European Access Hurdles Portal: initial results

April 2023

Executive summary

The European Access Hurdles Portal is 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 the root causes of delays in pricing and reimbursement (P&R) filing or the reimbursement decision-making process for European Union (EU) centrally approved medicines. This identification shows us that the reasons for delay are multifactorial. This allows data on delay and lack of availability to be put into context and thereby supports the broader understanding that it is a shared responsibility requiring a shared solution.

In this context, in April 2022, EFPIA and its members made a commitment to file P&R applications in all EU countries no later than two years after EU market authorisation, provided that local systems allow it.[1] To support transparency and the identification of the root causes for delayed filing and reimbursement, the Portal was also launched in April 2022. The data presented in this report include data collected on products that received marketing authorisation between January 2021 and June 2022;[2] therefore, the vast majority of products included in this report received marketing authorisation before the commitment to file was made.

This is the first report from the Portal; thus, the data are exploratory and cannot be used to infer the impact of EFPIA members' commitment to file. However, the expectation is that it will be possible to validate the results as more data become available, and this will also allow more sophisticated analysis to be undertaken.

We find that:

- There is a willingness from industry to provide more transparency on the root causes of unavailability, with over 90% of eligible EFPIA companies submitting data to the Portal. These companies were able to provide information on approximately 82% of all products

1 https://www.efpia.eu/media/677156/addressing-patient-access-inequalities-in-europe.pdf

2 The data collection phase consisted of two cycles. In the first cycle, data were initially collected on products with marketing authorisations between January and December 2021 (this was Cycle 1, and the data were collected during Q2 2022). In the second cycle, data were collected on products with marketing authorisations between January and June 2022, with updated data for products authorised during 2021 (this was Cycle 2, and data were also collected during Q4 2022). This report contains the preliminary results based on the first two cycles of data collected in the Portal. The Portal aims to cover all EU centrally approved products, both innovative medicines in their first indication(s) and biosimilars, that have been or will be granted marketing authorisation in Europe between January 2021 and June 2023. The Portal will be updated twice a year, with the last planned update occurring in December 2023.

by EFPIA companies that were approved between January 2021 and June 2022 (representing 38% of all products approved by the European Medicines Agency (EMA)).

- The Portal shows that in many instances of product unavailability (as captured in Patient W.A.I.T. survey),[3] the products have in fact been filed for reimbursement but have not yet been reimbursed. Looking at all products in this period (which covers products that are on average 14 months post-marketing authorisation):
    - Taking an average across European countries, 56% of products have been filed for P&R.
    - Of these filed products, 41% have been reimbursed, and 59% are pending a reimbursement decision.
- There is not a single country where all products have been filed for reimbursement. 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 Central and Eastern Europe.
- 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, 25% of the total time between marketing authorisation and availability can be attributed to the time between marketing authorisation and P&R filing, while 75% is attributable to the time between P&R filing and P&R decisions at the country level.
- As set out in the root causes analysis, the reasons for delays in both P&R filing and P&R decision-making are multifactorial. The most common reasons for not filing for P&R were related to the requirements of the P&R process and health system constraints and resources. However, these reasons clearly vary 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 Europe were due to health system constraints and the corresponding impact this has on commercial decision-making and resource allocation.
- Although the Portal will not report the results for individual products, we can look at anonymised results. These show a wide variation in the reasons for non-filing. For some products, the impact of external reference pricing was a key driver (commonly reported in Latvia and Hungary). In other cases, country requirements (where a country requires reimbursement information from another country) was listed as one of the reasons for non-filing (commonly cited in Estonia, Bulgaria and Romania).

Although only preliminary results are available, and the data will mature over time, it is clear that they can be used to increase transparency and shed significant light on the root causes of unavailability of innovative medicines in Europe.

3 "Availability" is defined as when a medicine is fully reimbursed through a national reimbursement system or fully automatically reimbursed by a hospital budget. "Availability" in this definition does not have a correlation to the use or uptake of medicines.

Introduction

New potentially curative treatments are being discovered, with the potential to transform not only the lives of patients but also the way we think, manage and resource healthcare. However, innovation only matters 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 the European Economic Area has reached 517 days; the times range from 128 days in Germany to 1351 days in Malta.[4]

Over the past three years, EFPIA has documented the drivers behind the delays and unavailability (defined as length of time from European marketing authorisation (MA) to availability at Member State level) – a key issue affecting patient access to innovative medicines. This has been published alongside the long-established Patient W.A.I.T. analysis. This recognises that there are significant differences across countries in the number of products that are available at a point in time, as well as in the length of time taken prior to national reimbursement. The analysis has gone further than in the past in setting out the multiple root causes for unavailability and delayed access, summarising five different categories and 10 root causes.[5]

