Productos biológicos aspectos económicos

Dr. Álvaro Hidalgo Vega

Comenzamos...

Analizando el peso de los biológicos en el mercado farmacéutico

Cuota de biológicos

- En EE.UU. en el año 2000 sólo uno de los 10 medicamentos más vendido era un biológico, mientras que en 2008 cinco de los 10 medicamentos más vendidos eran biológicos. (Blackstone and Fuhr, 2012).
- En 2011 esta tendencia se ha consolidado, ya que 10 de los 15 medicamentos más vendidos son medicamentos biológicos (Hoffman et al., 2012).
- A lo largo de 2012 se estima que las ventas totales de medicamentos biológicos se han incrementado un 8,2% en comparación a 2011, alcanzando los 117 miles de millones de U.S. dólares al final de 2012, representado el 13% del mercado farmacéutico mundial.
- Esta cifra se incrementará en 49 miles de millones de U.S. dólares hasta alcanzar al final de 2017 los 166 miles de millones de U.S. dólares de ventas totales de productos biológicos, lo que supondrá el 15% del mercado farmacéutico mundial (International Market Analysis & Research Consulting, 2012

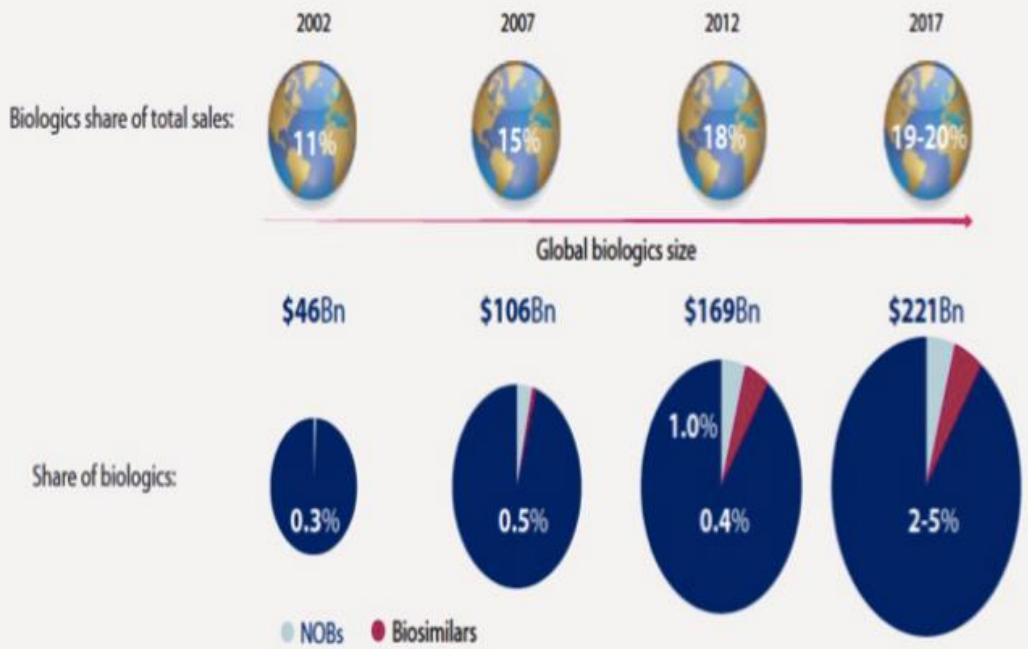
Areas tarapéuticas más importantes

Figura 1. Niveles de gasto farmacéutico estimados en 2017 por área terapéutica en los mercados farmacéuticos desarrollados y emergentes.

uente: (IMS Institute for Healthcare Informatics, 2013)

