EUROPOS ŠALIŲ PALYGINAMOJO TYRIMO APIE INOVATYVIŲ VAISTŲ PRIEINAMUMĄ IR JO LAUKIMO LAIKĄ REZULTATŲ **PRISTATYMAS**

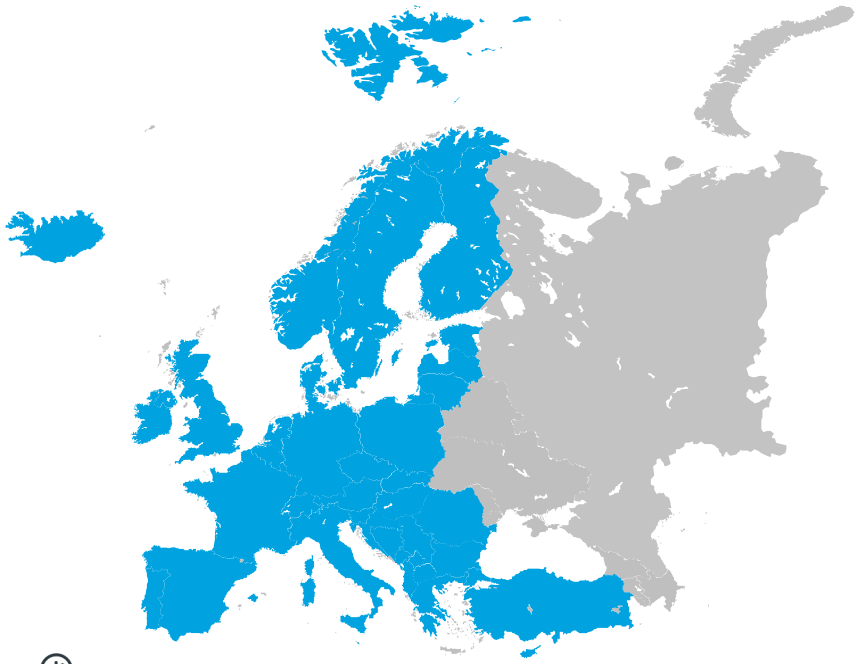
ipa
INOVATYVIOS FARMACIJOS PRAMONĖS ASOCIACIJA

Patients W.A.I.T. (Waiting to Access Innovative Therapies) 2022 indicator

INOVATYVIŲ VAISTŲ PRIEINAMUMO IR JO LAUKIMO LAIKO RODIKLIŲ TYRIMAS

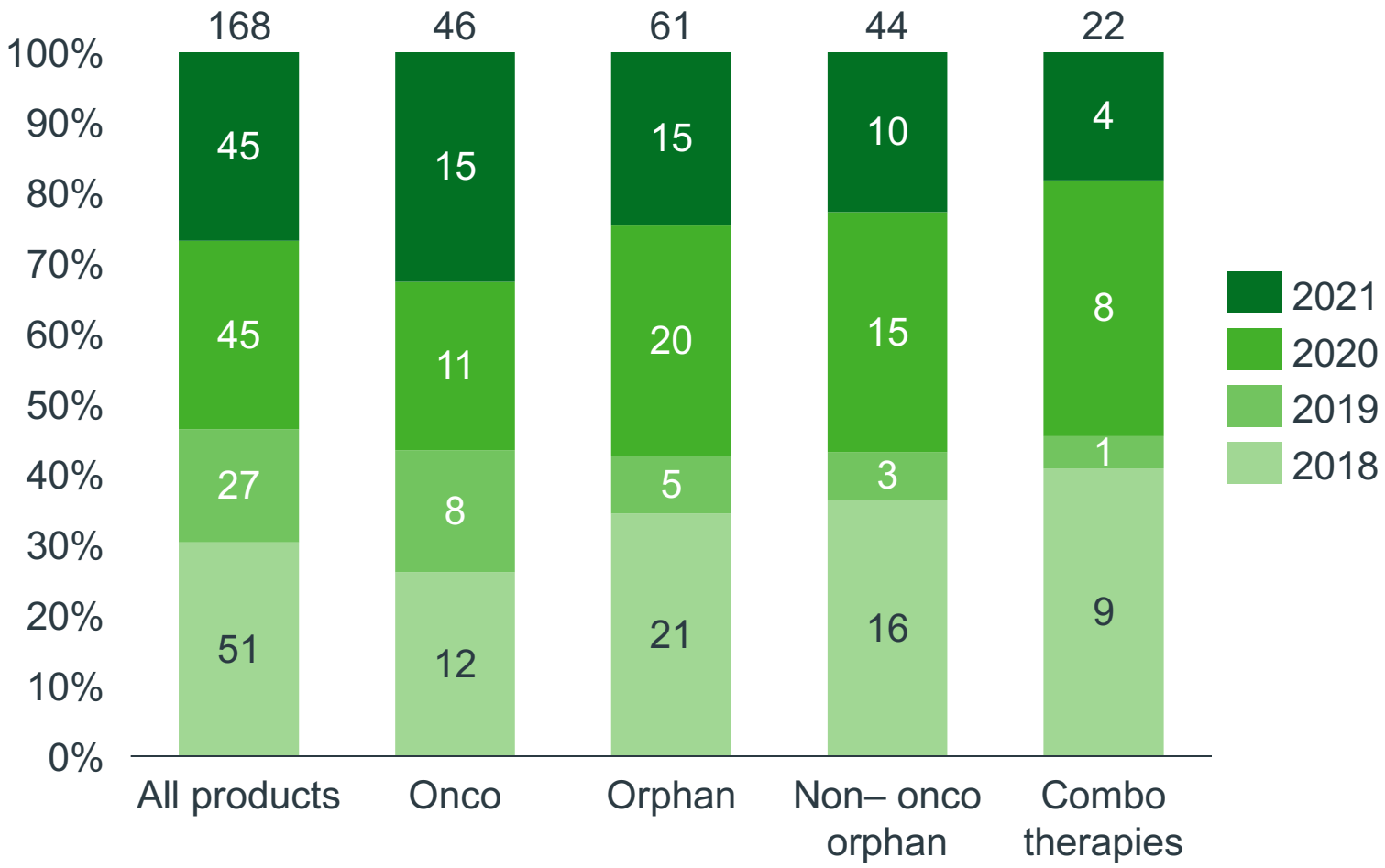
- *vyksta nuo 2004 metų, formatai kintantys*
- *atlieka **IQVIA** - tarptautine sveikatos rinkos duomenu tyrimo kompanija*
- *2022m. rodikliai paskelbti 2023m. balandžio 28d.*

