



Escuela Andaluza de Salud Pública

CONSEJERÍA DE IGUALDAD, SALUD Y POLÍTICAS SOCIALES

Mapping External Reference Pricing Practices for Medicines

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Previous studies by the authors

1. Analysis of Differences and Commonalties in Pricing and Reimbursement Systems in Europe. A Report Commissioned by DG Enterprise and Industry of the European Commission, 2007

Jaime Espín y Joan Rovira, EASP

http://ec.europa.eu/enterprise/phabiocom/comp_pf_en.htm.

2. WHO/HAI Project on Medicine Prices and Availability Review Series on Pharmaceutical Pricing Policies and Interventions

Working. Paper 1: External Reference Pricing, May 2011

Jaime Espin, Joan Rovira and Antonio Olry de Labry, EASP

[http:// www.haiweb.org/medicineprices/articles/index.html](http://www.haiweb.org/medicineprices/articles/index.html)

3. The effect of International Reference Pricing (IRP) in the EU medicines markets. Joan Rovira , Sandra Rodriguez, Jaime Espín and Antonio Olry de Labry , EASP (forthcoming)

Justification

- The UK's Intergovernmental Forum on Access to Medicines (IGFAM) has debated whether ERP is an impediment to differential pricing, especially in lower-income countries that may be referenced to by more wealthy and lucrative countries.

Objectives of the study

General objective

- To assess if ERP can affect the feasibility of the business model of pharmaceutical companies - setting lower prices in lower-income countries – due to higher income countries referencing lower-income countries' prices.

Specific objectives

- To map and better understand the use of ERP, in particular which countries do not use ERP, which countries use ERP, the structure and processes used, and which low- and lower-middle income countries are being referenced to.
- To use the previous information to test the hypothesis that a very limited number, if any, of low-income and lower-middle income countries are used as price reference countries by higher-income countries, and therefore this is not an obstacle for pharmaceutical companies not being able to offer lower prices to lower-income countries without affecting their business model in higher-income countries.

Methodology (1)

- Data collection was undertaken in two stages from October 2013 to August 2014.
- In Stage 1, a brief initial questionnaire was disseminated to 367 key national informants and contacts known to the World Health Organization (WHO) and Health Action International (HAI), and identified via various mailing list servers and other mechanisms. Questions were asked to ascertain which countries had medicine pricing and/or reimbursement regulations, were or were not using ERP, were planning to use ERP, and whether any countries were referencing to their prices.
- Data from 73 countries were collected and collated using LimeSurvey.

Methodology (2)

- In Stage 2, a detailed questionnaire was sent via email to countries using ERP according to the responses to the Stage 1 questionnaire, plus those in the Pharmaceutical Pricing and Reimbursement Information (PPRI) network, that covers mainly European countries, in order to characterise the use of ERP.
- Data from 27 countries which reported using ERP were analysed.
- Data was also collected from recently published research and other sources.
- A questionnaire was also sent to the countries who were planning to use ERP (5 responded).

Initial questionnaire

1. Contact details
2. Country
3. Are you in some way involved medicines pricing and/or the reimbursement of medicines in your country?
4. Do you know how medicines are priced and reimbursed in your country?
5. Do you have official price regulations and/or reimbursement regulations for medicines in your country?
6. Is External Reference Pricing used in your country?
7. Are you actively planning to use ERP in your country?
8. Are you aware of any countries, formally or informally, taking the price of medicines in your country as a reference for setting their own prices?
9. Please provide the names and contact details of officials working on medicine pricing and/or financing/reimbursement, or others who you feel we should contact, in your country.

Detailed questionnaire for countries using ERP

TWO KEY QUESTIONS

- When using ERP, to which countries and/or price databases does your country reference? Please name the countries and/or price databases
- Are you aware of any other countries referencing your country prices (i.e. using your prices as a reference for setting or negotiating their prices)?

