

Project number: 101100610

Project name: Development of early warning features and guidance in the area of pricing through the EURIPID database

Project acronym: EURIPID ACCESS

WP4: Analysis and Evidence

Task 4.3: Preparation of policy briefs

D4.3 Quick Check Policy Brief 4

Quick Check Policy Brief on ERP models

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August 2024



**Co-funded by
the European Union**

This Project is co-funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or HaDEA. Neither the European Union nor the granting authority can be held responsible for them.

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1 Executive summary

This study focused on: (1) the time to launch of selected medicinal products (MPs) across European Union (EU), (2) the availability of reference prices at the time of launch, and at the time of price revision i.e. External Reference Pricing (ERP) basket availability. To ensure clarity and facilitate conclusions we analysed only innovative MPs with a single indication registered by European Medicines Agency (EMA). Our aim was to understand differences in reimbursement timelines between Poland and other countries, to understand how ERP basket composition affects reference pricing availability at the time of the first reimbursement, and at the time of price revision.

Key messages:

1. 20 MPs (INN, strength, dosage form) with 11 active substances met the inclusion criteria for analysis.
2. The time to launch strategies varied between the countries. Early time to launch was associated with relatively high prices of reimbursed MPs; whereas, late time to launch was associated with lower MPs prices. For Poland, time to launch ranged from 450 to 1,186 days, and price ranged from 27% to 100% of the maximum price of index MP price at the time of the first reimbursement.
3. The average ERP basket availability in the EURIPID database at the time of the first reimbursement or the first price revision varied between the countries. In countries with small ERP baskets (10 or less countries, including Poland) pricing information was available only from 2.2 countries on average. The availability of reference pricing at the time of the first price revision increased, and for small ERP basket countries 1.5 more countries (3.7 in total) were available at the time of the first price revision when compared with the first reimbursement date.
4. The exploratory analysis of time to launch vs. reimbursement price level may help to determine or revise the country's ERP basket selection.

Keywords: ERP, reference price, time to launch, price setting, price revision.

2 Introduction

2.1 What is known

The comparison of prices of medicinal products (MPs), known as 'External Reference Pricing' (ERP) is widely used as a benchmark for price negotiations and price setting. The main principles for ERP were formulated by The EURIPID Collaboration to guide on a coordinated approach of national authorities on the use of ERP and to avoid/mitigate negative impact for patient access to medicines (EURIPID 2018; see Table 1). The degree of implementation of ERP Guidance across Europe was analysed previously in the Assessment report of the degree of ERP implementation at the country level (the ERP survey and report; EURIPID 2024).

Selection of reference countries for the ERP basket is crucial for implementation and development of ERP policies. Comparability of the pricing system, fairness, market effects, national up-date frequencies, missing price types, administrative burden, product status, and ERP formula may be considered.

The ERP survey and report (EURIPID 2024) showed that in Poland, ERP is used in pricing and reimbursement processes of original MPs in a mix with other policy tools: i.e. internal reference pricing, price negotiations, managed entry agreements, health technology assessment, tendering or tendering-

like system, and mark-ups regulation. Poland’s reference countries basket includes nine countries: Czech Republic (CZ), Estonia (EE), Hungary (HU), Lithuania (LT), Latvia (LV), Malta (MT), Romania (RO), Slovakia (SK) and Slovenia (SI). The lowest price of references countries is taken into consideration.

Table 1. Principles of EURIPID Guidance Document on External Reference Pricing (EURIPID 2018).

| |
|---|
| #01) ERP is an important policy tool that should be used in a mix with other instruments and not as stand-alone policy tool. |
| #02) ERP should take place on a single product basis rather than by indices |
| #03) The aim of the national pharmaceutical policy should determine the selection of reference countries. |
| #04) Evidence has shown that ERP is most effective when applied to pharmaceuticals without generic or therapeutic competition. |
| #05) The comparison of prices of medicinal products should be done on the first price (type) in the pharmaceutical distribution chain. |
| #06) Competent authorities should apply clear and transparent procedures to determine which pharmaceuticals are considered as comparable. |
| #07) The pricing formula applied for ERP should reflect the national pricing policy objective. |
| #08) ERP procedures should be performed with the highest possible accuracy and completeness of data sources. |
| #09) If price information is adjusted to national requirements, it should be done in a transparent and sustainable manner. |
| #10) ERP activities need careful planning and should also be considered as a policy tool for price revisions and monitoring. |
| #11) The procedures and price inputs to ERP should be transparent to ensure predictability and effectiveness. |
| #12) Policy makers should consider strengthening their cooperation, in particular through the contribution and benefits of existing policies. |

2.2 Objectives

Our aim was to analyse differences in reimbursement timelines between Poland and other countries, to understand how ERP basket composition affects reference pricing availability at the time of the first reimbursement, and at the time of price revision.

We analysed single indication MPs that are reimbursed in Poland. The study focused on: (1) the time to launch of selected MPs across EU, (2) the availability of reference prices at the time of launch, and at the time of price revision (i.e. ERP basket availability).

3 Study design

We analysed the composition of countries ERP baskets using the results of ERP survey and report (EURIPID 2024), and the information provided by EURIPID database, i.e. launch dates of MPs, and unit costs over time.

3.1 Data sources

Three main data sources were explored:

- (1) MPs reimbursed in Poland were selected based on the reimbursement list of medicinal products in Poland (<https://www.gov.pl/web/zdrowie/obwieszczenia-ministra-zdrowia-lista-lekow-refundowanych>, in Polish language. only).
- (2) Selection of single indication MPs was made based on the list of MPs indications registered by EMA and listed in EPAR – Product information (<https://www.ema.europa.eu/>).
- (3) Information on MPs’ pricing and launch dates by country was extracted from the EURIPID database (<https://database.euripid.eu/>).

3.2 Search strategy

To ensure clarity and facilitate conclusions we analysed only innovative MPs with a single indication registered by EMA. This was to minimise differences in price setting approaches for MPs with multiple

indications or with generic or therapeutic competition. To ensure data maturity, only widely reimbursed MPs as reported by the EURIPID database were preferred.

In conclusions, MPs selection was made based on the prespecified inclusion criteria:

- (1) MPs reimbursed in Poland in 2023 for the first time,
- (2) MPs without generic or therapeutic competition,
- (3) MPs with single indication registration by EMA,
- (4) MPs reimbursement price available in the EURIPID database for at least 15 countries.

