European Access Hurdles Portal: **Summary of the third external report**

May 2025

efpia

CRA Charles River Associates

The industry created the European Access Hurdles Portal to add new information to the debate on availability of innovative medicines

Created in April 2022, the role of the Portal is to **improve transparency regarding the root causes of unavailability and delay**, including the role of the environment and its corresponding impact on commercial decision-making

2010 – First report on the Patients W.A.I.T. (Waiting to Access Innovative Therapies) Indicator

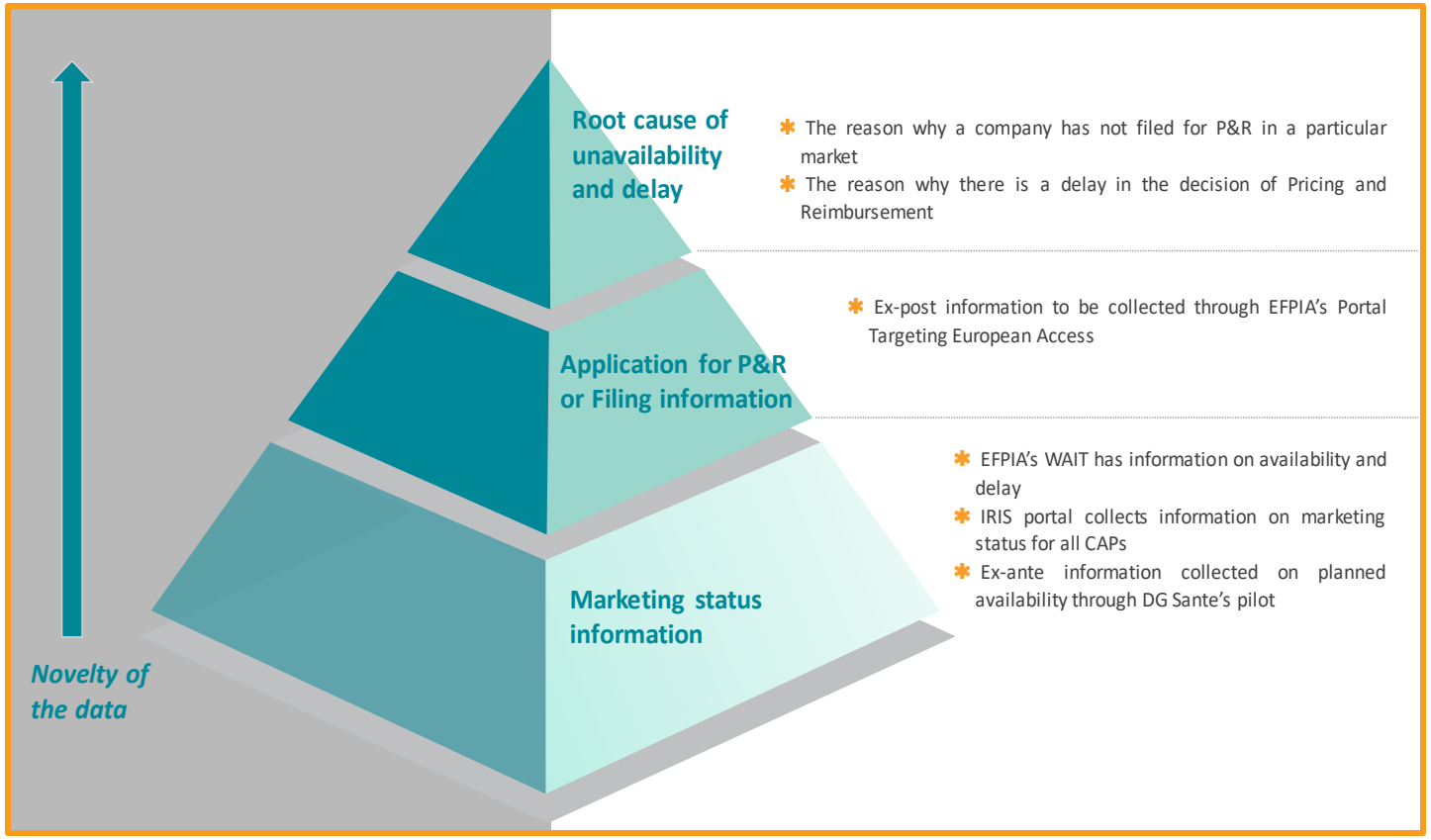
2020 onwards – Annual reporting on Patients W.A.I.T. Indicators and root causes of unavailability

April 2022 – Industry commitment to the creation of the European Access Hurdles Portal

April 2023 – Release of the first public report from the Portal

June 2024 – Release of the second public report from the Portal

May 2025 – Release of the third public report from the Portal



Results indicate a complete willingness from industry to provide more transparency on the root causes of unavailability

Industry participation

94

Data on **94 products** were submitted to the Portal.

All received European marketing authorisation between January 2021 and June 2024.

100%

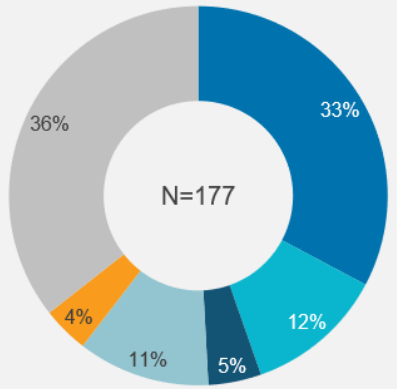
All **35** EFPIA member companies with eligible products submitted data to the Portal (100% participation)

100%

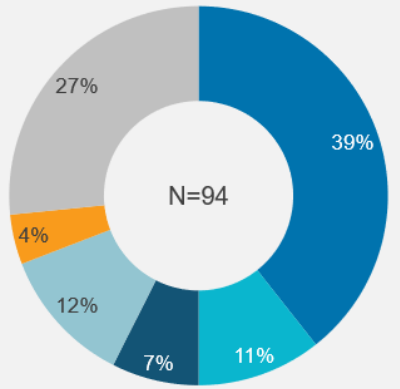
The analysis described in this report is therefore representative of **100% of all products** approved by the EMA between January 2021 and June 2024 that are marketed by EFPIA members

Data completeness and representativeness

Therapy areas of products approved by the EMA between Jan 2021-Jun 2024



Therapy areas of products included in the Portal dataset between Jan 2021-Jun 2024



The therapy areas of Portal products and the composition of products approved by the EMA over the same time period are similar – suggesting the products within the Portal are **representative** of the types of innovative medicines approved by the EMA over this period

Abbreviations: EFPIA = European Federation of Pharmaceutical Industries and Associations; EMA = European Medicines Agency

This report presents an updated analysis focusing on a set of key research questions

Speed of marketing authorisation

How does Europe compare to other regions in terms of the timing of marketing authorisation?

Of all new products approved by international regulators between January 2021 and June 2024, **EMA approval came later**, on average, than the US and by Japan **by 252 days and 24 days** respectively

Status of filing, availability and accessibility

What proportion of new medicines have been filed for P&R or made accessible via an AAS, and in how many countries?

Looking at the Portal's products (that are on average 25 months-post MA), taking an average across European countries, **more than half of products have been filed for P&R or made accessible via an AAS**

Speed of filing and reimbursement

To what extent is delayed reimbursement of new medicines due to the time taken at different steps of the P&R process?

While there are delays in P&R filing in for some products in some countries, this is **not a key driver of low availability of medicines in all countries** (accounting for 31% of the total time between MA and reimbursement on average)

Root causes of delays

Where new medicines have not been filed for P&R in all countries, what are the most prevalent root causes of this?