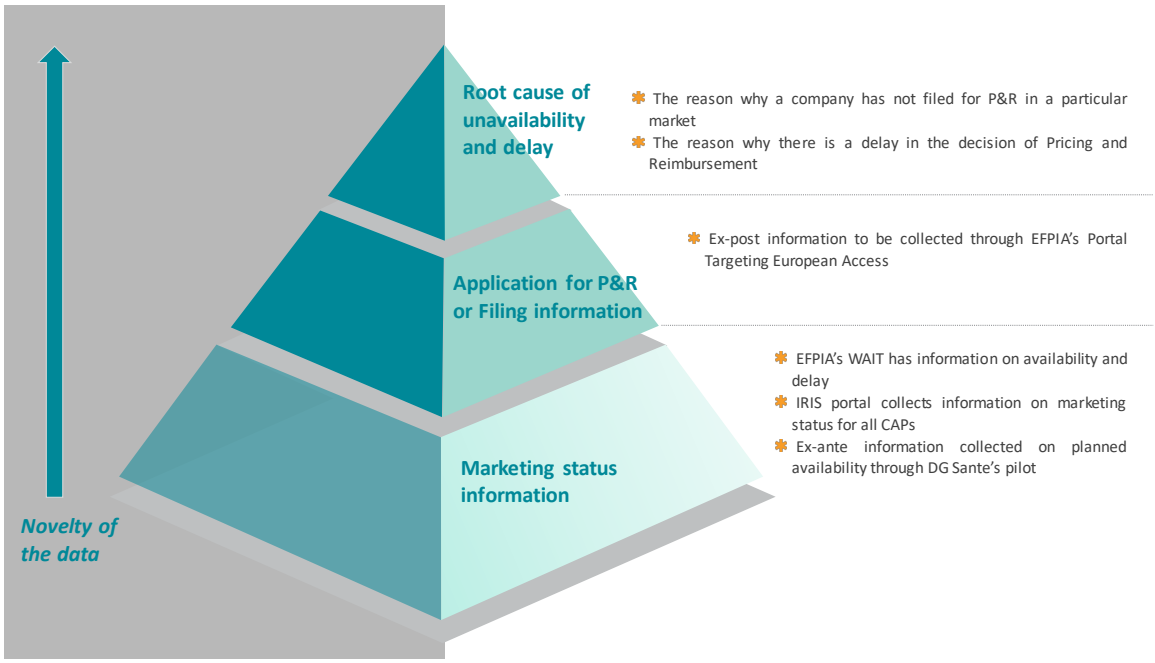
Throughout 2021, the industry investigated whether additional transparency regarding the cause of delays would be valuable to further understand the root causes and how these vary across products and countries.[6] This involved working with companies regarding the information that could be made publicly available, and a multistakeholder consultation on the types of data that would be valuable in the debate regarding the availability of innovative medicines.

4 EFPIA Patients W.A.I.T. Indicator 2022 Survey, April 2023

5 The root cause of unavailability and delay to innovative medicines, April 2023

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

Figure 1: New information on unavailability and delay



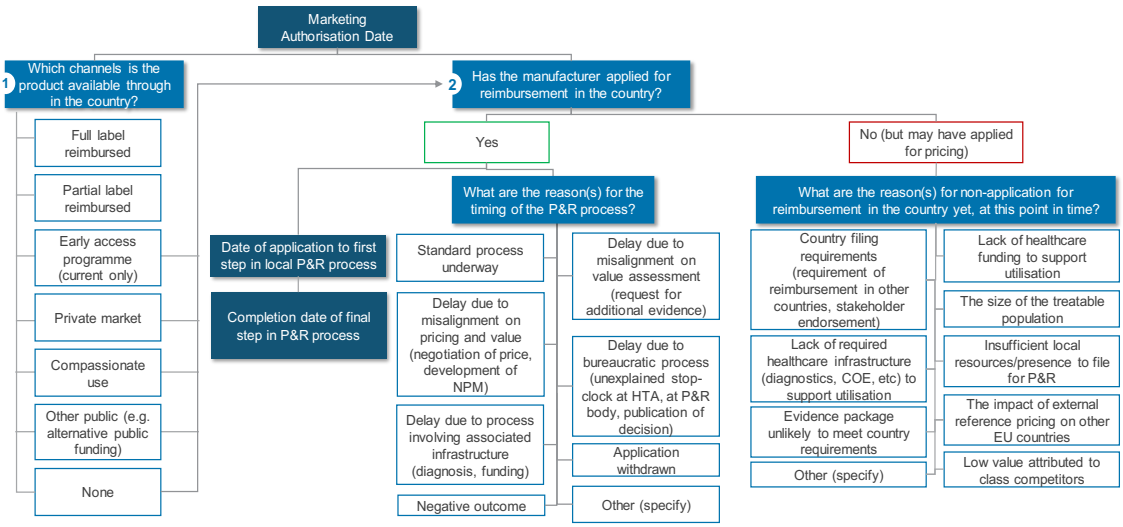
In this context, in April 2022, EFPIA and its members made a commitment to file pricing and reimbursement (P&R) applications in all EU countries no later than two years after EU market authorisation, provided that local systems allow it.[7] At the same time, to support transparency and the identification of the root causes for delayed filing and reimbursement, the industry committed to the creation of the European Access Hurdles Portal (which we refer to as the Portal). In the Portal, marketing authorisation holders (MAH) are requested to provide timely information regarding the timing and processing of P&R applications in the various European countries, including the reasons for any delay in the P&R decision or why the MAH has not filed in a particular market. This document sets out the progress that has been made on establishing this Portal and the preliminary results based on the data that have been collected to date.

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 filed for reimbursement, the reimbursement status and the reason for delays, as illustrated in Figure 2.

7 https://www.efpia.eu/media/677156/addressing-patient-access-inequalities-in-europe.pdf

Figure 2: Schematic of information collected through the Portal



Abbreviations: COE: centre of excellence; HTA: health technology assessment; NPM: novel payment model; P&R: pricing and reimbursement

It currently includes data collected on products that received a centrally authorised MA between January 2021 and June 2022.[8] Therefore, the vast majority of products included in this report received marketing authorisation before EFPIA members made the commitment to file, so the analysis described in this first report cannot yet be used to infer the impact of the commitment. The data within the Portal will mature over time, as more products are included and we can observe a longer period of time. This report therefore presents a preliminary analysis focusing on a short list of key research questions (Box 1). This will expand over time as more data become available.

Box 1: Research questions for the first analysis of the Portal data

- How does Europe compare to other regions in terms of the speed of approval of marketing authorisation?
- What proportion of new medicines have been filed for P&R, and in how many countries?
- To what extent is delayed reimbursement of new medicines in European countries due to the time taken to file for P&R? To what extent is this attributable to the time taken for reimbursement to be granted?

