Encuentro: "*Los nuevos medicamentos biológicos: revolución terapéutica y económica*". 4 y 5 septiembre 2014

UIMP Universidad Internacional Menéndez Pelayo Santander 2014

LOS MEDICAMENTOS BIOLOGICOS EN LA INVESTIGACION ECONOMICA

Dr. DAVID CANTARERO-PRIETO

Profesor Titular y Responsable del Grupo I+D+I en Economía Pública y Salud

Universidad de Cantabria. david.cantarero@unican.es

Dr. MANUEL GARCIA-GOÑI

Profesor Titular . Universidad Complutense de Madrid. mggoni@ucm.es

AGRADECIMIENTOS

Alguna reflexión de interés

- **¿Sabía que la sanidad en 2013 costó en media 1201 euros (gasto per cápita) y está por debajo del salario medio bruto que fue 1634 euros mensuales**

- **Aunque parece que protección de salud no tiene precio … "*tiene un elevado coste (más de 53.052 millones de euros en 2014) que hemos de pagar*".. ¿entre todos y de igual modo?**

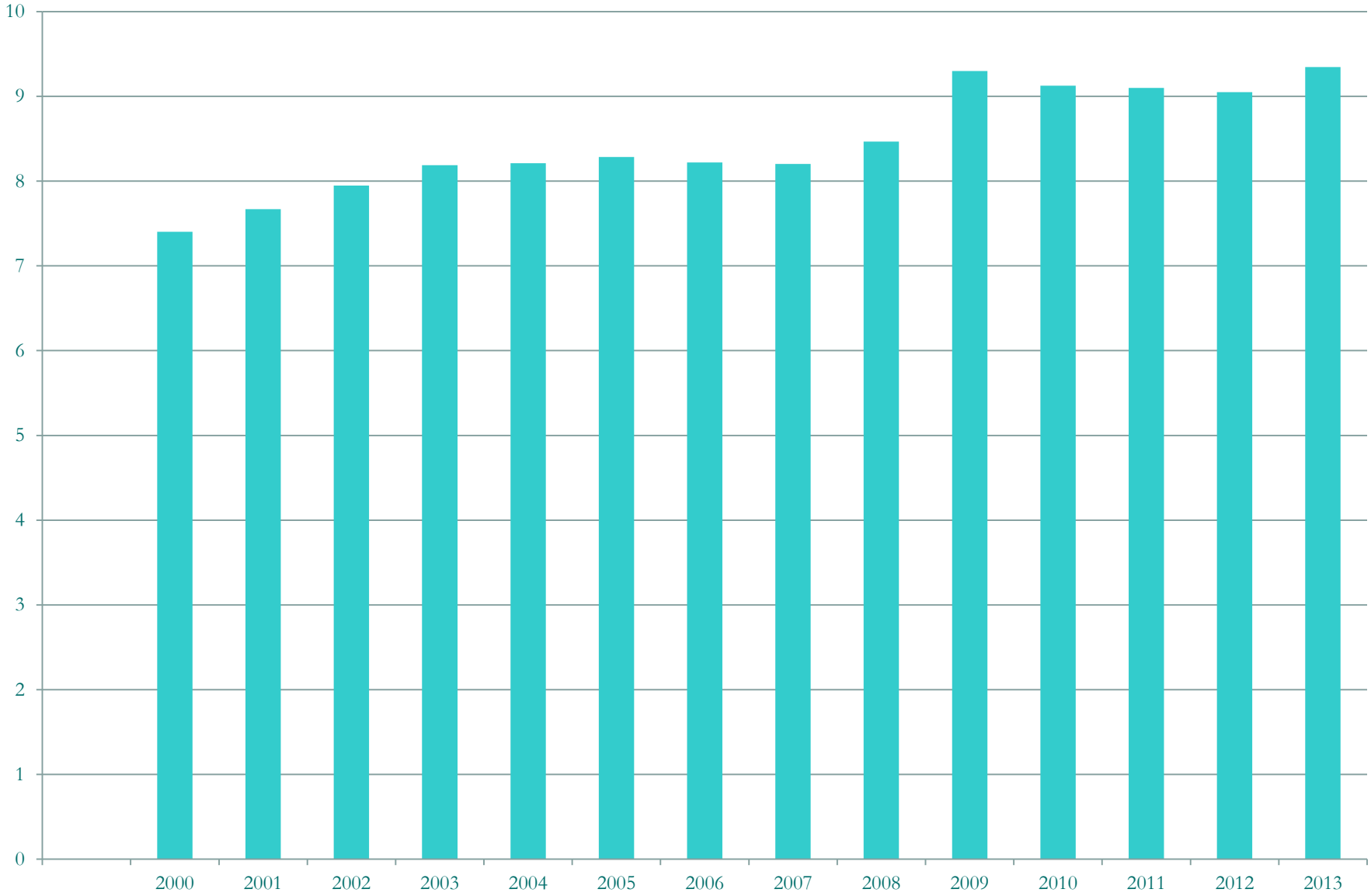
Índice

Años de vida ganados (AVACs)
Enfermedades prevenidas
Síntomas aliviados
Calidad de vida mejorada

