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Deliverable 4.5: Assessment report of the degree of ERP implementation at the country level

Prepared by Agency for Health Technology Assessment and Tariff System (AOTMiT)

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1. Executive summary

The study team performed a scoping review of published literature and an online survey to understand the awareness of the EURIPID Guidance Document on External Reference Pricing (ERP) and its implementation across the EURIPID member's institutions/countries.

Eight studies met inclusion criteria for the scoping review. Four were survey studies (three with a systematic literature review) and four were literature overviews. The present review shows that the availability of official information on ERP is limited and often inconsistent between the sources. This may be related to some sort of classification bias, as survey which gather policy information through standardised question items face limitations regarding classification and simplification of the far more complex reality.

The study team performed an online survey in November and December 2023. The response rate was 89% (25/28 countries), with replies from 29 institutions out of 25 countries. 11 countries provided official positions of their institutions (BE, BG, DK, EE, FI, IT, NL, PL, SK, SE, CH). The survey shows that majority of the countries (17/23) were aware of the EURIPID ERP Guidance. Recommendations are followed by majority of the countries despite a lack of full awareness on the exact contents of the guidance. This suggests that the EURIPID guidance document is a supportive document that sets main principles on ERP. A further dissemination effort should be considered.

To avoid the inconsistencies between the sources and limit the information collection bias, in the future, it may be feasible to study ERP implementation using a pre-filled survey (with information sourced from published literature), that is filled-in during a direct conversation, i.e. via an online meeting, preferably with more than one respondent for each country/institution.

2. Project Objectives

The objective of this report is to survey the practice of External Reference Pricing (ERP) among countries and to assess the implementation of the EURIPID guidance document across EURIPID members and beyond. The EURIPID guidance document discusses a coordinated approach of national authorities to ERP to avoid or mitigate negative impact for patient access to pharmaceuticals. ERP Guidance was published in 2018 by the EURIPID Collaboration. It aims to help coordinating national ERP policies by formulating joint 12 ERP principles (see chapter 5)[1] to guide policy makers and technical staff carrying out research and price comparisons. The principles laid down in the EURIPID guidance document are comparably simple to address and easy to understand for decision-makers and patients likewise.

Our assessment of the level of implementation of the EURIPID Guidance document within the member countries may help to roadmap future updates of ERP Guidance. The goal is to further strengthen the significance of the guidance by incorporating the experiences of its usage.

3. Scope of the study

ERP is widely used across the world, but its extent of implementation differs between the countries. The study team performed 1) a scoping review on ERP implementation, 2) an online survey among EURIPID member countries, and 3) an analysis of the survey results.

[1] Euripid Guidance Document on External Reference Pricing (ERP) Final Version 8.1 of 31 July 2018 (available on euripid (goeg.at))

The study at hand covers an analysis and assessment of the responses on the survey on the application of the EURIPID guidance document on ERP by EURIPID member countries. The tools and methods used as part of countries' ERP policies were studied in the context of their similarity to the solutions recommended in the ERP Guidance.

The geographical scope of our study covered: Austria (AT), Belgium (BE), Bulgaria (BG), Croatia (HR), Cyprus (CY), Czech Republic (CZ), Denmark (DK), Estonia (EE), France (FR), Finland (FI), Greece (GR), Hungary (HU), Izrael (IL), Italy (IT), Latvia (LV), Malta (MT), Netherlands (NL), Norway (NO), Poland (PL), Portugal (PT), Slovakia (SK), Slovenia (SI), Spain (ES), Sweden (SE), Switzerland (CH).

4. Literature overview

This chapter presents the results of the published literature overview. The results may differ from the current solutions in some countries.

4.1. Methods

We conducted a scoping review to identify existing data on ERP models (tools, methods). We performed a free-text search in PubMed using "Pharmaceutical policy", "Pharmaceutical pricing", "Regulation of pharmaceuticals", "External reference pricing" as keywords. Articles published after 01 Jan 2018 were included, only (the year of development of ERP Guidance). We included studies in European and EURIPID member countries, only. Two independent reviewers screened titles and abstracts first and subsequently the full texts of selected articles. We included primary and secondary studies on ERP implementation in European countries.

Data extraction included: method on ERP information gathering, reference countries basket composition (i.e. a set of countries used for ERP), scope of ERP with regard to the type of medicinal products applicable for ERP, methodological approaches to ERP (e.g. formula, procedures on adjusting price information to national requirements), , frequency of revisions for ERP based prices..

4.2. Results and conclusions

Eight studies (Gill 2019, Holtorf 2019, Kanavos 2020, Mitkova 2020, Radu 2018, Rodwin 2021, Vogler 2018, and Vogler 2020) met the inclusion criteria. Four studies included primary research via a survey (three of them also performed a systematic literature review) and four were overviews.

The main elements of ERP implementation include existence of ERP , its role in price setting (main vs. supportive criterion), legal farmwork, composition of reference countries basket, type of products applicable for ERP, reference price calculation methods, information sources, and ERP submission process.

Information on the ERP baskets was available for majority of the target countries, except for Denmark and Israel. The number of reference countries varies, with only one reference country in Luxembourg and up to 31 reference countries in Hungary and Poland (Holtorf 2019, Vogler 2020). We identified differences in reporting on the number of reference countries for Austria (24-26 countries), Belgium (26-27 countries), Bulgaria (10-17 countries), Czech Republic (17-19 countries), Greece (22-26 countries), Hungary (29-31 countries), Italy (not defined vs. 27 countries), Poland (30-31 countries), and Spain (not defined vs. 16 countries). Some of the above-mentioned differences are related to changing provisions with related on the EU Enlargement, as well as UK leaving the EU. In some cases, it is related to the forementioned classification bias as in some countries ERP procedures are not published (Gill 2019, Kanavos 2020, Vogler 2020).

Information on ERP calculation formula was available for all the target countries except for Denmark. For some countries information on ERP formula was inconsistent across the articles. The most common method for ERP calculations was the average price of all reference countries (AT, BE, HR, CY, FI, MT, NL, IE, LT, CH). Four countries use an average of the three lowest prices in the reference basket (CZ, GR, NO, SK). Bulgaria and Hungary use the lowest price, and Latvia uses the third lowest price. Some of the countries apply more than one strategy for ERP formula e.g. Portugal uses the average price for outpatient and the lowest price for inpatient pharmaceuticals. Since Luxembourg refers to a single country no calculations are applied. France uses a price range, the set price that cannot exceed the highest and cannot fall below the lowest price in the basket (Gill 2019, Kanavos 2020, Vogler 2020).