The reasons for both delays in P&R filing and P&R decision making are **multi-factorial,** varying with respect to the region. the size of company filing for P&R, the product features and whether a product is accessible via an AAS

Abbreviations: EMA = European Medicines Agency; MA = marketing authorisation; P&R = pricing and reimbursement; AAS – Alternative Access Scheme

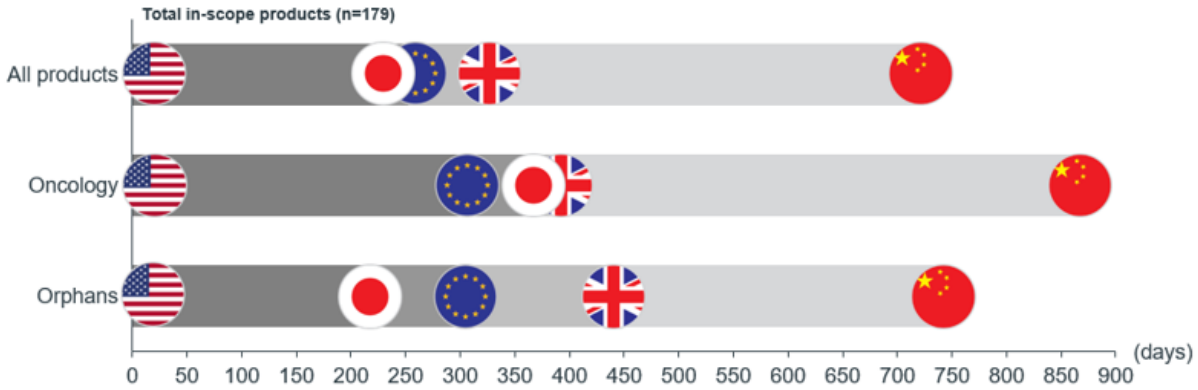
efpia CRA Charles River Associates

The products in-scope of the Portal received marketing authorisation later in Europe than in the US and Japan

Key findings: Speed of marketing authorisation

- Of all new products approved by international regulators between January 2021 and June 2024, **EMA approval came later**, on average, than the US and by Japan by 252 days and 24 days respectively; this represents the comparative speed of EMA approvals improving since the 2024 report
  - For **oncology drugs,** EMA approval happened, on average, 69 days earlier than in Japan and 303 days later than in the US. This represents a positive trend versus 2024, where EMA approval came 204 days after PMDA
  - For **orphan products**, EMA approval comes 312 days after the US, and 95 days after Japan
- This shows that even before considering the P&R process, **Europe is slower in approving new products** than the regulatory agencies in other regions[1]

Date of EMA approvals relative to the US, UK, Japan and China



Legend:

- FDA date
- EMA date
- PMDA date
- MHRA date
- NMPA date

No. of dates used to calculate averages (/ 179):

	FDA to EMA	FDA to PMDA	FDA to NMPA	FDA to MHRA
All products	155	61	30	141
Oncology	54	24	11	52
Orphans	54	22	12	46

1. This lag may also be due – at least in part – to companies taking more time to file for marketing authorisation through the EMA compared to the FDA. Data on submission dates to the FDA and EMA are not publicly available.

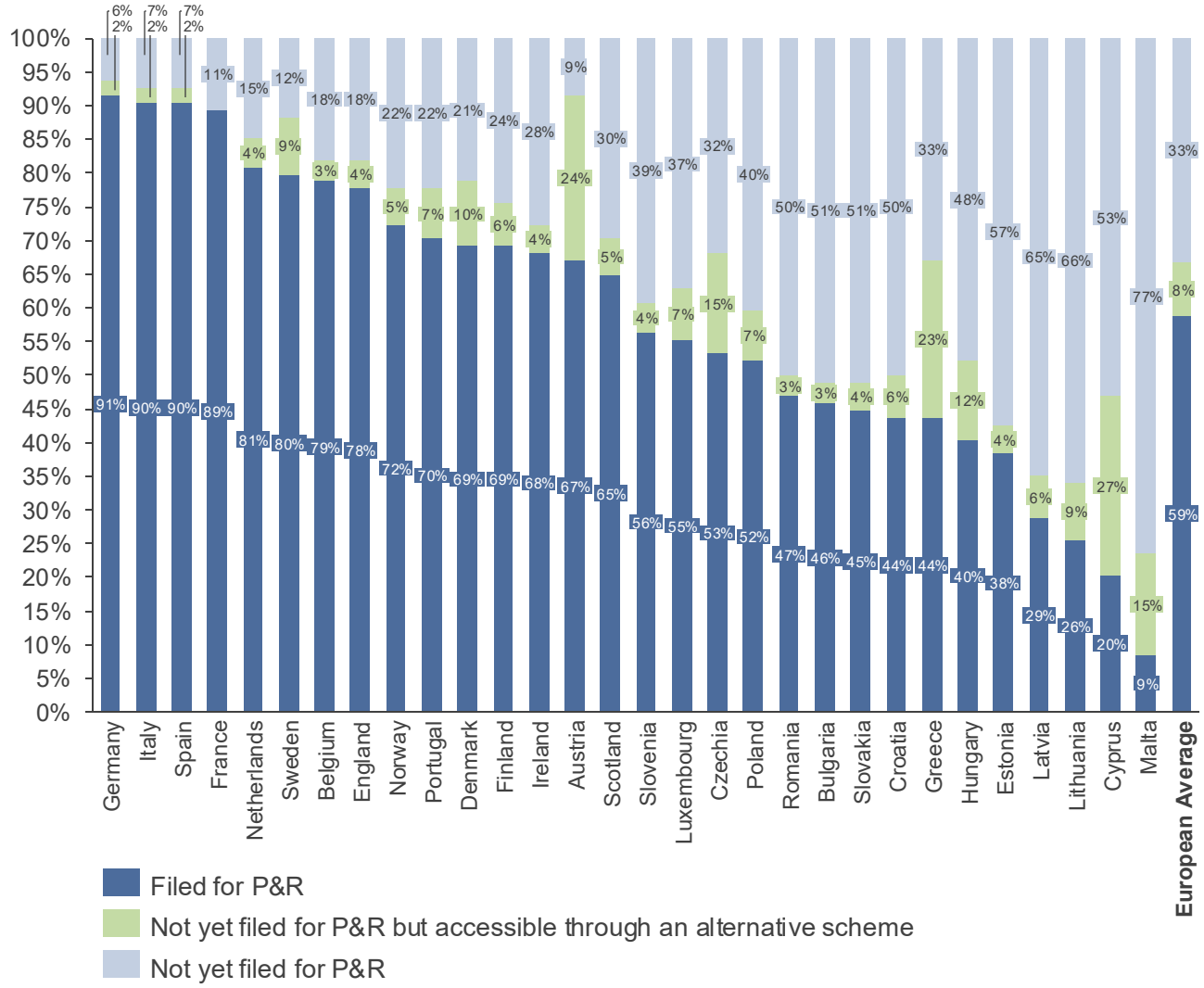
Abbreviations: EMA = European Medicines Agency; FDA = Food and Drug Administration; MHRA = Medicines and Healthcare products Regulatory Agency; NMPA = National Medical Products Administration; PMDA = Pharmaceuticals and Medical Devices Agency

In many instances of product unavailability, the products have in fact been filed for reimbursement but have not yet been reimbursed

