Problemática y Estrategias Para la Regulación los Medicamentos de Alto Costo

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Reunión Regional Medicamentos Estrategicos y de Alto Costo
Santiago, Chile Septiembre 2-3 de 2015

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Bulletin of the World Health Organization

Editorials

Expensive medicines: ensuring objective appraisal and equitable access

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Bulletin of the World Health Organization 2015;93:4. doi: http://dx.doi.org/10.2471/BLT.14.148924

Agenda

- La **justificación** de la **regulación** de los precios de los medicamentos
- ¿Existe **racionalidad** en los precios de los medicamentos?
- **Buenas prácticas** para la regulación de los precios. *WHO Guideline on Country Pharmaceutical Pricing Policies*.
- Algunas **propuestas alternativas**
- **Conclusiones**

¿Por qué algunos países regulan los precios de los medicamentos?

- a) la especial salvaguardia que requiere el bien jurídico protegido: la **salud de las personas**;
- b) la existencia de **fallos de mercado en** el sector, que además dificultan el acceso en condiciones de equidad a la protección de la salud; y
- c) la relevancia estratégica del sector en la economía, su intensidad innovadora y muy especialmente, el **impacto en las cuentas públicas** que conlleva la prestación farmacéutica

¿Por qué algunos países regulan los precios de los medicamentos? (2)

- D) carácter de bien público y **externalidades positivas de la salud**,
- E) la **deseable accesibilidad en condiciones de equidad** a las prestaciones y,
- F) especialmente en los últimos años, el **alto impacto de la factura farmacéutica** para los sistemas sanitarios

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NHS
National Institute for
Health and Clinical Excellence

Michael Rawlins, chairman NICE :
NICE has “to be fair to all patients in the National Health Service, not just the patients with macular degeneration or breast cancer or renal cancer. If we spend a lot of money on a few patients, we have less money to spend on everyone else. We are not trying to be unkind or cruel. We are trying to look after everybody.”

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Table 3: Pharmaceutical Price Regulation in Europe

	Product price regulation						
	Initial price decision based on clinical perfomance	Initial price decision based on economic evaluation	Initial price decision based on cost of existing treatments	Initial price decision based on cost-plus calculations	Initial price decision based on international prices	Controlled price updates	Other
AT	✓	✓	✓		✓		✓
BE	✓	✓	✓		✓	✓	
CY				◐	✓		
DE							
DK							✓
EE		✓	✓		✓		
EL				✓ ◐	✓	✓	
ES	✓		✓	✓	✓	✓	
FI	✓	✓	✓		✓	✓	✓
FR	✓		✓		✓		
HU			✓		✓		
IE	✓	✓	✓		✓		
IT	✓	✓	✓		◐	✓	
LT					✓	✓	
LV	✓	✓	✓			✓	
MT							
NL					✓		
NO					✓		
PL	✓				✓		
PT	✓	✓	✓		✓	✓	✓
RO					✓	✓	
SE	◐	✓	◐		◐		✓
SK	✓	✓			✓	✓	
SI		✓			✓	✓	✓
UK						✓	✓

✓ Currently applied
◐ Once applied but discontinued

Tabla 1: Regulación económica de medicamentos en las Américas

País	Regulación precio medicamento	Instituciones responsables	Criterios de precio basado en:					
			Eficacia terapéutica	Evaluación económica	Costo tratamiento similar	Precio internacional	Costo producción	Otros
Brasil	X	Cámara Interministerial presidida por el Ministerio de Salud y con la secretaría ejecutiva ejercida por ANVISA	X	X	X	X		X
Colombia	X	Ministerio de Protección Social, Ministerio de Comercio, Industria y Turismo y un delegado de la Presidencia de la República				X	X	
Cuba	X	Ministerio de Finanzas y Ministerio de Salud Pública	X		X	X	X	
Ecuador	X	MInisterio de Salud, Ministerio de Industria, Federación Nacional de Químicos y Bioquímicos Farmacéuticos					X	
México	X	Secretaría de Economía y Procuraduría Federal del Consumidor				X		
Nicaragua	X	Ministerio de Fomento, Industria y Comercio		X		X		X
Panamá	2001 a 2004	Órgano Ejecutivo y Autoridad de Protección del Consumidor				X	X	

Fuente: Resultados del cuestionario desarrollado por ANVISA y OPS para el Primer Seminario Latinoamericano de Regulación Económica de Medicamentos, celebrado en Brasilia del 17 al 19 de marzo de 2009.

¿Con la regulación de precios son mas **racionales** los precios de los medicamentos?

No Rational Theory for Drug Pricing

Michael C. Cox, William D. Figg and Paul W. Thurman

In conclusion, it appears that there is no standard method for setting the price on new oncology drugs. When drug companies set the price on the basis of free-market pricing, there may be more incentive to invest in risky ventures and boost the research and development arms of these companies. However, the price they set is not a function of profits expected during patent protection or from use in the target population.

blood

Prepublished online April 25, 2013;
doi:10.1182/blood-2013-03-490003

Price of drugs for chronic myeloid leukemia (CML), reflection of the unsustainable cancer drug prices: perspective of CML Experts

Experts in chronic myeloid leukemia

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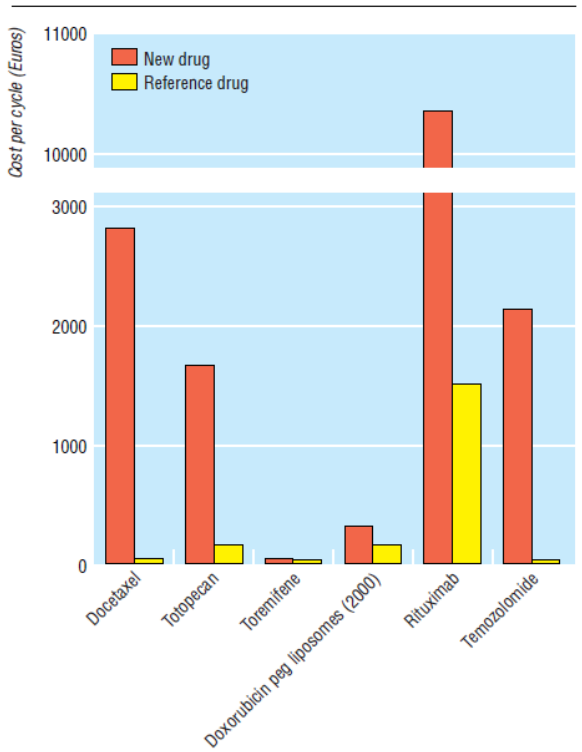
BMJ VOLUME 325 3 AUGUST 2002 bmj.com

