European Access Hurdles Portal:

Results from the third year of data collection

May 2025

Executive summary

In April 2022, EFPIA and its members committed to a series of actions designed to reduce disparities in access across Europe. The European Access Hurdles Portal (the "Portal") was launched then as an industry-led initiative to increase transparency regarding the root causes of unavailability of innovative medicines in Europe—a key issue affecting patient access to innovative medicines. It is intended to identify and report on the multifactorial root causes of delays in pricing and reimbursement (P&R) filing or the reimbursement decision-making process for European Union (EU) centrally approved medicines in their first indication. This allows data on delay and lack of availability to be put into context and thereby supports a shared understanding of these root causes and the collective responsibility to address these issues. The Portal can be used to support a multi-stakeholder dialogue to devise solutions that can address these challenges holistically.

This is the third report using evidence from the Portal. The Portal now includes data collected on medicines that received marketing authorisation in their first indication between January 2021 and June 2024. The data continue to mature over each iteration of the Portal, allowing us to validate results from previous reports, undertake more granular analysis and begin to assess trends in accessibility of innovative medicines over time.

Transparency: There is a commitment to providing more transparency on the root causes of unavailability and delay, with 100% participation from EFPIA member companies with eligible products. As a result, the Portal now contains a total of 94 products that were approved between January 2021 and June 2024 in their first indication (representing just over one-half of all products approved by the European Medicines Agency (EMA) in this period). The Portal has significantly increased in size over the past two years, demonstrating an ongoing willingness from the industry to help to address the barriers to unavailability and delay.

Filing, availability and accessibility: As we gain more data in the Portal, the complex interaction between filing, availability and accessibility is becoming more apparent. There is a distinction between products being available (included in the national reimbursement list) and patients having access to them. We find the following:

- To understand if products are accessible to patients, we need to consider filing, availability (inclusion of a centrally approved medicine on the public reimbursement list in a country) and whether patients have the possibility to access products through

alternative access schemes (AAS).[1] On average across European countries, 67% of products have either been filed for P&R (including filed and already reimbursed) or made accessible to patients through an AAS.

- Focusing on the formal price and reimbursement channel, taking an average across European countries, 59% of products have already been filed for P&R. Therefore, the Portal shows that in most instances of product unavailability, the products have been filed for reimbursement but have not yet been reimbursed. Looking at all products in this period (which are on average 25 months post-marketing authorisation (MA)), we find the following:
  - Of filed products, 55% have been reimbursed
  - 37% are pending a reimbursement decision, and
  - the remaining 7% have had a negative reimbursement decision or been withdrawn by the manufacturer[2]
- Given we have collected data over a number of years, we can observe if delays and unavailability are changing over time. When comparing how rates of filing for P&R and accessibility have changed over time for the 66 products included in the 2024 Portal report,[3] we find that there has been a 5% increase over the last year. This has been primarily driven by an increase in the proportion of products filed for P&R.
- Although there are delays in P&R filing for some products across European countries, this is not a key driver of low availability of medicines in all countries. Across products that have been successfully reimbursed, 31% of the total time between MA and availability can be attributed to the time between MA and P&R filing, while 69% is attributable to the time between P&R filing and P&R decisions at the country level.

Variation across countries and the role of AAS: The percentage of products that have been filed for P&R or made accessible to patients through an AAS varies significantly across European markets; the percentage is higher in larger markets than in smaller markets, particularly in Central Eastern Europe. In several smaller markets, such as Austria, Greece and Cyprus, a high proportion (over 20%) of products have been made accessible through AAS.

Root causes: The Portal also provides granular data on the reasons why products have not yet been filed for P&R across different countries. As set out in the CRA root causes analysis, evidence from the Portal continues to support that delays in both P&R filing and P&R decision-making are multifactorial. We find the following:

- Consistent with previous years, the most recent analysis shows an even spread across the main categories of root causes (health system infrastructure, economic viability, P&R

1 Alternative access schemes (AAS) can take different forms in different countries. These can include early access programmes (EAPs), compassionate access programmes (CAPs) and named patient programmes (NPPs).

2 Percentages do not sum to 100% due to rounding.

3 CRA (2024) European Access Hurdles Portal: Results from the second year of data collection. Available at: https://www.efpia.eu/media/0m4pswzd/european-access-hurdles-portal-2024-cra-report.pdf [Accessed March 2025]

process, and value assessment), supporting the conclusion that improving P&R filing and reimbursement rates is a shared responsibility that will require shared solutions from stakeholders involved in different aspects of the P&R process and access ecosystem.

- However, the frequency with which different categories of reasons are reported clearly varies between regions of Europe: delays in filing in Western Europe were largely due to the value assessment process and evidence requirements, while delays in Eastern and Southern Europe were due to health system constraints and the corresponding impact they have on commercial decision-making and resource allocation.
- We can also look at the results for different types of companies. We can distinguish between the reason for unavailability for the largest 20 companies and for midsize companies outside the top 20 but with annual European sales greater than €500 million. For larger companies, the most common reason for delayed filing is evidence development, value associated to class competitors, and country filing requirements, while, unsurprisingly, lack of geographical footprint is a significant issue for midsize companies.
- 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 are the biggest barriers to filing. With orphan products, companies struggle with the size of the treatable population. Advanced therapy medicinal products (ATMPs) face additional barriers related to country P&R processes.
- We can also distinguish between root causes for non-filing for products that accessible through AAS and those that are not accessible through AAS. Products facing a barrier to filing due to the size of the treatable population or countries' P&R requirements are more commonly made accessible through AAS, suggesting these barriers can be partially overcome in this way. Lack of company presence was found to be a barrier to both filing and use of AAS. This suggests alternative channels can help mitigate the barrier to filing for some products but are not a panacea.

Commitment to File: In April 2022, EFPIA member companies made a commitment to file (CTF) for P&R in all EU countries as soon as possible and no later than two years from the central EU MA, provided that local systems allow it.[4] Over time, the Portal will be able to provide insight into the role of EFPIA members' Commitment to File and specifically on where local systems do not currently permit filing within two years. Initial exploratory analysis is possible:

- It is still early to make any comprehensive assessment. Out of the 94 products included in the Portal dataset, only 22 products received MA after the CTF was made and have had MA for at least two years. This sample size will increase over time and enable more sophisticated analysis.
- Although based on a relatively small number of observations, and the overall level of filing has not changed significantly, the preliminary data suggest that the speed at which products are filing for P&R is increasing as more time passes from the launch of the CTF,

4 EFPIA (2022) Addressing patient access inequalities in Europe. Available at: https://www.efpia.eu/media/636830/addressing-patient-access-inequalities-in-europe.pdf [Accessed March 2025]

perhaps reflecting the progress of manufacturers putting systems in place to facilitate earlier filing.

- The data also suggest that there are barriers to filing that cannot be as effectively overcome by changes in company filing practices: 'the size of the treatable population' (which can be overcome via AAS for many products) and 'country filing requirements' (which requires changes in local systems' P&R policies) have become more salient root causes of non-filing since the CTF.

Clearly, evidence from the Portal can be used to increase transparency and shed significant light on the root causes of unavailability of innovative medicines in Europe. As the Portal continues to mature, we will be able to undertake more and more sophisticated analyses.

Introduction

New, potentially curative treatments are being discovered that can transform the lives of patients and the way we think, manage, and resource health care. However, innovation matters only if it reaches patients when and where they need it. As illustrated by the Patient W.A.I.T. Indicator survey, the average time to reimbursement for innovative treatments across countries in the EU and European Economic Area has reached 578 days; the times range from 121 days in Germany to 981 days in Turkey.[5]

To explain this, EFPIA, over the past five years, has documented the drivers and root causes of delays (defined as length of time from European marketing authorisation (MA) to availability at member state level) and unavailability for innovative medicines. This work has been published alongside the long-established Patient W.A.I.T. analysis. The evidence reveals multiple root causes of unavailability and delayed access across five categories and ten root causes.[6] This year, further analysis has also been conducted to examine the specific root causes of unavailability and delay in smaller European markets.[7]

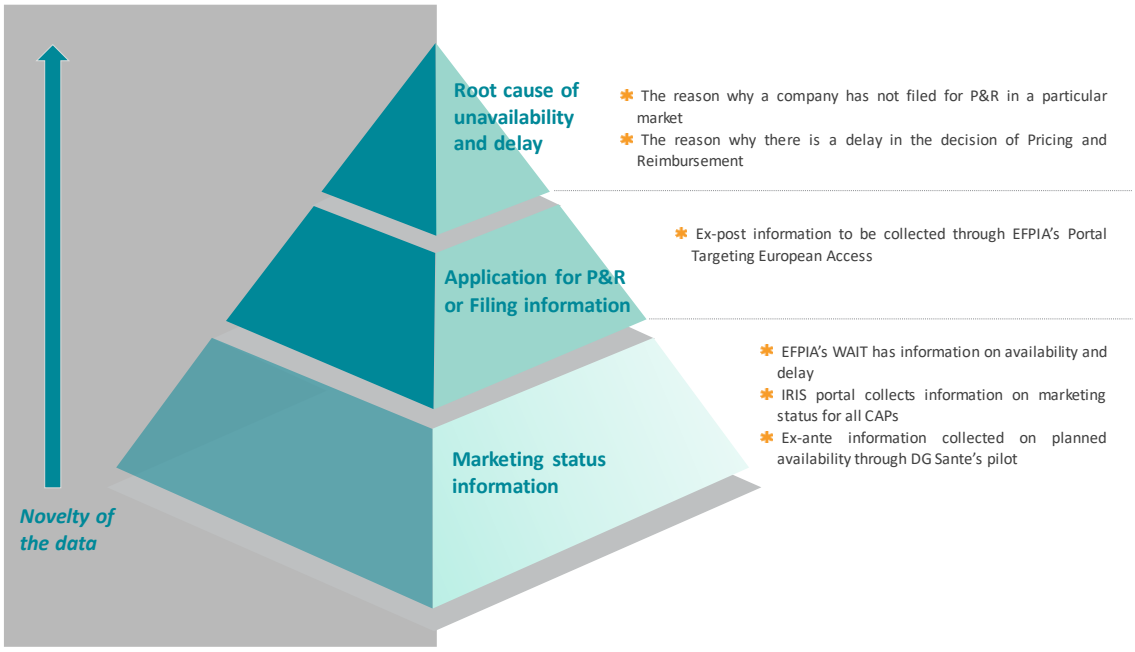
In April 2022, EFPIA and its members made a series of commitments to reduce disparities in access across Europe. To support transparency and the identification of the root causes of delayed filing and reimbursement, one of those commitments was the creation of the European Access Hurdles Portal (which we refer to as the Portal), to which marketing authorisation holders (MAHs) are requested to provide information about the timing and processing of pricing and reimbursement (P&R) applications in the various European countries, including the reasons for a delay in the P&R decision or the MAH having not yet filed in a particular market (Figure 1).

