

Gesundheit Österreich
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WHO Collaborating Centre
for Pharmaceutical Pricing
and Reimbursement Policies

4th PPRI Conference Medicines access challenge - The value of pricing and reimbursement policies

Wednesday, 23 October 2019 -
Thursday, 24 October 2019

Vienna, Austria



Strand 1: Local challenges, global learnings?



Escuela Andaluza de Salud Pública
CONSEJERÍA DE SALUD



WHO Collaborating Centre on Integrated
Health Services based on Primary Care

Jaime Espín, PhD

Professor - Andalusian School of Public Health

“THE PENGUIN EFFECT” in Pharmaceutical Policies



EFFECTIVENESS OF PHARMACEUTICAL POLICIES

The Pharmaceutical Industry and the State

**REFORMING PHARMACEUTICAL POLICIES IN THE
EUROPEAN UNION: A “PENGUIN EFFECT”?**

Ana M. Guillén and Laura Cabiedes

THEY CONCLUDE THAT THE EU
COUNTRIES ARE TAKING UP
APPARENTLY **SIMILAR MEASURES**
—DRESSING LIKE PENGUINS IN A ROW—
DESPITE THE **LIMITED**
EFFECTIVENESS AND **LIMITED**
EVALUATION OF MANY OF THE
MEASURES ADOPTED

Table 6

Impact of measures on the control of public pharmaceutical spending

	Effective in the control of pharmaceutical spending?	Rest of health spending up or down?	Efficiency increases?	Equity diminishes?
Co-payment	No		No (potent.)	Yes (potent.)





WHO GUIDELINE
ON COUNTRY
PHARMACEUTICAL
PRICING POLICIES



- ❖ Countries should consider exempting essential medicines from taxation.
- ❖ Countries should ensure any reductions or exemptions from taxes on medicines have the effect of reducing costs to the patient/purchaser.

Strand 1: Local challenges, global learnings?

Lack of local impact assessments, global mistakes?

Formal Price Referencing Today



Source: WHO/WTO report of the workshop on differential pricing and financing of essential drugs, available http://www.wto.org/english/tratop_e/trips_e/tn_hosbjor_e.htm.



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
Andalusian School of Public Health

Recomendations (II)

Suggestions in the case of ERP system:

- To apply to **on-patent products**
- To select as **reference countries** whose pricing policies look appropriate
- To use actual reference price (**transaction prices**) though more difficult to estimate them

Table 3. Summary table of key case study results

Country	Price setting	Products - ERP	Countries	Price used	Criteria	Sources of information
Brazil	Agência Nacional de Vigilância Sanitária (ANVISA)	On patent (Category I)	USA, Canada, Portugal, Spain, France, Italy, Greece, New Zealand and Australia	Ex-factory	Minimum	Websites;
Czech Republic	SUKL(State Institute for Drug Control)- maximum prices/reimbursement prices/ Health funds - price negotiations	Reimbursable	For pricing: Estonia, France, Italy, Lithuania, Hungary, Portugal, Greece, and Spain For reimbursement: all EU countries	Ex-factory	Average	Websites; Manufacturer
Hungary	National Health Insurance Fund Administration (OEP)	Reimbursable (new active substances)	Countries in the European Union and European Economic Area	Ex-factory	Minimum	Websites; Manufacturer
Iran	Pricing Commission	On-patent and imported	Greece, Spain, Turkey and the country of origin	Ex-factory and wholesaler	Minimum	Manufacturer
Jordan	Pricing committee of the Jordan Food and Drug Administration (FJDA)	All products	Selected European countries (UK, France, Spain, Italy, Belgium, Greece and the Netherlands), the export price to Kingdom of Saudi Arabia, and the country of origin	Ex-factory price of the reimbursed price	Median	Websites; Manufacturer
Lebanon	Pricing Committee - MoH	On- and off-patent products	Region: Jordan, Kingdom of Saudi Arabia, Kuwait, Sultanate of Oman, United Arab Emirates, Bahrain and Qatar. Comparative: France, England, Belgium, Switzerland, Italy, Spain and Portugal	All	Minimum	Manufacturer
South Africa	Pharmaceutical Economic Evaluations (PEE) Directorate	On- and off-patent products	Australia, New Zealand, Spain, and Canada	Ex-factory and import	Minimum	Manufacturer
Sultanate of Oman	Directorate General of Pharmaceutical Affairs & Drugs Control	All products	Gulf Cooperation Council (GCC) countries: Kingdom of Saudi Arabia, United Arab Emirates, Bahrain, Kuwait, and Qatar	Import price CIF (cost, insurance & freight)	Minimum	Manufacturer
United Arab Emirates	Committee - MoH	All products (some exceptions)	Country of origin and Gulf Cooperation Council (GCC) countries: Kingdom of Saudi Arabia, Kuwait, Bahrain, Qatar, and the Sultanate of Oman	Ex-factory and import	Minimum	Websites; Manufacturer