Tai yra didžiausias Europoje inovatyvių vaistų prieinamumo ir laiko, per kurį pacientai gali gauti gydymą jais, tyrimas.



Study composition

Tyrimo apimtis



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

Note: figures are subject to change versus previous year's due to product withdrawals.

Tyrimo rodikliai: prieinamumo lygis ir prieinamumo laukimo laikas

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

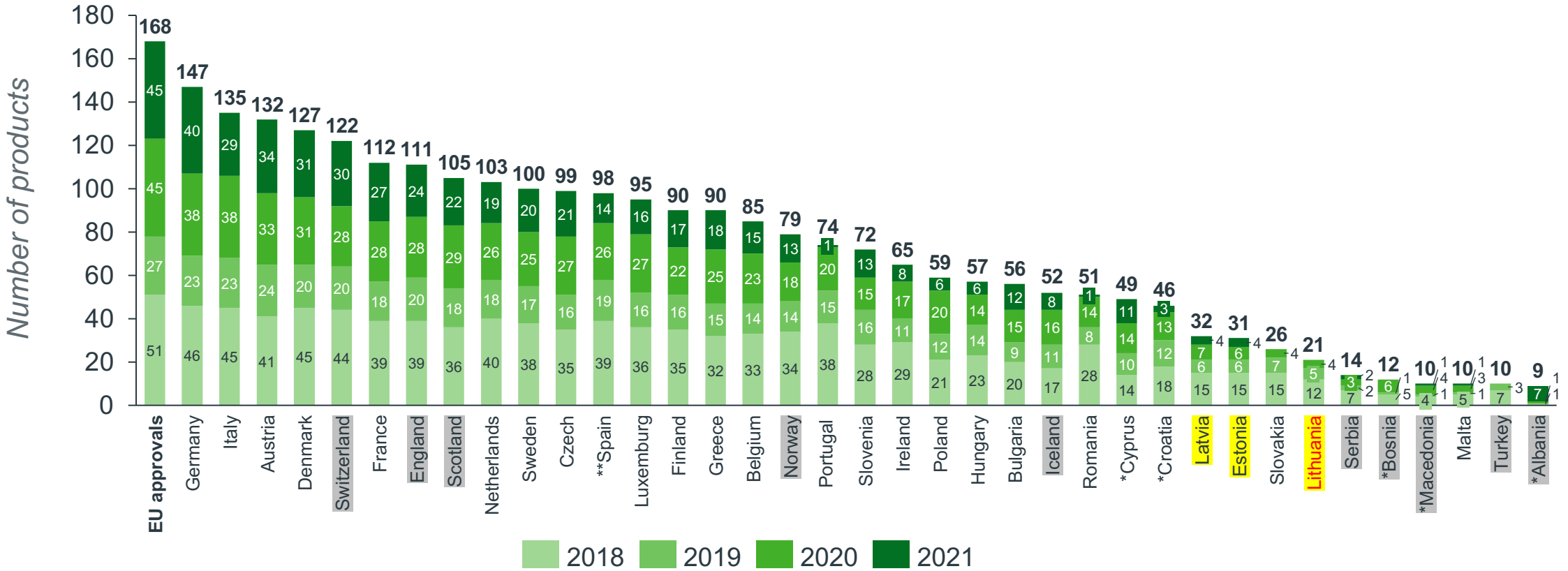
* **The Patients W.A.I.T. Indicator is not a measurement of the delays as defined in the "Transparency" Directive (directive 89/105/EEC)**. Delays under the "Transparency" Directive reflect the number of days that national competent authorities need to make their decisions regarding price and inclusion of medicines in the positive list, where applicable. These delays do not include the time needed to prepare submissions under relevant national regulations, which may also include clock-stops for supply of additional information during the process; neither do "Transparency" Directive delays include time required to complete other formalities before a new medicine can be made available in a given country. ^ LA = Limited Availability

1. Overview (all products)

Apžvalga: visi vaistai

Total availability by approval year (2018-2021)