5 EFPIA Patients W.A.I.T. Indicators 2024 Survey, May 2025

6 CRA Root causes of unavailability and delay report, May 2025

7 CRA Root causes of unavailability and delay in smaller markets report, May 2025

Figure 1: New information on unavailability and delay

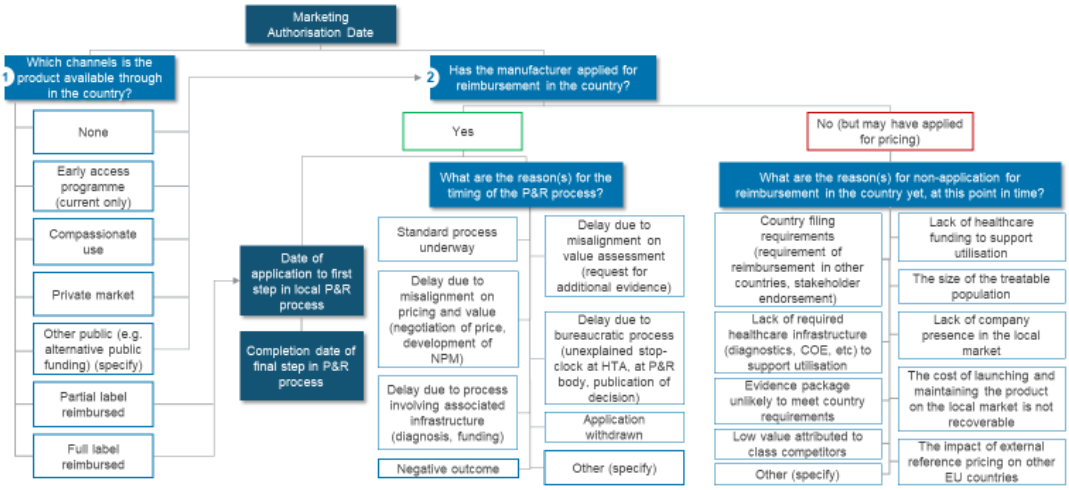


There have been two publications, in April 2023 and May 2024, which included data from the first year and the first two years of the portal, respectively. This document builds on these previous analyses and sets out the results from the most recent cycle of data collection.

The European Access Hurdles Portal

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. To this end, the Portal collects data regarding whether a product has been filed for reimbursement, the reimbursement status, and the reasons for delays, as illustrated in Figure 2. The Portal does not report data for individual products but rather describes trends based on analysis of aggregated, anonymized results.

Figure 2: Schematic of information collected through the Portal



The first public report from the Portal was published in April 2023 and was based on preliminary analysis of data collected on 32 innovative medicines. The second report in May 2024 included data analysis on 66 innovative medicines. Now, the Portal includes data collected on 94 innovative medicines from EFPIA member companies that received a centrally authorised MA for their first indication between January 2021 and June 2024.[8] The data have continued to mature since the publication of the first Portal report, with the inclusion of more products that have been observed over a longer period. This report builds on previous reports, allowing us to test whether the earlier findings are supported given the larger number of products and longer time period observed, and conduct greater depth analyses on factors affecting availability and delay.

The nature of the Portal's cyclical data collection process means that results presented in this report are a snapshot of the status of filing and reimbursement at the time of the most recent data collection cycle (Q4 2024). Therefore, results need to be interpreted taking into account that the dataset contains products that vary significantly with regard to their time since MA, from 5 months to 47 months.

8 See Appendix 2 for a description of the data collection phases.

Data submissions in the Portal

The data analysis described in this document uses the terminology and definitions listed in Box 1.

Box 1: Definition of key terms used throughout the document

- *Filing for marketing authorisation (MA) = "EMA filing" or "filed for MA"*
- *Filing for pricing and reimbursement (P&R) = "P&R filing" or "filed for P&R"*
- *Submission of data to the European Access Hurdles Portal = "submission"*
- *Inclusion of a centrally approved medicine on the public reimbursement list in a country = "available"*
- *The possibility for a patient to receive a medicine after prescription by a Healthcare Professional = "accessibility"*

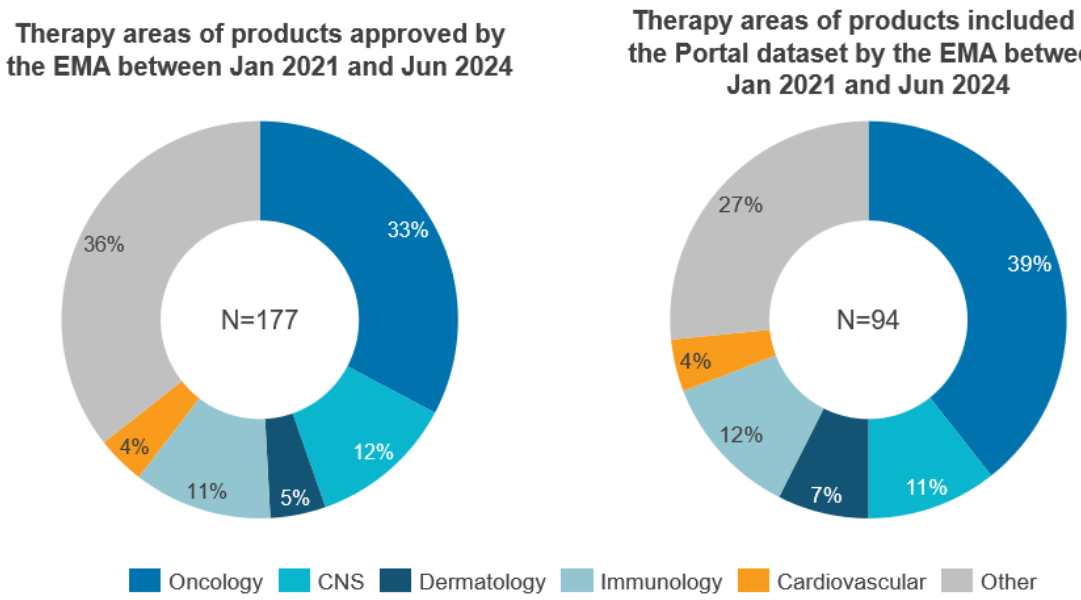
Size and representativeness of the dataset

As expected, both the quantity of the data and the quality of the dataset have improved over the collection periods. In the most recent data collection phase, there has been 100% participation from EFPIA member companies, with all 35 companies with eligible products submitting data to the Portal. As a result, the Portal contains a total of 94 products approved by the EMA between January 2021 and June 2024 in their first indication.

These products represent 53% of the total number of products approved for their first indication by the EMA between January 2021 and June 2024. Within the 94 products, a range of therapy areas are covered, including 36 oncology products (39% of the sample), and there are 27 orphan products (29% of the sample).[9] A comparison of the therapy areas of the 94 products marketed by EFPIA members and the total number of products approved by the European Medicine Agency (EMA) over the same period shows that the distribution of therapy areas in the Portal dataset is similar, suggesting that these products are broadly representative of the types of innovative medicines approved by the EMA from January 2021 to June 2024 (Figure 3).

9 In this report, we focus on the full cohort of 94 products and consider specific trends in the oncology and orphan medicine cohorts (N=36 and N=27 respectively, but note that any oncologic orphan medicines will be counted in both categories). We focus on these therapy areas to understand how the varied market-access landscape may affect therapy areas differently.

Figure 3: The distribution of products by therapeutic area in the Portal



Source: IQVIA – European Access Hurdles Portal (Q1 2021 – Q4 2024)

Completeness of the dataset

Companies were asked to submit data across 30 European countries[10] on the current filing status, reimbursement status and the reasons for any delay in filing for P&R. This report contains data on all 30 countries for all products in the scope of the Portal.

For the purposes of certain analyses in this report, countries included in the Portal have been grouped by geographic location:

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

From the outset it was understood that collecting data on the reason for delays in filing would be challenging. However, for 98**%** of products that have not yet been filed for P&R in a given country, companies were able to provide data on the reason for non-filing. The completeness of this dataset has been high over each data cycle, and this is expected to continue.

10 The EU-27 countries, England, Norway and Scotland

New analysis from the European Access Hurdles Portal

Speed of marketing authorisation

The focus of the Portal is primarily on national P&R processes. However, given that another major root cause of delay preceding the P&R step is the timing of marketing authorisation, it is interesting to first look at any delays at the regulatory approval stage.

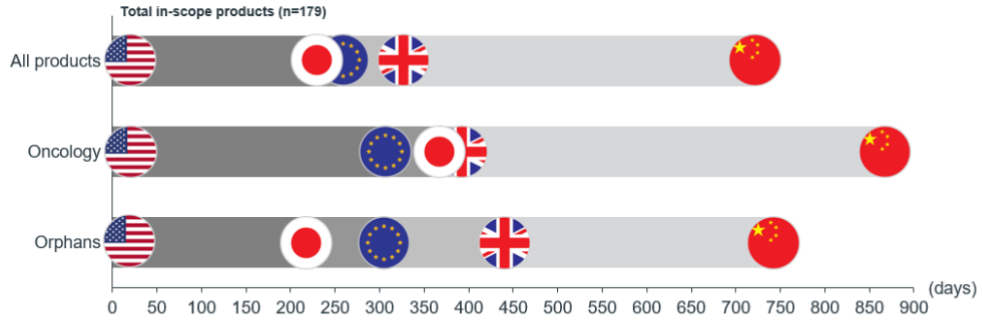
Of all new products approved by international regulators between January 2021 and June 2024, EMA approval came later, on average, than approval in the United States and Japan by 252 days and 24 days respectively (Figure 4). This general trend remains similar to what was observed in last year's report (which looked at new products approved between January 2021 and June 2023); however, the speed of EMA approvals has increased compared to both FDA and PMDA approvals. In the case of PMDA approvals, this is partially driven by a large increase in their time to approval relative to the FDA. Despite the gap between the EMA and other agencies beginning to narrow, regulatory approval still comes at a later stage in Europe than in other regions, especially the United States.[11]

The observed gap for oncology medicines between Europe and the United States is similar to the gap for all products, with EMA approval occurring later, on average, by 303 days. However, EMA approval now comes, on average, 69 days earlier than PMDA approval. This is an improvement from the 2024 Portal report, where EMA approval occurred 373 days and 204 days after the FDA and PMDA respectively.

For orphan products, EMA approval comes 312 days after approval in the United States on average, which is a slight improvement from last year (when it was 365 days after). However, EMA approval comes 95 days after approval in Japan. Compared to last year, this shows that the timing of PMDA approvals has overtaken the timing of EMA approvals for orphan products despite an overall acceleration in the timing of European marketing approvals.

11 The reasons for the later regulatory approval in Europe are not the focus of this report. However, it is likely due to a combination of manufacturers delaying their application for marketing authorisation and a timelier regulatory approval process. This is consistent with the literature and root causes analyses.

Figure 4: Date of EMA approvals relative to the US, UK, Japan, and China for all products approved between January 2021 and June 2024



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

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

Source: IQVIA analysis of EMA, FDA, PMDA, NMPA, MHRA (2025)

The Portal focuses on collecting data between EMA approval and national availability across the EU. Details on three non-EU countries are also included in the Portal: Norway, England, and Scotland.[12] We can observe that in the UK, the Medicines and Healthcare products Regulatory Agency (MHRA) approval comes, on average, 71 days later than EMA approval, which is largely consistent with data from the 2024 Portal report.

12 For the purposes of Portal calculations on time until P&R filing, all calculations are based on EMA marketing approval.