Fuente: Espin J, Rovira J, Olry A: External Reference Pricing. 2011. WHO/HAI

Principales recomendaciones

Sector de medicamentos

1. **Emitir una regulación vinculante** que determine las condiciones exactas en que se pueden conceder ventajas pecuniarias o beneficios de valor significativo a los médicos.
2. Con respecto a **la venta actual de medicamentos de marca** y a la prohibición al empleado de farmacia de realizar una sustitución cuando la prescripción médica indique una marca específica, la OCDE ofrece dos recomendaciones opcionales.

Opción 1) Obligar a los empleados de farmacia a informar a los pacientes sobre el genérico disponible más barato y permitir que los medicamentos prescritos se sustituyan con un genérico más barato cuando el paciente esté de acuerdo, a menos que el médico haya especificado que “la sustitución no está permitida”.

Opción 2) Establecer una disposición legal que obligue a los médicos a prescribir únicamente la denominación común internacional (DCI) de los medicamentos.

MEXICO USE AS REFERENCE THE SIX COUNTRIES WITH THE HIGHEST VOLUME OF SALES !!!!

4. **Dar a conocer la modificación al convenio de concertación de precios** entre la CANIFARMA y la Secretaría de Economía.
5. **Exigir que los registros sanitarios, necesarios para comercializar medicamentos, se renueven una sola vez, después de cinco años, y que posteriormente se vuelvan permanentes.** Esta recomendación requerirá en primer lugar, aumentar la calidad y la frecuencia de los controles in situ; la fijación de multas considerables en caso de que las empresas farmacéuticas no informen a tiempo a la COFEPRIS sobre los cambios realizados a un medicamento; y el otorgamiento de recursos suficientes a la COFEPRIS para que pueda realizar esta tarea.
6. **Abolir el requisito de contar con el permiso de un titular de registro** (generalmente el importador oficial) para importar medicamentos a México.