Eleven (11) active substances met the selection criteria and were included in the analysis: abrocitinib, acalabrutinib, asciminib, avatrombopag, bimekizumab, latotrectinib, pegcetacoplan, siponimod, trastuzumab deruxtecan, tucatinib, and zanubrutinib. The search strategies are presented below (Table 2).

Table 2. Search strategies used in EURIPID, EMA databases and Poland's lists of reimbursement of MPs.

| Search criteria | List of reimbursed MPs | EMA database | EURIPID database |
|-----------------|------------------------|--|--|
| Query | New MPs | Medicines for human use | First match query |
| Keywords | - | abrocitinib, acalabrutinib, asciminib, avatrombopag, bimekizumab, latotrectinib, pegcetacoplan, siponimod, trastuzumab deruxtecan, tucatinib, and zanubrutinib | abrocitinib, acalabrutinib, asciminib, avatrombopag, bimekizumab, latotrectinib, pegcetacoplan, siponimod, trastuzumab deruxtecan, tucatinib, and zanubrutinib |
| Countries | Poland | - | No restrictions |
| Data cut-off | 01.01.2023–31.12.2023 | no restrictions | 30.09.2019–30.06. 2024 |
| Search date | 12.05.2024 | 2.06.2024 | 19.07.2024 |
| Used filters | - | EPAR – Product information | Trade name |

3.3 Tool of collecting, modelling, and analysing searched data

All extracted data was exported to MS Excel and Power BI. MS Excel and/or Power BI were used for analyses and visualisations.

3.4 Methods

Qualitative and quantitative data analysis were performed to meet the objectives.

Dates of the first reimbursement in each country were collected for all MPs using the First match query in the EURIPID database. Date of reimbursement in the first country was considered as day 0. Time to launch was calculated as a difference between the dates of reimbursement in the index country and the country of the first reimbursement.

A ranking of reimbursement order across the countries was introduced, number “1” was assigned to the first country, number “2” to the second country that reimbursed index MP, etc. Minimum, average, and maximum ranking were analysed for each country. One rank for the same active substance (INN) and formulation, but different strengths or package size was used, and the most commonly reimbursed MP was considered as a basis for calculations.

Ex-factory prices were favoured for pricing analyses. Information related to other types of prices (i.e. wholesale price) were collected to register non-price related events only (i.e. date of reimbursement, ERP basket availability at the time of reimbursement in the index country, etc). Exchange rates were fixed to starting date. Comparison of pricing between the countries was calculated as a percentage of maximum price reached on the market (regardless the date/rank of reimbursement of the most expensive MP).

Number of countries in the ERP baskets was sourced from our previous ERP survey and report (EURIPID 2024; see also Table 3). In the table, rows show the ERP basket composition of the countries in the

row-heading, i.e. for example in Poland (designated with PL in the first column) the ERP basket consists of the Czech Republic (CZ), Estonia (EE), Hungary (HU), Lithuania (LT), Latvia (LV), Malta (MT), Romania (RO), Slovenia (SI), and Slovakia (SK).

ERP basket availability was calculated as a number (or percentage) of countries in the ERP basket with pricing information at the time of reimbursement in the index country. Countries were stratified by ERP basket size as countries with a (1) large basket (25 or more reference countries); (2) medium basket (11-24 reference countries); and (3) small basket (10 or less reference countries) as per the previous ERP survey and report (EURIPID 2024). For example, Poland has nine countries in the ERP basket, but at the time of reimbursement of bimekizumab (March 2023) only three countries from Poland’s ERP basket provided pricing information in the EURIPID database: Slovenia (SI; reimbursement from May 2022), Romania (RO; from August 2022) and Czech Republic (CZ; from November 2022). Therefore, Poland’s ERP basket availability at the time of reimbursement decision was up to 33%.

The time to the first price revision was analysed using the Price evolution graph in the EURIPID database. Price revisions were defined as price drops at fixed exchange rates. Data on the country name and the time to the first price revision were collected and analysed. The rate of price revisions for each country was calculated as a number of MPs with price drop divided by the number of selected MPs being reimbursed.

Table 3. Summary of reference countries basket composition (rows) for each of the index country (first column). Basket size stratification in colours: green for large baskets, white for medium baskets, and blue for small baskets (last column; cited after EURIPID 2024).

| | ERP basket composition (dark grey in rows show the reference countries for the countries in the row-heading) | | | | | | | | | | | | | | | | | | | | | | | | | No | | | | | | | | | | |
|----|--|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|--|----|
| | AT | BE | BG | CH | CY | CZ | DE | DK | EE | ES | FI | FR | GR | HR | HU | IE | IL | IS | IT | LI | LT | LU | LV | MT | NL | | NO | PL | PT | RO | SE | SI | SK | UK | | |
| AT | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 26 |
| BE | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 6 |
| BG | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 10 |
| CH | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 9 |
| CY | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 10 |
| CZ | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 25 |
| DK | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 9 |
| EE | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 3 |
| ES | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 9 |
| FI | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 29 |
| FR | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 4 |
| GR | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 19 |
| HR | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 5 |
| HU | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 29 |
| IL | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 7 |
| LV | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 8 |
| MT | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 11 |
| NL | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 4 |
| NO | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 9 |
| PL | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 9 |
| PT | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 4 |
| SI | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 3 |
| SK | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 25 |
| No | 12 | 14 | 5 | 1 | 7 | 8 | 14 | 10 | 9 | 13 | 9 | 16 | 7 | 6 | 9 | 9 | 0 | 2 | 13 | 1 | 10 | 6 | 9 | 5 | 12 | 4 | 7 | 9 | 8 | 10 | 11 | 10 | 7 | | | |

3.5 Limitations

The scope of this analysis was restricted by the principles of Quick Check Policy Briefs. The analysis covered only selected elements of pricing and reimbursement policies (innovative MPs, with one indication registered by EMA, and reimbursed in Poland).

The analysis was crafted to explore the ERP potential in Poland, the ex-factory pricing information was favoured against other price types. Only proportion of countries report the ex-factory pricing in the

EURIPID database, thus this restriction was the main limitation of our analysis. A built-in price recalculation feature (i.e. from wholesale price to ex-factory price) or the use of published formulas for price recalculations for each country (as practised in Austria; BSGPK 2023) could backbone this limitation in the future studies.

Information sourced from the EURIPID database was limited to the countries that agreed to share its data. For example, the pricing information from Germany, a country referenced by 14 other countries, is not available in the EURIPID database and was omitted. The analysis did not include information on managed entry agreements.