Key findings: Status of filing and reimbursement

- To truly understand **patient access**, we must consider **filing, availability** and **accessibility through alternative access schemes (AAS)***
  - Taking an average across European countries, **67%** of products have either been filed for P&R or made accessible through an AAS
- Focusing on the formal P&R channel, looking at all products in the Portal to date (which covers products that are on average **25 months post-marketing authorisation**):
  - Taking an average across European countries, **59% of products have been filed** for P&R. Of which:
    - **55%** of filed products have been reimbursed
    - **37%** of filed products are pending a reimbursement decision
    - **7%** have had a negative decision or been withdrawn
- The both the total percentage and the relative proportion of products that have been filed for P&R or made accessible through an AAS **varies significantly** based on **geography**

Status of product filing, availability and accessibility across countries



**AAS can take different forms in different countries, including early access programmes, compassionate access programmes and named patient programmes. These are investigated in more depth in select countries as part of the Smaller Markets Report*

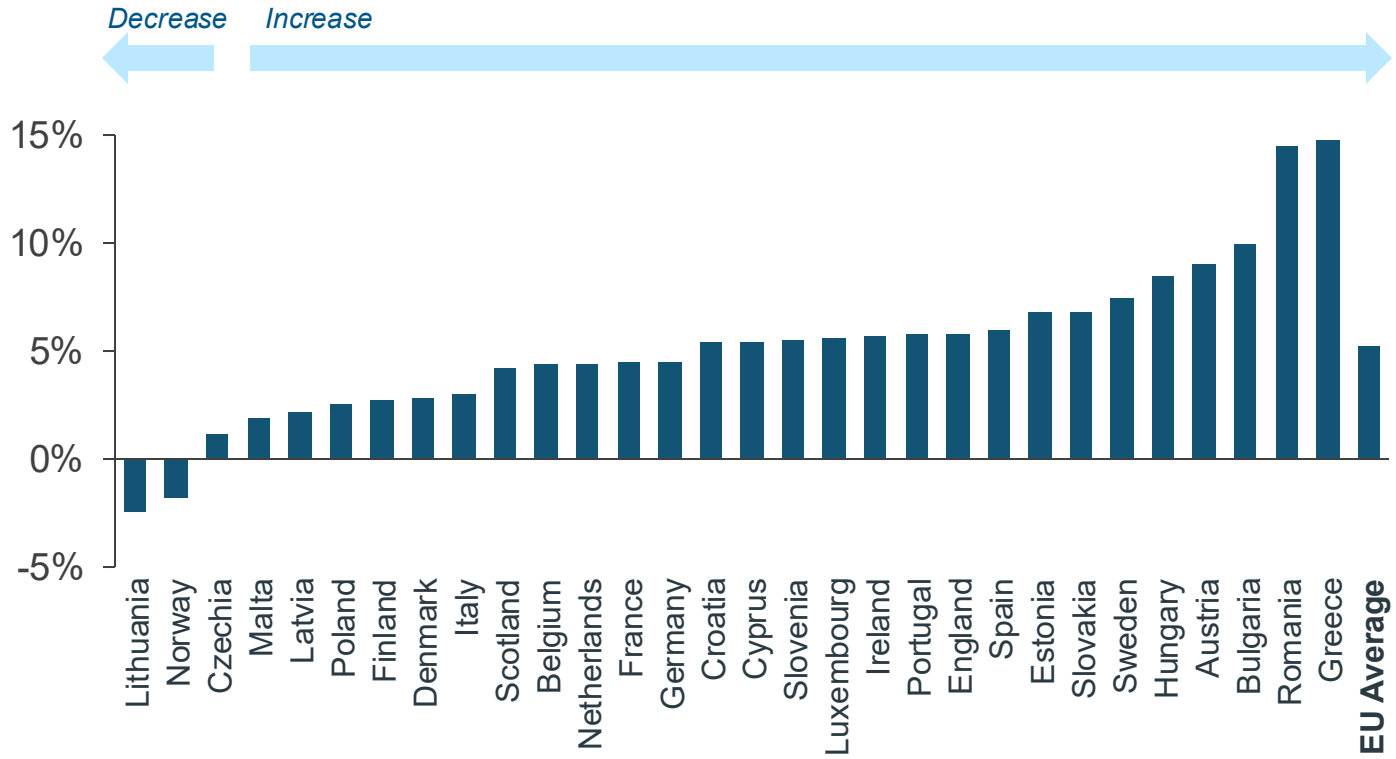
Abbreviations: P&R = pricing and reimbursement; MA – Marketing Authorisation

When following a cohort of products over time, there is an increase in the rate of filing, availability and accessibility

Key findings: Status of filing and reimbursement

- By investigating the current status **of the 66 products** included in the 2024 Portal Report we can understand the impact of time on the rate of **filing, availability and accessibility**
- There has been a **5% increase** in the rate of filing and accessibility via an AAS from at **32-months post MA (vs 20-months previously)**
- This is largely driven by an **increase in the proportion of products filed for P&R** that were previously inaccessible
- **The level of change varies significantly across Europe**
  - Considering the countries with the biggest changes, Romania and Greece, have country filing requirements, the portal underlines this is a significant factor contributing to delays in some countries

Change in rate of product filing, availability and accessibility across countries and over time



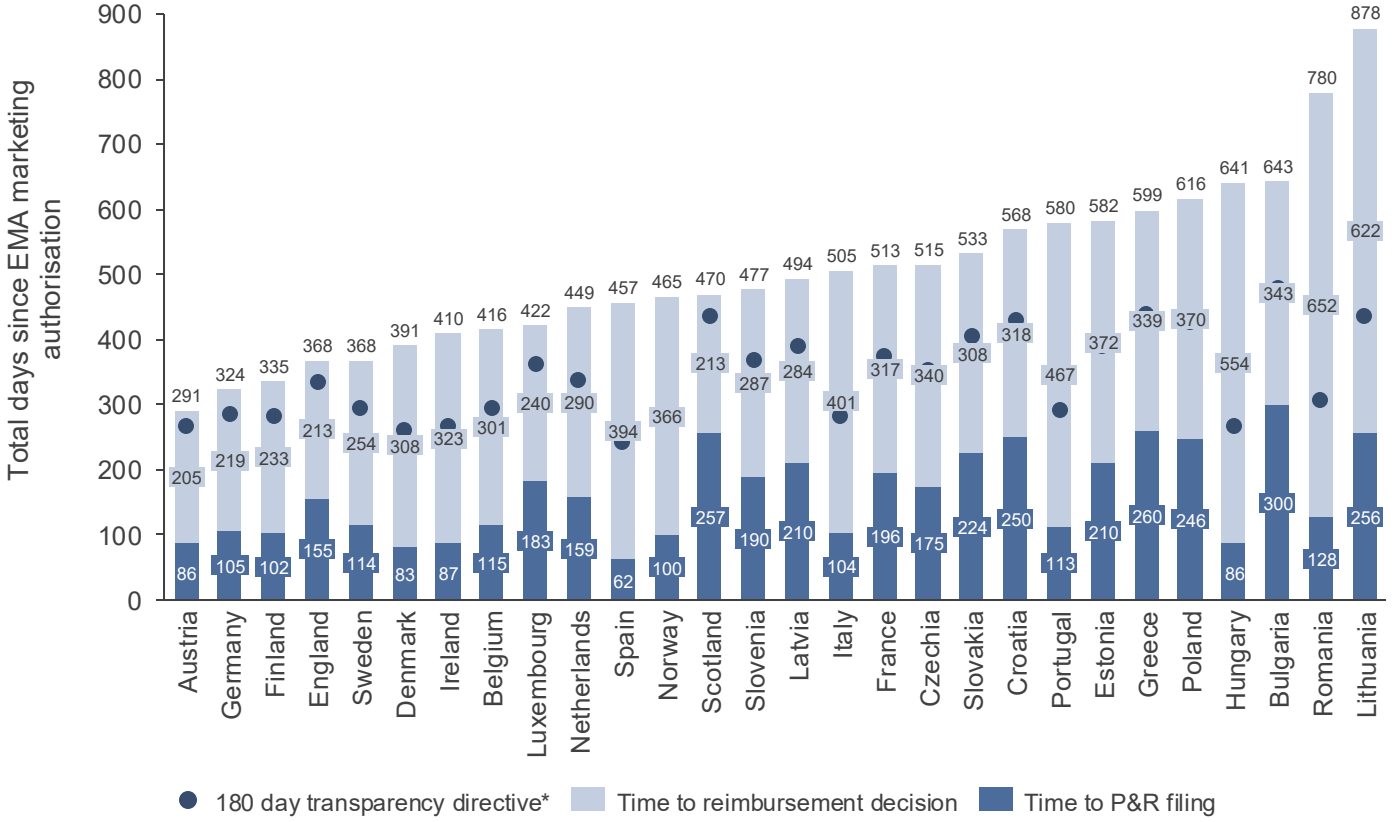
Abbreviations: AAS – Alternative Access Scheme; MA – Marketing Authorisation