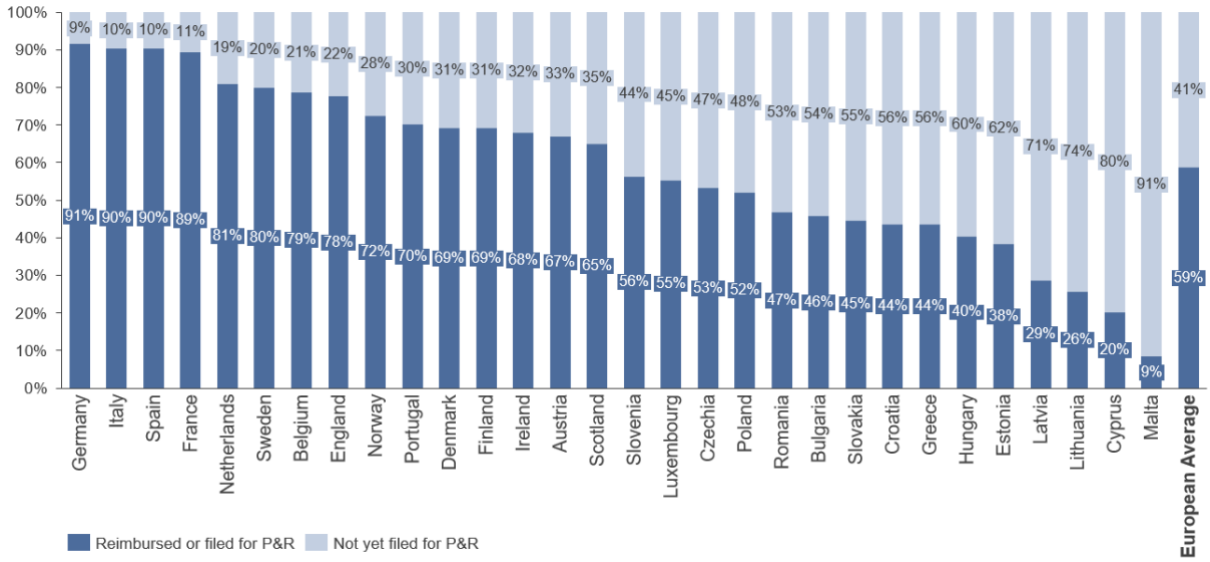
Status of product P&R filing, reimbursement and accessibility through alternative schemes

Before the Portal was established, the data from the annual Patient W.A.I.T. Indicator had already documented availability and delays in product reimbursement following MA. The Portal provides additional granular detail on the status of manufacturer filing for P&R for a product's first indications. We first consider the current evidence on unavailability and delay and then assess how this has changed over time.

The data demonstrate that in many instances of product unavailability (as previously captured in W.A.I.T.), the product has been filed for reimbursement by the manufacturer but has not yet been reimbursed or, in some cases, has been filed and has received a negative decision. Looking at all 94 products included in the Portal to date (which covers products that are on average 25 months post-MA), we find the following:

- On average, across the 30 European countries, the majority (59%) of products have been filed for P&R. Of these,
    - 37% of filed products are pending a reimbursement decision
    - 55% of filed products have been reimbursed, and
    - 7% of filed products have had a negative reimbursement decision or been withdrawn by the manufacturer[13]
- 41% of products have not yet been filed for P&R

Figure 5: Status of product filing for P&R across countries



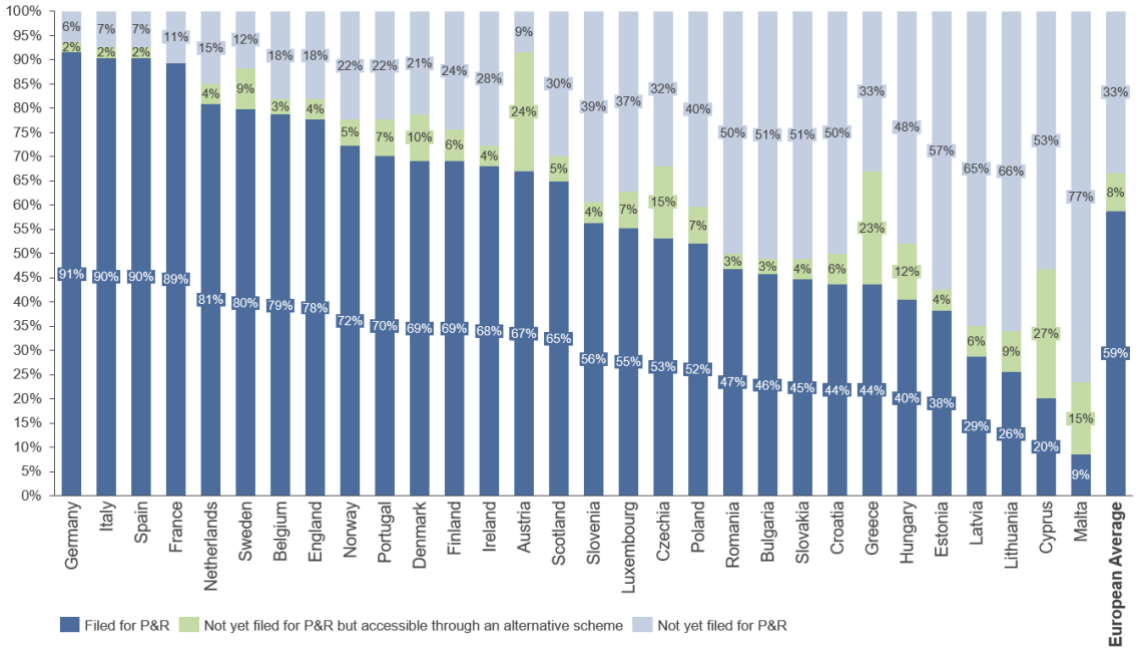
Source: IQVIA – European Access Hurdles Portal (Q1 2021 – Q4 2024)

13 N.B. Numbers do not sum to 100% due to rounding.

As we gain more data in the Portal, the complex interaction between filing, availability and accessibility is becoming more apparent. There is a distinction between products being available (included in the national reimbursement list) and patients having the possibility to access them. It is possible both for products to be available but for patients not to have access to them, and for a product to not be available but for patients to have access to them. The Portal has thrown further light on this issue.

Manufacturers, healthcare professionals and health authorities can enable patient access to innovative medicines through alternative access schemes (AAS), including both early-access programmes and named-patient programmes.[14] Many products in the Portal that have not yet been filed for P&R are accessible to patients through these AAS (Figure 6). The result is that of the 94 products included in the Portal, across the 30 countries, 67% are either reimbursed, filed for P&R or achieve some level of patient access through an alternative scheme. This demonstrates that in the great majority of cases, companies have acted to make their products accessible to patients in the market.

Figure 6: Status of product filing for P&R and accessibility across countries



Source: IQVIA – European Access Hurdles Portal (Q1 2021 – Q4 2024)

Both the rate and relative role of filing, reimbursement and accessibility via AAS differ across Europe. There are, therefore, significant differences in the level of patient access to innovative products between countries and regions. There are countries, such as Germany, Italy and France, where manufacturers have attempted to provide access to 92%–93% of products in the Portal, and largely this is enabled by companies filing for P&R. In other parts of Europe, particularly in Austria, Czechia, Greece, Croatia, Cyprus and Malta, a substantial number of

14 The variation in format and function of alternative access schemes across different European countries is described further in the CRA report "Root causes of unavailability and delay in smaller markets".

medicines are being made accessible to patients through AAS rather than inclusion on the national reimbursement lists. For example, in Austria, 67% of products have been filed for reimbursement and an additional 24% of products are accessible through an AAS. The total proportion of products manufacturers have attempted to make accessible (91%) is similar to that in Germany, Italy and France by result, but is achieved through different means. However, there are also countries where, despite often relatively high use of AAS, there is a lower percentage of products that have either been filed for P&R or been made accessible through an AAS, such as Malta (24%), Lithuania (35%) and Latvia (35%). This variability across Europe indicates that there are factors associated with individual countries that impact whether a product is filed for P&R or made accessible via an AAS; specific challenges associated with filing for P&R in certain smaller markets will be partially explored in this report, but this is expanded on to a greater extent in the CRA report on the root causes of unavailability in smaller markets, which examines the additional root causes of delays and unavailability in nine smaller European markets.[15]

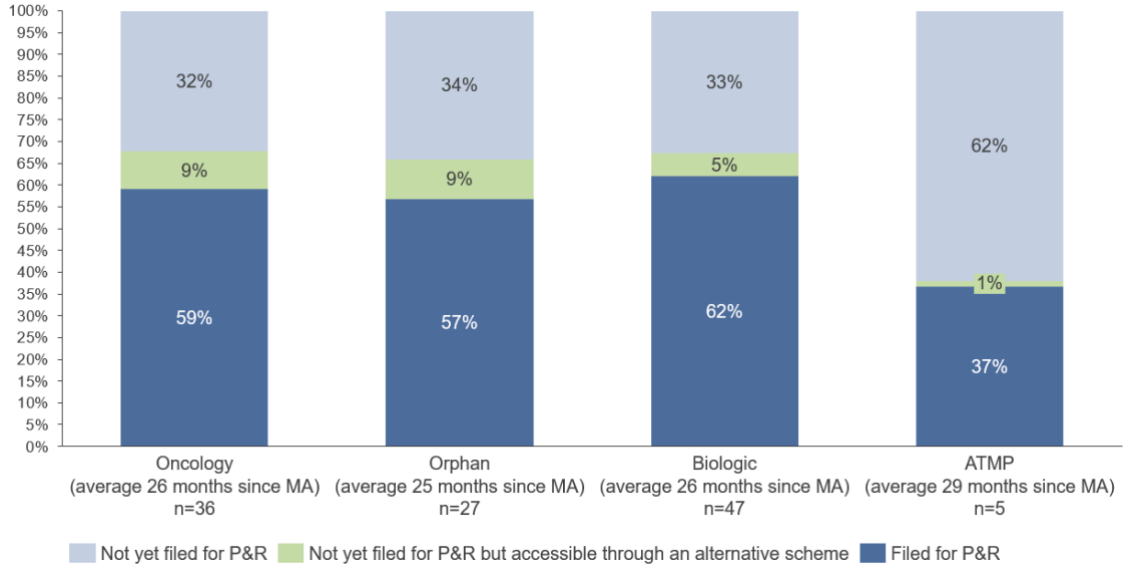
Filing, reimbursement and accessibility through AASs for different therapeutic areas and product types

The Portal also captures data on different types of products. When looking across these products, filing and accessibility rates remain fairly consistent across Oncology, Orphan and Biologic products at 67% after 26 months since MA (Figure 7).[16] A lower overall rate of filing for P&R and accessibility through AAS for ATMP products is observed, consistent with the understanding that there are particular access hurdles for ATMPs that must be addressed in order to enable patient access. However, these results must be treated with caution in the context of the low number of ATMPs included in the Portal. Nonetheless, it is notable that there are relatively low rates of accessibility to ATMPs via AASs; this suggests that these alternative pathways may not be well adapted for this product type or that they cannot address all root causes of unavailability and delay.

15 CRA Root causes of unavailability and delay in smaller markets report, May 2025

16 Note that these categories are not mutually exclusive; for example, orphan oncology products will be counted in both sections.