8 The data collection phase consisted of two cycles. In the first cycle, data were initially collected on products with marketing authorisations between January and December 2021 (this was Cycle 1, and the data were collected during Q2 2022). In the second cycle, data were collected on products with marketing authorisations between January and June 2022, with updated data for products authorised during 2021 (this was Cycle 2, and data were also collected during Q4 2022). This report contains the preliminary results based on the first two cycles of data collected in the Portal. The Portal aims to cover all EU centrally approved products, both innovative medicines in their first indication(s) and biosimilars, that have been or will be granted marketing authorisation in Europe between January 2021 and June 2023. The Portal will be updated twice a year, with the last planned update occurring in December 2023.

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

Data submissions included within the Portal

The data analysis described in this document uses the terminology and definitions listed in Box 2.

Box 2: 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'*
- *Medicine is fully reimbursed through a national reimbursement system or fully automatically reimbursed by a hospital budget (e.g. Nordic system) = 'availability'* [9]

Size and representativeness of the dataset

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

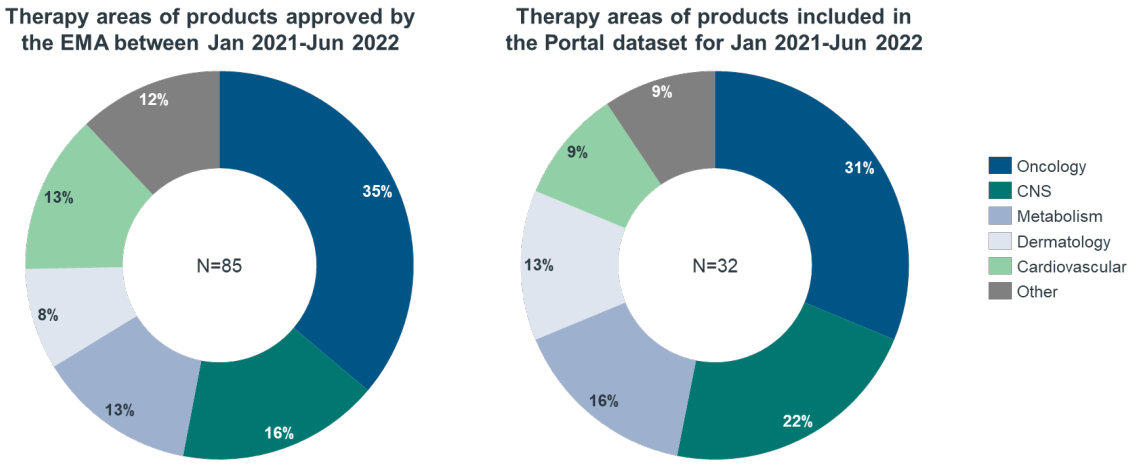
The provision of data to the Portal is voluntary, and it was understood from the outset that it would not include every product from the first instance of the Portal's launch. Instead, the aim was to build up the quantity of data over time. Indeed, this has been observed in practice.

Looking at company participation, 21 of the 23 EFPIA member companies with eligible products submitted data to the Portal (91%).[10] A total of 85 products approved by the EMA were eligible for the Portal; 39 of the products are marketed by EFPIA members, and data on 32 of these were submitted to the Portal. The full preliminary analysis described in this report is therefore representative of approximately 82% of all products that are marketed by EFPIA members and that were approved by the EMA between January 2021 and June 2022 (which is 38% of the total number of products approved by the EMA during this period). A range of therapy areas are covered (as shown in Figure 3), of which 31% are oncology and 22% are orphan products. The therapy areas of the products included in the Portal dataset are similar to those of the total number of products approved by the EMA over the same time period – suggesting the products within the Portal are representative.

9 Note: "Availability" is defined as when a medicine is fully reimbursed through a national reimbursement system or fully automatically reimbursed by a hospital budget. "Availability" does not mean patient access - as in many markets there are additional barriers to patient access after it is available on the market. Equally it is possible that although medicines are unavailable, patients have access to medicines through other channels.

10 The need to set up centralised reporting processes within companies to timely collect the information from country affiliates can explain the non-submission of data from the two missing EFPIA member companies.

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



Source: IQVIA – European Access Hurdles Portal (2022)

Completeness of the dataset

The completeness of data submitted to the Portal has been high:

The Portal is in early stages of implementation, but the completeness of data submitted by companies has been high. Companies were asked to submit data across 30 European countries (EU-27 countries, England, Norway and Scotland), including data on the current reimbursement status and the reason for any delay or for not filing for P&R. We received data on all 30 countries in the scope of the Portal. A high volume of information was provided for products that were submitted to the database. Across all European countries in the Portal, data were provided for an average of 95% of products submitted to the Portal.[11]

From the outset it was understood that collecting data on the reason for delays would be challenging. However, where product information was submitted to the Portal, for 93% of products that had not been filed for P&R in at least one country, companies provided data on the reason for non-filing.

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

Exploratory analysis of results from the Portal

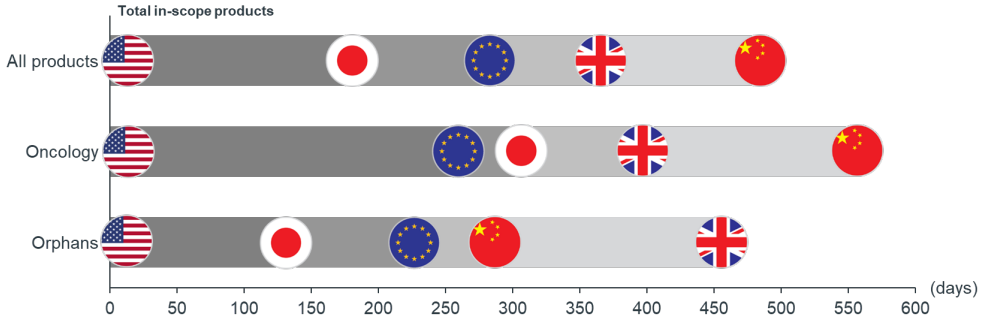
Speed of marketing authorisation

Given that one of the root causes of delay is the timing of marketing authorisation, it is interesting to look first at the delay occurring at the regulatory approval stage for products included in the Portal. For all new products approved by international regulators between January 2021 and June 2022, EMA approval came later, on average, than approval in the US and Japan by 285 days

