

# International Reference Pricing



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**EFPIA**



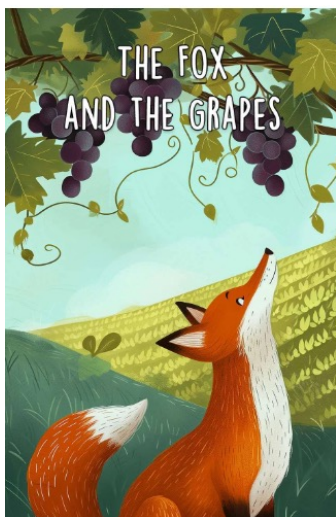
## Pricing & Access of medicines – What are the key elements?

### EU JCA

Comparative clinical effectiveness:

- Is the new medicine 'better' than the 'alternative'?
- What do we mean by 'better'?
- What do we mean by 'alternative'?
- Can we even answer the question itself (what is the evidence)?
- How 'certain' are we about the answer to this question?

All these elements influence discussions on price!



### Access in all Member States

Negotiating with each 'generic' Member State:

- Value do we understand by value? Value for whom? Societal value? Value or cost to a set budget?
- Involvement of other stakeholders (UMN)?
- Medicine position (first in class, me too?)
- Cost-effectiveness – what does it mean to be cost-effective?
- Willingness to pay
- Budget impact – is it all that matters?
- Price of existing competitor/alternative
- Actual negotiation (called 'dark art' for a reason)
- Can the Member State even make use of the product (infrastructure, testing, specialists etc)?
- Managed entry (price-volume, pay for performance)?
- Price/volume effect?
- Cost-containment/claw-backs?

=> 1 (theoretical/fictitious) price per product

Dynamic negotiation with all 27 Member States:

- Launch sequencing – why?
- External/international reference pricing
- List price & (confidential) net price
- Impact of parallel trade

### Uptake & peak sales

- How do you ensure uptake to your medicines (sales, promotion)?
- How do you compete in the market against other medicines?
- What is the risk that a new and 'better' medicine will completely 'ruin your market'?
- What are the 'costs' of being successful? (maintain sales force, local requirements (language), produce & distribute the medicines, PV systems etc)
- Cost-containment/claw-backs (what if being successful is penalized?)

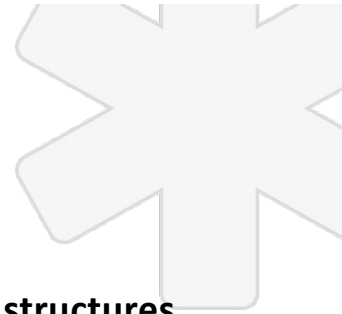
=> In actual Euros and cents – price per product x number of products sold

### Other 'ways to negotiate'?

- Art 56a
- Cost-plus pricing
- Cross Country Collaborations
- Joint Procurement
- Compulsory Licensing
- Localization 'premiums'

## Challenges with IRP

1. **Prices in different markets may not be comparable** due to:
  - Differences in the **burden of disease, indications, willingness and ability to pay, market structures, and in the components included in prices**
  - Medicines may be **at different stages in their life cycle in different countries**, with different IP
  - **Differences in pack size and presentation** may complicate comparisons
2. IRP is associated with **lower product availability, launch delays and higher relative per capita prices in low income countries** and undermines initiatives to improve accessibility and affordability through differential pricing schemes
3. IRP leads to a **levelling of prices in higher and lower income countries**, undermining equitable and affordable patient access among EU citizens
4. IRP **undermines value-based pricing and can lead to distortions** since currency fluctuations and price cuts imposed by structural problems in one country have a spillover effect in other countries