Figure 7: Average European status of product filing for P&R and accessibility through AAS across therapy areas and product types[17]

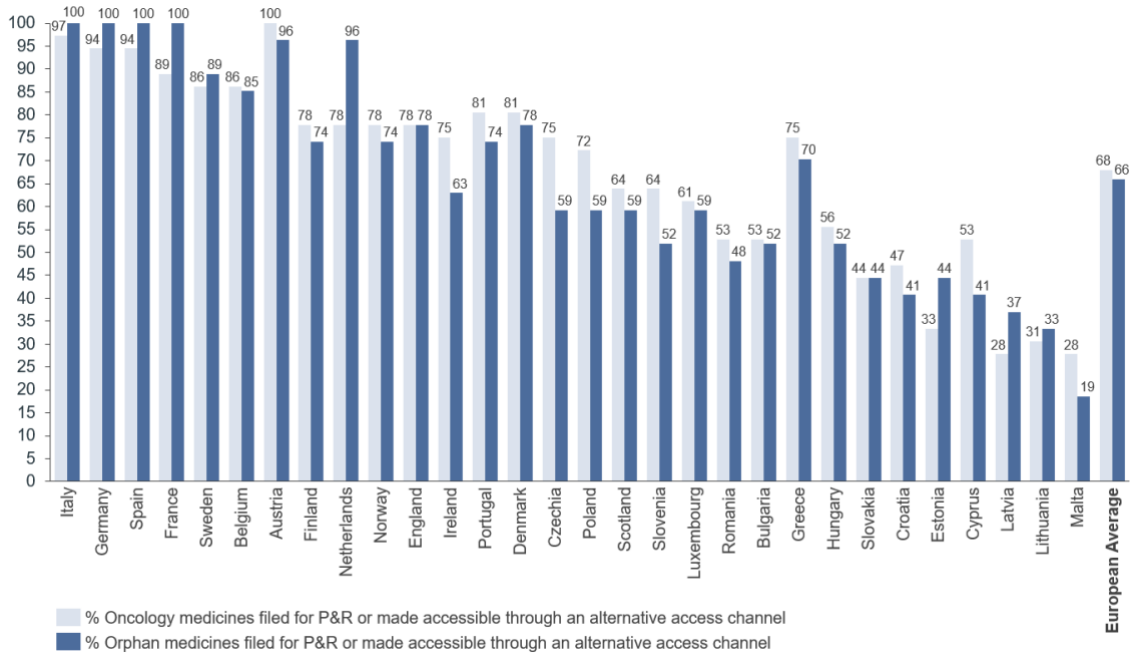


Source: IQVIA – European Access Hurdles Portal (Q1 2021 – Q4 2024)

Although the European average rate of filing for P&R and accessibility through an AAS of the different product types are relatively similar, individual countries vary (Figure 8). Analysis of the difference between orphan and oncology medicines filed or made accessible across countries highlights the between- and within-country variation. In the W.A.I.T. data, we observe orphan medicines facing greater delays in CEE countries and lower rates of reimbursement; however, these data suggest this is largely attributable to the reimbursement process, not a lack of product P&R filings.

17 Note that these categorisations are not mutually exclusive. For example, it is possible for a product to be both an orphan product and an oncology product.

Figure 8: Status of product filing for P&R or accessibility through an AAS across countries (orphan and oncology products only)



Source: IQVIA – European Access Hurdles Portal (Q1 2021 – Q4 2024)

Differences in the rates of P&R filing and accessibility through AAS across product types and therapy areas highlight the difficulty of examining how these trends are developing over time. Over each iteration of the Portal, data will be collected on more products, and the relative composition of the Portal will change as a result. Therefore, the impact of product type and therapy area on P&R filing and accessibility rate must be considered and, as much as possible, controlled for when attempting to determine how rates are changing over time.

Improvements in filing, reimbursement and accessibility through AAS over time

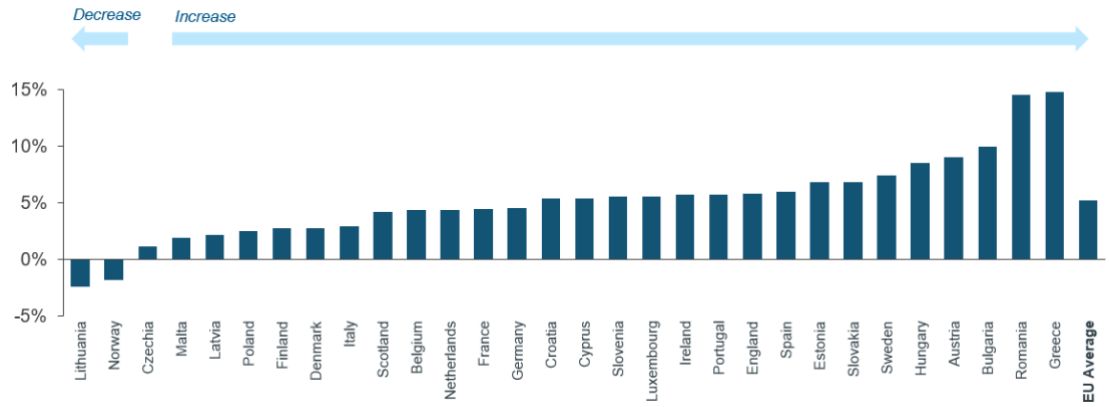
It is expected that as the Portal matures and includes data on products that have had MA for longer periods of time, the number of products that have filed for P&R should increase (assuming that barriers to filing can be overcome over time). However, with each iteration of the Portal, an additional cohort of more recent products is added to the dataset, which have only been authorised for a short period of time and are unique in their characteristics (e.g., different therapy areas and product types). Therefore, it is perhaps not surprising that the overall level of filing and accessibility through an AAS is largely similar to last year's figure (67% vs 66% in last year's Portal report).

To control for this as much as possible, we can follow a particular cohort of products over Portal reports to see if the time since MA impacts filing rate and overall rates of patient access. The 2024 Portal report included analysis of 66 products that received MA between January 2021 and June 2023 and were an average of 20 months post-MA. By analysing these same products

now,[18] at an average of 32 months post-MA, we observe a 5% increase in the average rate of filing for P&R and accessibility through an AAS versus the 2024 report (Figure 9). Interestingly, the percentage of products filed has increased 8%, while the proportion of unfiled products accessible through AAS has slightly decreased over time, from 10% in 2024 to 8% in 2025. This is consistent with the finding that alternative channels can often be used as an interim step to provide access when a product has not yet been filed for P&R or when national authorities are yet to issue a reimbursement decision.

Looking at countries with the biggest changes, the greatest increases occur in Greece and Romania. This is consistent with the fact that in Greece and Romania there are country filing requirements that impede the MAH from filing for P&R until a certain threshold of reimbursement decisions have been made in other countries; the Portal data support that this is a significant factor contributing to delays in these countries. Small decreases in overall accessibility are observed in Lithuania and Norway, but the type of access has changed: although a greater proportion of products have been filed for P&R, fewer products are available through AASs.

Figure 9: Percentage change in status of filing for P&R and accessibility through an AAS across Portal reports (from 20 months post-MA to 32 months post-MA)



Source: IQVIA – European Access Hurdles Portal (Q1 2021 – Q4 2024)

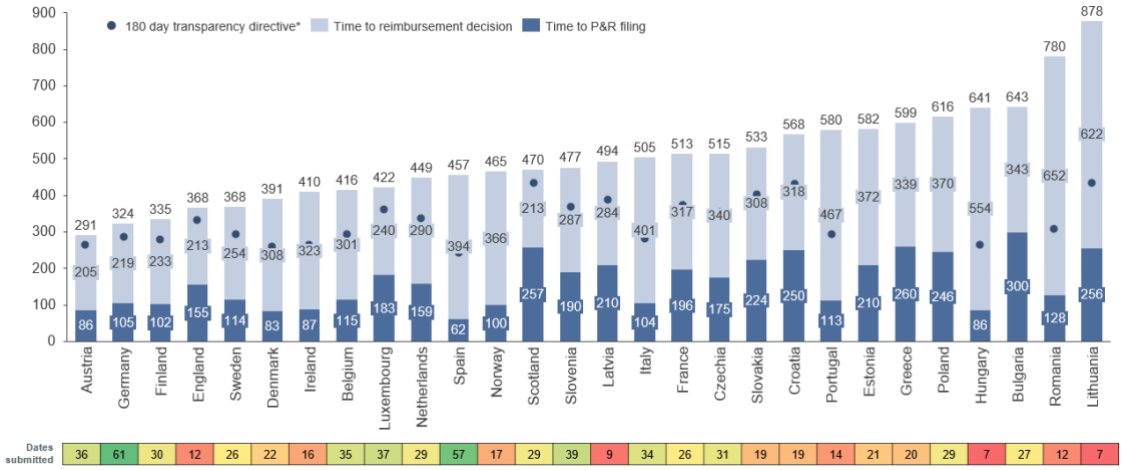
18 One product has been removed from the dataset as it is no longer marketed by an EFPIA company, so the data are being compared with 65 products in this report.

Speed of product P&R filing and reimbursement

The Patient W.A.I.T. Indicator documents the time from EMA approval to availability of innovative medicines.[19] The Portal allows a more granular analysis to understand the respective timings of the different steps within this process. We find that the majority (69%) of the total time between EMA approval and reimbursement is the time taken to reach a reimbursement decision after a product has filed for P&R (Figure 10). This has remained the same across the different cycles of data collected. The remaining 31% is the time taken by manufacturers to file for P&R. In absolute terms, this equates to an average number of 503 days between EMA approval and reimbursement; within this, companies file after 163 days, and the remaining 340 days are spent on the reimbursement decision.

Clearly, this pattern varies across countries. The proportion of total time until reimbursement attributable to the time taken by a company to file for P&R is lowest in Nordic markets (26% or 100 days on average), while in CEE countries, it is 34% (or 207 days on average). The average time taken to reach a reimbursement decision after an application is received is also longer on average in CEE countries (405 days) than in the EU4+UK, Nordic and Western regions (293 days, 290 days, and 304 days respectively).

Figure 10: Days taken to file for P&R and receive a reimbursement decision in relation to total time between MA and reimbursement[20]



Source: IQVIA – European Access Hurdles Portal (Q1 2021 – Q4 2024)

That this result has remained the same, with more products included in the Portal and with a longer period of observation, increases the confidence of these findings. However, there are still

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20 Data are not available for all products in all countries. Where the sample size of products in any given country was less than three (as occurred in Cyprus and Malta), the country's data were removed from the figure. This was done because of the risk of bias in the results from a very small number of products and the risk of de-anonymizing individual products. The data reported for Germany should be interpreted as time to completion of the full national P&R process rather than time to reimbursement because authorised products are immediately eligible for reimbursement in Germany in parallel with the submission and review of the P&R dossier. Time to availability for England and Scotland is based on the time of EMA decisions rather than MHRA decision.

caveats with this analysis. It is based only on the products that have received reimbursement to-date and there are no data on the speed with which accessibility is facilitated through AASs, necessitating a focus on product filing and formal price and reimbursement processes, despite this not capturing the full picture of patient access.

It is also important to note that the phased introduction of the EU Health Technology Assessment (HTA) process from the beginning of this year could impact both the length of time to filing for P&R and reimbursement decisions in the future. Depending on the efficiency of the implementation of the joint clinical assessment (JCA) framework in Europe, this may help to accelerate access in countries that currently face a longer time to reimbursement and reduce the burden of evidence requirements by streamlining processes and reducing duplication across countries with an existing HTA process. Additionally, the length of time to filing for P&R and reimbursement decisions may be impacted in the future by country-level P&R reforms.

Although the Portal focuses on national P&R processes, we should not forget that both the jurisdiction and role of P&R decisions varies by country. Some countries engage in P&R processes at a national level, while others organise these decisions—at least in part—at the regional level, which impacts the timing of reimbursement (and extent of availability) of medicines beyond what can be captured in the Portal.

Root causes of delays in P&R filing

The Portal provides granular data on the reasons why products have not yet been filed for P&R in different countries. Manufacturers have submitted at least one reason for 98% of products that were unfiled at the point of the last data collection; therefore, the analyses in this section describes the root causes that prevented filing *at the time of data collection,* which may or may not continue to prevent filing moving forwards.