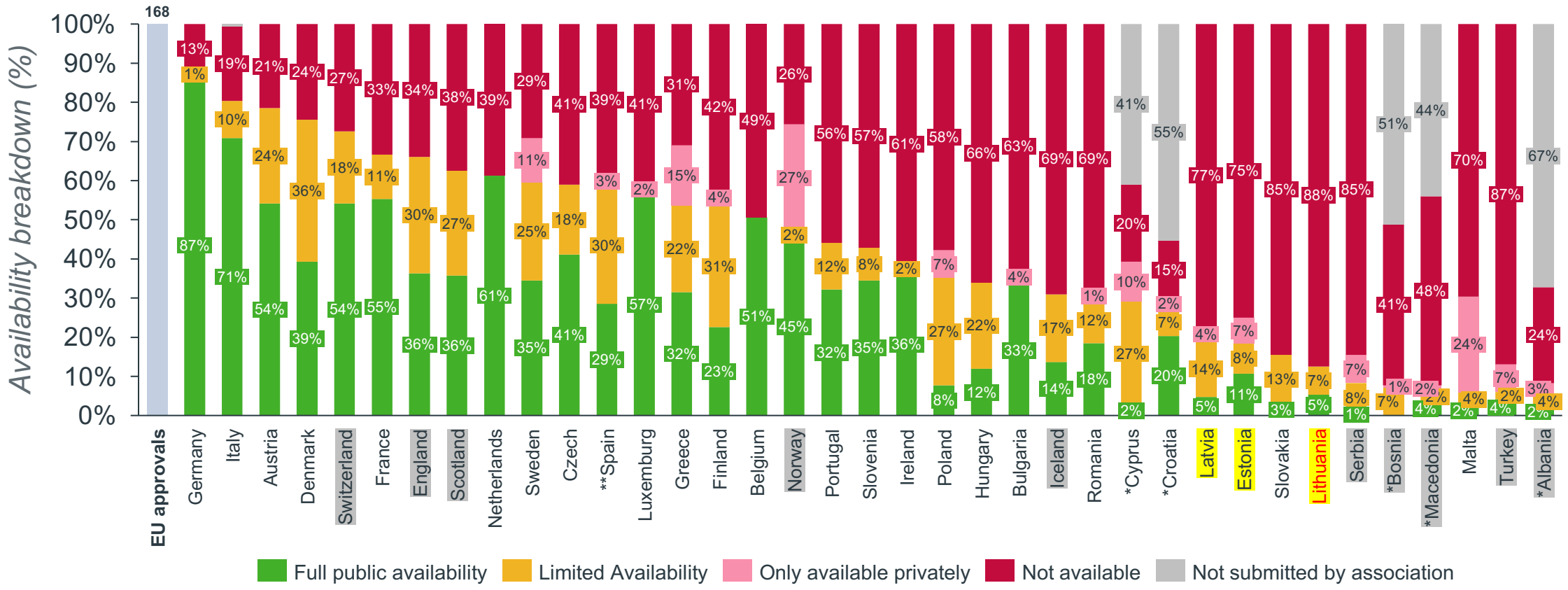
Bendras prieinamumas pagal registracijos metus



European Union average: 76 products available (45%) †In most countries availability equates to granting of access to the reimbursement list, except in DK, FI, LU, NO, SE where some hospital products are not covered by the general reimbursement scheme. Country-specific nuances are listed in the appendix. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. **In Spain, the WAIT analysis does not identify those medicinal products being accessible earlier in conformity with Spain's Royal Decree 1015/2009 relating to Medicines in Special Situations

Breakdown of availability (%, 2018-2021)

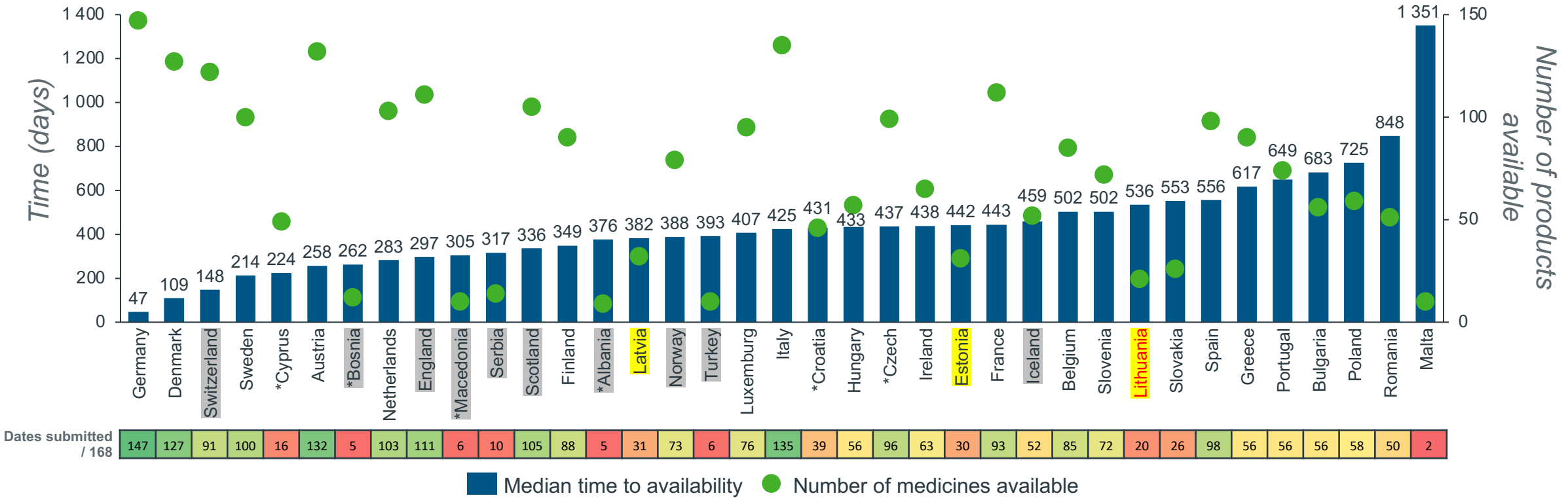
Prieinamumo suskirstymas (% nuo visų registruotų)



European Union average: 76 products available (45%), Limited availability (14% of all products). Netherlands did not submit complete information on restrictions to available medicines meaning LA* is not captured in these countries. †In most countries availability equates to granting of access to the reimbursement list, except in DK, FI, LU, NO, SE where some hospital products are not covered by the general reimbursement scheme. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. **In Spain, the WAIT analysis does not identify those medicinal products being accessible earlier in conformity with Spain's Royal Decree 1015/2009 relating to Medicines in Special Situations

Median time to availability (2018-2021)