11 Even with such a high level of data completeness, much of this is due to the late addition of countries (Norway) or the late addition of one product (for incomplete information in Austria, Czech, Finland and Lithuania).

and 110 days respectively (Figure 4).[12] This gap closes to 229 days and 97 days with the US and Japan respectively for orphan products. For oncology drugs, European marketing authorisation typically happens 47 days earlier than Japan, although still lagging behind the US. This shows that even before considering the P&R process, Europe is slower in approving new products than other regions.[13]

Figure 4: Days to approval in the EU, UK, Japan and China relative to the US



No. of dates used to calculate averages

	FDA to EMA	FDA to PMDA	FDA to NMPA	FDA to MHRA
All products	66	24	5	34
Oncology	22	6	3	13
Orphans	19	17	2	11

Source: IQVIA – European Access Hurdles Portal (2022)

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

Status of product P&R filing and reimbursement

Prior to the Portal, annual Patient W.A.I.T. data had already documented availability and delays in availability following market authorisation. The Portal provides additional detail on the status of product filing, showing that in many instances of product unavailability (as captured in W.A.I.T.), the products have in fact been filed for reimbursement but have not yet been reimbursed. Looking at all products included in the Portal to date (which covers products that are on average 14 months post-marketing authorisation):

- Taking an average across European countries, 56% of products have been filed for P&R. Of these:
  - 41% of filed products have been reimbursed
  - 59% of filed products are pending a reimbursement decision
- 39% of products have not yet been filed for P&R
- 6% of products have no information[14]

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

13 This is consistent with the literature and the root causes analysis.

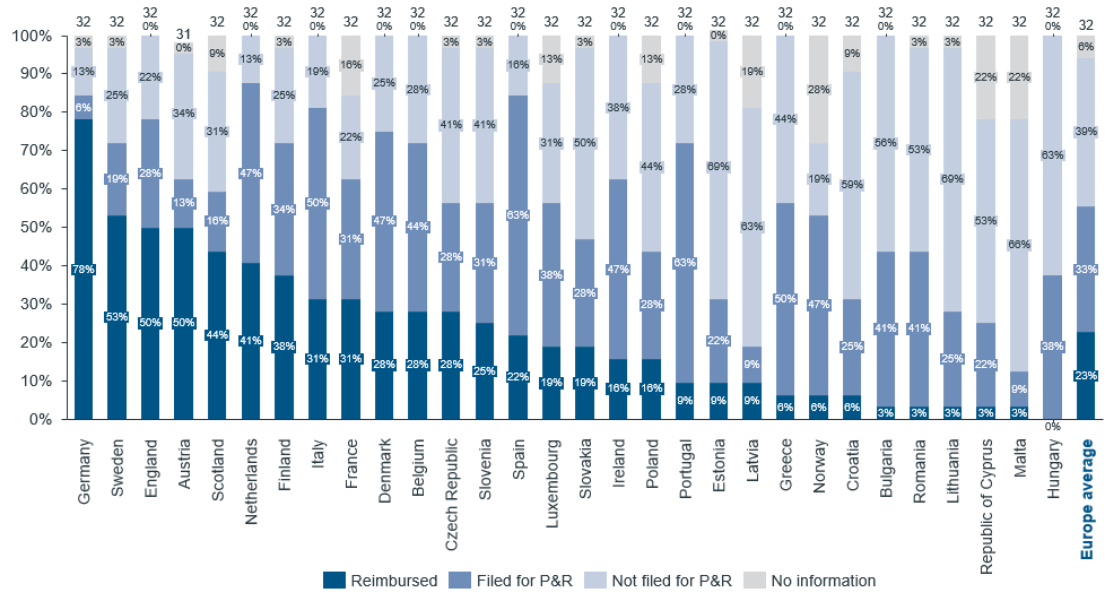
14 NB numbers do not add to 100% due to rounding.

We can also view this another way. Looking across products in the Portal, on average a product has been filed for P&R in 56% (approximately 17) of the 30 European countries included in the dataset within 14 months of receiving marketing authorisation.

The data are naturally limited due to the short period of data collection, and we expect the process and completion of data collection to improve over time. Notably, of the products included in this analysis had had marketing authorisation for two years at the time the data were collected, and most had been authorised prior to the commitment to file within two years. Therefore, it is not possible to measure whether or not this commitment is being met. We would expect products that have had marketing authorisation for two full years to have higher levels of filing for P&R and higher reimbursement levels. It should also be stressed that even if products are available for reimbursement in countries, there may be significant disparities in their availability to patients.[15]

The distribution across countries shows that this does vary significantly (as shown in Figure 5 below). The Netherlands is the country with the highest percentage (88%) of products that have been filed for P&R (although it is much lower when we look at reimbursement), followed by Germany (84%), Spain (84%), Italy (81%) and England (78%). On the other end of the spectrum the countries with the lowest percentage of products that have filed for P&R are Malta (13%), Latvia (19%), Cyprus (25%), Lithuania (28%) and Croatia (31%). There is some evidence that P&R filing speed is dependent on market size. An average of 81% of products were filed for P&R across the major European markets (Spain, Italy, England, Denmark, Finland, Sweden, Belgium, Portugal, Austria, France) compared to approximately 40% of filings in markets in the Central and Eastern Europe (CEE) region. Notably, some of the products submitted to the CEE region were for rare cancers, suggesting there is some variation in filing decisions by therapeutic area.