# Country Basket Matrix: EU/EFTA + UK

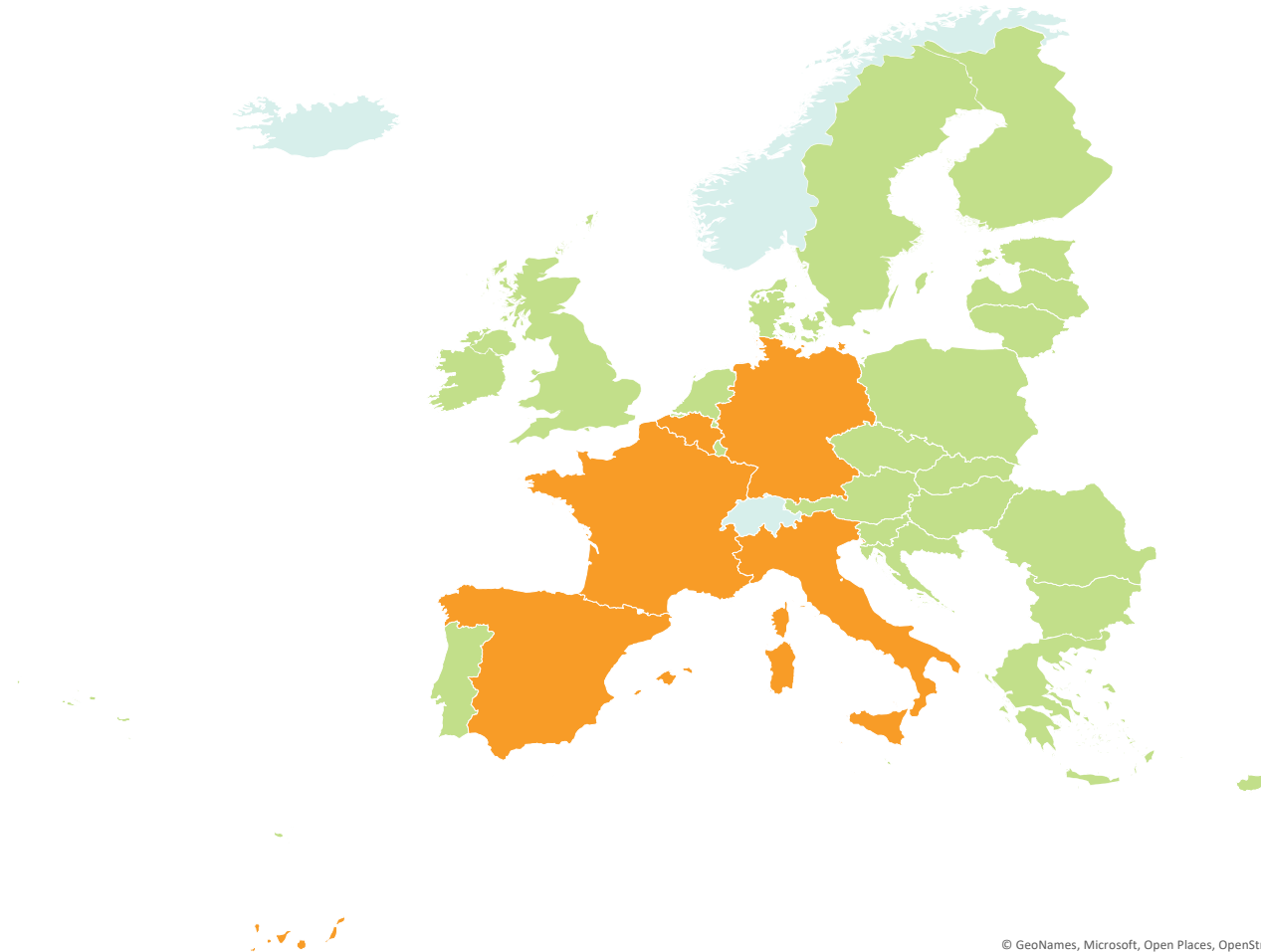
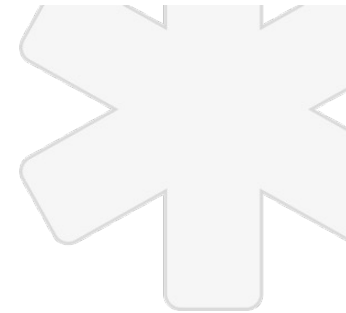
● Formal

● Informal

● Reimbursed Vaccines

Referencing (rows)	AUT	BEL	BGR	HRV	CYP	CZE	DNK	EST	FIN	FRA	DEU	GRC	HUN	ISL	IRL	ITA	LVA	LIE	LTU	LUX	MLT	NLD	NOR	POL	PRT	ROU	SVK	SVN	ESP	SWE	CHE	UK	
AUT																																	
BEL																																	
BGR																																	
HRV																																	
CYP																																	
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SVK																																	
SVN																																	
ESP																																	
SWE																																	
CHE																																	
UK																																	