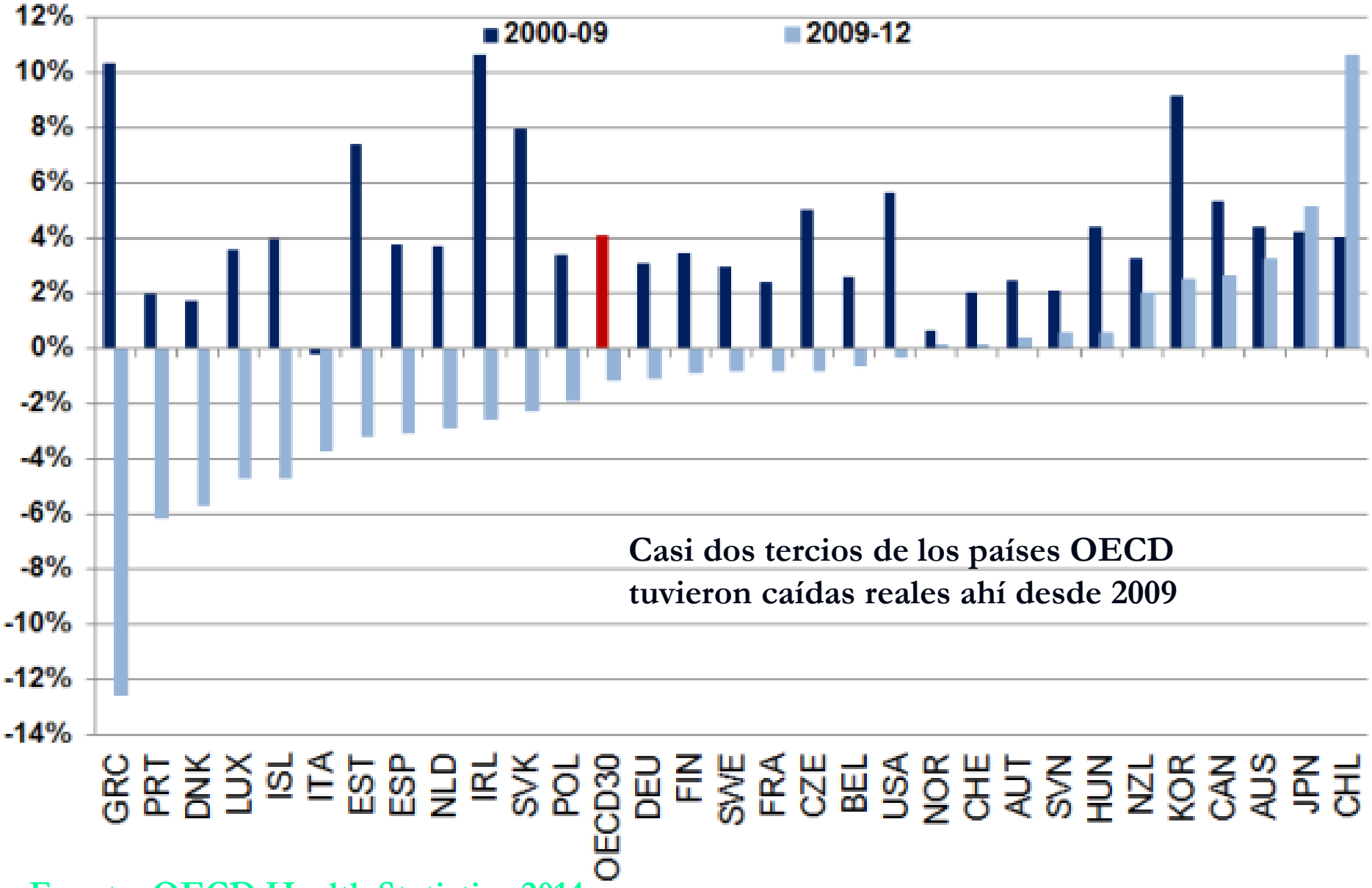
Pruebas realizadas
Intervenciones practicadas
Estancias causadas
Tratamientos aplicados

Personal sanitario
Medicamentos (….y biológicos)
Servicios exteriores
Tecnologías

Gasto sanitario medio como % PIB en países de OECD 2000-2013 (Fuente: OECD, 2014)



