

*¿Eficiencia o recortes? Incorporación de la evaluación económica
en el posicionamiento terapéutico*

Precio del medicamento basado en el valor

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Palma de Mallorca, 6 de mayo de 2016



DECLARACIÓN DE CONFLICTO DE INTERESES



¿Soy yo el único que aprecia aquí un claro conflicto de intereses?

- DECLARO CONFLICTO DE INTERESES CON EL SISTEMA PÚBLICO DE SALUD.
- DECLARO CONFLICTO DE INTERESES CON LOS PACIENTES.
- DECLARO CONFLICTO DE INTERESES CON EL GRUPO GENESIS-SEFH.



Hoja de ruta

- Valor y costes: ¿en qué basamos el precio?
- Estudios de coste-efectividad
- Valores umbral por AVAC





VALOR Y PRECIO











0,5 €



1.850.000 €



124.000 €



**Antonio Stradivari.
Violín "Duque de Alcántara"
(1732)**

"El precio es lo que pagas. El valor es lo que obtienes"

- Warren Buffett





***"Sólo el
necio
confunde
valor y
precio"***

Antonio Machado
—*AM*—



**¿CÓMO
FIJAR LOS
PRECIOS
DE LOS
MEDICAMENTOS?**

Opinion

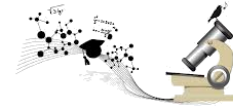
Dr. Fernando Lamata: "Es urgente definir métodos para evitar precios abusivos de medicamentos"

El sistema de fijación de precios de medicamentos "es un asunto de enorme importancia y su solución no puede esperar", según expone el Dr. Fernando Lamata en este artículo sobre la necesidad de establecer métodos adecuados para frenar precios abusivos de los fármacos



PRECIO BASADO EN LOS COSTES

(Cost-based pricing)



PRECIO BASADO EN EL VALOR

(Value-based pricing)

PRODUCTO



PRECIO



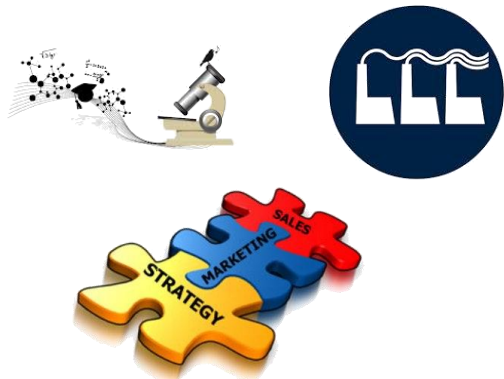
COSTE



VALOR



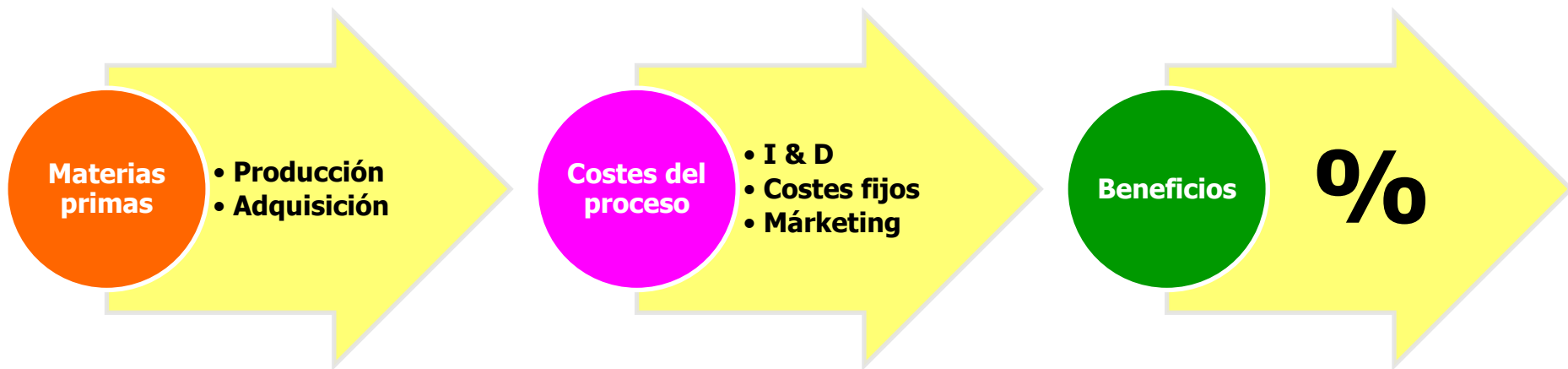
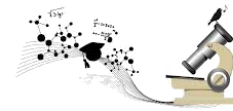
USUARIO



PRECIO BASADO EN LOS COSTES



PRECIO BASADO EN LOS COSTES





URGENTE

Alex Salmond dimite tras perder el referéndum de independencia de Escocia.

GALARDONES Ceremonia satírica en la Universidad de Harvard

La panceta que tapa hemorragias nasales, premio IgNobel 2014



Experimento ganador de un IgNobel por "tratar hemorragias nasales incontrolables, taponando la nariz con bacon".

[REUTERS

Noticias Relacionadas

Londres acogerá la 'catedral de las matemáticas' de Zaha Hadid

Boeing y Space X llevarán a los astronautas de la NASA a la Estación Espacial Internacional

La primera pirámide de la historia, en riesgo de colapso

Confirman la muerte de Ricardo III en el campo de batalla

La Expedición Malaspina empieza a arrojar luz sobre los océanos

Los blogs

Blogosaurio

Renacimiento tras el apocalipsis

LUIS ALCALÁ

19/09/2014

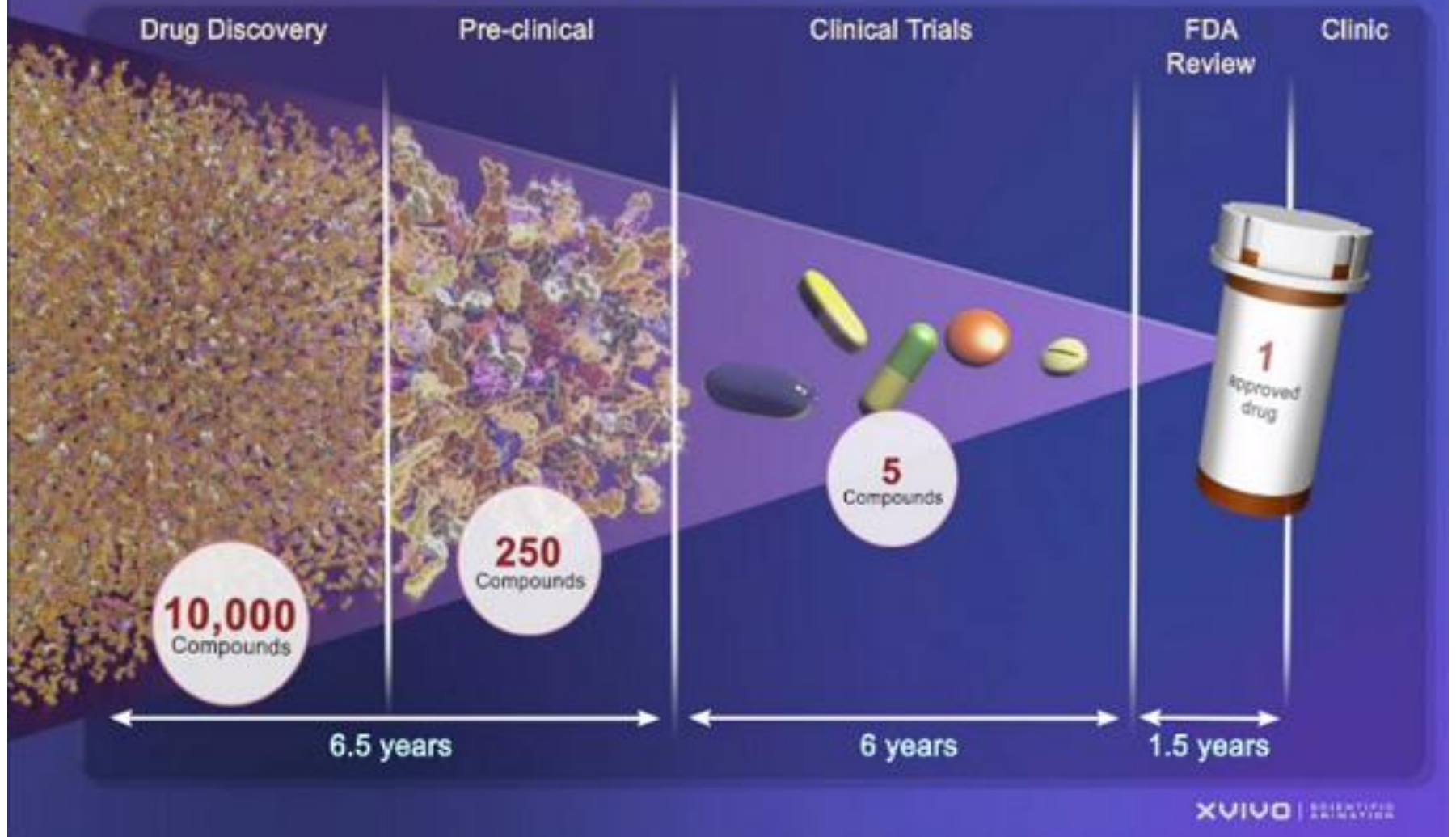
Clima

El clima, los disgustos y los elixires de la felicidad.

ANTONIO RUIZ DE ELVIRA

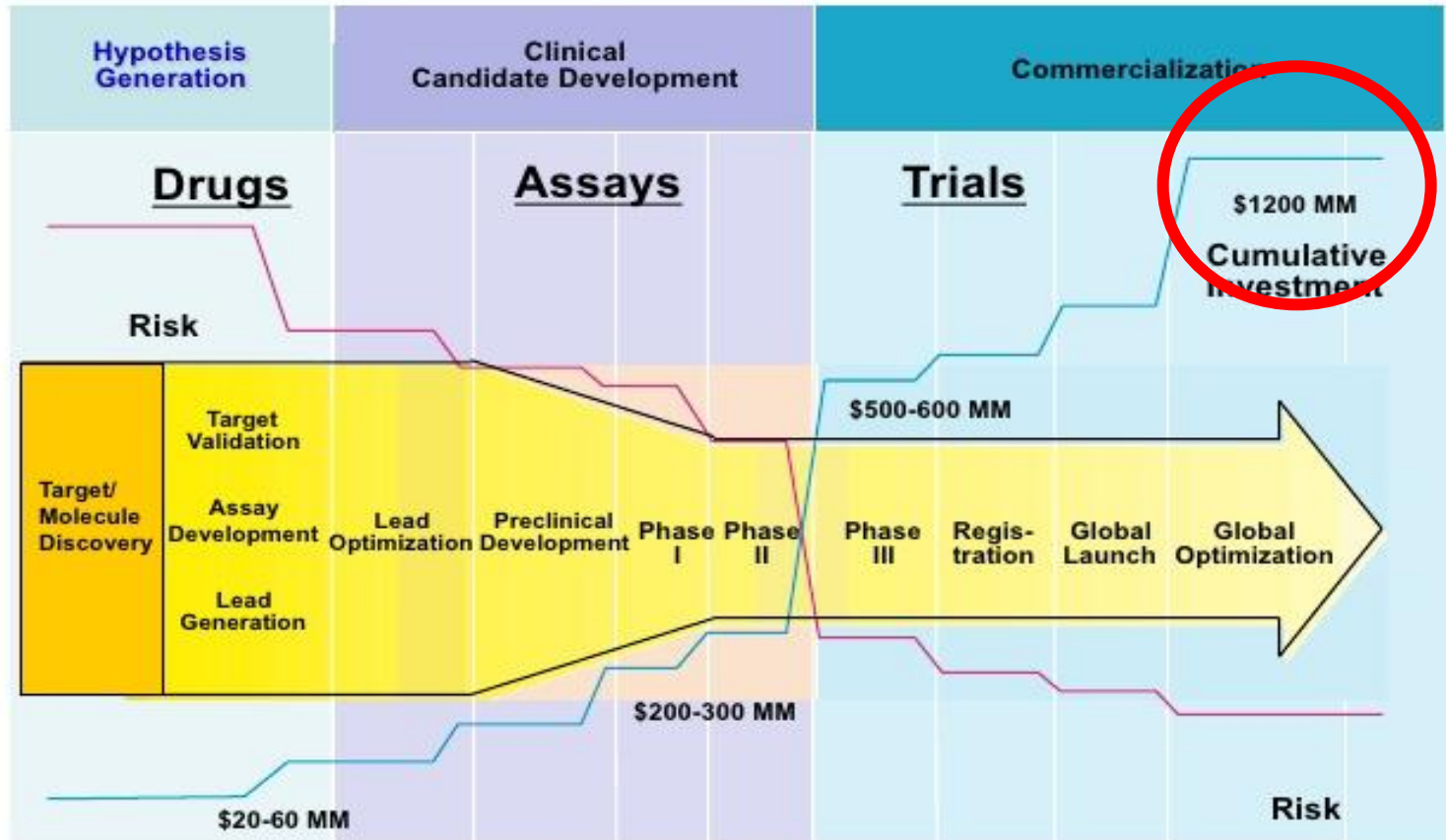
19/09/2014

Therapeutic Development Pipeline



<https://www.hemacare.com/blog/tag/drug-screening/>

Standard Drug Development Pipeline: Re-envisioned



GOAL:



HOW MUCH DOES BIG PHARMA SPEND ON: SALES & MARKETING vs. RESEARCH & DEVELOPMENT



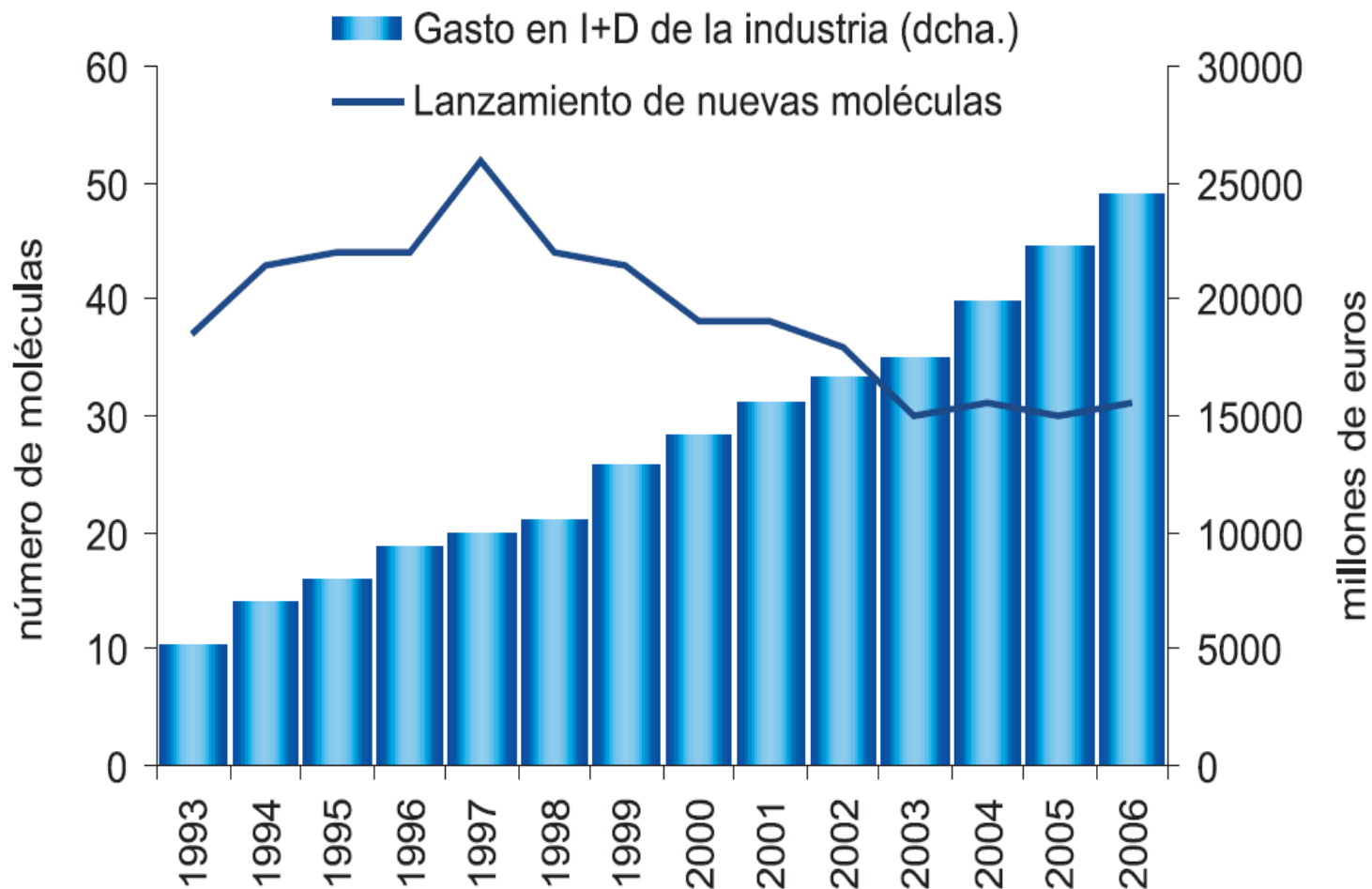
IN US \$ BILLION, FOR 2013

World's largest pharmaceutical firms

Company	Total revenue (\$bn)	R&D spend (\$bn)	Sales and marketing spend (\$bn)	Profit (\$bn)	Profit margin (%)
Johnson & Johnson (US)	71.3	8.2	17.5	13.8	19
Novartis (Swiss)	58.8	9.9	14.6	9.2	16
Pfizer (US)	51.6	6.6	11.4	22.0	43
Hoffmann-La Roche (Swiss)	50.3	9.3	9.0	12.0	24
Sanofi (France)	44.4	6.3	9.1	8.5	11
Merck (US)	44.0	7.5	9.5	4.4	10
GSK (UK)	41.4	5.3	9.9	8.5	21
Astra Zeneca (UK)	25.7	4.3	7.3	2.6	10
Eli Lilly (US)	23.1	5.5	5.7	4.7	20
AbbVie (US)	18.8	2.9	4.3	4.1	22