Vidutinis prieinamumo laukimo laikas



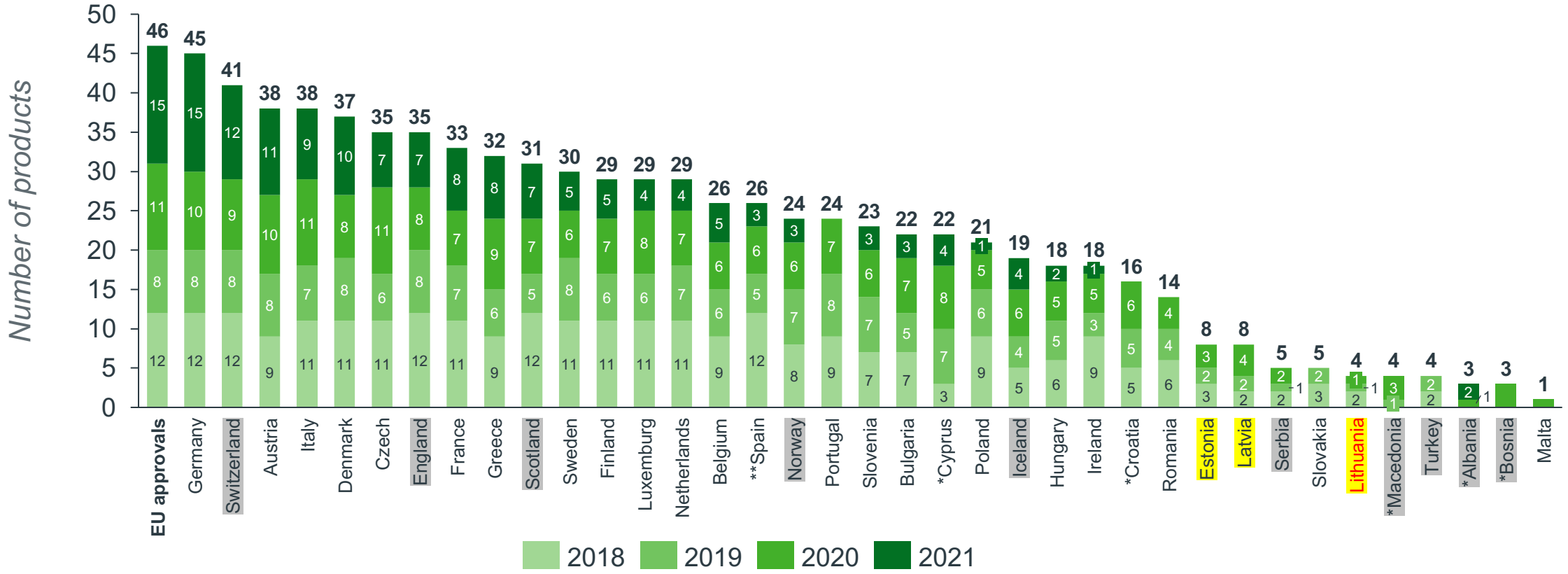
European Union average: 442 days (median) (Note: Malta is not included in EU27 average as only 2 dates were submitted in total) †In most countries availability equates to granting of access to the reimbursement list, except in DK, FI, NO, SE where some hospital products are not covered by the general reimbursement scheme. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative **For France, the median time to availability (443 days, n=93 dates submitted) does not include products under the ATU system for which the price negotiation process is usually longer. ***In the UK, MHRA's Early Access to Medicines Scheme provides access prior to marketing authorisation but is not included within this analysis, and would reduce the overall days for a small subset of medicines.

2. Oncology medicines

Onkologiniai vaistai

Oncology availability by approval year (2018-2021)

Bendras prieinamumas pagal registracijos metus



European Union average: 23 products available (50%) †In most countries availability equates to granting of access to the reimbursement list, except in DK, FI, LU, NO, SE where some hospital products are not covered by the general reimbursement scheme. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. **In Spain, the WAIT analysis does not identify those medicinal products being accessible earlier in conformity with Spain's Royal Decree 1015/2009 relating to Medicines in Special Situations

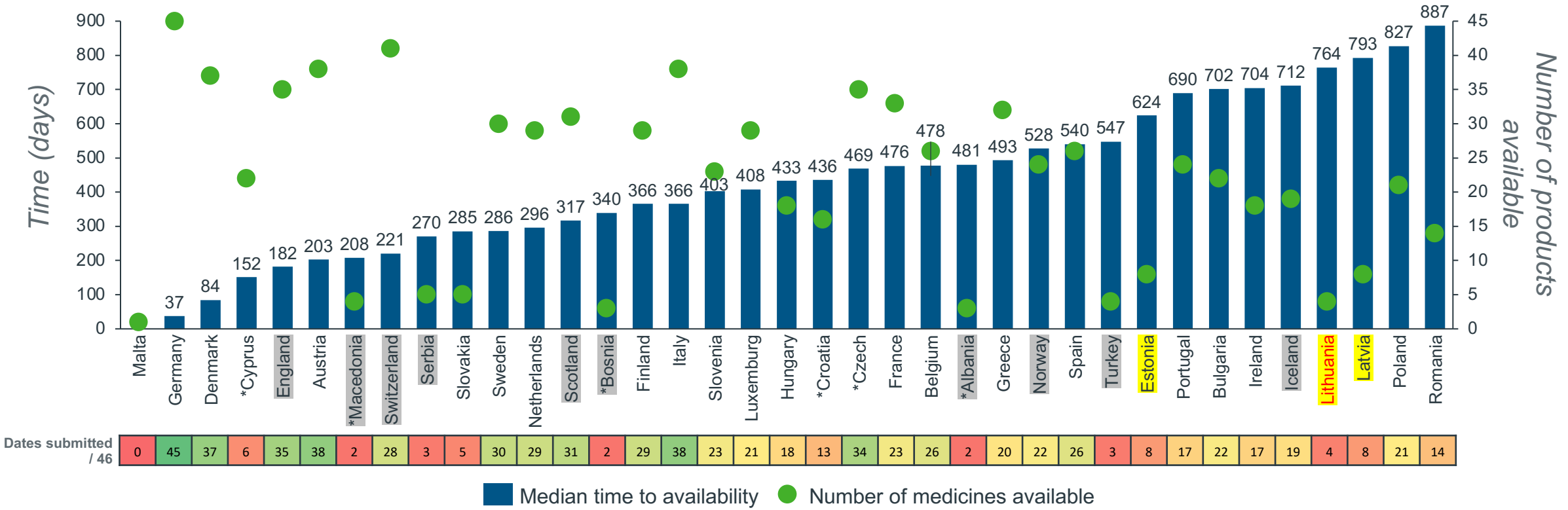
Oncology breakdown of availability (%, 2018-2021)