4 Results

4.1 MPs selection

20 MPs (INN, strength, dosage form) with 11 active substances met the inclusion criteria and were selected for the analysis. All MPs, except for acalabrutinib and larotrectinib, had one dosage form only. Larotrectinib was available in hard capsules and oral solution, whereas acalabrutinib was available in hard capsules and film-coated tablets. From the pharmaceutical perspective the hard capsule and the film-coated tablet doesn't mean a considerable difference (see Table 4).

Table 4. MPs selection for the analysis.

| INN (dosage form) | | Strength | Number of units in package |
|------------------------|--|----------|----------------------------|
| abrocitinib | hard capsules | 100 mg | 28, 30, 91 |
| | | 200 mg | 28, 30, 91 |
| | | 50 mg | 14, 28, 30, 91 |
| acalabrutinib | hard capsules | 100 mg | 56, 60 |
| | film-coated tablets | 100 mg | 60 |
| asciminib | film-coated tablets | 20 mg | 60 |
| | | 40 mg | 60 |
| avatrombopag | film-coated tablets | 20 mg | 10, 15, 30 |
| bimekizumab | solution for injection | 160 mg | 2 |
| larotrectinib | hard capsules | 100 mg | 56 |
| | oral solution | 20 mg/ml | 1, 100 |
| | hard capsules | 25 mg | 56 |
| pegcetacoplan | solution for injection | 1080 mg | 1, 8 |
| siponimod | film-coated tablets | 0,25 mg | 12, 120 |
| | | 1 mg | 28 |
| | | 2 mg | 28 |
| trastuzumab deruxtecan | powder for concentrate for solution for infusion | 100 mg | 1 |
| tucatinib | film-coated tablets | 150 mg | 84 |
| | | 50 mg | 88 |
| zanubrutinib | hard capsules | 80 mg | 120 |

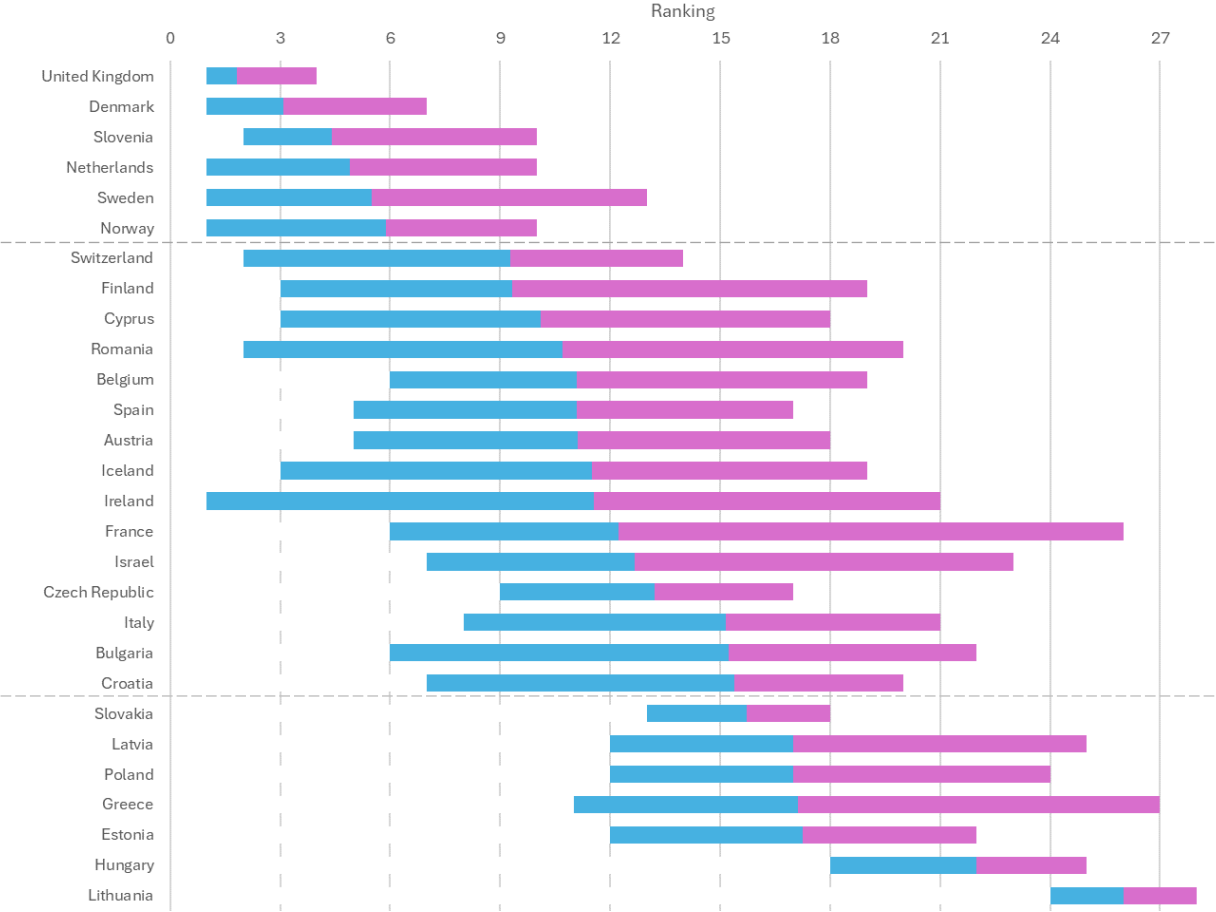
4.2 Time to launch vs. pricing

We analysed time to launch of selected MPs to understand differences in reimbursement timelines between Poland and other countries.

Different launch strategies were observed between the countries. United Kingdom (UK), Denmark (DK), Slovenia (SI), Netherlands (NL), Sweden (SE), Norway (NO), and Switzerland (CH) more often tend to reimburse MPs first. In contrary, Slovakia (SK), Latvia (LV), Poland (PL), Greece (GR), Estonia (EE), Hungary (HU), and Lithuania (LT) more often tend to reimburse MPs later than other countries (see

Figure 1). UK was the first to reimburse 58% of the analysed MPs. DK and NL were the first to reimburse 38% and 23% of MPs, respectively.

Figure 1 Country's earliest, average, and latest, place in the order of reimbursement of selected MPs.



We explored the effect of longer time to launch and price lowering for Poland when compared with countries referenced in Poland’s ERP basket, i.e. countries with similar to Poland GDP per capita. For this, we juxtaposed data on time to launch with pricing information.