Source: GlobalData

Gráfico 1.1. Esfuerzo innovador de la industria farmacéutica europea



Fuente: Eurostat, OCDE



Los laboratorios innovadores han perdido un 30% de su venta en farmacias

Evolución top 10 laboratorios de marca en 2014
En millones de euros

	2014	% CRECIMIENTO 2010-2014
Pfizer	863	↓ -39,6
Novartis	677	↓ -35,3
Sanofi	631	↓ -29,5
Glaxosmithkline	608	↓ -28,6
Merk & Co	575	↓ -35,9
Johnson & Johnson	484	↓ -26,0
Astrazeneca	472	↓ -35,1
Boehringer Ingel	466	↓ -14,3
Esteve	448	↓ -24,8
Almirall	365	↓ -41,5

Evolución top 10 laboratorios de genéricos en 2014
En millones de euros

	2014	% CRECIMIENTO 2010-2014
Cinfa	510	↑ 54,9
Teva	438	↑ 31,7
Stada	257	↑ 68,3
Normon	239	↑ 61,8
Grupo Indukern	191	↑ 53,0
Novartis	176	↑ 40,3
Mylan	121	↑ 9,5
Krka	108	-
Aurobindo	94	↑ 2.140,2
Alter	78	↑ 76,6

Fuente: IMS Health

elEconomista



El recorte en medicamentos y su efecto en la llegada de innovaciones

Datos sobre recetas facturadas al SNS, 2008-2013

AÑO	PAGADO POR EL SNS (MILL. €)	VAR. ANUAL (%)	NÚMERO DE RECETAS (EN MILLONES)	VAR. ANUAL (%)	GASTO MEDIO POR RECETA (EN EUROS)	VAR. ANUAL (%)
2003	8.962,11	↑ 12,10	706,7	↑ 6,90	14,08	↑ 5,30
2004	9.515,35	↑ 6,42	728,68	↑ 3,17	13,06	↑ 3,15
2005	10.051,33	↑ 5,63	764,63	↑ 4,93	13,15	↑ 0,67
2006	10.636,00	↑ 5,82	769	↑ 4,10	13,36	↑ 1,65
2007	11.191,10	↑ 5,20	843,36	↑ 5,90	13,27	↓ -0,69
2008	12.033,99	↑ 7,20	890,67	↑ 5,60	13,45	↑ 1,36
2009	12.636,78	↑ 5,00	936,26	↑ 5,10	13,39	↓ -0,45
2010	12.207,68	↓ -2,30	957,69	↑ 2,50	12,75	↓ -4,80
2011	11.135,40	↓ -8,78	973,21	↑ 1,60	11,44	↓ -10,24
2012	9.769,94	↓ -12,26	913,69	↓ -6,12	10,69	↓ -6,55
Mayo 2013	9.124,33	↓ -15,89	859,23	↓ -11,96	10,62	↓ -4,45

Solicitudes de autorización de nuevos medicamentos recibidas desde 2008

SOLICITUDES	2008	2009	2010	2011	2012
Medicamentos Genéricos (EFG)	1.423	1.214	1.629	1.393	1.169
Medicamentos Publicitarios (EFP)	43	42	22	0	0
Nuevos medicamentos	599	360	315	319	391
TOTAL	2.065	1.616	1.966	1.712	1.560

Resultados de las evaluaciones: Incluye el Procedimiento Nacional (PN) y los Procedimientos Europeos (RM + PD + PC)

RESOLUCIONES	2008	2009	2010	2011	2012
Autorizadas	940	1.165	1.393	1.934	1.829
Denegadas	76	64	78	22	47
Desistidas	161	197	156	230	187
TOTAL	1.177	1.426	1.627	2.186	2.063

EL MITO DE LOS MIL MILLONES DE DÓLARES

(o así)



EL MITO DE LOS MIL MILLONES DE DÓLARES

- Consideró **solo los nuevos medicamentos**, no los *me too*.
- Se trató de "**coste capitalizado**", es decir, incluye los beneficios estimados que se hubieran generado si el dinero gastado en I+D se hubiera invertido en bolsa.
- Se trató de dinero **antes de pagar impuestos**... pero los costes de I+D son **deducibles** en proporción variableiii



Angell M. The truth about the drug companies. Random House (NY), 2004





Innovation &

VALUE



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THE INNOVATIVE MEDICINES INITIATIVE

The Innovative Medicines Initiative (IMI) is Europe's largest public-private initiative aiming to speed up the development of better and safer medicines for patients.

IMI supports collaborative research projects and builds networks of industrial and academic experts in order to boost pharmaceutical innovation in Europe.

IMI is a joint undertaking between the European Union and the pharmaceutical industry association EFPIA.



IMI NEWSFLASH



29/04/2016 : RT @MikeKSmith: End of the last @DDMoRe_IMI consortium meeting. It's been a great experience. Lots of good work done. Check out <https://t.c...>

29/04/2016 : RT @EU_H2020: Researchers and innovators from #Georgia to have full access to #H2020 <https://t.co/9OFQa0nnBu> #opentotheworld <https://t.co/q...>

29/04/2016 : Reading tip: On the path to a science of patient input @KimTweetsDC @MargaretAinDC @FasterCures <https://t.co/6dNQ7p9Qpc> #patientsinvolved

Follow us on Twitter

IMI 2 - CALL 9 LAUNCHED

IMI has launched **IMI 2 - Call 9**, featuring topics on **antimicrobial resistance, rheumatic disease, data quality, medicines safety, liver disease, and flu vaccines.**

Read the [press release](#)

Sign up to the IMI 2 - Call 9 [webinars](#)



FORO POR UNA ATENCIÓN
ONCOLÓGICA DE CALIDAD
EL VALOR DE LA INNOVACIÓN

eco

Fundación para la Excelencia
y la Calidad de la Oncología

EL VALOR DE LA INNOVACIÓN Y NECESIDADES EN ONCOLOGÍA

Calidad de vida de los pacientes oncológicos
y atención a largos supervivientes



SEOM

Sociedad Española
de Oncología Médica

Con la colaboración de:





DOS AÑOS PARA ACCEDER A LA INNOVACIÓN ONCOLÓGICA

La sanidad española no está todavía preparada para priorizar ni rebajar los 24 meses que deben esperar los pacientes para disponer de las 40 nuevas moléculas e indicaciones contra el cáncer que se lanzarán al mercado en los próximos dos años, a juicio de los expertos



Amenazas para el futuro

En los próximos años, nuestro sistema sanitario afrontará diversas amenazas que le voy a leer a continuación. Para cada una de ellas, ¿siente que la amenaza es muy importante, algo importante, no muy importante o nada importante?

	AL	FR	IT	RU	SE	POL	AT	CZ	ES	EE.UU.
Amenaza muy importante (%)										
Falta de fondos públicos	50%	53%	85%	78%	61%	69%	50%	56%	75%	54%
Incremento de costes directos para las personas	55%	48%	54%	52%	43%	69%	51%	51%	73%	66%
Incremento de precios de los procedimientos médicos	53%	50%	66%	53%	42%	66%	43%	52%	73%	66%
Desigualdad en el acceso a la sanidad	53%	54%	68%	68%	71%	71%	49%	40%	66%	63%
Lista de espera para recibir un tratamiento	40%	45%	75%	70%	65%	88%	42%	41%	76%	58%
Escasez de médicos de cabecera	42%	58%	50%	68%	65%	56%	39%	34%	73%	63%
Riesgos de coger una infección en el hospital	67%	41%	64%	83%	65%	65%	41%	28%	80%	70%
Errores médicos	52%	40%	78%	79%	70%	65%	47%	37%	75%	71%



CHAM 2011 – Septiembre 2011

http://rochepacientes.es/cancer/wp-content/uploads/2015/01/informe_foro_eco.pdf

¿Ha percibido Vd. en el último año, que...?



INESME 2012

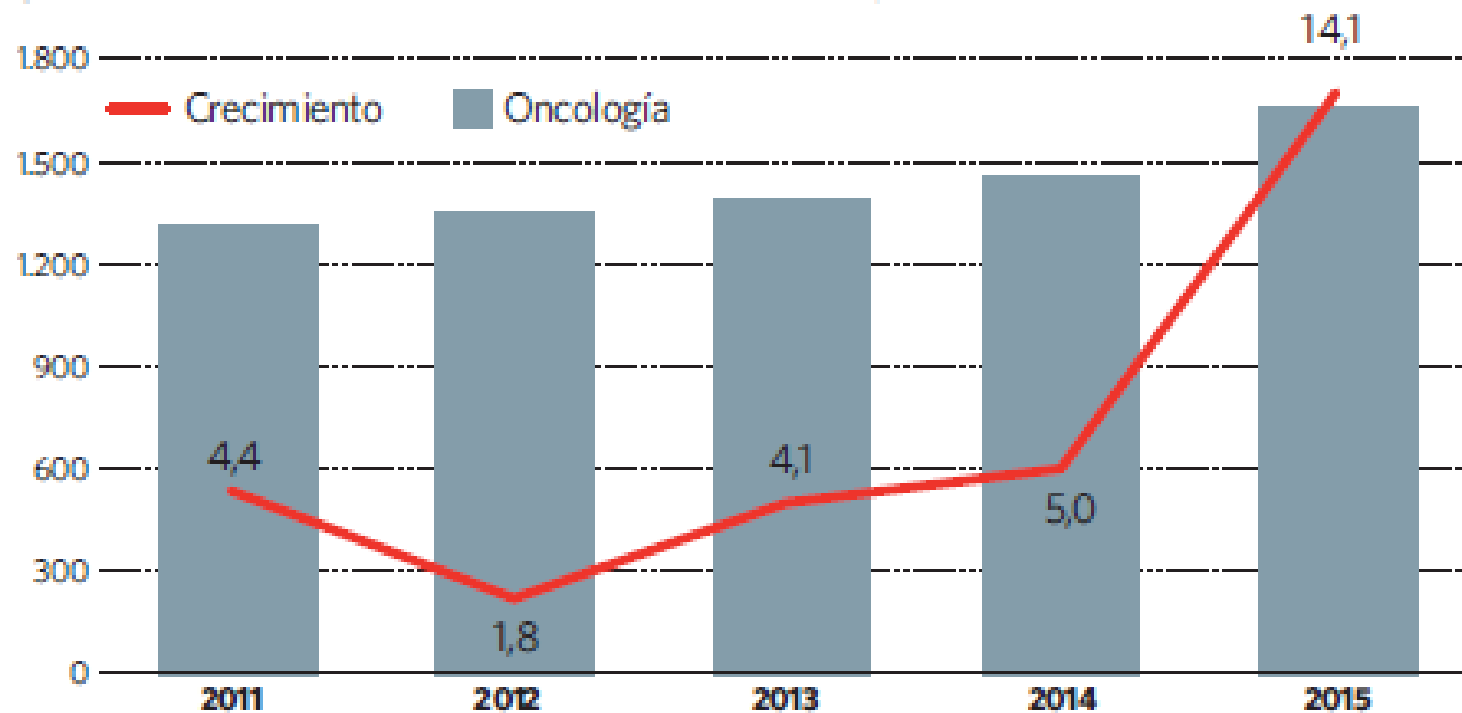
INSTITUTO DE ESTUDIOS MÉDICO CIENTÍFICOS

http://rochepacientes.es/cancer/wp-content/uploads/2015/01/informe_foro_eco.pdf

Acceso a la innovación farmacéutica

Mercado de Oncología en Hospitales

(incremento del consumo en millones de euros a PVL)



elEconomista

Revista mensual

7 de abril de 2016 | Nº 61



Table. Frequency and Characteristics of Cancer Drugs Described With Superlatives

Drug	Superlative Frequency, No. (%) ^a (N = 97)	Superlative(s) Used (Frequency)	Drug Classification	FDA-Approved Drug(s)	Clinical Data?
Ipilimumab and nivolumab (Yervoy-Opdivo combination)	20 (21)	Breakthrough (7), miracle (5), game changer (5), revolutionary (2), groundbreaking (1)	Immunotherapy-checkpoint inhibitor	Yes	Yes
Pembrolizumab (Keytruda)	12 (12)	Revolutionary (5), game changer (2), breakthrough (2), miracle (1)	Immunotherapy-checkpoint inhibitor	Yes	Yes
Palbociclib (Ibrance)	10 (10)	Game changer (5), revolutionary (2), breakthrough (1), miracle (1)	Targeted therapy	Yes	Yes
Trastuzumab emtansine (Kadcyla)	7 (7)	Revolutionary (2), breakthrough (1), game changer (1), miracle (1)	Targeted therapy	Yes	Yes
Dinutuximab (Unituxin)	4 (4)	Game changer (2), breakthrough (1), miracle (1)	Targeted therapy	Yes	Yes
MPDL3280A	3 (3)	Game changer (2), revolutionary (1)	Immunotherapy-checkpoint inhibitor	No	Yes
Olaparib (Lynparza)	3 (3)	Revolutionary (2), breakthrough (1)	Targeted therapy	Yes	Yes
T-VEC	3 (3)	Breakthrough (3)	Immunotherapy-vaccine	No	Yes
Pertuzumab (Perjeta)	3 (3)	Groundbreaking (3)	Targeted therapy	Yes	Yes
Unnamed	3 (3)	Breakthrough (1), miracle (1), game changer (1)
Radium-223 dichloride (Alpharadin or Xofigo)	2 (2)	Game changer (2)	Radiotherapeutic drug	Yes	Yes
BPM31510	2 (2)	Revolutionary (2)	Cytotoxic therapy	No	Yes

A variety of speakers were credited with using the superlative (53 journalists [55%], 26 physicians [27%], 9 industry experts [9%], 8 patients [8%], and 1 member of US Congress [1%]). In the majority of cases (55%) the superlative was used by the author of the article without any other attribution.

Abola MV et al. JAMA Oncol 2016; 2(1):139-41. doi: 10.1001/jamaoncol.2015.3931.

¿Qué es innovación?



- **Concepto comercial**



Producto comercializado recientemente .

- **Concepto tecnológico**



Innovaciones en el proceso de síntesis (biotecnología, isómeros), en la formulación galénica (nuevos sistemas de liberación).

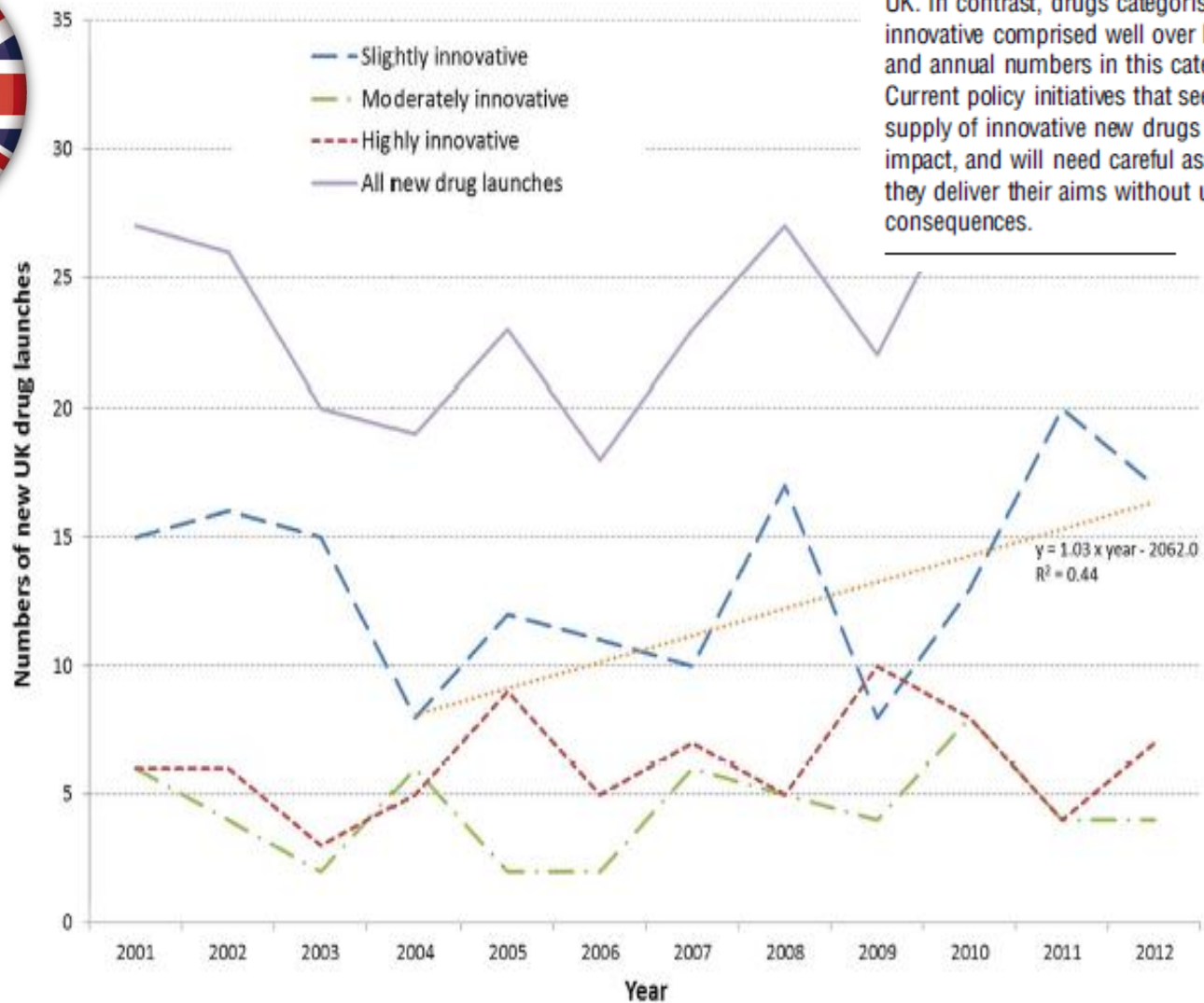
- **Concepto terapéutico**



Superioridad en resultados en salud sobre las mejores alternativas disponibles anteriormente.