Crecimiento anual del gasto farmacéutico en términos reales



Fuente: OECD Health Statistics 2014

Gasto farmacéutico

	DATOS MENSUALES			ACUMULADO INTERANUAL		
CCAA	**2014**	**2013**	**%14/13**	**AGO 13-JUL 14**	**AGO 12-JUL 13**	**% Δ**
Andalucía	139.764.742	136.462.767	2,42	1.624.099.510	1.572.030.606	3,31
Aragón	25.613.669	25.711.302	-0,38	290.187.110	281.439.204	3,11
Asturias	21.772.369	21.101.301	3,18	250.055.807	242.654.419	3,05
Baleares	15.582.885	14.998.164	3,90	176.534.859	168.461.160	4,79
Cantabria	10.702.570	10.403.297	2,88	122.244.146	117.052.555	4,44
Castilla La Mancha	38.978.969	37.773.048	3,19	448.559.838	437.567.038	2,51
Castilla León	47.698.676	46.179.674	3,29	535.858.929	513.725.078	4,31
Cataluña	118.852.842	118.534.595	0,27	1.330.422.724	1.294.128.924	2,80
Canarias	36.853.100	35.760.871	3,05	417.410.905	394.065.669	5,92
Extremadura	25.212.695	23.874.230	5,61	288.933.807	267.882.037	7,86
Galicia	58.559.990	60.111.552	-2,58	685.649.187	653.030.060	5,00
Madrid	94.607.757	89.357.086	5,88	1.039.762.860	983.897.645	5,68
Murcia	27.782.583	26.328.832	5,52	316.115.253	306.359.012	3,18
Navarra	10.716.610	10.172.081	5,35	121.552.949	117.076.689	3,82
C. Valenciana	93.363.512	95.003.464	-1,73	1.110.606.373	1.077.359.497	3,09
País Vasco	39.634.807	35.172.672	12,69	443.508.006	482.543.067	-8,09
La Rioja	5.742.277	5.575.329	2,99	64.242.734	62.339.896	3,05
Ceuta	1.074.576	1.077.706	-0,29	12.795.493	12.178.875	5,06
Melilla	1.018.348	901,613	12,95	11.233.135	10.302.078	9,04
NACIONAL	**813.532.977**	**794.499.588**	**2,40**	**9.289.773.626**	**8.994.093.509**	**3,29**

Fuente: Mª Sanidad (Agosto 2014)

¿Cuánto ha influido tras 2 años de copago por renta éste, el profesional o usuario en reducción de demanda?

Aplicación de copago farmacéutico por renta

CC.AA.	Datos mensuales								Acumulado interanual	
	2014	2013	2014	%14/13	%14/12	jul13-jun14	jul12-jun13	jul11- jun12	% Δ jul12-jun14	% Δ jul11-jun14
Andalucía	133.945.990	125.732.648	155.561.752	6,53	-13,90	1.620.797.535	1.556.527.850	1.792.422.528	4,13	-9,58
Aragón	24.526.730	23.214.309	33.128.328	5,65	-25,96	290.179.478	277.167.031	345.226.040	4,73	-15,92
Asturias	20.880.388	20.240.351	27.037.651	3,16	-22,77	249.384.739	240.436.629	307.043.952	3,72	-18,78
Baleares	14.603.983	13.810.363	17.718.055	5,75	-17,58	175.950.138	166.715.217	200.720.112	5,54	-12,34
Cantabria	10.007.397	9.486.133	12.569.205	5,50	-20,38	121.944.874	115.712.242	141.645.163	5,39	-13,91
Castilla-La Mancha	36,963668	37.346.794	51.447.370	-1,03	-28,15	447.353.917	432.166.322	540.423.954	3,51	-17,22
Castilla León	44.682.424	42.966.203	56.975.614	3,99	-21,58	534.339.928	505.088.868	644.612.788	5,79	-17,11
Cataluña	109.186.240	106.122.318	144.627.691	2,89	-24,51	1.329.624.476	1.283.689.758	1.636.444.706	3,58	-18,75
Canarias	35.263.232	32.850.335	40.543.163	7,35	-13,02	416.318.676	388.076.603	466.194.059	7,28	-10,70
Extremadura	24.018.677	22.049.267	28.029.890	8,93	-14,31	287.595.342	264.603.041	322.920.154	8,69	-10,94
Galicia	55.773.175	54.874.607	70.973.935	1,63	-21,42	687.200.749	648.753.410	816.832.598	5,93	-15,87
Madrid	91.203.737	88.685.743	119.693.658	2,84	-23,80	1.034.512.190	963.006.490	1.169.517.056	7,43	-11,54
Murcia	26.577.600	27.198.281	36.994.753	-2,28	-28,16	314.661.503	300.996.378	376.505.456	4,54	-16,43
Navarra	10.199.680	9.387.876	12.456.694	8,65	-18,12	121.008.420	116.345.188	143.789.040	40,1	-15,84
Com. Valenciana	89.768.833	88.710.891	121.595.932	1,19	-26,17	1.112.246.325	1.066.860.937	1.358.130.663	4,25	-18,10
País Vasco	37.296.112	44.168.623	41.175.460	-15,56	-9,42	439.045.871	488.682.182	511.285.964	10,16	-14,13
La Rioja	5.191.065	5.001.121	6.622.818	3,80	-21,62	64.075.787	61.568.517	76.712.040	4,07	-16,47
Ceuta	1.111.929	1.014.624	1.295.850	9,59	-14,19	12.798.624	11.987.576	14.456.314	6,77	-11,47
Melilla	955,068	881,098	1.044.722	8,40	-8,58	11.116.401	10.149.547	12.003.236	9,53	-7,39
NACIONAL	**772.155.929**	**753.743.046**	**979.492.540**	**2,44**	**-21,17**	**9.270.254.972**	**8.898.533.785**	**10.876.885.823**	**4,18**	**-14,77**