GENERAL QUESTIONS ABOUT PRICE REGULATIONS (4 questions)

USE OF ERP and LEGAL FRAMEWORK (2 questions)

ERP SETTINGS (19 questions)

CONSEQUENCES of using ERP (4 questions)

Table 5. Distribution of countries responding to the detailed questionnaire, by continent

Africa
Ghana - Republic of Guinea - Sudan
Americas
Canada - Colombia
Asia & Australasia
Iran - Japan - Jordan- Lebanon - Malaysia - Pakistan - Tuvalu
Europe
Albania - Austria - Belgium - Czech Republic - Hungary – Iceland - Latvia - Moldova - Poland - Slovakia - Spain - Switzerland - The Netherlands – Turkey - Ukraine

Table 6. Distribution of countries responding to the detailed questionnaire, by World Bank income levels

High-income
Austria - Belgium -Canada -Czech Republic - Iceland - Japan - Latvia -Poland -Slovakia -Spain -Switzerland- The Netherlands
Upper-middle income
Albania - Colombia - Hungary - Iran -Jordan - Lebanon -Malaysia -Turkey - Tuvalu
Lower-middle income
Ghana - Moldova - Pakistan - Sudan - Ukraine
Low-income
Republic of Guinea

Results (1)

- 55 countries are using ERP
- 45 countries are not, and
- 14 countries are planning to use ERP.

- Most countries using ERP are in the European region, and classified by the World Bank (2014) as high-income countries.
- Only five low-income countries are using ERP.
- The majority of countries (9 of 14) planning to use ERP are middle-income countries.

Results (2)

- Three criteria are mainly being used to select the countries to reference to
 - (1) in the same region
 - (2) similar/comparable income levels
 - (3) similar socioeconomics conditions.
- Countries using ERP are referencing mainly to countries in their geographical area, although there were exceptions.
- ERP-using countries tend to reference to countries with a higher GDP per capita.

Results (3)

- Most countries have a formal, explicit document regulating the application of ERP.
- While the majority of countries simultaneously use several criteria for pricing and reimbursement, it was not clear how these criteria are combined or weighted, or whether they are used according to a certain order or conditions.

Results (4)

- Almost all countries use ERP for on-patent prescription medicines, and many also use it for generic prescription medicines.
- The number of products where the price has been set using ERP varied substantially among the countries, from only a few to the several hundred.
- The most frequent prices sought are the manufacturer's/ex-factory price, followed by the wholesale price.

Results (5)

- Most countries stated that they use freely-accessible websites to access prices (*likely bias*)
- Most countries use official price lists (*rarely providing actual transaction prices*)
- In some countries, companies are required to provide prices in other countries.
- Some countries use international price databases, such as the Management Sciences for Health's (MSH) International Drug Price Indicator Guide or the EURIPID database.
- 11 out of the 27 countries do not validate or cross-check the price data with other sources

Results (6)

- 8 countries reported that they use the lowest price in the basket of countries
 - 5 countries use the median price, and
 - 6 countries use the mean price.
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- Most countries do not revise the price following price changes in the reference countries.

Table 10. Countries that reference countries with a lower GDPpc

Referencing country	GDPpc in US\$	Total number of referenced countries	Number of referenced countries with a lower GDPpc	Average difference in GDPpc as a %	Referenced country with the largest GDPpc difference as a % in relation to the referencing country
Hungary	19,637	30	4	-19.6	Romania: -34,8;
Latvia	18,254	7	1	-29.8	Romania: -29.8
Poland	20,591	8	3	-9.8	Croatia: -13.5;
Slovakia	24,249	27	9	-22,0	Romania: -47.2;
Czech Republic	27,191	27	13	-22,8	Romania: -52.9
Austria	42,409	27	26	-32,1	Romania: -69.8
Belgium	37,883	27	21	-32,7	Romania: - 66.2
Spain	30,557	27	16	-26,7	Romania: -58,1
Ukraine	7,374	8	1	-53.7	Moldova: -53.7
Malaysia	16,992	11	6	-22,7	South Africa: - 32.8
Pakistan	2,880	2	1	-29,9	Bangladesh: -29.9
Colombia	10,792	17	2	-3,7	Ecuador: -6,8