Efficacy, safety, and cost of new anticancer drugs

Silvio Garattini, Vittorio Bertele'

Italian pharmacologists Silvio Garattini and Vittorio Bertele' note that new anticancer drugs reaching the European market in 1995-2000 offered few or no substantial advantages over existing preparations, yet cost several times—in one case 350 times—as much



Comparison of some new drugs with existing drugs

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VOLUME 25 · NUMBER 2 · JANUARY 10 2007

JOURNAL OF CLINICAL ONCOLOGY

REVIEW ARTICLE

Cost of Cancer Care: Issues and Implications

Neal J. Meropol and Kevin A. Schulman

From the Divisions of Medical Science and Population Science, Fox Chase Cancer Center, Philadelphia, PA; and the Center for Clinical and Genetic Economics, Duke Clinical Research Institute, Duke University Medical Center, Durham, NC.

Submitted October 18, 2006; accepted October 18, 2006.

Presented in part in written format in the 2005 Ameican Society of Clinical Oncology Educational Book.

Authors' discolsures of potential

A B S T R A C T

Medical technology is increasingly costly in most fields of clinical medicine. Oncology has not been spared from issues related to cost, in part resulting from the tremendous scientific progress that has lead to new tools for diagnosis, treatment, and follow-up of our patients. The increasing cost of health care in general (and cancer care in particular) raises complex questions related to its effects on our economy and the citizens of our society. This article reviews the macroeconomic principles and individual behaviors that govern medical spending, and examines how cost disproportionately affects various populations. Our overall goal is to frame debate about health policy concerns that influence the clinical practice of oncology.

J Clin Oncol 25:180-186. © 2007 by American Society of Clinical Oncology

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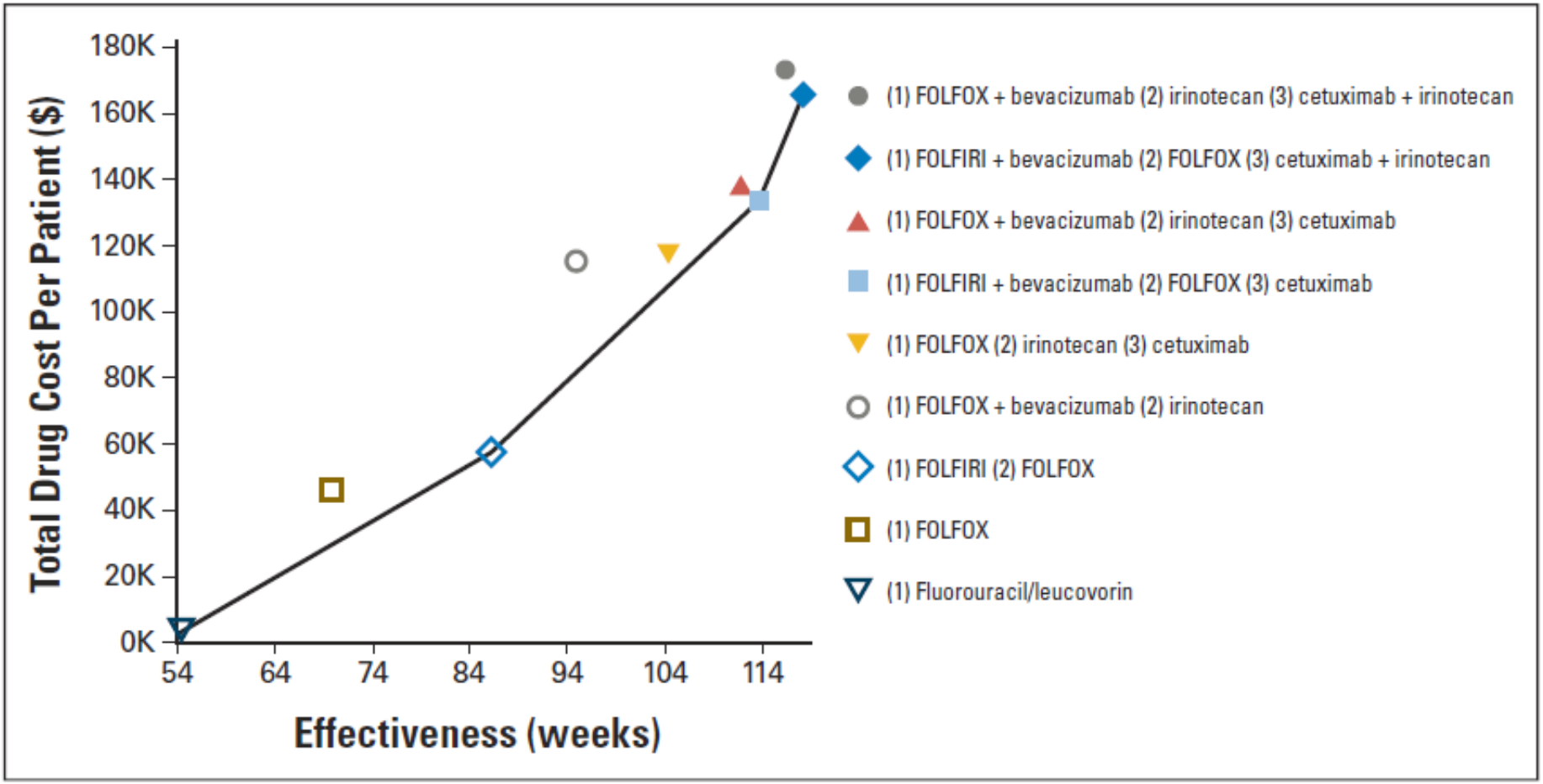
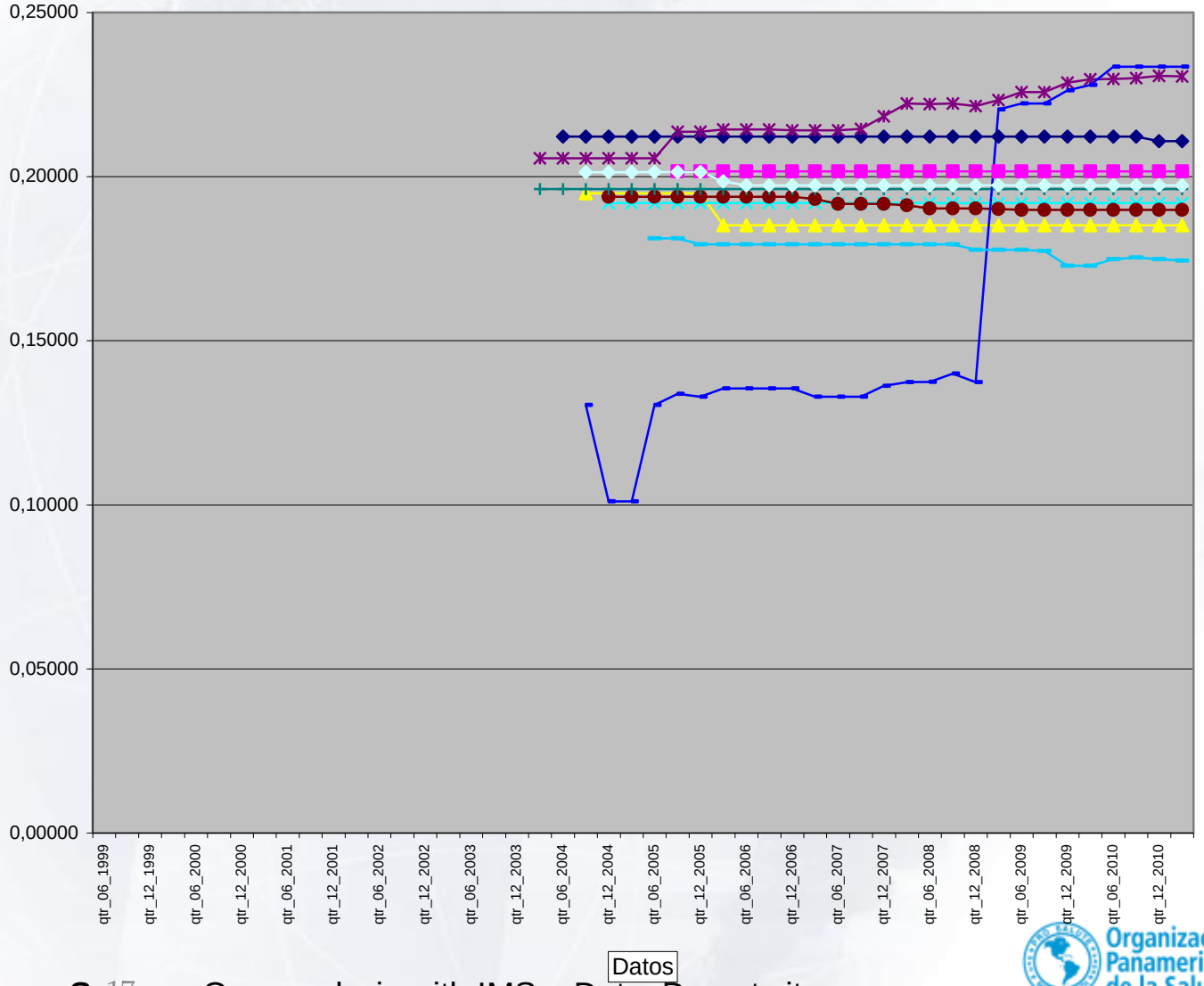
Table 4. Cost of Colorectal Cancer Treatment