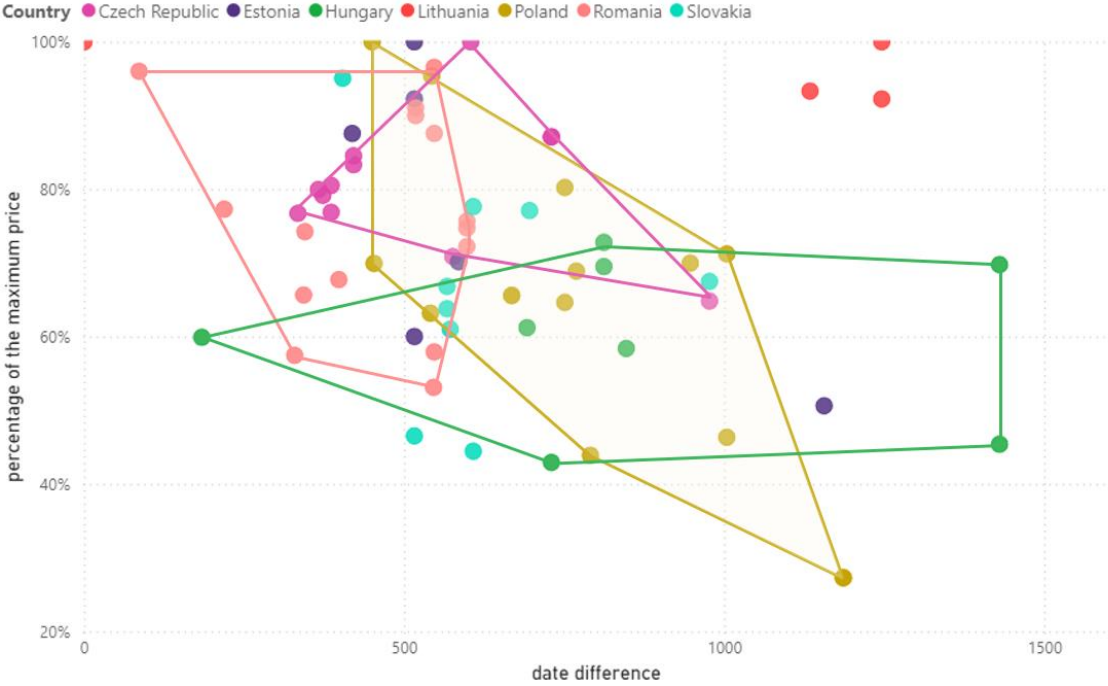
For Poland, the time to launch ranged from 450 (asciminib) to 1,186 days (larotrectinib). Pricing of the selected MPs ranged from 27% (asciminib) to 100% (larotrectinib) of the maximum price of index MP price at the time of the first reimbursement (see Figure 2). Data for Poland (yellow colour) showed relationship between the time to launch and the prices level, i.e. the later the index MP was reimbursed, the lower the price was achieved.

Most of the countries referenced by Poland tend to reimburse MPs earlier and with higher prices at the time of reimbursement, except for Lithuania (LT; red dots, later launch and higher prices) and Hungary (HU; green dots, similar timing of launch with lower prices).

The exploratory analysis of time to launch vs. reimbursement price level may help to determine or revise the country’s ERP basket selection. We used lines to show the overlap of timelines and pricing between the countries (see Figure 2; for graph clarity only selected countries were highlighted). For example, Romania (RO; light pink dots and lines) tends to reimburse MPs with higher prices and earlier to Poland (yellow dots and lines) resulting in low overlap of dotted areas between the countries. HU (green dots and lines) tends to reimburse MPs with lower prices to Poland, but the time to launch

varied, with some MPs being reimbursed earlier to Poland and some later to Poland. Thus, RO and HU may serve as reasonable ERP basket countries for Poland. In contrast, adding the Czech Republic (CZ; dark pink dots and lines) to Poland’s ERP basket may be less useful due to relatively high pricing and late time to launch in CZ. Times to launch in CZ are close to Poland’s and pricing may not be yet available at the time of price negotiations (greater overlap of dotted areas between CZ and Poland, see also Figure 2).

Figure 2. Time to launch vs. reimbursement price level. Dots represent level of pricing of selected MPs at the time of the first reimbursement in index countries (coloured). Lines to show the overlap of timelines and pricing between the countries. For graph clarity only selected countries were highlighted with lines.



4.3 Rate of ERP baskets availability at the time of reimbursement

We analysed the pricing availability in the ERP baskets at the time of the first reimbursement to understand the value of ERP basket composition in price setting and to explore the need of ERP basket updates to cope the changes in the reimbursement market.

The average ERP basket availability in the EURIPID database at the time of the first reimbursement ranged from 0% to 52%. Countries with large ERP baskets (25 or more countries) had greater availability of pricing information for ERP purposes, i.e. on average pricing from 8.2 countries was available. This greater availability of pricing information may be a trade-off for lower control over the choice of countries used for ERP. In countries with small ERP baskets (10 or less countries, including Poland) pricing information was available only from 2.2 countries on average (see Table 5).

Not all of the EU countries share their pricing information within the EURIPID database, thus different sources of information may be necessary for effective ERP. The countries that are often referenced and not available in the EURIPID database include Germany (referenced by 14 countries, see also Table 3). Although, Italy (referenced by 13 countries) already shares pricing information within the EURIPID database, we were not able to obtain it due to delays in data provision at the time of the analysis.

Table 5. Rate (percentage) of country basket availability at the time of reimbursement. Basket size stratification in colours: green for large baskets, white for medium baskets, and blue for small baskets

| Country | Number of countries in the ERP basket / available in the EURIPID database | Average number of countries reimbursing MPs before the index country | Average availability of ERP basket in the EURIPID database at the time of reimbursement |
|----------------|---|--|---|
| Finland | 29/24 | 6.2 | 21% |
| Hungary | 29/24 | 11.3 | 39% |
| Austria | 26/22 | 6.0 | 23% |
| Czech Republic | 25/21 | 7.9 | 32% |
| Slovakia | 25/21 | 9.4 | 38% |
| Greece | 19/15 | 5.9 | 31% |
| Bulgaria | 10/9 | 3.5 | 35% |
| Cyprus | 10/8 | 2.1 | 21% |
| Poland | 9/9 | 2.2 | 24% |
| Spain | 9/8 | 3.2 | 35% |
| Switzerland | 9/8 | 4.0 | 44% |
| Denmark | 9/7 | 1.9 | 21% |
| Norway | 9/7 | 3.1 | 35% |
| Latvia | 8/8 | 2.8 | 35% |
| Israel | 7/6 | 2.7 | 39% |
| Belgium | 6/4 | 2.1 | 34% |
| Croatia | 5/4 | 2.6 | 53% |
| Netherlands | 4/4 | 1.1 | 27% |
| France | 4/2 | 1.3 | 32% |
| Estonia | 3/3 | 0.3 | 11% |
| Slovenia | 3/2 | 0.0 | 0% |

4.4 ERP basket availability at the time of the first price revision

We analysed the ERP baskets pricing availability at the time of the first price revision to understand if price revision might serve as a solution for improvement of the availability of the reference pricing information.