Prieinamumo suskirstymas (% nuo visų registruotų)

European Union average: 23 products available (50%), Limited availability (16% of all oncology products). Netherlands did not submit complete information on restrictions to available medicines meaning LA* is not captured in these countries. †In most countries availability equates to granting of access to the reimbursement list, except in DK, FI, LU, NO, SE where some hospital products are not covered by the general reimbursement scheme. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. **In Spain, the WAIT analysis does not identify those medicinal products being accessible earlier in conformity with Spain's Royal Decree 1015/2009 relating to Medicines in Special Situations

Oncology median time to availability (2018-2021)

Vidutinis prieinamumo laukimo laikas



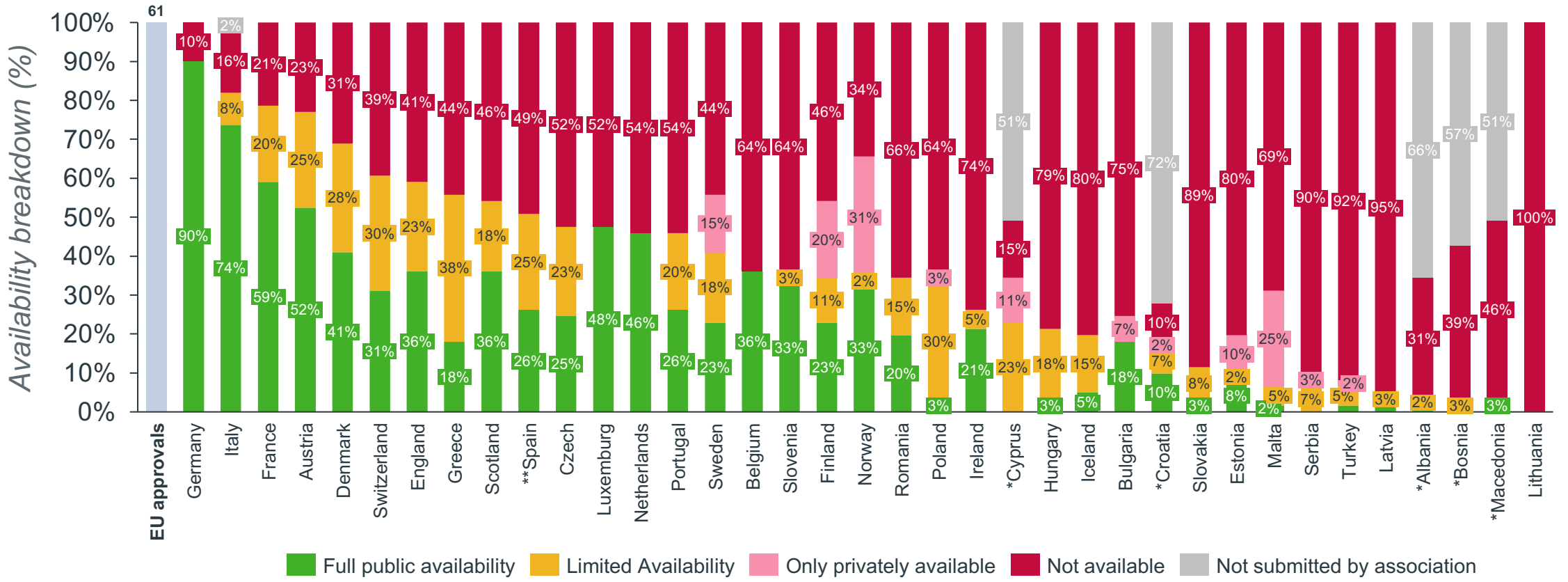
European Union average: 469 days (median) †In most countries availability equates to granting of access to the reimbursement list, except in DK, FI, NO, SE where some hospital products are not covered by the general reimbursement scheme. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative **For France, the median time to availability (476 days, n=23 dates submitted) does not include products under the ATU system for which the price negotiation process is usually longer. ***In the UK, MHRA's Early Access to Medicines Scheme provides access prior to marketing authorisation but is not included within this analysis, and would reduce the overall days for a small subset of medicines.

3. Orphan medicines
4. Non-oncology orphan medicines

Retieji vaistai ir
retieji neonkologiniai vaistai

Orphan rate of availability (%, 2018-2021)

