overlapping both studies

Length of market access delays (average, maximum, minimum)

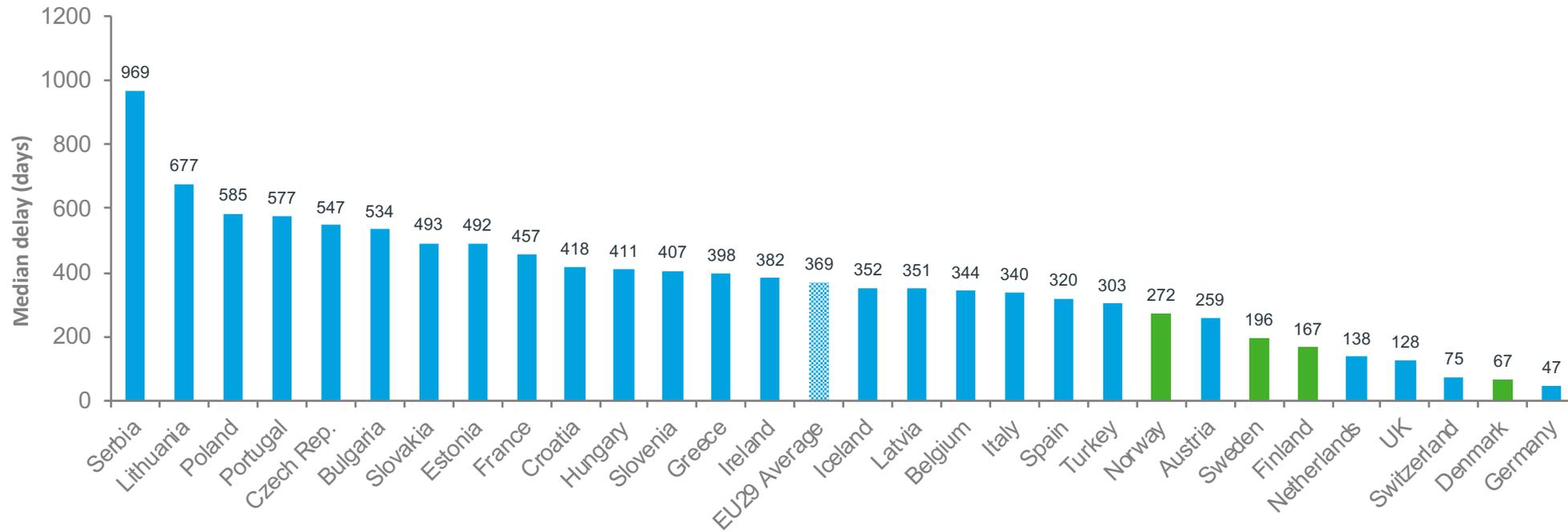
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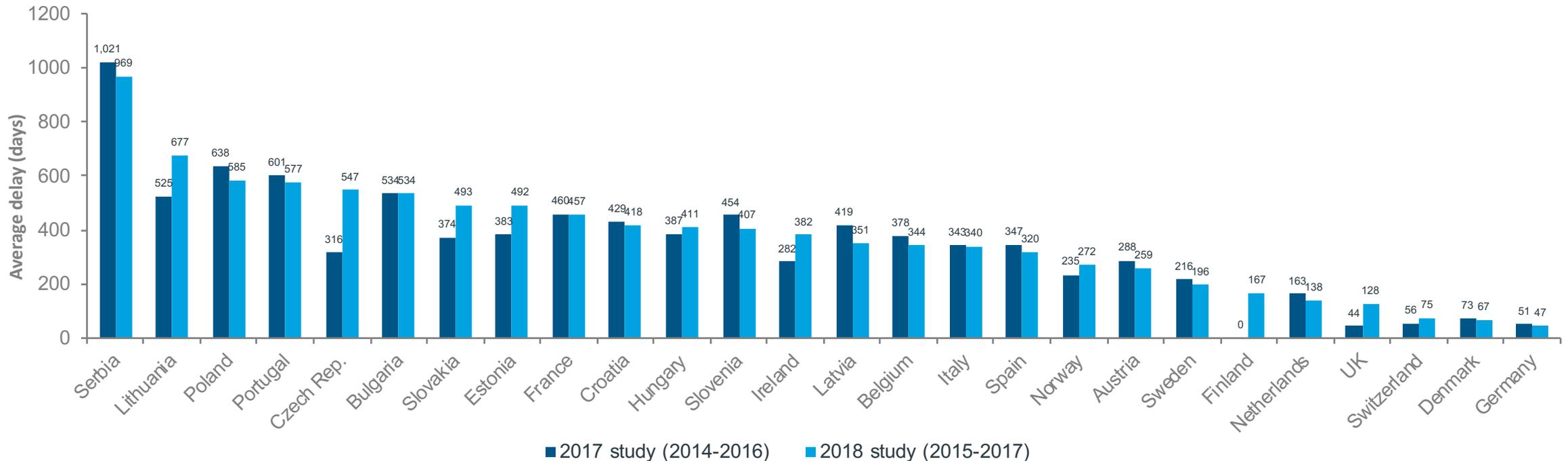


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Length of market access delays (median)

The **average time between marketing authorisation and patient access** - compared to the average delay in the 2017 W.A.I.T. indicator study



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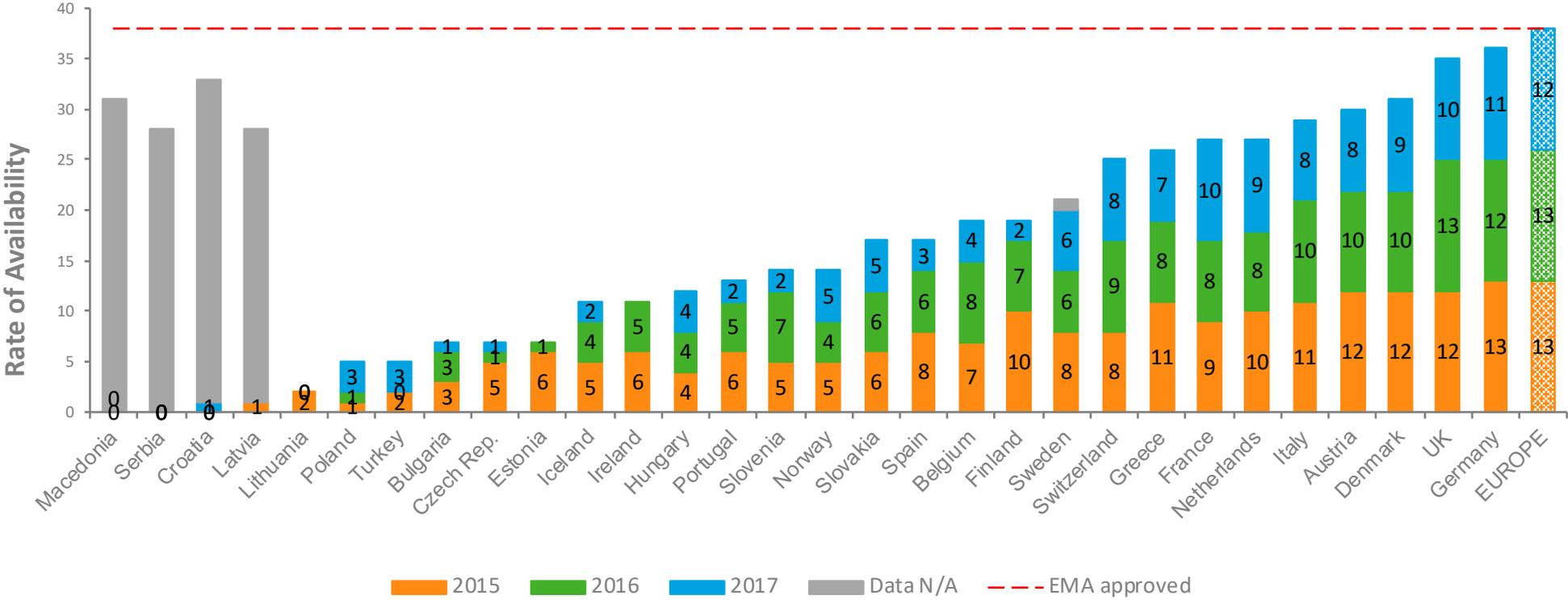
Key observations

- **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, over 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 7 across Europe**, with patients in Northern /Western Europe accessing new products 100-200 days after market authorisation and patients mainly in Southern/ Eastern Europe between 600-1000 days.
- **Countries with more products available tend to have faster access to medicines.**
- **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 Estonia (21 vs. 1443 days), Ireland (0 vs. 1321 days) and Austria (33 vs. 1383 days).
- **Comparison to 2017 W.A.I.T. indicator study:** of the countries overlapping both analyses, 65% countries have a higher rate of availability, and 58% countries have a longer delay in the 2018 study.