Figure 1: Map showing countries that are, and those that are not, using ERP

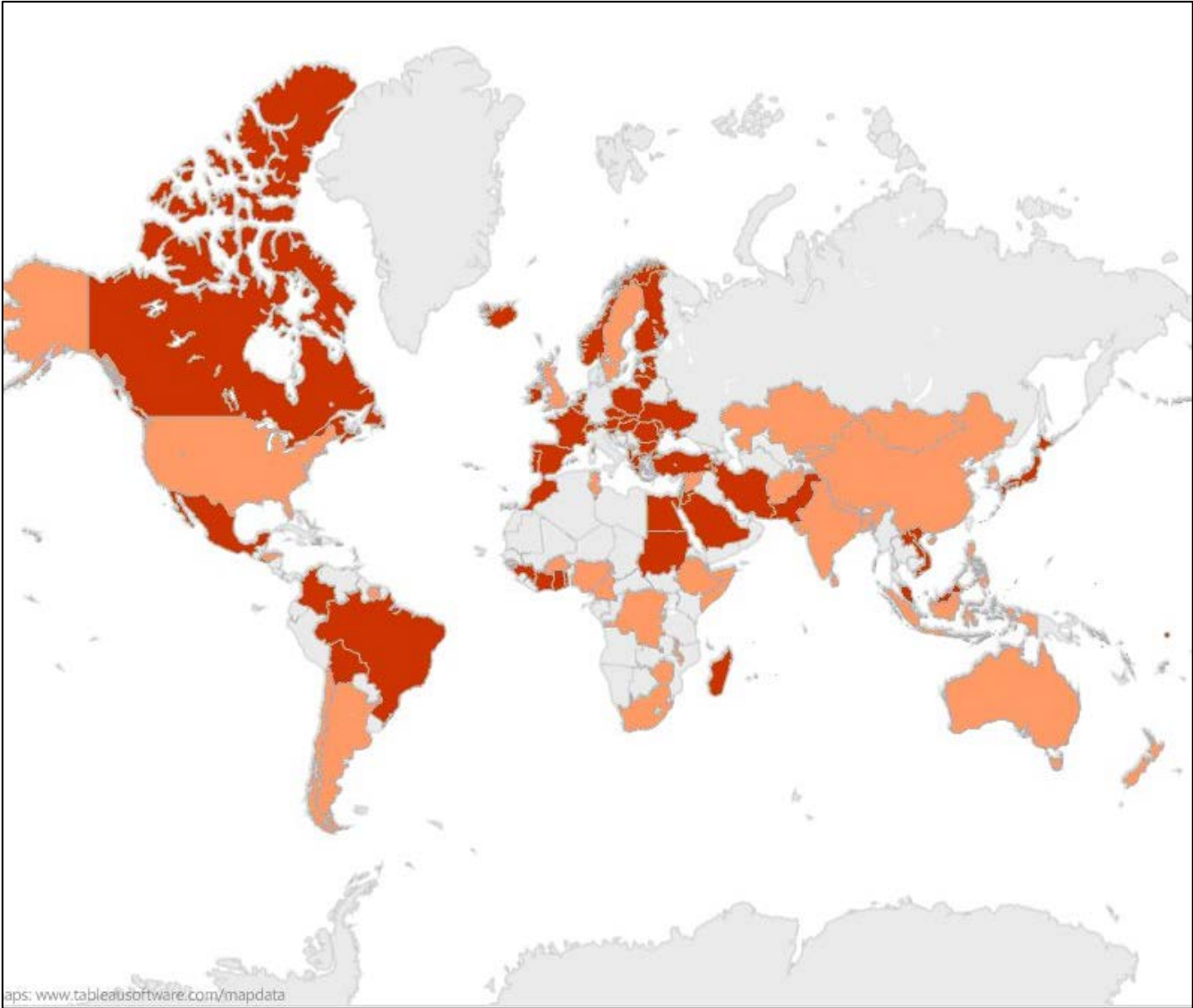
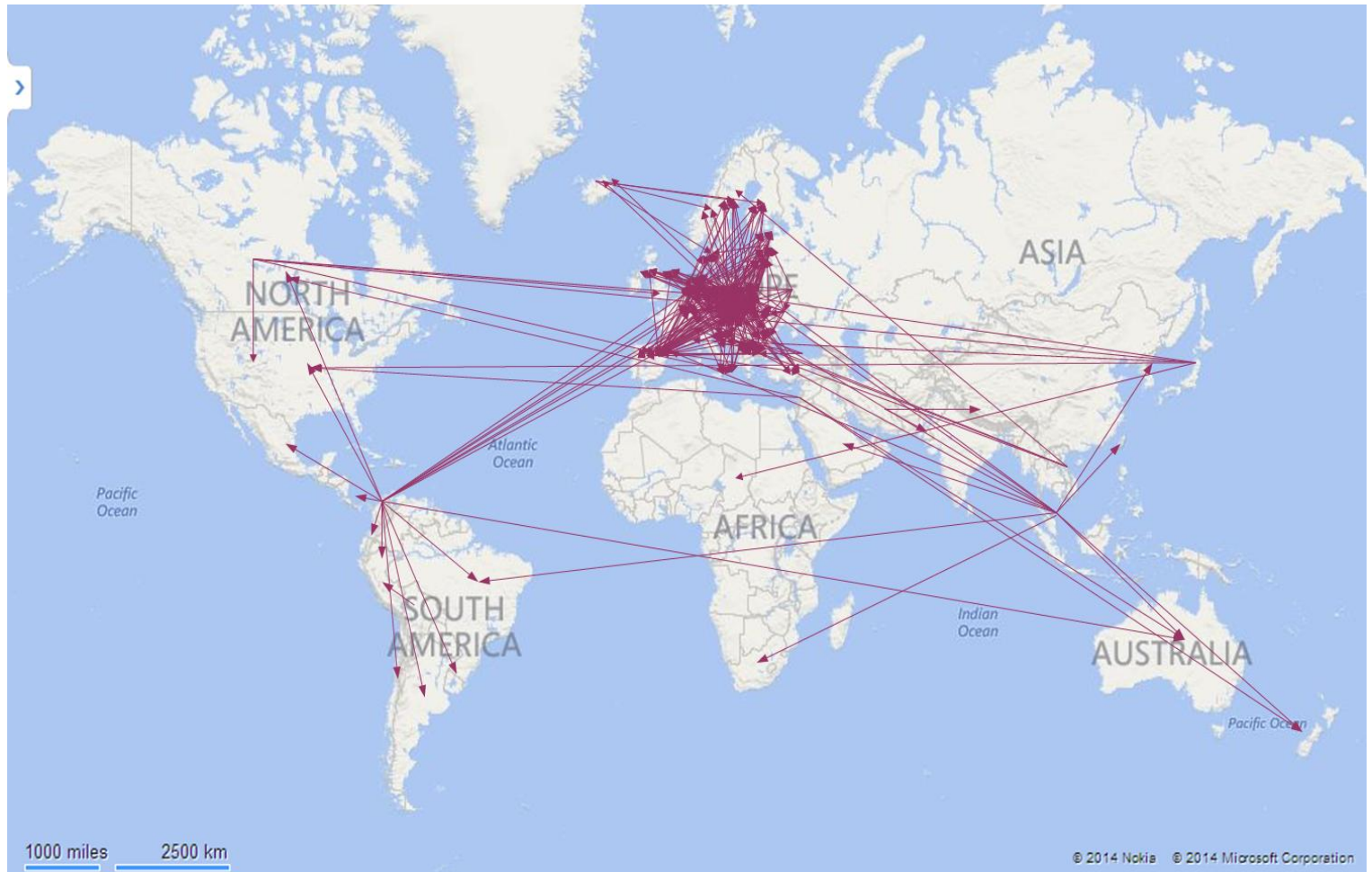


