European Access Hurdles Portal:

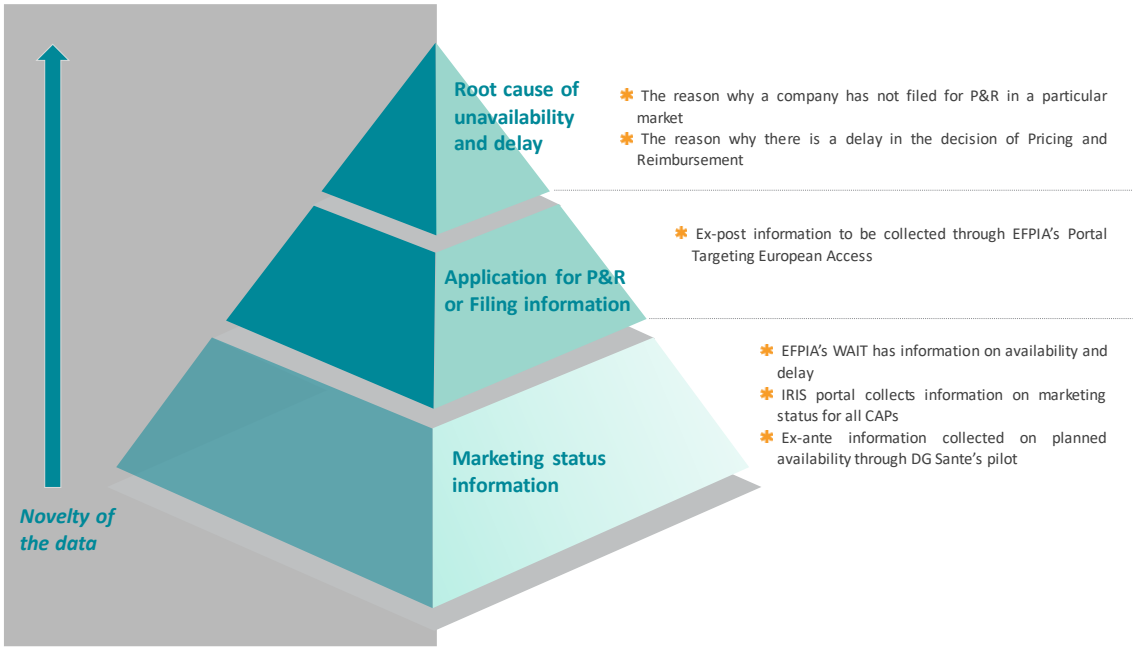
Results from the second year of data collection

June 2024

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.

Figure 1: New information on unavailability and delay



This is the second report using evidence from the Portal. The evidence now includes data collected on medicines that received marketing authorisation in their first indication between January 2021 and June 2023.[1] The data have matured over the past year, which allows us to validate the results from the first report and undertake more granular analysis.

We find the following:

- There is a commitment to providing more transparency on the root causes of unavailability and delay, with 100% of EFPIA member companies participating in the Portal and submitting data on 100% of their products that were approved between January 2021 and June 2023 (representing just over one-half of all products approved by the European Medicines Agency (EMA) in this period). This represents a significant increase compared to last year.
- The Portal shows that in most instances of product unavailability (as captured in the Patient W.A.I.T. survey), the products have been filed for reimbursement but have not yet been reimbursed. Looking at all products in this period (which covers products that are on average 20 months post-marketing authorisation), we find the following:
    - Taking an average across European countries, 56% of products have already been filed for P&R.
    - Of these filed products, 45% have been reimbursed and 49% are pending a reimbursement decision. The remainder (7%) of filed products have had a negative reimbursement decision or been withdrawn by the manufacturer.[2]
- While 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. Although the Portal contains products that have been on the market for different lengths of time, across products that have been successfully reimbursed, 29% of the total time between marketing authorisation and availability can be attributed to the time between marketing authorisation and P&R filing, while 71% is attributable to the time between P&R filing and P&R decisions at the country level.
- In a significant number of instances, patients have access to products that have not yet been filed for P&R because manufacturers and health authorities have made them available through early-access programmes (EAPs) or compassionate-access programmes (CAPs). On average across European countries, 66% of products have

1 The data collection phase consisted of four cycles. In cycle 1, data were initially collected on products with marketing authorisations between January and December 2021 (the data were collected during Q2 2022). In cycle 2, data were collected on products with marketing authorisations between January and June 2022 (the data were collected during Q4 2022). Cycle 3 data were collected on products with marketing authorisations between July and December 2022 (the data were collected during Q2 2023). In cycle 4, data were collected on products with marketing authorisations between January and June 2023 (the data were collected during Q4 2023). During each cycle, updated data for products with marketing authorisations in earlier periods were collected. This report analyses the first four cycles of data collected in the Portal. The Portal aims to cover all EU centrally approved products, both innovative medicines in their first indications and biosimilars, that have been or will be granted marketing authorisation in Europe between January 2021 and June 2023.

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

either been filed for P&R or made available to patients through an alternative access scheme.

- The percentage of products that have been filed for P&R varies significantly across European markets; the percentage is higher in larger markets than in smaller markets, particularly (as to the latter) in Central and Eastern Europe.
- As set out in the CRA root causes analysis, evidence from the Portal supports that delays in both P&R filing and P&R decision-making are multifactorial. The most recent analysis shows an even spread across the main categories of root causes (health system infrastructure, economic viability, P&R 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 and value associated to class competitors, while, unsurprisingly, lack of geographical footprint is a significant issue for midsize companies.
- We have also begun to look at what determines whether filing rates increase over time. To understand how filing rates change over time, we will need to allow for the changing composition of the Portal (and for different types of products having different filing rates and lengths of time since marketing authorisation, and for some products reaching a ceiling in terms of filing—the root causes appear to persist).

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 531 days**;** the times range from 126 days to 990 days**.**[3]

To explain this, EFPIA, over the past four years, has documented the drivers of delays and unavailability (defined as length of time from European marketing authorisation (MA) to availability at member state level)—key issues affecting patient access to innovative medicines. This work has been published alongside the long-established Patient W.A.I.T. analysis. The evidence reveals significant differences across countries in the number of products available at any given time and the length of time it takes for these products to become available. The analysis has gone further than in the past in setting out the multiple root causes of unavailability and delayed access and summarising five categories and ten root causes.[4]

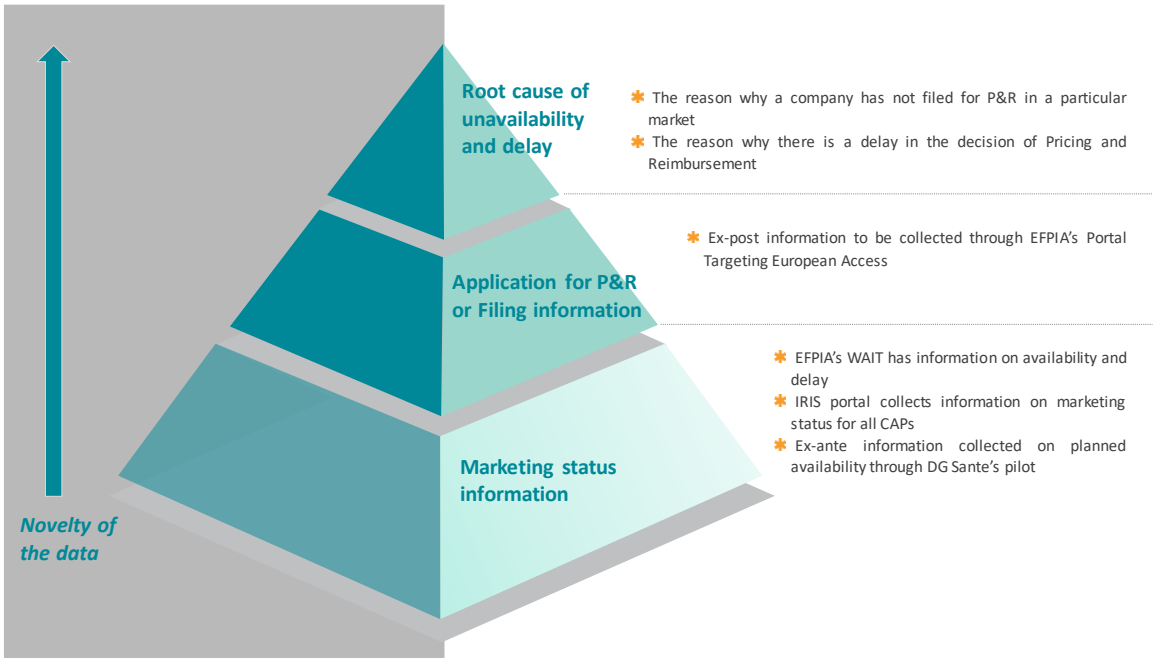
Throughout 2021, the industry investigated whether additional transparency regarding the causes of delays would be valuable to help people further understand those causes and how they vary across products and countries.[5] This investigation involved working with companies with respect to information that could be made publicly available and a multi-stakeholder consultation on the types of data that would be valuable in the debate about the availability of innovative medicines (Figure 2).