Can Fam Physician 2002; 48: 1413-5





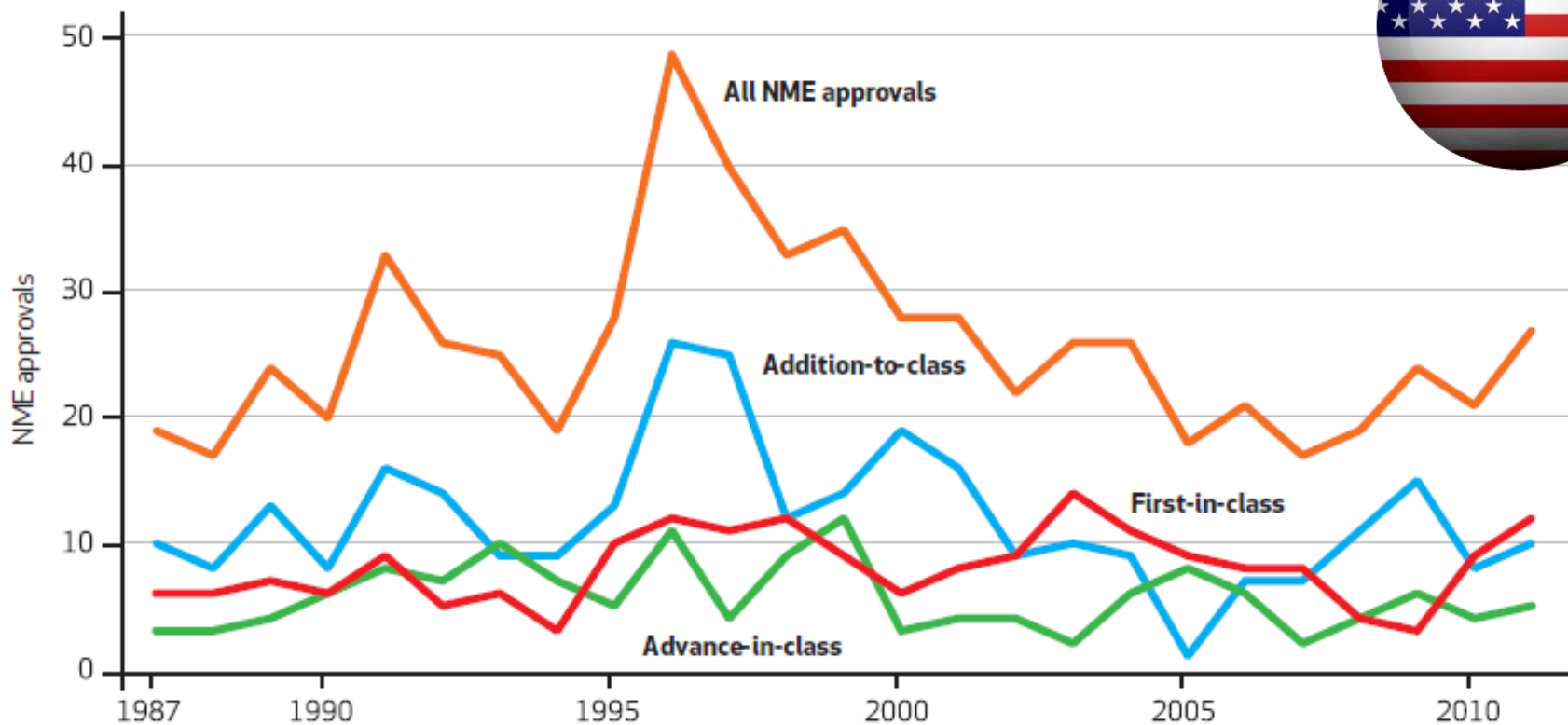
Conclusions: Highly innovative new drugs comprise only around a quarter of all new drug launches in the UK. In contrast, drugs categorised as only slightly innovative comprised well over half of all new drugs and annual numbers in this category are increasing. Current policy initiatives that seek to increase the supply of innovative new drugs have long-lead times to impact, and will need careful assessment to ensure they deliver their aims without unintended consequences.

Ward DJ, et al. BMJ Open 2014;4:e006235. doi:10.1136/bmjopen-2014-006235





New Molecular Entity (NME) Approvals, By Innovation Category, 1987-2011



SOURCE Food and Drug Administration drug-approval data. **NOTE** Innovation categories are defined in the text.

Lanther M et al. Health Aff. 2013;32:1433-9.



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- **SIEMPRE SON UNA BUENA NOTICIA**
- **SURGEN DE MANERA CONTINUA, INDEFECTIBLEMENTE**
- **INCLUSO BAJO UNA CONSIDERACIÓN ESTRICTA, MEJORAN LO PREVIO.**
- **SON CARAS. DEBEN PAGAR LOS ÉXITOS Y LOS FRACASOS.**
- **SON UNA PREOCUPACION PARA EL PAGADOR, MÁS EN SITUACION DE CRISIS**
- **REQUIEREN NUEVOS MODELOS DE ACCESO Y FINANCIACIÓN.**
- **SUPONDRÁN CAMBIOS EN LA COMERCIALIZACIÓN TRADICIONAL.**
- **SI QUEREMOS TENERLAS, DEBEMOS ENTENDERNOS**

y ENCONTRAR EL EQUILIBRIO



Key Summary Points

Less-expensive, lower-quality innovations are ubiquitous in other economic sectors but have not been described in health care.

Despite yielding lower health benefits than an alternative, decrementally cost-effective innovations would yield sufficient cost savings to make them attractive.

In theory, decrementally cost-effective innovations offer an opportunity to improve the efficiency of health resource allocation, because the resources saved can be applied to higher-value medical interventions.

Systematic review of the cost-effectiveness literature published in English from 2002 to 2007 revealed that only 0.4% of cost-utility analyses described innovations that might be considered decrementally cost-effective.

Decrementally cost-effective innovations are rarely described yet potentially useful instruments for maximizing health benefits while minimizing costs.

Much Cheaper, Almost as Good: Decrementally Cost-Effective Medical Innovation

Aaron L. Nelson, MD, PhD; Joshua T. Cohen, PhD; Dan Greenberg, PhD; and David M. Kent, MD, MS

Nelson AL et al. Ann Intern Med. 2009;151:662-7.

Innovations Identified

Intervention	Comparator	QALY Loss	Savings, \$	CER, \$*		
Percutaneous coronary intervention	Coronary artery bypass graft	0.0015	4944	3 210 306		
Repetitive transcranial magnetic stimulation	Electroconvulsive treatment	0.0212	11 672	550 562		
Use of sterilized hemodialyzer	Typical single-use dialyzer	0.0040	1009	252 366		
Watchful waiting	Tension-free surgical repair	0.0140	2721	194 331		
Self, manual-assisted cognitive behavioral therapy	Usual care (problem solving, psychotherapy)	0.0118	1476	125 065		
Group physiotherapy intervention	Usual physiotherapy management	0.0010	122	122 278		
Romagnuolo et al, 2002 (32)	Reflux esophagitis	Laparoscopic Nissen fundoplication	Medical treatment with omeprazole	0.0150	1638	109 172
Esnaola et al, 2002 (18)	Non-small-cell lung adenocarcinoma	Selective mediastinoscopy	Routine mediastinoscopy	0.0203	2067	101 836

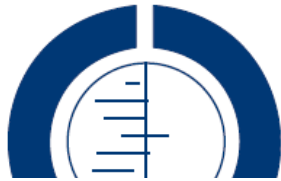
CER = cost-effectiveness ratio; QALY = quality-adjusted life-year.

* The CER is the savings per QALY lost.



New treatments compared to established treatments in randomized trials (Review)

Djulbegovic B, Kumar A, Glasziou PP, Perera R, Reljic T, Dent L, Raftery J, Johansen M, Di Tanna GL, Miladinovic B, Soares HP, Vist GE, Chalmers I



Authors' conclusions

Society can expect that slightly more than half of new experimental treatments will prove to be better than established treatments when tested in RCTs, but few will be substantially better. This is an important finding for patients (as they contemplate participation in RCTs), researchers (as they plan design of the new trials), and funders (as they assess the 'return on investment'). Although we provide the current best evidence on the question of expected 'success rate' of new versus established treatments consistent with a priori theoretical predictions reflective of 'uncertainty or equipoise hypothesis', it should be noted that our sample represents less than 1% of all available randomized trials; therefore, one should exercise the appropriate caution in interpretation of our findings. In addition, our conclusion applies to publicly funded trials only, as we did not include studies funded by commercial sponsors in our analysis.

This is a reprint of
2012, Issue 10



New treatments compared to established treatments in randomized trials (Review)
Copyright © 2012 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Djulbegovic B et al. Cochrane Database of Systematic Reviews 2012, Issue 10. Art. No.: MR000024. DOI: 10.1002/14651858.MR000024.pub3.



Faster Drug Approvals Are Not Always Better and Can Be Worse

Rita F. Redberg, MD, MSc

A shared goal of all health professionals is to relieve suffering and prolong life. At times these goals are at odds, particularly in oncology care. Patients with severe disease and low chance



Related article

of survival may be offered therapies in the hope of buying a few more weeks or even months. However, the treatments themselves are often toxic, with many unpleasant adverse effects—nausea, pain, vomiting, hair loss, and others—that detract from quality of life and result in patients spending more time in the hospital and clinic and less time at home. It is a difficult choice: extend life, or offer higher quality of life at home.

Or is it? This choice assumes that the drugs really do extend life. The analysis by Prasad et al¹ shows that many oncology drugs have never been shown to increase survival, meaning that patients suffer reduced quality of life but do not necessarily gain extra time. In the effort to get more new drugs on the market more quickly, many agents are approved on the basis of surrogate end points, such as progression-free survival. Unfortunately, these surrogate end points do not necessarily translate into any mortality benefits, in which case patients experience the toxic effects but do not get any extra time.

Even when the US Food and Drug Administration takes the dramatic (and rare) step of withdrawing approval (as it should)

when a drug approved based on surrogate markers later turns out to not offer any mortality benefit, as was the case for bevacizumab (Avastin; Genentech/Roche) for metastatic breast cancer, women continue to be treated with this harmful drug although we know it will not extend life.

The 21st Century Cures legislation² now being considered by Congress would make this situation much worse by allowing accelerated approval of new drugs based on preliminary results of clinical trials on surrogate markers. It even has a clause that stipulates that a drug on a restricted hospital or industry formulary list is actually approved for the indication and can be prescribed for that purpose. In fact, it introduces 2 more categories of fast drug approvals. However, in 2014 over 60% of approved drugs were already approved using expedited review or orphan drug status, which also has reduced evidence standards for safety and effectiveness.³ We must reduce drug approvals based on unreliable surrogates and change practice when clinical studies show no survival benefit. If there are no drugs available that can extend life with tolerable adverse effect, we must extend warmth and compassion and support in a continued therapeutic relationship without further chemotherapy. In our rush to find new effective treatments, we should not harm our patients with ineffective toxic ones.

Redberg RF. JAMA Intern Med 2015 Aug;175(8):1398. doi: 10.1001/jamainternmed.2015.2857.





***“Un medicamento no es un coche:
más moderno no es mejor, más caro
no es mejor, más rápido no es mejor”***

**“Conoce lo
último, pero usa
lo penúltimo”**

**Gregorio Marañón
(1887-1960)**



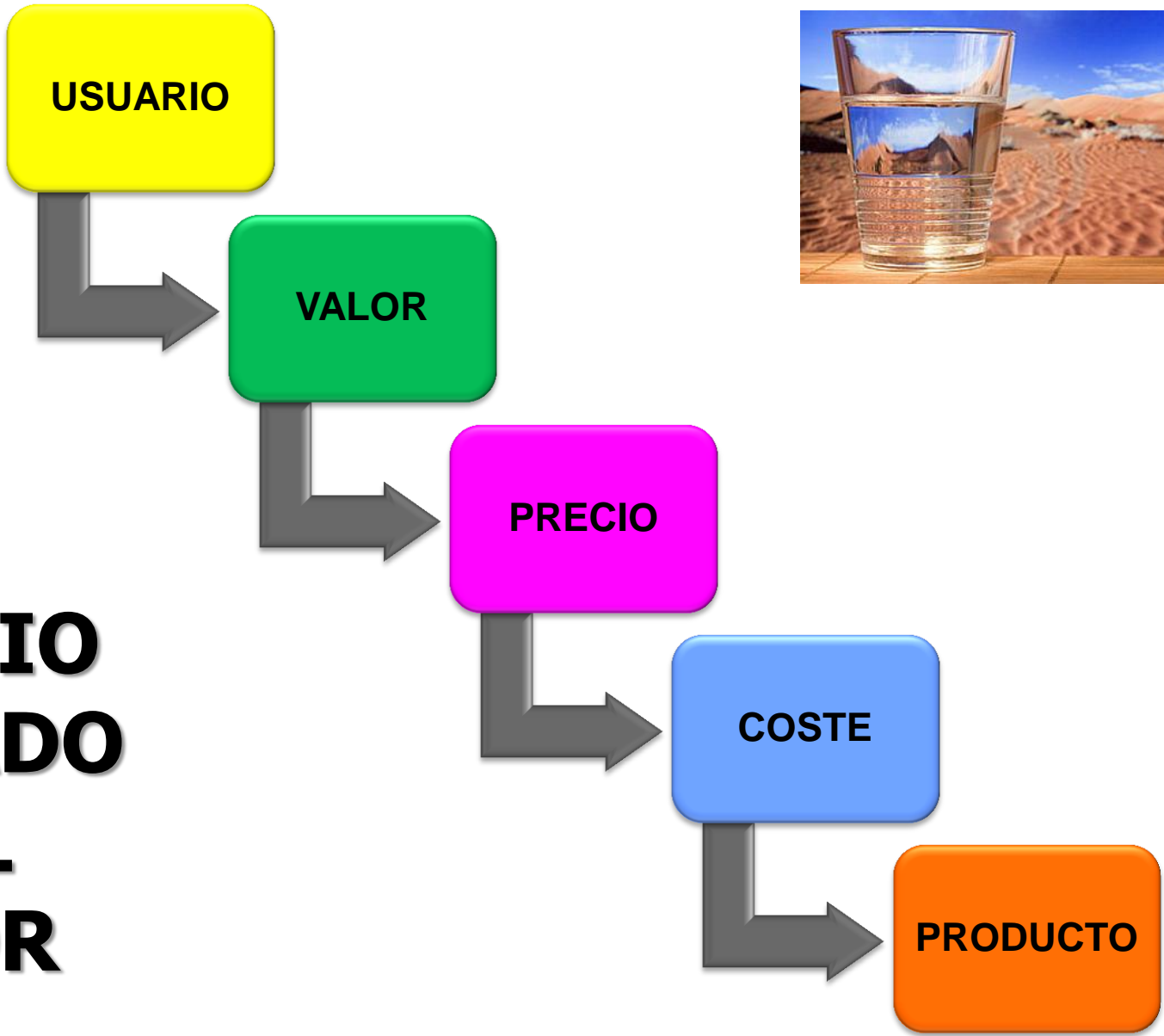
Asignación de precios a los nuevos medicamentos de acuerdo con en el valor que ofrecen a la sociedad

Husereau D, Cameron C (2011). *Value-Based Pricing of Pharmaceuticals in Canada: Opportunities to Expand the Role of Health Technology Assessment? Paper 5*. Canadian Health Services Research Foundation.



PRECIO BASADO EN EL VALOR

(Value-based pricing)



PRECIO BASADO EN EL VALOR



¿Qué “*valor*” pueden ofrecer los medicamentos a la sociedad?





AÑOS DE VIDA GANADOS

(AVG, *LYG*)



AÑOS DE VIDA AJUSTADOS POR CALIDAD

(AVAC, *QALY*)



A standardised, generic, validated approach to stratify the magnitude of clinical benefit that can be anticipated from anti-cancer therapies: the European Society for Medical Oncology Magnitude of Clinical Benefit Scale (ESMO-MCBS)

N. I. Cherny^{1*}, R. Sullivan², U. Dafni³, J. M. Kerst⁴, A. Sobrero⁵, C. Zielinski⁶, E. G. E. de Vries⁷ & M. J. Piccart^{8,9}

Table 1. Potential benefits of a new treatment

Living longer

Improved OS

Improved surrogate of OS

DFS (when OS data are immature in adjuvant setting)

Improved PFS

Living better

Improved quality of life

Improved surrogate of quality of life

Improved PFS

Reduced toxicity



QUE NO ES
QUE NO ESTÉ,
ES QUE NO
QUIERO ABRIR



¿NECESITAMOS UN UMBRAL COSTE-EFECTIVIDAD?