Regimen	Cost per 6 Months ($)
FU/LV daily for 5 days, monthly	96
Infusional FU/LV every 2 weeks	352
Capecitabine for 14 days, every 3 weeks	11,648
Irinotecan every 3 weeks	30,100
Irinotecan weekly for 4 weeks, every 6 weeks	21,500
FOLFIRI every 2 weeks	23,572
FOLFOX every 2 weeks	29,989
Bevacizumab (alone) every 2 weeks	23,897
Cetuximab monotherapy weekly	52,131
Panitumumab	44,720

NOTE. Only drug costs included. Costs based upon average sales price for 70 kg patient with body surface area 1.7 m^2. Wholesale acquisition costs were used for panitumumab, as average sales price was not available at the time of publication.
Abbreviations: FU, fluorouracil; LV, leucovorin; FOLFIRI, irinotecan, LV, and infusional fluorouracil for 46 hours; FOLFOX, oxaliplatin, LV, infusional FU for 46 hours.



Example of Price Corridor



Source: Own analysis with IMS – Data. Do not cite

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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 Guideline on Country Pharmaceutical Pricing Policies

A. Should countries use price control measures to manage medicine prices? If so:

- Can ERP be an effective pricing strategy in low- and middle-income countries?
- Should HTA be considered as part of (i) decision-making and/or (ii) price setting in low- and middle-income countries?
- Can cost-plus price setting be an effective pricing strategy in low- and middle-income countries?

5.6.5 Recommendations

The panel took account of the evidence and experiences documented above and in the evidence summary; noted the capacity requirements of HTA; and made the recommendations below.

- Countries should use HTA as a tool to support reimbursement decision-making as well as price setting/negotiation.
- Countries should combine HTA with other policies and strategies, particularly within-country reference pricing (by chemical entity, pharmacological class, or indication).
- Countries should consider the following actions when using HTA: review applicability and adaptation of reports from other countries; review reports submitted by pharmaceutical companies; and conduct assessments based on local information and local data. The choice of approach depends on technical capacity and local decision-making structures.
- Countries could take a stepwise approach to develop legislative and technical capacity to take full advantage of the potential utility of HTA in pharmaceutical price setting.
- In establishing the legislative/administrative framework, countries should clearly define the roles and responsibilities of the decision-makers and other stakeholders, and the process of decision-making.
- Countries should ensure that HTA processes are transparent and that the assessment reports and decisions are made publicly available and effectively disseminated to stakeholders.
- Countries should collaborate to promote exchange of information and develop common requirements for HTA.