Orphans

Rate of Availability

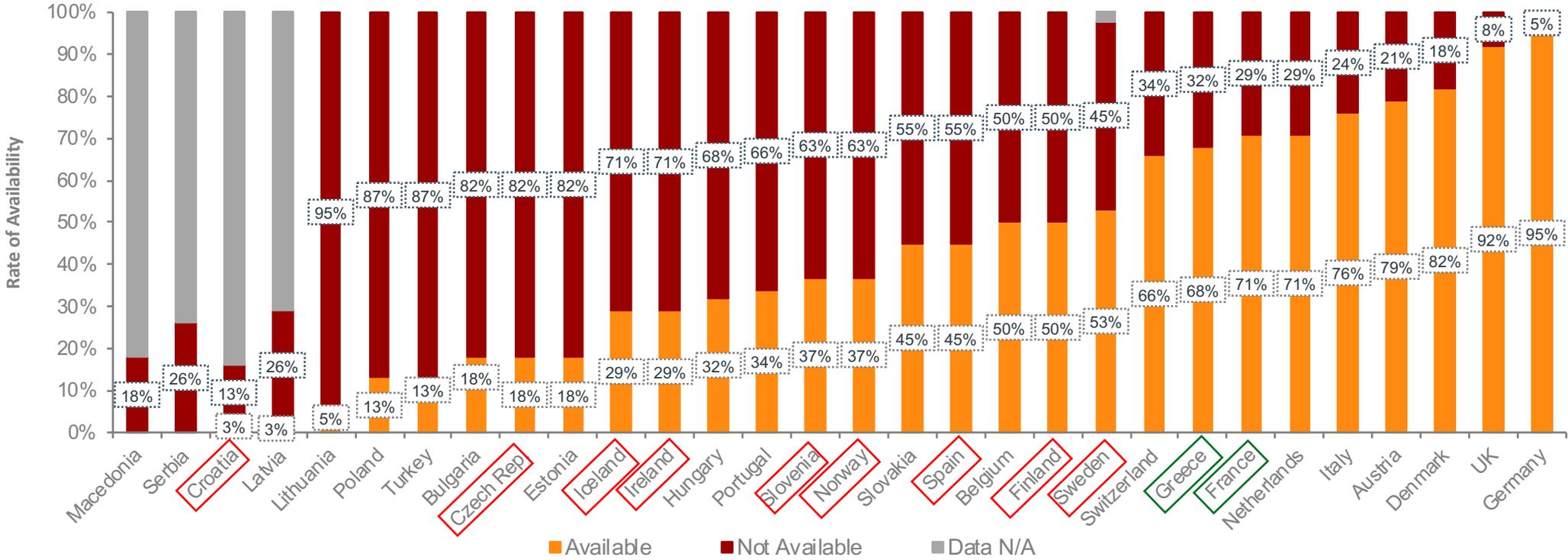
The **rate of availability**, measured by the number of medicines available to patients in European countries as of 2018: for most countries this is the point at which the product gains access to the reimbursement list.



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Orphan status from EMA (September 2018)

Rate of Availability (%)

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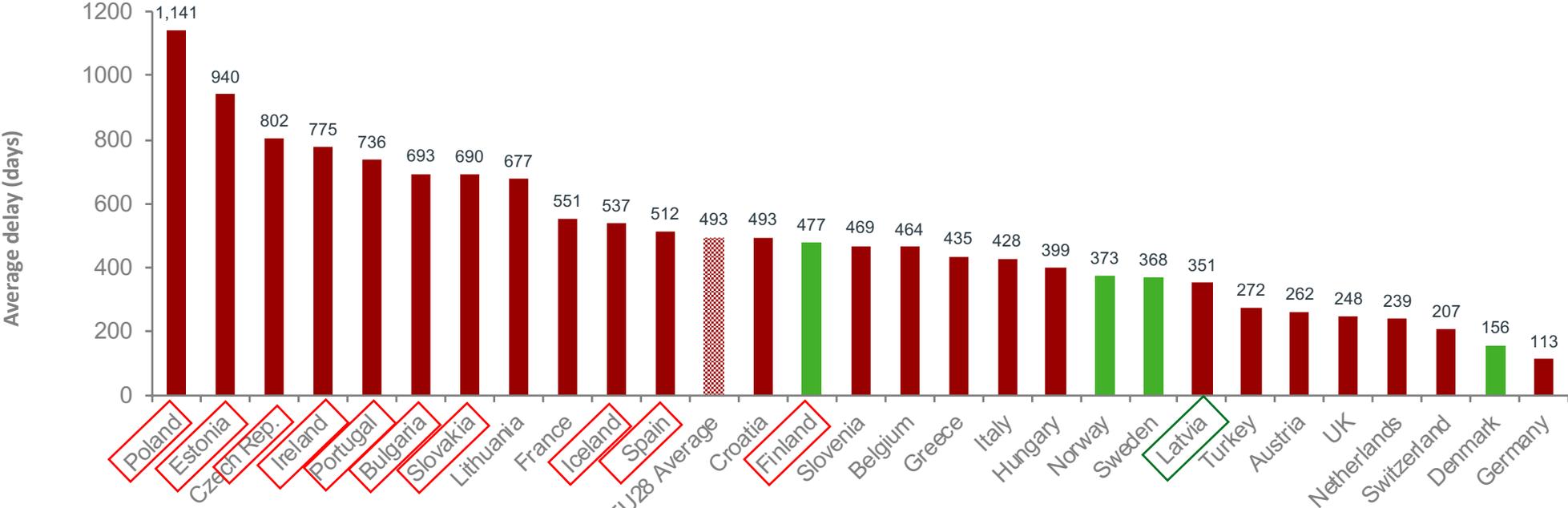


- Rate of availability for Orphans is at least 10% lower than all products approved 2015-2017
- Rate of availability for Orphans is at least 10% higher than all products approved 2015-2017

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Orphan status from EMA (September 2018)

Length of market access delays (average)

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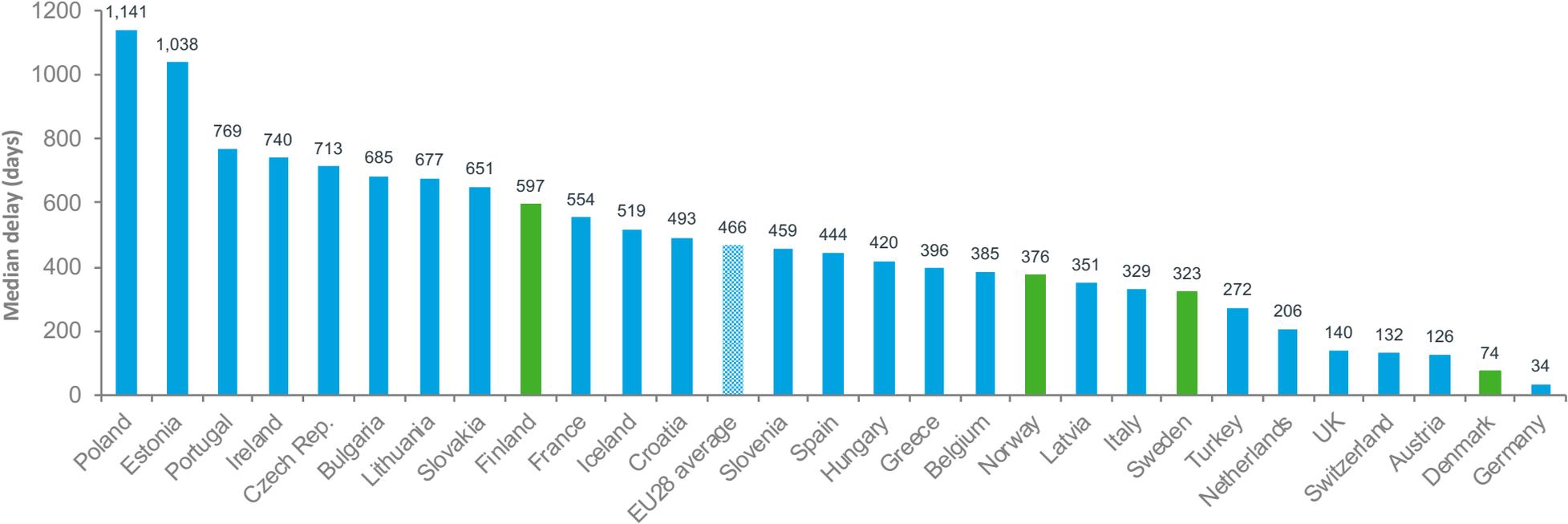
 Average delay for Orphans is at least 100 days longer than all products approved 2015-2017
 Average delay for Orphans is at least 100 days shorter than all products approved 2015-2017

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

- 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 is higher than in reality.
- Average of 28 European countries in the analysis (excludes Macedonia, Serbia)
- Orphan status from EMA (September 2018)

Length of market access delays (median)

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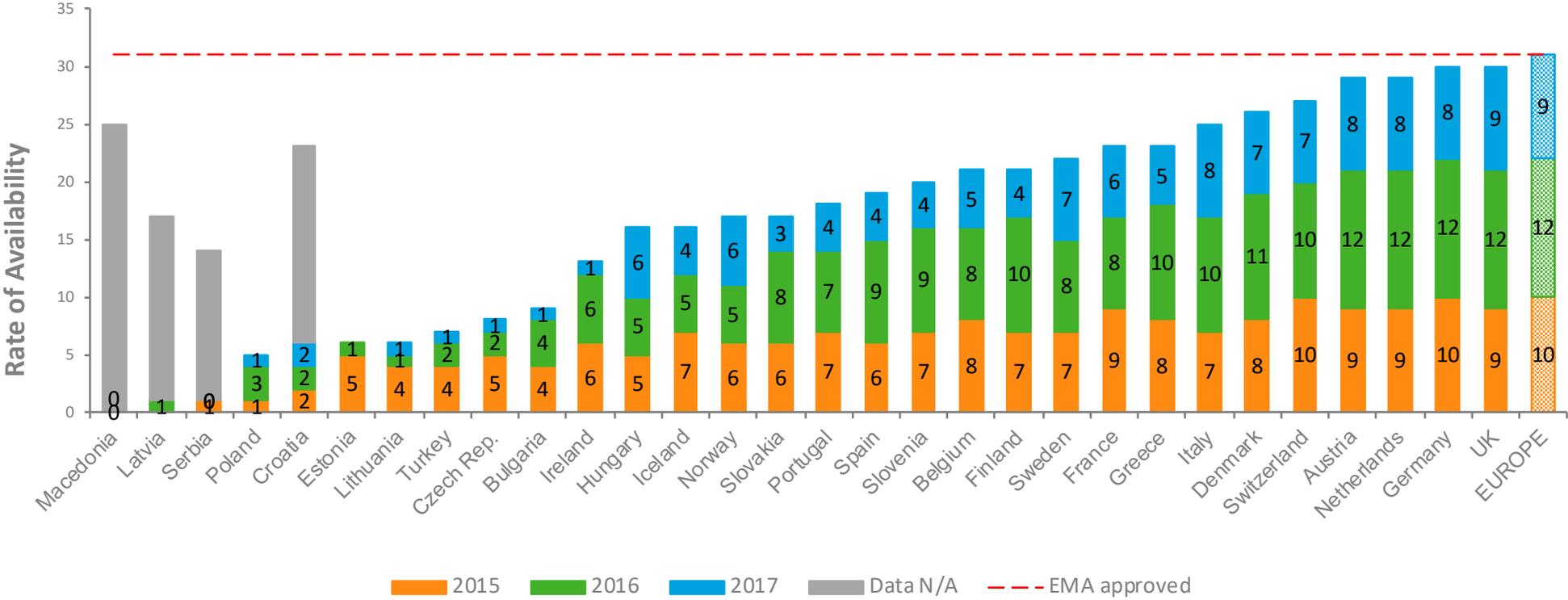
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Oncology