Cuota de mercado de los biológicos

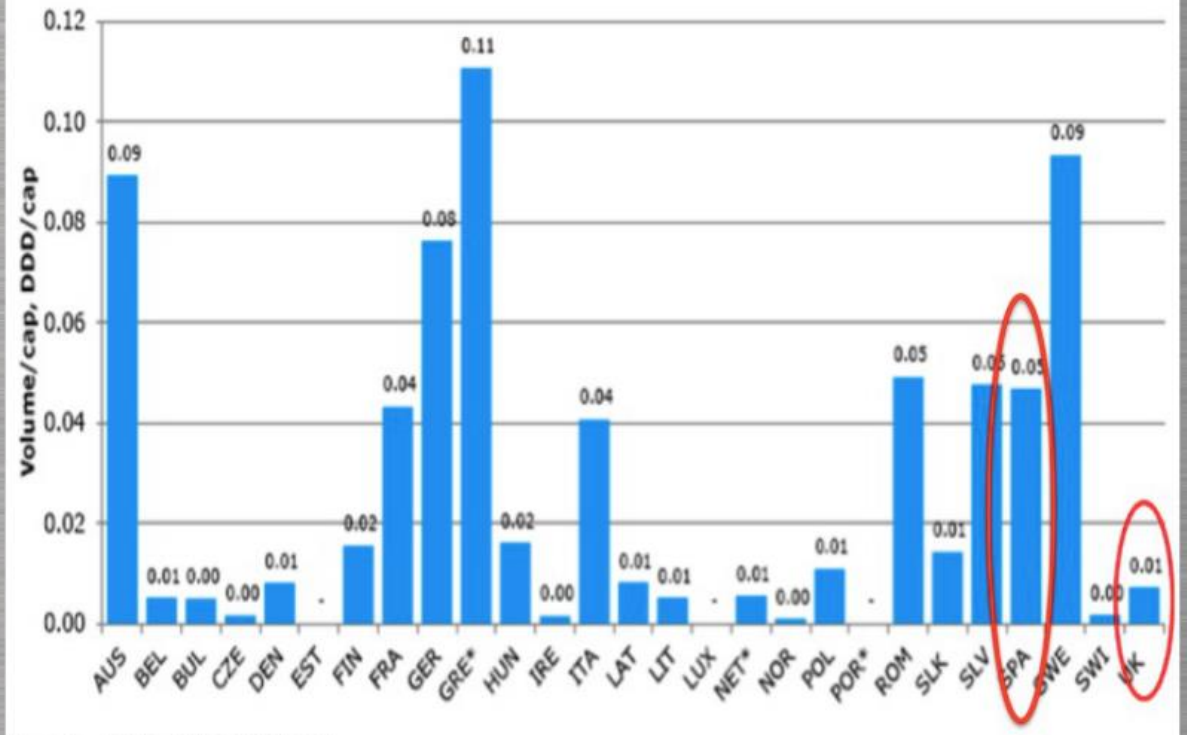
Figura 1. Porcentaje de ventas de los medicamentos biológicos como porcentaje del total del mercado farmacéutico: 2002 a 2017.



Fuente: (IMS Institute for Healthcare Informatics, 2013)