While there are delays in P&R filing in for some products, this is not a key driver of low availability of medicines in all countries

Key findings: Speed of filing and reimbursement

- Although the Portal contains products that have been on the market for different lengths of time, across products that have been successfully reimbursed:
  - **31% (or an average of 163 days)** of the total time between EMA approval and availability can be attributed to the time between receiving EMA marketing authorization and P&R filing
  - **69% (or an average of 340 days)** of this time is attributable to the time between P&R filing and P&R decisions at the country-level
- This pattern varies across countries: the proportion of the total time taken up by the time it takes a company to file for P&R is **lowest in Nordic markets** (**26%** on average) and **highest in CEE** (**34%** on average)

Time to file for P&R as proportion of the total time until reimbursement following EMA marketing authorisation



Note: Data is not available for all products in all countries. Where the sample size of products in any given country was less than three, these countries have been removed from the figure and include Cyprus snd Malta. This is due to the risk of bias in the results from a very small number of products and due to the risk of de-anonymizing individual products. The data reported for Germany should be interpreted as time to completion of the national P&R process rather than time to reimbursement, as authorised products are immediately eligible for reimbursement in Germany.

**The time to the reimbursement decision does not distinguish between time taken for stop-clocks, negotiations with manufacturers and active decision-making by the national HTA body*

As set out in the root causes analysis, the reasons for both delays in P&R filing and P&R decision making are multi-factorial

Key findings: Reasons for not filing for P&R

- Root causes for non-filing have been grouped according to the stage of the P&R process and the stakeholders involved
- There is an even spread across the different categories of root causes, reflecting the **multi-factorial and varied nature** of the P&R filing process
- The even distribution across different categories of root causes for non-filing underline that **improving P&R filing rate is a shared responsibility,** that will require a shared solution from all different stakeholders

Categorization of root causes

Health system infrastructure

Lack of required healthcare infrastructure to support utilization

Lack of healthcare funding to support utilization

Economic viability

The size of the treatable population

Lack of company presence in the local market

The cost of launching is not recoverable

P&R process

Country filing requirements

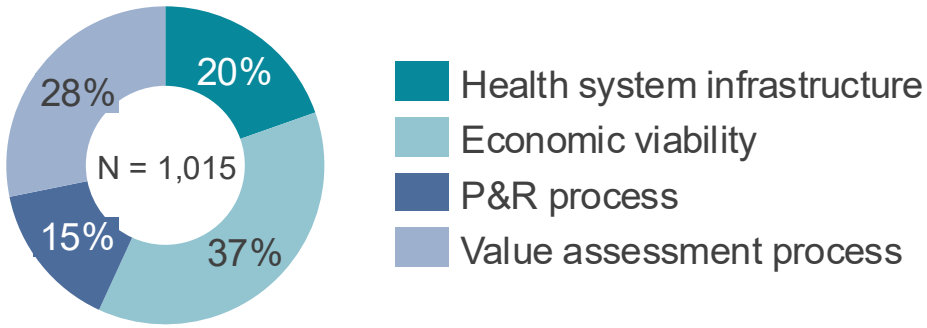
The impact of external reference pricing on other EU countries

Value assessment process

Evidence package unlikely to meet country requirements

Low value attributed to class competitors

Reasons for non-filing for P&R across all data collection cycles*



***Note**: The 'Other' category was selected in 413 instances. These have been omitted from the root-causes analysis since they cannot be assigned to a specific root cause.*

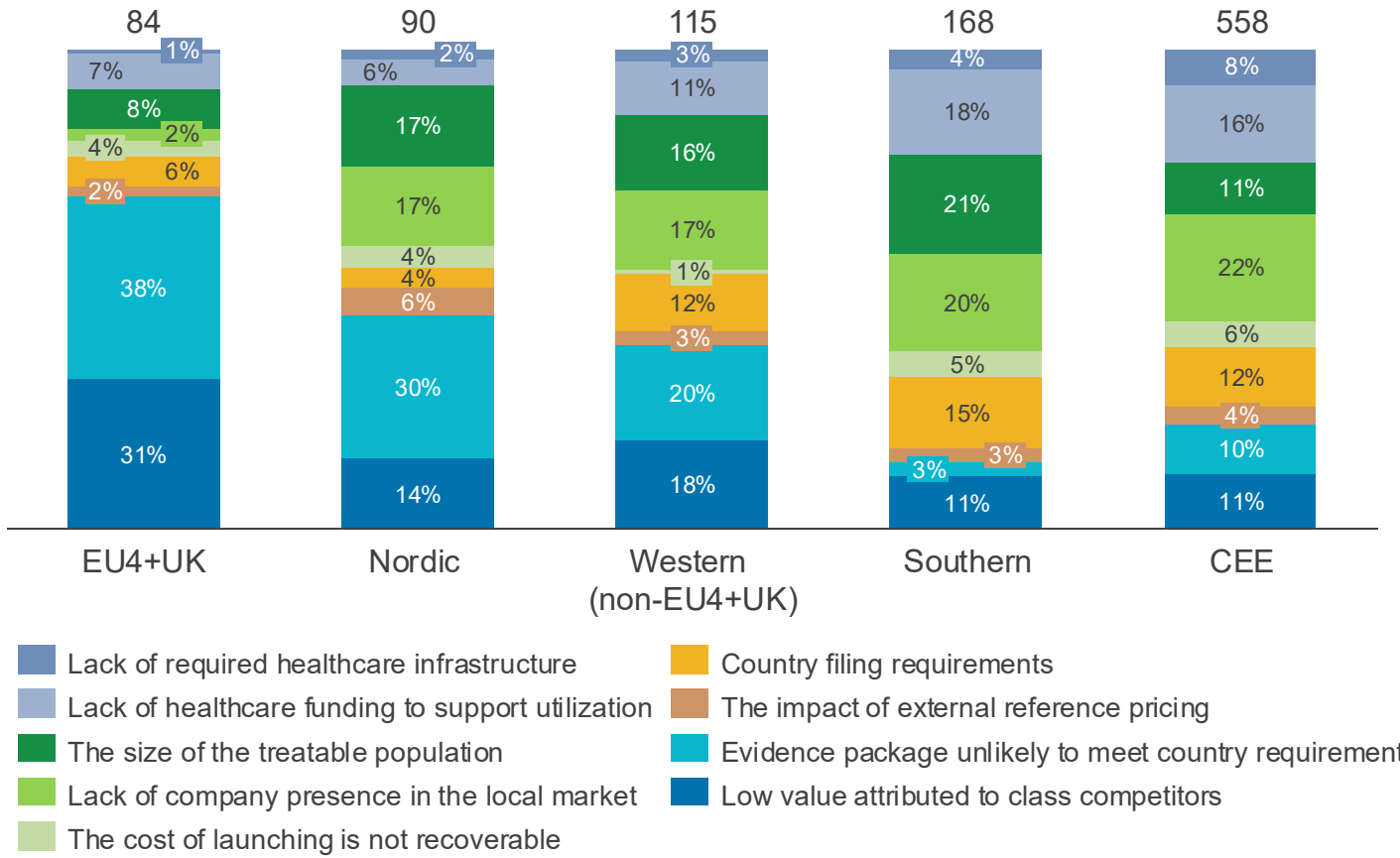
***Abbreviations**: P&R = pricing and reimbursement*