Information on the role of ERP during price revisions was available for majority of the target countries, except for Denmark and Israel. For some countries the information was inconsistent between the sources. Belgium, Germany, and Hungary do not use ERP for price revisions. Bulgaria, Slovenia and Slovakia revise ERP-based prices biannually (Gill 2019, Mitkova 2020, Kanavos 2020, Vogler 2020). Estonia (inpatient products) and Portugal perform price revision annually (Gill 2019, Kanavos 2020, Vogler 2020). Revisions of outpatient products pricing in Estonia is linked to the duration of price agreements between public payer and the pharmaceutical manufacturer or distributor. France revises prices every five years (Gill 2019, Kanavos 2020, Vogler 2020).

The scoping review shows that the availability of official information on ERP is limited and often inconsistent between the sources. The results of the scoping review showed that information on ERP implementation is usually studied through review of published literature and national documents (i.e. policy, guidelines, etc), or through surveys.

Inclusion of grey literature may be helpful in the future searches for information gathering (i.e. the PPRI Report 2018. Pharmaceutical pricing and reimbursement policies in 47 PPRI network member countries by Vogler et al.).

5. Survey on ERP extent and application of Euripid Guidance Document on External Reference Pricing (ERP)

5.1. Methods

The study team prepared an online survey to study ERP development and implementation. The survey questions were crafted based on the recommendations of the EURIPID Guidance Document on ERP and subsequently tested and discussed multiple times within a task group consisting of members from Austria, Bulgaria, Hungary, and Poland. The survey had four parts and 46 questions in total (single, multiple choice, and open text questions; see annex 1 for full survey).

The target group included European and/or EURIPID Collaborations members institutions responsible for pricing and/or reimbursement. Generally, one survey was completed for each country. In some cases, more than one survey was completed (AT, FR, GR, MT, SI). In such cases the study team analysed answers collectively.

5.2. Results

The study team performed an online survey between November 7, 2023, and December 29, 2023. The response rate was 89% (25/28 countries), with replies from 29 institutions out of 25 countries. 11 institutions from 11 countries provided official positions of their institutions (BE, BG, DK, EE, FI, IT, NL, PL, SK, SE, CH), others provided personal expert opinions (AT, HR, CY, CZ, FR, GR, HU, IL, LV, MT, NO, PT, SI, ES).

5.1.1. Use of ERP for decision making

ERP is an important policy tool that should be used in a mix with other instruments and not as stand-alone policy tool.

Out of 25 surveyed countries, 23 countries perform ERP (AT, BE, BG, HR, CY, CZ, DK, EE, FI, FR, GR, HU, IL, LV, MT, NL, NO, PL, PT, SK, SI, ES, CH). Italy and Sweden declared lack ERP-related activities. 17 countries declared awareness of the EURIPID guidance document (AT, BE, BG, CY, CZ, DK, EE, FI, GR, HU, IL, LV, MT, CH, PT, SI, ES).

Out of 23 countries that perform ERP, 21 countries perform ERP for reimbursable original pharmaceuticals (AT, BE, BG, CH, CY, CZ, EE, FI, FR, GR, HR, HU, IL, LV, MT, NL, NO, PL, PT, SI, SK). Only three countries use ERP as a stand-alone policy tool (IL, NO, SI) for reimbursable original pharmaceuticals. In countries that use ERP in conjunction, the other pricing policy tools for reimbursable original pharmaceuticals include: internal reference pricing (IRP; 12 countries; BE, BG, CH, CZ, EE, FI, FR, LV, NL, PL, PT, SK), price negotiations (17 countries; AT, BE, BG, CH, CY, EE, FI, FR, GR, HR, HU, LV, MT, NL, PL, PT, SK), Manage Entry Agreements (MEA; 14 countries; AT, BE, BG, CH, CZ, EE, FI, FR, HU, LV, MT, PL, PT, SK), Health Technology Assessment (HTA; 16 countries; AT, BE, BG, CH, CZ, EE, FI, FR, GR, HU, LV, MT, NL, PL, PT, SK), tendering or tendering-like systems (seven countries; BG, CH, FR, HU, MT, PL, PT), and mark-ups regulation (13 countries; AT, BE, BG, CY, CZ, EE, FI, FR, HU, LV, PL, PT, SK).

Figure 1. Does your country perform ERP?

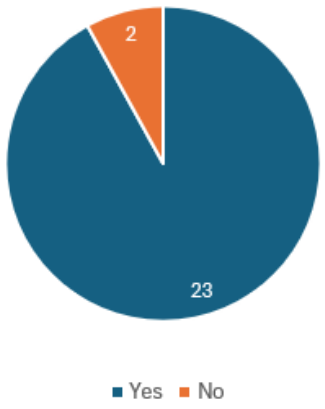
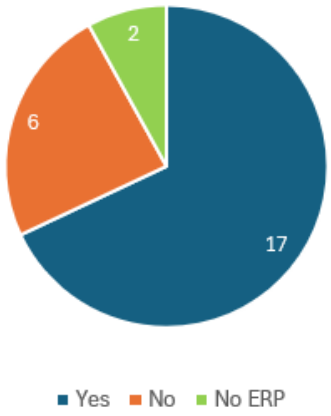


Figure 2. Awareness of the Euripid ERP Guidance.



5.1.2 Type of price comparison

ERP should take place on single product (package) basis rather than by indices.

All of the countries perform ERP on a single product basis and comply with the principle in the EURIPID guidance document. None of the countries indicated to only consider the macro perspective to ERP by calculating prices or indices for groups of pharmaceuticals (e.g. ATC-4 level) or entire markets.

5.1.3 Scope/Selection of reference countries

The aim of the national pharmaceutical policy should determine the selection of reference countries

Performing ERP requires information on medicine prices in other countries. The selection of reference countries should be determined by policy and should take into consideration several factors, i.e. comparability of the pricing system, fairness, etc. Larger country baskets require more administrative

resources. Low number of reference countries require less administrative staff but more consideration on choice of countries for ERP to produce feasible results.

All of the countries indicated that the selection of reference countries align with national pharmaceutical policy goals. Majority of the countries indicated that geographical location (BE, DK, EE, HR, HU, IL, LV, NL, PL, PT) and comparable economic development (e.g. measured by GDP per capita; AT, BE, CH, CY, DK, EE, ES, FR, HR, IL, LV, MT, NL, NO, PL, PT) are the key factors to determine reference countries basket for ERP. Only eight countries indicated the similarities in health system organisation (e.g. social health system or national health system) as the key consideration factor (BE, CH, DK, EE, ES, NL, PT, SK). Five countries (AU, CZ, FI, HU, SK) have large reference countries baskets (25 or more countries referenced). 16 countries (BE, BG, CH, HR, CY, DK, EE, ES, FR, IL, LV, NL, NO, PL, PT, SI) have small reference countries baskets (10 or less countries referenced). Majority of the countries reference prices from France (16), Germany (14), Belgium (14), Italy (13), and Spain (12). None of the countries references Israel. Please see the Table below for detailed results.