Figure 5: Status of product reimbursement and filing across countries

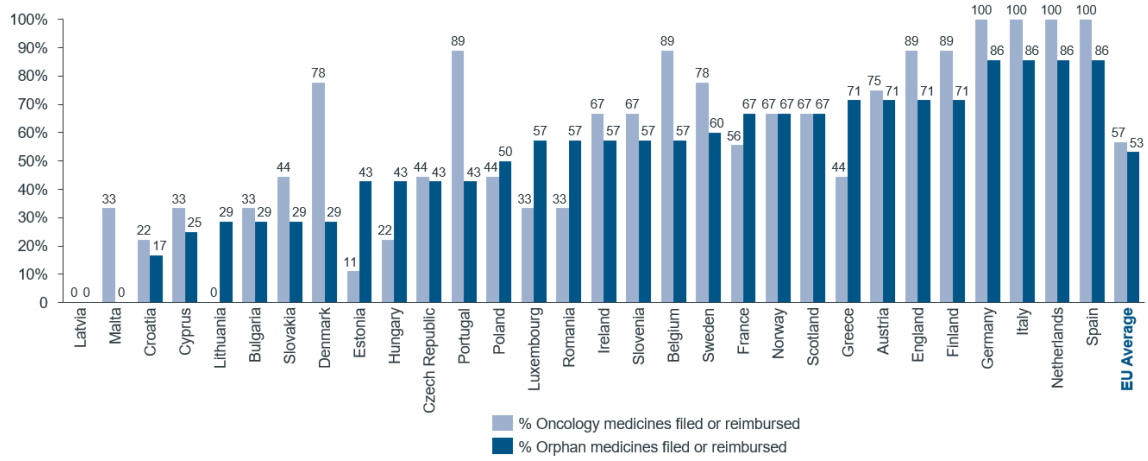


15 Refer to CRA's 'Root causes of unavailability and delay to innovative medicines' (2023) for more information on post-reimbursement barriers to availability.

Source: IQVIA – European Access Hurdles Portal (2022)

It is also useful to look at types of products; for oncology products the level of filing for P&R is 57% on average, compared to 53% for orphan products, but this varies from country to country (see **Figure 6**).[16] Figure 7 shows the difference between the percentage of orphan medicines reimbursed or filed for P&R (of the products for which information was submitted). This result shows the new insights offered by the Portal. 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 the lack of product P&R filings.

Figure 6: Status of product reimbursement/filing across countries (orphan and oncology products only) [17]

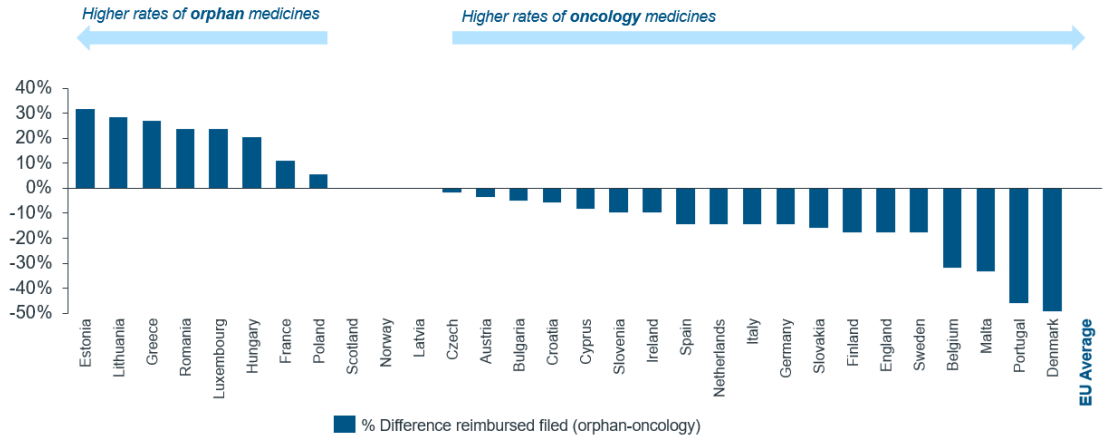


Source: IQVIA – European Access Hurdles Portal (2022)

16 Orphan medicines are classified following the EMA's definition: any medicine indicated for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition that is rare (affecting not more than five in 10,000 people in the EU). Oncology medicines are classified as any medicine indicated for the treatment of cancer. Note there is one product that is counted in both categories as it is an orphan drug indicated for oncology.

17 Reported as a percentage of total products for which information was submitted to the Portal. Missing information for some countries was removed from the calculation. Information was submitted for all nine oncology medicines in the Portal for each country, except for the following 13 countries: Austria=8, Cyprus=6, Czech=8, France=6, Finland=8, Latvia=6, Lithuania=8, Luxembourg=6, Scotland=7, Malta=6, and Norway=7, Slovenia=8, and Sweden=8. Information was submitted for all seven orphan medicines in the Portal for each country, except for the following nine countries: Croatia=6, Cyprus=4, France=3, Latvia=4, Malta=4, Norway=3, Poland=6, Scotland=6, and Sweden=5.