In submitting data to the Portal, manufacturers could select from a list of nine root causes, which can be grouped into four distinct categories:

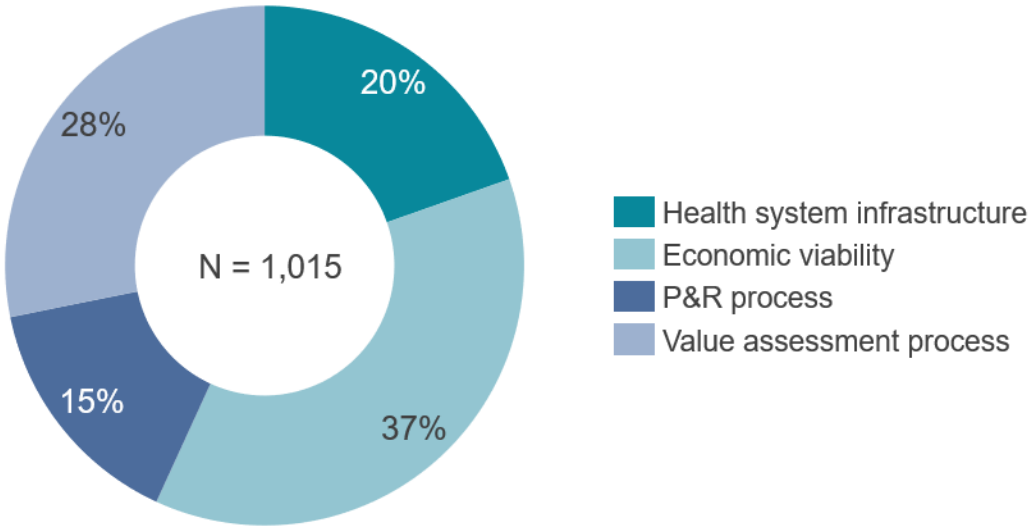
- **Health system infrastructure** (indicated as a reason **190** times), which includes 'lack of required healthcare infrastructure' and 'lack of healthcare funding to support utilization'
- **Economic viability** (indicated as a reason **382** times), which includes 'the size of the treatable population', 'lack of company presence in the local market', and 'the cost of launching is not recoverable'
- **P&R process** (indicated as a reason **147** times), which includes 'country filing requirements' and 'the impact of external reference pricing'
- **Value assessment process** (indicated as a reason **287** times), which includes 'evidence package unlikely to meet country requirements' and 'low value attributed to class competitors'

It is important to note that these categories are not mutually exclusive, as a result of the interconnected nature of root causes of unavailability and delay. For example, the decision to establish a company presence in a market (categorised under 'Economic viability') is likely to be related to the capacity of that market to fund and support utilisation of novel medicines (i.e. 'Health system infrastructure'). Equally, the lack of a company presence in a market may make it harder for that company to overcome certain barriers related to the P&R process and value assessment process, due to the need to operate through third-party distributors. Manufacturers also have the option to select 'Other' (indicated as a reason 413 times) if they believe that the reason for non-filing could not be mapped to any of the above root causes. This partly reflects that the launch environment for innovative medicines is extremely complicated, and decision-making is influenced by a range of indication-, product- and country-specific characteristics. However, it should also be noted that in 60% of cases where manufacturers indicated 'Other' as the reason for non-filing, manufacturers highlighted that there was no specific reason for non-filing or that the company was preparing to file at the point of data collection. In some instances, this may reflect that a product had only recently received MA, and manufacturers were still preparing to file for P&R within their normal operations and there cannot yet be considered a delay at the time of data collection. Since we cannot assign these responses to a specific root cause, we exclude them from the following analyses on the root causes of delays in P&R filing.

Common reasons for non-filing

Looking at the 94 products across all 30 countries included in the database and allowing for the fact that it is possible to submit multiple reasons to explain a product's lack of filing, we have 1,015 responses. Consistent with findings from previous reports, the reasons for delays are multifactorial and are spread across each category (Figure 11), with some categories determined primarily by the external environment and others determined by strategic decisions of the manufacturers. Improving P&R filing rates remains a shared responsibility that will require shared solutions from all stakeholders involved in the many different aspects of the P&R process and the broader access ecosystem. No one party can solve discrepancies in P&R filing rate across Europe; instead there must be collaboration to address these challenges in a holistic manner.

Figure 11: Reasons for non-filing for P&R across all data collection cycles

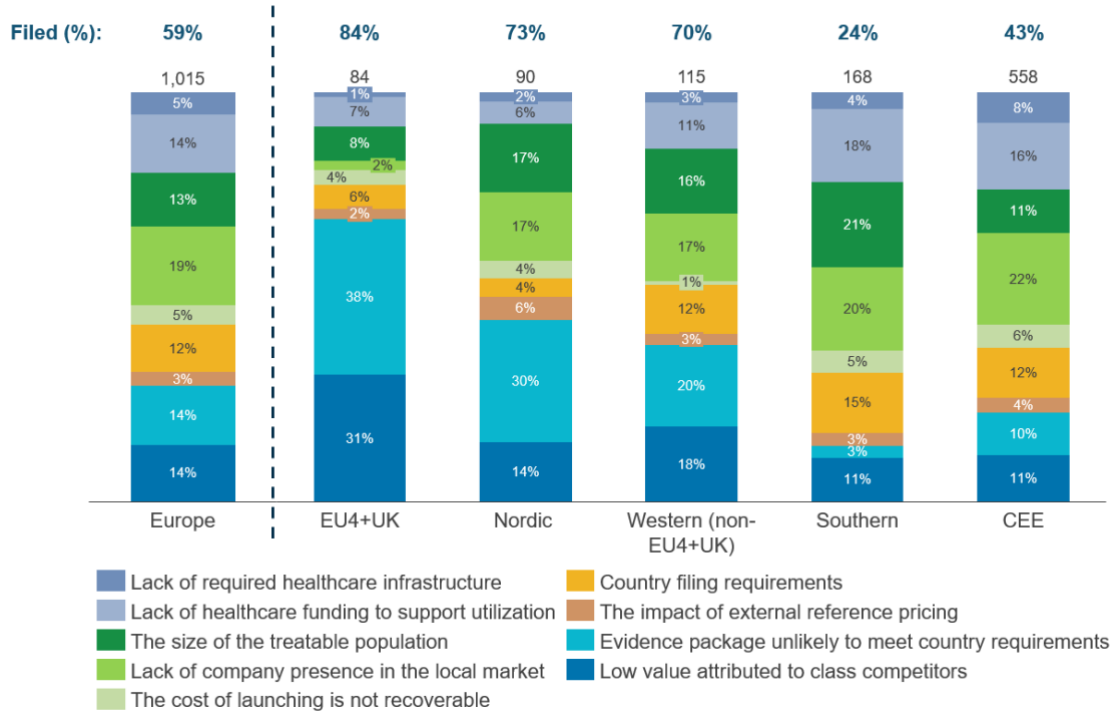


Source: IQVIA – European Access Hurdles Portal (Q1 2021 – Q4 2024)

It is important to note that this analysis is of the root causes affecting only the filing rates *for a product's first indication*; logically, the extent to which the factors affect a company's ability to file for P&R will differ between a first launch and a subsequent indication expansion, but this is not captured in the Portal.

The Portal does collect data on how reasons for delays in P&R filing differ across the different regions of Europe. Root causes of non-filing are relatively similar in CEE and Southern Europe. The root cause for non-filing is largely driven by it not being economically viable for manufacturers. By contrast, in the EU4+UK region, most delays in filing for P&R are related to the requirements of value assessment processes (Figure 12).

Figure 12: Distribution of reasons for non-filing in all countries (excluding 'other' category) by country grouping



Source: IQVIA – European Access Hurdles Portal (Q1 2021 – Q4 2024)

We can also look at the pattern of root causes for non-filing in the countries with the lowest filing rate (Malta, Cyprus, Lithuania, Latvia, Estonia) (Figure 13). In doing so, specific reasons for the delay in P&R filing stand out. Across all these countries, 'lack of company presence in the local market' is a major barrier to filing for P&R. This is supported by findings from the report on root causes in smaller markets,[21] which describes complex, opaque and often bureaucratic P&R systems in many of these smaller markets, which require a level of local expertise to navigate. Furthermore, in Malta and Cyprus, the most common reason for a lack of P&R filing is 'the size of the treatable population', which highlights the difficulties manufacturers face in providing for a country with a population of less than 1 million people. Across these five markets, there is a higher rate of products being made accessible via AASs (12%) compared to the European average (8%); this perhaps suggests that manufacturers are working with payers to secure access by alternative means in the face of greater challenges to filing. Specific root causes that can be overcome through alternative channels will be further investigated later in the report.

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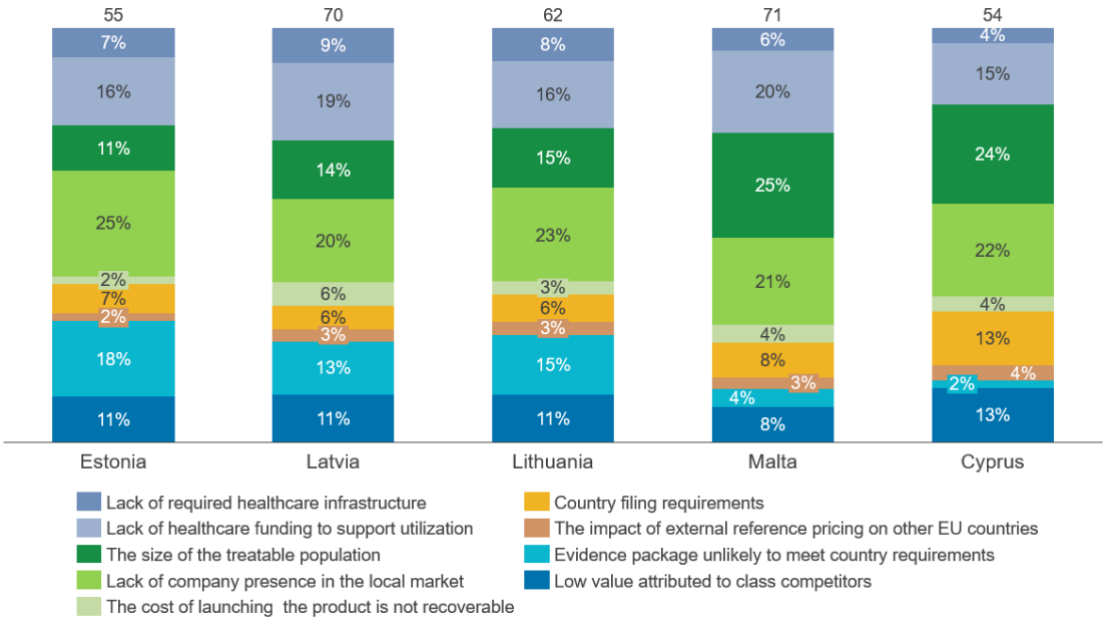
Figure 13: Root causes for non-filing in the five countries with the lowest P&R filing rate



Source: IQVIA – European Access Hurdles Portal (Q1 2021 – Q4 2024)

Taking together the high proportion of alternative channel use, the lower relative rate of accessibility and high number (28% of responses) of 'other' responses for the root causes of non-filing in these countries, there are clearly specific issues affecting smaller markets. Workshops were undertaken with industry experts and have been reported in a separate report.[22] The report finds that in many of these smaller markets there are additional issues associated with transparency, funding and evolving HTA or P&R processes. The Portal could be improved to capture these additional nuanced barriers to filing in future data collection cycles to understand their relative importance and impact on availability.