Rate of Availability

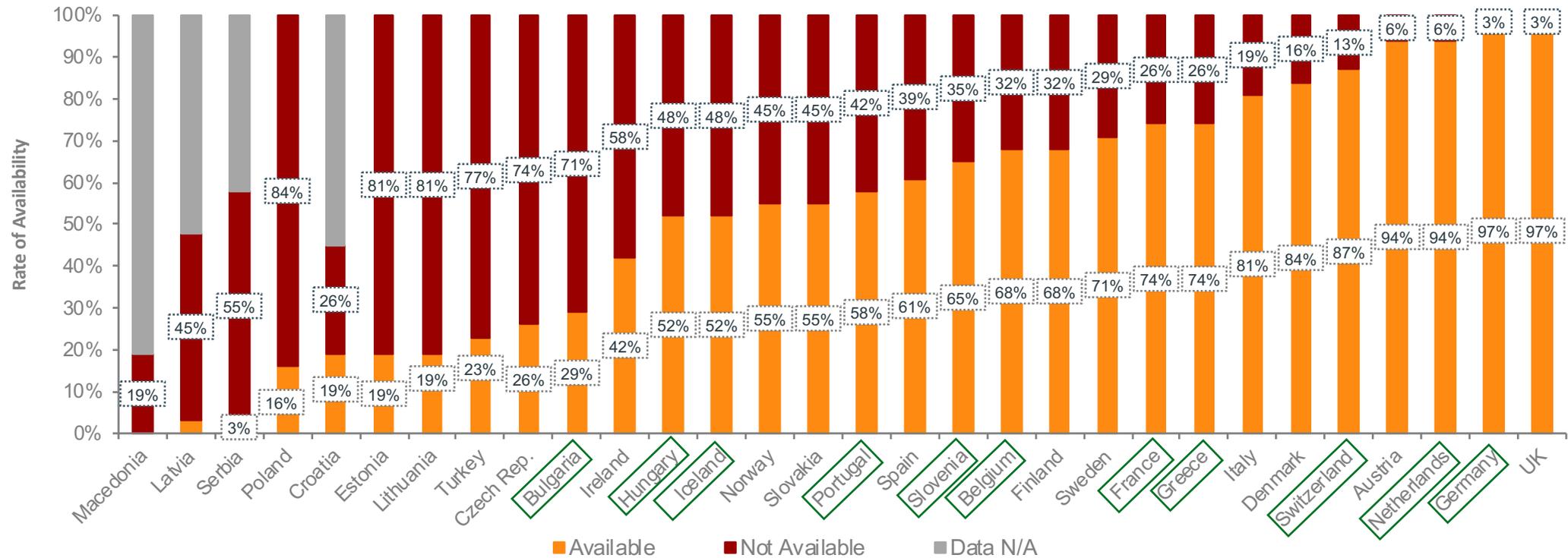
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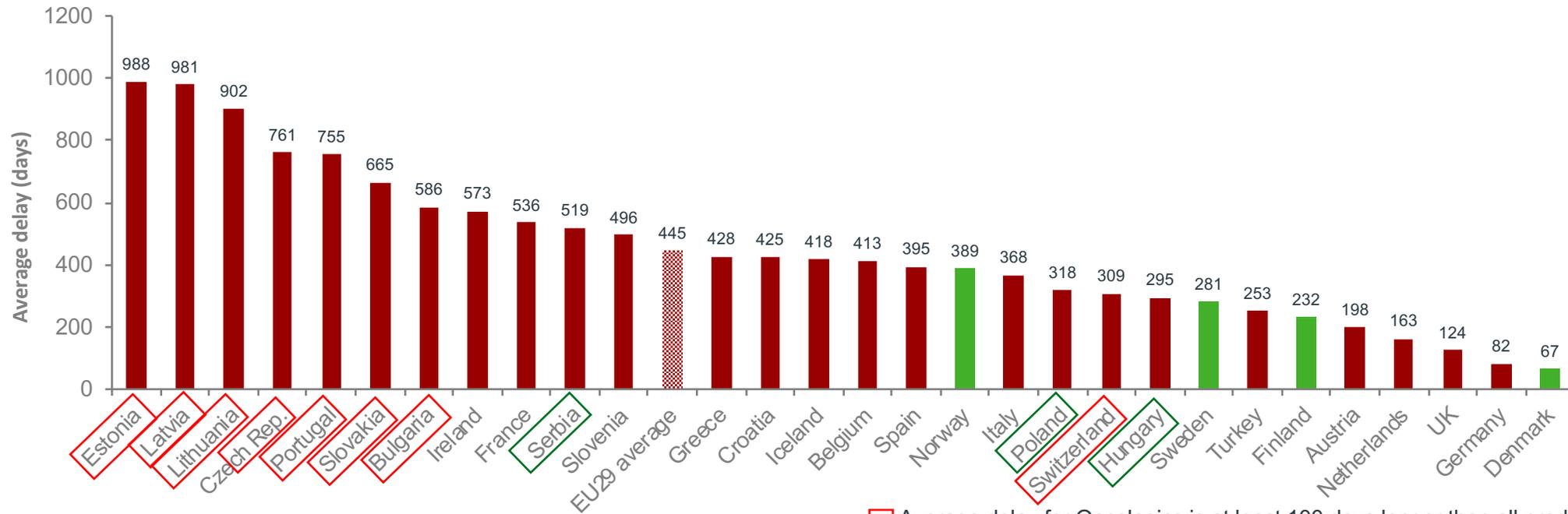


- Rate of availability for Oncologics is at least 10% lower than all products approved 2015-2017
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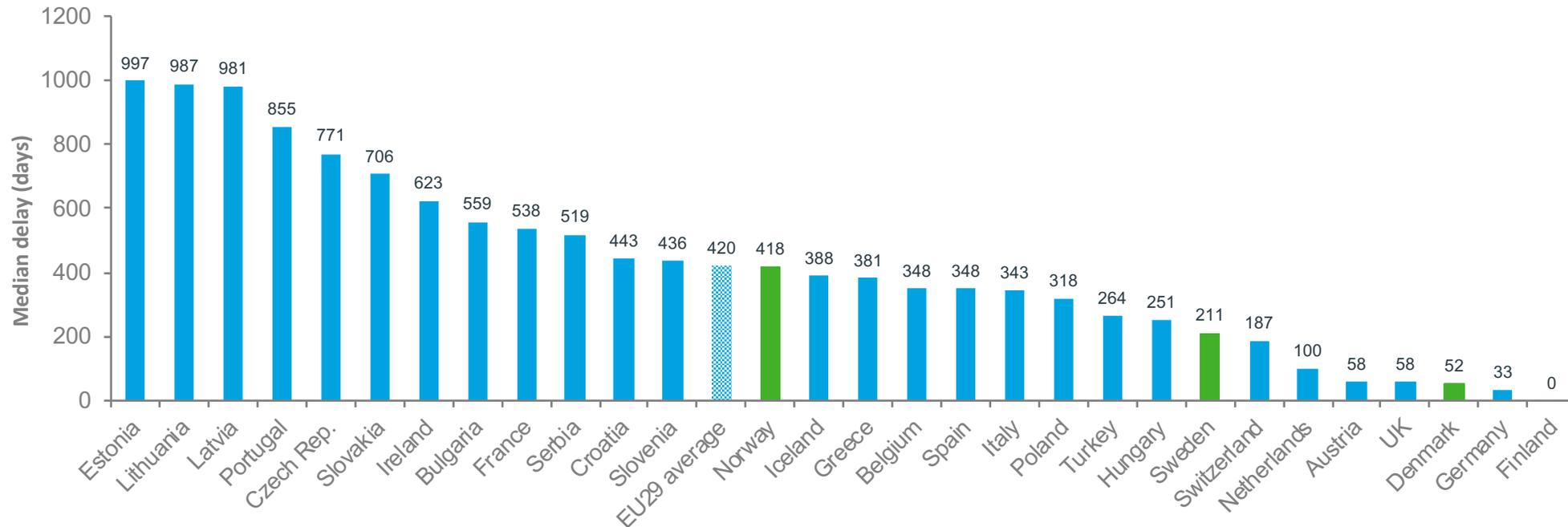
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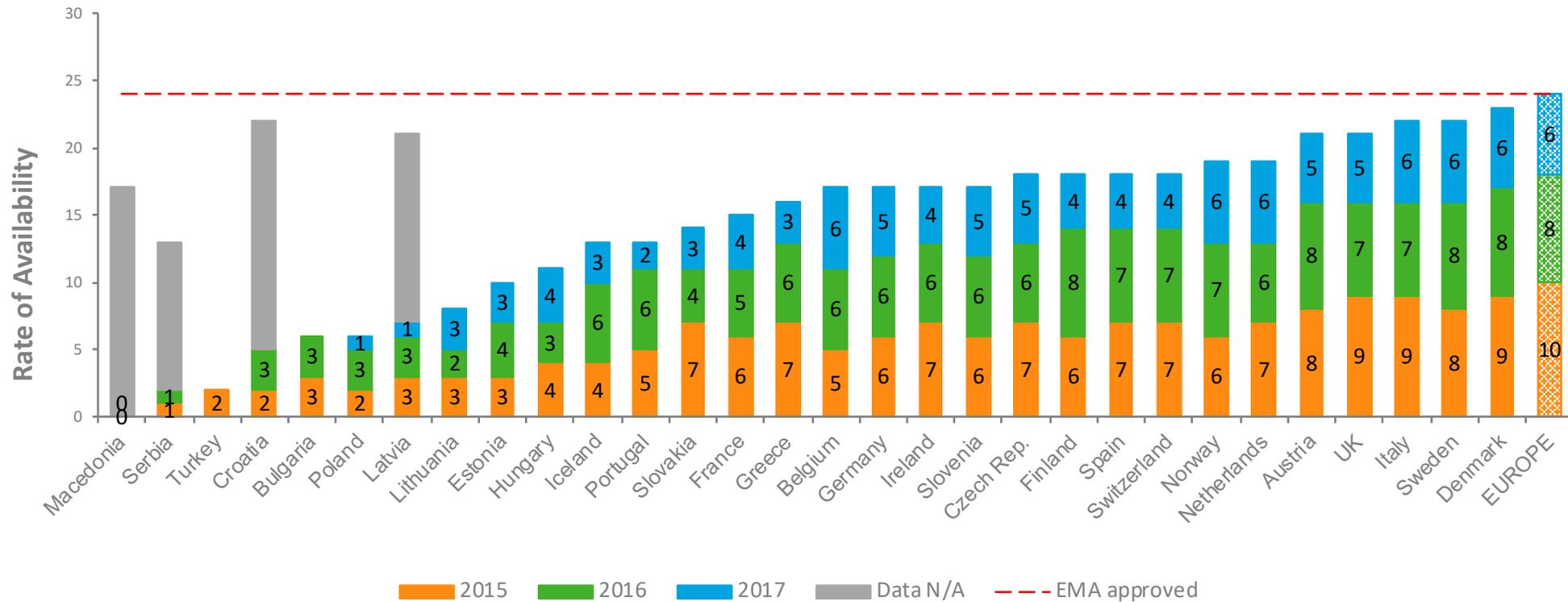
Key observations: Orphan and Oncology drugs

