efpia
European Federation of Pharmaceutical Industries and Associations

Principles for application of international reference pricing systems

International reference pricing (IRP) is a widely used element of price regulation in the vast majority of EU and EFTA countries. While IRP is inherently problematic as a means of ensuring optimal prices, these negative consequences could be at least reduced if international reference pricing systems were operated according to an established set of principles. Poorly designed pricing systems can have major negative consequences on access and affordability.

Background

International reference pricing (IRP), also known as external reference pricing, is a price control mechanism whereby a government considers the price of a medicine in other countries to inform or establish the price in its own country. IRP is used by, in particular, smaller countries with limited bargaining power or HTA capabilities to ensure that they do not pay more for medicines than other countries.

International price referencing may be used formally or informally to set reimbursement prices; at launch or on a regular basis; as the primary criterion for price setting or as one of the many inputs used to inform the pricing decision. IRP is extremely common – all EU and EFTA countries except Sweden and UK[1] use external price referencing in one or the other form. However it creates a number of problems such as:

- Prices in different markets may not be comparable due to differences in the burden of disease, indications, willingness (preferences) and ability (income) to pay, market structures, and in the components included in prices e.g. distributor margins, sales taxes, etc. Medicines may be at different stages in their life cycle in different countries, potentially with different intellectual property protection. Furthermore, differences in pack size and presentation may complicate comparisons.

- International reference pricing can be regarded as a useful cost containment tool, but with important risks as regards patient access, innovation and R&D spend in Europe.[2][3] 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 of medicines through differential pricing schemes.[4][5]

[1] External reference pricing of medicinal products: simulation-based considerations for cross-country coordination, Creativ-Ceutical, December 2013

[2] According to the December 2013 Creativ-Ceutical study, at the EU level prices are expected to decrease by around 15% after 10 years as a direct consequence of the use of IRP policies. The price decrease is expected to be even stronger if indirect effects of IRP are taken into account.

[3] '*Using IRP can for instance result in industry disinvesting from Europe or can induce strategic behavior of pharmaceutical companies in delaying the introduction of medicinal products on the markets*', EU Reflection Process, Towards modern, responsive and sustainable health systems, Report of subgroup on cost effective use of medicines, January 2014

[4] Pharmaceutical Pricing Policies in a Global Market, OECD Health Policy Studies, 2008

[5] EU Reflection Process, Towards modern, responsive and sustainable health systems, Report of subgroup on cost effective use of medicines, January 2014

Fédération Européenne
d'Associations et d'Industries
Pharmaceutiques

Leopold Plaza Building
Rue du Trône 108 Boîte 1
B-1050 Bruxelles

T +32 2 626 25 55
F +32 2 626 25 66
www.efpia.eu

- The concept of price differentiation in markets for products with relatively high fixed cost is a fundamental principle in economics and its advantages with regards to efficiency as well as social justice are scientifically well described. In practice IPR leads to a leveling[6] of prices in higher- and lower-income countries therefore undermining equitable and affordable patient access among EU citizens.

- IRP does not take the value of the product to patients' health and to society into consideration. 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, and, in this respect, contradicts the principle endorsed by the High level Pharmaceutical Forum of the European Commission whereby the impact of national price controls should be limited to the territory of the country concerned.[7]

EFPIA does not believe that International Reference Pricing is an optimal way of ensuring appropriate and competitive price levels, since it impedes flexibility to price according to local market conditions and tends to reinforce narrow price ranges across markets. Competitive and dynamic pricing that enable products to demonstrate value in their national context would be a more sustainable pricing model to the benefit of patient access to affordable medicines.

Several of the problems created by international reference pricing could be addressed if governments, in particular in the richer countries, refrained from referencing to lower income countries and would accept that enhancing affordability and accessibility for patients in poorer countries requires solidarity of the wealthier nations with the poor countries. While EFPIA recognizes that IRP is a widely used element of price regulation in the vast majority of countries in Europe, it stresses that poorly designed systems can have negative consequences on access and affordability. These negative consequences could be reduced if IRP systems were operated according to an established set of principles:

1. **Use in price setting**: It may be preferable to use IRP as an indicator in the context of a broader pricing and reimbursement methodology that takes other factors into account and provides for flexibility in price negotiations. When countries have established reimbursement decisions based on the assessment of the value of the product or have contracting mechanisms like pay for performance or price-volume, IRP should not be used since price is determined by other means. Moreover, IRP should be limited to in-patent reimbursed medicines in order to limit the distortive effects of IRP.