Majority of the countries (17) regulated information on reference prices sources. Documents are publicly available in 11 countries, e.g. legislation, guidelines, other types of publicly available information (AT, BG, CH, CY, CZ, FR, GR, NL, PT, SI, SK), and internally available in six countries (BE, HR, IL, LV, MT, PL). The results indicate that the transparency of national ERP policies on the reference countries selection could be improved (principle 11).

Table 1. Summary of reference countries basket composition (rows) for each of the index country (first column).

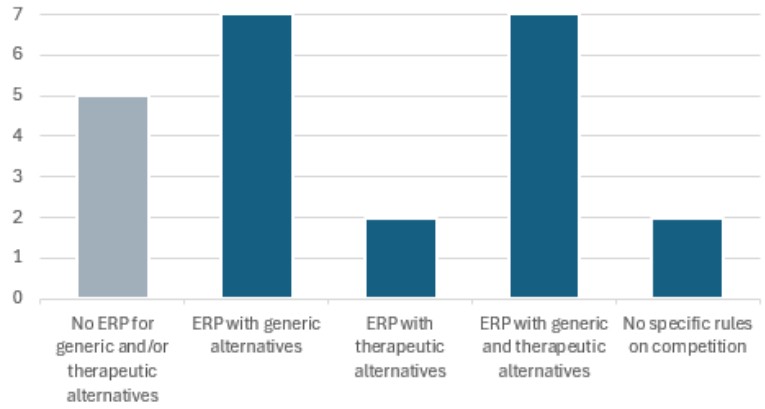
	Reference countries basket																																
	AT	BE	BG	CH	CY	CZ	DE	DK	EE	ES	FI	FR	GR	HR	HU	IE	IL	IS	IT	LI	LT	LU	LV	MT	NL	NO	PL	PT	RO	SE	SI	SK	UK	No
AT		■	■		■	■	■	■	■	■	■	■	■	■	■	■			■		■	■	■	■	■		■	■	■	■	■	■		26
BE	■						■				■	■				■									■									6
BG		■								■		■	■						■		■		■					■		■	■			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	

5.1.4 Scope/Selection of pharmaceuticals for ERP

Evidence shows that ERP is most effective when it is used for determining the maximum price of pharmaceuticals without generic or therapeutic competition.

Majority of the countries perform ERP with generic alternatives (BG, ES, EE, HU, LV, NL, SI), therapeutic alternatives (AT, FR) or both (BE, CZ, HR, IL, MT, PL, SK). Only five countries follow the EURIPID ERP Guidance to refrain from ERP for products with generic or therapeutic competition (CY, DK, FI, PT, and CH). Two countries have no specific rules of competition (GR, NO).

Figure 3. Selection of pharmaceuticals for ERP.



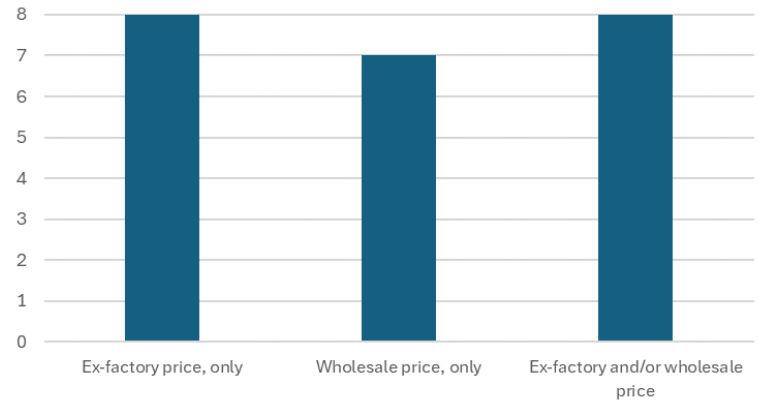
5.1.5 Selection of price type

The comparison of prices of medicinal products should be done on the first price (type) in the pharmaceutical distribution chain

The first possible price type in the pharmaceutical distribution chain, i.e. ex-factory price is preferred for ERP. Wholesale and retail mark-ups differ between the countries attributing price differences not only to the MAH, but also to national distributors and policies.

Majority of the countries use ex-factory prices during ERP. Eight countries limit price type selection to ex-factory price, only (BG EE, FR, HU, PL, PT, SI, SK) and eight countries accept both ex-factory and wholesale prices (AT, BE, CH, CY, CZ, ES, GR, LV). Wholesale price is usually accepted only if ex-factory price is not available. Some countries convert wholesale to ex-factory prices (i.e. CZ). Seven countries prefer wholesale prices, only (DK, FI, HR, IL, MT, NL, NO).

Figure 4. Selection of price type for ERP purposes.



5.1.6 Comparability of pharmaceutical specialities

Competent authorities should apply clear and transparent procedures to determine which pharmaceuticals are considered as comparable

ERP should be done only for products that are considered comparable, i.e. products with identical pharmaceutical characteristics (active substance(s), strength, pharmaceutical form group and pack size group). The selection criteria need to be clear and transparent.

Majority of the countries require the following dimensions to must be the same: ATC family (19 countries), active substance (21 countries), dosage of the active substance (in unit; 15 countries), dosage form group (e.g. oral solid forms; 17 countries), pharmaceutical form (eg. tablet only, but not film-coated tablet, capsules, etc.; 12 countries) and packaging (eg. pre-filled pen vs pre-filled syringe vs. vial vs. cartridge; 11 countries). Majority of the countries allow for price adjustment or recalculation in case of differences in pharmaceutical pack size (20 countries) and accept differences without any adjustments for the trade name (17 countries), MAH (10 countries) and manufacturer name (14 countries). Only one country (NO) does not apply clear procedures to determine which pharmaceuticals are considered comparable. Please see the Table below for details.

Majority of the countries (19) developed regulations or guidelines on determination of pharmaceuticals that are considered comparable for ERP. In 17 countries comparability rules are publicly available (BG, CH, CY, CZ, DK, EE, FI, FR, GR, HR, IL, LV, NL, NO, PT, SI, SK) and in two countries internally available (AT, BE).