The Portal highlights distinct differences in the reasons for non-filing across regions

Key findings: Reasons for not filing for P&R

- However, the reasons for non-filing for P&R clearly vary between regions of Europe:
  - Delays in filing in **Western Europe** are largely due to the requirements of the **value assessment process**
  - Delays in filing in **Central and Eastern Europe** are largely due to **health system infrastructure** and the corresponding impact this has on commercial decision-making and resource allocation, captured under **economic viability**

Distribution of reasons for non-filing for P&R in all countries, by country grouping*

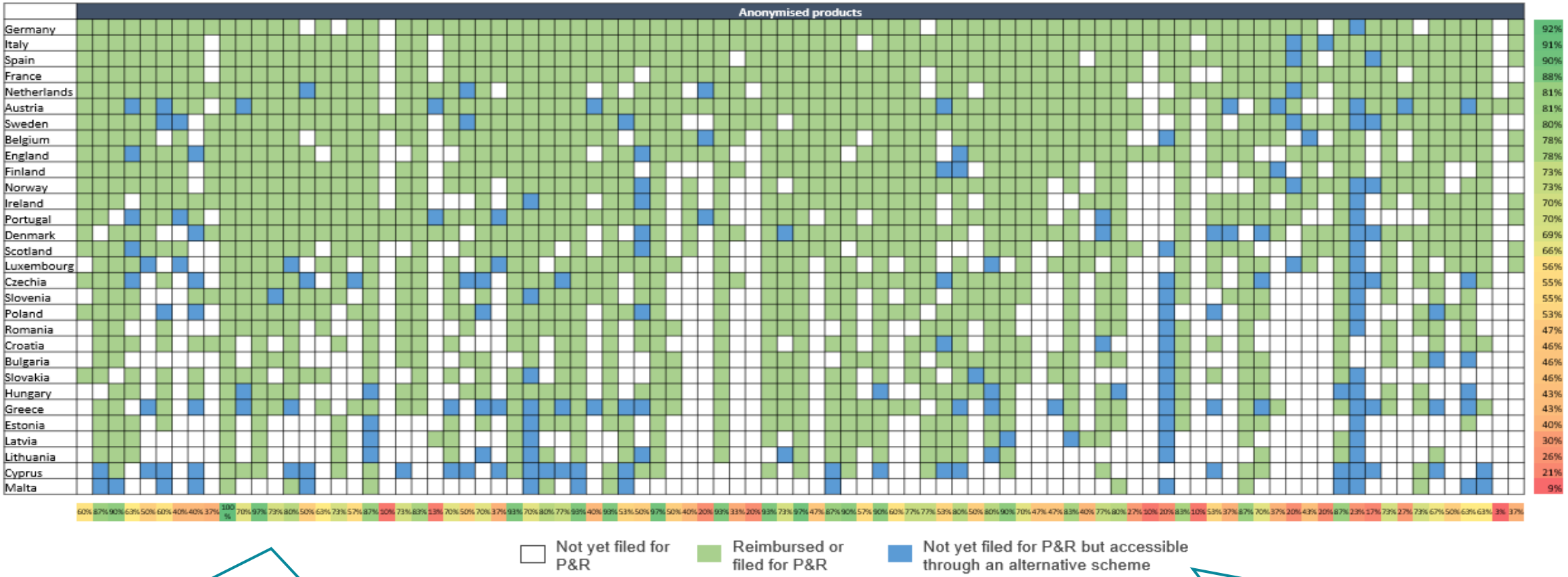


*Country groupings:
EU4+UK: *England, France, Germany, Italy, Scotland, Spain*
Western (Other): *Austria, Belgium, Ireland, Luxembourg, Netherlands, Portugal*
Southern: *Cyprus, Greece, Malta*
CEE: *Bulgaria, Croatia, Czechia, Estonia, Hungary, Latvia, Lithuania, Poland, Romania, Slovakia, Slovenia*
Nordic: *Denmark, Finland, Norway, Sweden*

Abbreviations: CEE = Central and Eastern Europe; P&R = pricing and reimbursement

There is a significant country-product interaction which leads to variation in whether a product has filed for reimbursement

Anonymised distribution of product-level P&R filing across countries



Some products have a high filing rate but have not been filed in high-filing countries such as France and Germany. Whereas other products have a lower filing rate but have been filed in smaller markets such as Cyprus