The impact of company size

We can also look at results for different types of companies (Figure 14). Here, large pharmaceutical companies are identified as those in the top 20 companies in Europe by European sales, and midsize pharmaceutical companies are defined as companies with >€500 million annual European sales but outside the top 20.[23,24] When comparing the average rate of filing for P&R and accessibility through an AAS for large and mid-sized pharmaceutical companies, it is significantly higher (70%) for large pharmaceutical companies compared to mid-

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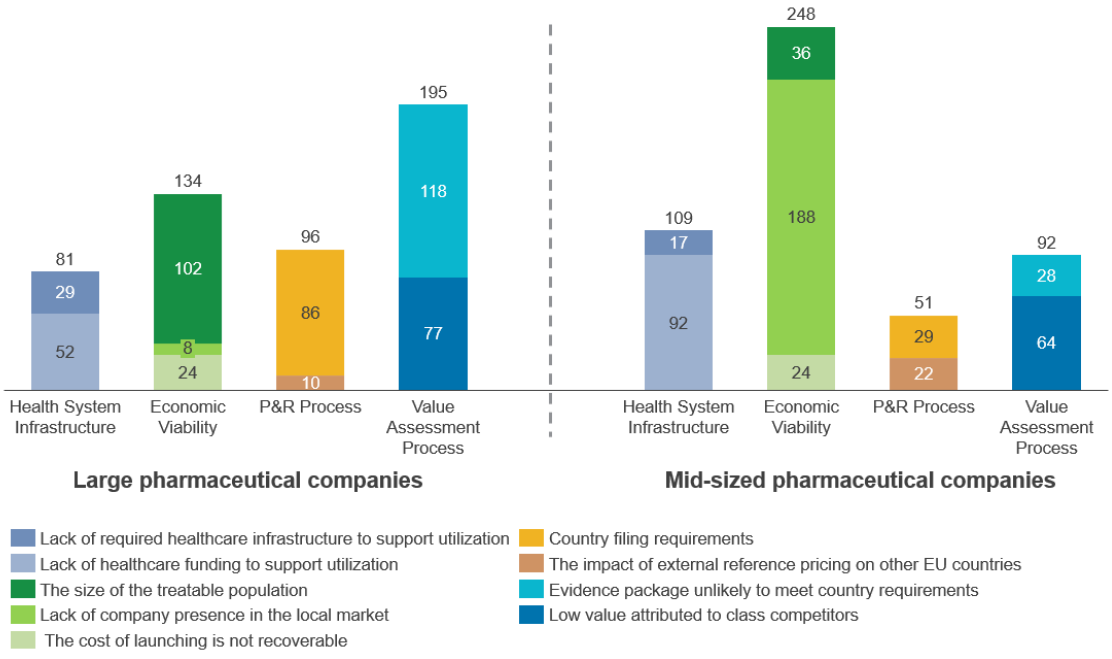
23 Large companies are the MAH of 63 (67%) of products included in the Portal, with a rate of filing for P&R or accessibility via an AAS of 70%; whereas mid-sized and small companies are the MAH of 31 (33%) of products, with an average rate of 59%.

24 Small pharmaceutical companies are defined as companies with <€500 million annual European sales. Only one small pharmaceutical company participated in the Portal, so data have been incorporated into the mid-sized pharmaceutical companies to maintain anonymity.

sized (59%) pharmaceutical companies. This suggests that there are different and significant barriers that mid-sized companies face when attempting to make innovative products accessible.

We can distinguish between the reasons for delays in P&R filing for products marketed by large pharmaceutical companies and for midsize and small pharmaceutical companies. For large companies, as before, the root causes are fairly evenly distributed, with the most commonly cited reasons relating to the requirements of the value assessment process. However, looking at mid-sized companies, the predominant factors relate to the economic viability of the decision to launch. We find that the reason many products in the Portal had not yet been filed for smaller companies was a lack of company presence in the market. However, it is also notable that the next-most-commonly cited reasons for a delay in filing for midsize companies relate to the lack of healthcare funding and the size of the treatable population in a given country. This is consistent with the conclusion that the root cause of delays is usually a combination of factors, including the external environment and its impact on internal decision-making and resource allocation within companies.

Figure 14: Total number of reasons for non-filing by company size



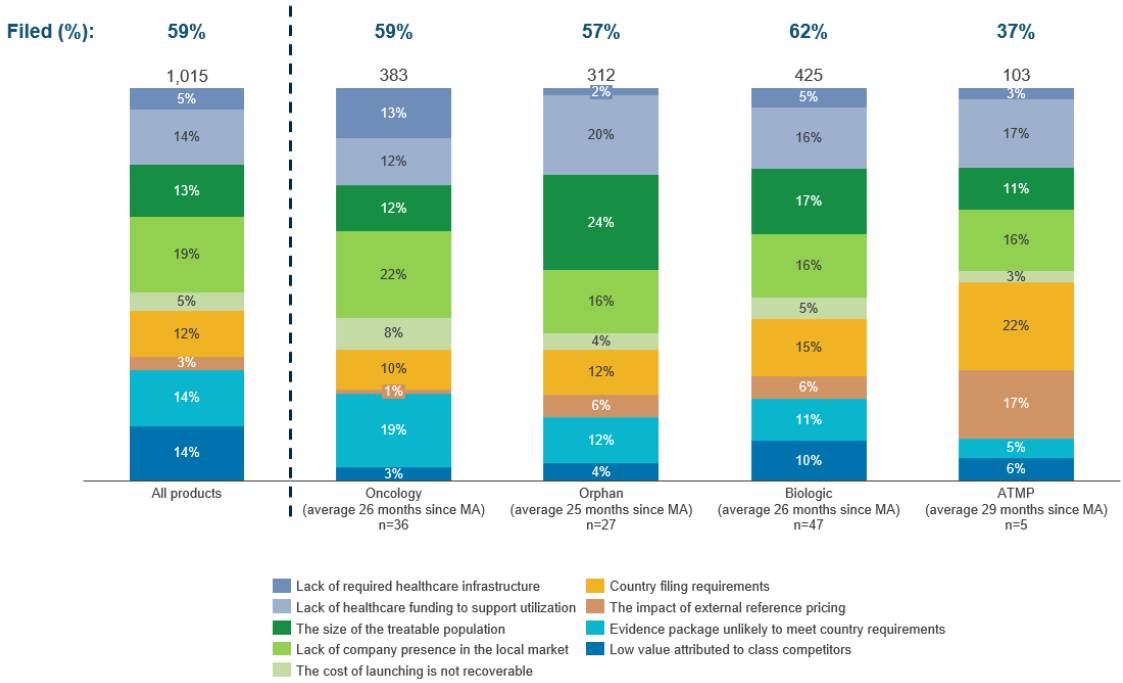
Source: IQVIA – European Access Hurdles Portal (Q1 2021 – Q4 2024)

Trends across therapy areas and product types

In previous reports on the results from the Portal we have focused on aggregate results across therapy areas and product types. For the first time, we can also look at indicative results for different product types (Figure 15). We can distinguish between the reasons for delays in P&R filing for oncology, orphan, biologic and ATMP products, with the caveat that these are not mutually exclusive (some products are both orphan and oncology for example), there are different sample sizes, and average time since MA varies across the product types. For oncology products, 'lack of company presence in the local market' and 'evidence package unlikely to meet country requirements' are the most cited reasons for non-filing, perhaps reflecting a more complex filing

process for these types of product. Whereas, looking at orphan products, 'the size of the treatable population' is the biggest barrier to filing, suggesting the intrinsic challenges facing products with very small number of patients, and that the processes some countries have in place to address the lower eligible patient populations for orphan medicines are not always effective. Reasons for non-filing for biologic products are largely in line with the trends for all products, suggesting there may not be specific challenges associated with filing these product types. This is a striking contrast with ATMPs, for which the most commonly cited reasons for non-filing are related to a country's P&R system, perhaps indicating that P&R processes have not yet adapted to these new types of product. However, data on ATMPs are based on a much smaller sample size than other product types or therapy areas.

Figure 15: Distribution of reasons for non-filing across all countries (excluding the 'other' category) by product type



Source: IQVIA – European Access Hurdles Portal (Q1 2021 – Q4 2024)

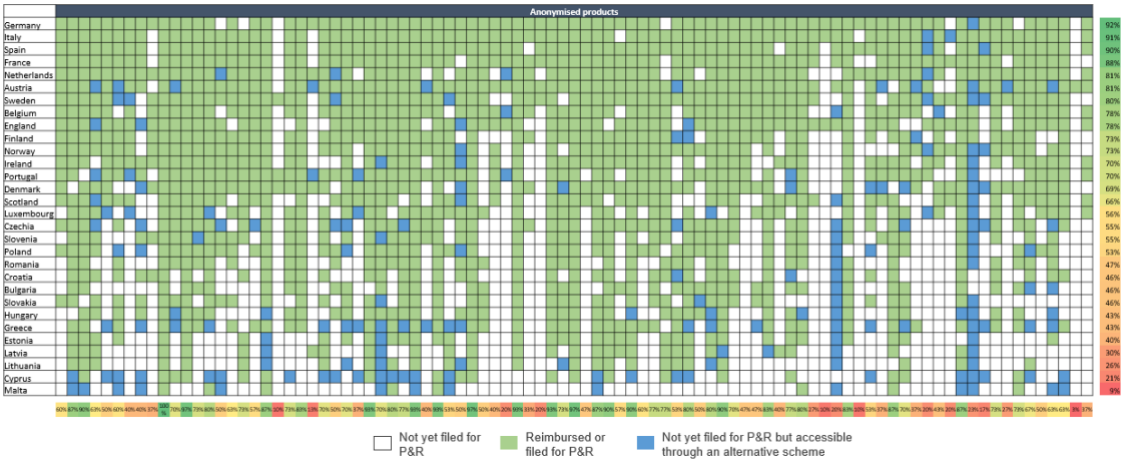
Product-country interaction

Alongside the established differences in reasons for non-filing for P&R across different types of product and countries, there remains a great deal of variation (Figure 16). This suggests a specific product–country interaction, whereby certain features of a country's P&R system may be less suited to a particular product. Some individual products have a filing rate above the European average for all products included in the Portal but have not been filed in high-filing countries such as France and Germany. Whereas other products have a lower level of filing across Europe but have been filed in smaller markets such as Cyprus.

In the results for this cycle, we have included accessibility via an AAS. It is also interesting to note that the frequency of use of alternative channels to provide access seems to be dictated by both the individual county, as noted previously, but also the product type. This clustering of alternative access scheme 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 schemes provide a vital route for patient access.

Figure 16: Anonymised distribution of product filing and accessibility across countries



Source: IQVIA – European Access Hurdles Portal (Q1 2021 – Q4 2024)

Alternative access schemes

Analysis of the root causes for non-filing can help provide insights on how to improve filing rates for innovative medicines. However, as highlighted throughout the report, when a product has not yet been filed for P&R this does not mean that patients cannot have access to it through an alternative access scheme.

Interestingly, the distribution of reasons for non-filing across regions is markedly different on the basis of whether a product is unfiled but accessible through an AAS or unfiled and not accessible (Figure 17). Across all regions, products that are prevented from filing due to 'the size of the treatable population' are more likely to be made accessible through AASs. Similarly, 'evidence package unlikely to meet country requirements' occurs more frequently in products accessible through an AAS in EU4+UK, Nordic and Western (other) regions. On the other hand, 'lack of company presence in the local market' is more likely to be a reason preventing filing for a product that is not accessible (in other words, lack of company presence is a barrier to both filing and use of alternative channels). This suggests alternative channels can help mitigate the barriers to filing for some products but are not a panacea. This is further explored in the CRA smaller markets report,[25] which outlines how alternative access schemes in countries such as Malta and Cyprus offer viable routes for access when barriers associated with the standard P&R process would likely prevent reimbursement and subsequent availability.