3 EFPIA Patients W.A.I.T. Indicators 2023 Survey, May 2024

4 CRA Root Causes of unavailability and delay report, May 2024

5 Of these potential root causes, the Portal focuses on four categories: the speed of the regulatory process, the price and reimbursement process, the value assessment process, and health system readiness.

Figure 2: New information on unavailability and delay

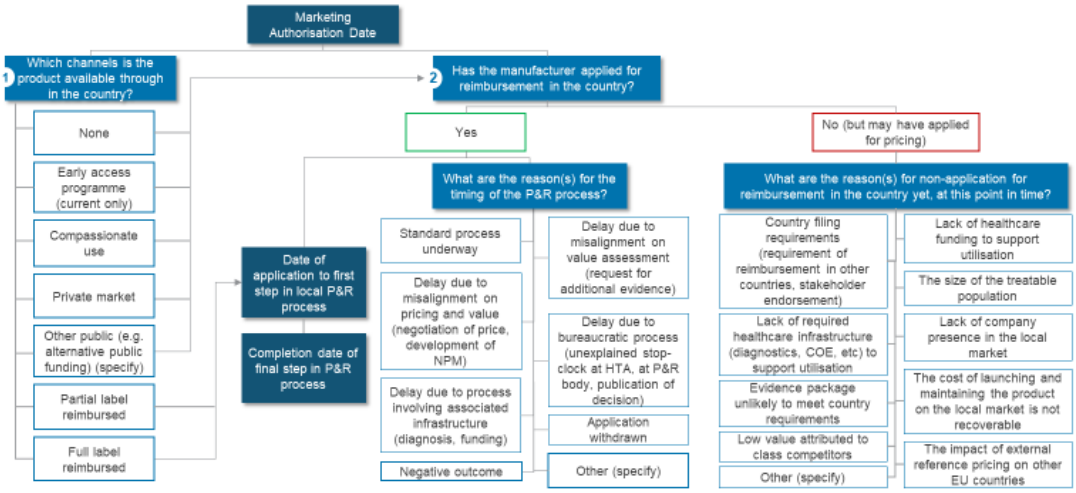


In this context, in April 2022, EFPIA and its members made a series of commitments to reduce disparities in access across Europe. To support transparency and the identification of the root causes of delayed filing and reimbursement, one of those commitments was the creation of the European Access Hurdles 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. The initial results, which included data from the first year of the Portal, were published in April 2023. This document 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 3. The Portal does not report data for individual products but rather describes trends based on analysis of aggregated, anonymized results.

Figure 3: Updated 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. Now, the Portal includes data collected on 66 innovative medicines from EFPIA member companies that received a centrally authorised MA for their first indication between January 2021 and June 2023.[6] The data have matured 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 the first report, validating the earlier findings and conducting more in-depth analyses of the impact of various factors that can affect availability and delay.

6 The data collection phase consisted of four cycles. In cycle 1, data were initially collected on products with marketing authorisations between January and December 2021 (the data were collected during Q2 2022). In cycle 2, data were collected on products with marketing authorisations between January and June 2022 (the data were collected during Q4 2022). Cycle 3 data were collected on products with marketing authorisations between July and December 2022 (the data were collected during Q2 2023). In cycle 4, data were collected on products with marketing authorisations between January and June 2023 (the data were collected during Q4 2023). During each cycle, updated data for products with marketing authorisations in earlier periods were collected. This report analyses the first four cycles of data collected in the Portal. The Portal aims to cover all EU centrally approved products, both innovative medicines in their first indications and biosimilars, that have been or will be granted marketing authorisation in Europe between January 2021 and June 2023. The Portal does not currently cover vaccines.

Data submissions included 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 pricing and reimbursement (P&R) = "P&R filing" or "filed for P&R"*
- *Filing for marketing authorisation (MA) = "EMA filing" or "filed for MA"*
- *Submission of data to the European Access Hurdles Portal = "submission"*

Size and representativeness of the dataset

The quantity of data in the Portal has increased over time, demonstrating a complete willingness of EFPIA companies to add new information to the debate on medicine availability:

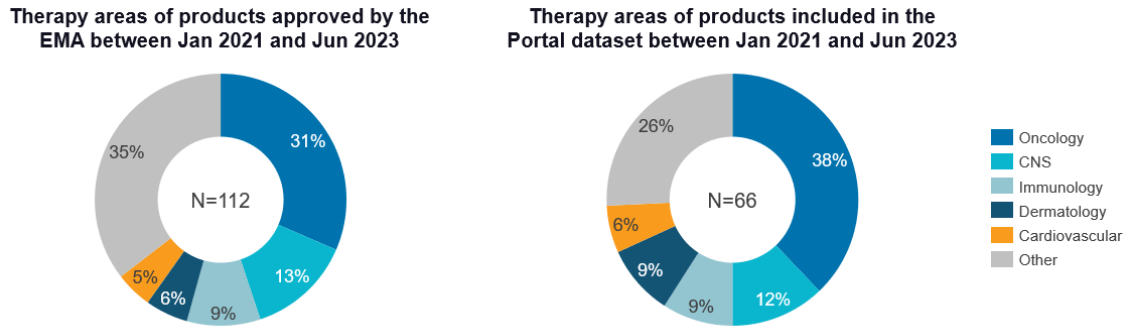
Submission of data to the Portal is voluntary, and it was understood from the outset that the Portal would not include every product from the first instance of the Portal's launch. The aim was to build up the quantity of data over time, and this has been observed in practice.

As expected, the quantity of data and quality of the dataset has improved over the collection periods. In the most recent data collection phase, all 32 of the EFPIA member companies with eligible products submitted data to the Portal. This constitutes 100% participation from EFPIA's member companies. It means that the analysis described in this report is representative of all EFPIA members' products approved by the EMA between January 2021 and June 2023 for their first indication (a total of 66 products). This represents 52% of the total number of medicines approved for their first indication by the EMA during this period.

Of the 66 products included in the Portal, a range of therapy areas are covered (as shown in Figure 4). 38% are oncology medicines and 29% are orphan products.[7] A comparison of the therapy areas of these products to the total number of products approved by the EMA over the same period shows that the therapy areas of the products included in the Portal dataset are similar. This suggests that the products in the Portal are broadly representative of the types of innovative medicines approved by the EMA over this period.

7 In this report, we focus on the full cohort of 66 products and consider specific trends in the oncology and orphan medicine cohorts (N=25 and N=19 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 4: The distribution of products by therapeutic area in the Portal



Source: IQVIA – European Access Hurdles Portal (Q1 2021–Q4 2023)

Completeness of the dataset

The completeness of data submitted to the Portal has been high

The completeness of data submitted by companies was high in the first preliminary report on the Portal and has become higher. Companies were asked to submit data across 30 European countries (the EU-27 countries, England, Norway, and Scotland), including data on the current reimbursement status and the reason for any delay or for not yet filing for P&R. We received data on all 30 countries for all products in the scope of the Portal.