*Table 2. Comparability rules, if prices only for products different from the reference product are available (**S** – must be the **same**, **A/R** – **adjustment/recalculation** of price, **D** – can be **different**, **N** – **no defined** procedure)*

Country	ATC family	Active substance	Dosage of the active substance	Dosage form group	Pharmaceutical form	Pack size	Packaging	Trade name	MAH	Manufacturer/s
AT	S	S	A/R	A/R	S	A/R	A/R	D	N	D
BE	S	S	S	S	S	A/R	A/R	D	N	D
BG	N	S	S	N	S	A/R	S	D	D	S
CH	S	S	S	S	S	A/R	S	D	D	D
CY	S	S	S	S	D	A/R	S	D	D	D
CZ	A/R	A/R	A/R	A/R	A/R	A/R	A/R	D	S	D
DK	S	S	A/R	S	D	A/R	N	D	S	S
EE	S	S	S	S	S	S	S	S	S	S
ES	N	S	S	S	S	A/R	N	D	D	S
FI	S	S	N	N	D	A/R	N	D	S	D
FR	S	S	S	S	S	A/R	S	S	S	D
GR	S	S	S	S	A/R	A/R	S	S	S	N
HR	S	S	S	S	A/R	A/R	S	D	D	D
HU	S	S	A/R	S	A/R	A/R	D	D	D	D
IL	S	S	S	S	S	A/R	S	D	D	D
LV	S	S	S	S	S	A/R	S	D	N	S
MT	S	S	S	S	D	D	D	N	N	N
NL	S	S	S	S	S	A/R	S	D	D	D
NO	N	N	N	N	N	N	N	N	N	N
PL	S	S	S	S	D	A/R	D	S	N	N
PT	S	S	A/R	S	S	A/R	D	D	D	D
SI	S	S	A/R	D	D	A/R	D	D	D	D
SK	S	S	S	S	S	A/R	S	D	S	D
Sum (maximum with bolded font)										
S	**19**	**21**	**15**	**17**	**12**	1	**11**	4	7	5
A/R	1	1	6	2	4	**20**	3	0	0	0
D	0	0	0	1	6	1	5	**17**	**10**	**14**
N	3	1	2	3	1	1	4	2	6	4

5.1.7 ERP formula

The pricing formula applied for ERP should reflect the national pricing policy objective

The choice of ERP pricing formula is crucial for countries where ERP is the main criterion during the pricing process. Several solutions may be considered, i.e. for countries with similar GDP per capita basket, the lowest price approach (or a modified method) could be used; for countries with higher GDP per capita basket, the average price approach (or a modified method) may be feasible.

Majority of the surveyed countries (AT, CH, CY, CZ, DK, GR, HR, HU, IL, MT, NL, NO, SK) prefer the average based formula approach. This may include the average of all reference countries or average of selected reference countries, i.e. average of two or three lowest reference prices and other solutions. Other solutions include using the lowest price (BE, BG, ES, PL, SI), the highest price among selected reference countries (EE), not higher then the second lowest (LV), or not lower than the lowest (FR) approaches. Some countries use multiple formula depending on the pharmaceutical type and/or settings, i.e. PT uses the average price for outpatient and the lowest price for inpatient settings.

The authors compared GDP per capita of index countries with average of GDP per capita of its reference basket countries. In four countries (AT, CH, NO, MT) reference basket composes of countries with lower GDP per capita, in seven (CY, DK, EE, FI, FR, NL, PL) reference basket composes of countries with similar GDP (+/-10%), and in 12 (BE, BG, CZ, ES, HR, HU, GR, IL, LV, PT, SI, SK) reference basket composes of countries with higher GDP per capita. Our survey showed that currently Belgium has smaller reference basket when compared with Austria please see tab 1 above. Countries with lower than domestic GDP per capita in the reference basket tend to use average based ERP formula, whereas countries with higher than domestic GDP per capita in the reference basket tend to use a mix of lowest and/or average based ERP formulas.

5.1.8 Data sources and quality

ERP procedures should be performed with the highest possible accuracy and completeness of data sources

Data availability and continuous access to valid sources are critical. Price information should be cross-checked in independent resources e.g., EURIPID database or the PPRI network. Preferably the true availability (or uptake) of pharmaceutical should be taken into account. The EURIPID guidance document recommends that MAH should have the possibility to challenge determined prices in ERP procedures.

Majority of the countries (AT, BE, BG, CH, CY, CZ, EE, ES, FR, GR, HU, IL, LV, MT, NO, PL, PT, SI, SK) use more than one source of information for ERP. Usually pricing information in other countries is provided by MAH (requirement in AT, BE, BG, CH, CY, CZ, DK, EE, ES, FI, FR, GR, HU, IL, LV, MT, NO, PL, PT, SI, SK), independent searches of official websites of pricing or reimbursement regulatory authorities (AT, BG, CH, CY, CZ, EE, FR, GR, HU, IL, LV, MT, NL, PL, PT, SK, SI) or EURIPID database (AT, BE, BG, CY, EE, ES, GR, HU, IL, LV, MT, NO, PL, PT, SK). Six countries (AT, CZ, FR, HR, SI, SK) use commercial databases for ERP purposes.

Majority of the countries always verify prices used for ERP via a secondary source of information (AT, BE, BG, CY, ES, FR, HR, LV, PL, PT, SI, SK) or at least on an occasional basis (EE, GR, HU, IL, MT, NO). In situations when information on pharmaceutical pricing is not available in any of the reference countries ERP is usually omitted (BE, BG, CH, DK, ES, HU, LV, NL, SK) or a range of other solutions may be applied, i.e. internal or external reference pricing based on therapeutic alternative comparators. 15 countries take into account whether the product is available at the market of a reference country during the ERP. Six countries (CH, CY, CZ, DK, HR, SK) search for information on the pharmaceutical's

true availability actively and nine not actively, i.e. they use the information only if provided by MAH or found occasionally (AT, BG, FR, GR, HU, IL, MT, NL, PL). Majority of the countries allow for the MAH to challenge or appeal the prices used for ERP (AT, BE, BG, CH, CY, CZ, DK, EE, ES, GR, HR, HU, IL, LV, NL, PL, PT, SI, SK).

5.1.9 Prices can be adjusted to national requirements

If price information is adjusted to national requirements, it should be done in a transparent and sustainable manner

Differences in national regulations, marketed products and reporting standards, impose the need of price adjustments, especially for differences in a price type, currency exchange rates, or a pharmaceutical's characteristics. Selection of exchange rates should preferably include averages of a longer period to limit the effect of fluctuations. The adjustment of prices should be done in a transparent and sustainable manner.

For situations where the selected price type is not available in a reference country (i.e. ex-factory price) but another price type is available (i.e. wholesale price), majority of the countries (AT, BG, CH, CY, CZ, EE, FR, GR, HR, IL, LV, PL, PT, SK) use price recalculations with regulated or estimated mark-ups or margins. Five countries haven't developed specific rules for price adjustments (BE, ES, FI, HU, MT), two countries limit ERP to only reference countries where the price type is the same (NL, SI), and in two more countries MAH is responsible for recalculations (DK, NO).