Biosimilares en Europa

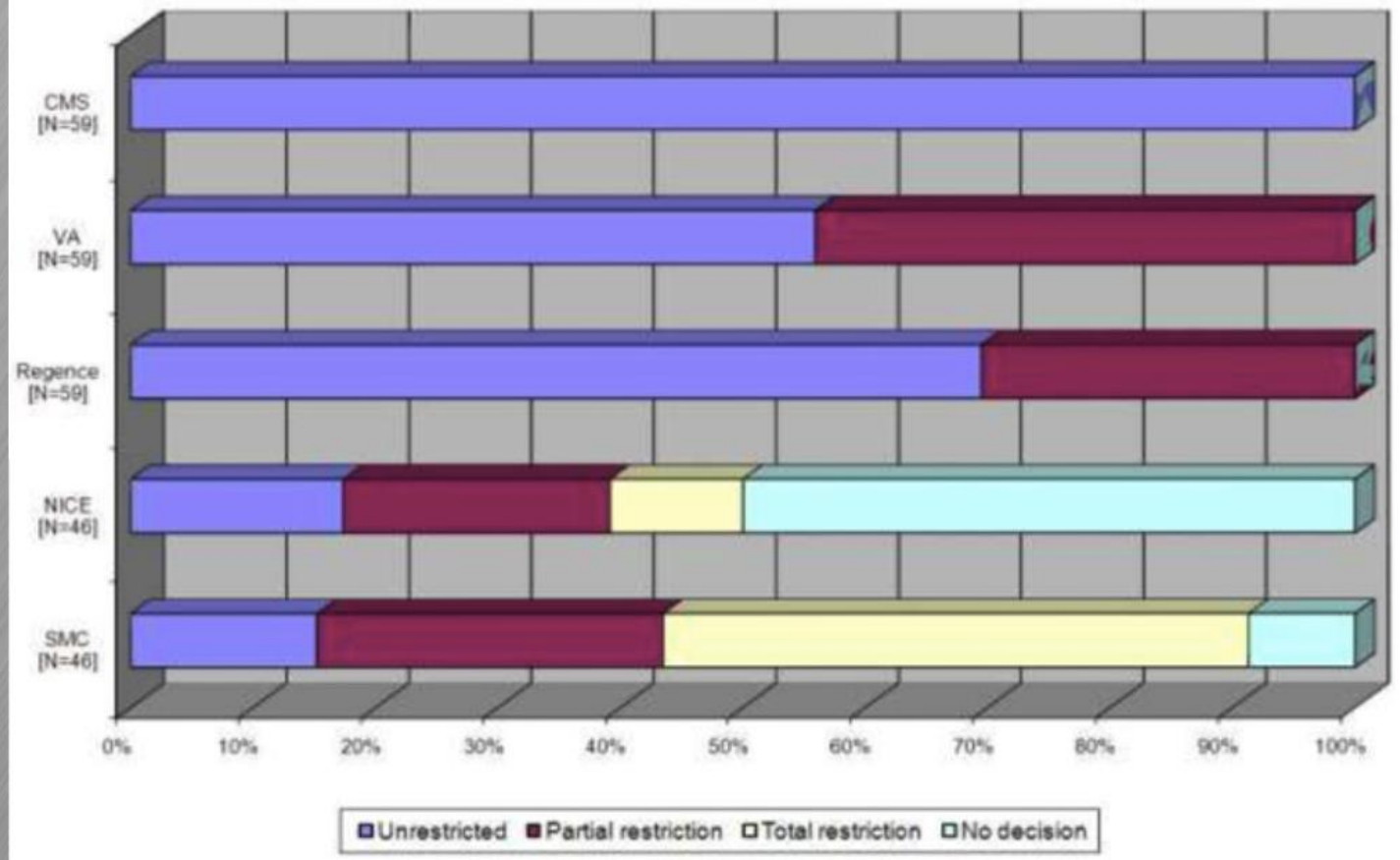
Figura 1 Mercado de biosimilares en Europa. Ranking de país por volumen. DDD