**Experiences and Impact of European
Risk-Sharing Schemes
Focusing on Oncology Medicines**

Jaime Espin, Joan Rovira and Leticia Garcia

Andalusian School of Public Health

JANUARY 2011



Escuela Andaluza de Salud Pública
CONSEJERÍA DE SALUD

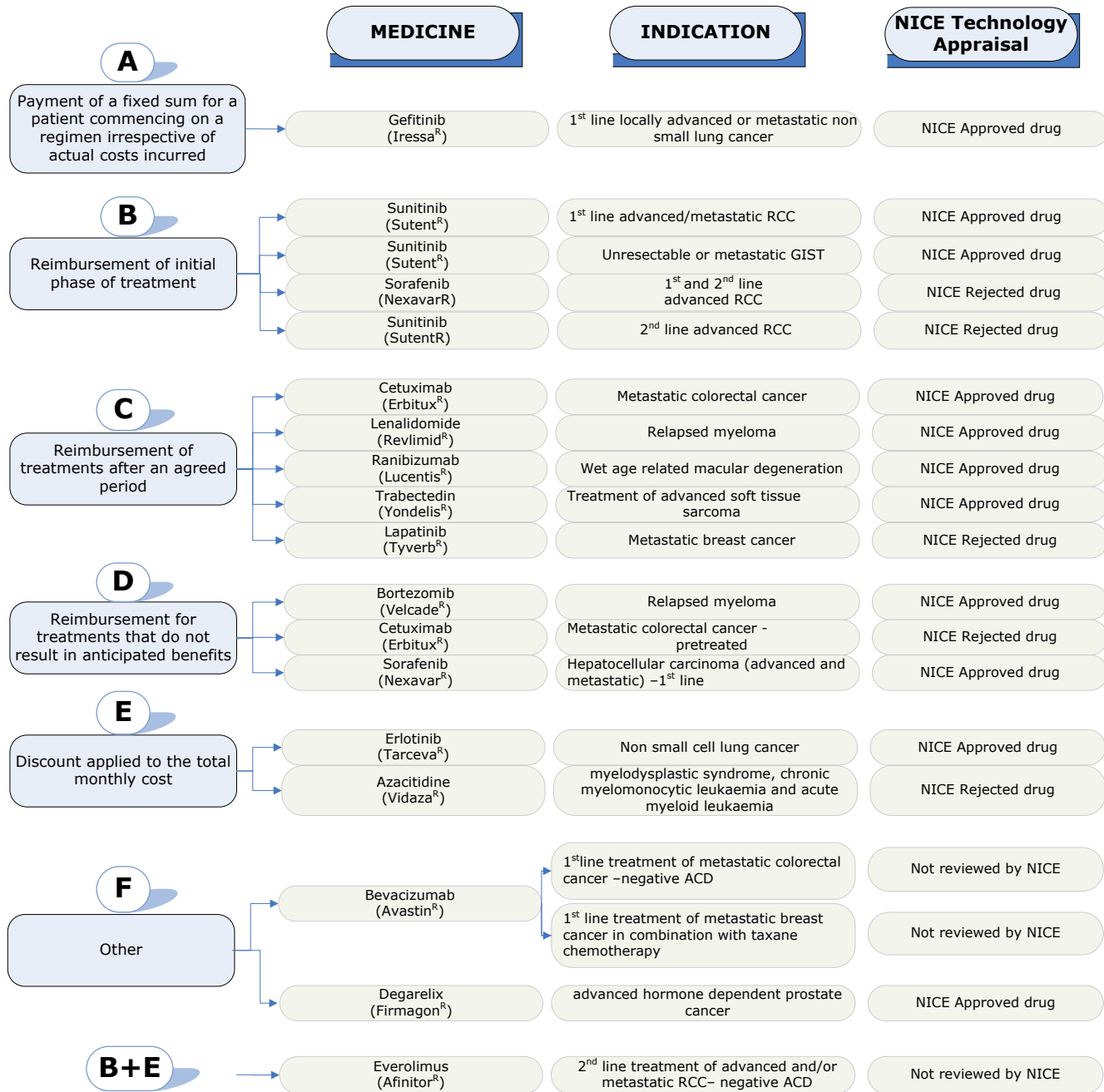
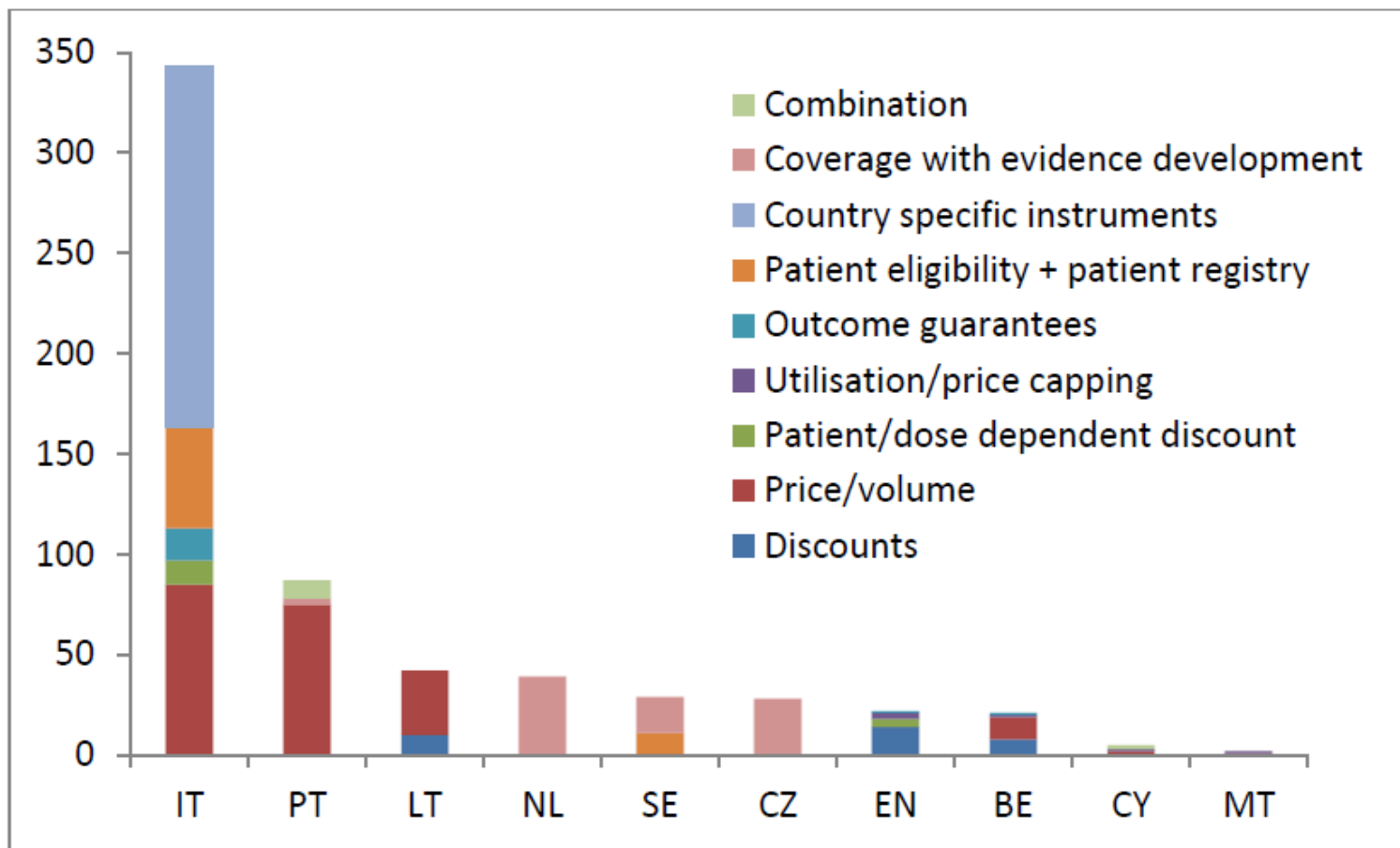