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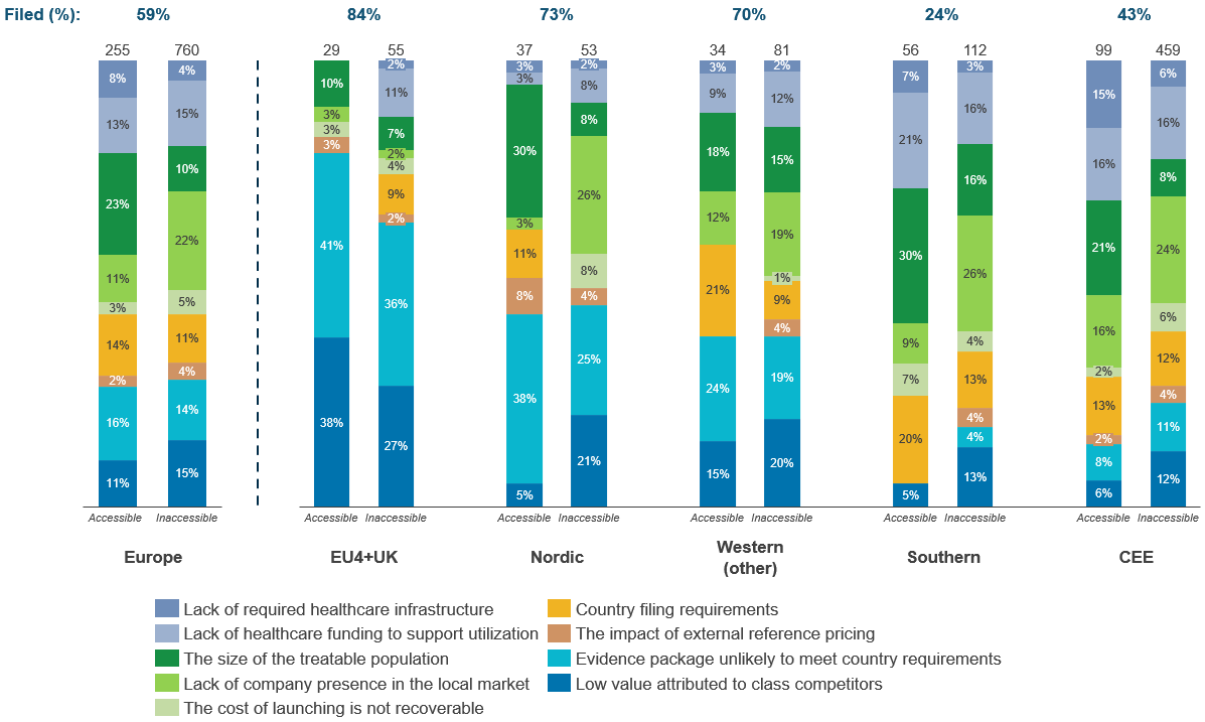
Figure 17: Distribution of root causes for non-filing in products that are accessible (via alternative access schemes) and inaccessible, by region



Reviewing the impact of industry's Commitment to File

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 two years from the central EU market authorisation, provided that local systems allow it.[26]

Over time the Portal will be able to provide insight into the role of EFPIA members' Commitment to File and specifically on where local systems do not currently permit filing within two years. Currently, it is still early to make this assessment; as has been noted throughout this report, there are issues—truncation of data, the composition of products (with regards to therapy area, product type and time since MA) changing with each iteration of the Portal, and the impact of individual country circumstances—that make it very difficult to understand any impact of either the CTF or time on the likelihood of a product having been filed for P&R. However, an initial analysis is possible.

The CTF was made in April 2022; therefore, it is helpful to compare a cohort of products that received their MA before and after this point and investigate their filing rate at approximately two years post-MA. Within the Portal, only 33 products received their MA before the CTF, while 61 products have received their MA since the CTF was announced. However, to measure any impact of the CTF, and to control as best as possible for time since MA, we can only examine a subset of the post-CTF cohort, resulting in 22 products, which have had MA for at least two years. The filing status of the 33 products pre-CTF at an average of 29 months post-MA can be compared with the filing status of 22 products post-CTF at an average of 28 months post-MA (Figure 18; Figure 19). Comparing these two cohorts, it can be seen that the rate of efforts by manufacturers to make innovative products accessible is the same, at 71%. However, there are differences in the composition, with a greater number of products made accessible through an AAS in the post-CTF cohort and a greater number (28% vs 22%) filed but not yet reimbursed, which could reflect changes in the composition of products or perhaps indicate that manufacturers are trying harder to make their products accessible.

26 EFPIA (2022) Addressing patient access inequalities in Europe. Available at: https://www.efpia.eu/media/636830/addressing-patient-access-inequalities-in-europe.pdf

Figure 18: Status of P&R filing and accessibility across countries for 33 products at an average of 29 months post-MA that received MA pre-CTF

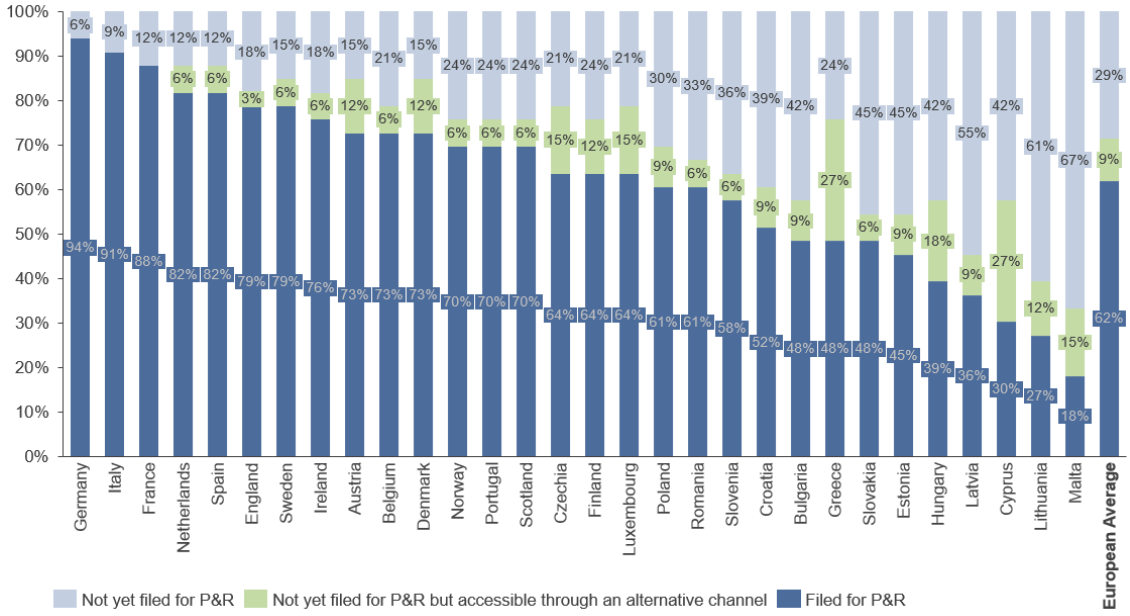
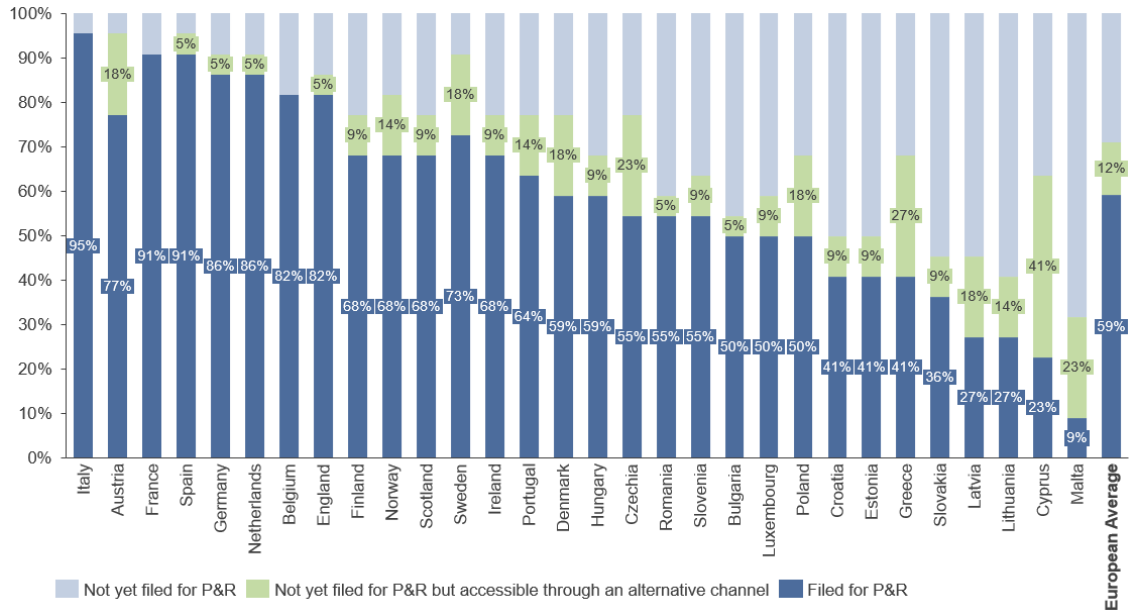


Figure 19: Status of P&R filing and accessibility across countries for 22 products at an average of 28 months post-MA that received MA post-CTF

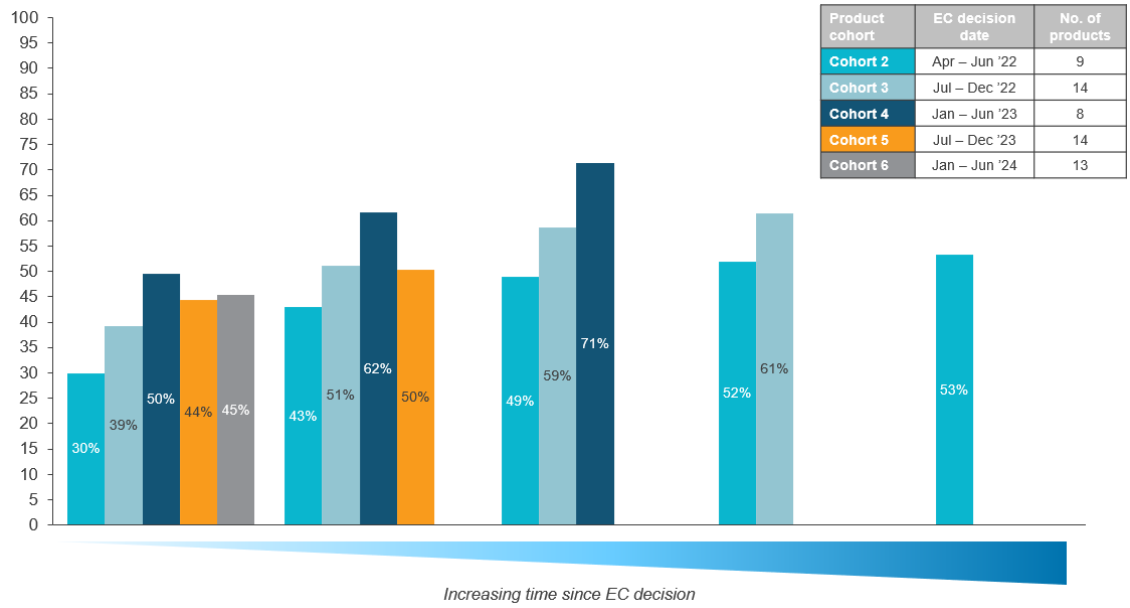


Source: IQVIA – European Access Hurdles Portal (Q1 2021 – Q4 2024)

We can also consider a cohort-based approach to analyse changes over time. This may be useful as, although EFPIA members made the CTF in April 2022, it is likely that some of the changes manufacturers needed to put in place to facilitate increased speed of filing for P&R would require time to implement. The evidence shows that there are differences in the speed of filing of different cohorts of products that achieved their MA after the CTF (Figure 20). Although based on a relatively small number of observations, this suggests that the speed at which products are filing

for P&R initially is increasing as more time passes from the CTF, perhaps reflecting the success of manufacturers putting systems in place to facilitate earlier filing. Cohort 5 would appear to be the exception to this trend, but this may be explained by the increased number of oncologic products (57% vs an average of 40% for all other post-CTF cohorts).