Fuente: Ministerio de Sanidad, Servicios Sociales e Igualdad

- **Gasto farmacéutico (según Mº a Agosto 2014). Creció al 3,29% interanual y sube por 1ª vez desde 2009**

- Pero, tras nuevo copago desde 1-7-2012 Sanidad (2 años después son 3.584,9 millones de euros de ahorro) sigue sin hacer (¿es tarea de CCAA?) ***estudio con datos desagregados*** **(*Mix* ENS y EPF?)** ***para ver quién ha reducido uso de fármacos, cuáles se están dejando de tomar*** **(falta de adherencia hace aumentar utilización sanitaria?)** ***o qué efectos puede ocasionar la bajada "histórica" en consumo***

- Según EPF en 2013, l gasto farmacéutico de las familias (399,22 euros anuales) creció 9,2% con respecto a 2012 (15% en jubilados). 1ª vez que esta partida crece desde 2008

- ***Por qué no se mejora con topes mensuales? Se consigue así dinero para financiar fármacos innovadores? Por qué no se mejoran los tramos actuales dado que son muy "amplios"?***

1. INTRODUCCION

- **Aparición de medicamentos biológicos tuvo efecto notable en salud pública pero 1º pasos difíciles**

- **Problema: su no accesibilidad para todos por altos costes e incapacidad para financiarlos bien especialmente desde crisis de 2008 aunque gran beneficiado seguirá siendo el paciente**

- **Importancia de Economía de la Salud cada vez mayor en por incremento del gasto sanitario OECD dónde dentro del farmacéutico los % de este tipo de medicamentos son cada vez mayores y se espera lleguen al 20% en 2017 (oncología, nefrología, reumatología, etc. según IMS *Institute of HealthCare Informatics*, 2013)**

1. INTRODUCCION

- **Crecimiento del mercado de medicamentos biológicos viene muy impulsado por uso de anticuerpos monoclonales (enfermedades degenerativas y tumorales)**

- **Dentro de ese mercado la cuota de biosimilares es reducida (no llega al 0,5%) e ídem su grado de competencia aunque va en aumento (Farfan *et al*., 2014)**

- **Farmaeconomía como evaluación económica de medicamentos (tecnología más eficiente) ha ido en aumento: *¿cuánto hay que pagar por cierta ganancia o retorno en salud?* (Cutler, 2014)**

- **Idea: generar ahorros y encontrar alternativas más eficientes en medicamentos para sistemas sanitarios (García-Goñi y Cantarero, en curso)**

EVALUACION ECONOMICA. MEDIR Y VALORAR. METODOS

- **COSTE-Bº (ACB). Costes y efectos equivalentes en unidades monetarias**
- **COSTE-EFECTIVIDAD (ACE). Costes en unidades monetarias y efectos en unidades clínicas habituales**
- **COSTE-UTILIDAD (ACU). Costes en unidades monetarias y efectos en cantidad y calidad de vida**
- **MINIMIZACIÓN DE COSTES (AMC). Costes en unidades monetarias y efectos en equivalentes**

POSIBLES MEDIDAS EVALUACIÓN ECONÓMICA

C: Udes monetarias
C_1 = Costes directos
C_2 = Costes indirectos
C_3 = Udes monetarias

E: Udes naturales (medidas clínicas)

U: Utilidad (Años de vida ajustados por calidad AVAC)

B: Udes monetarias
B_1 = Beneficios directos
B_2 = Beneficios indirectos
B_3 = Beneficios intangibles

ANALISIS DE MINIMIZACION DE COSTES (*AMC*)

Evalúa tecnologías sanitarias con mismo efecto s/salud

$AMC = C_1 + C_2$

ANALISIS COSTE EFECTIVIDAD (*ACE*)

Compara dftes tecnologías sanitarias alternativas con dftes efectos s/salud medidos en udes naturales, como años vida ganados, mg mercurio en tensión arterial reducidos, etc

$$ACE = \frac{C_1 + C_2 - B_1 - B_2}{E}$$

ANALISIS COSTE UTILIDAD (*ACU*)

Rtdos en salud se miden en AVAC teniendo en cta tanto supervivencia como calidad

$$ACU = \frac{C_1 + C_2 - B_1 - B_2}{U}$$

ANALISIS COSTE BENEFICIO (*ACB*)