PERSPECTIVE

Two Ideas To Increase Innovation And Reduce Pharmaceutical Costs And Prices

What policy proposals can be made to best increase current consumer welfare while maintaining or increasing incentives to innovate?

by Arjun Jayadev and Joseph Stiglitz

ABSTRACT: The pharmaceutical industry is undergoing a period of uncertainty. Profits are being squeezed by increasing costs and competitive pressures, and new drug production is slowing down. This Perspective reviews two policies that could assist in realigning incentives toward genuine innovation while also keeping drug spending growth under check. Value-based pricing can incentivize genuinely new discoveries and align research and development with social welfare. Public funding of clinical trials likewise can reduce both pharmaceutical costs and prices and direct research effort in a manner that is more socially productive than the current state of affairs. [*Health Affairs* 28, no. 1 (2009): w165–w168 (published online 16 December 2008; 10.1377/hlthaff.28.1.w165)]

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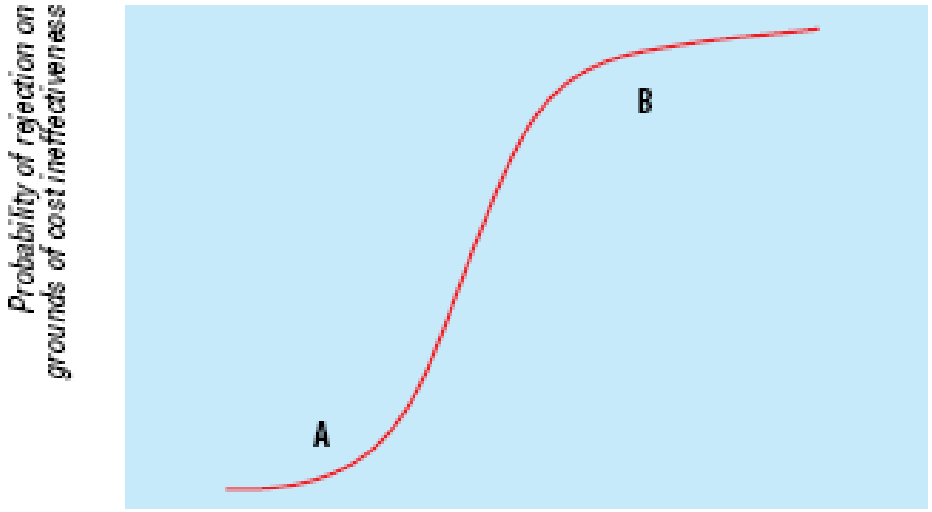
National Institute for Clinical Excellence and its value judgments

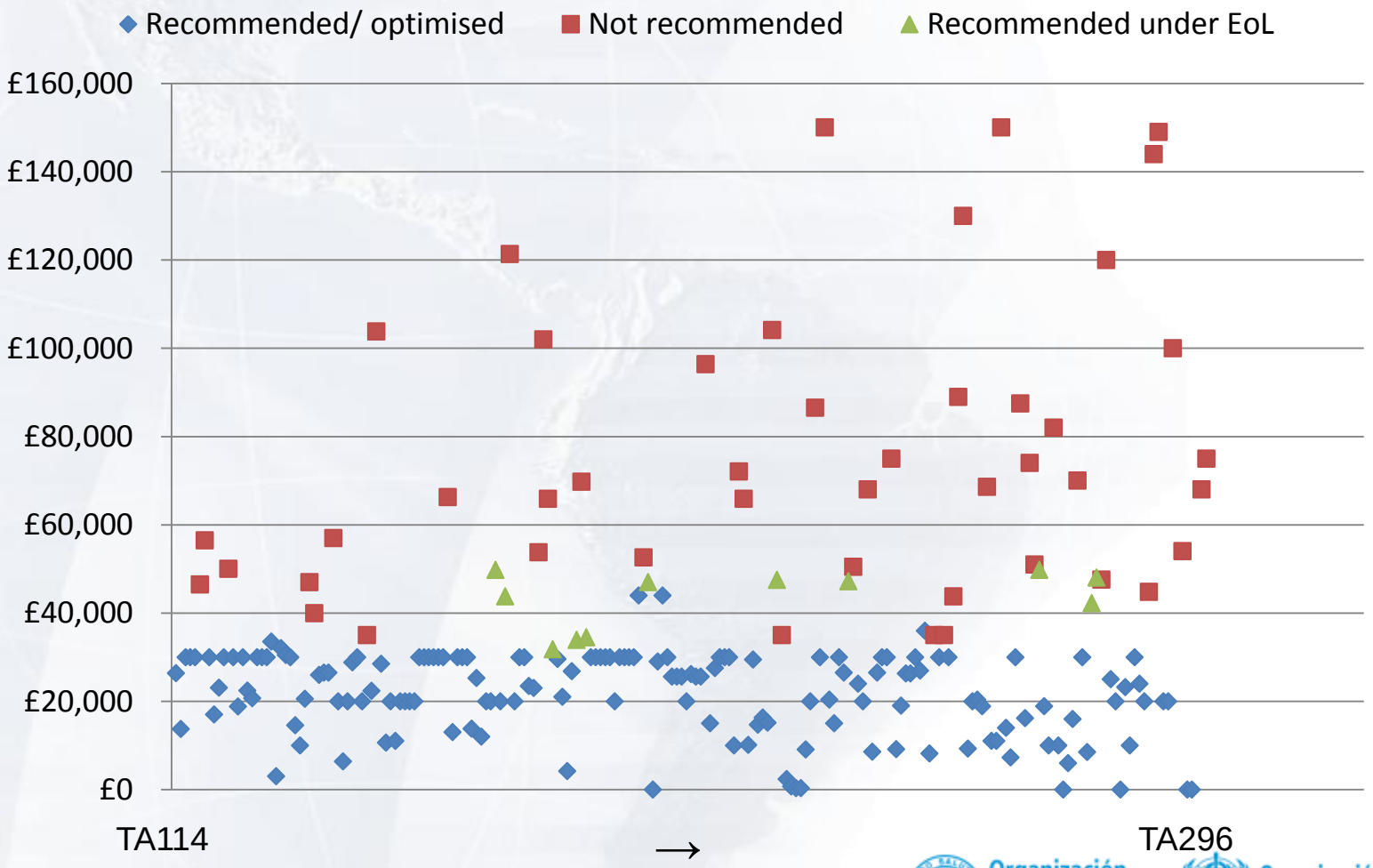
Michael D Rawlins, Anthony J Culyer

BMJ VOLUME 329 24 JULY 2004 bmj.com



Relation between likelihood of a technology being considered as cost ineffective plotted against the log of the incremental cost effectiveness ratio