- Patient access to new Orphan and Oncology medicines is highly varied across Europe, with the greatest rate of availability in Northern and Western European countries.
- **Orphan drugs**
 - In over 80% of the countries, the rate of availability is **lower for Orphan drugs** compared to all products approved between 2015-2017
 - 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 4 months to 3 years
- **Oncology drugs**
 - In 73% of the countries, the rate of availability is **higher for Oncology products** compared to all products approved between 2015-2017
 - The average delay between market authorisation and patient access for Oncology products is between 2 months to over 2.5 years

Combination products

Rate of Availability

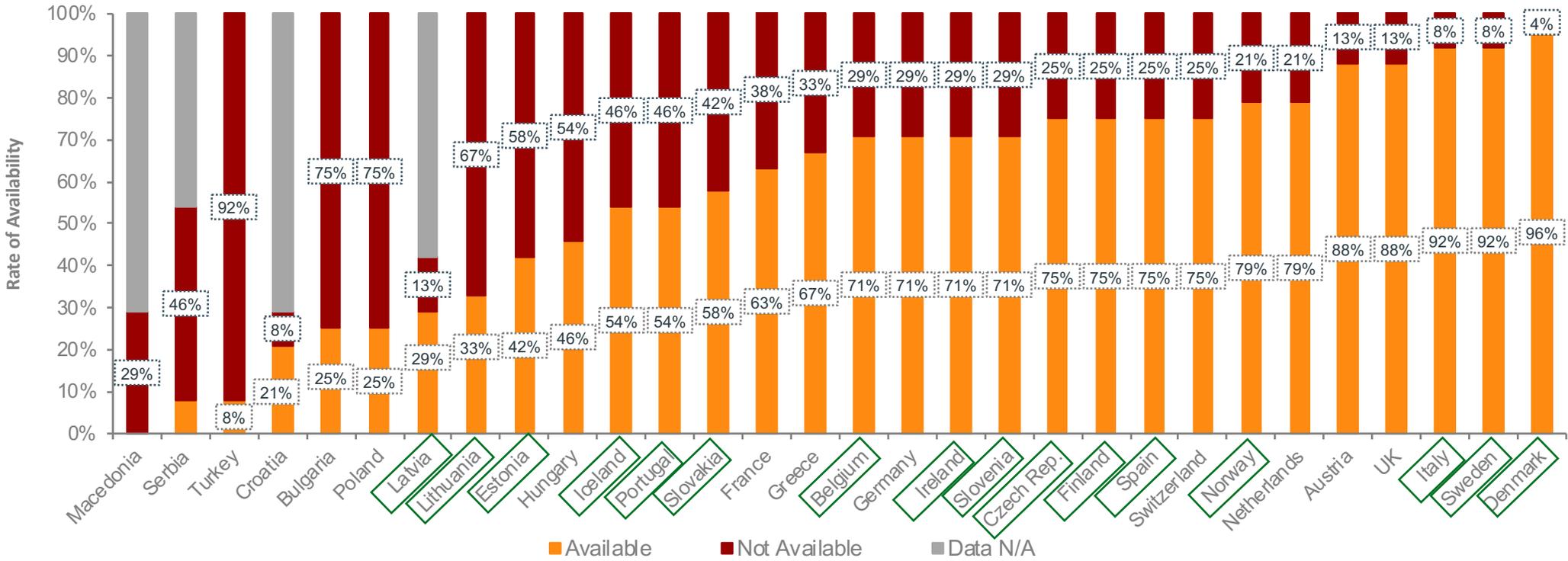
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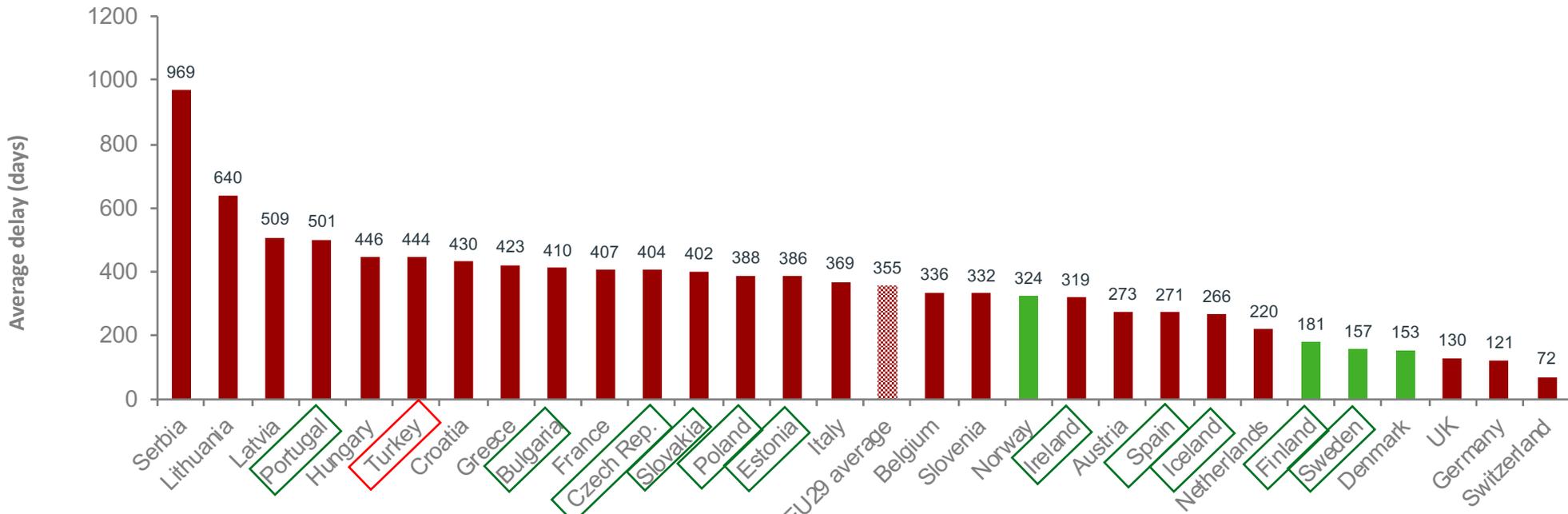


- Rate of availability for Combinations is at least 10% lower than all products approved 2015-2017
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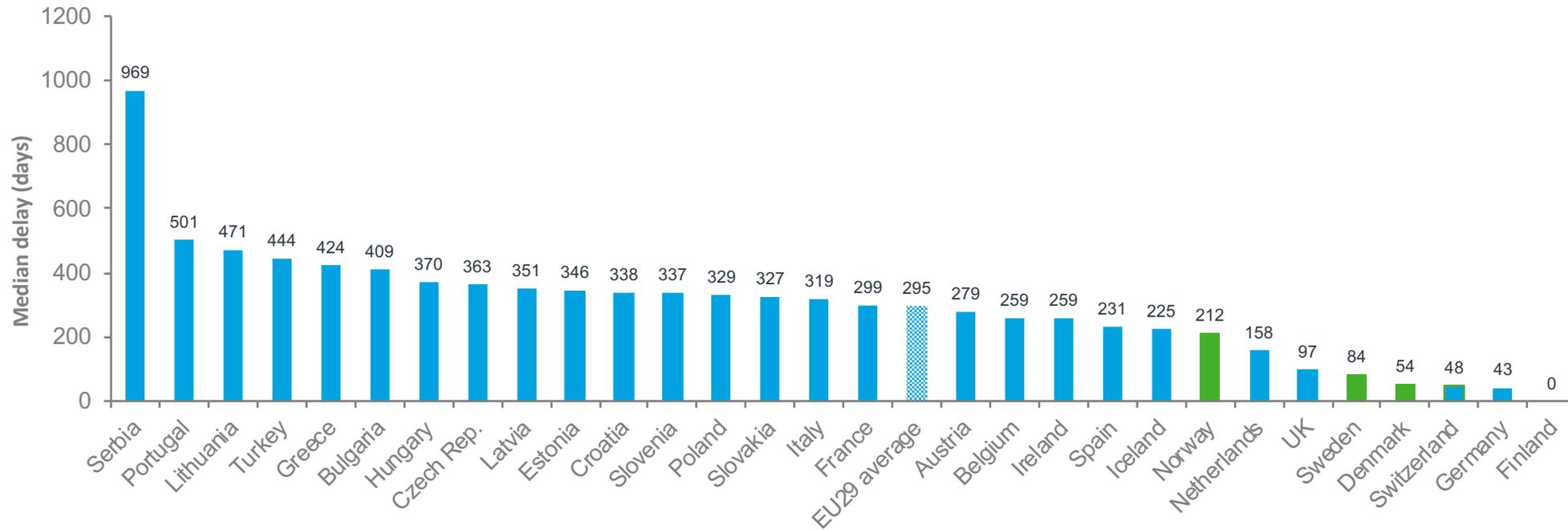
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In most countries patient access equates to granting of access to the reimbursement list, except for hospital products in DK, FI, NO, SE where some products are not covered by the general reimbursement scheme and so this shorter delay is artificially declining the median and average.