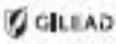
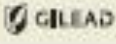

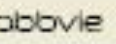



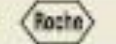







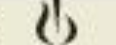






Fixed Budget & Opportunity Cost

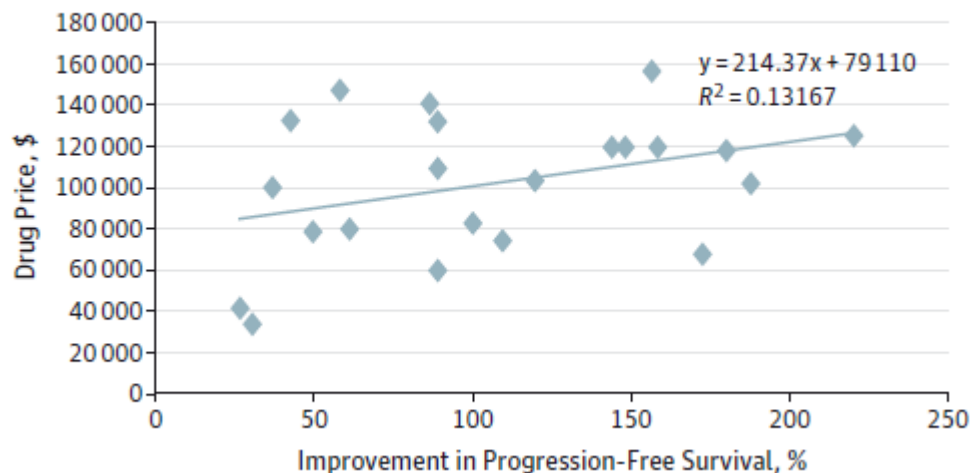


Los 20 medicamentos con mayor facturación en España en 2015

Datos en euros. Total: 3.933.653.920

RANKING	FÁRMACO	COMPAÑÍA	INDICACIÓN	EURMAY/11/2015
1	Harvoni	 Gilead	Hepatitis C	604.840.000
2	Sovaldi	 Gilead	Hepatitis C	569.003.968
3	Humira	 Abbvie	Artritis reumatoide	315.966.752
4	Viekirax	 Abbvie	Hepatitis C	270.465.504
5	Olysio	 Janssen	Hepatitis C	217.525.568
6	Enbrel	 Pfizer	Artritis reumatoide	169.568.912
7	Remicade	 MSD	Artritis psoriásica	162.802.272
8	Avastin	 Roche	Cáncer de mama	155.967.904
9	Herceptin	 Roche	Cáncer de mama	153.628.992
10	Atripla	 Gilead	VIH	150.098.256
11	Daklinza	 Bristol-Myers Squibb	Hepatitis C	146.549.136
12	Mabthera	 Roche	Linfoma no-Hodgkin	132.191.128
13	Truvada	 Gilead	VIH	129.039.808
14	Revlimid	 Celgene	Mieloma múltiple	122.903.472
15	Prezista	 Janssen	VIH	122.304.808
16	Glivec	 Novartis	Leucemia mieloide crónica	119.325.320
17	Xolair	 Novartis	Asma	103.369.648
18	Alimta	 Lilly	Cáncer de pulmón	99.513.120
19	Kivexa	 GSK	VIH	97.575.560
20	Gilenya	 Novartis	Esclerosis múltiple	91.013.792

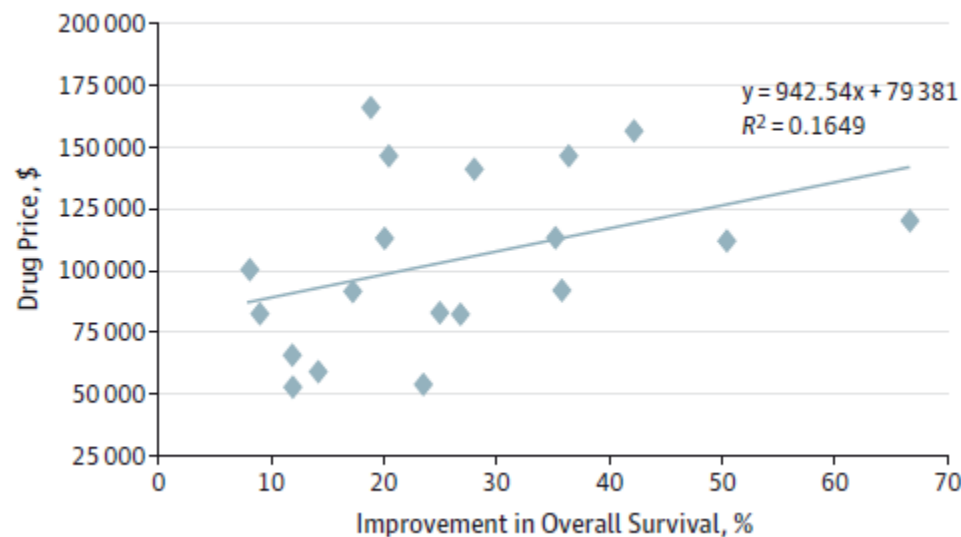
A Progression-free survival



PFS

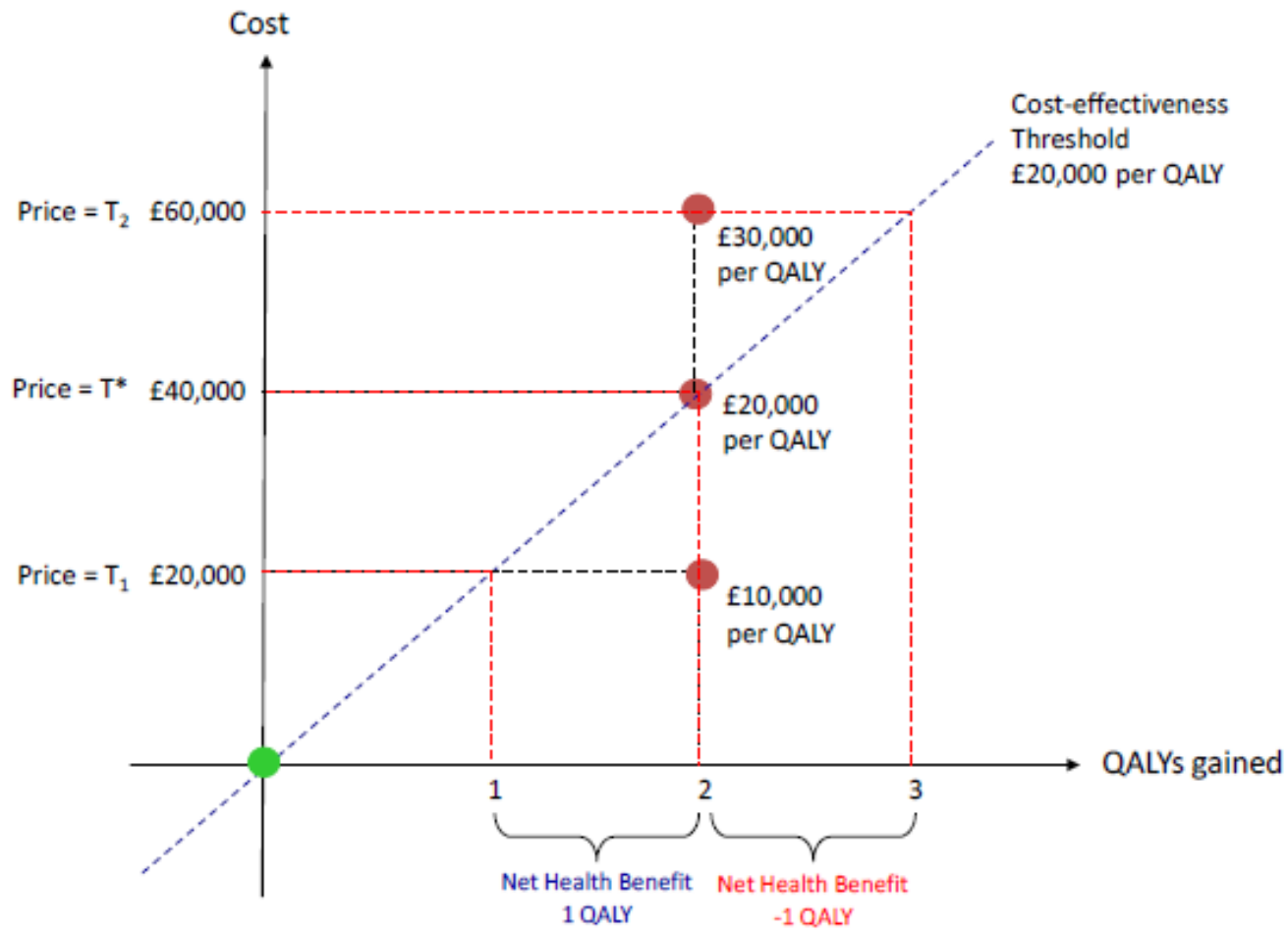
OS

B Overall survival



Mailankody S et al.
JAMA Oncol JAMA Oncol. 2015;1(4):539-40





https://www.york.ac.uk/media/che/documents/papers/researchpapers/CHERP60_value_based_pricing_for_pharmaceuticals.pdf



¿CÓMO DETERMINAR EL UMBRAL COSTE-EFECTIVIDAD?



PERSPECTIVA DE LA OFERTA

Valor que la sociedad otorga a un AVAC (preferencias = disponibilidad a pagar)

PERSPECTIVA DE LA DEMANDA

Coste que supone generar un AVAC para el sistema de salud (EV, CVRS)





















PIB en dólares en PPA (miles de millones) y porcentaje sobre el total mundial (2014, FMI)

País	PIB USD	Peso	País	PIB USD	Peso
1 EEUU	17.528	19,2%	26 Pakistán	602	0,7%
2 China	14.625	16,1%	27 Egipto	575	0,6%
3 India	5.425	6,0%	28 Malasia	561	0,6%
4 Japón	4.835	5,3%	29 Colombia	560	0,6%
5 Alemania	3.338	3,7%	30 Nigeria	521	0,6%
6 Rusia	2.630	2,9%	31 Filipinas	493	0,5%
7 Brasil	2.505	2,8%	32 Bélgica	435	0,5%
8 Reino Unido	2.497	2,7%	33 Suecia	414	0,5%
9 Francia	2.337	2,6%	34 Venezuela	412	0,5%
10 México	1.927	2,1%	35 Hong Kong	402	0,4%
11 Italia	1.847	2,0%	36 Vietnam	386	0,4%
12 Corea	1.755	1,9%	37 Suiza	385	0,4%
13 Canadá	1.585	1,7%	38 Austria	373	0,4%
14 España	1.425	1,6%	39 Perú	369	0,4%
15 Indonesia	1.383	1,5%	40 Singapur	367	0,4%
16 Turquía	1.219	1,3%	41 Chile	352	0,4%
17 Australia	1.041	1,1%	42 Bangladesh	350	0,4%
18 Arabia Saudí	990	1,1%	43 Argelia	302	0,3%
19 Irán	974	1,1%	44 Rumanía	296	0,3%
20 Taiwán	973	1,1%	45 República Checa	296	0,3%
21 Polonia	856	0,9%	46 Noruega	289	0,3%
22 Argentina	794	0,9%	47 Emiratos Árabes	288	0,3%
23 Holanda	717	0,8%	48 Israel	287	0,3%
24 Tailandia	701	0,8%	49 Iraq	276	0,3%
25 Sudáfrica	620	0,7%	50 Grecia	271	0,3%

TABLA RANKING PAÍSES SEGÚN PIB PER CÁPITA

PIB PER CÁPITA

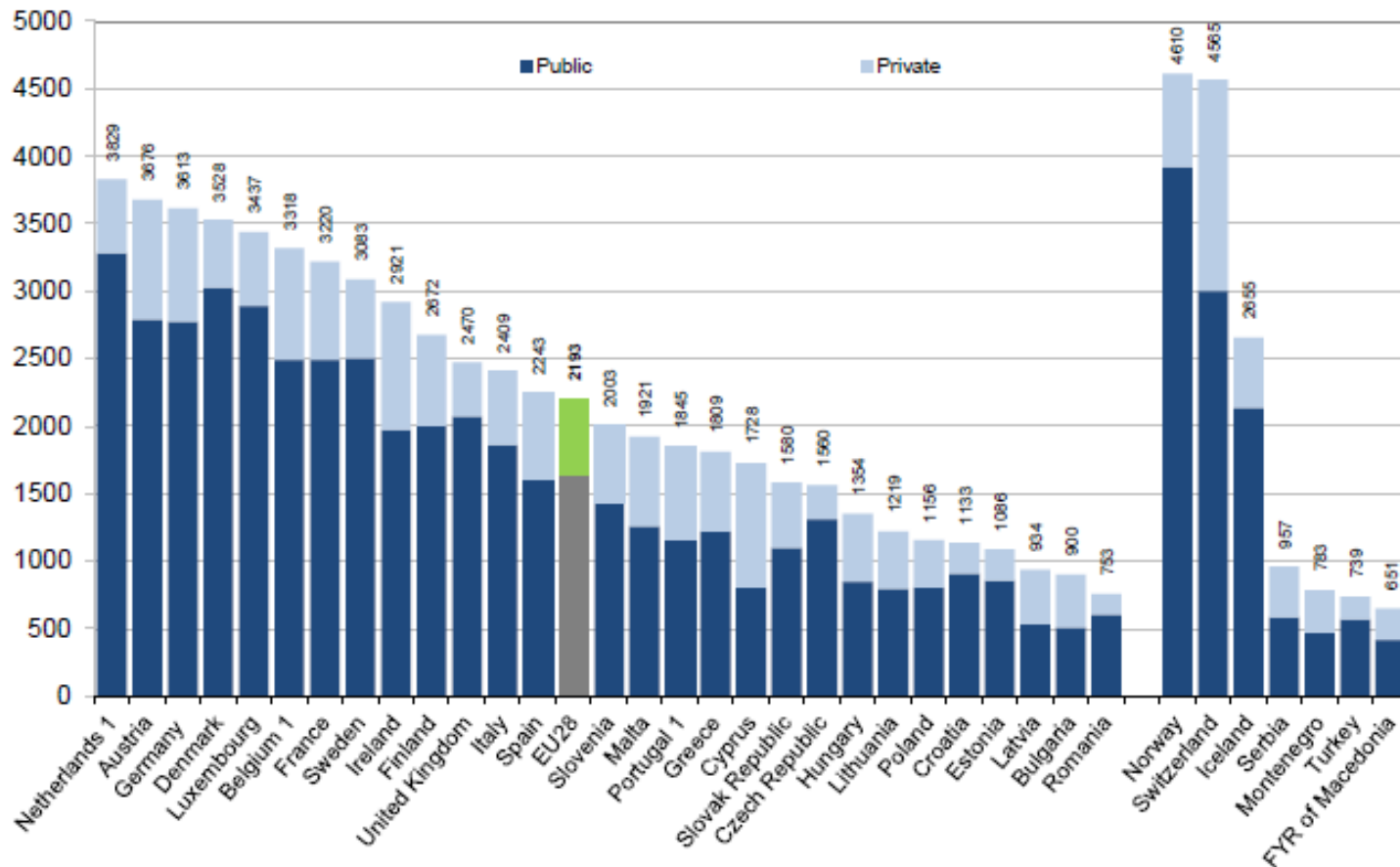
Orden	País	Indicador	Valor actual	Fecha
1	 Luxemburgo	PIB Per Cápita	91.889,971 €	2015
2	 Suiza	PIB Per Cápita	72.683,148 €	2015
3	 Qatar	PIB Per Cápita	68.990,013 €	2015
4	 Noruega	PIB Per Cápita	67.409,798 €	2015
5	 Estados Unidos	PIB Per Cápita	50.276,819 €	2015
6	 Singapur	PIB Per Cápita	47.648,403 €	2015
7	 Dinamarca	PIB Per Cápita	46.951,436 €	2015
8	 Irlanda	PIB Per Cápita	46.263,644 €	2015
9	 Australia	PIB Per Cápita	45.913,289 €	2015
10	 Islandia	PIB Per Cápita	45.816,635 €	2015
11	 Suecia	PIB Per Cápita	44.926,227 €	2015
12	 San Marino	PIB Per Cápita	44.908,776 €	2015
13	 Reino Unido	PIB Per Cápita	39.434,512 €	2015
14	 Austria	PIB Per Cápita	39.392,477 €	2015
15	 Países Bajos	PIB Per Cápita	39.283,540 €	2015
16	 Canadá	PIB Per Cápita	39.039,248 €	2015



31

(23.302 €)

GASTO SANITARIO PER CAPITA (2012)

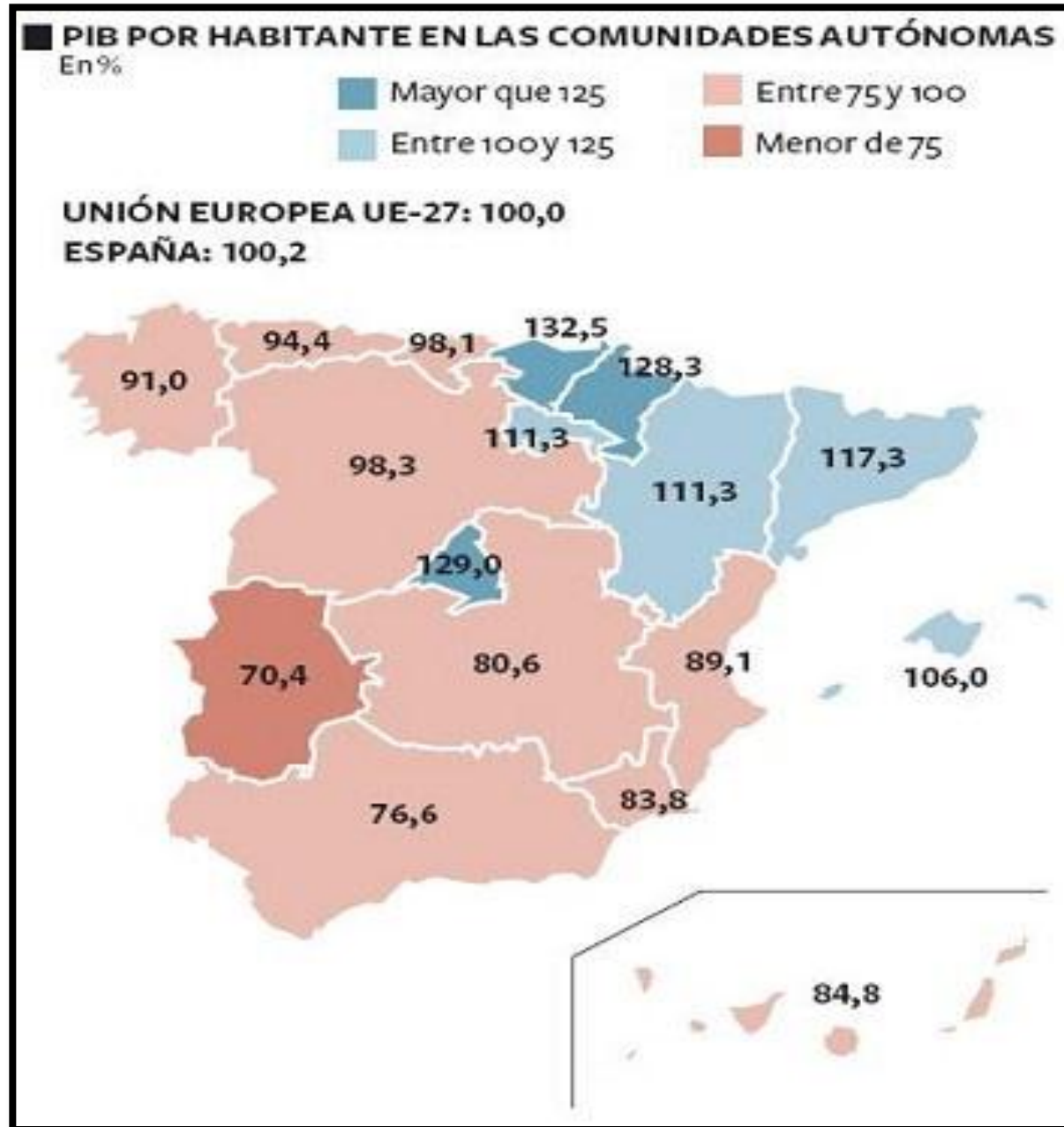


OCDE 2014. <http://dx.doi.org/10.1787/888933155816>











¿CUÁNTO ESTAMOS DISPUESTOS A PAGAR POR UN AVAC?