Fuente: IMS. MIDAS 2011


Aspectos claves
100
20
90
30
80
40

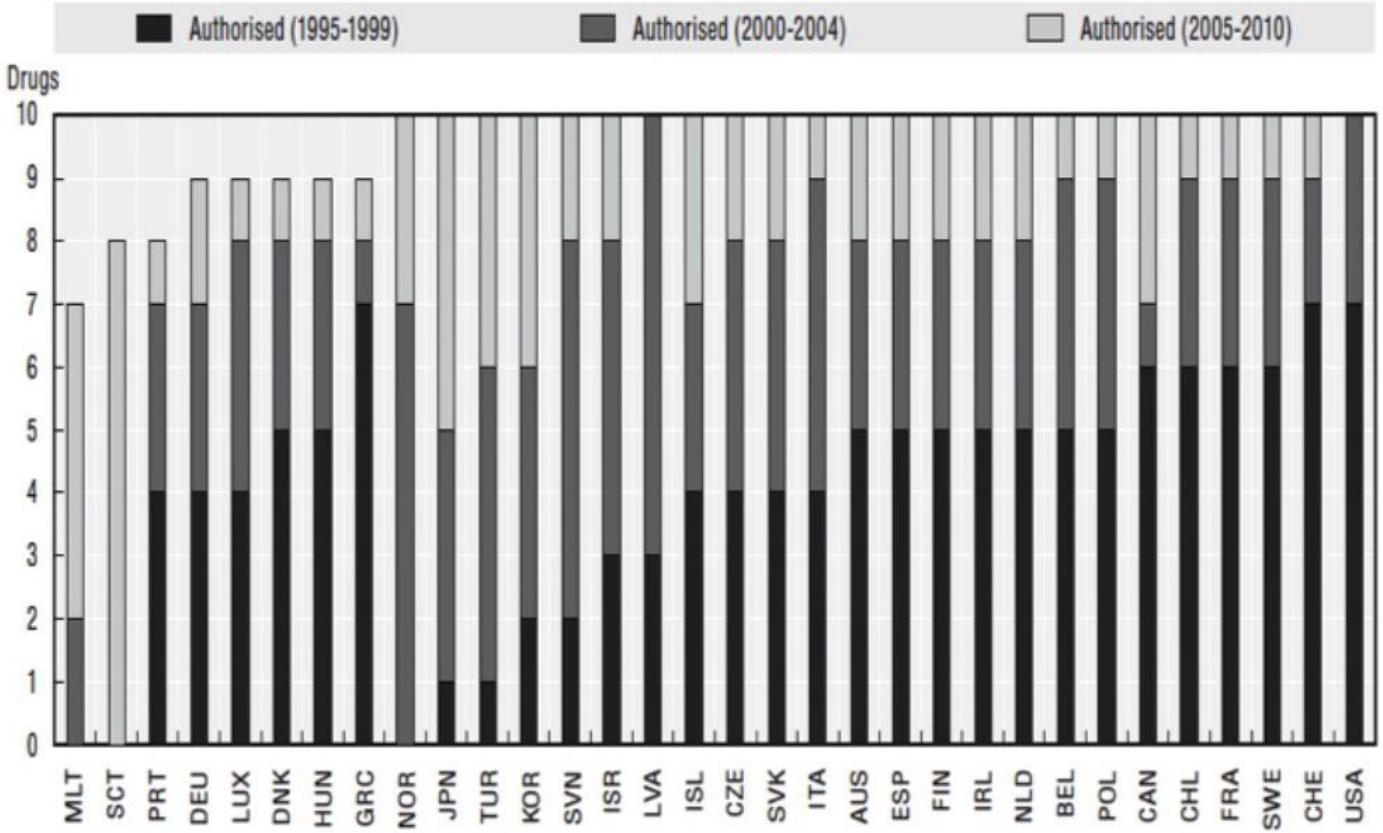
10 Acceso de los pacientes a los nuevos medicamentos



Source: Mason et al (2010)

Figure 4. Coverage restrictions for eligible anticancer drugs, FDA approved 2004 2008