Figure 20: Average filing rate across all post-CTF product cohorts over time

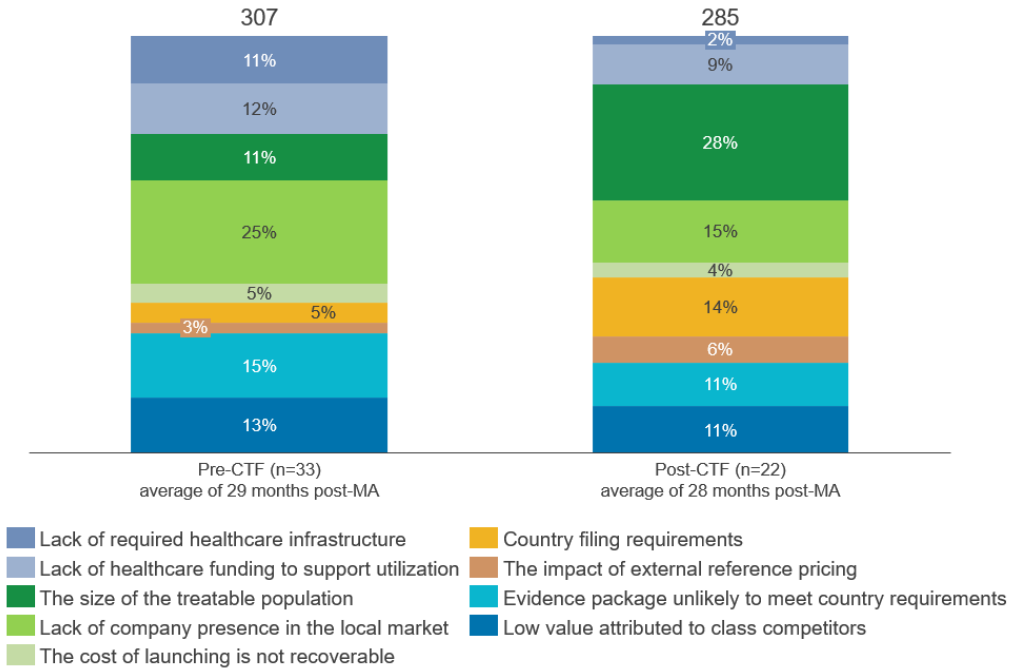


Product cohort	EC decision date	No. of products
Cohort 2	Apr – Jun '22	9
Cohort 3	Jul – Dec '22	14
Cohort 4	Jan – Jun '23	8
Cohort 5	Jul – Dec '23	14
Cohort 6	Jan – Jun '24	13

Source: IQVIA – European Access Hurdles Portal (Q1 2021 – Q4 2024)

Analysis of the change in root causes for non-filing between the pre- and post-CTF cohorts at ~two years post-MA also supports that manufacturers are attempting to address barriers to filing that are within their control (Figure 21). Comparing the reasons for non-filing, there is a significant decrease in 'lack of company presence in the local market' as a barrier for non-filing. 'The size of the treatable population' has become more salient since the CTF; however, as set out above, this can be addressed by AASs in some markets. 'Country filing requirements' has also increased proportionally as a barrier for non-filing since the CTF; addressing this requires changes in local systems' P&R policies and further highlights the need for collaborative solutions between manufacturers and national authorities to overcome barriers to access.

Figure 21: Distribution of root causes for non-filing products in the pre- and post-CTF cohort



As we have more information from the Portal it is possible to segment the products into different categories. And the assessment of the role of the CTF should track how these groups change over time. For example, if a product is not filed for P&R within two years of receiving its MA, there are a number of different possibilities:

- **A product is unfiled because it is unnecessary to file to obtain access:** In some countries, such as Malta and Greece, filing for P&R is not necessary to provide widespread patient access for a product.
- **A product is unfiled because local requirements make it difficult or impossible for the MAH to file:** In countries such as Greece, MAHs are prohibited from filing for reimbursement until a product has been reimbursed in a pre-defined number of other countries, while in other smaller countries, more unofficial requirements for local data or reimbursement outcomes in larger markets mean that earlier filing by the MAH may reduce the likelihood of a successful reimbursement outcome.
- **A product is unfiled because features of the local system make it impractical for the MAH to file:** When the P&R system or value assessment system of a given country is either non-transparent, under-resourced or employs criteria that reduce the chances of a successful outcome, MAHs are dissuaded from investing in the necessary preparations to file for P&R.
- **A product is unfiled because it is unsustainable for the MAH to file:** In some countries, especially those with unsustainable pricing rules, use of cost-containment practices such as clawbacks, or unpredictable budget allocation, the MAH may believe that filing for and achieving reimbursement is not viable.

These themes are especially important for smaller markets, where there is a significantly lower rate of filing and accessibility through AAS compared to larger Western markets. They are

explored in more depth in the new CRA report on root causes of unavailability and delay in small markets.[27] This suggests that in order to improving filing, reimbursement and accessibility to innovative products across Europe, manufacturers and national authorities will need to work together to develop shared solutions which address the issues in the local systems that are currently preventing patient access and which are tailored to the issues experienced by different groups of countries.[28,29]

Finally, it is still early to assess the impact of the CTF. There are limitations in the Portal data which make it difficult to soundly examine how filing rates can change over time. For example, we have established that filing rate can be impacted by time since MA and product type, which cannot be fully controlled for across the pre- and post-CTF cohorts. Although the Portal now contains products that have been on the market for two years since the CTF, this is only a small sample size of 22, making it difficult to draw strong conclusions.

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28 CRA Root causes of unavailability and delay in smaller markets report, May 2025

29 CRA Root causes of unavailability and delay report, May 2025

Future direction of the Portal

The data collected in the Portal will continue to mature as more cycles of data are collected. This will allow continued validation of these results and a more detailed look at underlying root causes and how this varies by type of product (while protecting the confidentiality of data on individual products).

There is a continued need to refine and optimise the data collection process. As has been noted previously, we cannot always identify the reasons for a delay in filing for specific products, as 'other' is frequently selected. In this most recent data collection cycle, a total of 416 responses submitted were 'other'. In 55% of cases, 'other' was elaborated by manufacturers as 'delayed filing'. This describes circumstances where companies were preparing to file at the time of data collection but had not yet filed. This is a significant reduction compared to the Portal's earlier cohorts, but it remains important to continually refine the collection of the data to decrease the selection of 'other' as a main rationale for non-filing. The smaller markets report provides useful insights into how this can be achieved.

Furthermore, in the current version of the Portal, manufacturers can select multiple reasons for non-filing but cannot distinguish between the level of impact each of these reasons has had on any decisions; future iterations of the Portal could address this to better understand the relative salience and impact of different reasons for non-filing.

Data from biosimilars were absent in this round of data collection, which made it impossible to draw conclusions about challenges experienced by innovative products compared to biosimilars. Data were collected only from EFPIA members, which limited the ability to draw conclusions about the impact of company size on product availability and reduced the size of the sample that could be analysed.

As more data are collected, we will be able to conduct more detailed analyses while protecting the confidentiality of data on individual products. This should provide more insights into the root causes of unavailability and delay, how they vary across European countries, and how they are changing over time.

Appendix

Appendix Table 1: Products with information submitted into the Portal (n=94)

Corporation name	Medicine name	Corporation name	Medicine name
Abecma	Bristol Myers Squibb	Nexviadyme	Sanofi
Adtralza	LEO Pharma	Ngenla	Pfizer
Akeega	Janssen-Cilag	Obgemsa	Pierre Fabre Medicament
Aquipta	AbbVie	Omjjara	GlaxoSmithKline
Awiqli	Novo Nordisk	Omvoh	Eli Lilly
Bekemv	Amgen	Opdualag	Bristol Myers Squibb
Bimzelx	UCB	Orserdu	Menarini
Breyanzi	Bristol Myers Squibb	Padcev	Astellas
Bylvay	Ipsen	Pluvicto	Novartis
Camzyos	Bristol Myers Squibb	Ponvory	Janssen-Cilag
Carvykti	Janssen-Cilag	Qalsody	Biogen
Cibinqo	Pfizer	Quviviq	Idorsia
Columvi	Roche	Rayvow	Eli Lilly
Ebglyss	Almirall	Retsevmo	Eli Lilly
Ebvallo	Pierre Fabre Medicament	Rybrevant	Janssen-Cilag
Elfabrio	Chiesi	Rystiggo	UCB Pharma
Elrexfio	Pfizer	Saphnelo	AstraZeneca
Elzonris	Menarini	Scemblix	Novartis
Emblaveo	Pfizer	Skyclarys	Biogen
Enhertu	Daiichi Sankyo	Sogroya	Novo Nordisk
Enjaymo	Sanofi	Sotyktu	Bristol Myers Squibb
Enspryng	Roche	Spevigo	Boehringer Ingelheim
Evrenzo	Astellas	Sunlenca	Gilead
Evrysdi	Roche	Tabrecta	Novartis
Fabhalta	Novartis	Talvey	Janssen-Cilag
Filspari	Vifor	Tavneos	Vifor

Fruzaqla	Takeda	Tecvayli	Janssen-Cilag
Hemgenix	CSL Behring	Tepkinly	AbbVie
Imjudo	AstraZeneca	Tepmetko	Merck & co
Inaqovi	Otsuka	Tezspire	AstraZeneca
Inrebic	Bristol Myers Squibb	Tibsovo	Servier
Jaypirca	Eli Lilly	Tofidence	Biogen
Jemperli	GlaxoSmithKline	Trodelvy	Gilead
Kapruvia	Vifor	Truqap	AstraZeneca
Kerendia	Bayer	Vabysmo	Roche
Kesimpta	Novartis	Vanflyta	Daiichi Sankyo
Klisyri	Almirall	Velsipity	Pfizer
Koselugo	AstraZeneca	Veoza	Astellas
Krazati	Bristol Myers Squibb	Verquvo	Bayer
Litfulo	Pfizer	Vumerity	Biogen
Livtencity	Takeda	Vydura	Pfizer
Lumykras	Amgen	Vyepti	Lundbeck
Lunsumio	Roche	Wegovy	Novo Nordisk
Lupkynis	Otsuka	Wezenla	Amgen
Lyfnua	MSD	Xenpozyme	Sanofi
Mounjaro	Eli Lilly	Xofluza	Roche
Nexpovio	Menarini	Zilbrysq	UCB

Appendix Table 2: Data collection cycles

Product cohort (data version)	MA period	All products	Date of data collection
Cohort 1 (v6)	Jan 2021 – Dec 2021	52	Oct 2024 – Jan 2025
Cohort 2 (v5)	Jan 2022 – Jun 2022	28	Oct 2024 – Jan 2025
Cohort 3 (v4)	Jul 2022 – Dec 2022	29	Oct 2024 – Jan 2025
Cohort 4 (v3)	Jan 2023 – Jun 2023	15	Oct 2024 – Jan 2025

Cohort 5 (v2)	Jul 2023 – Dec 2023	25	Oct 2024 – Jan 2025
Cohort 6 (v1)	Jan 2024 – Jun 2024	28	Oct 2024 – Jan 2025