Ten countries (AT, CH, CY, CZ, DK, HR, HU, IL, NO, SK) use long-term, monthly to yearly, average of exchange rate for ERP purposes, whereas eight countries use short-term, (e.g. daily) exchange rates (EE, FI, GR, LV, MT, NL, PL, PT) . Exchange rates are sourced mostly form the National Central Banks (12 countries; CH, CZ, DK, EE, GR, HR, HU, IL, NO, PL, PT, SI) or the European Central Bank (seven countries; AT, BE, CY, LV, MT, NL, SK).

Majority of the countries developed provisions or guidelines on the application of exchange rates for ERP. In 18 countries information is publicly available (AT, BG, CH, CY, CZ, DK, EE, FI, FR, HR, HU, IL, LV, NL, NO, PT, SI, SK) and in three internally available (GR, MT, PL).

5.1.10 ERP planning and timeliness determination

ERP activities need careful planning and should also be considered as a policy tool for price revisions and monitoring

ERP may be considered as a useful tool for price revisions and monitoring price developments of pharmaceuticals. ERP activities should be subject to comprehensive planning and pre-determined timelines.

Majority of the countries monitor price evolution on the regular basis (seven countries; BE, CY, FR, NI, PL, PT, SK) or occasionally (nine countries; AT, BG, CH, ES, HR, IL, LV, NO, SI). ERP is used in 20 countries (AT, BE, BG, CH, CY, CZ, EE, ES, FR, GR, HR, IL, LV, MT, NL, NO, PL, PT, SI, SK) for post-launch price revisions. Price revisions are usually performed on a regular basis on fixed intervals and/or ad hoc (BE, BG, CH, CY, CZ, EE, ES, FR, GR, HR, IL, LV, MT, NL, NO, PL, PT, SI, SK). Some countries (CH, CY, CZ, EE, FR, LV, MT, NL, SI, SK) revise and update exchange rates for ERP during price revisions.

Majority of the countries developed regulations or guidelines on timelines of ERP-related activities (i.e. period of data collection, frequency of price comparisons, revisions). In 15 countries (BE, BG, CH, CY, CZ, FI, FR, HR, IL, LV, NL, NO, PT, SI, SK) information is publicly available and in four countries (DK, EE, GR, MT) information is internally available. Four countries have no/limited regulations, provisions or guidelines (AT, ES, HU, PL).

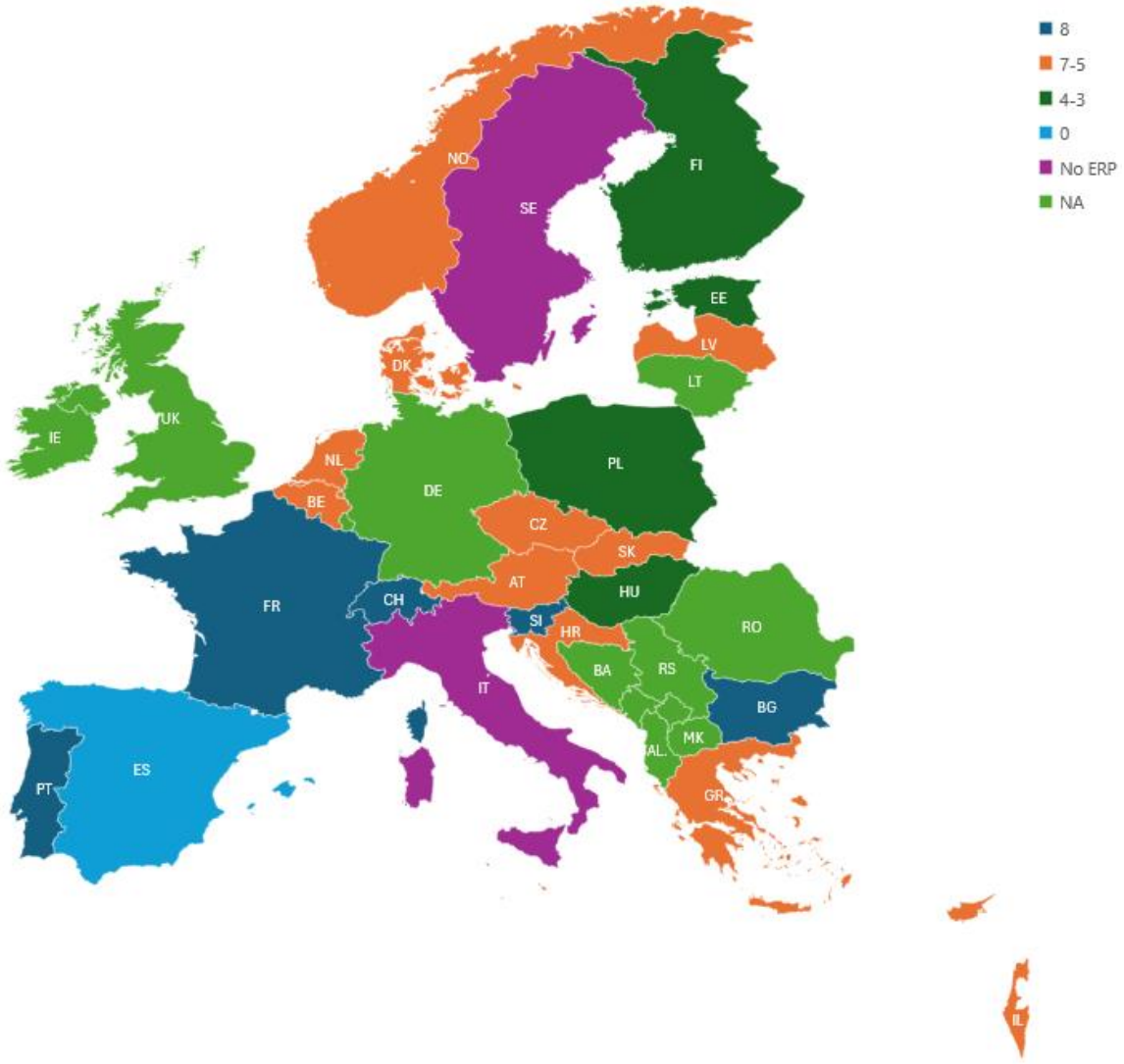
5.1.11 Transparency of ERP procedures and its inputs

The procedures and price inputs to ERP should be transparent to ensure predictability and effectiveness

ERP procedures and price inputs should be transparent to ensure predictability and effectiveness of the process.