Mide efectos s/salud en udes monetarias

$$ACB = \frac{B_1 + B_2 + B_3}{C_1 + C_2 + C_3}$$

1. INTRODUCCION

- **Importantes son guías de práctica clínica, buenas prácticas, protocolos de actuación, por consenso en grupos de sociedades científicas pero da problemas a facultativos si pretenden indicar fármacos de ultima generación difíciles de conseguir**

- **Incluso puede que más enfermedades (reuma, onco, neuro…) con estas medicaciones se convierten en crónicas de más larga evolución y gasto**

- **Hándicap para controlar gasto pues si se trata a pacientes más años se podría bajar coste del fármaco a niveles "aceptables" (...cuales son?) según lo que pueda "pagarse" (en SRS de entre 10 fármacos de más gasto 6 eran de estos con coste persona y año de hasta 48.000 euros en onco) y "negociarse" (riesgo compartido?, techo máximo de gasto…pero no de enfermos?) pero según su <u>VALOR</u>**

2. ESTADO ACTUAL DE LA INVESTIGACION ECONOMICA

JCR2013 Impact Factor(q1): 3.33-1.91

Eur J Health Econ (2014) 15:223–228
DOI 10.1007/s10198-013-0538-4

EDITORIAL

Are biosimilars the next tool to guarantee cost-containment for pharmaceutical expenditures?

María-Isabel Farfan-Portet · Sophie Gerkens · Isabelle Lepage-Nefkens · Irmgard Vinck · Frank Hulstaert

Competencia parecida a genéricos? Bajarán más los precios? Serán más aceptados? Ahorros? Fúturo?

Received: 28 May 2013 / Accepted: 16 October 2013 / Published online: 23 November 2013

Introduction

Biological medicines contain a biological substance that is produced by or derived from a living organism. The active substances of biologicals are usually larger and more complex than those of chemically derived medicines (non-biological medicine). Biologicals are used for the treatment of chronic and life-threatening diseases such as cancer, multiple sclerosis and rheumatoid arthritis. Treatment with biologicals is usually expensive and represents ever-increasing pharmaceutical expenditures for the third-party payer.

In analogy with the introduction of generics for chemically derived medicines, the expiration of patents of the overview on economic aspects of the new biosimilar competition.

Can biosimilar competition resemble generic competition?

A brief reminder of the differences between generics and biosimilars is required before presenting evidence on biosimilar competition. Whilst generics are considered to be exact copies of chemically derived medicines, biosimilars are considered not identical but rather similar to the originator medicine [1]. According to the European Medicines

Health Policy

journal homepage: www.elsevier.com/locate/healthpol

Regional tenders on biosimilars in Italy: An empirical analysis of awarded prices

Sandro Curto[a], Simone Ghislandi[a,b], Katelijne van de Vooren[a], Silvy Duranti[a], Livio Garattini[a,*]

[a] Centre for Health Economics, IRCCS Mario Negri Institute for Pharmacological Research, Ranica, Italy
[b] Department for Policy Analysis and Public Management, Università Commerciale Luigi Bocconi, Milan, Italy

ARTICLE INFO

Article history:
Received 11 October 2013
Received in revised form 5 February 2014
Accepted 8 February 2014

Keywords:
Italy
Tenders
Biosimilars
Competition

Más competencia (aún no alta) baja precios

ABSTRACT

Objective: The goal of the present study is to assess the awarded prices and thus the real level of competition the regional tenders referring to biosimilars in Italy achieved.
Methods: We conducted a web-based analysis to collect detailed information on regional biosimilar tenders, up to December 2012. We identified 191 lots referring to the three off-patent biologicals (somatropin, epoetin and filgrastim) mentioned in the 24 tenders that took place during the study period (2008–2012).

A multiple linear regression analysis was conducted to assess the relationship between prices awarded (dependent variable) and potentially explanatory variables (base quantities, bioagent, number of competitors, purchasing region and time).
Results: While the price of somatropin stayed steady, those of filgrastim and epoetin dropped steeply. The mean number of competitors was lowest for somatropin and highest for filgrastim. One additional competitor was associated with about a 10% reduction in the price on average. The benefits of having many competitors did not fade with increasing numbers of companies.
Discussion: Our analysis confirms the theory that worthwhile savings can be generated in tenders, once the bid is designed in such a way that competition can produce its effects, i.e. allowing more than one manufacturer to tender. However, most of the Italian regional tenders on off-patent bioagents do not seem to exploit potential competition to the full.

PharmacoEconomics. July 2014, Volume 32, Issue 7, pp 681-691

Barriers to the Uptake of Biosimilars and Possible Solutions: A Belgian Case Study

- Pieter Dylst,
- Arnold Vulto,
- Steven Simoens

$55.95 / €44.95 /

Menos confianza, incertidumbre, financiación no incentivan a prescriptores

Abstract

Background

Biosimilars are medicinal products that are similar to a biopharmaceutical that has already been authorised. As biopharmaceuticals are expected to dominate the best-selling pharmaceuticals worldwide by 2016, the emergence of biosimilars imposes an important challenge for governments. At this moment, the uptake of biosimilars in Belgium is limited, with market shares close to 0 %.