2. **Country selection**: IRP should cluster countries with comparable GDP per capita (adjusted for purchasing power parity), health care funding systems, and IP standards. The number of countries in a comparator basket should neither be too small, since too few countries give too much weight to a single country, in particular bearing in mind that not all medicines are sold in all countries, and inclusion of too many countries in a basket makes a system very complex to run (the Greek IRP system referencing prices in 22 countries has generated many errors since its inception resulting in interruptions in patient access to some medicines)[8]. Moreover, a basket with many countries will not

[6] On average a country uses a number of countries for price referencing with a lower representative income than the referencing country itself.
[7] High Level Pharmaceutical Forum, 2 October 2008
[8] IHS Global Insight, Latest attempt at new Greek drug price bulletin still contains errors, 4 January 2013

meet the criterion of "comparable" countries and creates unnecessary administrative burden without adding value, not least because in such a case many countries will be cross referenced more than once. Selection of a manageable number of comparable countries helps minimize administrative burden and the potential for errors. It is felt that an optimal number of reference countries lies between 5 and 7 reference countries. IRP systems should also be flexible enough to allow for reference basket adjustments in the case of a crisis situation in a reference country, for example in Greece since 2010.

3. **How drugs are used**: Off-patent medicines should not be included in IRP systems since there are other, more dynamic and effective means to achieve competitive prices on off-patent markets. Moreover, price comparison of patented with off-patent medicines undermines patent protection.

4. **Price level and selection**: It is most appropriate to reference ex-manufacturer prices (excluding distribution margins and value added tax) since distribution structures and tax rates vary widely across countries and would lead to distortions. Prices should be for the same presentation and pack size in each market, using the same product for comparison[9]. As it is currently applied by some countries (e.g., Netherlands), predictability could be increased by using the reference prices calculated six months in advance to their entry into force.

5. **Rebates:** Only official list prices[10] should be taken into account. Prices set by tender, subnationally negotiated prices, or commercial confidential discounts should not be referenced since doing so would undermine the flexibility of customers to agree to terms with the manufacturer which often include multiple parameters.[11]

6. **Methodology:** For matter of predictability and fairness IRP calculation should be on the basis of average or median price and not the lowest price in the basket.

7. **Frequency of the referencing procedure**: IRP is ideally limited to the launch of a product, after which normal competitive forces within markets should lead to price or quantity adjustments over time. Too frequent re-referencing distorts market forces and reduces predictability for all parties, is administratively burdensome, and can lead to errors, in particular if combined with large basket of comparator countries. Re-referencing should be predictable and limited to reasonable intervals, such as every three years.

8. **Exchange rate fluctuation:** Restricting country baskets to the same currency zone (e.g. Eurozone) avoids distortions due to currency fluctuation. Where countries with different currencies are included in a basket, calculation should reflect currency fluctuations/ exchange rates and inflationary adjustments in a symmetrical way and/ or within a tolerance band. In practice calculations should use average exchange rates over a 12-month period within a 10% tolerance band.

[9] By same product we refer to the same INN by the same producer and having the same Marketing Authorisation characteristics.

[10] Medicines prices published by Member States in their relevant official publication(s) in accordance to the provisions of the Transparency Directive (Directive 89/105/EC) and Member States' legislation relating to the protection of confidential business information (any information or data considered to be confidential under the law of Member States should fall oustide the scope of application of IRP systems).

[11] If rebates are considered, this should be limited to permanent official mandatory rebates (e.g. 7% in Germany) and exclude rebates, discounts and claw backs which are temporary or due to structural adjustment measures.

9. **Data sources**: data sources should be valid, reliable, public and vetted by stakeholders with direct interest in the pricing process.

If IRP is done in a responsible manner and according to the afore-mentioned principles – e.g. as one of several inputs to inform pricing processes, take the weighted average of a 'basket' as a reference price instead of the lowest, and periodically allows for inflationary or exchange rate adjustments, using baskets of comparable countries – , the worst negative consequences of IRP can be mitigated. Nevertheless it has to be restated that IRP as a regulatory concept – though widely used in Europe - is fundamentally flawed from an economical point of view and will ultimately lead to greater inequalities in patient access across Europe.