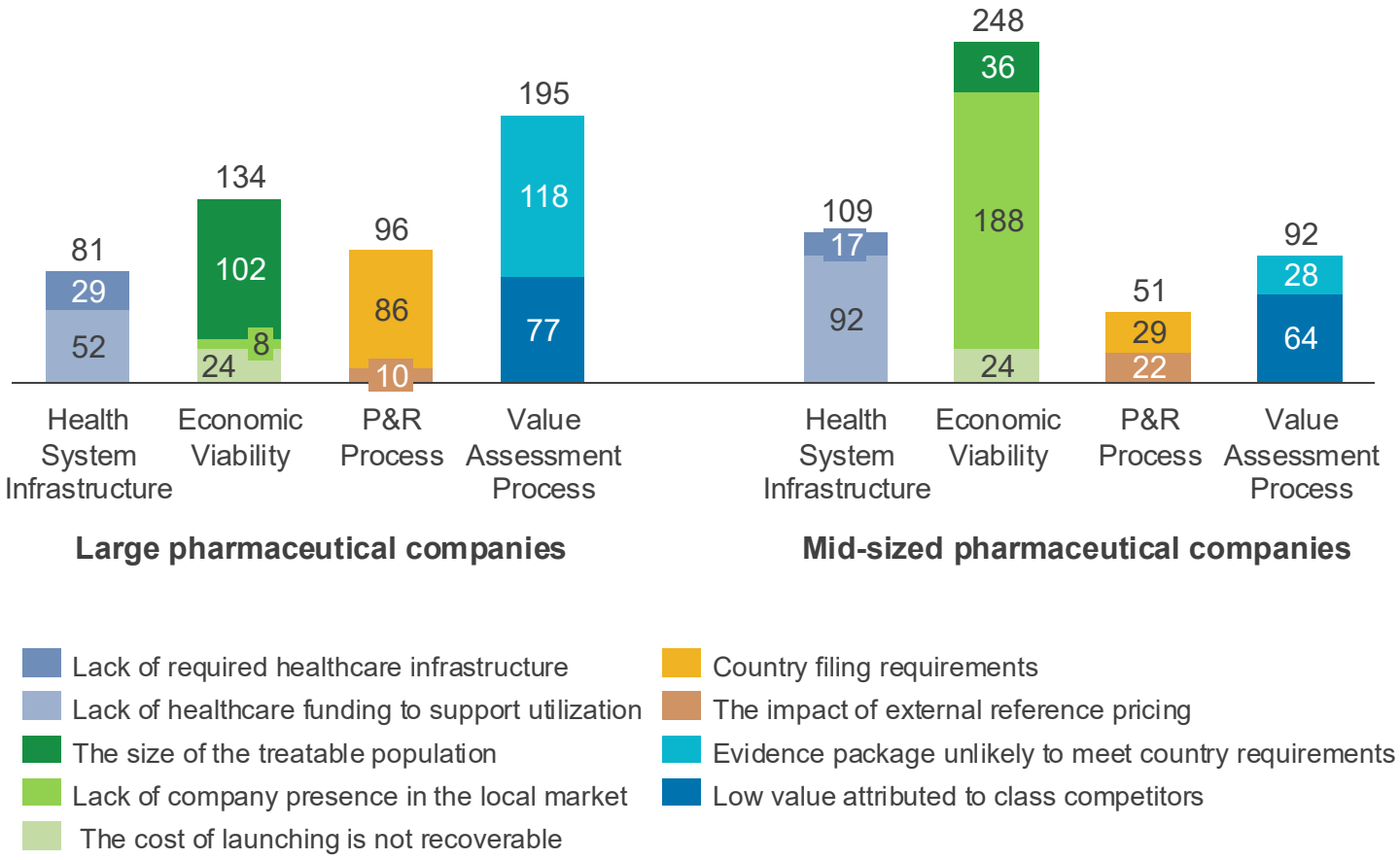
This clustering of AAS use, across both typically low- and high-filing countries, suggests that some products are ill-adapted to the standard reimbursement pathway initiated by filing, and that alternative access provides a vital route for patient access.

The Portal also emphasizes the impact of company size on the reasons for non-filing for P&R

Key findings: Reasons for not yet filing for P&R

- The reasons for non-filing for P&R also vary between different sized companies:
  - Delays in filing for **large companies** are fairly **well distributed** across the root causes, with factors relating to evidence development, value of class competitors and country filing requirements being most important
  - However, delays in filing in **mid-sized companies** relate largely to the **economic viability** of the decision to launch. More specifically, a 'Lack of company presence in the local market' make up the majority of reasons for delay

Distribution of reasons for non-filing for P&R by company size*



*Company definitions:
Large company: *Top 20 companies in Europe by European Sales*
Medium company: *Companies with >€500 million annual European sales, but outside the Top 20*
Small company: *Companies with <€500 million annual European sales – only 1 small company participated in the Portal, and was grouped with Medium to maintain anonymity.*

Abbreviations: CEE = Central and Eastern Europe; P&R = pricing and reimbursement

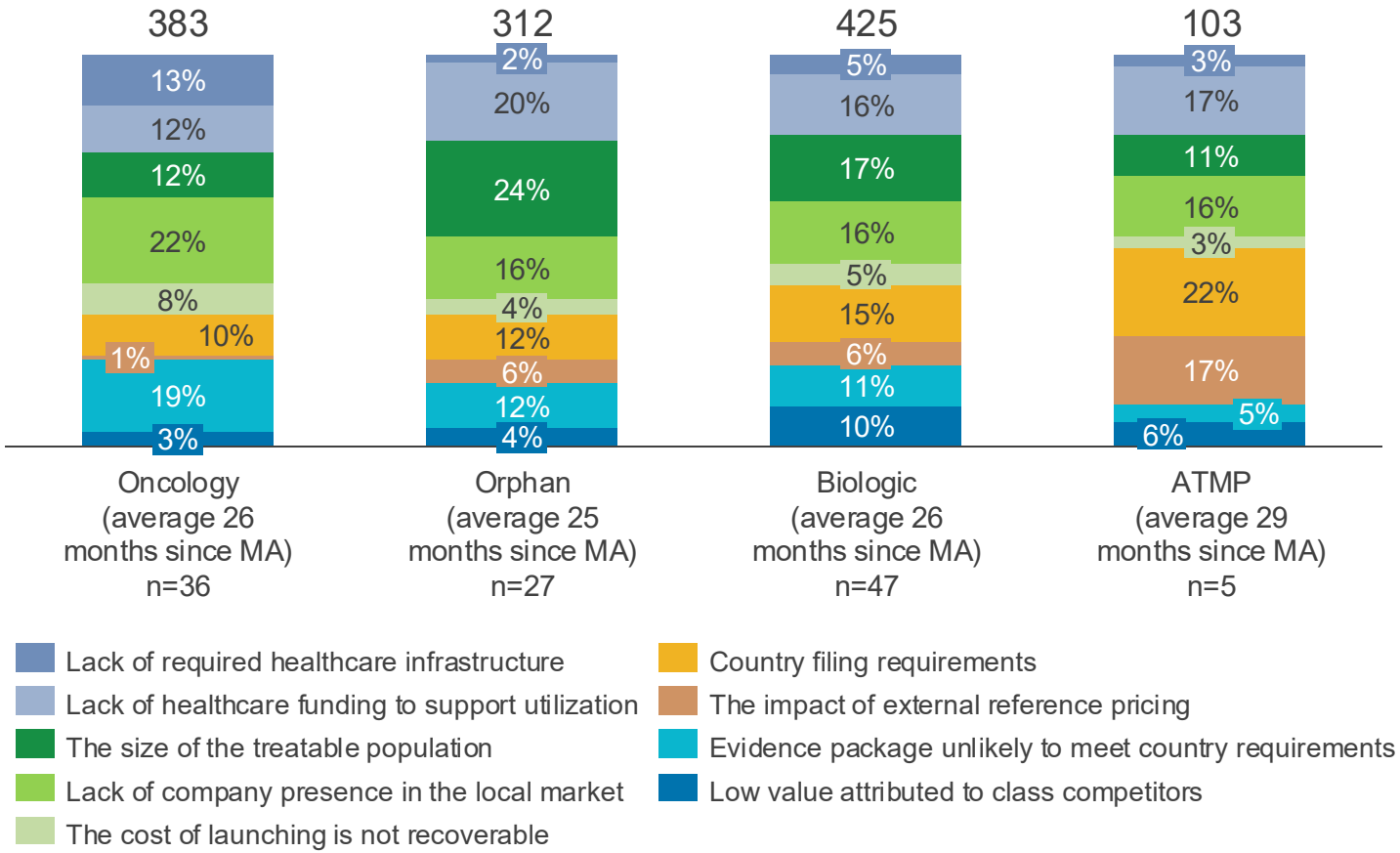
The 2025 Portal report introduces data on different root causes for delays in filing different types of product

Key findings: Reasons for not yet filing for P&R

Root causes for non-filing for P&R also differ according to **product type:**

- For **oncology products**, evidence requirements and the lack of company presence in the local market represent the biggest barriers
- **For orphan products**, companies struggle with the size of the treatable population
- **ATMP products** face challenges related to a country's P&R process