## Most Referred Countries in the EU/EFTA + UK



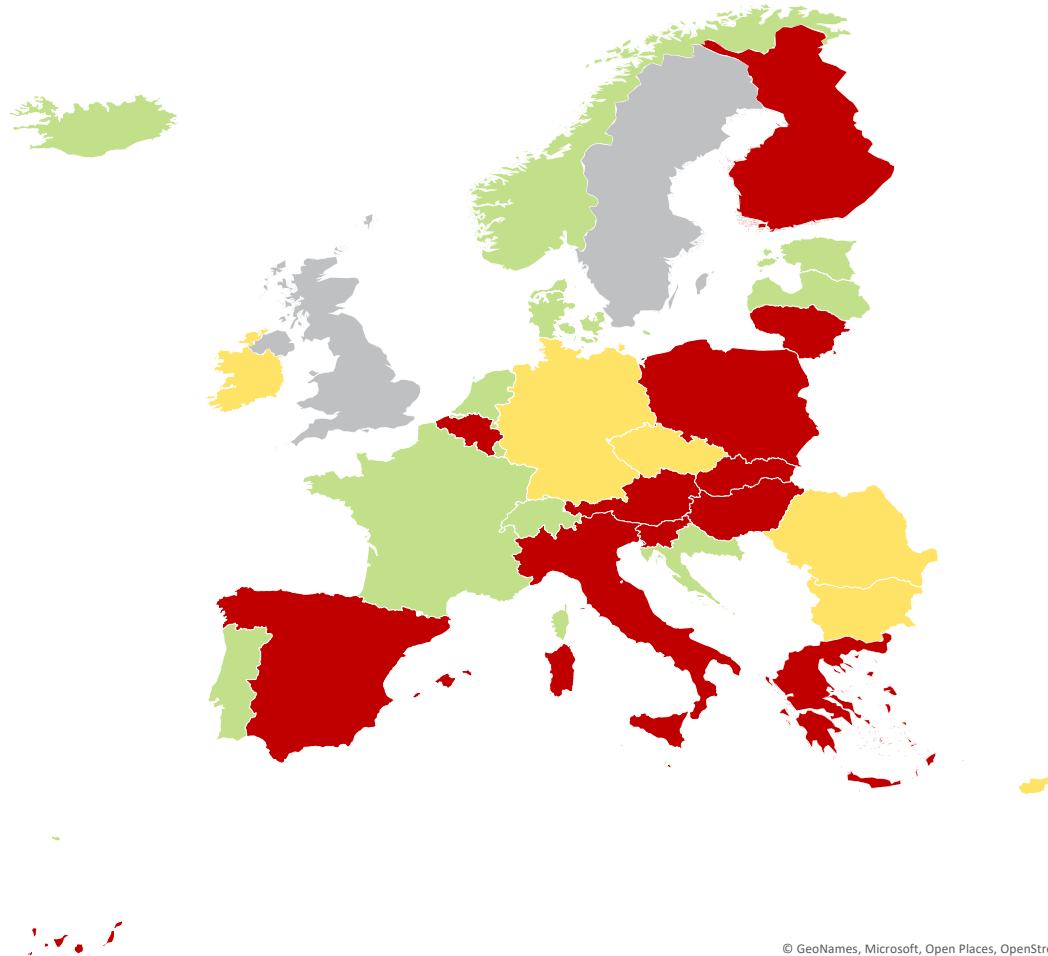
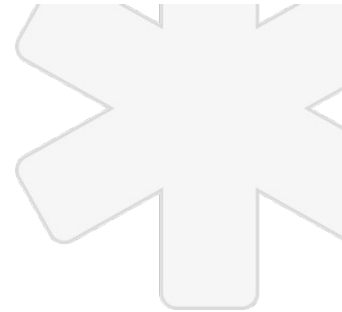
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Referred\* by ● <10 countries; ● 10 to 19 countries; ● ≥20 countries **efpia**