Figure 7: Status of product reimbursement/filing across countries: difference between orphan and oncology medicines



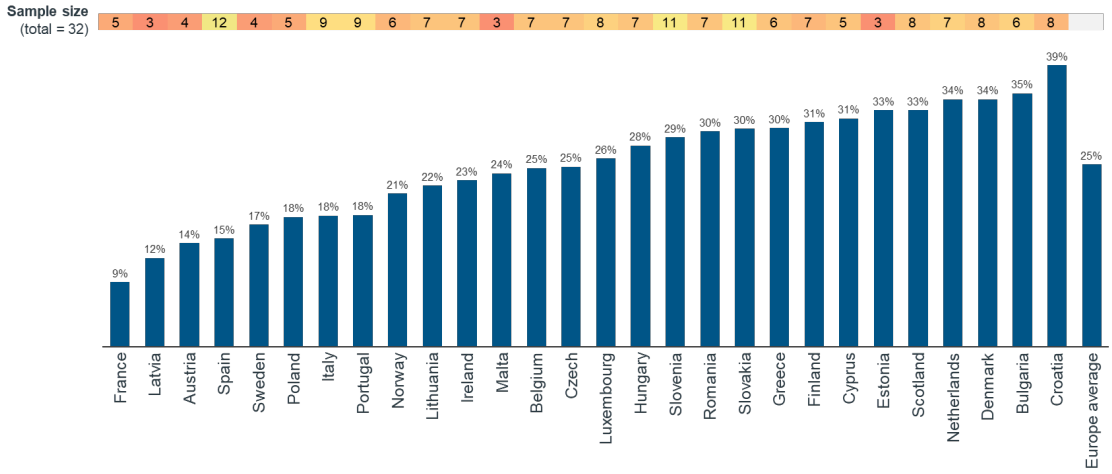
Source: IQVIA – European Access Hurdles Portal (2022)

Speed of product P&R filing and reimbursement

For the first time, we have preliminary data on the length of delayed availability due to the time from filing for P&R to reimbursement. This suggests 25% of the total time between EMA approval and reimbursement can be attributed to delays in filing and 75% to delayed reimbursement decisions.

This pattern varies across countries: As a proportion of the total time, the time taken by a company to file for P&R is lowest in EU4+UK markets (19%), indicating that companies file for P&R sooner in these markets or that the reimbursement decision takes proportionately longer. In CEE countries, the time it takes companies to file for P&R is 27% of the total time between EMA approval and reimbursement. Given the relative limited size of the sample, the time percentages should be considered indicative at this stage and should be interpreted in the context of local P&R processes and requirements.

Figure 8: Proportion of time to reimbursement that is due to time to file for P&R



Source: IQVIA – European Access Hurdles Portal (2022)

Note: Data are not available for all products in all countries. Where the sample size of products in any given country was less than 3 (Germany and England), these countries have been removed from the figure. This is due to the risk of bias in the results from a very small number of products and due to the risk of de-anonymising individual products.

Caveats must be applied when interpreting these data, as due to the timing of the data collection periods for each cycle, some of the data are truncated. For example, we do not adjust these data for average time since marketing authorisation for each product across the period assessed in the cycle. Some products will only have received EMA approval at the latter end of the period, therefore making it less likely that they have filed for P&R or been reimbursed. As future cycles of data collection are incorporated into the assessment, we can consider a wider time frame and take this into account.

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

Root causes of lack of P&R filing

The Portal provides preliminary data on the reasons why products have not been filed for P&R in different countries. Multiple reasons have been provided for non-filing, with manufacturers submitting at least one reason for 93% of un-filed products. As this is collected only for products that are not filed for reimbursement, the sample sizes are inevitably smaller and hence we focus on more aggregated results.

As set out in the root causes analysis, the reasons for not filing for reimbursement are multifactorial. The most common reasons given were:

- Health system constraints and resources (136 reasons altogether),[18] including ‘insufficient local company resources/presence to file for pricing and reimbursement’,[19]

18 The total number of reasons submitted was 210, excluding the reason ‘other’. Across all products and countries, a total of 365 reasons were submitted altogether (including the reason ‘other').

19 Where companies have insufficient resources or presence to file for P&R in a given country, this is considered to be a reflection of the commercial viability of allocating company resources to that country or the limited size of the company (lack of direct local presence on all markets). We categorise this under ‘health system constraints and resources’ because if a health system lacks sufficient funding, infrastructure or patient numbers it is unlikely that all companies will be able to sustain sufficient resources in that country.

'lack of healthcare funding to support utilisation', 'lack of required healthcare infrastructure' and 'size of the treatable population'.[20]

- The value assessment process (50 reasons altogether), including 'evidence package unlikely to meet country requirements', 'low value attributed to class competitors' and 'due to non-alignment with PICO'.[21]
- The P&R process (35 responses altogether), including 'country filing requirements' and 'the impact of external reference pricing on other EU countries'.
- Other more nuanced reasons for not filing for P&R were also provided, which do not map to the categories described above. This reflects that the launch environment for innovative medicines is influenced by the specific dynamics of the indication and product characteristics. Additional categories will be included in the Portal in order to best capture all reasons mentioned.

From the data, there is a clear difference in the rationales for not filing for P&R across regions of Europe.[22] Figure 9 shows the total reasons provided for non-filing in each country. Here, we see there are two key groups – the CEE region and western Europe. In the CEE region, the decision not to file is largely driven by a lack of healthcare system constraints and resources as well as the P&R process, while in western European countries the reason for non-filing is driven by the value assessment process, due to stringent evidence requirements in these countries. This is consistent with countries with strict HTA systems having more rigid information requirements and this acting as one of the barriers to filing for reimbursement. However, it should be recognised that this is based on a relatively small sample of observations (only the 'Other' category is removed from the analysis).[23]