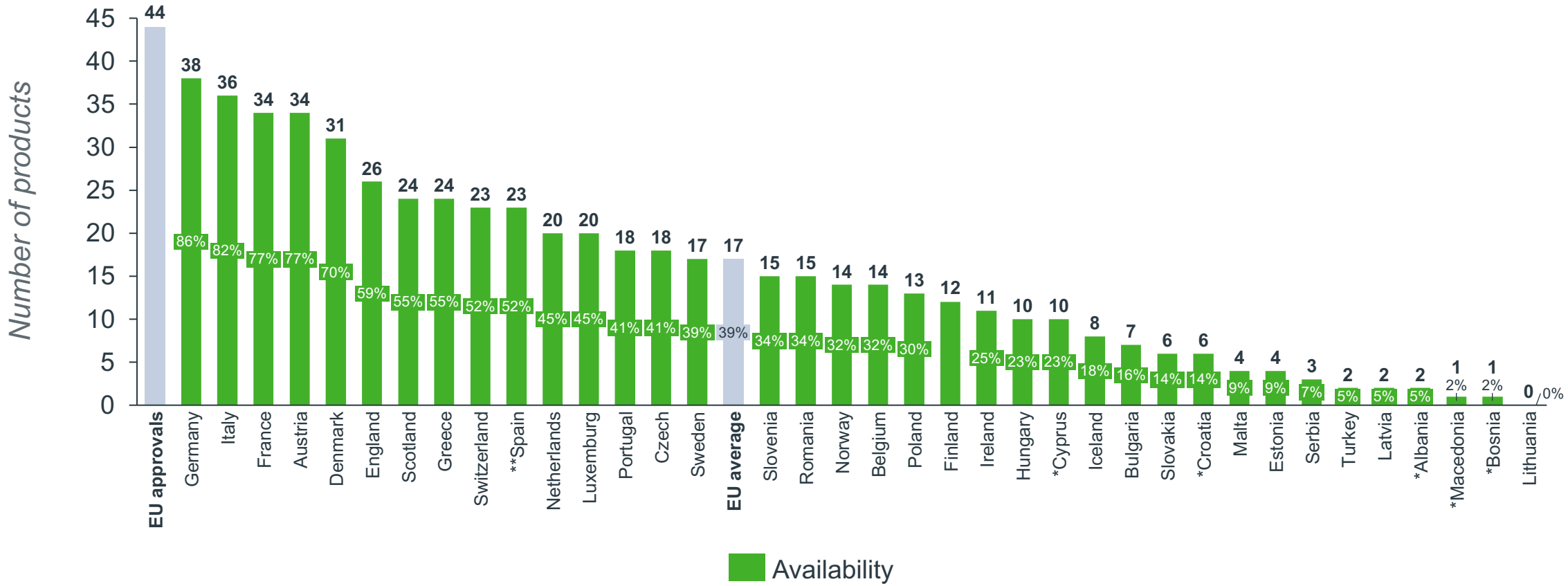
Prieinamumo suskirstymas (% nuo visų registruotų)



European Union average: 24 products available (39%), Limited availability (12% of all orphan products). Netherlands did not submit complete information on restrictions to available medicines meaning LA* is not captured in these countries. †In most countries availability equates to granting of access to the reimbursement list, except in DK, FI, LU, NO, SE where some hospital products are not covered by the general reimbursement scheme. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. **In Spain, the WAIT analysis does not identify those medicinal products being accessible earlier in conformity with Spain's Royal Decree 1015/2009 relating to Medicines in Special Situations

Non-oncology orphan rate of availability (2018-2021)

Bendras prieinamumas pagal registracijos metus



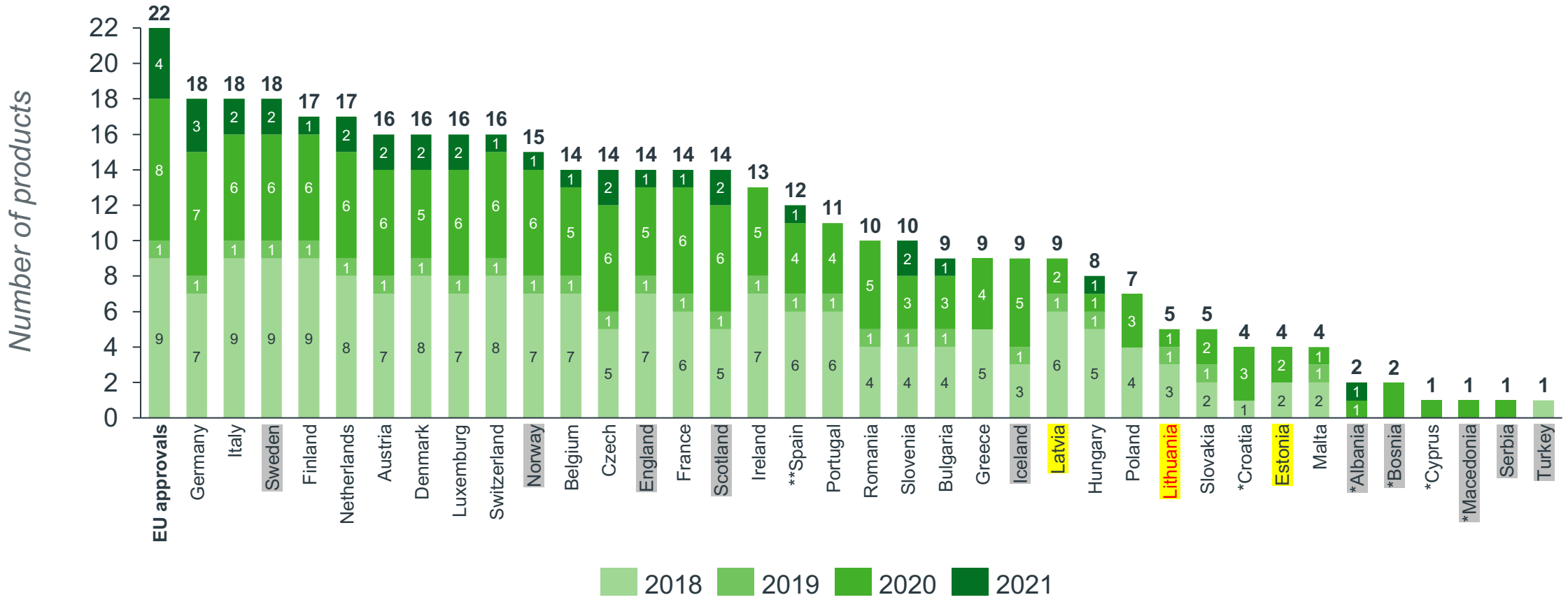
European Union average: 17 products available (39%) †In most countries availability equates to granting of access to the reimbursement list, except in DK, FI, LU, NO, SE where some hospital products are not covered by the general reimbursement scheme. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. **In Spain, the WAIT analysis does not identify those medicinal products being accessible earlier in conformity with Spain's Royal Decree 1015/2009 relating to Medicines in Special Situations