Objective

This study aimed to identify the barriers that impede the uptake of biosimilars in Belgium.

Methods

Semi-structured interviews were conducted to investigate in depth the barriers to the uptake of biosimilars in Belgium. Respondents were selected through selective sampling so that all different stakeholders were represented (authorities, physicians, pharmacists, patients, academics and industry). Respondents were contacted by e-mail and letter with a request for participation. A thematic framework was used to analyze the data.

Results

Three main barriers to the uptake of biosimilars in the Belgian market were identified: a lack of confidence towards biosimilars by some stakeholders; uncertainty about the interchangeability and substitution of biosimilars; and a hospital financing system that discourages the use of them. Providing all stakeholders with objective information on the concept of biosimilars, reforming the financing of hospitals, developing and implementing prescription quota in hospitals, setting up patient registries for biosimilars and speeding up the pricing and reimbursement process of biosimilars are suggested solutions to increase the uptake of biosimilars in Belgium.

Conclusions

To fully capture the potential savings of biosimilars, governments should take measures to increase their uptake. The Belgian government, and also the manufacturers of biosimilars, should take measures to reduce the uncertainties related to biosimilars and raise confidence among prescribers. In addition, the financing of hospitals should be reformed and incentives should be developed to stimulate physicians to prescribe biosimilars.

KCE REPORT 199

Federaal Kenniscentrum voor de Gezondheidszorg
Centre Fédéral d'Expertise des Soins de Santé
Belgian Health Care Knowledge Centre

BARRIERS AND OPPORTUNITIES FOR THE UPTAKE OF BIOSIMILAR MEDICINES IN BELGIUM

2013 www.kce.fgov.be

LIBRO BLANCO DE LOS MEDICAMENTOS BIOSIMILARES EN ESPAÑA: CALIDAD SOSTENIBLE

La garantía del acceso universal a medicamentos clave

Edición: Fundación Gaspar Casal

Coordinación: Gema Pi Corrales

ISBN: 978-84-697-0300-7
Depósito Legal: M-13997-2014

| Álvaro Hidalgo Vega |

3. EL VALOR DE LOS BIOSIMILARES PARA PARA LOS SISTEMAS SANITARIOS: UN SENCILLO MODELO DESDE LA ECONOMÍA DE LA SALUD

PharmacoEconomics (2013) 31:933–957
DOI 10.1007/s40273-013-0082-1

ORIGINAL RESEARCH ARTICLE

Projecting Expenditure on Medicines in the UK NHS

Phill O'Neill · Jorge Mestre-Ferrandiz · Ruth Puig-Peiro · Jon Sussex

Dificultad para predecir bien comportamientos de precios a futuro

Published online: 14 September 2013

Abstract

Background Expenditure on medicines is a readily identifiable element of health service costs. It is the focus of much attention by payers, not least in the UK even though the cost of medicines represents less than 10 % of total UK National Health Service (NHS) expenditure. Projecting future medicines spending enables the likely cost pressure to be allowed for in planning the scale and allocation of NHS resources. Simple extrapolations of past trends in expenditure fail to account for changes in the rate and mix of new medicines becoming available and in the scope for windfall savings when some medicines lose their patent protection. The objective of this study is to develop and test an improved method to project NHS pharmaceutical expenditure in the UK for the period 2012–2015.

Methods We have adopted a
up approach, which means tha
from individual products to t
tions of the impact of gener
prices and quantities of medi
uptake of newly launched me
from regression analysis of
tainty, we have created a basel
scenarios. We have compared
expenditure for 2012.

Results Our projections esti
2015, with no change in polic
total medicines bill would i
pound annual growth rate (C
4.1 %. Total NHS spending or

Saving money in the European healthcare systems with biosimilars

Generics and Biosimilars Initiative Journal (GaBI Journal). 2012;1(3-4).120-6.

Published in: Volume 1 / Year 2012 / Issue 3-4

Author(s): 1 Robert Haustein, 2 Christoph de Millas, 3 Ariane Höer, MD, 4 Professor Bertram Häussler, MD

Keywords: biologicals, biosimilars, cost savings, costs, epo, Europe, G-CSF, mab

Modelo de cálculo:
Opción válida de ahorro 11,8 a 33,4 billones de euros en 2007-2020 (escenarios de lenta/rápida penetración y min/máx reducción precio

Introduction: The use of biotechnological manufactured drugs, or biologicals, has increased massively over the past few years. Used especially in the treatment of cancer and other severe diseases, biologicals incur high annual therapy costs and represent an additional burden for healthcare systems. Expenditure can be decreased by using cheaper biosimilars, produced following the patent expiration of the reference product. Here we present a model calculation that demonstrates the potential savings from using biosimilars for erythropoietins, granulocyte colony-stimulating factors, and monoclonal antibodies in EU national markets between 2007 and 2020.