- 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 is higher than in reality.
- Average of 29 European countries in the analysis (excludes Macedonia)

Length of market access delays (median)

The **average time between marketing authorisation and patient access** - the number of days elapsing from the date of EU marketing authorisation (or effective marketing authorisation in non-EEA countries) to the day of completion of post-marketing authorisation administrative processes



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Key observations: Combination drugs

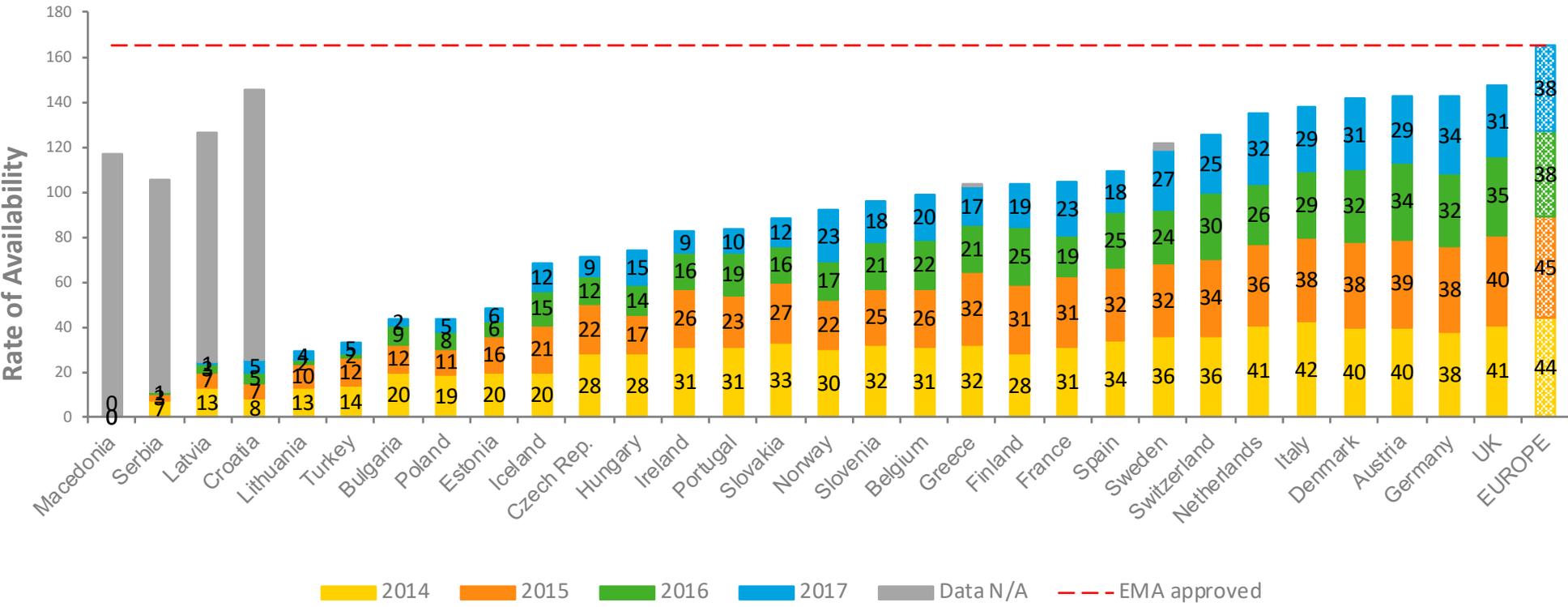
- Patient access to new combination medicines is highly varied across Europe
- Over 40% of these combinations are for HIV or Hep C. One product is an Oncology combination.
- In 87% of the countries, the rate of availability is **higher for combination products** compared to all products approved between 2015-2017
- Over 80% of the countries have a **shorter average delay** to EMA authorisation for combination drugs compared to all products approved 2015-2017
- The average delay between market authorisation and patient access for combination products is between 2.4 months to over 2.5 years

Appendix

- Products approved between **2014-2015-2016-2017** (165 products)
- Products approved between **2014-2015-2016** (127 products)

Rate of Availability

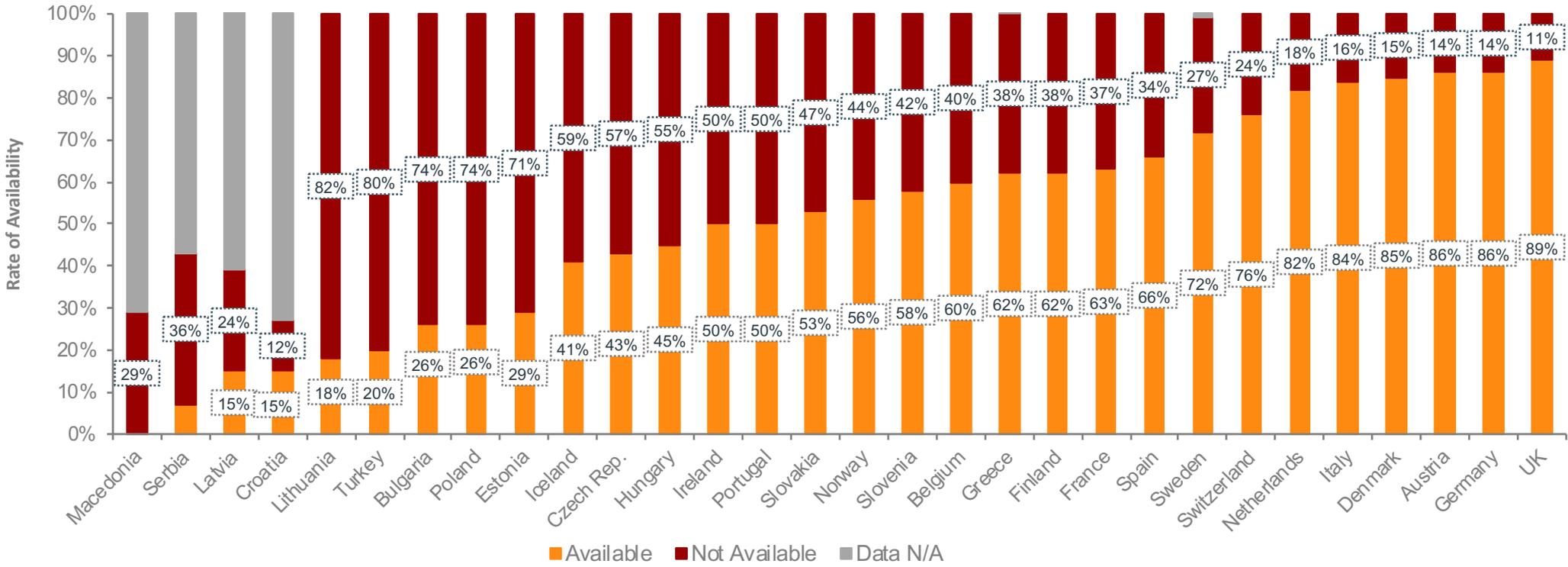
The **rate of availability**, measured by the number of medicines available to patients in European countries as of 2018: for most countries this is the point at which the product gains access to the reimbursement list.



Data N/A- data is not provided by associations (companies have not sent data or are not members of the association)

Rate of Availability (%)

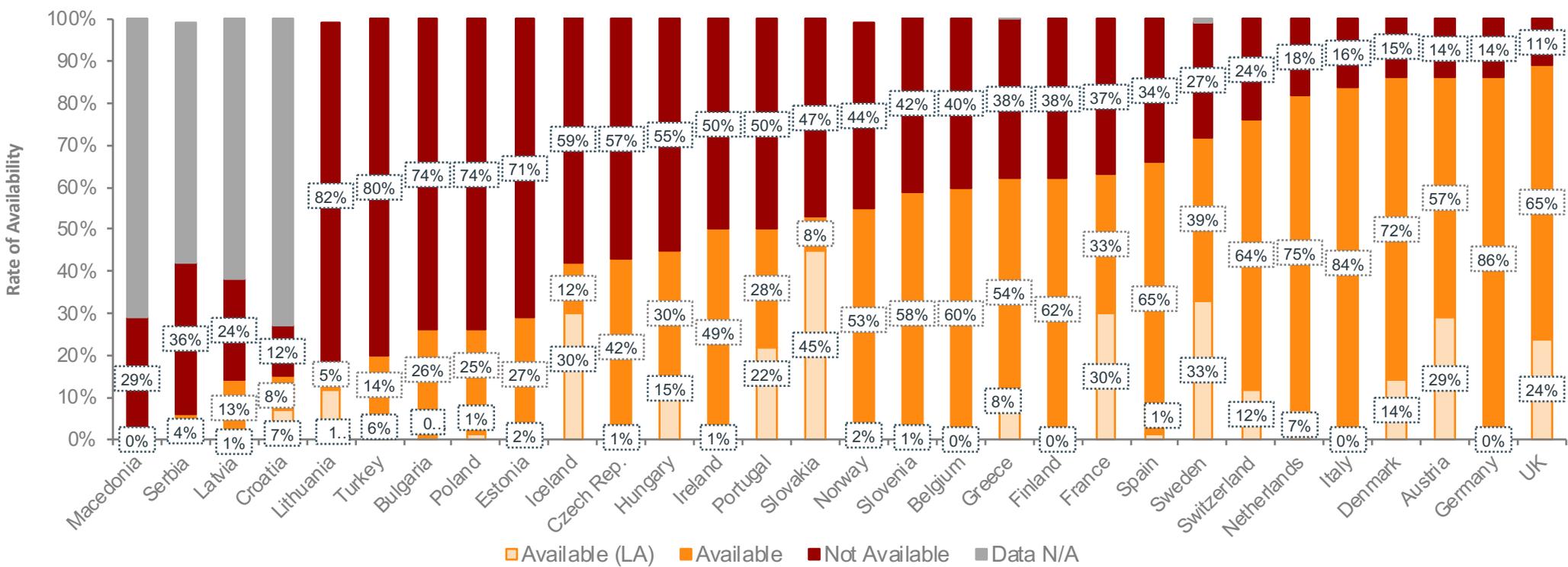
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Rate of Availability (%)