From the outset it was understood that collecting data on the reason for delays in filing would be challenging. However, for 94% of products that had not yet been filed for P&R in at least one country, companies were able to provide data on the reason for non-filing.

It is expected that completeness of the Portal's data will continue to improve in future data cycles.

Updated analysis of new data from the Portal

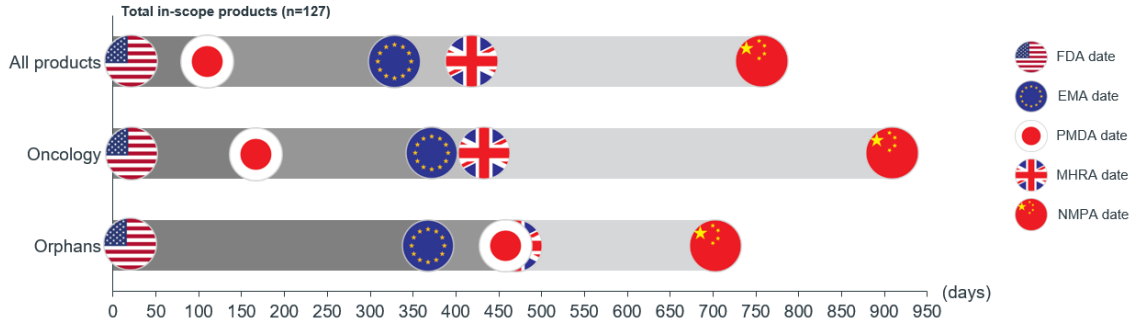
Speed of marketing authorisation

Although the focus of the Portal is primarily on P&R processes, 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 2023, EMA approval came later, on average, than approval in the United States and Japan by 327 days and 214 days, respectively (Figure 5). 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 2022); however, the timing of EMA approvals has fallen further behind FDA and PMDA approvals. This shows that even before considering the P&R process, regulatory approval comes at a later stage in Europe than in other regions.[8]

The observed gap for oncology medicines between Europe and other regions is similar to the gap for all products, with EMA approval occurring later, on average, than approval in the United States and Japan by 373 days and 204 days, respectively. This contrasts with the analysis in last year's Portal report, in which EMA approval for oncology medicines came, on average, 262 days after FDA approval and 47 days before PMDA approval.

For orphan products, EMA approval comes one year (365 days) after approval in the United States on average, but 94 days before approval in Japan. Compared to last year, this shows that that the timing of EMA approvals has overtaken the timing of PMDA approvals but the gap between the timing of FDA and EMA approvals of new orphan products is widening.

Figure 5: Date of EMA approvals relative to the US, UK, Japan, and China for all products approved between January 2021 and June 2023



No. of dates used to calculate averages (/ 127)

	FDA to EMA	FDA to PMDA	FDA to NMDA	FDA to MHRA
All products	109	38	20	86
Oncology	36	7	8	32
Orphans	38	12	7	31

Source: IQVIA analysis of EMA, FDA, PMDA, NMPA, MHRA (2024)

8 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.

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.[9] From Figure 5, we can observe that in the UK, the Medicines and Healthcare products Regulatory Agency (MHRA) approval comes, on average, 91 days later than EMA approval.

Status of product P&R filing and reimbursement

Before the Portal was established, annual Patient W.A.I.T. data had already documented availability and delays in reimbursement following market authorisation. The Portal provides additional detail on the status of product filing for products' first indications, showing that in many instances of product unavailability (as captured in W.A.I.T.), the products have been filed for reimbursement but have not yet been reimbursed or have received a negative decision. Looking at all products included in the Portal to date (which covers products that are on average 20 months post-marketing authorisation), we find the following:

- On average, across European countries, the majority (56%) of products have been filed for P&R. Of these,
    - Approximately half (49%) of filed products are pending a reimbursement decision,
    - 45% of filed products have been reimbursed, and
    - 7% of filed products have had a negative reimbursement decision or been withdrawn by the manufacturer.[10]
- 44% of products have not yet been filed for P&R

These results are a snapshot of the status of filing and reimbursement at the time of the most recent data collection cycle (Q4 2023). We can compare these results with the status of filing and reimbursement from an earlier data collection cycle (Q4 2022, published in April 2023). It is expected that products that have had marketing authorisation for longer will have higher rates of filing for P&R across Europe and higher rates of reimbursement. However, the Portal now also includes a cohort of more recent products that have only been authorised for a short time; therefore, it is perhaps not surprising that the overall level of filing is similar to last year's.

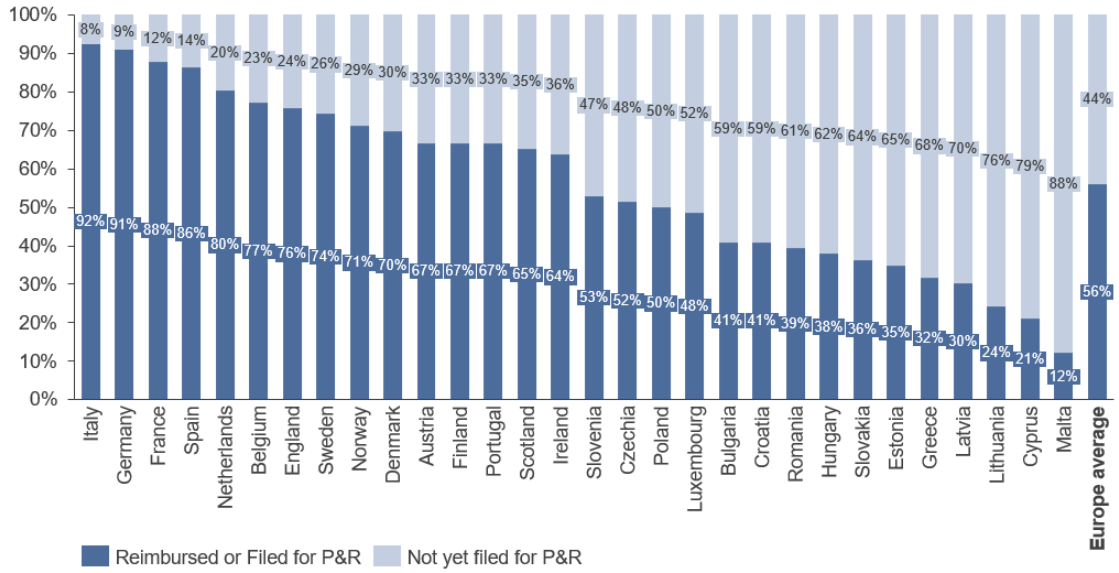
The data show that product P&R filing varies significantly throughout Europe (Figure 6). Italy is the country with the highest percentage (92%) of products that have been filed for P&R, followed by Germany (91%), France (88%), Spain (86%), and the Netherlands (80%). On the other end of the spectrum, the countries with the lowest percentage of products that have filed for P&R are Malta (12%), Cyprus (21%), Lithuania (24%), Latvia (30%), and Greece (32%). This could indicate that P&R filing speed is, to some degree, associated with the extent to which well-structured P&R processes are in place.[11]

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

10 N.B. numbers do not sum to 100% due to rounding

11 Testing this hypothesis would require additional data analysis not currently within the scope of the Portal.

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



Source: IQVIA – European Access Hurdles Portal (Q1 2021–Q4 2023)

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 (Other):** 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