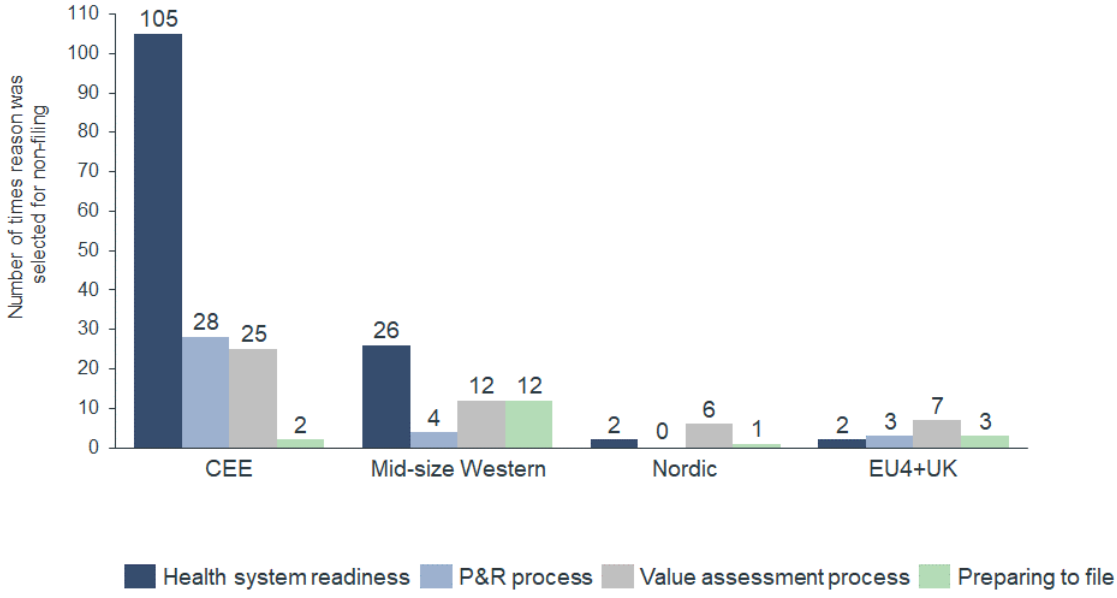
20 The following rationales were clustered for each of the three categories: **(1) Health system constraints and resources:** Lack of required healthcare infrastructure, Size of the treatable population, Lack of healthcare funding to support utilization, Insufficient local resources/presence to file for P&R; **(2) Value assessment process:** Low value attributed to class competitors, Due to non-alignment with PICO, Evidence package unlikely to meet country requirements; **(3) P&R process:** The impact of external reference pricing on other EU countries, Country filing requirements.

21 The PICO framework is a common model in evidence-based medicine. PICO stands for: **P**atient or problem; **I**ntervention or exposure; **C**omparison or control; **O**utcome(s)

22 Countries for which manufacturers provided fewer than three reasons were Austria, Luxembourg, Finland, Sweden, Italy, the Netherlands, Norway and Germany

23 'Other' reasons were removed from this preliminary analysis as it is not yet possible to draw conclusions from these data

Figure 9: Reasons for non-filing in all countries (excluding other category) by country grouping[24, 25]



Source: IQVIA – European Access Hurdles Portal (2022)

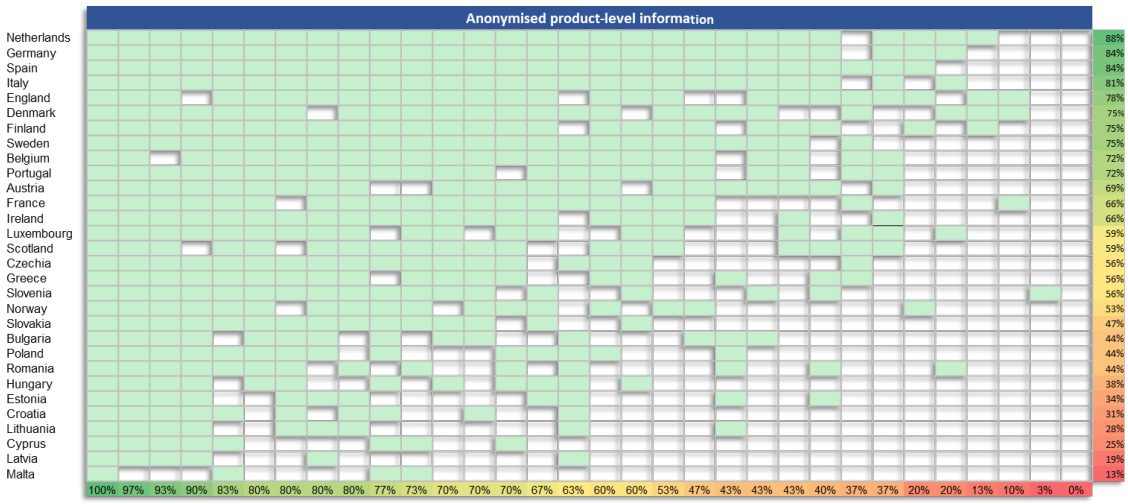
As expected, the reasons for not filing for P&R vary significantly from product to product and from country to country. As seen in Figure 10 below, there is significant variation, which is due to the length of time products have since marketing authorisation but also the types of product and conditions in different markets. For some products, there are high levels of filing overall across Europe but they have not been filed in markets such as England or Belgium. For some products currently with a lower level of filing overall, they have been filed in Romania or Lithuania but not in some of the largest markets in Europe.

It is interesting to look at different groups of products. For some groups, the impact of external reference pricing was a key driver (commonly reported as affecting Latvia and Hungary). In other cases, 'country requirements' was listed as one of the reasons for non-submission (commonly cited in Estonia, Bulgaria and Romania).

24 The following rationales were clustered for each of the three categories: **(1) P&R process:** The impact of external reference pricing on other EU countries, Country filing requirements; **(2) Value assessment process:** Low value attributed to class competitors, Due to non-alignment with PICO, Evidence package unlikely to meet country requirements; **(3) Health system constraints and resources:** Lack of required healthcare infrastructure, Size of the treatable population, Lack of healthcare funding to support utilisation, Insufficient local company resources/presence to file for P&R.