The availability of regulations, provisions or guidelines on performing ERP-related activities was surveyed in eight domains, i.e. price information validity and sources, determining a comparable reference product, rules and formulas and exchange rates for ERP, prices recalculation in case of differences in product or price type differences, timelines of ERP-related activities and role of ERP in new technologies pricing. Five countries developed publicly available information in all eight domains (BG, CH, FR, PT, and SI). Two more countries (CY and CZ) developed publicly available information on seven domains (except for the role of ERP in new technologies pricing). All except one of the countries developed publicly or at least internally available information in some of the domains. The least regulated domains include role of ERP in new technology pricing, adjusting prices if the reference product differs, and adjusting prices if certain price type differs.

Figure 5. Map of transparency of ERP procedures.

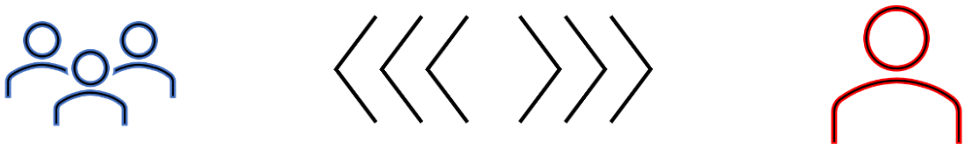


5.1.12 Coordinated European Approach for better ERP

Policy-makers should consider strengthening their cooperation, in particular through the contribution and benefits of existing policies

Exercising close cooperation between countries, i.e. via the Network of National Competent Authorities on Pricing and Reimbursement and Public Healthcare Payers (NCAPR), Pharma Policy Directors' Meetings, PPRI etc. may be helpful to obtain general information on healthcare systems and deepen understanding about pharmaceutical pricing policies in other countries. EURIPID may serve as an important platform for information exchange.

Almost half of the surveyed countries practise international cooperation for ERP purposes beyond using the reference prices, only (AT, BG, CY, DK, ES, FR, HR, HU, LV, NL, PL, SK).



12 countries

10 countries

6 Summary of survey results

The authors summarised below the information to what extent surveyed countries follow the EURIPID ERP Guidance. Please see Table below for details.

Table 3. Summary of survey results.

ERP Guidance recommendation	Application (out of 23 countries that use ERP)
#01) ERP is an important policy tool that should be used in a mix with other instruments and not as stand-alone policy tool.	18 countries use ERP with a mix of other pricing instruments (IRP, price negotiations, mark-ups regulation, HTA, MEA, tendering, etc).
#02) ERP should take place on a single product basis rather than by indices	All of the countries perform ERP on a single product basis.
#03) The aim of the national pharmaceutical policy should determine the selection of reference countries.	All of the countries have determined the selection of reference countries. The geographical location (10) and comparable economic development (16) were the most common factors of choice.
#04) Evidence has shown that ERP is most effective when applied to pharmaceuticals without generic or therapeutic competition.	Only five countries use ERP solely for 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.	Eight countries perform ERP using ex-factory prices only. Another eight countries perform ERP using any ex-factory or wholesale price.
#06) Competent authorities should apply clear and transparent procedures to determine which pharmaceuticals are considered as comparable.	19 countries developed clear rules to determine which pharmaceuticals are considered comparable.
#07) The pricing formula applied for ERP should reflect the national pricing policy objective.	22 countries stated that their ERP formula reflects national pricing policy objective
#08) ERP procedures should be performed with the highest possible accuracy and completeness of data sources.	19 countries use more than one source of pricing during ERP to obtain the highest possible accuracy and data completeness.
#09) If price information is adjusted to national requirements, it should be done in a transparent and sustainable manner.	Majority of the countries developed procedures on prices adjustments to national requirements, i.e. price type recalculation (14 countries), exchange rate period and source (18 countries).
#10) ERP activities need careful planning and should also be considered as a policy tool for price revisions and monitoring.	20 countries use ERP for post-launch price revisions.
#11) The procedures and price inputs to ERP should be transparent to ensure predictability and effectiveness.	Five countries exercise excellent transparency on ERP procedures. 10 more countries developed transparent procedures in at least some areas.
#12) Policy-makers should consider strengthening their cooperation, in particular through the contribution and benefits of existing policies.	12 countries exercise international cooperation for ERP purposes beyond using the reference prices, only.

7 Conclusions

The results of the scoping literature overview showed that information on ERP implementation is usually studied through review of published literature and national documents (i.e. policy, guidelines, etc), or through surveys.

The results of the survey showed that majority of the countries (17/23) were aware of the EURIPID guidance document on ERP. Recommendations are followed by majority of the countries. This suggests, that the principles in the guidance document has a universal character that sets the framework for ERP. Increasing awareness of the EURIPID guidance document may help to improve the regulation and transparency of ERP in Europe and Worldwide.

The survey showed further inconsistencies on ERP information in some countries when compared with published data. This suggest that using an online survey as a tool for information gathering may be prone bias, i.e.: institution selection, respondent selection, questions misunderstanding, and may result in data inconsistencies.

In the future, it may be considered to study ERP implementation using a pre-filled survey (with information sourced from published literature), that is filled-in during a direct conversation, i.e. via an online meeting, and preferably with more than one respondent for each country/institution.

8 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
ERP	External Reference Pricing
ERP Guidance	EURIPID Technical Guidance Document on External Reference Pricing
ES	Spain
FR	France
FI	Finland
GR	Greece
HR	Croatia
HU	Hungary
IL	Israel
IT	Italy
LV	Latvia
MT	Malta
NL	Netherlands
NO	Norway
PL	Poland
PT	Portugal
SE	Sweden
SI	Slovenia
SK	Slovakia

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12 Annex: Survey On The Applying Of The Euripid Guidance Document On External Reference Pricing (ERP)

A. Administrative part

A.1. Your country [drop down list + other]

- Austria
- Belgium
- Bulgaria
- Croatia
- Cyprus
- Czech Republic
- Denmark
- Estonia
- Finland
- France
- Germany
- Greece
- Hungary
- Ireland
- Italy
- Israel
- Latvia
- Lithuania
- Luxembourg
- Malta
- Netherlands
- Poland
- Portugal
- Romania
- Slovakia
- Slovenia
- Spain
- Sweden
- Other [please type in]

A.2.1 Respondent name [open]

[please type in]

A.2.2 Institution [open]

[please type in]

A.2.3 Email [open]

[please type in]

A.3. The answers to the survey represent: [one answer]

◯ The official position of my organisation

◯ My personal expert opinion

A.4. My Institution is: [one answer]

◯ Member of the EURIPID Collaboration and responsible solely for pricing of pharmaceuticals

◯ Member of the EURIPID Collaboration and responsible for pricing AND reimbursement of pharmaceuticals

◯ Not a member of the EURIPID Collaboration, and responsible solely for pricing of pharmaceuticals

◯ Not a member of the EURIPID Collaboration, and responsible for pricing AND reimbursement of pharmaceuticals

◯ None of the above; Please Specify: [please type in]