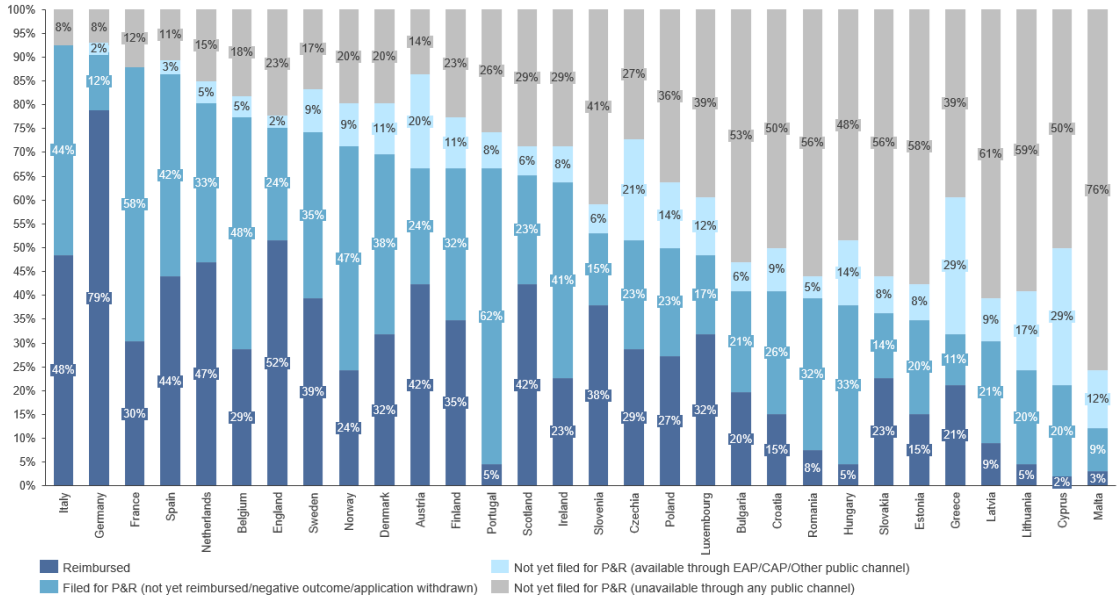
Using these groupings, we can observe that an average of 83% of products were filed for P&R across the EU4+UK countries, compared to approximately 40% of products in countries in the CEE region. The factors affecting these filing patterns are explained later in the report (see 'Root causes of delays in P&R filing')

The Portal focuses on national processes, but we should not forget that the jurisdiction of P&R decisions varies by country, with some countries engaging in P&R processes and decision-making at a national level while others organise these decisions – at least in part – at the regional level, which impacts the timing of reimbursement and availability of medicines. Equally, even completion of the national and regional processes does not mean that all patients have access to the medicine.

There is also an important distinction between products being available (successfully included in the national reimbursement list) and patients having access to them. It is possible both for products to be available but for patients to not have access and for products to not be generally available but for patients to have access. This is explored in the CRA Root Causes paper. Using data from the Portal, we can observe products to which patients have access though the products have not yet been filed for P&R. Manufacturers and health authorities can grant patients access

to products through alternative access schemes, including early-access programmes and compassionate-access programmes. As shown in Figure 7, many products in the Portal are accessed through these channels.

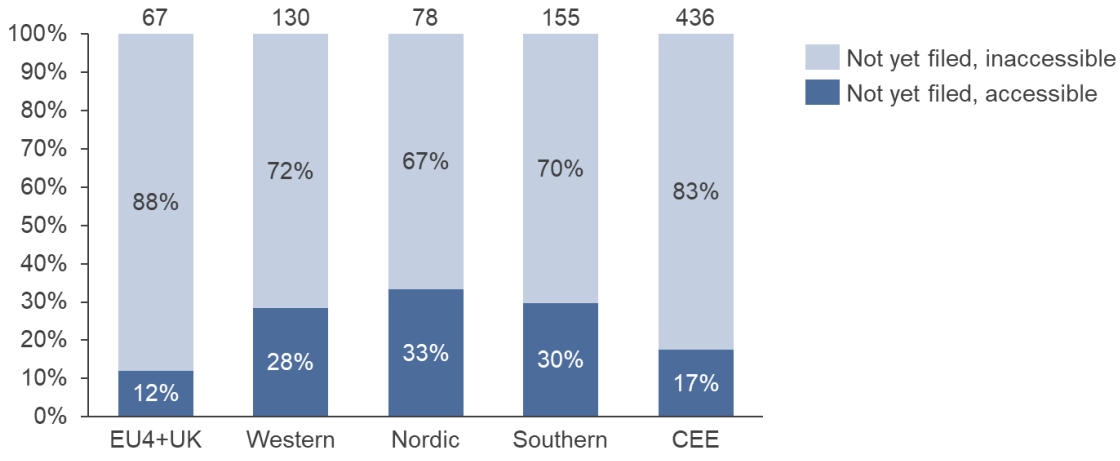
Figure 7: Status of filing and reimbursement across Europe for all 66 products in the Portal



Source: IQVIA – European Access Hurdles Portal (Q1 2021–Q4 2023)

The number of products that have not yet been filed for P&R but that are accessible through alternative access channels varies across regions (Figure 8). Across Western, Southern, and Nordic markets, in approximately 30% of instances where a product has not been filed for P&R, it is accessible through other channels. There is less reliance on these channels in the CEE region, where there are the highest number of instances of non-filing, perhaps suggesting either that alternative channels are not in place or there are barriers to their use.

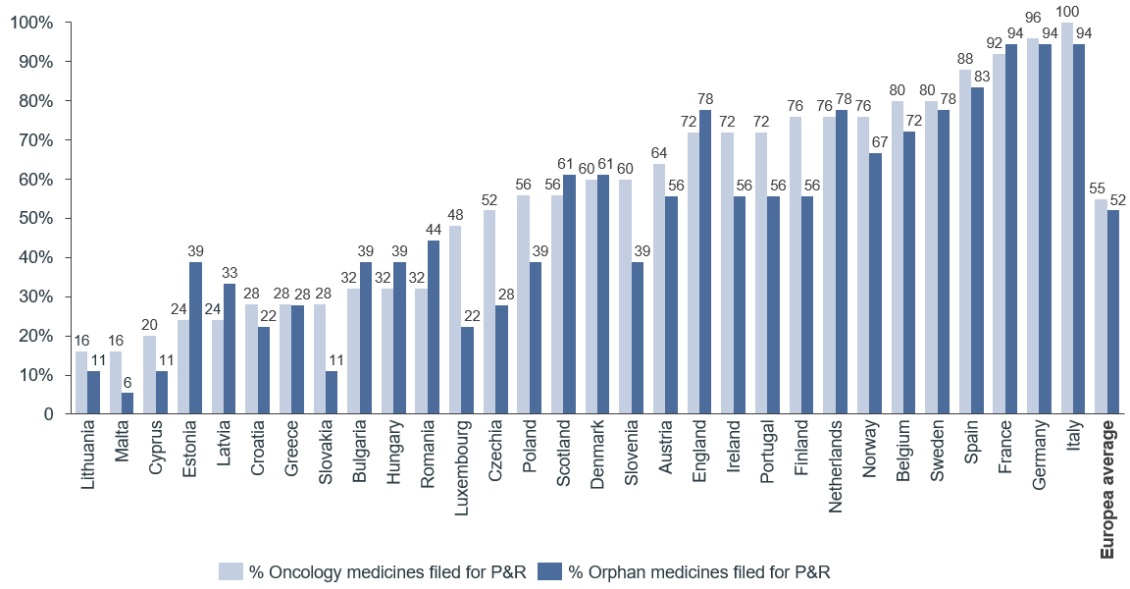
Figure 8: The proportion of products that are not yet filed for P&R but are accessible through other channels, by region



Source: IQVIA – European Access Hurdles Portal (Q1 2021–Q4 2023)