EFPIA
June 2014

Fédération Européenne
d'Associations et d'Industries
Pharmaceutiques

Leopold Plaza Building
Rue du Trône 108 Boîte 1
B-1050 Bruxelles

T +32 2 626 25 55
F +32 2 626 25 66
www.efpia.eu

efpia
European Federation of Pharmaceutical Industries and Associations

International Referencing Price rules in Europe

Country	IRP used	Formal/ Informal	Calculation used	Price referenced	Medicines	Frequency of re-referencing (months)	Number of reference countries (Basket)	Number of times the country is referenced
Austria	Y	F	Average	MNF	Reimbursed	_	26	16
Belgium	Y	I	Average	MNF	Reimbursed	Undefined	6	16
Bulgaria	Y	F	Lowest	MNF	POM	6	17	11
Croatia	Y	F	90% of Avg of 3	PPP		12	3	4
Cyprus	Y	F	Average	PPP	Imported Med	12	4	10
Czech Republic	Y	F	Avg lowest 3	MNF	All	36	20	14
Denmark	Y	I	Avg price	PPP	Hospital-only	_	9	15
Estonia	Y	F	Lowest	MNF	Reimbursed	6	3	12
Finland	Y	I	No calculation scheme	PPP	Reimbursed	Up to 60	29	14
France	Y	I/F	Average	MNF	Innovative Med	60	4	19
Germany	Y	I	Not defined	MNF	Innovative Med	_	15	17
Greece	Y	F	Avg lowest 3	MNF	All	6	22	14
Hungary	Y	F	Lowest	PPP	Reimbursed	12	30	14
Ireland	Y	F	Average	MNF	Innovative Med	24	9	13
Italy	Y	I/F	Average	MNF	Reimbursed	24	26	13
Latvia	Y	F	Third lowest	MNF	Reimbursed	12	30	13
Lithuania	Y	F	Average	MNF	Reimbursed	12	8	14
Luxembourg	Y	I	Average	MNF	All	18	_	9
Malta	Y	F	Average	MNF	All	18	11	9
Netherlands	Y	F	Average	PPP	POM	6	4	15
Norway	Y	F	Avg lowest 3	PPP	POM	12	9	3
Poland	Y	I	Benchmark in negotiations	MNF	Reimbursed	24	30	13
Portugal	Y	F	Average	MNF	POM	12	3	13
Romania	Y	F	Lowest	MNF	Reimbursed	12	12	11
Slovakia	Y	F	Avg lowest 3	MNF	Reimbursed	6	26	14
Slovenia	Y	F	Lowest	MNF	Reimbursed	6	3	13
Spain	Y	I	Lowest	MNF	Innovative Med	_	17	15
Sweden	N	_	_	_	_	_		13
Switzerland	Y	F	Average	MNF		36	6	
UK	N	_	_	_	_	_	_	_

Source: IMS Health, Creativ-Ceutical, EFPIA members

Fédération Européenne
d'Associations et d'Industries
Pharmaceutiques

Leopold Plaza Building
Rue du Trône 108 Boîte 1
B-1050 Bruxelles

T +32 2 626 25 55
F +32 2 626 25 66
www.efpia.eu

Comments:

- Finland: No legislation (or established practice) for average price in Finland; companies are only requested to submit international reference price data of EU and EFTA countries. There are two referencing schedules in the legislation, one for relatively new products (re-referencing up to 3 years) and another for old (established) products (up to 5 years). In both cases these are maximum times and re-referencing frequency could be less than 12 months for new products.
- Germany: IRP is one element of the negotiation process for price setting (benchmark in the context of broader pricing and reimbursement methodology that takes other factors into account and provides for flexibility in price negotiations).
- Netherlands: IRP applies to oral retail products only, some injectables and expensive hospital products
- U.K.: Criteria for approval of new launch prices in statutory scheme include IRP. We understand from the DH in practice the PPRS criteria for launch prices for line extensions etc may also include IRP. There are no published details on method used or countries referenced.