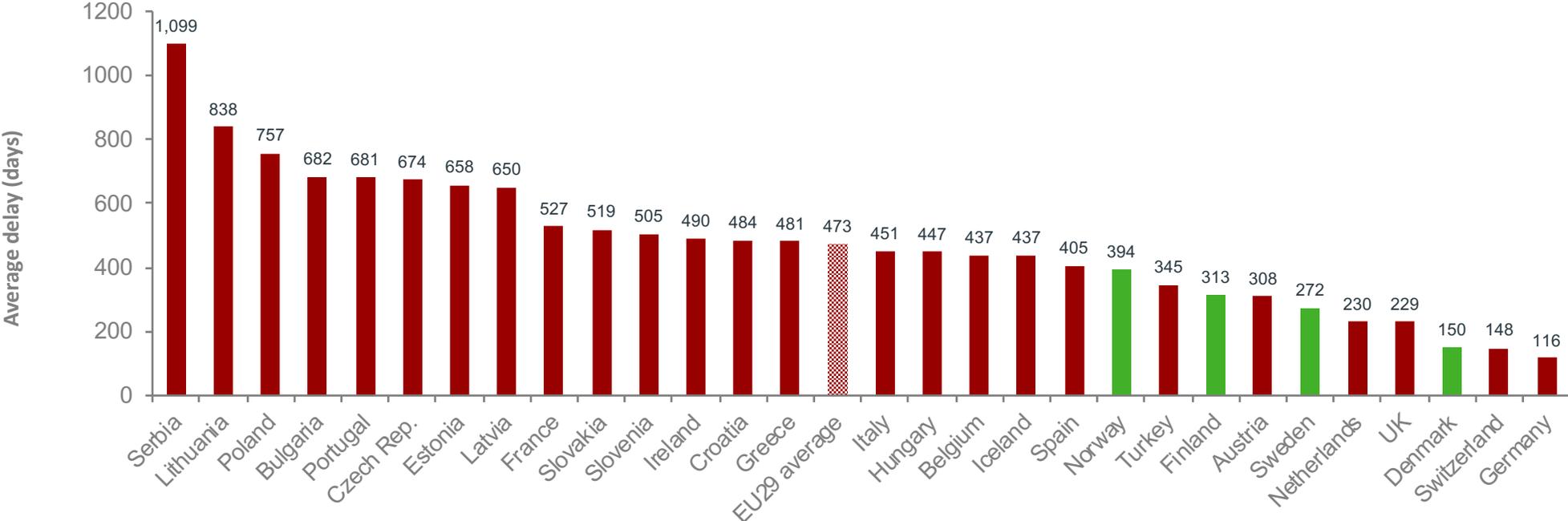
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Available (LA) - products which have been reimbursed or are pending reimbursement, with specific conditions

Length of market access delays (average)

The **average time between marketing authorisation and patient access** - the number of days elapsing from the date of EU marketing authorisation (or effective marketing authorisation in non-EEA countries) to the day of completion of post-marketing authorisation administrative processes

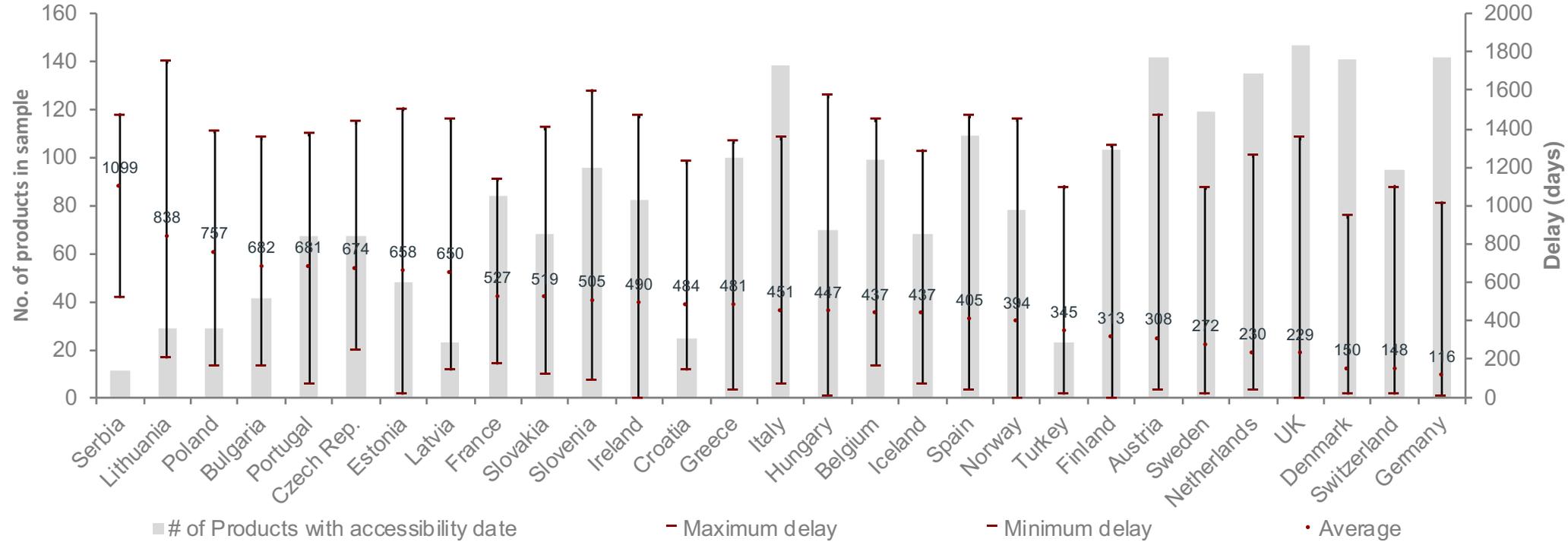


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Length of market access delays (average, maximum, minimum)