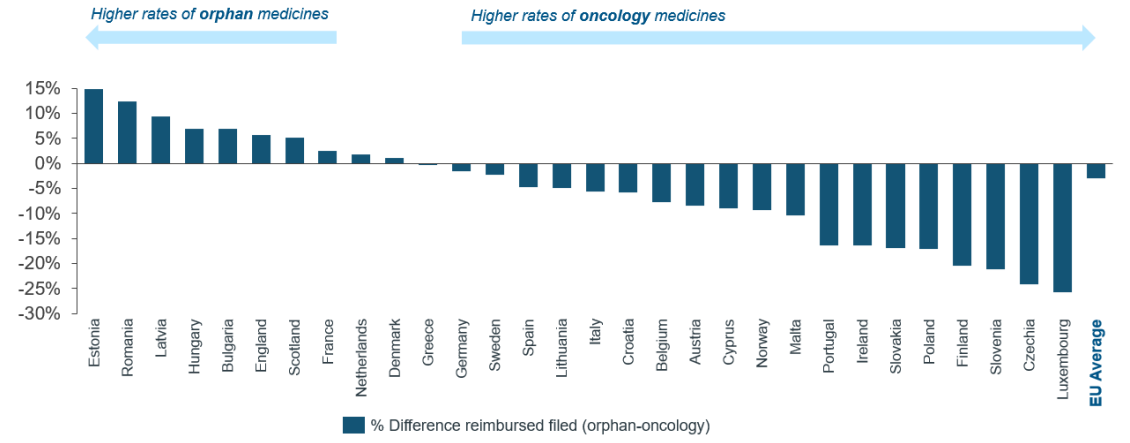
It is also useful to look at types of products: for oncology products, the level of filing for P&R is 55% on average; for orphan products, it is 52% (see Figure 9). However, this varies by country. Figure 9 shows the difference between the percentage of orphan medicines reimbursed or filed for P&R. In the W.A.I.T. data, we observe greater delays for CEE countries and lower rates of reimbursement for orphan medicines. The Portal shows that this is due to the reimbursement process, not a lack of product P&R filings.

Figure 9: Status of product filing for P&R across countries (orphan and oncology products only)



Source: IQVIA – European Access Hurdles Portal (Q1 2021–Q4 2023)

Figure 10: Status of product reimbursement/filing across countries: difference between orphan and oncology medicines



Source: IQVIA – European Access Hurdles Portal (Q1 2021–Q4 2023)

As more data is collected, we can begin to observe differences in the filing rate for different types of products. Differences are already observable for oncology and orphan products, for example. The composition of products in the Portal is changing over time. The most recent cohort has more

ATMPs and orphan drugs compared to the first cohort included in the April 2023 report. This will need to be taken into account when we examine how filing is changing over time.

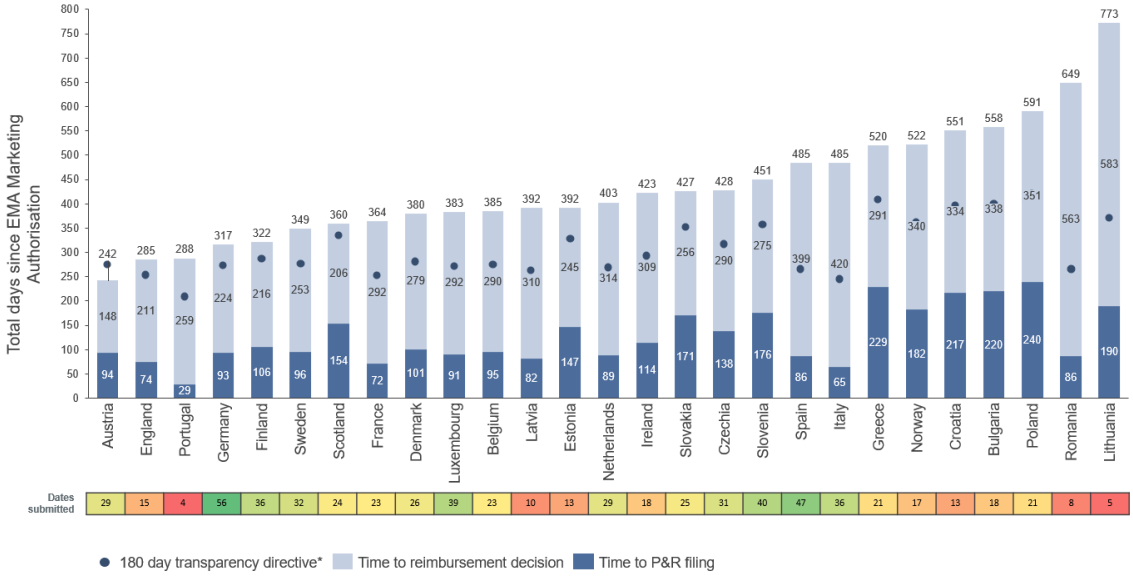
Speed of product P&R filing and reimbursement

The Patient W.A.I.T. Indicator documents the time from EMA approval to availability (reimbursement) of innovative medicines.[12] With the Portal, we are now able to look in greater detail at the timings of different steps in that process. We find that the majority (71%) 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 11). The remaining 29% is the time taken by manufacturers take to file for P&R. In absolute terms, across all in-scope countries, the average number of days between EMA approval and reimbursement is 434. On average, companies filed after 127 days, with the remaining 307 days being 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 EU4+UK markets (25%, or 90 days on average); in CEE countries, it is 30% (or 167 days on average). The time taken to reach a reimbursement decision after an application is received is longer in CEE countries (356 days on average) than in EU4+UK (292 days on average).

12 EFPIA Patients W.A.I.T. Indicators 2023 Survey, May 2024

Figure 11: Days taken to file for P&R and receive a reimbursement decision in relation to total time between MA and reimbursement[13]



Source: IQVIA – European Access Hurdles Portal (Q1 2021–Q4 2023)

**Note: The time to reimbursement decision does not distinguish between time taken for clock stops, negotiations with manufacturers, and active decision-making by the national HTA body.*

These new results are broadly consistent with the preliminary results published in April 2023. Issues with truncation of data remain – some products received EMA approval at the end of the data collection period, making it less likely they have been filed for P&R or been reimbursed. However, the wider time frame and consistency with initial report findings permit increased confidence in the findings.

It is also important to note that the introduction of the EU HTA process from next year may impact both the length of time to filing for P&R and reimbursement decisions. 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.

Root causes of delays in P&R filing

The Portal provides granular data on the reason products have not yet been filed for P&R at the time of data collection in different countries. Multiple reasons have been provided for the lack of

13 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 sometimes occurred in Cyprus, Malta, or Hungary), 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.

P&R filing, with manufacturers submitting at least one reason for 94% of unfiled products. Since this information is collected only for products not yet filed for reimbursement, the sample sizes are inevitably smaller, so we focus on aggregated results. It is important to note that the data collected in the Portal reflects a distinct time period; for example, the most recent data period is June 2023 and January 2024. The analyses in this section describe the root causes for non-filing *at the time of data collection*, which may or may not continue to prevent filing moving forward.

In submitting data to the Portal, manufacturers could select from a list of root causes, which, for the purposes of this report, have been grouped into the following four categories:[14]

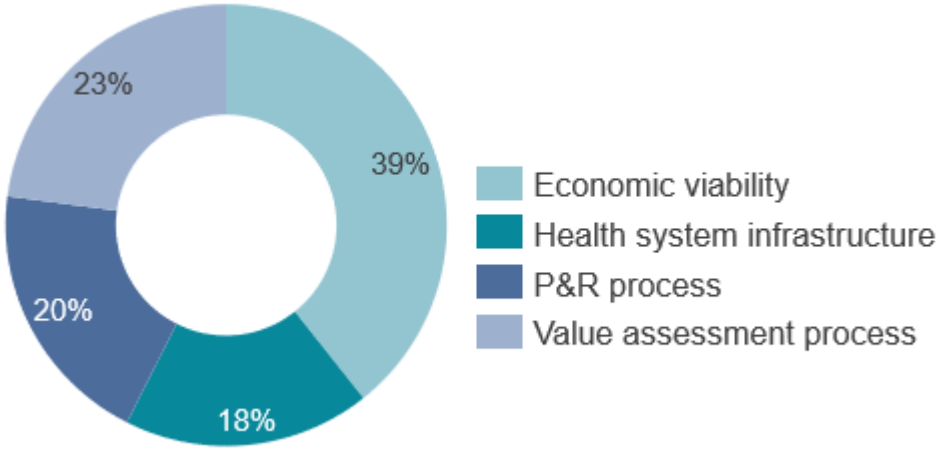
- **Health system infrastructure** (indicated as a reason 128 times),[15] which includes 'lack of required healthcare infrastructure' and 'lack of healthcare funding to support utilization'.
- **Economic viability** (indicated as a reason 278 times), which includes 'the size of the treatable population', 'lack of company presence in the local market', and 'the cost of launching is not recoverable'.
- **P&R process** (indicated as a reason 139 times), which includes 'country filing requirements' and 'the impact of external reference pricing'.
- **Value assessment process** (indicated as a reason 162 times), which includes 'evidence package unlikely to meet country requirements' and 'low value attributed to class competitors'.