Distribution of reasons for non-filing by product type and therapy area

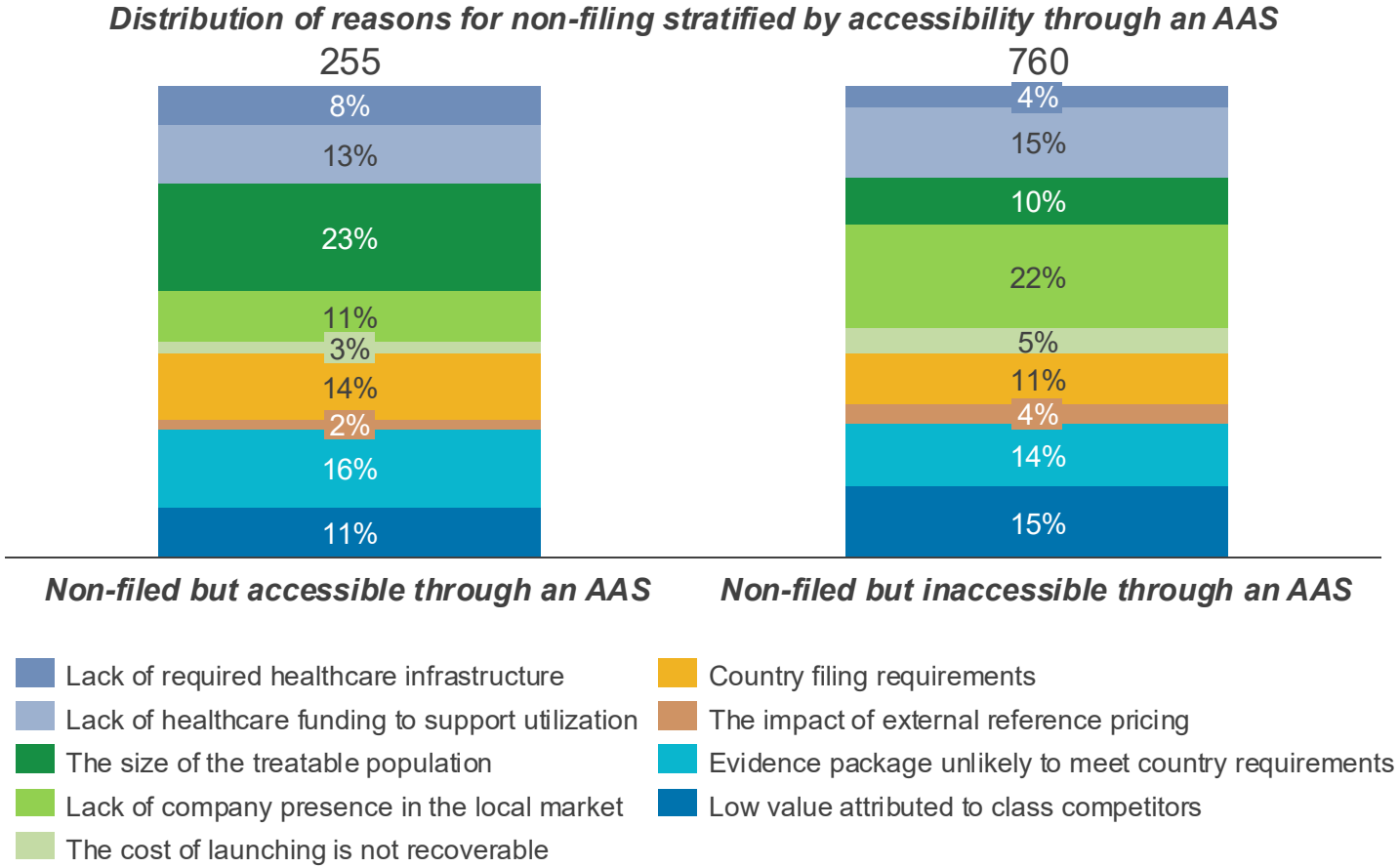


Abbreviations: P&R = pricing and reimbursement; MA – Marketing Authorisation

Some barriers occur more frequently in products accessible via an AAS, suggesting AASs can be used to partially overcome them

Key findings: Reasons for not yet filing for P&R

- The distribution of reasons for non-filing are different on the basis of whether a product is **unfiled but accessible through an AAS or unfiled and not accessible**
- This suggests that AASs may **help mitigate some barriers to filing, but are not a pancea**
  - Products facing a barrier to filing due to the size of the **treatable population or country P&R requirements** are more commonly accessible through AASs
  - However, the **lack of company presence** is a barrier to both filing and use of AASs



Abbreviations: P&R = pricing and reimbursement; AAS – Alternative Access Scheme

Despite increased maturity compared to 2024, it is still too early to make a judgement on the CTF

In April 2022, EFPIA member companies made a commitment to file (CTF) for pricing and reimbursement in all EU countries as soon as possible and no later than 2 years from the central EU marketing authorization, provided that local systems allow it

Key findings: Analysis of the Commitment to file

- There is now a **cohort of products** that have received their **MA for at least 2 years** since the CTF
  - Comparison of this **post-CTF cohort** with a cohort of products that had received their MA for at least 2 years pre-CTF suggests that the rate of filing and accessibility through an AAS has remained consistent at **71%**
- However, of the 94 products included in the Portal dataset, **only 22 products** received their MA after the CTF was made and have had MA for at least two years
- The **sample size will continue to increase over future iterations of the Portal**, which will allow analysis to take factors such as the changing composition of products in the Portal and the length of time since marketing authorization

Breakdown of cohorts of products included in the analysis

Product cohort overview	Pre-CTF products (n=33)	Post-CTF products (n=22)	All post-CTF products (n=61)
Oncology	39%	36%	38%
Orphan	27%	27%	30%
Biologic	48%	63%	51%
Standard EC approval	72%	81%	79%
Advanced therapies	6%	4%	5%
Time since EC approval (months)	*29*	*28*	*18*
Total product number	**33**	**22**	**61**

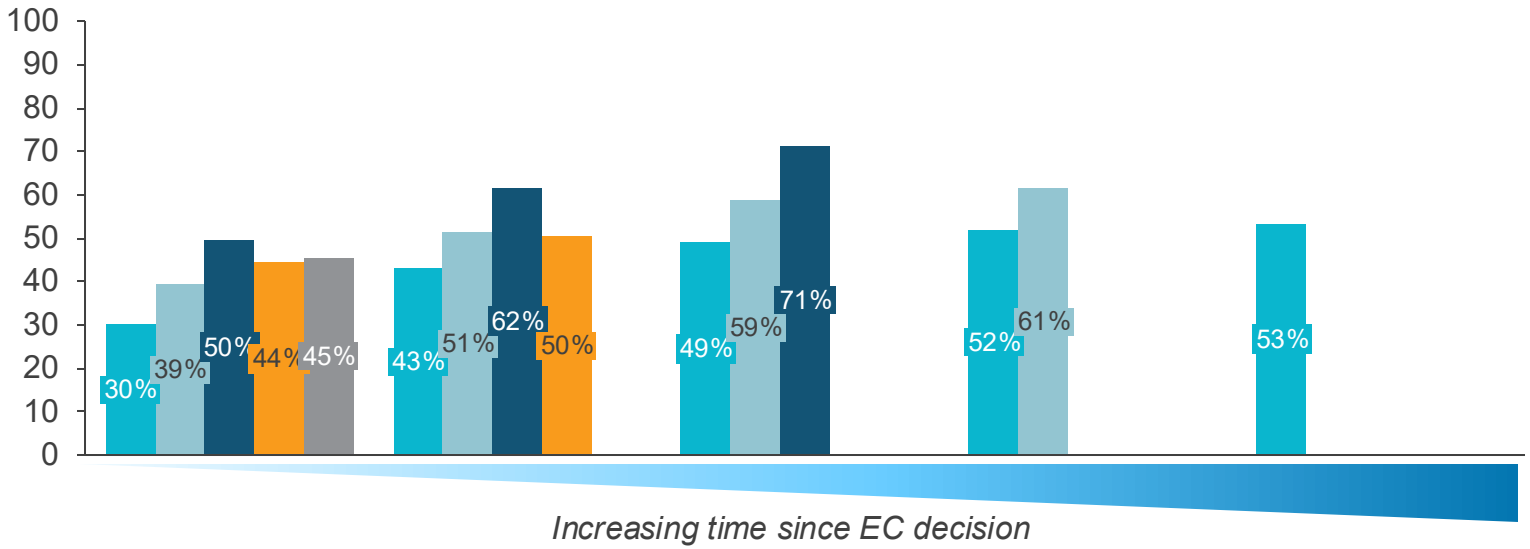
Abbreviations: CTF – Commitment to File; MA – Marketing Authorisation