The rate of price revisions for each country was calculated as a number of MPs with price drop divided by the number of selected MPs being reimbursed. Out of 21 countries providing pricing information for selected MPs, 16 performed price revisions (see also Figure 3). The number of drugs that underwent price revisions varied across the countries, with Finland (FI), Denmark (DK), Slovenia (SI), Switzerland (CH), and Slovakia (SK) revising prices of over 60% of selected MPs (see Figure 3).

The availability of the ERP basket pricing improved universally, by 2.1 more countries with pricing information being available in the EURIPID database at the time of the first price revision (see Table 6). The improvement was most significant for countries with large ERP baskets, i.e. Finland (FI), Austria (AT), and Slovakia (SK). Small ERP basket countries improved by 1.5 more countries being available at the time of the first price revision. The availability improvement was minimal for Poland (0.2 more countries being available) and may be explained by relatively late launch dates of analysed MPs.

Figure 3. The rate of price revisions per country (in brackets: number of MPs with price revision per number of the selected MPs being reimbursed).

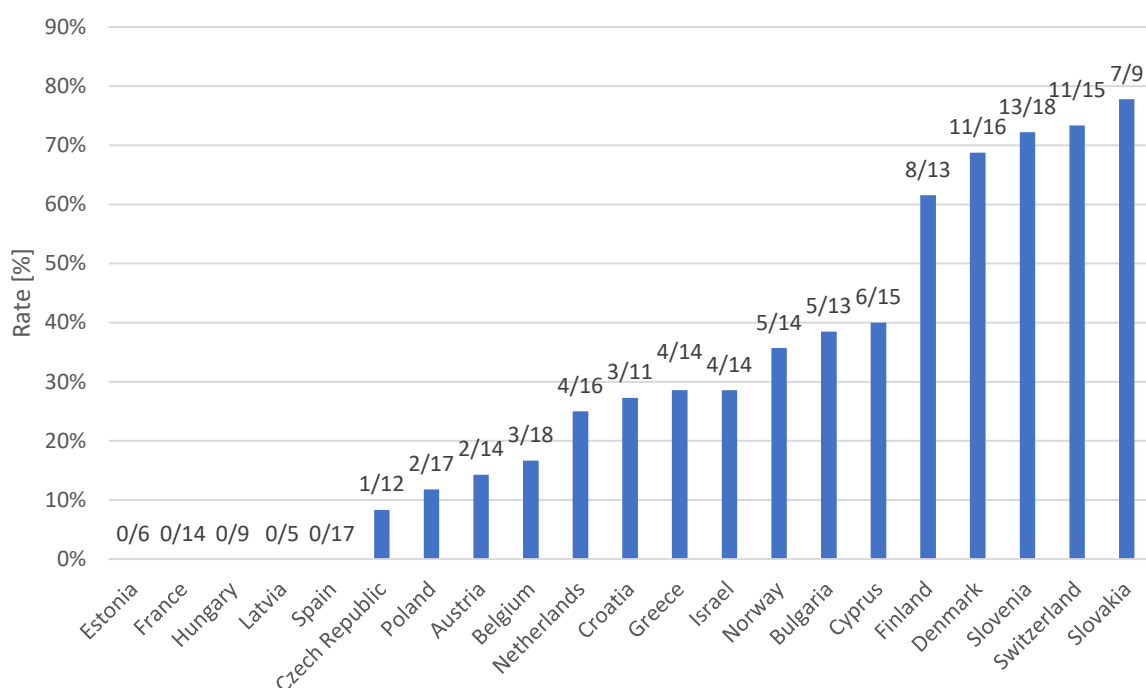


Table 6. Improvement of the reference basket utilisation at the first price revision (small basket countries in blue).

| Survey respondent | Available prices at launch | Available prices at the first revision | Improvement |
|-------------------|----------------------------|--|-------------|
| Finland | 6.8 | 13.9 | 7.1 |
| Austria | 6.5 | 11.0 | 4.5 |
| Slovakia | 11.4 | 15.6 | 4.2 |
| Cyprus | 2.8 | 6.3 | 3.5 |
| Switzerland | 4.5 | 6.6 | 2.1 |
| Bulgaria | 5.0 | 7.0 | 2.0 |
| Denmark | 1.9 | 3.8 | 1.9 |
| Netherlands | 1.1 | 2.5 | 1.4 |
| Belgium | 2.6 | 4.0 | 1.4 |
| Slovenia | 0.0 | 1.3 | 1.3 |
| Norway | 3.1 | 4.4 | 1.3 |
| Greece | 9.1 | 10.3 | 1.2 |
| Croatia | 3.0 | 4.0 | 1.0 |
| Czech Republic | 9.2 | 10.0 | 0.8 |
| Israel | 3.6 | 4.0 | 0.4 |
| Poland | 3.3 | 3.5 | 0.2 |
| Average | 4.8 | 6.8 | 2.1 |

5 Conclusions

The study focused on: (1) the time to launch of selected MPs across EU, (2) the availability of reference prices at the time of launch, and at the time of price revision (i.e. ERP basket availability).

Early time to launch was associated with higher reimbursement prices, whereas later launches were able to achieve lower list prices of the MPs, especially for Poland. Early launch doesn't allow for inclusion of ERP in the price setting due to low availability of reference pricing information. However, this can be mitigated by the subsequent price revisions at the later time.

The EURIPID database served as a useful source of information and a tool for pricing analysis. Inclusion of further countries (i.e. pricing information from Germany) and exploring prices recalculation solution for countries reporting only one type of the price (i.e. recalculation of wholesale price to ex-factory price or opposite) would be helpful for future studies. In the future studies, the Pricing & Reimbursement (P&R) tracker that is planned in the EURIPID database, would give a more granular view on MP's times to launch. It may help to understand whether the differences between the countries come from the launch sequences set by the industry, lengths of countries' P&R processes, i.e. due to scope of health technology assessment, length of pricing negotiations, or others.