Looking at the 66 products across all 30 countries included in the database, and allowing for the fact that we collect multiple reasons to explain each product's lack of filling, we have 707 responses. The reasons for a lack of or delay in filing for P&R are multifactorial, and the factors are to some extent interlinked, with significant contributions from each category (see Figure 12). There is an even spread across the categories of root causes, which supports the conclusion that improving P&R filing rates is a shared responsibility that will require shared solutions from stakeholders involved in different aspects of the P&R process and broader access ecosystem to address these challenges in a holistic manner.

14 The Portal also recorded 395 instances of manufacturers providing reasons for non-filing that do not map to the four categories. This partly reflects that the launch environment for innovative medicines is complicated by different indication- and product-specific characteristics. However, in 88% of these instances, manufacturers highlighted that there was no specific reason why filing had not yet occurred or that the company was preparing to file at the time of data collection. Because we cannot assign these responses to a specific root cause, we excludes them from the root causes of lack of P&R filing analysis.

15 The total number of responses submitted was 707, excluding the reason 'other'. Across all products and countries, a total of 1,102 responses were submitted (including the reason 'other').

Figure 12: Reasons for non-filing for P&R across all data collection cycles

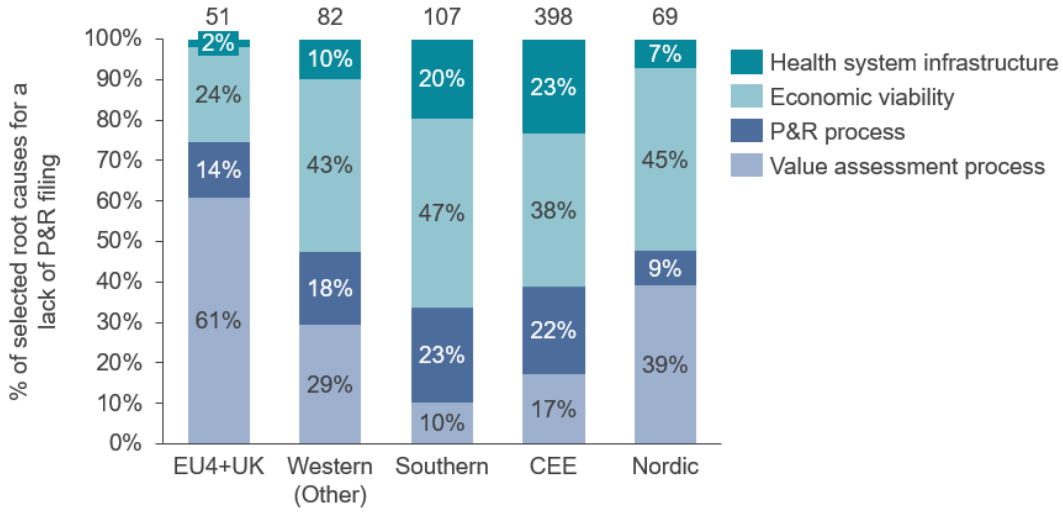


Source: IQVIA – European Access Hurdles Portal (Q1 2021–Q4 2023)

Importantly, this analysis is of the root causes affecting 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.

Rationales for a delay in P&R filing differ clearly across the regions of Europe. As shown in Figure 13, root causes 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 13: Distribution of reasons for non-filing in all countries (excluding the "other" category) by country grouping[16]



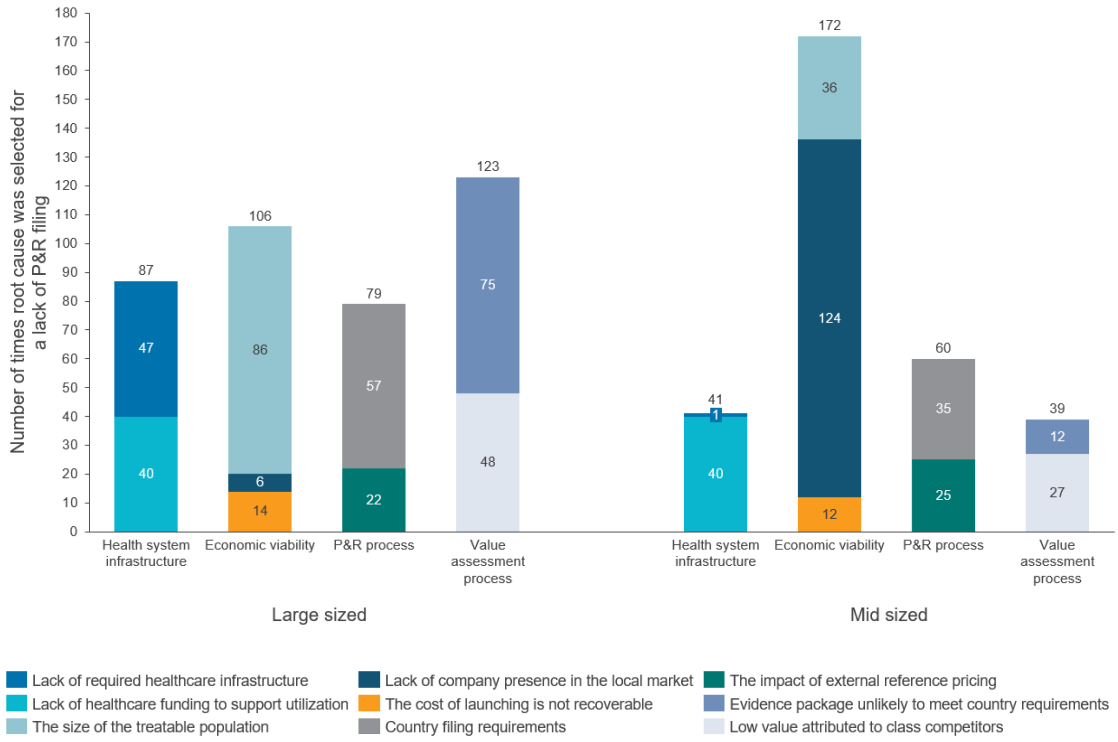
Source: IQVIA – European Access Hurdles Portal (Q1 2021–Q4 2023)

For the first time, we can also look at indicative results for different types of companies (Figure 14). We can distinguish between the reasons for delays in P&R filing for products marketed by large pharmaceutical companies and for midsize pharmaceutical companies. 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. Only one small pharmaceutical company participated in the Portal, so it has been included with the midsize companies to maintain anonymity. For large companies, root causes are fairly evenly distributed, with the most commonly cited reasons relating to the requirements of the value assessment process.

However, if we look at midsize companies, the largest category relates 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.

16 For each product and within each country, manufacturers were able to provide multiple reasons for non-filing. Multiple reasons were typically provided, with 707 reasons being provided across products and countries.