Most credible ICER for technologies appraised by NICE 2007 – Sept 2013



Fuente: Dr. Freiberg. NICE International

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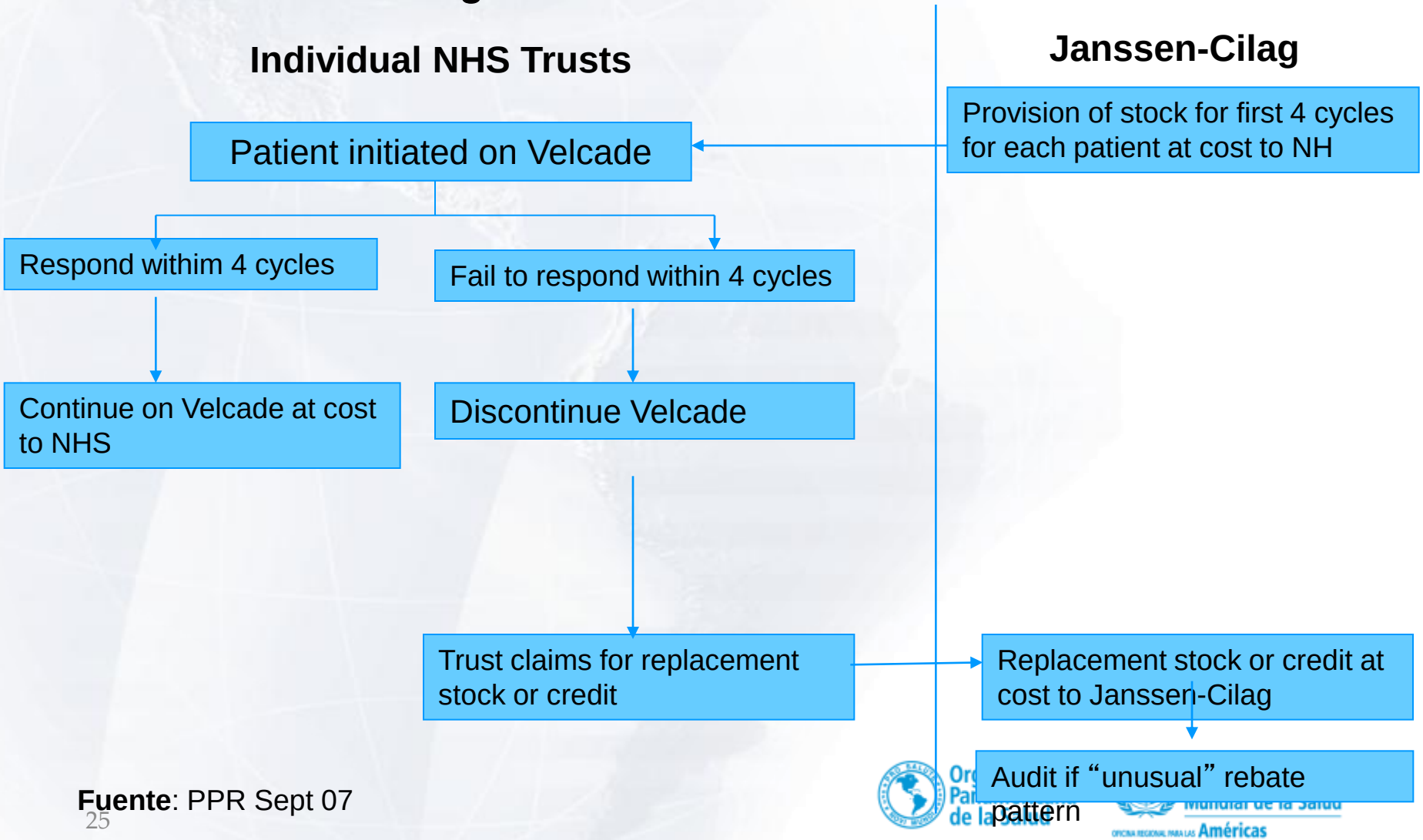
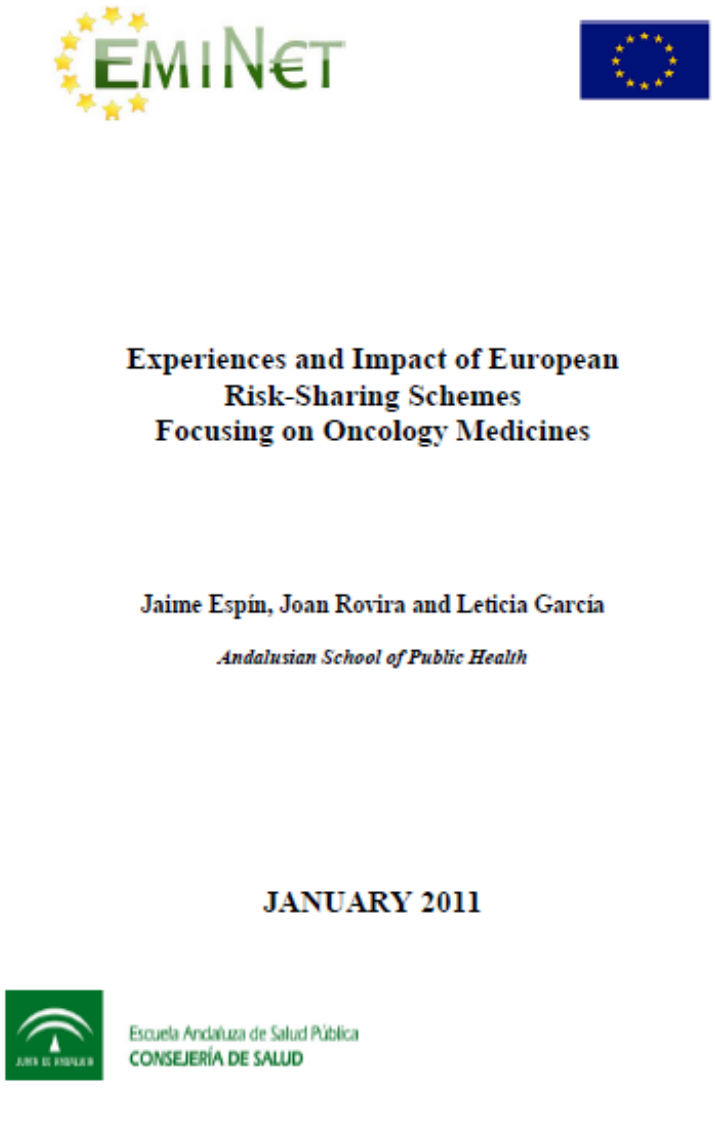
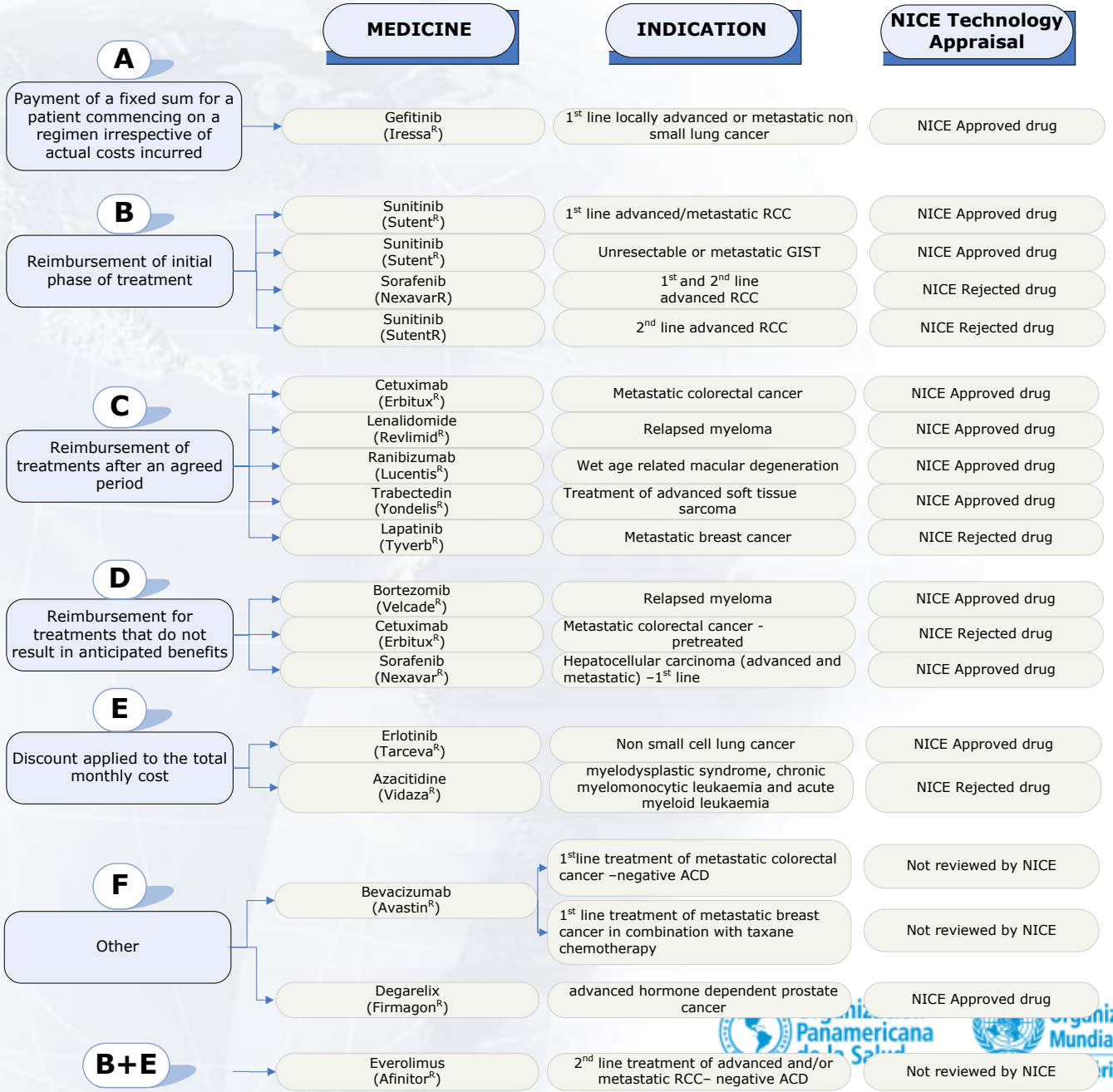
Velcade Risk-Sharing Scheme