Disclaimer: The views expressed in this publication are those of the author/s and should not be attributed to EURIPID COLLABORATION and/or its funders.

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| EURIPID 2024 | Pelczarska, A; Mucha, K; Zachariasz, A; Dzik, M; Kuriata; E. Assessment report of the degree of ERP implementation at the country level, February 2024 available on EU Funding & Tenders Portal (https://ec.europa.eu/info/funding-tenders/opportunities/grants/docs/080166e50c135a6f/Attachment_0.pdf) |
| BSGPK 2023 | Federal Ministry of Social Affairs, Health, Care and Consumer Protection pursuant to Section 9 Paragraph 3 of the Price Act 1992, Federal Law Gazette 145/1992 (https://www.google.com/url?sa=t&source=web&rct=j&opi=89978449&url=https://www.sozialministerium.at/dam/jcr:55290a07-2ffe-4353-aff9-a00b9f30fdef/Vorgehensweise_Preiskommission_1.2.2023_.pdf&ved=2ahUKEwjtIJOc7diHAXMQVUIHV8sL5IQFnoECBcQAQ&usg=AOvVaw3Tc9zhLTQRLKILFtZwOpk) |

7 List of abbreviations

| | |
|---------------------|---|
| AOTMIT | Agency of Health Technology and Tariff System |
| AT | Austria |
| BE | Belgium |
| BG | Bulgaria |
| CH | Switzerland |
| CY | Cyprus |
| CZ | Czech Republic |
| DK | Denmark |
| EE | Estonia |
| EMA database | European Medicine Agency's finder |
| ERP | External Reference Pricing |
| ERP Guidance | EURIPID Technical Guidance Document on External Reference Pricing |
| ES | Spain |
| FR | France |
| FI | Finland |
| GR | Greece |
| HR | Croatia |
| HTA | Health Technology Assessment |
| HU | Hungary |
| IL | Israel |
| IRP | Internal Reference Pricing |
| IT | Italy |
| LV | Latvia |
| MEA | Managed Entry Agreement |
| MPs | Medical products |

| | |
|-----------|-------------|
| MT | Malta |
| NL | Netherlands |
| NO | Norway |
| PL | Poland |
| PT | Portugal |
| SE | Sweden |
| SI | Slovenia |
| SK | Slovakia |

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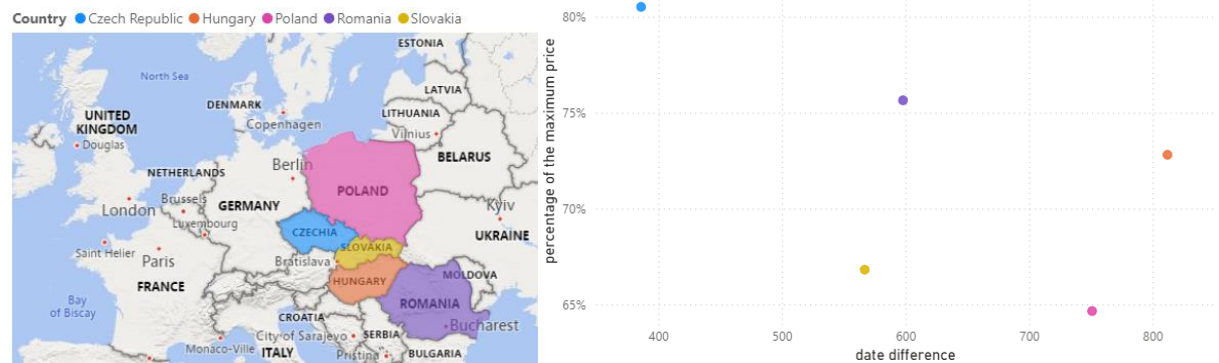
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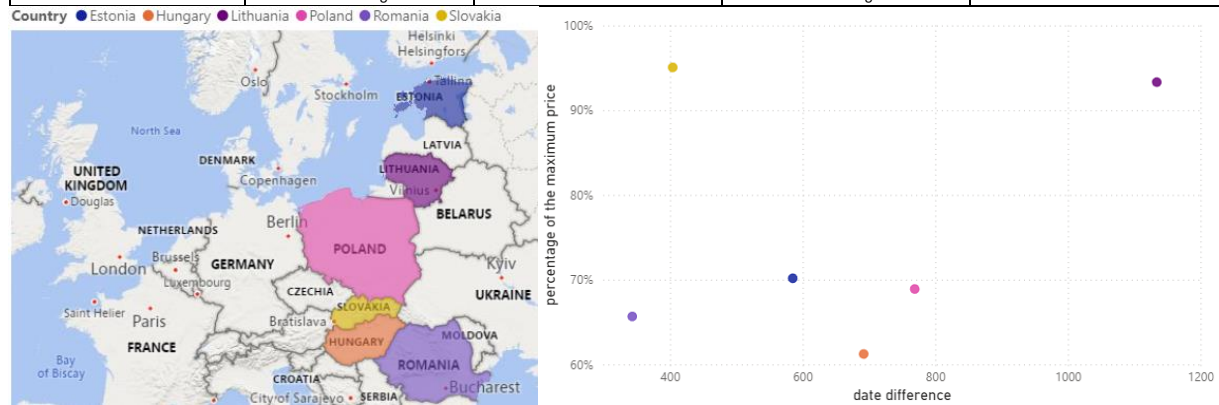
10 Appendix 1. Time to launch and the pricing for Poland's ERP basket

Please find below the detailed information on the time to launch and the pricing of the MPs analysed for the Poland's ERP basket (the Czech Republic, Estonia, Hungary, Lithuania, Latvia, Malta, Romania, Slovakia, and Slovenia). For the consistency of referencing between the analyses the information on the country of the first launch and the country of maximum price were collected on a broader level, i.e. from all of the countries available in the EURIPID database.