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

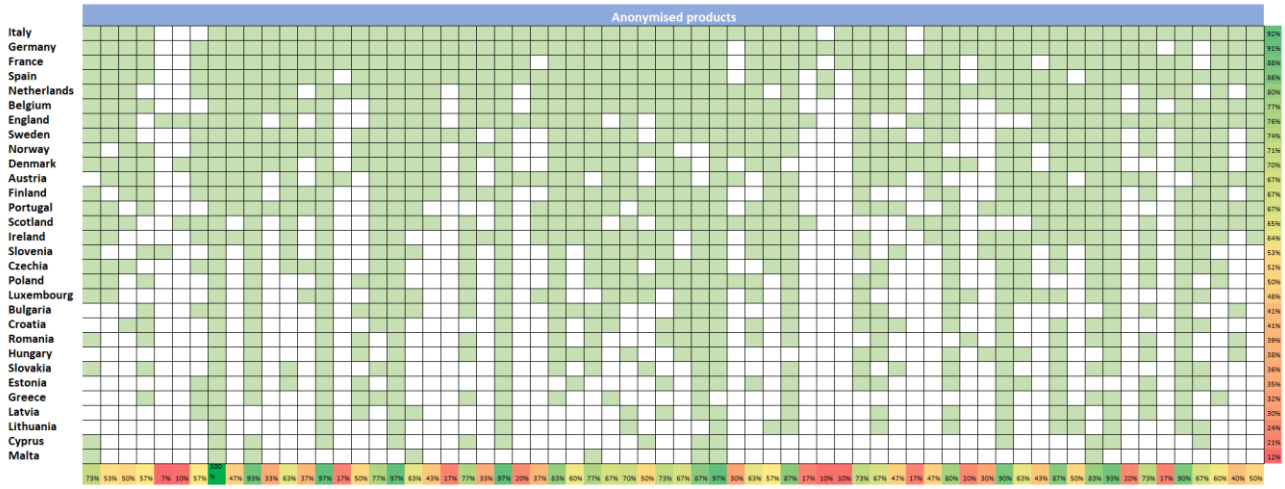


Source: IQVIA – European Access Hurdles Portal (Q1 2021–Q4 2023)

***Note:** Large companies are the MAHs of 47 products in the Portal, which have an average filing rate of 57%, while midsize and small companies are the MAHs of 19 products in the Portal, which have an average filing rate of 54%.*

The reasons for non-filing for P&R also vary significantly from product to product and from country to country. As seen in Figure 15, market conditions and product types cause significant variation in whether a product has been filed for P&R. Some products have a filing rate above the average in the Portal, but they have not been filed in larger markets such as Germany and France. And some products with a lower level of filing overall have been filed in countries such as Cyprus and Slovakia but not in larger markets such as England.

Figure 15: Anonymised distribution of product filing across countries



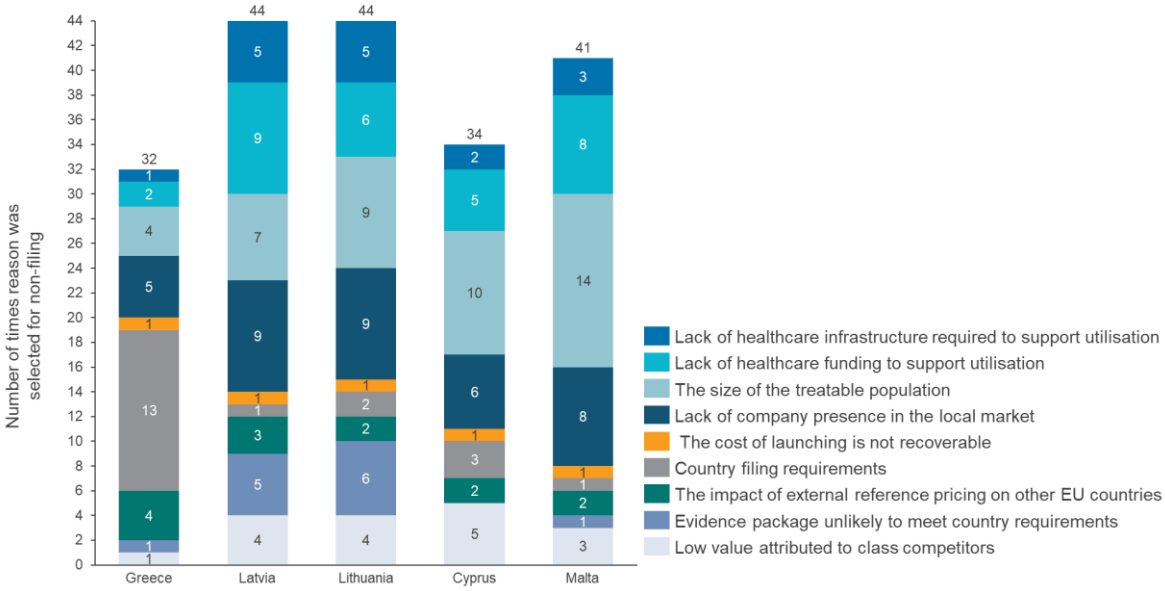
Green = products that have been filed for P&R

Source: IQVIA – European Access Hurdles Portal (Q1 2021–Q4 2023)

When looking at the root causes for non-filing in the five countries with the lowest filing rate (Greece, Latvia, Lithuania, Cyprus, and Malta), specific reasons for the delay in P&R filing stand out (as shown in Figure 16). For example, in Greece, 'country filing requirements' were found to be a major contributor to the low rate of filed products; this is likely due to the requirement in Greece that products be considered for HTA only if they are reimbursed in at least five 5 of a list of 11 Western European countries.[17] In Malta, 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 just over half a million people. This demonstrates the value of the Portal in increasing the transparency of root causes of a lack of P&R filing across European markets. Hopefully, these data can guide the development of solutions tailored to specific countries and products.

17 Greece: article 22 of Law 4633/2019: medicines with patent protection are subject to health technology assessment (HTA) in Greece only if they are reimbursed in five other countries with an HTA process from the following list: Austria, Belgium, France, Germany, Denmark, Spain, Netherlands, Italy, Portugal, Sweden, and Finland.

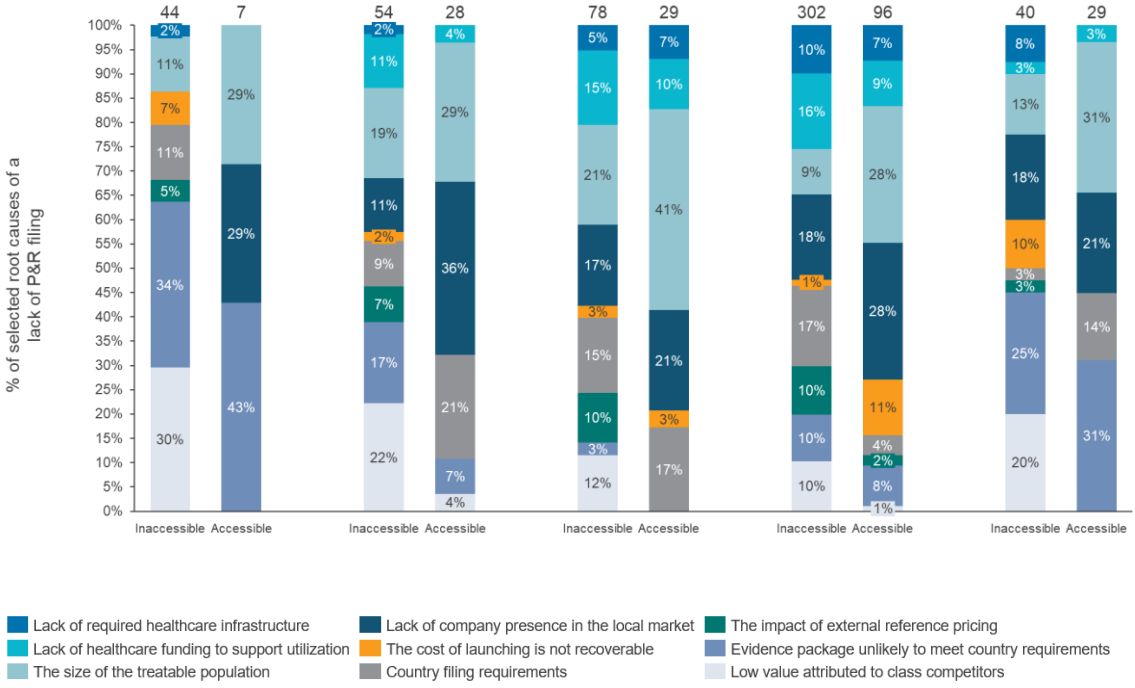
Figure 16: Total number of root causes for non-filing in the five countries with the lowest P&R filing rate