25 For each product and within each country, manufacturers were able to provide multiple reasons for non-filing. Multiple reasons were typically provided, totaling to 210 reasons across products and countries.

Figure 10: Anonymised distribution of filing and reimbursement



Green = products that have been filed for P&R

Source: IQVIA – European Access Hurdles Portal (2022)

The Portal focuses on national processes, but we should not forget that the jurisdiction of P&R decisions also varies by country, with some countries engaging in P&R processes and decision-making at a national level while other countries organise these decisions – at least in part – at the regional level, impacting the timing of reimbursement and availability of medicines.[26] Equally, even after the national and regional processes, this does not mean all patients have access to the medicine.

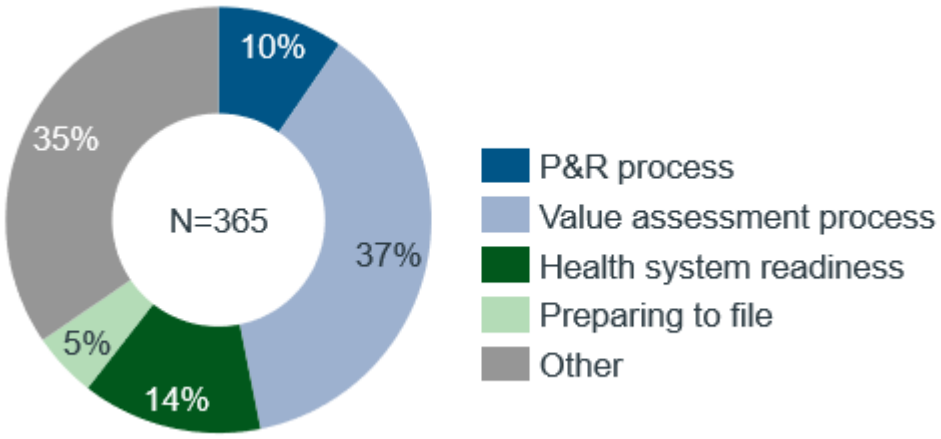
Future direction for the Portal

The data collected in the Portal will 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. There are a range of areas for consideration.

A sizable minority of companies did not provide granular reasons for product non-filing (selecting 'other' as a rationale), indicating a new category(ies) may be needed in the next cycle of data collection. To date, a total 39% of responses submitted were 'other' (see Figure 11), and for some countries (Germany, the Netherlands and Italy) 'other' was the only reason provided by manufacturers for not submitting to these countries. For 41% of all instances in which a product had not been filed for P&R, 'other' was the only response provided.

26 For example, in Italy a recent paper found that both the timing and the number of medicines available for patients were widely different from region to region. The mean best regional time (defined as the average number of days after AIFA (Agenzia Italiana del Farmaco | Italian Medicines Agency) market authorisation, as published in the GU (Gazzetta Ufficiale | Official Gazette), and the first purchase date in the first Italian region) was 29 days. The longest regional time (the number of days between GU and the first purchase in the last region for which data are available to date (July 2016)) was 293 days. Rada, M. (2017) Timeline of Authorization and Reimbursement for Oncology Drugs in Italy in the last three years.

Figure 11: Rationale(s) for not filing in European markets[27]



Source: IQVIA – European Access Hurdles Portal (2022)

'Preparing to file' refers to instances of which, at the time of Portal data collection, companies were preparing their P&R application dossiers for the product but had not yet formally submitted

Data from biosimilars were absent in this round of data collection, limiting the ability to draw conclusions about the challenges experienced by innovative products compared to biosimilars. Data were only collected from EFPIA members, limiting the ability to draw conclusions about the impact of company size on product availability, and reducing the sample that could be analysed.[28]

As we collect more data, we will be able to look in more detail while protecting confidentiality of data on individual products. For example, it will be possible to look at how the length of time since marketing authorisation affects the product status and reason for delays, and as we have more product information we can look in more detail at the reasons for not filing for P&R and whether this varies by product type and therapy area. This should provide more insights into the root causes of unavailability and delay, how this varies across European countries and how it is changing overtime.

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

28 In Cycle 1 (the period of products with marketing authorisations between January and December 2021; data were collected during Q4 2022), of the 48 products in scope for data collection, 26 were not marketed by EFPIA companies (54% of total in-scope products). In Cycle 2 (the period of products with marketing authorisations between January and June 2022; data were also collected during Q4 2022) of the 37 new products added to the scope, 20 were not marketed by EFPIA companies (54% of total in-scope products).

Appendix

Appendix Table 1: Products with information submitted into the Portal (n=32)

Corporation name	Medicine name	Corporation name	Medicine name
Almirall	*Klisyri*	Merck KGaA	*Tepmetko*
Amgen	*Lumykras*	Novartis	*Kesimpta*
Astellas	*Evrenzo*	Novo Nordisk	*Sogroya*
Astellas	*Padcev*	Novo Nordisk	*Wegovy*
AstraZeneca	*Saphnelo*	Pfizer	*Apexxnar*
Bayer	*Kerendia*	Pfizer	*Cibinqo*
Bayer	*Verquvo*	Pfizer	*Ngenla*
Bial	*Ontilyv*	Roche	*Enspryng*
Biogen	*Vumerity*	Roche	*Evrysdi*
Bristol Myers Squibb	*Inrebic*	Roche	*Gavreto*
Eli Lilly	*Retsevmo*	Roche	*Lunsumio*
Gilead	*Trodelvy*	Roche	*Xofluza*
GlaxoSmithKline	*Jemperli*	Sanofi	*Nexviadyme*
Janssen-Cilag	*Ponvory*	UCB	*Bimzelx*
Janssen-Cilag	*Rybrevant*	Vifor	*Kapruvia*
Lundbeck	*Vyepti*	Vifor	*Tavneos*