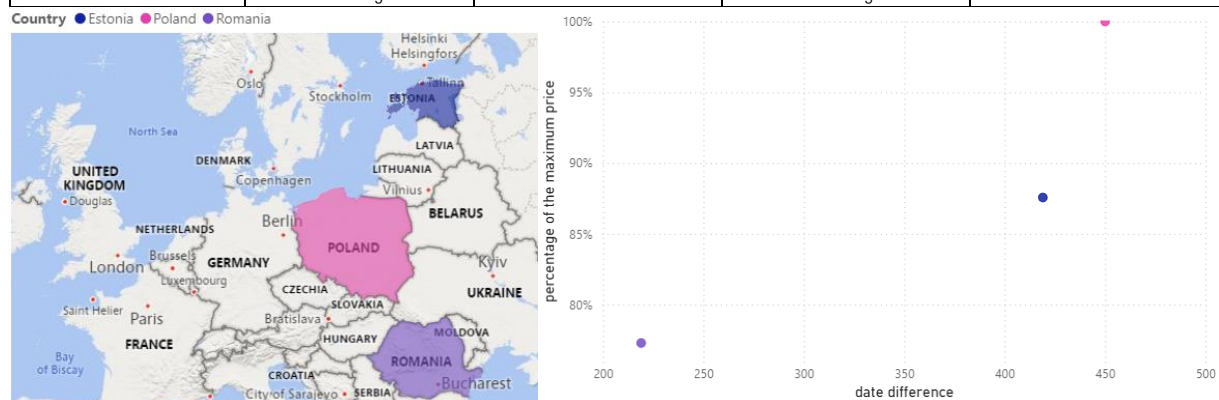
| Active substance | Strength | Number of units | First launch country | Maximum price country |
|------------------|----------|-----------------|----------------------|-----------------------|
| abrocitinib | 100 mg | 28 | United Kingdom | Italy |



| Active substance | Strength | Number of units | First launch country | Maximum price country |
|------------------|----------|-----------------|----------------------|-----------------------|
| acalabrutinib | 100 mg | 60 | United Kingdom | Slovenia |

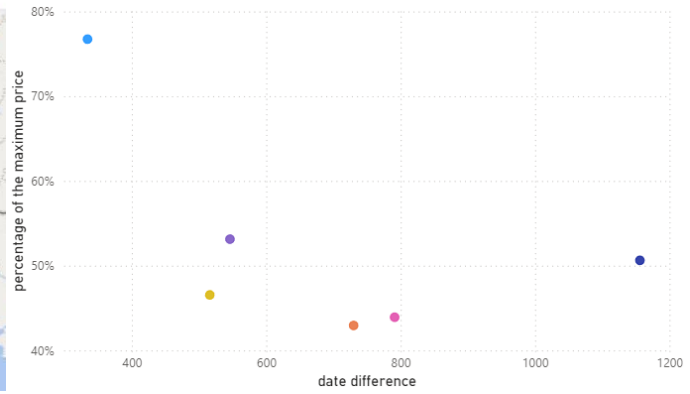
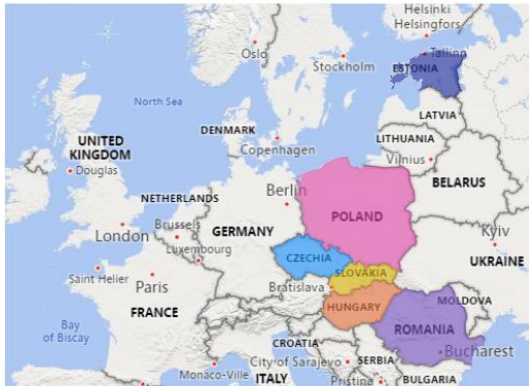


| Active substance | Strength | Number of units | First launch country | Maximum price country |
|------------------|----------|-----------------|----------------------|-----------------------|
| asciminib | 40 mg | 60 | United Kingdom | Poland |



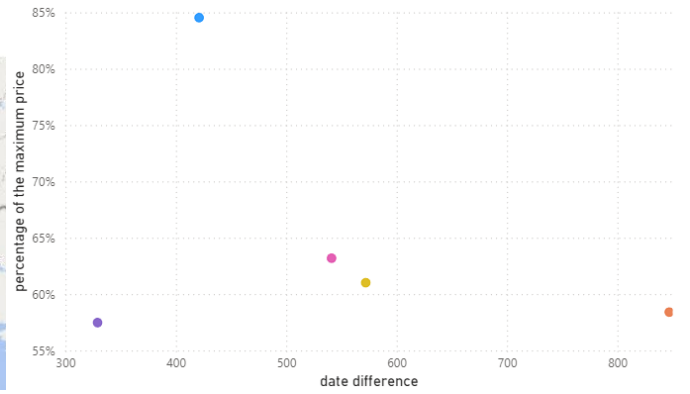
| Active substance | Strength | Number of units | First launch country | Maximum price country |
|------------------|----------|-----------------|----------------------|-----------------------|
| avatrombopag | 20 mg | 10 | Ireland | Slovenia |

Country ● Czech Republic ● Estonia ● Hungary ● Poland ● Romania ● Slovakia



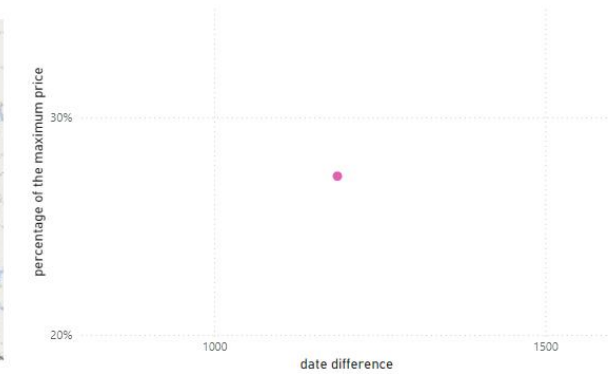
| Active substance | Strength | Number of units | First launch country | Maximum price country |
|------------------|----------|-----------------|----------------------|-----------------------|
| bimekizumab | 160 | 2 | United Kingdom | Slovenia |