Figure 2.1. **Years of authorisation for ten selected innovative cancer drugs**



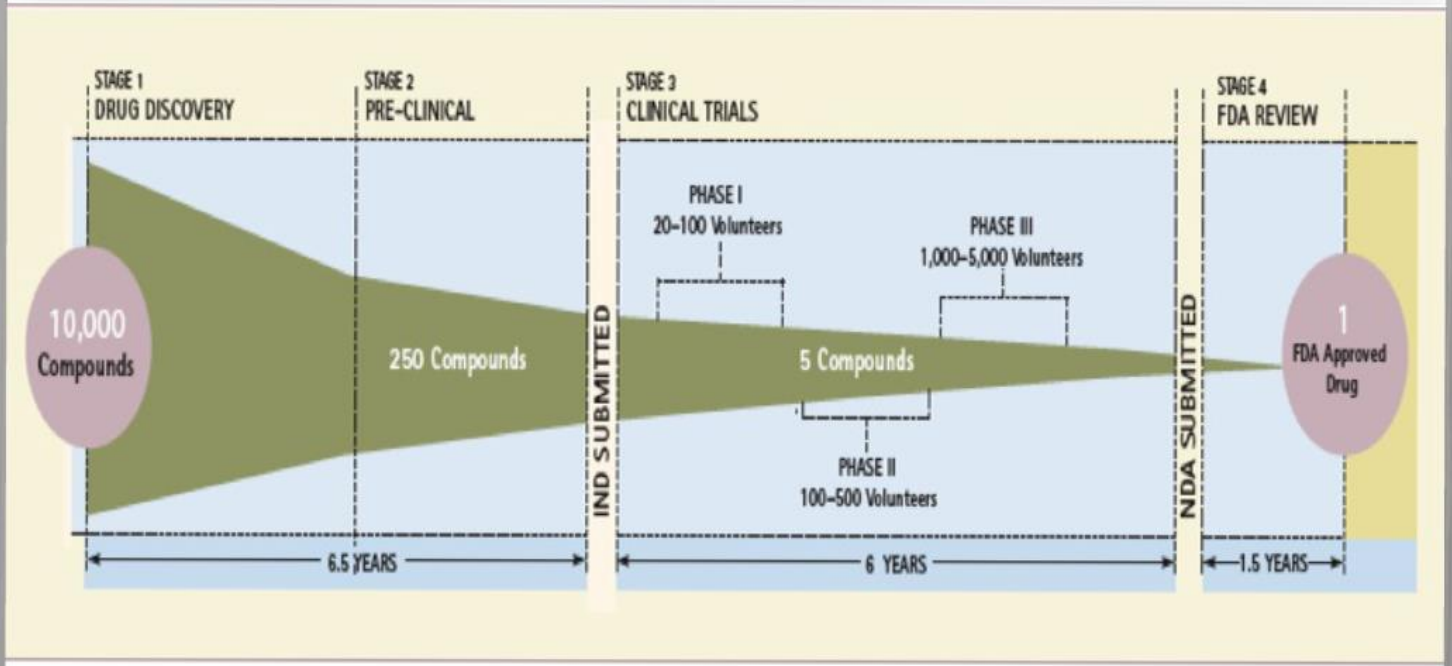
Source: OECD HCQI Questionnaire on Systems of Cancer Care.