20.000-30.000£/AVAC

National Institute for Health and Clinical Excellence (2008a). Guide to the Methods of Technology Appraisal. London, United Kingdom.

50.000 – 100.000 \$/AVAC

Basado en el estándar: coste anual de diálisis supuesto para los pacientes con insuficiencia renal crónica. Desde 1982 (ino ajustes por inflación!)

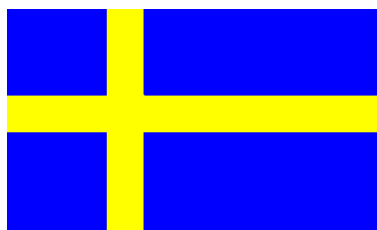


20.000-100.000 \$ CAN/AVAC

Laupacis A et al. CMAJ. 1992;146(4):473-81.

20.000 - 80.000 €/AVAC

Boersma C et al. Value Health. 2010; 13(6):853-6



500.000 SEK/AVAC

Hultkranz L, Svensson M. Orebro University. Swedish Business School. Working Papers 5/2012



23.981-35.836 €/AVAC

National Institute for Health and Clinical Excellence (2008a). Guide to the Methods of Technology Appraisal. London, United Kingdom.

35.928 – 71.857 €/AVAC

Basado en el estándar: coste anual de diálisis supuesto para los pacientes con insuficiencia renal crónica. Desde 1982 (ino ajustes por inflación!)

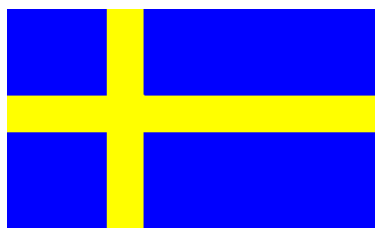


12.861-64.307 €/AVAC

Laupacis A et al. CMAJ. 1992;146(4):473-81.

20.000 - 80.000 €/AVAC

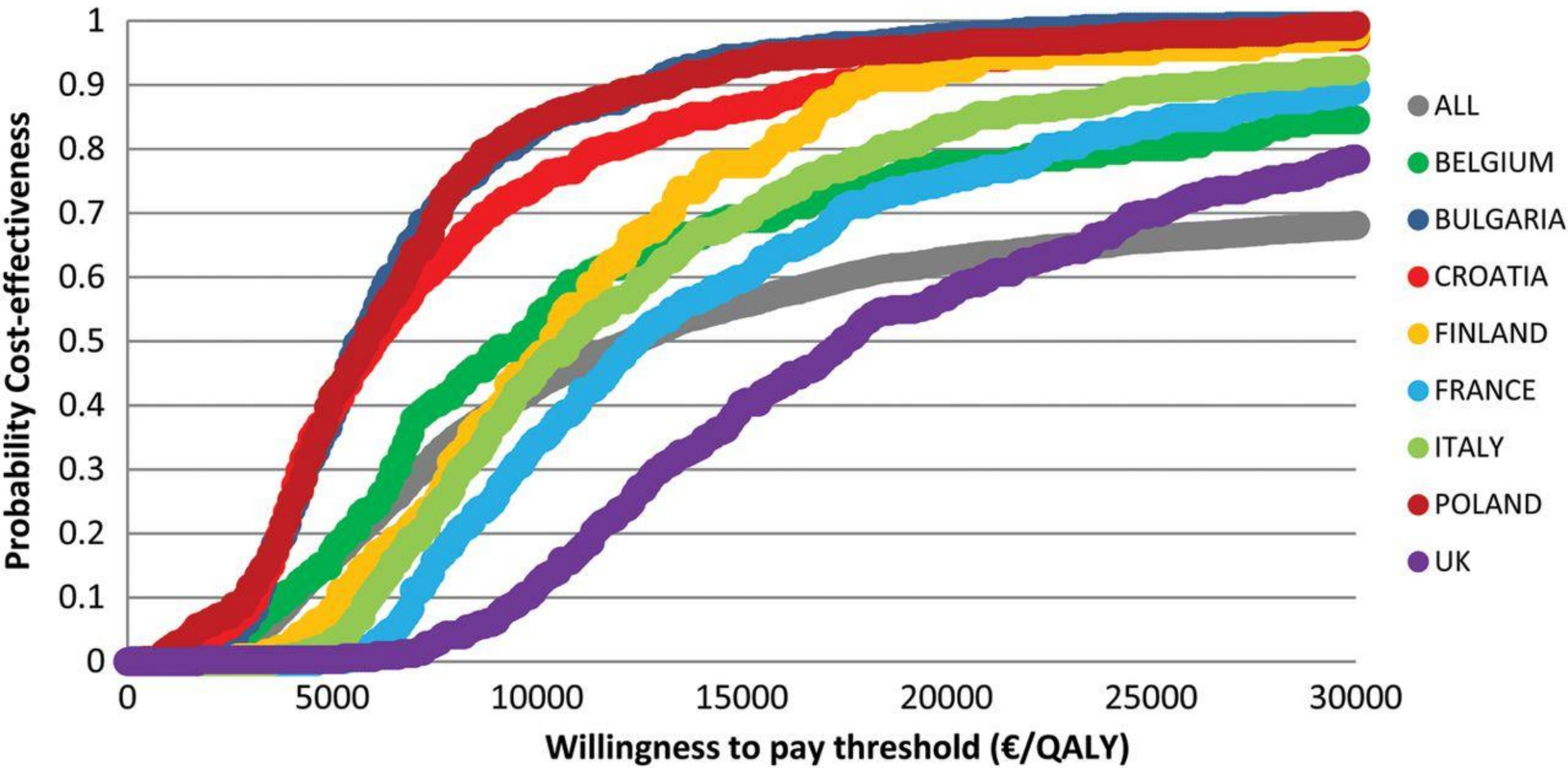
Boersma C et al. Value Health. 2010; 13(6):853-6



56.576 €/AVAC

Hultkranz L, Svensson M. Orebro University. Swedish Business School. Working Papers 5/2012

Cost-effectiveness acceptability curve



De Smedt D et al. Eur Heart J 2012; 33, 2865–72



Table 3 Country-specific cost of diseases

	Belgium (€)	Bulgaria (€)	Croatia (€)	Finland (€)	France (€)	Italy (€)	Poland (€)	UK (€)
CHD (acute cost)	6178 ⁵²	2108	4000	6400	4337	6200 ^{53,54}	2077 ⁵³	1599 ⁵⁵
CHD (first 6 months after the event)	2660 ⁵²	442	3000	3215	1850	4200 ^{53,54}	501 ⁵³	1333 ⁵⁶
CHD (second and further 6 months after acute event)	1197 ⁵²	442	1250	708	1850	1800 ^{53,54}	430 ⁵³	1333 ⁵⁶
Stroke (acute cost)	7366 ⁵²	1423	2500	6500	5029	3926 ⁵⁷	1365 ⁵³	2830 ⁵⁵
Stroke (first 6 months after the event)	3712 ⁵²	220	4530	8610	4821	2500 ⁵⁷	4164 ⁵³	1263 ⁵⁶
Stroke (second and further 6 months after acute event)	2591 ⁵²	256	4150	2000	4821	1500 ⁵⁷	1014 ⁵³	1263 ⁵⁶
Congestive heart failure	1444 ⁵⁸	189	1856	4000	1021	2948 ⁵⁷	1859 ⁵³	1618 ⁵⁵

Bulgaria: 2010 contract between Ministry of Health and National Health Fund.

Croatia: Croatian National Health Insurance Institute data.

Finland: KELA-Social insurance institute of Finland.

France: hospital data and reimbursement data.

De Smedt D et al. Eur Heart J 2012; 33, 2865–72

CIRCUNSTANCIAS EXCEPCIONALES

(“Regla del rescate”)

- **Enfermedades con una “carga” elevada:** necesidades sanitarias no cubiertas o enfermedades particularmente graves (EoL, *End of Life*, NICE 2008)
- Medicamentos que pueden **demostrar una gran innovación terapéutica** e importantes mejoras sobre los productos existentes
- Medicamentos que pueden **demostrar amplios beneficios sociales**



CIRCUNSTANCIAS EXCEPCIONALES (EoL)

- **Enfermedades con esperanza de vida menor de 24 meses.**
- **Mejora en la supervivencia de al menos 3 meses (comparado con tratamiento habitual.)**
- **Pequeño número de casos.**

<https://www.nice.org.uk/guidance/gid-tag387/resources/appraising-life-extending-end-of-life-treatments-paper2>





**¿Y LOS
MEDICAMENTOS
CON INDICACIONES
HUÉRFANAS?**



**El Gobierno de Aragón
no les da a nuestros
hijos el medicamento
que necesitan para
frenar su enfermedad**

ATALUREN TREATMENT OF PATIENTS WITH NONSENSE MUTATION DYSTROPHINOPATHY

KATHARINE BUSHBY, MD,^{1*} RICHARD FINKEL, MD,^{2*} BRENDA WONG, MD,³ RICHARD BAROHN, MD,⁴ CRAIG CAMPBELL, MD,⁵ GIACOMO P. COMI, MD,⁶ ANNE M. CONNOLLY, MD,⁷ JOHN W. DAY, MD, PhD,⁸ KEVIN M. FLANIGAN, MD,⁹ NATHALIE GOEMANS, MD,¹⁰ KRISTI J. JONES, MD, PhD,¹¹ EUGENIO MERCURI, MD,¹² ROS QUINLIVAN, MD,¹³ JAMES B. RENFROE, MD,¹⁴ BARRY RUSSMAN, MD,¹⁵ MONIQUE M. RYAN, MD BS,¹⁶ MAR TULINIUS, MD, PhD,¹⁷ THOMAS VOIT, MD,¹⁸ STEVEN A. MOORE, MD, PhD,¹⁹ H. LEE SWEENEY, PhD,²⁰ RICHARD T. ABRESCH, MS,²¹ KIM L. COLEMAN, MS,²² MICHELLE EAGLE, PhD,¹ JULAINE FLORENCE, PhD,⁷ EDUARD GAPPMAIER, PhD,²³ ALLAN M. GLANZMAN, DPT,² ERIK HENRICSON, MPH,²¹ JAY BARTH, MD,²⁴ GARY L. ELFRING, MS,²⁴ ALLEN REHA, MS,²⁴ ROBERT J. SPIEGEL, MD,²⁴ MICHAEL W. O'DONNELL, MS,²⁴ STUART W. PELTZ, PhD,²⁴ and CRAIG M. MCDONALD, MD,²¹ FOR THE PTC124-GD-007-DMD STUDY GROUP**

ABSTRACT: *Introduction:* Dystrophinopathy is a rare, severe muscle disorder, and nonsense mutations are found in 13% of cases. Ataluren was developed to enable ribosomal readthrough of premature stop codons in nonsense mutation (nm) genetic disorders. *Methods:* Randomized, double-blind, placebo-controlled study; males ≥ 5 years with nm-dystrophinopathy received study drug orally 3 times daily, ataluren 10, 10, 20 mg/kg ($N=57$); ataluren 20, 20, 40 mg/kg ($N=60$); or placebo ($N=57$) for 48 weeks. **The primary endpoint was change in 6-Minute Walk Distance (6MWD) at Week 48.** *Results:* Ataluren was generally well tolerated. **The primary endpoint favored ataluren 10, 10, 20 mg/kg versus placebo; the week 48 6MWD $\Delta = 31.3$ meters, *post hoc* $P=0.056$.** Secondary endpoints (timed function tests) showed meaningful differences between ataluren 10, 10, 20 mg/kg, and placebo. *Conclusions:* As the first investigational new drug targeting the underlying cause of nm-dystrophinopathy, ataluren offers promise as a treatment for this orphan genetic disorder with high unmet medical need.

Muscle Nerve 50: 477–487, 2014

425.000 €/año



Orphan drug pricing may warrant a competition law investigation

EU legislation offers an exclusive marketing period as an incentive for companies to develop drugs for rare diseases. But pricing for orphan drugs hinders access and may warrant a competition law investigation, say **Jonathan C P Roos**, **Hanna I Hyry**, and **Timothy M Cox**