Methods: Using a sequential approach, we calculated the savings through the use of biosimilars for France, Germany, Italy, Poland, Romania, Spain, Sweden and UK. First, either a 'top-down' or a 'bottom-up' approach was chosen to forecast the expected quantity of consumed drugs. We then calculated average reimbursement prices using additional information about the healthcare systems in each country. Finally, we estimated the potential savings for the above molecule groups using developed country specific scenarios.

Results: The use of biosimilars is expected to result in overall savings between Euros 11.8 billion and Euros 33.4 billion between 2007 and 2020, with largest savings expected for France, Germany and UK. Biosimilar monoclonal antibodies are expected to produce the greatest savings ranging from Euros 1.8 billion to Euros 20.4 billion. Biosimilar erythropoietins are expected to provide savings of between Euros 9.4 billion and Euros 11.2 billion, while granulocyte colony-stimulating factors could produce savings of between Euros 0.7 billion to Euros 1.8 billion.

Conclusion: The increasing use of biosimilars is a valid option for decreasing healthcare expenditure on biological drugs.

ClinicoEconomics and Outcomes Research

Dovepress
open access to scientific and medical research

Open Access Full Text Article

REVIEW

Biosimilar medicines and cost-effectiveness

This article was published in the following Dove Press journal:
ClinicoEconomics and Outcomes Research
9 February 2011
Number of times this article has been viewed

Steven Simoens

Research Centre for Pharmaceutical Care and Pharmaco-economics, Faculty of Pharmaceutical Sciences, Katholieke Universiteit Leuven, Leuven, Belgium

AMC si hay equivalencia en efectividad y sino es así pues emplear ACE o ACU. Dada incertidumbre esos ACE o ACU han de hacerse a través del ciclo vital del medicamento

Abstract: Given that biosimilars are agents that are similar but not identical to the reference biopharmaceutical, this study aims to introduce and describe specific issues related to the economic evaluation of biosimilars by focusing on the relative costs, relative effectiveness, and cost-effectiveness of biosimilars. Economic evaluation assesses the cost-effectiveness of a medicine by comparing the costs and outcomes of a medicine with those of a relevant comparator. The assessment of cost-effectiveness of a biosimilar is complicated by the fact that evidence needed to obtain marketing authorization from a registration authority does not always correspond to the data requirements of a reimbursement authority. In particular, this relates to the availability of adequately powered equivalence or noninferiority studies, the need for comparative data about the effectiveness in a real-world setting rather than the efficacy in a structured setting, and the use of health outcome measures instead of surrogate endpoints. As a biosimilar is likely to be less expensive than the comparator (eg, the reference biopharmaceutical), the assessment of the cost-effectiveness of a biosimilar depends on the relative effectiveness. If appropriately designed and powered clinical studies demonstrate equivalent effectiveness between a biosimilar and the comparator, then a cost-minimization analysis identifies the least expensive medicine. If there are differences in the effectiveness of a biosimilar and the comparator, other techniques of economic evaluation need to be employed, such as cost-effectiveness analysis or cost-utility analysis. Given that there may be uncertainty surrounding the long-term safety (ie, risk of immunogenicity and rare adverse events) and effectiveness of a biosimilar, the cost-effectiveness of a biosimilar needs to be calculated at multiple time points throughout the life cycle of the product.

The impact of biosimilars' entry in the EU market

Joan Rovira, Jaime Espín, Leticia García
and Antonio Olry de Labry

Andalusian School of Public Health

Ellos avalan caídas de precio menores a las esperadas y sin datos independientes para validar resultados

January, 2011

OHE Research
Office of Health Economics
OHE Briefing
No 45 October 2008

The market for biosimilars: evolution and policy options

Gran reto: demanda más conciencia social, sanitaria, empresarial y política (tipos de intervención pública). Proponen modelo duopolio con diferenciación, y bajada del precio depende de cómo de sensible sea demanda al precio

Deven Chauhan, *MerckSerono - formerly of the Office of Health Economics*
Adrian Towse, *Office of Health Economics*
& **Jorge Mestre-Ferrandiz,** *Office of Health Economics*

Key Points

- Biopharmaceuticals are more complex agents than conventional chemical entities and therefore are more difficult to replicate on patent expiry. Off-patent versions of the originator product cannot rely on a simple demonstration of chemical comparability. They are best described as biosimilar.
- As a consequence biosimilar markets will evolve in a more complex way than traditional small molecule chemical generics markets.
- Regulators will need clinical trial evidence pre-launch of efficacy and safety, and clinicians will
- As a consequence generic companies may need commercial partners to enter biosimilar markets successfully and governments and other payers need to behave differently. Post patent expiry price cuts and/or the use of reference pricing will deter biosimilar entry and reduce long term savings.
- Governments and other payers should encourage pharmacovigilance and other outcomes studies that produce PSY data that will encourage interchangeability and greater price competition. Over time these markets can become biogeneric.