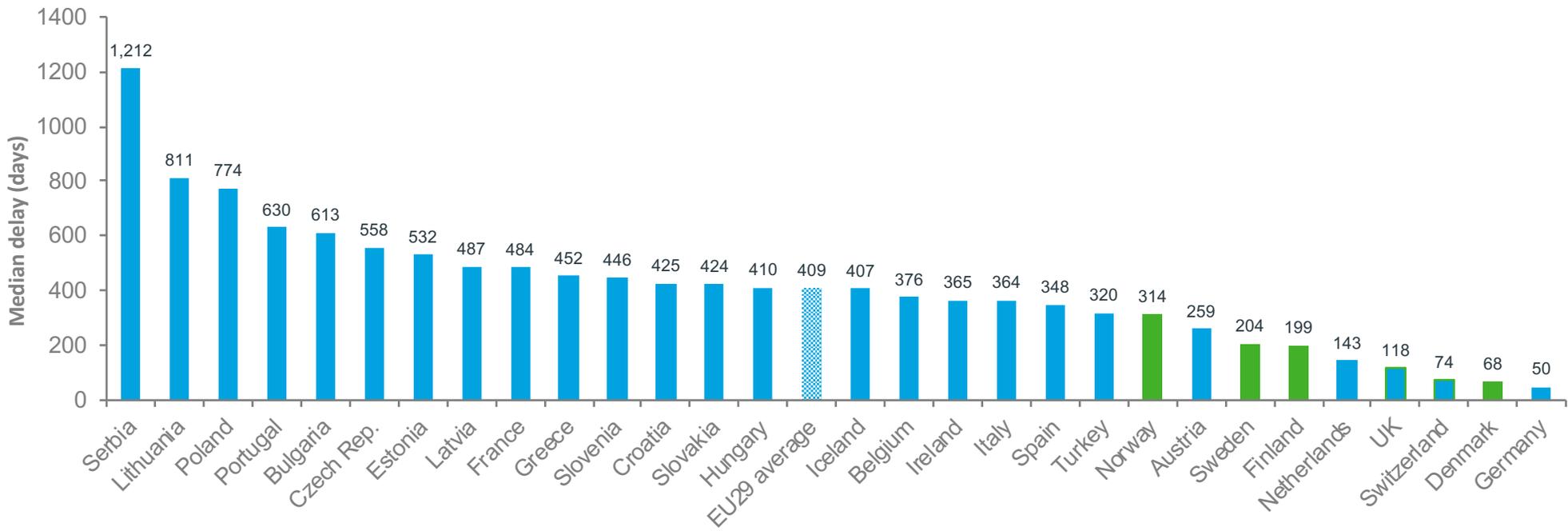
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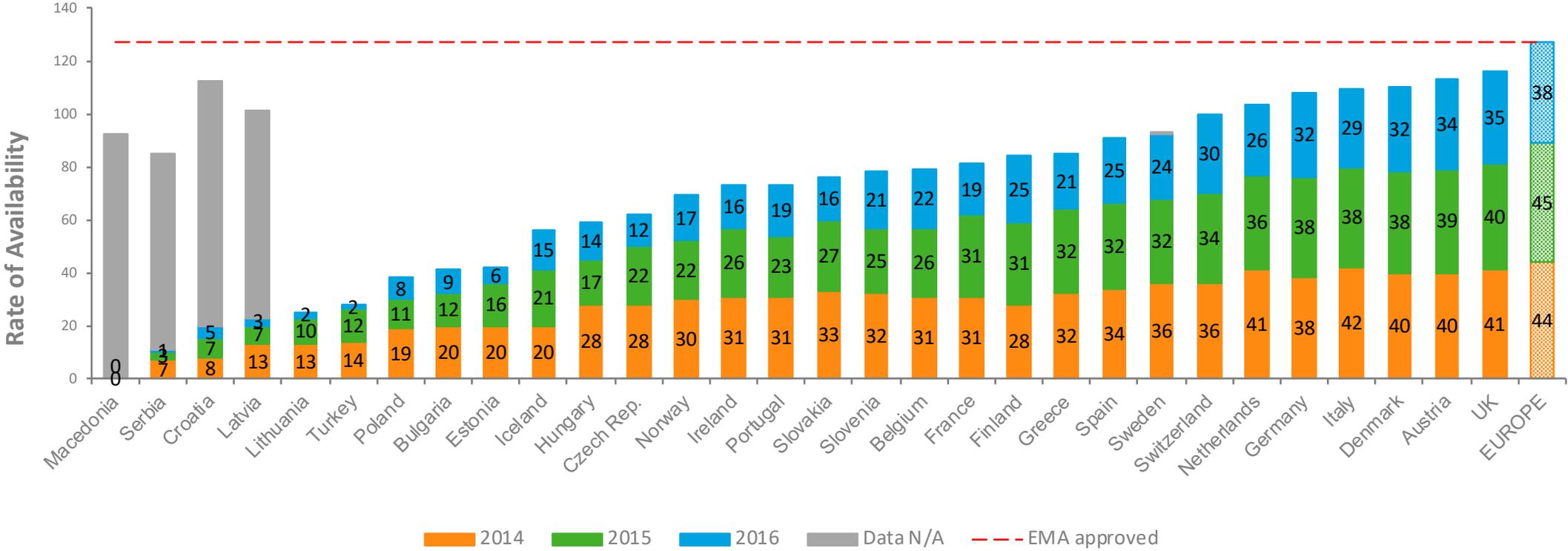
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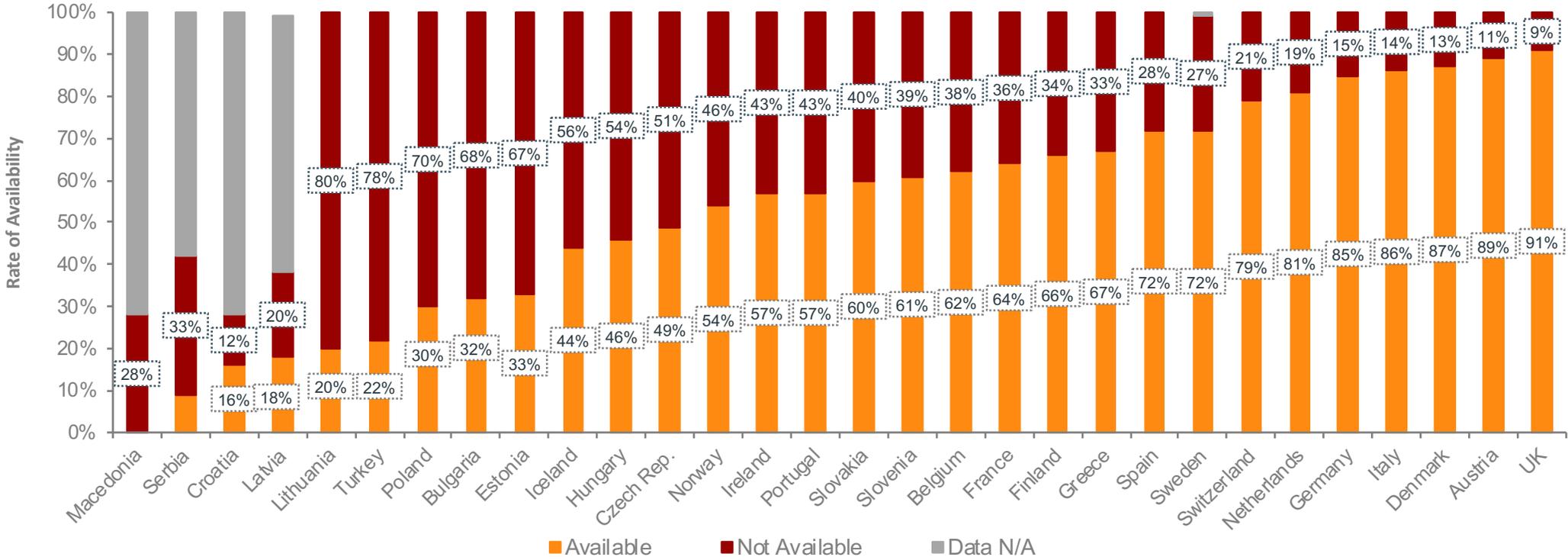
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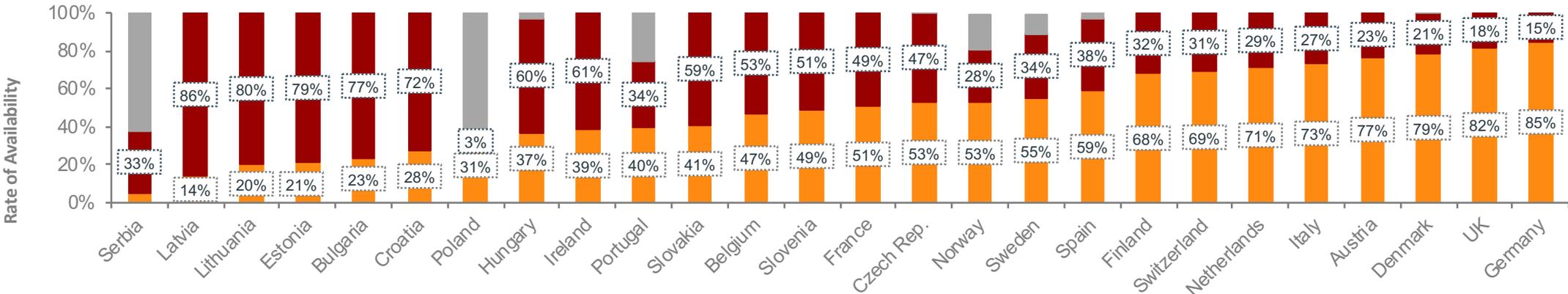


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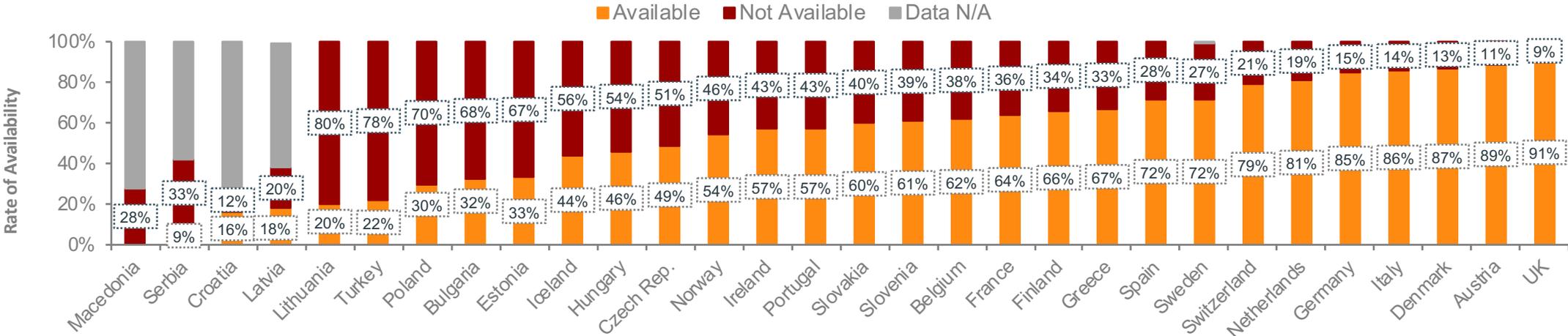
Rate of Availability (%)

The **rate of availability**, measured by the number of medicines available to patients in European countries as of 2018, compared to the rate of availability in the 2017 W.A.I.T. indicator study

2017 study
(2014-2016)