Figure 2. Use of ERP globally showing countries referenced to



Use of External Reference Pricing for Medicines

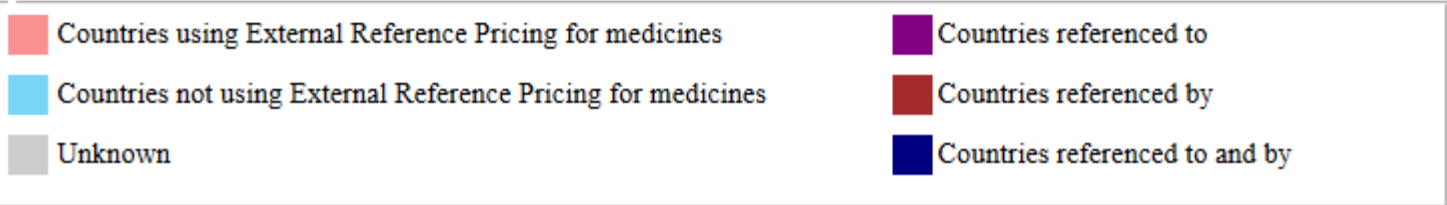
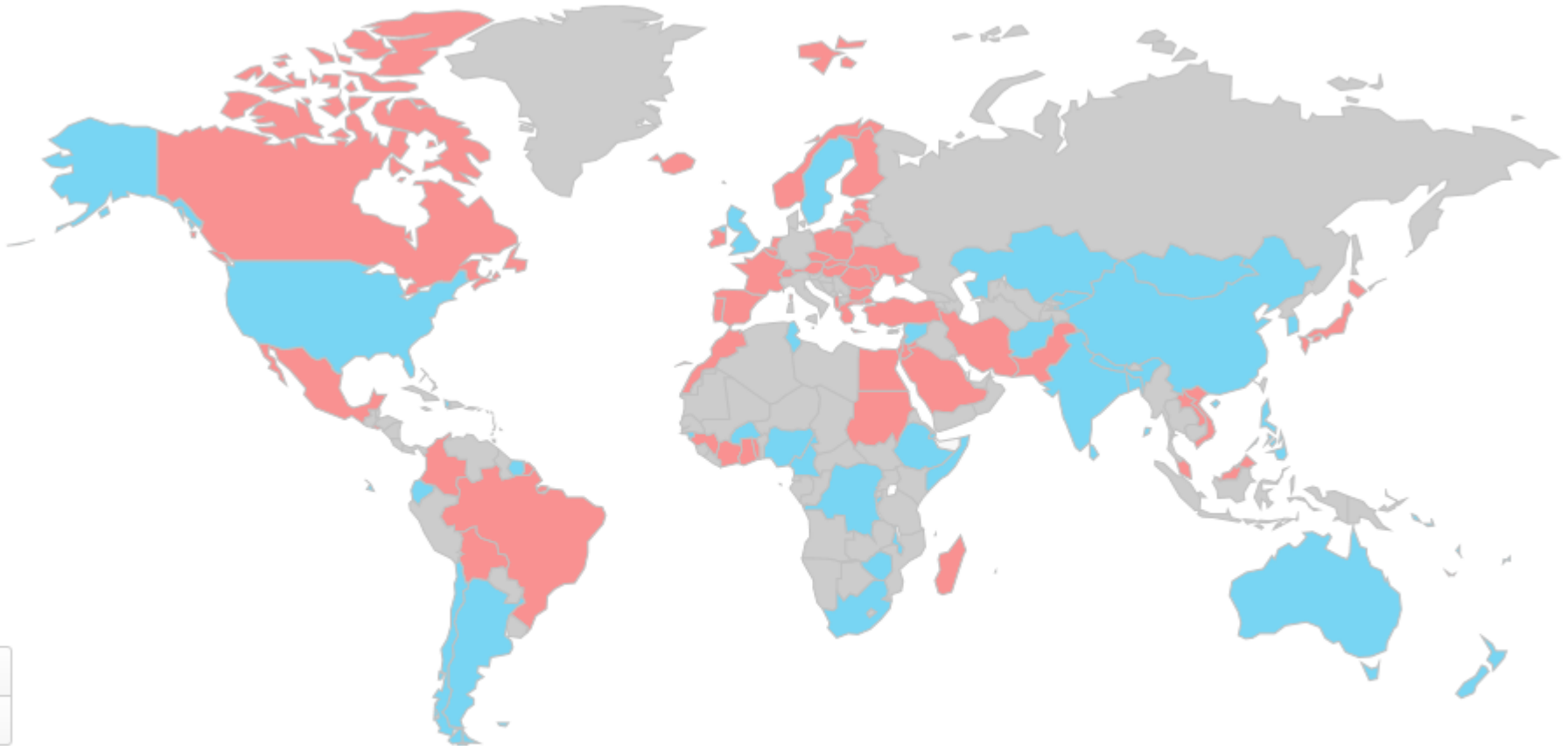