\*Referred by EU/EAA + CHE



## Most Referencing Countries in the EU/EFTA + UK



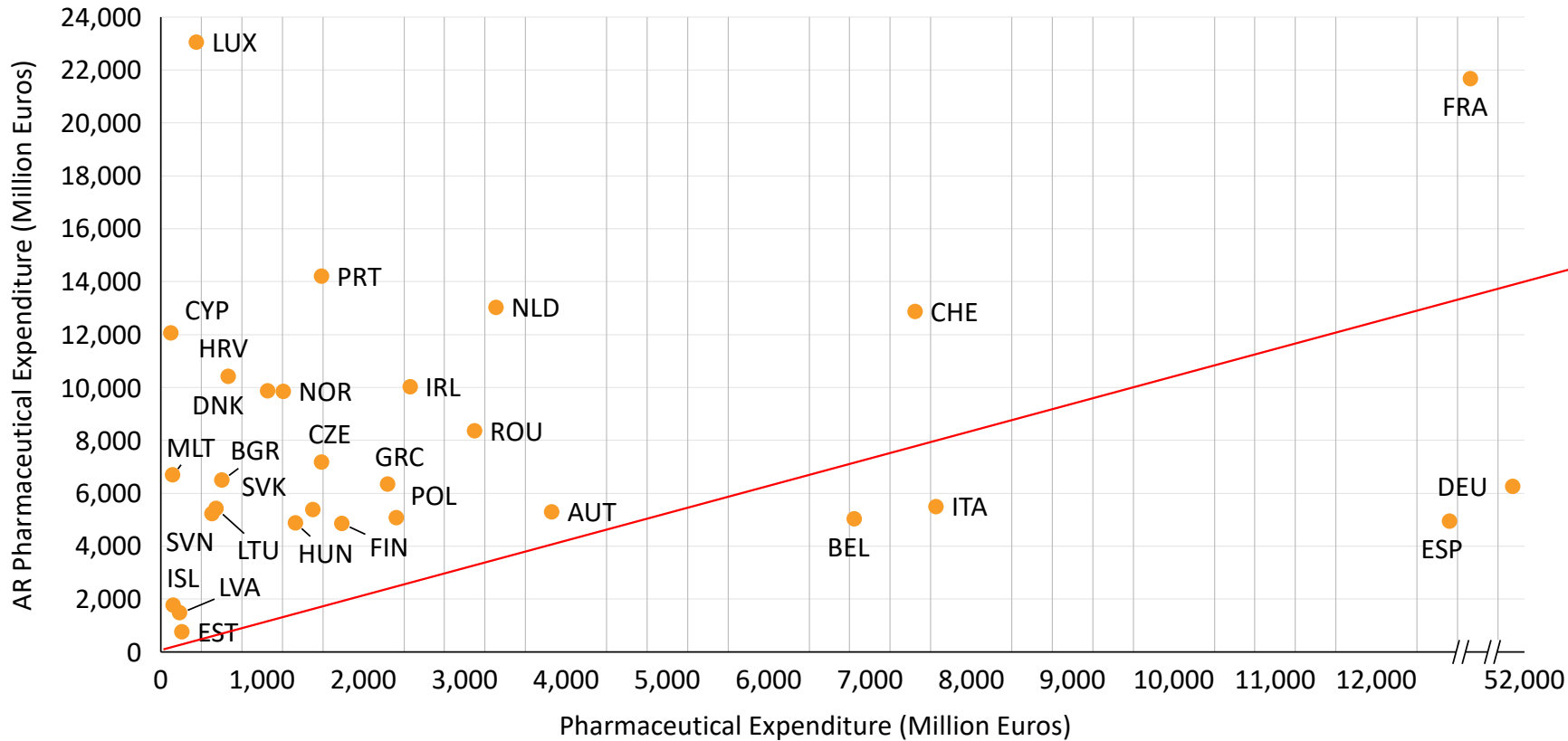
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\*Refer countries in the EU/EAA + CHE



# Relationship Between Country Pharmaceutical Expenditure and the Pharmaceutical Expenditure of Their IRP Reference Baskets (EU/EFTA)



**How to read:**  
**X-axis:** Country pharmaceutical expenditure (million euros)  
**Y-axis:** Average pharmaceutical expenditure (million euros) of the countries included in its IRP reference basket  
**Red line:** Parity (country expenditure equals the average expenditure of its reference basket)  
**Above the line:** The average pharmaceutical expenditure of the reference basket is higher than the country's own expenditure  
**Below the line:** The country's pharmaceutical expenditure is higher than the average of its reference basket

**Note:** IRP formulas differ across countries (e.g. average, lowest price, or other calculation rules).

## EFPIA suggested Principles on IRP

These negative consequences could be reduced if IRP systems were to operate according to an established set of principles:

1. Use in price setting: IRP is preferable as an **indicator, among other factors, of a broader P&R methodology**. It should be **limited to reimbursed on patent medicines**
2. Country selection: IRP should cluster **countries with comparable GDP per capita**, healthcare funding systems and IP standards (ideally **between 5 and 7 countries**)
3. Product selection: **Off-patent medicines should not be included** (comparison undermines patent protection)
4. Price selection: **Ex-manufacturer prices** (excl. distribution margins and VAT) for the same presentation and pack size
5. Rebates: **Only official list prices** should be taken into account
6. Methodology: On the basis of **average or median price** rather than the lowest of the basket
7. Frequency: **Limited to the launch of a product**. Re-referencing, if needed, should be predictable, limited to reasonable intervals (e.g., 3 years)
8. Exchange rate: **Restrict country baskets to the same currency zone** to avoid distortions by currency fluctuation. If needed, calculations should use average exchange rates over 12-month period with 10% tolerance band
9. Data source: **Valid, reliable, public, and vetted by stakeholders** with direct interests in the pricing process



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THANK YOU