StatLink http://dx.doi.org/10.1787/888932866526

20 El precio de los medicamentos biológicos es elevado, pero también lo es su valor

El desarrollo de nuevos fármacos

Un proceso largo y costoso



Source: www.innovation.org

1 nuevo medicamento = 1.000 millones de euros

Enfermedad de Alzheimer

Fármacos en investigación

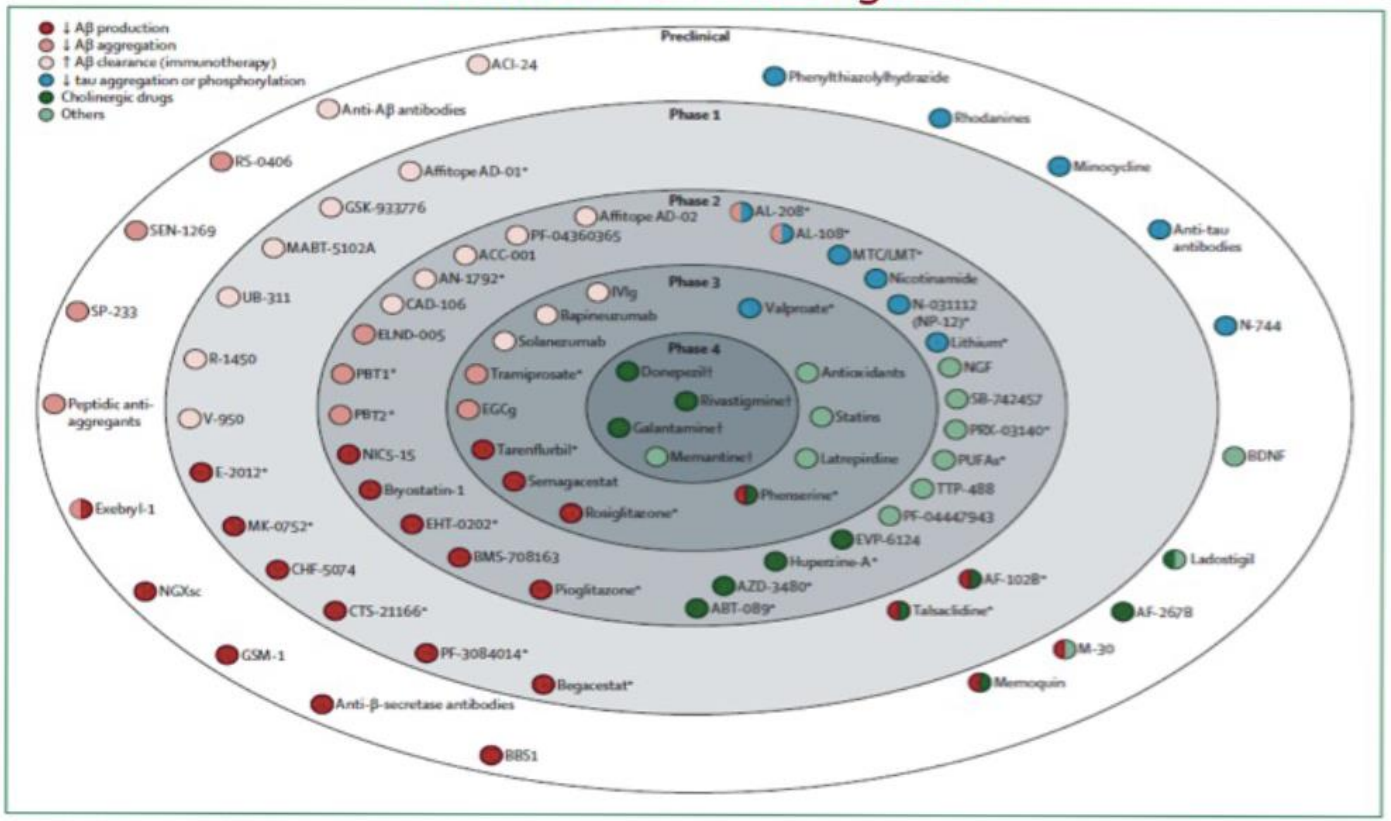
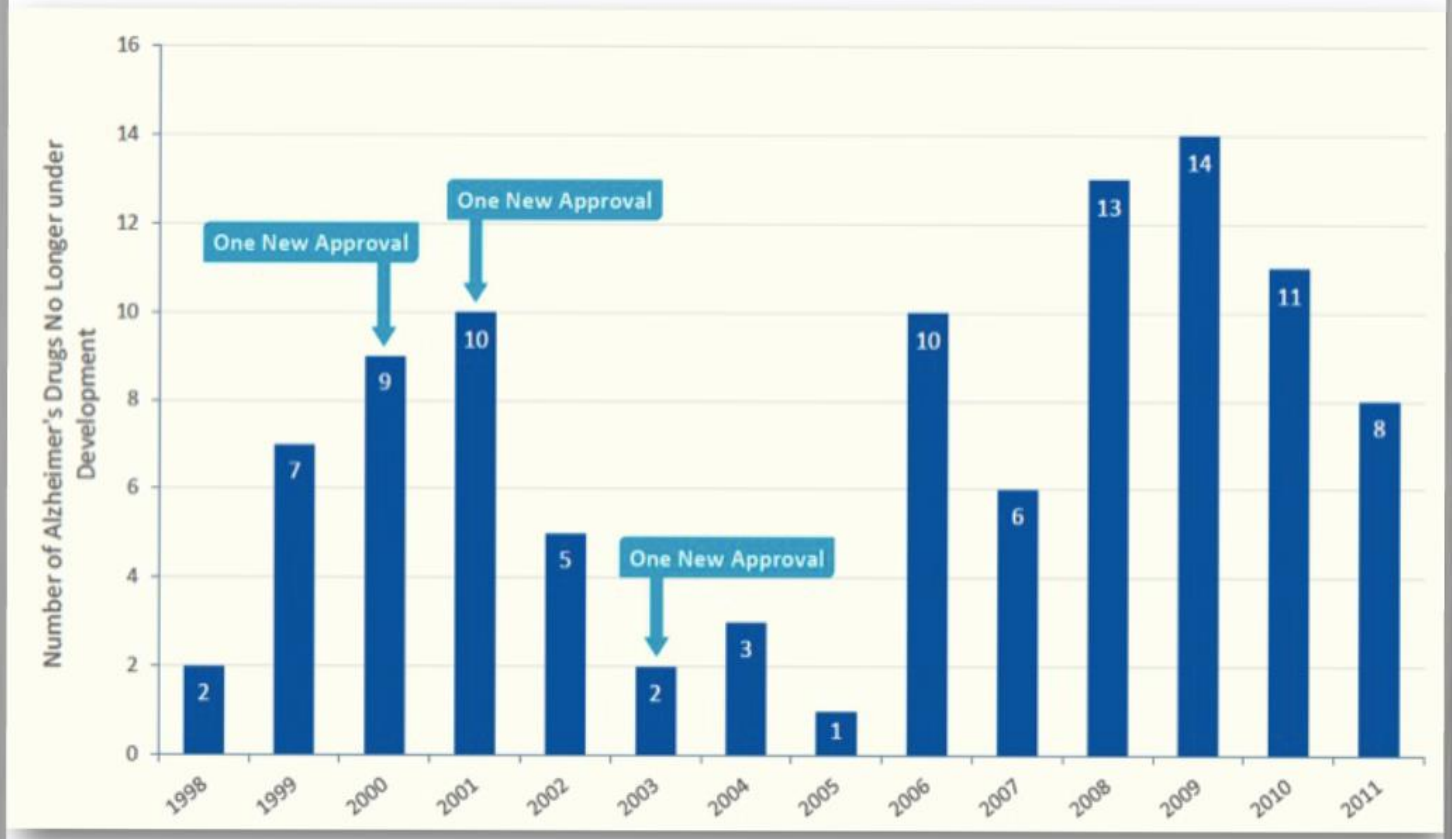