Figure 4. Association between GDP per capita and the average GDP per capita of the reference countries

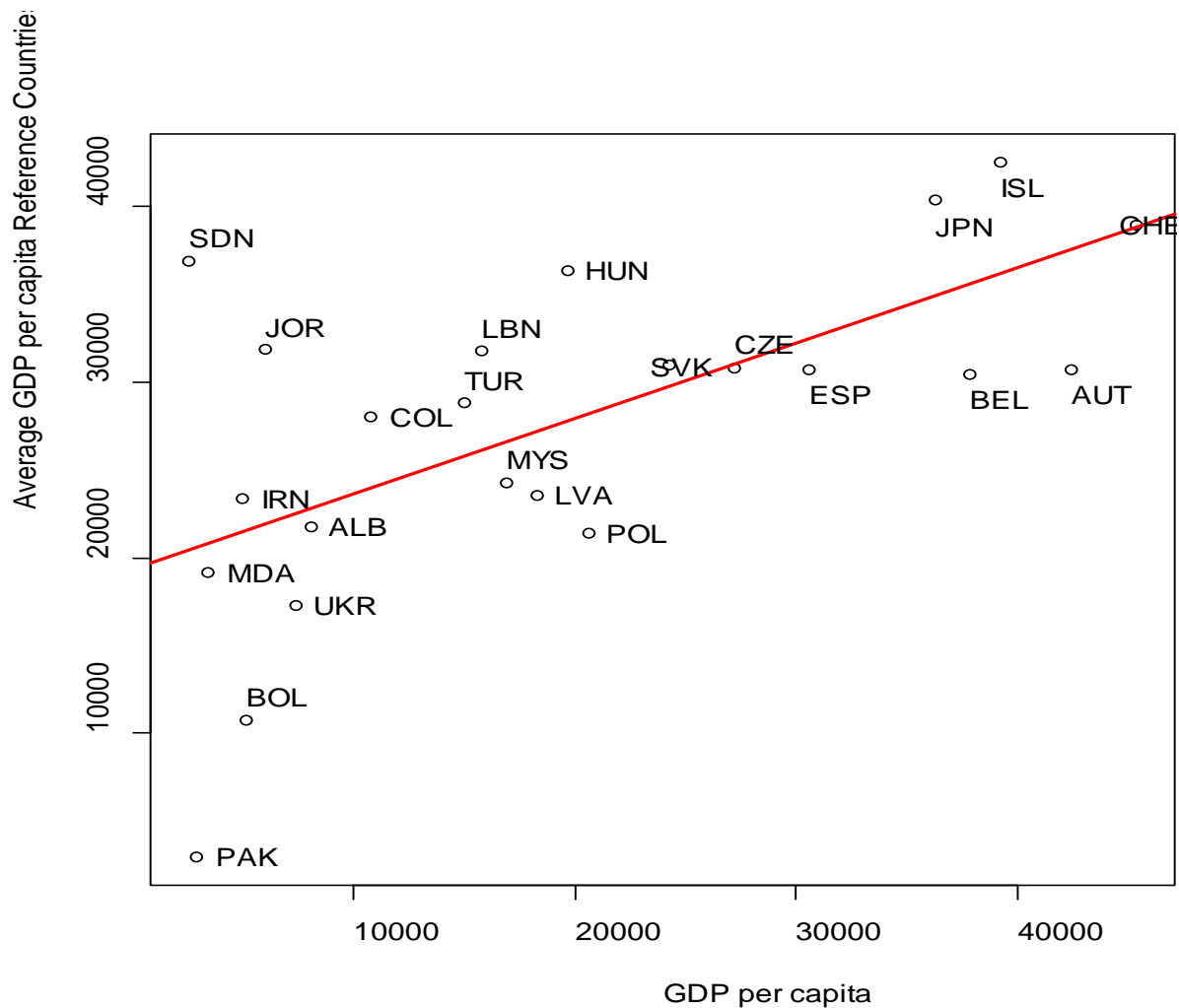


Table 9. Countries more frequently referenced by countries with a higher GDPpc

Number of countries referencing	Countries referenced
7	Latvia, Romania
5	Bulgaria, Croatia, Hungary
5	Estonia, Lithuania, Poland, Portugal
4	Cyprus, Greece, Malta, Slovakia
3	Czech Republic, Italy

Limitations of the study

- The dataset is limited by the key informant identification and the response rate to the questionnaires. Most responses, but not all, were from key informants.
- Postings on the various mailing list servers (such as E-Drug) did not boost the number of responses to the initial questionnaire, although data was received from a few countries where we had no contacts or key informants.
- The response rate to the longer and detailed questionnaire was far lower than hoped, especially for countries outside of Europe. This was a key limitation in identifying which countries were being referenced to and to characterising the use of ERP.
- In some cases conflicting answers were given, probably due to responders misunderstanding the terminology.

Conclusions (1)

- Based on information from 100 countries, we found no examples of high-income countries referencing low-income countries as defined by the World Bank.
- On the basis of this finding, low prices offered by pharmaceutical companies to low-income countries would not result in reduced prices in high-income countries as a consequence of current, formal ERP practices.

Conclusions (2)