Figure 9.3: MEA analysis by type of instrument



Notes: BE: Belgium, CY: Cyprus, CZ: Czech Republic, EN: England, IT: Italy, LT: Lithuania, MT: Malta, NL: Netherlands, PT: Portugal, SE: Sweden.

"managed entry agreements" medicines



Aproximadamente 1.030 resultados (0,10 s)

+ "impact assessment"

"impact assessment" and "managed entry agreements" medicines



Aproximadamente 58 resultados (0,09 s)

[HTML] Projecting **pharmaceutical** expenditure in EU5 to 2021: adjusting for the impact of discounts and rebates

[J Espin](#), [M Schlander](#), [B Godman](#), [P Anderson](#)... - ... health economics and ..., 2018 - Springer

... level agreements include mandatory discounts applied across a particular **drug** class (eg ... agencies at the time of launch (eg the Italian **Medicines** Agency [AIFA ... These national product-specific discounts also encompass more complex **managed entry agreements** (MEAs); these ...

☆ Citado por 2 Artículos relacionados Las 11 versiones

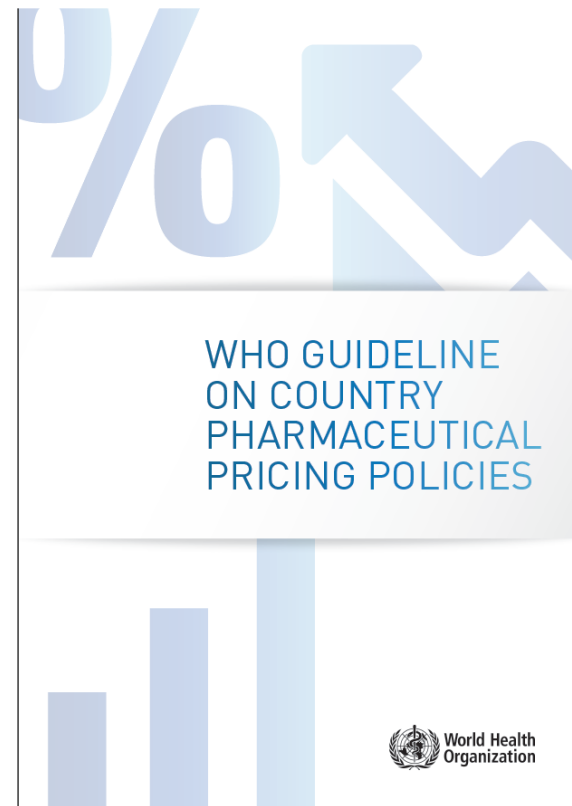
Conclusions (I) – We need....

- More pharmaceutical policy impact assessments are needed.....

- **Abstract Presentation:** Biosimilars in Canada: current environment and future opportunity
Jeffrey Menzies, Patented Medicine Prices Review Board, Canada
- **Abstract Presentation:** An exploratory study into the use and pricing of schedule zero medicines post exemption from the Single Exit Price policy in South Africa
Fatima Suleman, Discipline of Pharmaceutical Sciences, School of Health Sciences, University of KwaZulu-Natal, South Africa
- **Abstract Presentation:** Promoting access to cancer medicines in Mexico: Seguro Popular key policy components
Daniela Moyer-Holz, Department of Community and Occupational Medicine, Medical University Center Groningen, University of Groningen, Groningen, the Netherlands.

Conclusions (II) – We need....

- More policy makers that follow pricing and reimbursement recommendations







Thank you very much for your attention.

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