Fuente: PPR Sept 07



Link: http://ec.europa.eu/enterprise/sectors/healthcare/files/docs/risksharing_oncology_012011_en.pdf



This is an exciting time in multiple sclerosis therapy, with new drugs becoming available. Ensuring the cost-effectiveness of increasingly expensive drugs is becoming imperative. Managed-entry and risk-sharing agreements between commissioners and manufacturers are increasingly used to deliver value for money of new and expensive therapies. The application of prognostic models supports the use of this type of scheme for other chronic diseases for which long-term trials are not thought appropriate. This 6 year analysis supports a predicted long-term effect of multiple sclerosis DMTs in patients with relapsing-onset disease, consistent with their UK cost-effectiveness at an aggregate level. The final 10 year analysis will confirm whether these benefits are maintained.

Source: Jacqueline Palace, Martin Duddy, Thomas Bregenzer, Michael Lawton, Feng Zhu, Mike Boggild, Benjamin Piske, Neil P Robertson, Joel Oger, Helen Tremlett, Kate Tilling, Yoav Ben-Shlomo, Charles Dobson, Effectiveness and cost-effectiveness of interferon beta and glatiramer acetate in the UK Multiple Sclerosis Risk Sharing Scheme at 6 years: a clinical cohort study with natural history comparator, **The Lancet Neurology, Volume 14, Issue 5, May 2015**, Pages 497-505, ISSN 1474-4422,

Resultados de las negociaciones de precios en los dos primeros años de la normativa AMNOG

Marca comercial	Principio activo	Precio de venta en euros	Beneficio	Descuento en euros	Descuento en porcentaje
Brilique®	Ticagrelor	99	Significativo	13	19
Zytiga®	Abirateron	4.400	Significativo	1.144	26
Benlysta®	Belimumab	742	Significativo	244	38
Yervoy®	Ipilimumab	4.250	Significativo	950	22
Jevtana®	Cabazitaxel	4.395	Discreto	912	21
Gilenya®	Fingolimod	1.850	Discreto	550	30
Vyndaqel	Tafamidis	15.239	Discreto	2.438	15
Edurant®	Rilpivirin	358	Discreto	65	18
Yellox®	Bromfenac	8	Sin beneficio terapéutico añadido	6	77
Rapiscan®	Regadenoson	70	Sin beneficio terapéutico añadido	27	39
Victrelis®	Boceprevir	3.200	No cuantificable	680	21
Incivo®	Telaprevir	9.921	No cuantificable	1.910	19
Halaven®	Erebulin	2.400	Menor que el comparador	384	16

EL GLOBAL

Fuente: International Law Office.

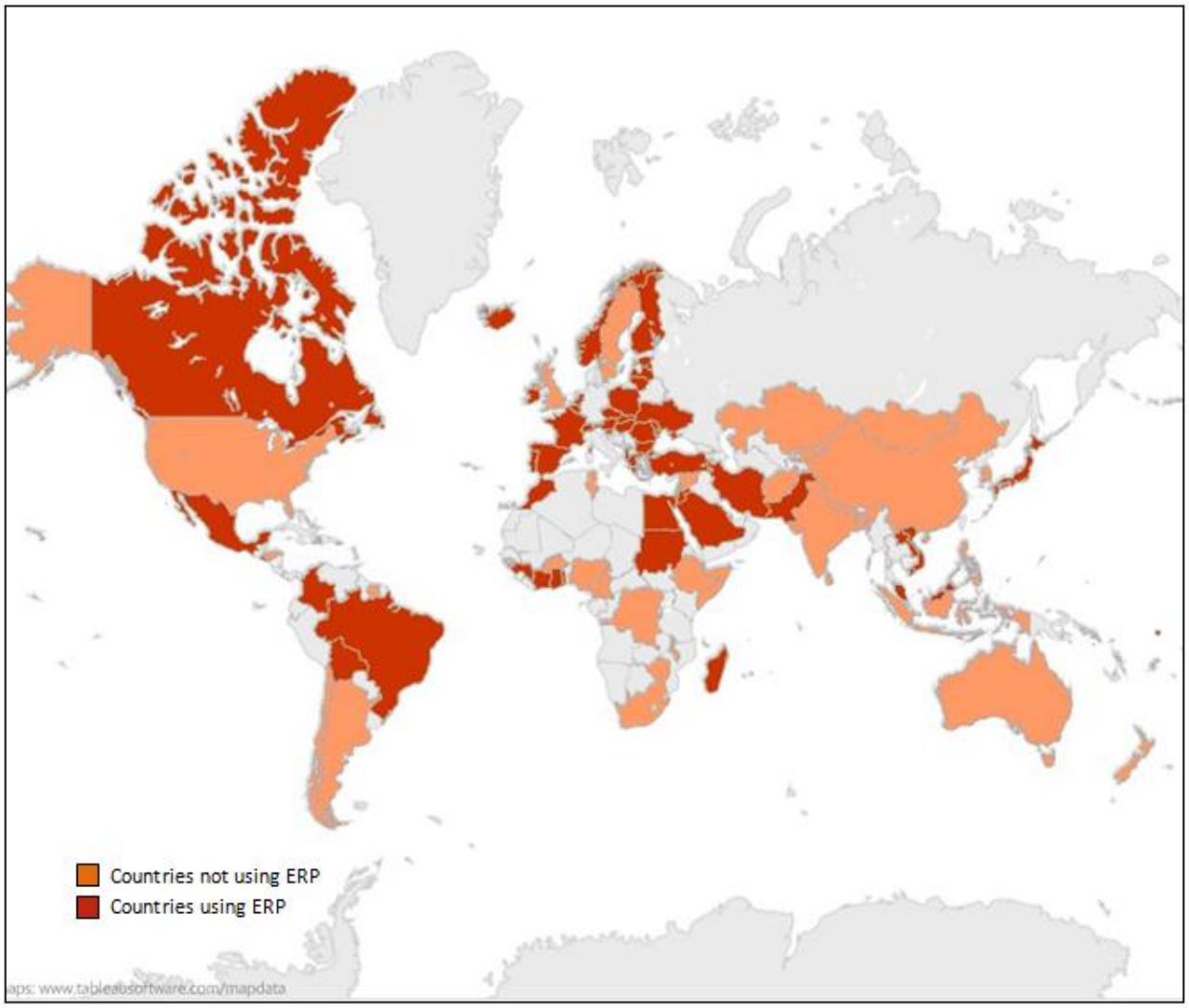


Figure 1: Map showing countries that are, and those that are not, using ERP

Fuente: Espin, Rovira, Ewen, Laing. Mapping External Reference Pricing Practices for Medicines. HAI/EASP. September 2014

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5.4.5 Recommendations

The panel took account of the evidence and experiences documented above and in the evidence summary; noted the experience in the use ERP; and made the recommendations below.

- Countries should consider using ERP as a method for negotiating or benchmarking the price of a medicine.
- Countries should consider using ERP as part of an overall strategy, in combination with other methods, for setting the price of a medicine.
- In developing an ERP system, countries should define transparent methods and processes to be used.
- Countries/payers should select comparator countries to use for ERP based on economic status, pharmaceutical pricing systems in place, published actual versus negotiated or concealed prices, exact comparator products supplied, and similar burden of disease.

Association between GDP per capita and the average GDP per capita of the reference countries

Fuente: Espin, Rovira, Ewen, Laing. Mapping External Reference Pricing Practices for Medicines. HAI/EASP. September 2014

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6.1 Key principles for policy planning and implementation

- Countries should use a combination of different pharmaceutical pricing policies that should be selected based on the objective, context and health system.
- Countries should make their pricing policies, processes, and decisions transparent.
- Pricing policies should have an appropriate legislative framework and governance and administrative structures, supported by technical capacity. They should be regularly reviewed, monitored (including actual prices), and evaluated and amended as necessary.
- In promoting the use of affordable medicines, countries should employ a combination of pharmaceutical policies that address both supply and demand issues.
- If regulation of pharmaceutical prices is introduced, effective implementation will be required to ensure compliance (e.g. incentives, enforcement, price monitoring system, fines).
- Countries should adopt policies to promote the use of quality assured generic medicines in order to increase access and affordability.
- Countries should collaborate to promote exchange of information about policies, and their impacts, and pharmaceutical prices.