- Moreover, the practical difficulties of identifying prices in low-income countries, especially actual prices (net of discounts, rebates, etc.) as opposed to official prices, makes the possibility of high-income countries referencing prices in low-income countries very unlikely.

Conclusions (3)

- Large variety of ERP approaches: from very loose to highly detailed procedures (Canada)
- ERP is so far primarily used by high income countries and is at present expanding to low income countries

A recommendation for pricing drugs under exclusivity in middle and low-income countries

- Use a basket of countries with transparent value-based pricing procedures (UK-NICE, Canada, The Netherlands, Australia, etc)
- Try to estimate discounts, i.e. transaction prices
- Adjust the average or median price of the basket for PPP or relative income per capita.
- Use Value Based Pricing as a second line approach.

Additional readings

- European Commission External reference pricing of medicinal products: simulation-based considerations for cross-country coordination Final Report, 2014
http://ec.europa.eu/health/healthcare/docs/erp_reimbursement_medicinal_products_en.pdf
- RAND EUROPE, Pharmaceutical pricing. The use of external reference pricing by Kai Ruggeri, Ellen Nolte
http://www.rand.org/pubs/research_reports/RR240.html
- Medicine prices, availability, and affordability in 36 developing and middle-income countries: a secondary analysis A
Cameron, M Ewen, D Ross-Degnan, D Ball, R Laing MD
<http://www.thelancet.com/journals/lancet/article/PIIS0140-6736%2808%2961762-6/fulltext>

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