BMJ | 20 NOVEMBER 2010 | VOLUME 341

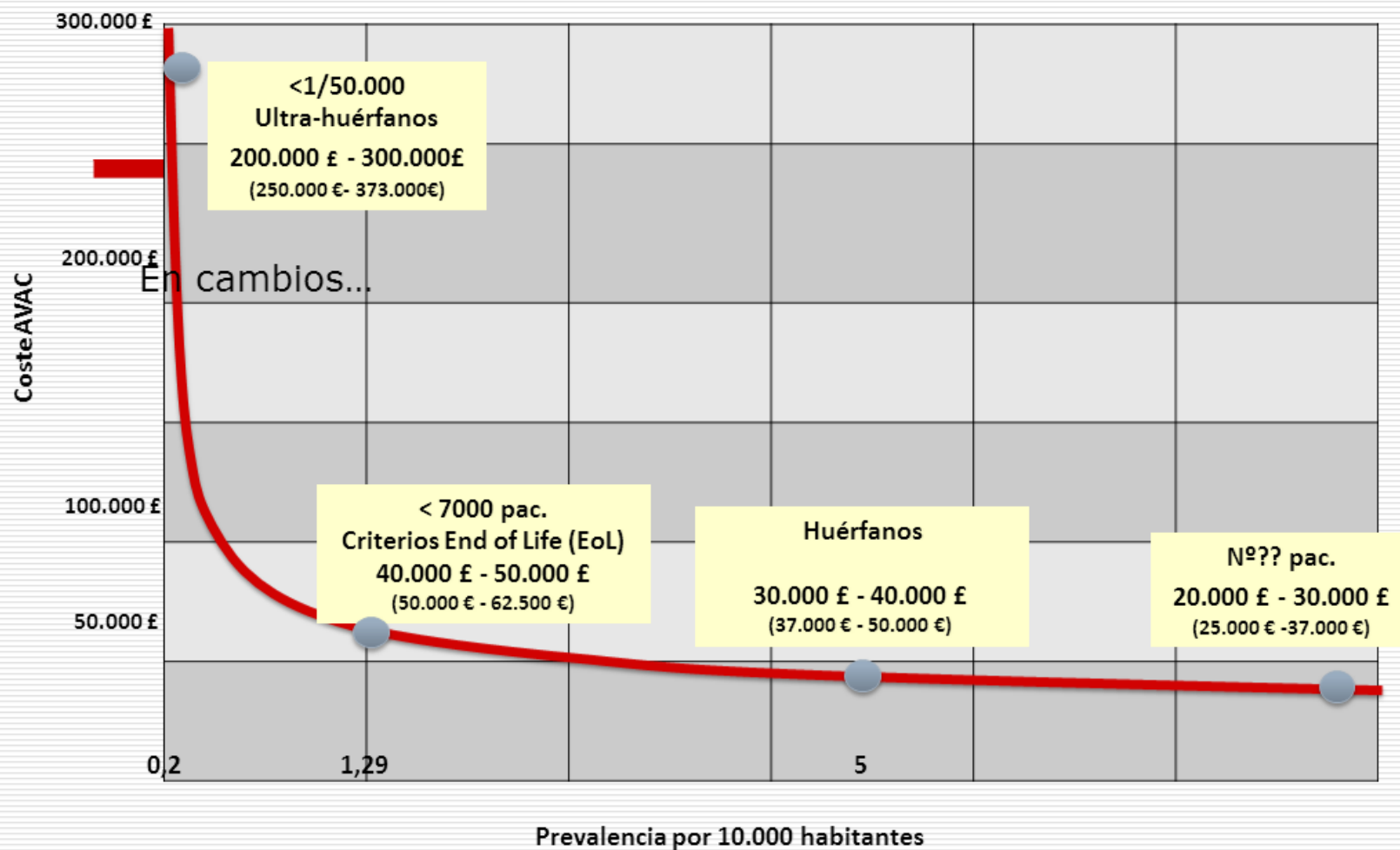


Table 4 | Price setting for orphan drugs compared with non-orphan drugs

Drug price determinant in the orphan drug context
Prevalence (the less prevalent a condition the more it costs to treat per capita)	Orphan drug pricing correlates to some extent with disease prevalence. ⁵ However, the relation is not linear and exceptions exist. For example, arsenic trioxide is priced similarly to bosentan even though acute promyelocytic leukaemia and primary pulmonary hypertension differ almost tenfold in prevalence. ⁵ Indeed, the price of drugs for diseases with similar prevalence can vary by up to a factor of seven ⁵
Production costs	Companies do not typically disclose production costs but they do not appear to feature strongly in orphan price setting. Changes in production methods have apparently not led to an analogous reduction in consumer price, despite substantial savings in costs and a likely substantial rise in profit margins ⁴⁰
Molecular complexity	Complexity of the compound does not seem to readily correlate with orphan prices. ⁵ Arsenic trioxide (consisting only of three oxygen and two arsenic atoms and in regular production since the 18th century) ⁴¹ was re-priced as an orphan agent at \$50 000 for one year's therapy (currently approximately £13 000 in the UK). ⁴² Sapropterin, a simple orphan molecule with a molecular weight of 314.17 Da (C ₉ H ₁₅ N ₅ O ₃ -2HCl), which can be used to treat phenylketonuria, retails at around £102 000 per year. This is similar to the price charged for enzyme replacement therapy for Gaucher disease, even though the latter's structures are much more complicated, with molecular weights in tens of kilodaltons, and with pH sensitive three dimensional structures, as well as the need for post-translational modification of glycans for targeting to lysosomal compartments. Moreover, monoclonal antibodies, probably of equal molecular and manufacturing complexity, can retail at less than £10 000 (adalimumab) or over £230 000 (eculizumab)
Need to recover investment	That orphan drug companies very readily recoup their investments at the current high price levels is suggested by the large influx of mainstream pharmaceutical companies into this niche area through, for example, a hostile takeover bid. ⁴³⁻⁴⁵ Recovery of investment seems to be facilitated by the relatively low development costs: it has been suggested that by 1992 a biotech company's annual profits on the original enzyme replacement therapy for Gaucher disease exceeded \$200m compared with the cost of developing the drug, which a federal study estimated to have been less than \$30m ^{46,47}
Perceived medical benefit	Therapeutic benefit does not seem to play a part in pricing. Efficacy frequently remains under investigation as a condition of marketing authorisation for rare disorders. As an example, highly effective enzyme replacement therapy for Gaucher disease is priced at a lower level than that for Fabry, even though the therapeutic benefit of the latter is less clear ^{48,49}



Valores umbrales en diferentes tipos de medicamento



Ref: Olga Delgado: Propuestas y estimaciones





**BIENVENIDO
A LA REPÚBLICA
INDEPENDIENTE
DE MI CASA**

RAPSODIA ESPAÑOLA



El que **consume**, **ni paga**
(parcialmente) **ni elige**.

El que elige (**prescriptor**), **no**
consume ni paga.

Y el que paga (SNS), **ni elige**
ni consume.

(Estes Kefauver 1903-1963)

¿Qué es una tecnología sanitaria eficiente en España?

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²Fundación Gaspar Casal, Madrid.
³Universidad Carlos III, Madrid.
⁴Universitat Pompeu Fabra, Barcelona.

Correspondencia: José Antonio Sacristán, Dept. de Investigación Clínica, Lilly S.A. Avda. de la Industria, 30, 28111 Cerro de Lepe, Sevilla.
 Correo electrónico: sacristan_jasa@lilly.com

Recibido: 12
 Aceptado:

(What is an efficient health technology in Spain?)

Resumen

Introducción: A pesar del creciente reconocimiento de la potencial utilidad de los estudios de coste-efectividad, en España no existe ningún criterio que permita establecer si una determinada tecnología sanitaria puede considerarse rentable o no. El objetivo de este trabajo es describir cuáles han sido los límites y criterios utilizados en España para recomendar la adopción o el rechazo de intervenciones sanitarias en función de su coste-efectividad.

Método: Se realizó una revisión de las evaluaciones económicas de intervenciones sanitarias publicadas en España desde 1990 hasta 2007. Se seleccionaron las evaluaciones económicas completas en las que el cociente coste-efectividad se había expresado como coste por año de vida ganado (AVG), como coste por año de vida ajustado por calidad (AVAC) o como coste por vida salvada. Se analizaron las intervenciones sobre las que los autores establecieron algún tipo de recomendación (de adopción o rechazo), así como los criterios utilizados.

Resultados: Veinte (20%) de las 100 evaluaciones económicas completas publicadas cumplen con los criterios señalados. En 16 de los estudios, los resultados se expresaron como coste por AVG, en 6 como coste por AVAC y en 1 como coste por vida salvada. Se evaluaron un total de 82 intervenciones sanitarias, en 44 de las cuales se realizó algún tipo de recomendación. Los autores recomendaron la adopción de todas las intervenciones sanitarias con un coste-efectividad inferior a 30.000 euros (5 millones de pesetas) por AVG. Por encima de esa cifra no se apreció ninguna tendencia.

Conclusiones: Si bien los resultados deben ser interpretados con mucha precaución, dadas las limitaciones del estudio, los límites de coste-efectividad presentados en este trabajo podrían constituir una primera referencia a la que podría considerarse como una intervención sanitaria eficiente en España.

Palabras clave: Eficiencia, Coste-efectividad, Evaluación, Tecnología sanitaria.

Abstract

Introduction: Despite the growing recognition of the potential utility of cost-effectiveness assessments, what is an efficient health technology in Spain. The objective of this work is to describe what health interventions in Spain to recommend the adoption or the rejection of health interventions.

Method: A review of the economic technologies published in Spain from 1990 to 2007. Complete economic assessments were expressed as cost per quality-adjusted life-year (QALY), cost per quality-adjusted life-year saved (QALYs) were selected. These interventions have established recommendations (adoption or rejection) and the criteria used were analyzed.

Results: Twenty (20%) of the 100 technologies fulfilled the selection criteria. In 16 studies, the results were expressed as cost per LYQ, in 6 studies and in 1 as cost per saved life. A total of 82 technologies were assessed and some kind of recommendation was established in 44 of them. All technologies with a cost-effectiveness ratio lower than 30,000 euros per QALY were recommended for adoption and there was no clear trend. Above this figure, no clear trend was observed.

Conclusions: Although the results must be interpreted with much caution, given the limitations of the study, the limits of cost-effectiveness presented in this reference to which would be an efficient health intervention in Spain.

Key words: Efficiency, Cost-effectiveness technology.

Resultados: Veinte (20%) de las 100 evaluaciones económicas completas publicadas cumplieron con los criterios señalados. En 16 de los estudios, los resultados se expresaron como coste por AVG, en 6 como coste por AVAC y en 1 como coste por vida salvada. Se evaluaron un total de 82 intervenciones sanitarias, en 44 de las cuales se realizó algún tipo de recomendación. Los autores recomendaron la adopción de todas las intervenciones sanitarias con un coste-efectividad inferior a 30.000 euros (5 millones de pesetas) por AVG. Por encima de esa cifra no se apreció ninguna tendencia.

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Tabla 1. Estimaciones disponibles del umbral de coste-efectividad en España

Artículo	Valor en € de 2014	Perspectiva
Pinto-Prades 2005	~10.000 €-42.500 €	Valoración social
Pinto-Prades 2009	~4.500 €-125.000 €	Valoración social
Donaldson 2011	~20.500 €-41.000 €	Valoración social
Martín-Fernández 2014	~13.000 €-31.000 €	Valoración social
Donaldson 2010	~96.000 €-186.000 €	Valoración social
Abellán-Perpiñán 2011	~54.000 €	Valoración social
Puig-Junoy, 2004	~11.000 €-15.000 €	Coste de oportunidad
Sacristán 2002*	~30.000 €	Revisión de Literatura
De Cock 2008*	~30.000 €-45.000 €	Revisión de Literatura

*No actualizados a € de 2014 al tratarse de una revisión

Vallejo-Torres L et al. MSSSI . Servicio de Evaluación del SCS . 2015. Informes de Evaluación de Tecnologías Sanitarias.



Valor Monetario de un Año de Vida Ajustado por Calidad: Estimación empírica del coste de oportunidad en el Sistema Nacional de Salud

Informes de Evaluación de Tecnologías Sanitarias
SESCS

INFORMES, ESTUDIOS E INVESTIGACIÓN



GOBIERNO DE ESPAÑA
MINISTERIO DE SANIDAD Y SERVICIOS SOCIALES Y POLÍTICAS TERRITORIALES



PRO ESPANOLA DE AGENCIA DE EVALUACION
E INNOVACION TECNOLÓGICA EN SALUD



Gobierno de Canarias



Estimamos que el **coste promedio por AVAC en el SNS se encuentra en torno a los 21.000 € y 24.000 €.** Estos valores ofrecen una aproximación en base a la mejor evidencia disponible, pero no deben considerarse como una cifra exacta.

GENERALITAT VALENCIANA

LaFe
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Innovación y experiencia al servicio del paciente

Introduction

Cost-effectiveness (CE) is increasingly used for resource allocation worldwide. One key hurdle for its widespread use is the lack of a widely accepted methodology to derive thresholds at the healthcare system (HS) or country level.

Objectives

To propose a methodology and derive local CE thresholds based on per capita health expenditures (pCHE) and life expectancy (LE) or Healthy Life Expectancy.

Methods I: Conceptual Framework

- Our approach was based on depicting how the ICER of new interventions affect the pace of increase of health expenditures while population life expectancy increases:

$$I = \frac{NOR_{t+1} - NOR_t}{(LE_{t+1} - LE_t)} \quad \text{EQUATION 1 (See Annex 1)}$$

I: ratio of increase in health expenditure per capita once a one-year increase in life expectancy is achieved (e.g. 1.1 for a 10% increase).
LE: life expectancy (in years).
NOR: net effectiveness ratio of the interventions expressed in units of overall per capita health expenditures (e.g. in US\$) of 85 interventions that the cost-effectiveness of the intervention is equal to 0.5 per capita health expenditure per life-year gained.

-Based on this relationship, if HS can establish the maximum increase in per capita health expenditure ("I_{max}") they are willing to accept to gain one year in population life expectancy, the cost-effectiveness threshold that new interventions should not exceed in order to keep health expenditures within the limits set by "I_{max}" can be estimated:

$$CET_{I_{max}} = I_{max} * (LE + 1) - LE \quad \text{EQUATION 2 (See Annex 1)}$$

CET_{I_{max}}: effectiveness threshold measured in units of per capita health expenditures (e.g. CET_{1.1} indicates that the cost-effectiveness threshold that the new interventions should not exceed is 1.1 health expenditures per capita per life-year gained).
I_{max}: maximum ratio of increase in health expenditure per capita the health care system is able to tolerate to the median level since it has reached the goal of a one-year increase in population life expectancy (e.g. 1.1 for a 10% increase).
LE: life expectancy.

-This approach is called "Maintaining spending trend approach". For those HS willing to contain the pace of increase an alternative approach ("Reducing spending trend approach") was used: CET_{0.5} = ((LE+1)/I_{max}).

Methods II: Analysis of HE and LE

- We used OLS to predict "I", following both a cross-sectional (2013) and a secular trend analysis (2008-2013) using World Bank data.

- For both approaches, we tested a crude LE model as well as a healthy life expectancy model.

-Countries were stratified by World Bank income levels

Methods III: Guidance values of cost-effectiveness threshold

- We applied predicted country "I" estimates to derive cost-effectiveness thresholds

-We estimated them for LE and QALYs, for both the "Maintaining spending trend" and "Reducing spending trend" approaches.

-Reported ranges reflect the difference between the cross-sectional and the secular trend analyses.

-Thresholds are reported in units of per capita health expenditures, US dollars and as a proportion of GDP

Results

- Regression models showed a high correlation between life expectancy and health expenditure
-In low-income countries, cost-effectiveness thresholds ranged between 5 and 7 annual per capita health expenditure per life-year gained and between 6 and 8 annual per capita health expenditures per QALY; while in countries cost-effectiveness thresholds ranged between 7 and 10, and between 8 and 11 annual per capita health expenditures per life-year or QALY, respectively.

-Only in 15 out of 178 countries the threshold exceeded one GDP per capita per life-year and in 34 of 178 countries it exceeded one GDP per capita per QALY (8.4% y 18.8% of the countries respectively). In only one country the CE threshold per life-year was above 1.5 GDP (United States), and only in two countries (United States and Lesotho) was above 1.5 GDP per QALY. There was no case in which the estimated threshold was above two GDP per capita.

Table 1. Cost-effectiveness thresholds measured in units of per capita health expenditures

	Life Years		Quality Adjusted Life Years	
	Reducing spending trend approach	Maintaining spending trend approach	Reducing spending trend approach	Maintaining spending trend approach
High income OECD	6.82 - 8.58	7.36 - 9.36	8.07 - 9.79	8.83 - 11.13
Australia	6.76 - 8.76	7.28 - 9.23	7.91 - 9.65	8.63 - 11.01
Canada	6.88 - 8.82	7.38 - 9.63	8.20 - 9.89	8.72 - 11.24
France	6.80 - 8.58	7.20 - 8.89	7.98 - 9.87	8.64 - 11.27
United Kingdom	6.80 - 8.58	7.20 - 8.58	8.05 - 9.78	8.76 - 11.10
United States	7.11 - 8.88	7.60 - 8.98	8.29 - 9.88	9.09 - 11.00
High income non-OECD	3.68 - 6.23	4.26 - 5.26	4.66 - 6.28	5.48 - 10.14
Chile	2.28 - 4.22	3.02 - 5.18	3.68 - 6.48	4.68 - 10.71
Singapore	2.77 - 4.78	3.28 - 4.78	3.68 - 5.08	4.68 - 11.10
United Arab Emirates	2.77 - 4.22	3.02 - 5.18	3.68 - 6.42	4.68 - 10.60
Upper middle income	3.18 - 5.17	3.76 - 5.24	4.04 - 6.28	4.82 - 10.77
Argentina	2.50 - 2.80	3.00 - 3.70	3.68 - 6.28	4.68 - 10.12
Brazil	2.80 - 3.80	3.08 - 4.02	3.28 - 4.89	4.20 - 10.14
China	2.68 - 3.82	3.22 - 4.63	3.64 - 6.28	4.68 - 10.78
Hungary	2.62 - 3.92	3.22 - 4.64	3.25 - 6.24	4.25 - 10.81
Mexico	2.60 - 3.72	3.40 - 4.58	3.61 - 6.00	4.68 - 9.86
Peru	2.68 - 3.76	3.17 - 4.90	3.41 - 6.29	4.68 - 10.16
Thailand	2.68 - 4.02	3.14 - 4.90	3.68 - 6.44	4.67 - 10.61
Lower middle income	3.12 - 3.98	3.78 - 5.11	4.79 - 6.41	5.78 - 10.68
Bolivia	3.17 - 3.98	3.71 - 4.82	4.71 - 6.28	5.80 - 10.10
Colombia	3.22 - 4.87	3.78 - 5.70	4.09 - 10.68	6.77 - 12.67
India	3.11 - 4.09	3.71 - 5.11	4.69 - 6.48	5.69 - 10.61
Nicaragua	3.16 - 3.28	3.68 - 3.78	3.68 - 6.48	4.29 - 6.42
Nigeria	3.12 - 4.04	3.58 - 11.04	6.11 - 10.61	6.82 - 12.67
Low income	3.18 - 4.08	3.21 - 3.28	3.64 - 3.68	4.21 - 6.30
Afghanistan	3.42 - 4.08	3.40 - 3.09	3.81 - 3.42	3.80 - 10.20
Guatemala	3.42 - 4.08	3.42 - 3.71	3.81 - 3.42	4.40 - 7.85
Mali	4.14 - 3.84	4.07 - 4.18	3.10 - 3.68	3.62 - 10.10
Niger	3.14 - 4.40	3.40 - 3.42	3.69 - 3.70	4.05 - 6.46
Yemen	3.18 - 4.18	3.40 - 3.42	3.72 - 3.42	4.00 - 6.48

Table 2. Cost-effectiveness thresholds measured in US Dollars and proportion of GDP per capita