MANAGERIAL AND DECISION ECONOMICS
Manage. Decis. Econ. **28:** 439–451 (2007)
Published online in Wiley InterScience
(www.interscience.wiley.com) DOI: 10.1002/mde.1352

Entry and Competition in Generic Biologics

Henry G. Grabowski*, David B. Ridley and Kevin A. Schulman

Health Sector Management Program, The Fuqua School of Business, Duke University, NC, USA

Competencia monopolística y diferenciación hace bajada de precios notan acusada como con genéricos

Patents for several blockbuster biological products are expected to expire soon. The Food and Drug Administration is examining whether biologics can and should be treated like pharmaceuticals with regard to generics. In contrast with pharmaceuticals, which are manufactured through chemical synthesis, biologics are manufactured through fermentation, a process that is more variable and costly. Regulators might require extensive clinical testing of generic biologics to demonstrate equivalence to the branded product. The focus of the debate on generic biologics has been on legal and health concerns, but there are important economic implications. We combine a theoretical model of generic biologics with regression estimates from generic pharmaceuticals to estimate market entry and prices in the generic biologic market. We find that generic biologics will have high fixed costs from clinical testing and from manufacturing, so there will be less entry than would be expected for generic pharmaceuticals. With fewer generic competitors, generic biologics will be relatively close in price to branded biologics. Policy makers should be prudent in estimating financial benefits of generic biologics for consumers and payers. We also examine possible government strategies to promote generic competition.

3. CONCLUSIONES

- **Medicamentos biológicos aportan VALOR a sistemas sanitarios por ganancias marginales de salud y eficiencia**
- **Pero su coste es muy elevado…**
- **Expiración de patentes de estos productos ha creado posibilidad de generación del mercado de productos BIOSIMILARES…**
- **… que algunos querrían ver como "*nuevo mercado de genéricos*"… pero a día de hoy, su penetración en diferentes mercados es reducida (0,5% del total) y heterogénea según país**
- **¿Es esto posible?**

3. CONCLUSIONES

- **¿Podemos fomentar mercado de biosimilares para reducir gasto farmacéutico? Pues….**
  - **Los genéricos son copias exactas**
  - **Los biosimilares son similares pero… no idénticos (no se cumple intercambiabilidad)**
  - **Costes de producción de biosimilares es mayor al de genéricos… menor nº de empresas esperado**
  - **Aprobación por EMA o FDA… aunque existan cauces rápidos, sigue siendo más costosa (seguridad y eficacia) que en el caso de genéricos**
  - **Uso del *International Nonproperty Name* (INN) es mucho más complicado que con los genéricos… "pelea legal" todavía en curso**

3. CONCLUSIONES

- **Modelos en Economía de la salud…**
  - **Todavía no hay muchas variantes. Ejemplos:**
    - **Grabowski *et al* (2008): competencia monopolística en la que diferenciación permite que bajada de precios no sea tan acusada como con los genéricos**
    - **Chauchan *et al* (2009): modelo de duopolio con diferenciación, en el que bajada del precio depende de cómo de sensible sea la demanda al precio**
  - **Evidencia empírica**
    - **Caídas de precio menores a las esperadas (Rovira et al, 2011) y sin datos independientes para validar resultados**

3. CONCLUSIONES

- **Factores a tener en cuenta en futuros modelos:**
  - **Evolución y aprendizaje de regulación**
  - **Aceptabilidad de biosimilares por los clínicos**
  - **Seguimiento de políticas de precios y reembolsos**
  - **<u>INCENTIVOS</u> tanto en demanda como oferta**
    - **¿Quién compra? ¿A qué precio? (hospital, médico, paciente, central de compras??)**
    - **¿Qué influye en la decisión de un clínico?**
      - **¿La relación del centro sanitario con la industria y sus ensayos clínicos?**
      - ***Compliance*… y la idea de mantener (CI) los tratamientos de pacientes crónicos fijos…**
    - **Marketing… necesario para que los productos sean conocidos**

3. CONCLUSIONES

- **Muchos obstáculos se encuentra industria de biosimilares para ser nicho de ahorro en gasto farmacéutico**

- **Pero, podrían jugar a favor del desarrollo de este mercado:**

  - El tiempo con lenta penetración (si continúa ocurriendo)

  - La obtención de datos y análisis de evaluación económica que compare biosimilar con su originador

  - La fabricación de biosimilares por empresas de marca

- **Hay investigación reciente cada vez mayor acerca de modelos de competencia y evaluación económica pero aún horizonte temporal pequeño (competencia en biosimilares es novedosa) y agencias reguladoras se basan excesivamente en AMC**

3. CONCLUSIONES

- **Con tiempo y una caña…**

  … los biosimilares *que muestren eficacia, seguridad… y coste-efectividad comparada* con los originales (retraso tras la pérdida de patente) impulsarán competencia, bajada en precios al menos moderada (menor que la de los genéricos) y darían <u>VALOR</u> al sistema sanitario