5. Combination therapies

Sudėtiniai vaistai

Combination therapies availability by approval year (2018-2021)

Bendras prieinamumas pagal registracijos metus



European Union average: 11 products available (50%) Combination products can include innovative branded / generic combinations. †In most countries availability equates to granting of access to the reimbursement list, except in DK, FI, LU, NO, SE where some hospital products are not covered by the general reimbursement scheme. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. **In Spain, the WAIT analysis does not identify those medicinal products being accessible earlier in conformity with Spain's Royal Decree 1015/2009 relating to Medicines in Special Situations

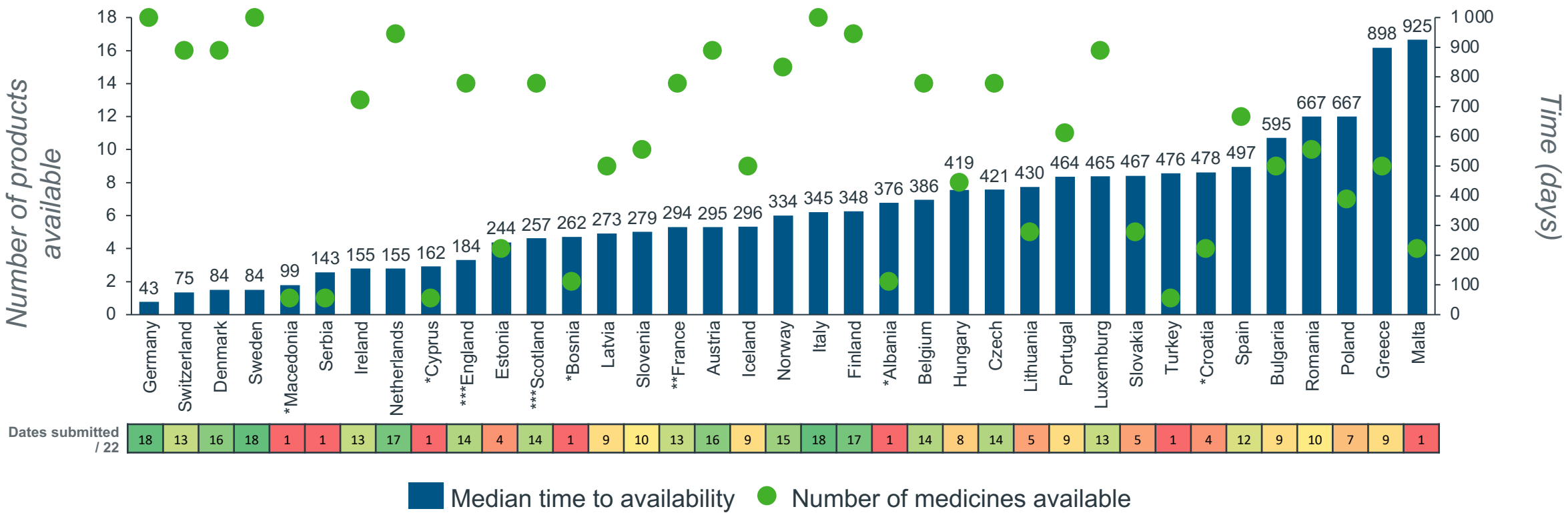
Combination therapies breakdown of availability (%, 2018-2021)

Prieinamumo suskirstymas (% nuo visų registruotų)

European Union average: 11 products available (50%) , Limited availability (9% of all products). Combination products can include innovative branded / generic combinations; Netherlands did not submit complete information on restrictions to available medicines meaning LA* is not captured in these countries.†In most countries availability equates to granting of access to the reimbursement list, except in DK, FI, LU, NO, SE where some hospital products are not covered by the general reimbursement scheme. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. **In Spain, the WAIT analysis does not identify those medicinal products being accessible earlier in conformity with Spain's Royal Decree 1015/2009 relating to Medicines in Special Situations

Combination median time to availability (2018-2021)

Vidutinis prieinamumo laukimo laikas



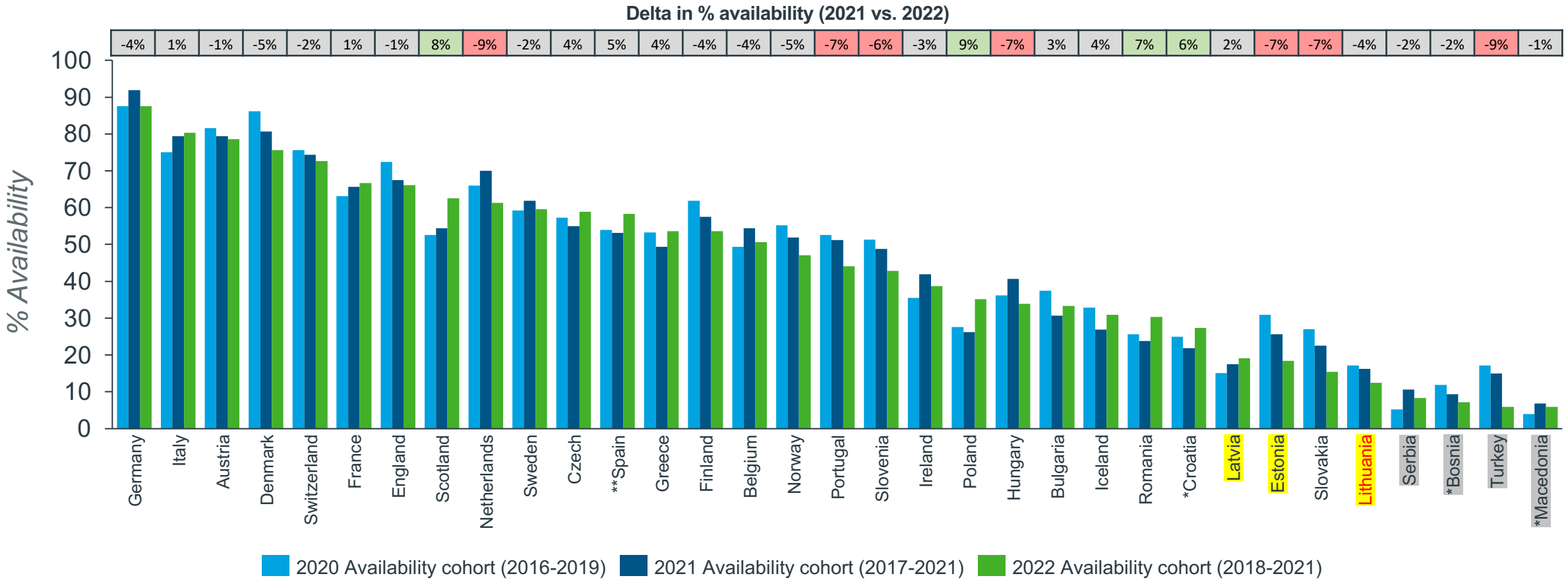
European Union average: 370 days (median) †In most countries availability equates to granting of access to the reimbursement list, except in DK, FI, NO, SE where some hospital products are not covered by the general reimbursement scheme. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative **For France, the median time to availability (294 days, n=13 dates submitted) does not include products under the ATU system for which the price negotiation process is usually longer. ***In the UK, MHRA's Early Access to Medicines Scheme provides access prior to marketing authorisation but is not included within this analysis, and would reduce the overall days for a small subset of medicines.