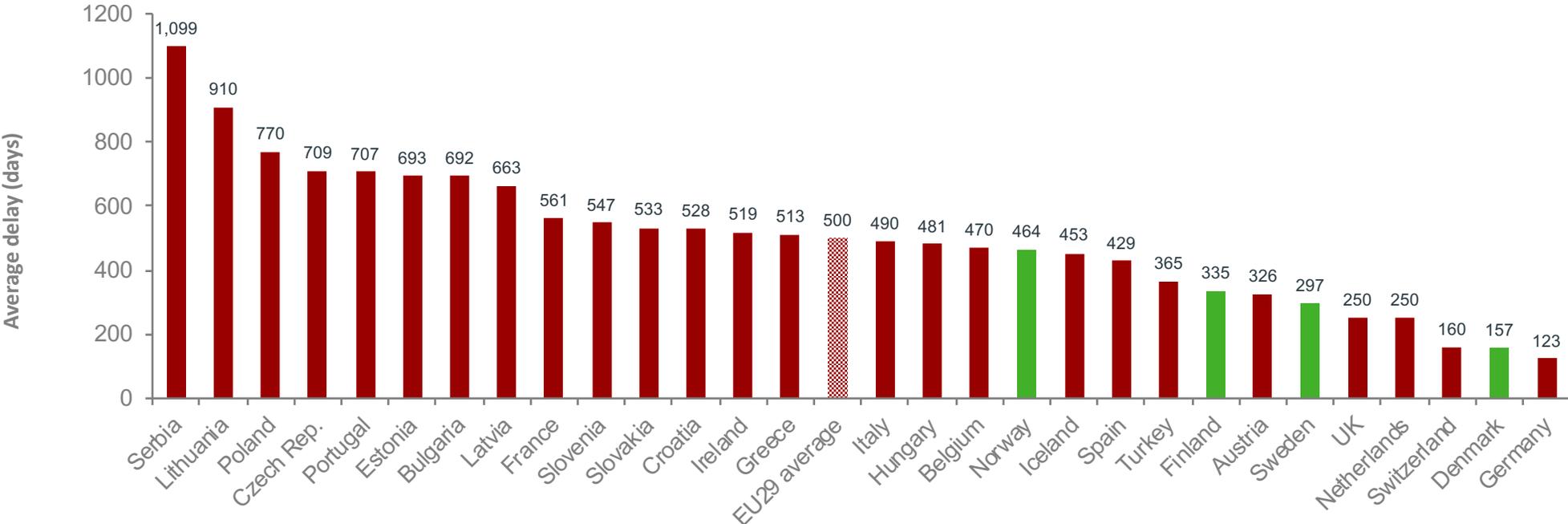
2018 study
(2014-2016)



Data N/A- data is not provided by associations (companies have not sent data or are not members of the association)
 Note: there are differences in country scope and methodology for product selection between the 2017 and 2018 studies (26 countries included in 2017 study; 30 countries in 2018 study); For the 2018 study, the date of availability cut-off point is December 2018

Length of market access delays (average)

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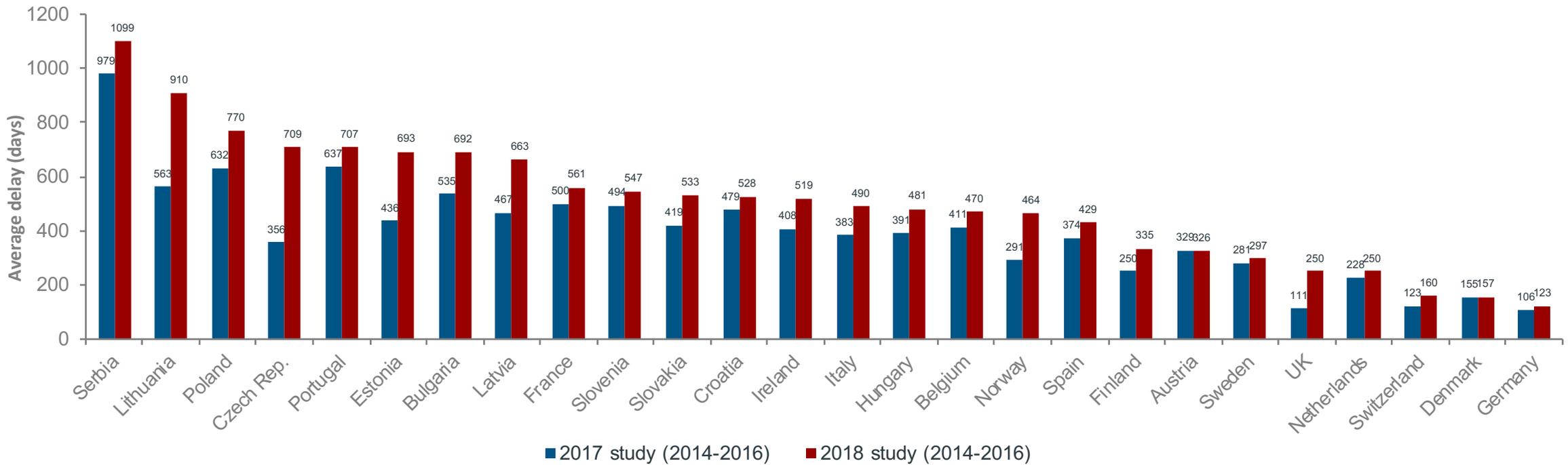


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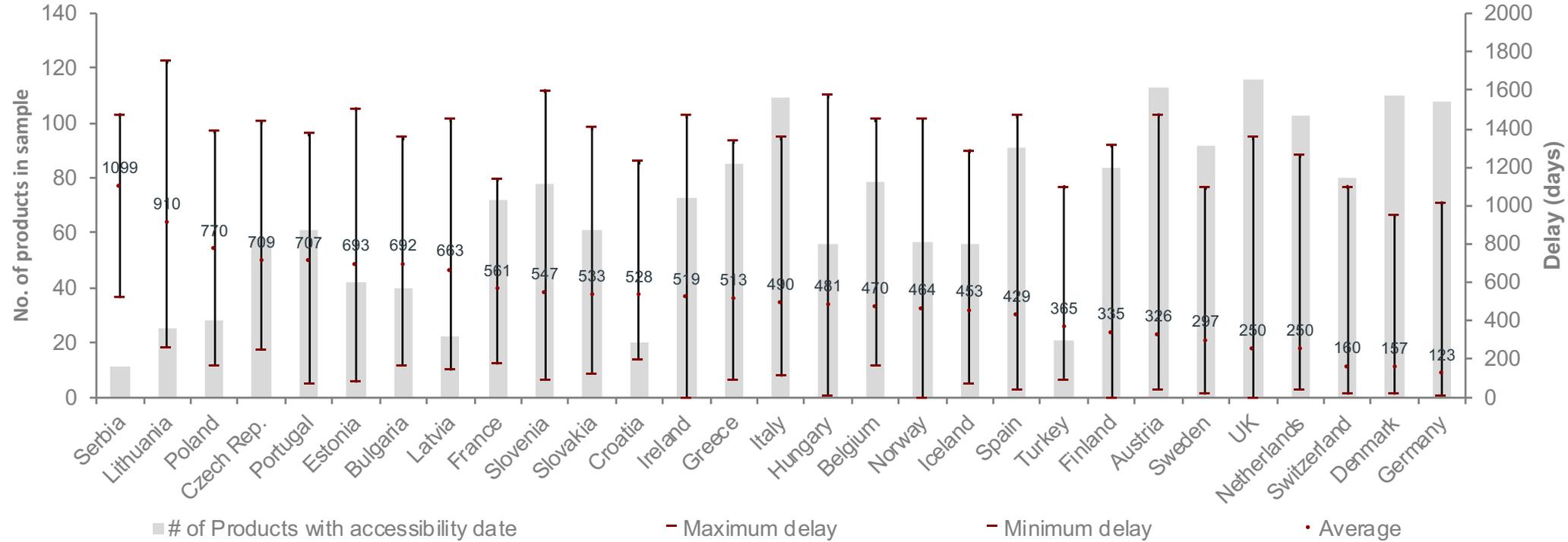
The **average time between marketing authorisation and patient access** - compared to the average delay in the 2017 W.A.I.T. indicator study



Note: there are differences in methodology for product selection between the 2017 and 2018 studies; chart only shows countries overlapping both studies
For the 2018 study, the date of availability cut-off point is December 2018

Length of market access delays (average, maximum, minimum)

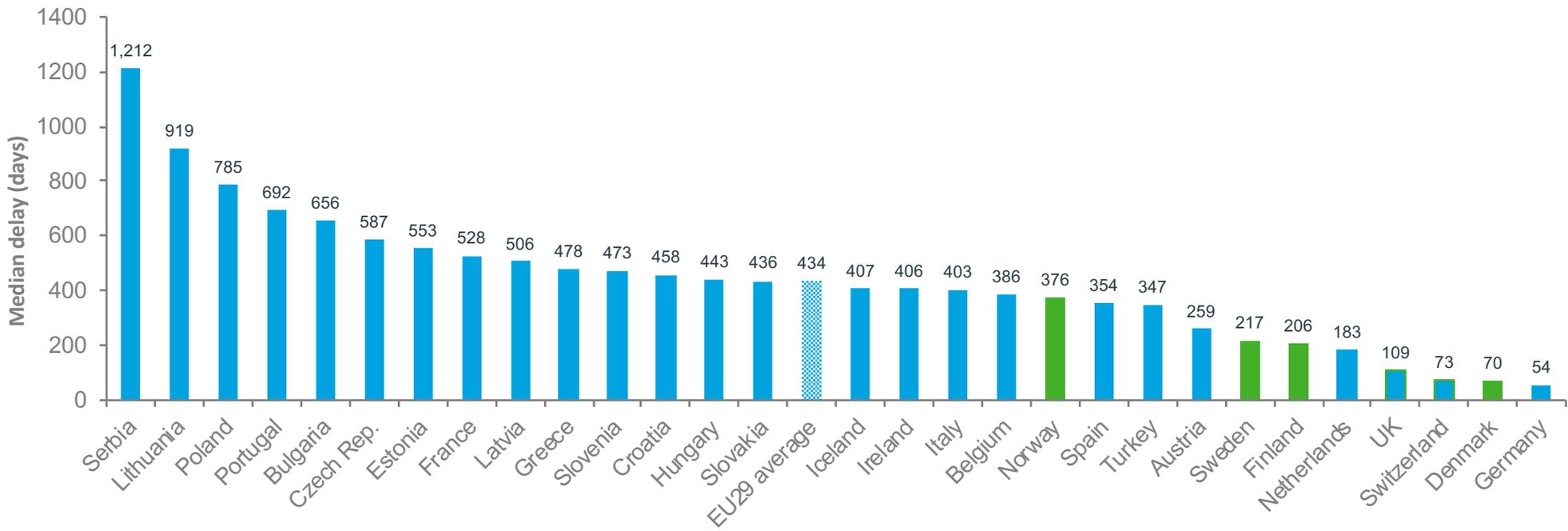
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