Source: IQVIA – European Access Hurdles Portal (Q1 2021–Q4 2023)

Analysis of the root causes for non-filing can help improve patient access to innovative medicines. However, as described earlier, a product having not yet been filed for P&R does not mean that patients will not have access to it through an alternative access channel. For example, looking at the Southern region, 30% of products that are not yet filed for P&R are currently accessible through an early-access programme, compassionate-access programme, or other access programme. The root causes of non-filing are distinctly different on the basis of whether a product is accessible to patients through alternative access channels or completely inaccessible (Figure 17). Across all regions, reasons relating to 'economic viability', specifically 'the size of the treatable population' and the 'lack of company presence in the local market', are more common for products accessible through alternative access channels. The issue of 'low value attributed to class competitors' arises more frequently with products not accessible through these channels. This suggests that some of the root causes analysed represent a greater barrier to patient access. On the other hand, some root causes, such as companies not having the necessary presence to file for P&R or the country lacking a large enough patient population to make filing for P&R economically viable, do not present as great a barrier to patient access (despite preventing P&R filing), since products are often made accessible through alternative channels.

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



Source: IQVIA – European Access Hurdles Portal (Q1 2021–Q4 2023)

Factors affecting increasing filing rates

With more data, we can begin to examine how filing rates change over time. Portal data show that how P&R filing rates change over time are impacted by a number of different factors.

First, differences are emerging between product types (such as orphan and oncology products). Second, the Portal's composition is changing; it now reflects a large range in the length of time since products received marketing authorisation. Finally, changes to the overarching environment and the situation in individual member states are likely to impact P&R filing rate. Drawing conclusions about how filing patterns evolve over time is challenging because cohorts comprise products with different compositions, different average times since marketing authorisation, and different filing ecosystems. The root causes for non-filing are multifactorial, and to understand trends, this must be recognised.

We can also begin to understand the root causes that can be addressed over time and those that are more intractable. We can observe products for which filling rates have increased and products that have reached an apparent filing-rate ceiling (P&R filing rates do not increase with an increase in time since marketing authorisation). In analysing products over our four data collection cycles, 13 products showed evidence of a plateau after which there was no increase in the P&R filing rate. Preliminary analysis suggests that products that reached a P&R filing-rate ceiling were often prevented from being filed by barriers outside manufacturers' control, including a 'lack of healthcare funding to support utilization' and the 'evidence package being unlikely to meet country requirements.' This perhaps suggests that manufacturers are not filing for P&R in circumstances where local systems do not 'allow' it. The products where we saw continued growth in filing rates had a mixture of root causes (with a greater focus on those partly within the company's control).

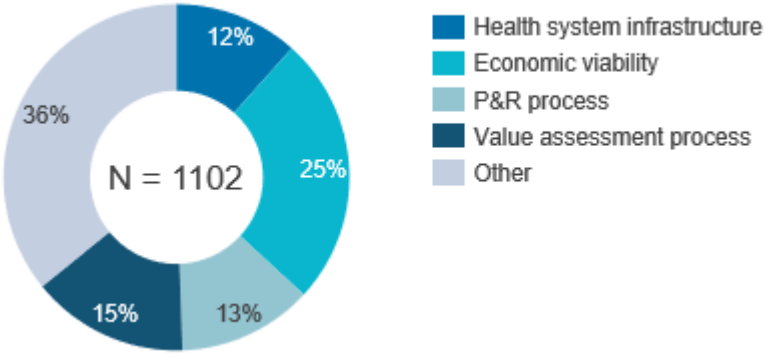
Overall, this suggests that to understand how filing rates change over time, we will need to allow for the changing composition of the Portal (and the fact that different types of products have different filing rates), the length of time since marketing authorisation, and that some products reach a ceiling in terms of filing; i.e., the root cause of non-filing appears to persist over time.

Future direction for the Portal

The data collected in the Portal will continue to mature as more cycles of data are collected. This will allow us to validate some of these early results and to look in more detail at the underlying root causes. Several issues should be considered.

One issue identified is that a minority of companies were not able to provide granular reasons for a delay in filing for specific products, instead selecting 'other' as the rationale. In the latest cycle of data collection, a total 395 of responses submitted were 'other'. In 88% 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 lower than in the Portal's earlier cohorts, but it will be important to refine the collection of data to decrease the selection of 'other' as a main rationale for non-filing.

Figure 18: Rationales for not yet filing in European markets[18]



Source: IQVIA – European Access Hurdles Portal (Q1 2021–Q4 2023)

Data from biosimilars were absent in this round of data collection, which makes drawing conclusions about challenges experienced by innovative products compared to biosimilars impossible. Data were collected only from EFPIA members, which limits the ability to draw conclusions about the impact of company size on product availability and reduces 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.

18 For each product, companies could select multiple reasons for non-filing.

Appendix

Appendix Table 1: Products with information submitted into the Portal (n=66)

Corporation name	Medicine name	Corporation name	Medicine name
Almirall	Klisyri	Lilly	Rayvow
Amgen	Lumykras	Gilead	Trodelvy
Amgen	Bekemv	Gilead	Sunlenca
Astellas	Evrenzo	GlaxoSmithKline	Jemperli
Astellas	Padcev	Idorsia	Quviviq
AstraZeneca	Imjudo	Ipsen	Bylvay
AstraZeneca	Koselugo	Janssen-Cilag	Ponvory
AstraZeneca	Saphnelo	Janssen-Cilag	Rybrevant
AstraZeneca	Tezspire	Janssen-Cilag	Tecvayli
Bayer	Kerendia	Janssen-Cilag	Carvykti
Bayer	Verquvo	Janssen-Cilag	Akeega
Biogen	Vumerity	LEO Pharma	Adtralza
Boehringer Ingelheim	Spevigo	Lundbeck	Vyepti
Bristol Myers Squibb	Camzyos	Menarini	Elzonris
Bristol Myers Squibb	Inrebic	Menarini	Nexpovio
Bristol Myers Squibb	Opdualag	Merck	Tepmetko
Bristol Myers Squibb	Sotyktu	Novartis	Kesimpta
Bristol Myers Squibb	Abecma	Novartis	Scemblix
Bristol Myers Squibb	Breyanzi	Novartis	Tabrecta
Chiesi	Elfabrio	Novartis	Pluvicto
CSL Behring	Hemgenix	Novo Nordisk	Sogroya
Daiichi Sankyo	Enhertu	Novo Nordisk	Wegovy
Lilly	Mounjaro	Otsuka	Lupkynis
Lilly	Retsevmo	Pfizer	Cibinqo
Lilly	Omvoh	Pfizer	Ngenla

Corporation name	Medicine name	Corporation name	Medicine name
Pfizer	Vydura	sanofi	Nexviadyme
Pierre Fabre Medica-ment	Ebvallo	sanofi	Xenpozyme
Roche	Xofluza	sanofi	Enjaymo
Roche	Evrysdi	Servier	Tibsovo
Roche	Enspryng	Takeda	Livtencity
Roche	Gavreto	UCB Pharma	Bimzelx
Roche	Lunsumio	Vifor	Tavneos
Roche	Vabysmo	Vifor	Kapruvia