A.5. During pricing of pharmaceuticals, which tools/instruments/policies apply? (Please scroll the table left/right to see all the answers. In the first row, for reimbursable medicines in general, please select policy tools that are applied to all categories of reimbursable medicines. In the next rows please select the policy tools that are specific to each category of medicines. For example, in Poland for reimbursable original medicines – there are no additional policy tools. In the last

row, for non-reimbursable medicines in general, please select policy tools that are applied to non-reimbursable medicines) [multiple answers] [minimum one in a row]

	No additional policy tools	External Reference Pricing (EPR)	Internal Reference Pricing (IPR)[2]	Price negotiations	Managed Entry Agreements (MEA)[3]	Health Technology Assessment (HTA)[4]	Tendering or tender-like systems	Mark-ups regulation	Can't be reimbursed or subsidised
Reimbursable Medicines (in general)									
Reimbursable: Original medicines									
Reimbursable: Generics									
Reimbursable: Biosimilars									
Reimbursable: Orphan medicines									
Reimbursable: POM (prescription only)									
Reimbursable: NPM / OTC									
Reimbursable: Out-patient medicines									
Subsidised: Hospital only medicines									
Non-reimbursable medicines (in general)									

A.5.1. Additional comments on pricing (and reimbursement) procedures in your country (optional)

(open text)

B. Extent of implementation of the EURIPID Guidance Document on External Reference Pricing (ERP)

B.1 Does your institution perform ERP-related activities to set prices of pharmaceuticals? [one answer]

◯ Yes

◯ No

B.3 Which of the following criteria do you apply when choosing reference countries? (conditional question, only if B.1 = Yes) [multiple answers]

☐ Geographical location

☐ Comparable economic development (e.g. measured by GDP per capita)

☐ Similar health system (e.g. social health system or national health system)

☐ Similar pricing mechanism

☐ Easy access to prices and related information

☐ Using the same currency

☐ Other (please specify):

[2] incl. Reference Price Systems (RPS) and Price links i.e. Practice of setting the price of a product in relationship to the originator medicine, usually at a certain percentage lower than the originator medicine price.

[3] incl. Financial schemes (discounts, price-volume-agreements Utilisation or dose capping) or performance based agreements (Coverage with evidence development, Payment-by result,)

[4] Or other elements of value-based-pricing i.e. health economic evaluations (cost analysis, Cost-effectiveness analysis, cost-utility analysis, Cost-benefit analysis, budget impact analysis)

B.3.1 Specify the reference countries included in the ERP in your country? [multiple answers]

- ☐ no fixed list of reference countries
- ☐ Austria
- ☐ Belgium
- ☐ Bulgaria
- ☐ Croatia
- ☐ Cyprus
- ☐ Czech Republic
- ☐ Denmark
- ☐ Estonia
- ☐ Finland
- ☐ France
- ☐ Germany
- ☐ Greece
- ☐ Hungary
- ☐ Iceland
- ☐ Ireland
- ☐ Italy
- ☐ Israel
- ☐ Latvia
- ☐ Liechtenstein
- ☐ Lithuania
- ☐ Luxembourg
- ☐ Malta
- ☐ Netherlands
- ☐ Norway ☐ Poland
- ☐ Portugal
- ☐ Romania
- ☐ Slovakia
- ☐ Slovenia
- ☐ Spain
- ☐ Sweden
- ☐ Switzerland
- ☐ United Kingdom
- ☐ Other (please specify):

B.4. Do you use ERP for pharmaceuticals with generic (ATC5 level) or therapeutic (ATC-4 level) alternatives? [one answer]

- ◯ Yes, with generic alternatives
- ◯ Yes, with therapeutic alternatives
- ◯ Yes, both
- ◯ No
- ◯ No specific rules on competition

B.5. When applying ERP, which type of price do you use for reference? [multiple answers]

- ☐ Ex-factory price (manufacturer price)
- ☐ Wholesale price (pharmacy purchasing price)
- ☐ Pharmacy retail price (net)
- ☐ Pharmacy retail price (gross)
- ☐ Other (please specify):

B.6. How do you proceed if prices only for products different from the reference product are available? [multiple answers] [one in a row]

	MUST be the same	Adjustment/ Recalculation of prices	Can be different. NO price adjustments	No defined procedures
ATC family				
Active substance				
Dosage[5] of the active substance (in unit)				
Dosage form group (e.g. oral solid forms)				
Pharmaceutical form (eg. tablet only, but not film-coated tablet, capsules, etc.)				
Pack size				
Packaging (eg. tablet only, but not film-coated tablet, capsules, etc.)				
Trade name				
MAH				
Manufacturer/s				

B.7. When applying ERP, which formula do you use to calculate the reference price of the medicinal product? (below, „selected“ refers to situation where pricing formula does not include "all" of the reference countries picked in B.3.1.) [one answer]

◯ Lowest price of selected reference countries

◯ Lowest price of all reference countries

◯ Average price of selected reference countries

◯ Average price of all reference countries

◯ Median price of selected reference countries

◯ Median price of all reference countries

◯ Other specific formula (please specify):

B.8. Specify the sources of information on the prices of medicinal products, when applying ERP? [multiple answers]

☐ Independent research on official websites of pricing/reimbursement regulatory authorities

☐ Marketing authorisation holders (MAH) are required to submit price information from reference countries

☐ EURIPID database

☐ Commercial databases

☐ Other sources of information (please specify):

B.8.1. Do you verify the prices used for ERP via a secondary source of information (e.g. official source vs. EURIPID)? [one answer]

◯ Yes

◯ No

◯ Other (please specify)

[5] dosage is the quantity in relation to its content, particularly important for liquid forms; e.g. Adalimumab 40 mg in 0.8 ml and Adalimumab 40 mg in 0.4 ml have the same quantity but different dosages i.e. 50 mg/ml or 100 mg/ml (standardised to 1 ml)

B.8.2. Can the marketing authorization holder challenge/appeal the prices used in the ERP procedure and/or the benchmark yielded through ERP procedure? [one answer]

◯ Yes

◯ No

◯ Other (please specify):

B.8.3. Please indicate how do you handle the situation when information on the medicinal product is not available in any of the reference countries? [multiple answers]

☐ There is no specific rule for adjustments

☐ No external reference pricing applies

☐ Price approximation applies for different reimbursement status (i.e. price of a non-reimbursed medicine can be used for reimbursement purposes as a reference)

☐ Price approximation applies for different patent status (i.e. price of biosimilar can be used for original medicine as a reference)

☐ Other (please specify):

B.8.4. Do you take into account whether the product is available at the market when performing ERP? [one answer]

◯ Yes, actively

◯ Yes, not actively (i.e., only if information of product being unavailable is provided or found occasionally)

◯ No

◯ Other (please specify):