	Life Years		Quality Adjusted Life Years	
	Reducing spending trend approach	Maintaining spending trend approach	Reducing spending trend approach	Maintaining spending trend approach
High income OECD	\$16,120 - \$20,480	\$18,840 - \$22,800	\$24,840 - \$27,360	\$27,360 - \$33,840
Australia	\$16,120 - \$20,480	\$18,840 - \$22,800	\$24,840 - \$27,360	\$27,360 - \$33,840
Canada	\$16,120 - \$20,480	\$18,840 - \$22,800	\$24,840 - \$27,360	\$27,360 - \$33,840
France	\$16,120 - \$20,480	\$18,840 - \$22,800	\$24,840 - \$27,360	\$27,360 - \$33,840
United Kingdom	\$16,120 - \$20,480	\$18,840 - \$22,800	\$24,840 - \$27,360	\$27,360 - \$33,840
United States	\$16,120 - \$20,480	\$18,840 - \$22,800	\$24,840 - \$27,360	\$27,360 - \$33,840
High income non-OECD	\$3,120 - \$5,160	\$3,760 - \$5,240	\$4,040 - \$6,280	\$4,820 - \$10,770
Chile	\$3,120 - \$5,160	\$3,760 - \$5,240	\$4,040 - \$6,280	\$4,820 - \$10,770
Singapore	\$3,120 - \$5,160	\$3,760 - \$5,240	\$4,040 - \$6,280	\$4,820 - \$10,770
United Arab Emirates	\$3,120 - \$5,160	\$3,760 - \$5,240	\$4,040 - \$6,280	\$4,820 - \$10,770
Upper middle income	\$3,180 - \$5,170	\$3,760 - \$5,240	\$4,040 - \$6,280	\$4,820 - \$10,770
Argentina	\$3,180 - \$5,170	\$3,760 - \$5,240	\$4,040 - \$6,280	\$4,820 - \$10,770
Brazil	\$3,180 - \$5,170	\$3,760 - \$5,240	\$4,040 - \$6,280	\$4,820 - \$10,770
China	\$3,180 - \$5,170	\$3,760 - \$5,240	\$4,040 - \$6,280	\$4,820 - \$10,770
Hungary	\$3,180 - \$5,170	\$3,760 - \$5,240	\$4,040 - \$6,280	\$4,820 - \$10,770
Mexico	\$3,180 - \$5,170	\$3,760 - \$5,240	\$4,040 - \$6,280	\$4,820 - \$10,770
Peru	\$3,180 - \$5,170	\$3,760 - \$5,240	\$4,040 - \$6,280	\$4,820 - \$10,770
Thailand	\$3,180 - \$5,170	\$3,760 - \$5,240	\$4,040 - \$6,280	\$4,820 - \$10,770
Lower middle income	\$3,120 - \$3,980	\$3,780 - \$5,110	\$4,790 - \$6,410	\$5,780 - \$10,680
Bolivia	\$3,120 - \$3,980	\$3,780 - \$5,110	\$4,790 - \$6,410	\$5,780 - \$10,680
Colombia	\$3,120 - \$3,980	\$3,780 - \$5,110	\$4,790 - \$6,410	\$5,780 - \$10,680
India	\$3,120 - \$3,980	\$3,780 - \$5,110	\$4,790 - \$6,410	\$5,780 - \$10,680
Nicaragua	\$3,120 - \$3,980	\$3,780 - \$5,110	\$4,790 - \$6,410	\$5,780 - \$10,680
Nigeria	\$3,120 - \$3,980	\$3,780 - \$5,110	\$4,790 - \$6,410	\$5,780 - \$10,680
Low income	\$3,180 - \$4,080	\$3,210 - \$3,280	\$3,640 - \$3,680	\$4,210 - \$6,300
Afghanistan	\$3,180 - \$4,080	\$3,210 - \$3,280	\$3,640 - \$3,680	\$4,210 - \$6,300
Guatemala	\$3,180 - \$4,080	\$3,210 - \$3,280	\$3,640 - \$3,680	\$4,210 - \$6,300
Mali	\$3,180 - \$4,080	\$3,210 - \$3,280	\$3,640 - \$3,680	\$4,210 - \$6,300
Niger	\$3,180 - \$4,080	\$3,210 - \$3,280	\$3,640 - \$3,680	\$4,210 - \$6,300
Yemen	\$3,180 - \$4,080	\$3,210 - \$3,280	\$3,640 - \$3,680	\$4,210 - \$6,300

Conclusions

- This approach, based on widely available data, can be useful to inform decisions in all countries using economic evaluations.

-Our results show thresholds lower than those promoted by WHO, and generally below 1 GDP per capita.

AVAC = coste de aumentar 1 año la expectativa de vida

AVG 5-10 * GSPC
AVAC 6-11 * GSPC

AVG = 2243 * 8
AVAC = 2243 * 9

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I: ratio of increase in health expenditure per capita once a one-year increase in life expectancy is achieved (e.g. 1.1 for a 10% increase)
NOR: accumulated cost-effectiveness ratio of the interventions expressed in units of overall per capita health expenditures (e.g. in \$/QALY) at the end of the period of the intervention to which I is per capita health expenditure per life-year gained.

-Based on this relationship, if HS can establish the maximum increase in per capita health expenditure ("I_{max}") they are willing to accept to gain one year in population life expectancy, the cost-effectiveness threshold that new interventions should not exceed in order to keep health expenditures within the limits set by "I_{max}" can be estimated:

$$CET_{t+1} = I_{t+1} * (LE_{t+1} - LE_t) \quad \text{EQUATION 2 (See Annex 1)}$$

CET_{t+1}: cost-effectiveness threshold measured in units of per capita health expenditures (e.g. CET_{t+1} of \$/QALY indicates that the cost-effectiveness threshold that the new interventions should not exceed is \$/QALY health expenditures per capita per life-year gained)
I_{max}: maximum ratio of increase in health expenditure per capita the health care system is able to tolerate to the median term since it has reached the goal of a one-year increase in population life expectancy (e.g. 1.1 for a 10% increase)
LE: life expectancy

-This approach is called "Maintaining spending trend approach". For those HS willing to contain the pace of increase an alternative approach ("Reducing spending trend approach") was used: CET_{t+1} = LE_{t+1} - LE_t

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- We used OLS to predict "I", following both a cross-sectional (2013) and a secular trend analysis (2008-2013) using World Bank data.

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High income OECD	6.82 - 8.58	7.36 - 9.36	8.07 - 9.79	8.83 - 11.13
Australia	6.76 - 8.76	7.28 - 9.23	7.91 - 9.65	8.63 - 11.01
Canada	6.88 - 8.82	7.38 - 9.63	8.20 - 9.89	8.72 - 11.24
France	6.80 - 8.68	7.40 - 9.69	7.98 - 9.87	8.64 - 11.27
United Kingdom	6.80 - 8.58	7.40 - 9.58	8.05 - 9.78	8.76 - 11.10
United States	7.11 - 8.88	7.60 - 9.58	8.29 - 9.88	9.09 - 11.00
High income non-OECD	5.68 - 8.28	6.26 - 9.26	6.86 - 9.28	6.88 - 10.54
Chile	7.28 - 8.22	8.20 - 9.18	8.68 - 9.68	8.68 - 10.74
Singapore	7.37 - 8.78	7.80 - 9.58	7.89 - 10.08	8.68 - 11.43
United Arab Emirates	7.27 - 8.22	8.02 - 9.18	8.68 - 9.82	8.81 - 10.60
Upper middle income	5.18 - 6.17	7.06 - 8.24	6.04 - 6.28	6.02 - 10.77
Argentina	7.50 - 7.80	8.80 - 9.70	8.68 - 9.18	8.68 - 10.12
Brazil	7.80 - 8.00	8.08 - 9.02	8.20 - 9.09	8.20 - 10.14
China	7.68 - 7.81	8.23 - 8.63	8.64 - 8.28	8.68 - 10.28
Hungary	7.62 - 7.92	8.20 - 8.68	8.20 - 8.24	8.20 - 10.87
Mexico	7.60 - 7.72	8.40 - 8.58	8.51 - 9.00	8.68 - 9.86
Peru	7.68 - 7.96	8.17 - 8.90	8.41 - 8.29	8.68 - 10.16
Thailand	7.68 - 8.01	8.14 - 8.90	8.18 - 8.44	8.47 - 10.61
Lower middle income	6.13 - 7.08	6.78 - 9.11	6.79 - 9.41	7.38 - 10.68
Bolivia	6.17 - 7.06	7.11 - 8.28	7.11 - 8.28	7.80 - 10.59
Colombia	6.22 - 8.67	7.30 - 10.70	6.99 - 10.68	6.77 - 12.67
India	6.11 - 8.09	6.79 - 9.11	6.89 - 9.18	7.69 - 10.61
Nicaragua	6.16 - 7.28	7.01 - 7.89	7.48 - 8.68	8.29 - 9.62
Nigeria	6.10 - 8.04	5.58 - 11.04	6.11 - 10.61	6.80 - 12.67
Low income	5.18 - 6.18	5.21 - 7.29	5.64 - 7.08	6.21 - 8.30
Afghanistan	6.42 - 8.00	5.80 - 7.09	5.81 - 7.42	6.80 - 10.20
Guatemala	5.62 - 6.78	6.47 - 6.78	6.67 - 7.12	6.60 - 7.85
Mali	6.14 - 7.84	6.40 - 6.18	6.10 - 6.68	6.62 - 10.00
Niger	6.14 - 8.40	5.80 - 7.62	5.89 - 7.70	6.05 - 8.86
Yemen	6.18 - 8.40	5.80 - 7.62	6.72 - 7.62	6.60 - 8.68

Table 2. Cost-effectiveness thresholds measured in US Dollars and proportion of GDP per capita

	Life Years		Quality Adjusted Life Years	
	Reducing spending trend approach	Maintaining spending trend approach	Reducing spending trend approach	Maintaining spending trend approach
High income OECD	\$16,120 - \$20,480	\$18,180 - \$22,860	\$19,800 - \$23,380	\$21,340 - \$26,960
Australia	\$16,000 - \$19,760	\$17,680 - \$22,020	\$19,120 - \$22,880	\$20,720 - \$26,440
Canada	\$16,120 - \$19,880	\$18,180 - \$22,860	\$19,800 - \$23,380	\$21,340 - \$26,960
France	\$16,000 - \$19,760	\$17,680 - \$22,020	\$19,120 - \$22,880	\$20,720 - \$26,440
United Kingdom	\$16,120 - \$19,880	\$18,180 - \$22,860	\$19,800 - \$23,380	\$21,340 - \$26,960
United States	\$16,640 - \$19,880	\$17,680 - \$22,020	\$19,120 - \$22,880	\$20,720 - \$26,440
High income non-OECD	\$11,440 - \$15,160	\$12,520 - \$17,160	\$13,160 - \$17,800	\$13,800 - \$19,440
Chile	\$16,000 - \$19,760	\$17,680 - \$22,020	\$19,120 - \$22,880	\$20,720 - \$26,440
Singapore	\$16,120 - \$19,880	\$18,180 - \$22,860	\$19,800 - \$23,380	\$21,340 - \$26,960
United Arab Emirates	\$16,120 - \$19,880	\$18,180 - \$22,860	\$19,800 - \$23,380	\$21,340 - \$26,960
Upper middle income	\$8,440 - \$10,120	\$10,120 - \$12,800	\$10,120 - \$12,800	\$10,120 - \$12,800
Argentina	\$16,120 - \$19,880	\$18,180 - \$22,860	\$19,800 - \$23,380	\$21,340 - \$26,960
Brazil	\$16,120 - \$19,880	\$18,180 - \$22,860	\$19,800 - \$23,380	\$21,340 - \$26,960
China	\$16,120 - \$19,880	\$18,180 - \$22,860	\$19,800 - \$23,380	\$21,340 - \$26,960
Hungary	\$16,120 - \$19,880	\$18,180 - \$22,860	\$19,800 - \$23,380	\$21,340 - \$26,960
Mexico	\$16,120 - \$19,880	\$18,180 - \$22,860	\$19,800 - \$23,380	\$21,340 - \$26,960
Peru	\$16,120 - \$19,880	\$18,180 - \$22,860	\$19,800 - \$23,380	\$21,340 - \$26,960
Thailand	\$16,120 - \$19,880	\$18,180 - \$22,860	\$19,800 - \$23,380	\$21,340 - \$26,960
Lower middle income	\$6,800 - \$8,400	\$7,400 - \$10,000	\$7,400 - \$10,000	\$7,400 - \$10,000
Bolivia	\$16,120 - \$19,880	\$18,180 - \$22,860	\$19,800 - \$23,380	\$21,340 - \$26,960
Colombia	\$16,120 - \$19,880	\$18,180 - \$22,860	\$19,800 - \$23,380	\$21,340 - \$26,960
India	\$16,120 - \$19,880	\$18,180 - \$22,860	\$19,800 - \$23,380	\$21,340 - \$26,960
Nicaragua	\$16,120 - \$19,880	\$18,180 - \$22,860	\$19,800 - \$23,380	\$21,340 - \$26,960
Nigeria	\$16,120 - \$19,880	\$18,180 - \$22,860	\$19,800 - \$23,380	\$21,340 - \$26,960
Yemen	\$16,120 - \$19,880	\$18,180 - \$22,860	\$19,800 - \$23,380	\$21,340 - \$26,960
Low income	\$5,160 - \$6,160	\$5,200 - \$7,200	\$5,600 - \$7,000	\$6,200 - \$8,600
Afghanistan	\$16,120 - \$19,880	\$18,180 - \$22,860	\$19,800 - \$23,380	\$21,340 - \$26,960
Guatemala	\$16,120 - \$19,880	\$18,180 - \$22,860	\$19,800 - \$23,380	\$21,340 - \$26,960
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AVAC = coste de aumentar 1 año la expectativa de vida

AVG 5-10 * GSPC
AVAC 6-11 * GSPC

AVG = 17.944 \$
AVAC = 20.187 \$

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To propose a methodology and derive local CE thresholds based on per capita health expenditures (pCHE) and life expectancy (LE) or Healthy Life Expectancy.

Methods I: Conceptual Framework

- Our approach was based on depicting how the ICER of new interventions affect the pace of increase of health expenditures while population life expectancy increases:

$$I = \frac{NOR_{LE}}{LE} \quad \text{EQUATION 1 (See Annex 1)}$$

I: ratio of increase in health expenditure per capita once a one-year increase in life expectancy is achieved (e.g. 1.1) for a 10% increase.
LE: accelerated cost-effectiveness ratio of the interventions expressed in units of annual per capita health expenditures (e.g. in US\$) of 8.5 (value that the cost-effectiveness of the intervention is equal to 8.5 per capita health expenditure per life year gained).

-Based on this relationship, if HS can establish the maximum increase in per capita health expenditure ("I_{max}") they are willing to accept to gain one year in population life expectancy, the cost-effectiveness threshold that new interventions should not exceed in order to keep health expenditures within the limits set by "I_{max}" can be estimated:

$$CET_{I_{max}} = I_{max} * (LE + 1) - LE \quad \text{EQUATION 2 (See Annex 1)}$$

CET_{I_{max}}: effectiveness threshold measured in units of per capita health expenditures (e.g. CET_{I_{max}} of 8.5 indicates that the cost-effectiveness threshold that the new interventions should not exceed is 8.5 health expenditures per capita per life year gained).
I_{max}: maximum ratio of increase in health expenditure per capita the health care system is able to tolerate to the median term since it has reached the goal of a one-year increase in population life expectancy (e.g. 1.1 for a 10% increase).
LE: life expectancy.

-This approach is called "Maintaining spending trend approach". For those HS willing to contain the pace of increase an alternative approach ("Reducing spending trend approach") was used: CET_{U-LE} = ((LE-1)I_{max}).

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Results

- Regression models showed a high correlation between life expectancy and health expenditure

-In low-income countries, cost-effectiveness thresholds ranged between 5 and 7 annual per capita health expenditure per life-year gained and between 6 and 8 annual per capita health expenditures per QALY; while in countries cost-effectiveness thresholds ranged between 7 and 10, and between 8 and 11 annual per capita health expenditures per life-year or QALY, respectively.

-Only in 15 out of 178 countries the threshold exceeded one GDP per capita per life-year and in 34 of 178 countries the threshold exceeded one GDP per capita per QALY (8.4% y 18.8% of the countries respectively). In only one country the CE threshold per life-year was above 1.5 GDP (United States), and only in two countries (United States and Lesotho) was above 1.5 GDP per QALY. There was no case in which the estimated threshold was above two GDP per capita.