Preliminary analysis on the speed of filing for P&R suggests an acceleration since the CTF

Key findings: Speed of manufacturer filing

- Preliminary analysis of the cohorts of products that have received MA since the CTF over time suggests that **the speed at which products are filing for P&R is increasing** as more time passes from the launch of the CTF
- This could suggest **manufacturers are making progress in putting systems in place** to facilitate earlier filing
  - These processes require time to implement, but could now be demonstrating success
- Although cohort 5 would appear to be an exception, this may be explained by an increased number of oncologic products

Status of product filing over time across product cohorts since the CTF



Product cohort	EC decision date	No. of products
Cohort 2	Apr – Jun ’22	9
Cohort 3	Jul – Dec ’22	14
Cohort 4	Jan – Jun ’23	8
Cohort 5	Jul – Dec ’23	14
Cohort 6	Jan – Jun ’24	13

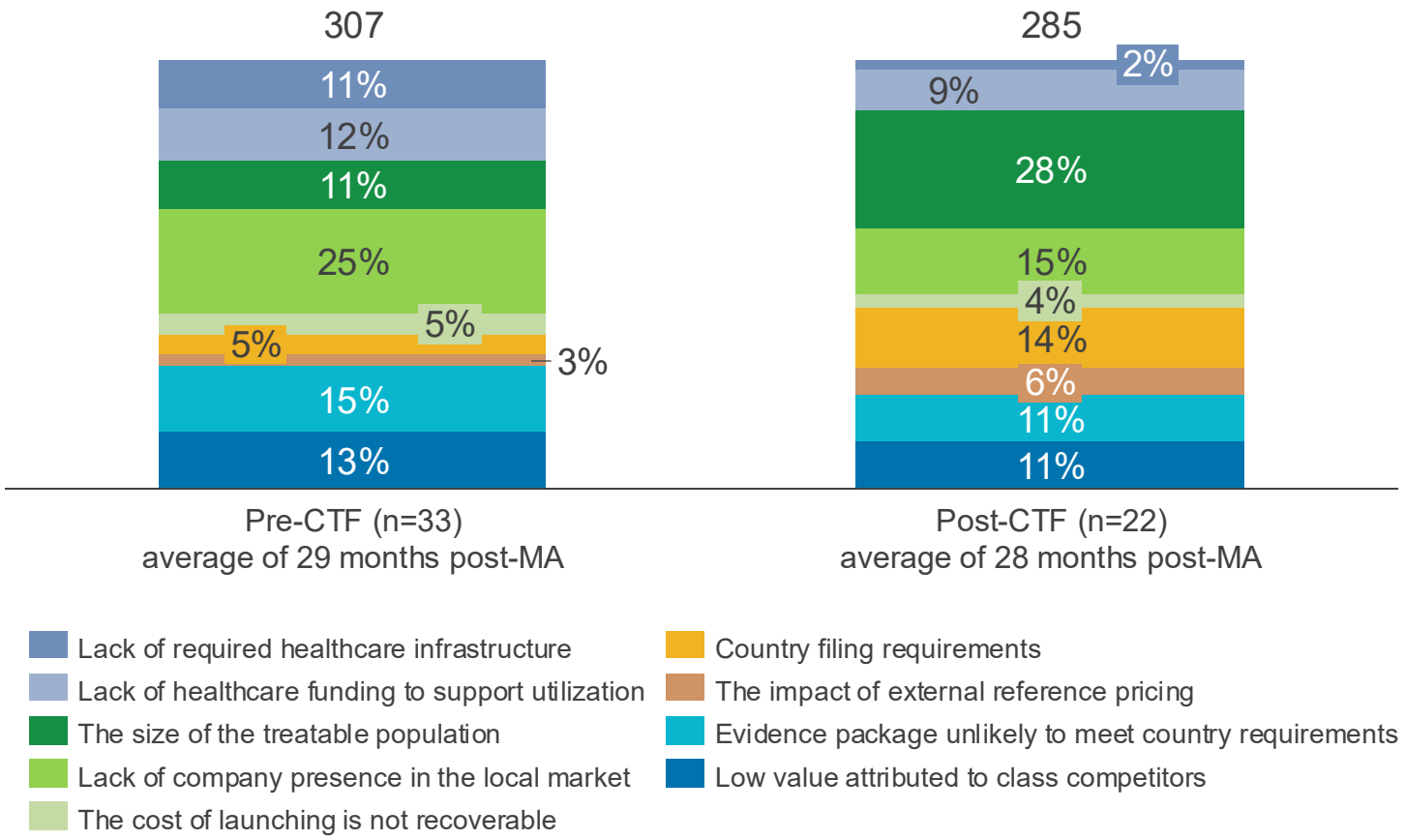
Abbreviations: CTF – Commitment to File; MA – Marketing Authorisation; P&R – Pricing and Reimbursement; EC – European Commission

Analysis of root causes post-CTF suggest that manufacturers are attempting to address barriers within their control

Key findings: Root causes for non-filing

- Analysis suggests there are **differences** between the **root causes for non-filing** between the **pre- and post-CTF cohorts** at approximately 2 years post-MA
  - There has been a significant decrease in a **lack of company presence** as a barrier
  - However, the **size of the treatable population** and **country filing requirements** have increased proportionally as a barrier since the CTF
- Some barriers **require changes in local systems' P&R policies** and **highlights the need for collaborative solutions** between manufacturers and national authorities

Distribution of reasons for non-filing at approximately 2 years for pre- and post-CTF cohorts



Abbreviations: CTF – Commitment to File; AAS – Alternative Access Scheme; MA – Marketing Authorisation

The Smaller Markets report provides the opportunity to adjust data collection in future iterations

This is the 3rd annual Portal report

Opportunities to improve the Portal in future iterations

The data will **continue to mature as more cycles of data are collected**, allowing for validation of results and more granular analysis while protecting product confidentiality

This year, the Portal suggests **some key issues** to consider during future data analysis cycles:

- The continued need to **refine the data collection process to continue the trend of reducing the 'other' responses**. Insights from the Smaller Markets report could be leveraged to accomplish this
- The need to distinguish between the impact of root causes on decisions to non-file **when multiple root causes are selected**
- The benefits of **including data from a broader range of companies** than solely EFPIA members
- The possibility to include and differentiate analysis for **biosimilars**