B.9. Indicate how do you handle the situation when the selected price type (i.e. ex-factory price) for ERP purposes is not available in a reference country, but another price type (i.e. wholesale price) is available: [multiple answers]

☐ There is no specific rule for price adjustments

☐ No external reference pricing applies in such situation

☐ Not applicable (we only reference countries where the price type is the same)

☐ Price recalculation with regulated mark-ups / margins

☐ Price recalculation with estimated mark-ups / margins

☐ Other (please specify):

B.9.1. If there is a different currency, what type of exchange rate do you apply for ERP purposes? [one answer]

◯ Daily (average) exchange rate

◯ Weekly (average) exchange rate

◯ Monthly (average) exchange rate

◯ Quarterly (average) exchange rate

◯ Yearly (average) exchange rate

◯ Exchange rate at the time of reimbursement decision in the reference country

◯ There is no fixed approach

◯ Other exchange rate (please specify):

B.9.2. What is the source of exchange rate for ERP purposes? [one answer]

◯ National Central Bank

◯ European Central Bank

◯ Other (please specify):

B.10. Do you use ERP for regular post-launch price revisions ? [one answer]

◯ Yes

◯ No

B.10.1 If ERP revisions are applied, please specify how often: [multiple answers]

☐ Fixed intervals

☐ Ad hoc: When the medicinal product applies for a price increase

☐ Ad hoc: When the medicinal product applies for a price decrease

☐ Ad hoc: When the price in one of the reference countries changes

☐ Other: (please specify)

B.10.2. In case of price revision, please indicate how do you handle exchange rate changes? [one answer]

◯ No change to exchange rate (the first used exchange rate is kept)

◯ Revision of exchange rate: always

◯ Revision of exchange rate: only if exchange rate change is above specified tolerance band

◯ Other (please specify):

B.10.3. Do you monitor price evolution in your country? [one answer]

◯ Yes, regularly

◯ Occasionally, for certain medicines

◯ No

◯ Other (please specify):

B.11. Do you practice any cross-country cooperation during ERP? (i.e. within platforms like the CAPR Network, Pharma Policy Directors' Meetings, PPRI, or other dialogue platforms to deepen the scope of information beyond just the reference prices) [one answer]

◯ Yes

◯ No

B.12. Are there any regulations, provisions or guidelines on performing ERP-related activities? [multiple answers] [one in a row]

	Yes, publicly available (e.g. legislation, public website)	**Yes, internally available**	**No**
3. Validity of the price information used for ERP (i.e. price sources)			
6a. Determination of medicines that are considered comparable for ERP			
6b. Adjusting prices if the reference product differs (product approximation)			
7. Data calculation methods (i.e. ERP formula)			
9a. Adjusting prices if certain price type differs			
9b. Application of exchange rates			
10. Timeline of ERP-related activities (i.e. period of data collection, frequency of price comparisons, revisions)			
11. Role of ERP in new technology pricing			

B.12.1. Are there any regulations, provisions or guidelines on performing ERP-related activities? Please provide links & description

(open text)

C. Utilisation of the Database

C.1. In the last month, how often have you / your institution used the EURIPID database? [one answer]

◯ Regularly (i.e. daily)

◯ Often (1-2 times per week)

◯ Occasionally (2-3 times per Month)

◯ Unfrequently (1 time per Month)

◯ Never

C.1.1 Which of the functions of the EURIPID database have you used in the last 3 months [multiple answers, max 3]

☐ Standard Search

☐ Queries

☐ Graphs

☐ Country Information

☐ Submitting Error Tickets

☐ Other (please specify)

C.2. For what purposes do you use the EURIPID database for? [multiple answers]

☐ To perform external reference pricing (ERP)

☐ To monitor the evolution of list prices

☐ To conduct studies and analysis

☐ To obtain further information: Prices of individual medicinal products

☐ To obtain further information: Managed entry agreements

☐ To obtain further information: Sales volumes

☐ To obtain further information: Reimbursement of medicinal products

☐ To obtain further information: Specific information for each country

☐ Other information (please specify)

C.3. For the purposes indicated, does the EURIPID database meet your information needs? [one answer]

◯ Yes

◯ Mostly

◯ No

C.3.1 For the purposes indicated, does the up-to-dateness of information in the database meet your information needs? [one answer]

◯ Yes

◯ Mostly

◯ No

C.3.3. Please indicate which additional type of information would be helpful to you. Please select the 5 most important options [multiple answers, max 5]

☐ Price information from all EU Member States

☐ Price information on non-reimbursed products

☐ Price information on hospital products

☐ Information on sales volumes from all participating countries

☐ Manufacturer prices from all participating countries (either through re-calculation or approximation)

☐ Wholesale prices from all participating countries (either through re-calculation or approximation)

☐ Net retail prices from all participating countries (either through re-calculation or approximation)

☐ Gross retail prices from all participating countries (either through re-calculation or approximation)

☐ Information on the conditions of reimbursement

☐ Information on the details of managed entry agreements without infringing confidentiality clauses

☐ Information on aggregated pay-backs by the pharmaceutical industry

☐ Information on rate of reimbursement

☐ Information on the Existence of all Managed entry Agreements from all participating countries

☐ At which phase is a product in pricing & Reimbursement procedures ("P&R Tracker")

☐ Willingness-to-pay thresholds

☐ Other information (please specify)

C.3.4. Is the EURIPID database implemented in any way in your regulatory framework? [one answer]

◯ Yes

◯ No

C.3.5. Please describe how EURIPID could better support your ERP activity (eg. how could you make better use of EURIPID in your pricing and reimbursement procedures)

(open text)

D. Application of the EURIPID guidance document

D.1. Are you aware of the EURIPID guidance document on External Reference Pricing (ERP) [one answer]

◯ Yes

◯ No

D1.1 Do you consider the recommendations of the EURIPID Guidance Document helpful to your work? (condition Question on YES to D.1) [one answer]

◯ Yes

◯ No

◯ I don't know

D.2. In the last 5 years, has there been a change in the procedures on pharmaceutical pricing in your country? [one answer]

◯ Yes

◯ No

◯ I don't know

D.2.1. Please specify changes in the procedures on pharmaceutical pricing in your country in the last 5 years (conditional Question on YES to D.2)

(open text)

D.2.1 Do you think, that these changes were in line with the recommendations of the EURIPID ERP Guidance Document? (conditional question on YES to D.2) [one answer]

◯ Yes

◯ No

D.3 Do you think the EURIPID Guidance Document is still able to address current challenges of pharmaceutical pricing and reimbursement? [one answer]

◯ Yes

◯ No

D.3.1 What goals are not adequately addressed by the guidance document and need an update: (conditional Question on NO to D.3)

(open text)