Table 1. Cost-effectiveness thresholds measured in units of per capita health expenditures

	Life Years		Quality Adjusted Life Years	
	Reducing spending trend approach	Maintaining spending trend approach	Reducing spending trend approach	Maintaining spending trend approach
High income OECD	6.82 - 8.58	7.36 - 9.36	8.07 - 9.79	8.83 - 11.13
Australia	6.76 - 8.76	7.28 - 9.23	7.91 - 9.65	8.63 - 11.01
Canada	6.88 - 8.82	7.38 - 9.63	8.20 - 9.89	8.72 - 11.24
France	6.80 - 8.68	7.40 - 9.69	7.98 - 9.87	8.64 - 11.27
United Kingdom	6.80 - 8.58	7.40 - 9.58	8.05 - 9.78	8.76 - 11.10
United States	7.11 - 8.88	7.80 - 9.88	8.29 - 9.88	9.09 - 11.00
High income non-OECD	5.68 - 8.28	6.26 - 9.26	6.66 - 9.26	6.68 - 10.54
Chile	7.28 - 8.22	8.20 - 9.18	8.68 - 9.68	8.68 - 10.72
Singapore	7.37 - 8.78	7.80 - 10.08	7.89 - 10.08	8.68 - 11.63
United Arab Emirates	7.27 - 8.22	8.02 - 9.18	8.68 - 9.82	8.81 - 10.60
Upper middle income	5.19 - 8.17	7.06 - 9.24	6.04 - 8.26	6.02 - 10.77
Argentina	7.50 - 7.89	8.40 - 8.71	8.68 - 8.28	8.68 - 10.12
Brazil	7.80 - 8.08	8.08 - 8.52	8.20 - 8.89	8.20 - 10.14
China	7.68 - 7.81	8.21 - 8.63	8.64 - 8.28	8.68 - 10.78
Hungary	7.62 - 7.92	8.21 - 8.64	8.25 - 8.24	8.25 - 10.81
Mexico	7.60 - 7.72	8.41 - 8.58	8.51 - 8.50	8.68 - 9.86
Peru	7.68 - 7.96	8.17 - 8.90	8.41 - 8.29	8.68 - 10.58
Thailand	7.68 - 8.01	8.14 - 8.99	8.16 - 8.44	8.47 - 10.61
Lower middle income	6.13 - 7.99	6.79 - 9.11	6.79 - 9.41	7.58 - 10.68
Bolivia	6.17 - 7.98	7.13 - 8.28	7.13 - 8.28	7.89 - 10.59
Colombia	6.22 - 8.67	7.30 - 10.70	6.99 - 10.68	6.77 - 12.67
India	6.13 - 8.09	6.79 - 9.11	6.89 - 8.90	7.69 - 10.61
Nicaragua	6.19 - 7.29	6.88 - 7.89	6.88 - 8.68	6.29 - 8.62
Nigeria	6.10 - 8.04	5.58 - 11.04	6.11 - 10.61	6.80 - 12.67
Low income	5.18 - 6.68	5.21 - 7.29	5.64 - 7.08	6.21 - 8.30
Afghanistan	6.42 - 6.68	5.80 - 7.09	5.85 - 7.62	6.80 - 10.20
Albania	5.62 - 6.78	6.47 - 6.78	6.67 - 7.12	6.60 - 7.85
Malawi	4.64 - 7.84	4.67 - 6.18	5.10 - 6.08	5.62 - 10.20
Niger	5.14 - 6.40	5.60 - 7.62	5.69 - 7.70	6.05 - 8.96
Yemen	6.18 - 6.48	5.67 - 7.62	6.72 - 7.62	6.60 - 8.68

Table 2. Cost-effectiveness thresholds measured in US Dollars and proportion of GDP per capita

	Life Years		Quality Adjusted Life Years	
	Reducing spending trend approach	Maintaining spending trend approach	Reducing spending trend approach	Maintaining spending trend approach
High income OECD	\$16,120 - \$20,280	\$18,180 - \$22,140	\$19,800 - \$23,160	\$21,810 - \$26,560
Australia	\$16,010 - \$19,260	\$16,890 - \$20,100	\$17,730 - \$19,800	\$17,710 - \$21,000
Canada	\$16,120 - \$19,890	\$17,170 - \$21,010	\$18,160 - \$20,100	\$18,690 - \$20,260
France	\$16,090 - \$19,260	\$17,090 - \$21,010	\$17,890 - \$20,100	\$18,610 - \$20,260
United Kingdom	\$16,090 - \$19,260	\$17,090 - \$21,010	\$17,890 - \$20,100	\$18,610 - \$20,260
United States	\$16,610 - \$19,890	\$17,130 - \$21,010	\$17,810 - \$20,100	\$18,610 - \$20,260
High income non-OECD	\$11,110 - \$13,110	\$12,110 - \$15,110	\$12,110 - \$15,110	\$12,110 - \$15,110
Chile	\$16,010 - \$19,260	\$17,010 - \$20,260	\$17,010 - \$20,260	\$17,010 - \$20,260
Singapore	\$16,010 - \$19,260	\$17,010 - \$20,260	\$17,010 - \$20,260	\$17,010 - \$20,260
United Arab Emirates	\$16,010 - \$19,260	\$17,010 - \$20,260	\$17,010 - \$20,260	\$17,010 - \$20,260
Upper middle income	\$11,110 - \$13,110	\$12,110 - \$15,110	\$12,110 - \$15,110	\$12,110 - \$15,110
Argentina	\$16,010 - \$19,260	\$17,010 - \$20,260	\$17,010 - \$20,260	\$17,010 - \$20,260
Brazil	\$16,010 - \$19,260	\$17,010 - \$20,260	\$17,010 - \$20,260	\$17,010 - \$20,260
China	\$16,010 - \$19,260	\$17,010 - \$20,260	\$17,010 - \$20,260	\$17,010 - \$20,260
Hungary	\$16,010 - \$19,260	\$17,010 - \$20,260	\$17,010 - \$20,260	\$17,010 - \$20,260
Mexico	\$16,010 - \$19,260	\$17,010 - \$20,260	\$17,010 - \$20,260	\$17,010 - \$20,260
Peru	\$16,010 - \$19,260	\$17,010 - \$20,260	\$17,010 - \$20,260	\$17,010 - \$20,260
Thailand	\$16,010 - \$19,260	\$17,010 - \$20,260	\$17,010 - \$20,260	\$17,010 - \$20,260
Lower middle income	\$11,110 - \$13,110	\$12,110 - \$15,110	\$12,110 - \$15,110	\$12,110 - \$15,110
Bolivia	\$16,010 - \$19,260	\$17,010 - \$20,260	\$17,010 - \$20,260	\$17,010 - \$20,260
Colombia	\$16,010 - \$19,260	\$17,010 - \$20,260	\$17,010 - \$20,260	\$17,010 - \$20,260
India	\$16,010 - \$19,260	\$17,010 - \$20,260	\$17,010 - \$20,260	\$17,010 - \$20,260
Nicaragua	\$16,010 - \$19,260	\$17,010 - \$20,260	\$17,010 - \$20,260	\$17,010 - \$20,260
Nigeria	\$16,010 - \$19,260	\$17,010 - \$20,260	\$17,010 - \$20,260	\$17,010 - \$20,260
Yemen	\$16,010 - \$19,260	\$17,010 - \$20,260	\$17,010 - \$20,260	\$17,010 - \$20,260
Low income	\$11,110 - \$13,110	\$12,110 - \$15,110	\$12,110 - \$15,110	\$12,110 - \$15,110
Afghanistan	\$16,010 - \$19,260	\$17,010 - \$20,260	\$17,010 - \$20,260	\$17,010 - \$20,260
Albania	\$16,010 - \$19,260	\$17,010 - \$20,260	\$17,010 - \$20,260	\$17,010 - \$20,260
Malawi	\$16,010 - \$19,260	\$17,010 - \$20,260	\$17,010 - \$20,260	\$17,010 - \$20,260
Niger	\$16,010 - \$19,260	\$17,010 - \$20,260	\$17,010 - \$20,260	\$17,010 - \$20,260
Yemen	\$16,010 - \$19,260	\$17,010 - \$20,260	\$17,010 - \$20,260	\$17,010 - \$20,260

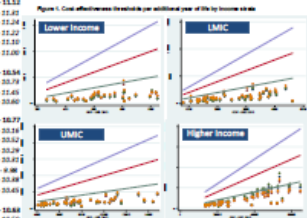


Figure 1 shows graphs for the four income strata with the four life years calculated for each country (the "maintaining spending trend" approach) and the "reducing spending trend approach", both calculated as sectional and secular trend approaches. The three solid lines represent the threshold of one, two, and three GDP per capita per life-year or QALY. For high-income countries, trends are not estimable due to caps.



This figure shows the geographical distribution of different cost-effectiveness thresholds per life-year as a proportion of per capita GDP among countries, in four different categories from less than 0.5 GDP per capita to more than 0.5 GDP per life-year.

Conclusions

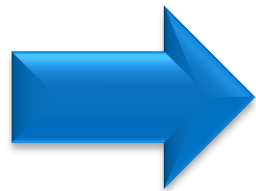
- This approach, based on widely available data, can be useful to inform decisions in all countries using economic evaluations.

-Our results show thresholds lower than those promoted by WHO, and generally below 1 GDP per capita.

AVAC = coste de aumentar 1 año la expectativa de vida

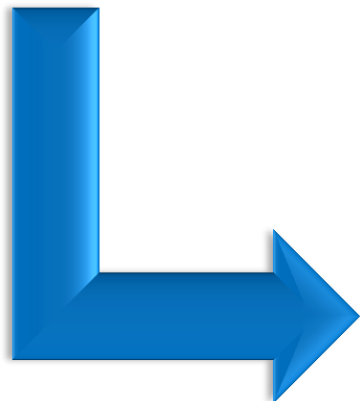
AVG 5-10 * GSPC
AVAC 6-11 * GSPC

AVG = 15.582 €
AVAC = 17.530 €

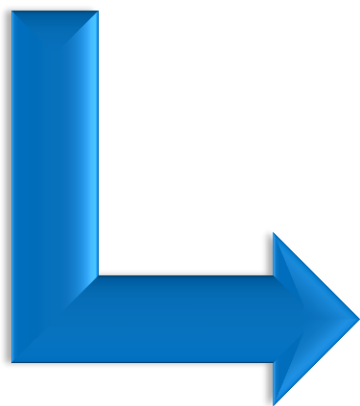


AVAD & AVAC: 1-3 veces el PIB/cápita

http://www.who.int/choice/costs/CER_levels/en/



**PIB/cápita
23.302 €**



**PIB/cápita
39.435 \$**



Estudio ONCOVALOR

EL VALOR DE LOS FÁRMACOS ONCOLÓGICOS: PERSPECTIVA DE LOS PACIENTES, ONCÓLOGOS, DECISORES SANITARIOS Y POBLACIÓN GENERAL



60

Incremento mínimo en supervivencia para un nuevo tratamiento oncológico que costaba 50.000 € más que el tratamiento estándar.



53

Disponibilidad a pagar por un tratamiento nuevo que producía una mejoría en la calidad de vida de 40-80 (escala de 0 a 100). El tratamiento estándar, además de presentar un valor de calidad de vida de 40, costaba 25.000 euros y proporcionaba una OS de 1 año.



50



25



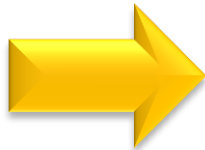
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Incremento mínimo en supervivencia para un nuevo tratamiento oncológico que costaba 50.000 € más que el tratamiento estándar.



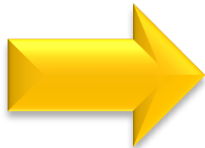
60



8,2 meses (73.520 €/AVAC)



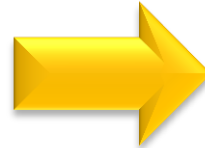
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5,7 meses (106.000 €/AVAC)



50



9,1 meses (66.074 €/AVAC)



25



10,4 meses (57.471 €/AVAC)



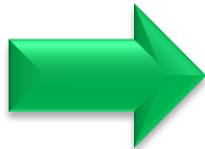
Estudio ONCOVALOR

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Disponibilidad a pagar por un tratamiento nuevo que producía una mejoría en la calidad de vida de 40-80 (escala de 0 a 100). El tratamiento estándar, además de presentar un valor de calidad de vida de 40, costaba 25.000 euros y proporcionaba una OS de 1 año.



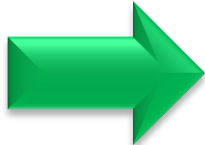
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33.167 € (82.917 €/AVAC)



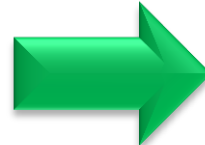
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26.000 € (65.000 €/AVAC)



50



30.200 € (75.500 €/AVAC)



25



17.040 € (42.600 €/AVAC)



PROBLEMAS DEL UMBRAL DE EFICIENCIA

¿Justificación?

No actualizados por inflación

Diferencias entre países

Perspectiva social

¿Quién los fija?



Estrategias para mejorar la relación coste-efectividad

a) *Aumento (relativo) de la efectividad*

Cuando hablamos de aumento *relativo* de la efectividad englobamos dos aspectos. Por un lado, la aplicación del tratamiento a subgrupos de pacientes en los que el beneficio clínico sea máximo y, por otro, la implementación de programas de riesgo compartido, en los que se consideren únicamente los "éxitos" del tratamiento. En cualquiera de los casos se mantienen los costes (numerador) pero se consigue disminuir el CEI al aumentar las unidades de efectividad (denominador).

b) *Disminución del coste de adquisición*

Si se aceptan los parámetros NICE descritos previamente para los medicamentos oncológicos usados en situaciones terminales (ver tabla anterior) y respetamos los AVAC originales, es posible calcular el precio de venta para que el coste por AVAC se sitúe entre 49.200 € y 61.500 € (valores según umbral EoL): El precio por [REDACTED] (IVA incluido) debe situarse entre xxxx € y xxxx €.



**Disminución del
coste de
adquisición**



€



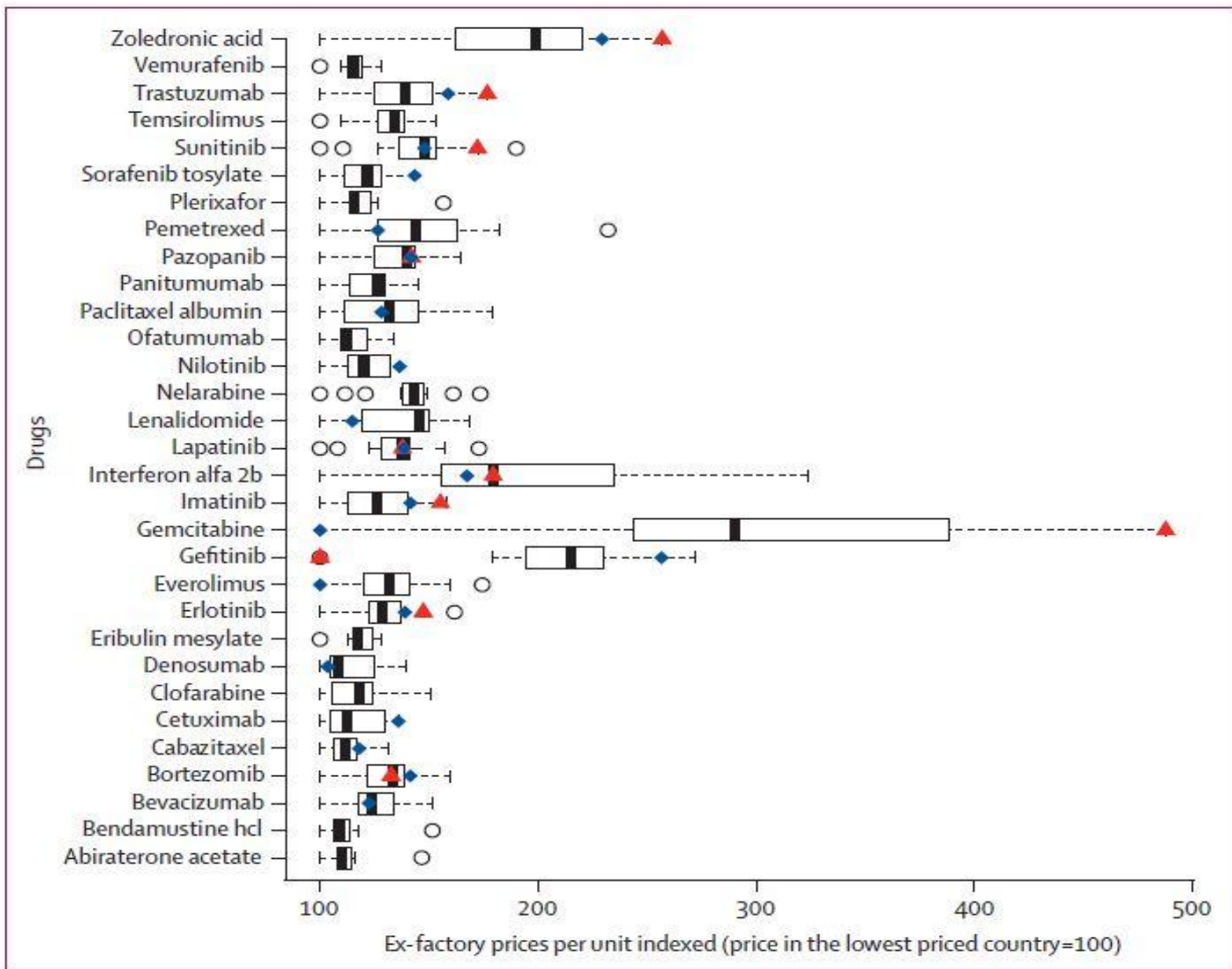
AVAC



**Contratos de
riesgo
compartido**

**Selección de
subgrupos de
ptes. con
beneficio máximo**





En resumen...





Resolution 2071 (2015)¹

Public health and the interests of the pharmaceutical industry:

6.2. with regard to research and development for new therapeutic molecules, to:

6.2.1. oblige pharmaceutical companies to ensure absolute transparency regarding the real costs of research and development, particularly in relation to the public research portion;

6.2.2. adopt a stricter marketing authorisation policy, by:

6.2.2.1. introducing criteria such as added therapeutic value (in relation to existing treatments), or a "need clause", implying that a drug must also be assessed in relation to medical need;

6.2.2.2. making it mandatory to publish the results of all clinical tests relating to the medicine for which authorisation is being requested;

6.2.2.3. where appropriate, considering restricting reimbursement by the social security system to only those medicines which satisfy such criteria and requirements;

6.2.3. ensure that medicines whose effectiveness has been established remain on the market by having recourse, where necessary, to mandatory licences in return for the payment of royalties;

6.2.4. set up a public fund to finance independent research geared to unmet health needs, including in the field of rare and paediatric diseases.

5. In recent years, there have been various developments seen an upsurge in prices, nonetheless, the industry is of particular concern their ability to

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- Las autoridades deben hacer un esfuerzo importante por asignar a los medicamentos un **precio basado en su valor para la sociedad**
- La **EE** se hace **imprescindible** (ya lo era...)
- Deben introducirse y usarse **umbrales de aceptabilidad explícitos**
- Los **criterios de financiación** deben ser **claros** y ligados a la EE y al UCEI





«Si vamos a cenar y la carta no tiene los precios, no nos sorprendamos luego del importe de la factura»

Robada a Juan Oliva. I'm sorry iii

Siempre



con

nosotros,

Roberto



AGRADECIMIENTOS

A mis compañeros del grupo coordinador de GENESIS por ser y por estar



**¡Muchas
gracias por
vuestra atención!**