6. Historic comparisons and extension

Istorinių rodiklių palyginimas ir išplėtimas

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

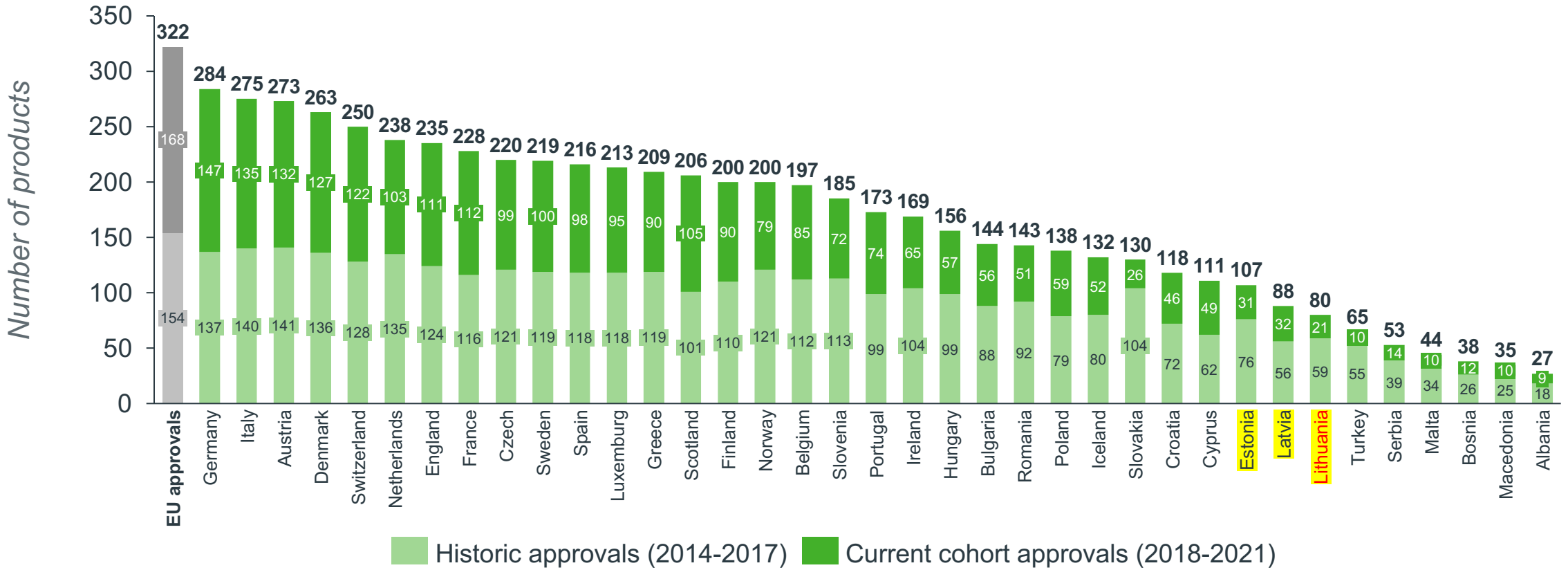
Prieinamumo palyginimas (2020-2021-2022 tyrimai)



Increases of <=5% are not considered to be statistically significant and are therefore highlighted in grey. Note: Netherlands has retrospectively corrected 2020 data; †In most countries availability equates to granting of access to the reimbursement list, except in DK, FI, LU, NO, SE some hospital products are not covered by the general reimbursement scheme. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. **In Spain, the WAIT analysis does not identify those medicinal products being accessible earlier in conformity with Spain's Royal Decree 1015/2009 relating to Medicines in Special Situations

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

Išplėsto laikotarpio bendras prieinamumas (2014-2021 metai)



European Union average: 179 products available (56%) †In most countries availability equates to granting of access to the reimbursement list, except in DK, FI, LU, NO, SE some hospital products are not covered by the general reimbursement scheme.
*Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative.
Note: National Associations perform checks on historic products on a best efforts basis, although it has been noted that status changes do not often occur.

Ką rodo inovatyvių vaistų prieinamumo ir laukimo laiko duomenys?

Comparing availability across European countries[1]

Sources: [1] Patient W.A.I.T. Indicator 2022 Survey