Country ● Czech Republic ● Hungary ● Poland ● Romania ● Slovakia

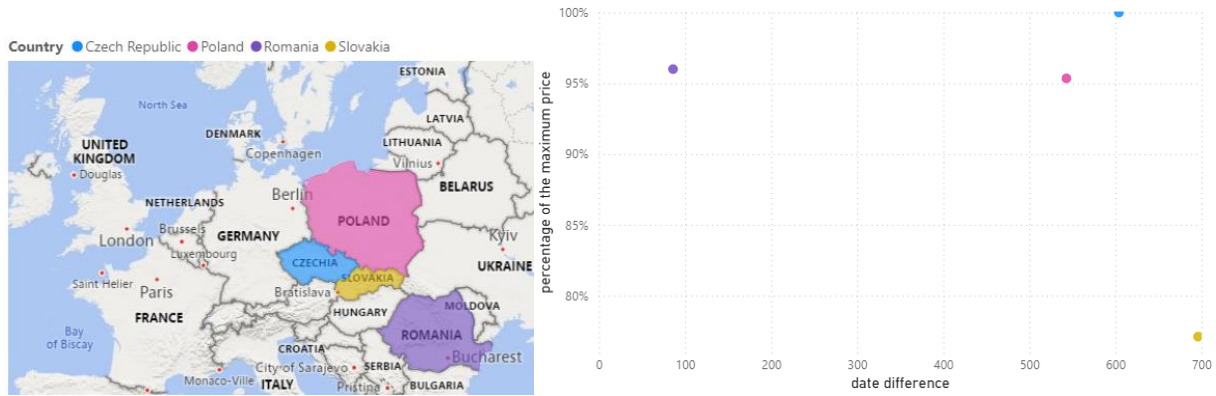


| Active substance | Strength | Number of units | First launch country | Maximum price country |
|------------------|----------|-----------------|----------------------|-----------------------|
| loracetinib | 100 | 56 | Norway | France |

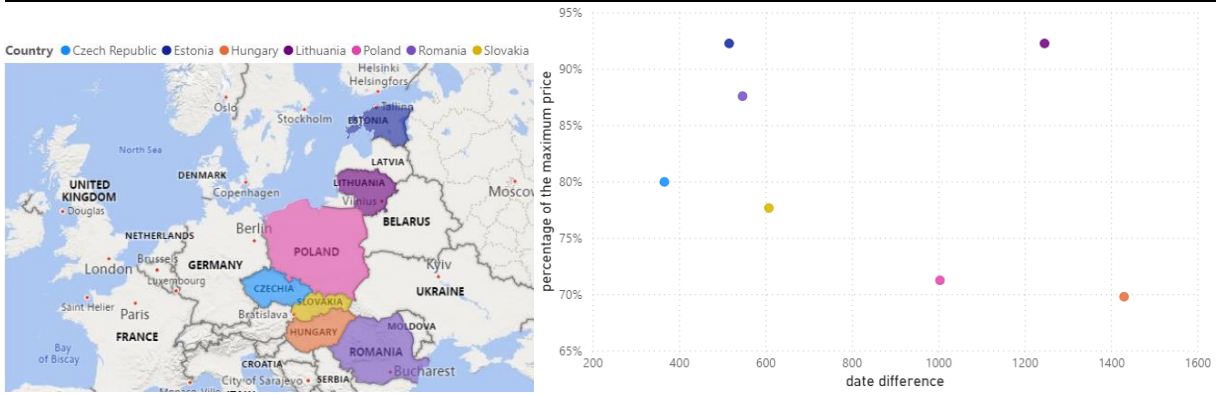
Country ● Poland



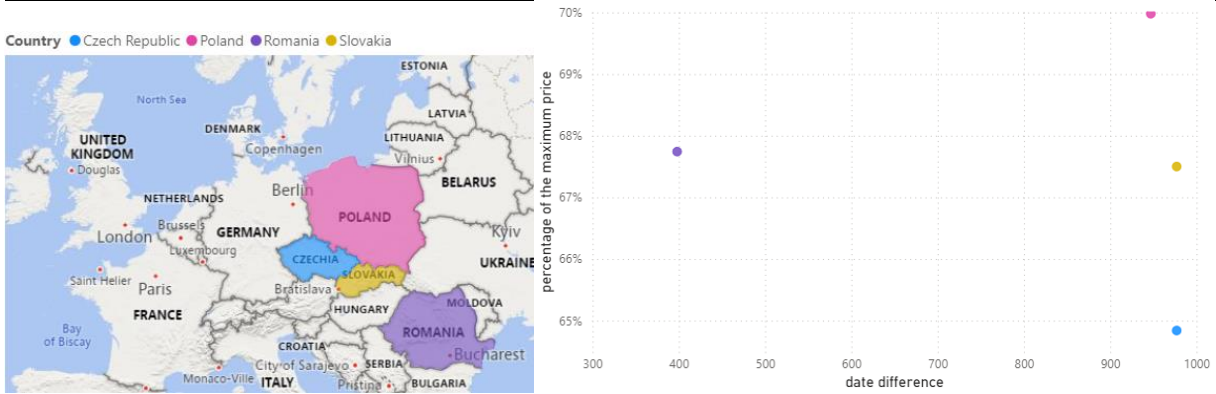
| Active substance | Strength | Number of units | First launch country | Maximum price country |
|------------------|----------|-----------------|----------------------|-----------------------|
| pegcetacoplan | 1,080 mg | 8 | United Kingdom | Czech Republic |



| Active substance | Strength | Number of units | First launch country | Maximum price country |
|------------------|----------|-----------------|----------------------|-----------------------|
| simponimod | 2 mg | 28 | Sweden | Spain |

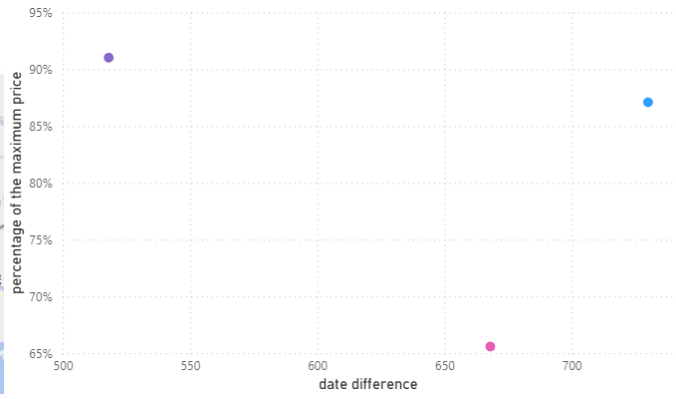


| Active substance | Strength | Number of units | First launch country | Maximum price country |
|------------------------|----------|-----------------|----------------------|-----------------------|
| trastuzumab deruxtecan | 100 mg | 1 | United Kingdom | Italy |



| Active substance | Strength | Number of units | First launch country | Maximum price country |
|------------------|----------|-----------------|----------------------|-----------------------|
| tucatinib | 150 mg | 84 | Netherlands | Slovenia |

Country ● Czech Republic ● Poland ● Romania



| Active substance | Strength | Number of units | First launch country | Maximum price country |
|------------------|----------|-----------------|----------------------|-----------------------|
| zanubrutinib | 80 mg | 120 | Denmark | Spain |

Country ● Czech Republic ● Poland ● Romania