Algunas "Nuevas" Propuestas

VALUE-BASED DIFFERENTIAL PRICING: EFFICIENT PRICES FOR DRUGS IN A GLOBAL CONTEXT

PATRICIA DANZON[a,*], ADRIAN TOWSE[b] and JORGE MESTRE-FERRANDIZ[b]

[a]*The Wharton School, University of Pennsylvania, Philadelphia, PA, USA*
[b]*Office of Health Economics, London, UK*

ABSTRACT

This paper analyzes pharmaceutical pricing between and within countries to achieve second-best static and dynamic efficiency. We distinguish countries with and without universal insurance, because insurance undermines patients' price sensitivity, potentially leading to prices above second-best efficient levels. In countries with universal insurance, if each payer unilaterally sets an incremental cost-effectiveness ratio (ICER) threshold based on its citizens' willingness-to-pay for health; manufacturers price to that ICER threshold; and payers limit reimbursement to patients for whom a drug is cost-effective at that price and ICER, then the resulting price levels and use within each country and price differentials across countries are roughly consistent with second-best static and dynamic efficiency. These value-based prices are expected to differ cross-nationally with per capita income and be broadly consistent with Ramsey optimal prices. Countries without comprehensive insurance avoid its distorting effects on prices but also lack financial protection and affordability for the poor. Improving pricing efficiency in these self-pay countries includes improving regulation and consumer information about product quality and enabling firms to price discriminate within and between countries. © 2013 The Authors. *Health Economics* published by John Wiley & Sons Ltd.

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Original Article

Medicine for tomorrow: Some alternative proposals to promote socially beneficial research and development in pharmaceuticals

Received (in revised form): 25th May 2010

Joseph E. Stiglitz

is a professor at Columbia University, the winner of the 2001 Nobel Memorial Prize in Economics, and a lead author of the 1995 IPCC report, which shared the 2007 Nobel Peace Prize. He was chairman of the US Council of Economic Advisors under President Clinton, and chief economist and senior vice president of the World Bank for 1997–2000. He received the John Bates Clark Medal, awarded biennially to the American economist under 40 who has made the most significant contribution to the subject. He is a member of the National Academy of Sciences and a corresponding Fellow of the British Academy and the Royal Society.

Arjun Jayadev

is an assistant professor of Economics at the University of Massachusetts Boston. He has been a research fellow at the Committee on Global Thought at Columbia University and is currently a fellow at the Roosevelt Institute. Among his interests is the development of an effective and fair global intellectual property regime. He has published in specialist economics journals such as the *Journal of Development Economics* and *Economics Letters*, as well as in policy-oriented journals such as *Health Affairs*.

ABSTRACT **The current models of pharmaceutical drug discovery display significant inefficiencies. One inefficiency is the widespread prevalence of me-too drugs. Second, some patents can act as barriers to knowledge, by slowing down the pace of new discoveries. Third, there are higher costs for the public, who end up paying double costs – subsidizing or funding research and development (R&D) that leads to new discoveries on the one hand, and, on the other, paying the social costs of restricted access to knowledge when the discoveries are privatized. Fourth, when the market returns are the sole guide to R&D of new drugs, diseases that are prevalent in markets with weaker buying power are neglected. Thus, policymakers need to identify a new, more cost-effective and innovative productive system for R&D. Policymakers are faced with very complex choices in designing their regulations. They want to promote access to medicines, to lower costs and to encourage research. Politically, they have to balance pressure from the industry with increasingly forceful demands from health advocacy groups. The article looks at four different sorts of policies that may be used to address some of the inadequacies in the current system, especially with regard to the management of R&D: promoting prizes over patents; directing innovation toward socially beneficial outputs by adopting some form of value-based pricing; publicly funding clinical trials to reduce conflicts of interest while reducing costs; and actively managing frontier technologies to maximize positive social spillovers.**

Journal of Generic Medicines (2010) **7**, 217–226. doi:10.1057/jgm.2010.21

- Separación el mercado de innovación del de producción
  - Se retribuye la innovación por si misma y se crea competencia en la producción
- Defendida por Joseph Stiglitz (Premio Nobel de Economía)
  - Creación de un fondo de premios multimillonarios (financiados por países ricos) para enfermedades que afecten a mucha gente.
  - El premio seria de acuerdo a la aportación terapeútica

COUNCIL OF
THE EUROPEAN UNION

EN

Council conclusions on the EU role in Global Health

3011th FOREIGN AFFAIRS Council meeting
Brussels, 10 May 2010

18. As regards to research and evidence based dialogue and action, the Council calls on the EU and its Member States to promote effective and fair financing of research that benefits the health of all. Towards that aim the EU will ensure that innovations and interventions produce products and services that are accessible and affordable. This should be achieved by the EU and its Member States through:

    a. working towards a global framework for research and development that addresses the priority health needs of developing countries and prioritises pertinent research actions to tackle global health challenges in accordance with the WHO Global Research Strategy.

    b. increasing research capacities in public health and health systems in partner countries and strengthening cooperation between the EU and partner countries in this respect.

    c. exploring models that dissociate the cost of Research and Development and the prices of medicines in relation to the Global Strategy and Plan of Action on Public Health, innovation and intellectual property, including the opportunities for EU technology transfer to developing countries.

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Algunas conclusiones

- **No existe una única política** de regulación de precios **"perfecta"** para todos los países, sino un **conjunto de políticas** que deben utilizarse de modo **combinado** según las características de cada país.
- Evaluación de Tecnologías Sanitarias y Precios de Referencia Internacionales son ampliamente utilizados y se recomienda su uso de acuerdo a la **evidencia** existente
- Existen otros **instrumentos "alternativos"** que puede ser utilizados para intentar un mejor control de los medicamentos de alto costo

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Muchas gracias por vuestra atención!!!!

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