Figure: Drug development in Alzheimer's disease
Drugs being investigated for Alzheimer's disease therapy, reported according to the most advanced phase of study and main therapeutic properties (including data from studies in vitro and animal models). Aβ=amyloid β. BBS1=anti-β-site antibodies. BDNF=brain-derived neurotrophic factor. EGCg=epigallocatechin-3-gallate. IVIg=intravenous immunoglobulin. LMT=leuco-methylthioninium. MTC=methylthioninium chloride. NGF=nerve growth factor. NGXsc=NGX series compounds. PUFAs=polyunsaturated fatty acids. GSM=γ-secretase modulator. RCT=randomised controlled trial. *RCTs in Alzheimer's disease not ongoing. †Drugs approved for the treatment of Alzheimer's disease.

Enfermedad de Alzheimer: 100 fracasos en 13 años

Sólo algunos tratamientos sintomáticos



SOURCE: Pharmaceutical Research and Manufacturers of America. "Researching Alzheimer's Medicines: Setbacks and Stepping Stones." Washington, DC: PhRMA, September 2012. Available at http://phrma.org/sites/default/files/1864/alzheimersetbacksreportfinal912.pdf (accessed February 2013).

30

Para fijar el precio, la denominación es importantes desde el punto de vista de la economía

- Las ventajas de la diferenciación:
  - La competencia perfecta versus la competencia monopolística
  - El concepto de first-mover advantage
  - El modelo de Schmalensee sobre las ventajas del innovador


Kellogg's
CORN
FLAKES
The Sunshine Breakfast

40

Es importante empezar a introducir la dinámica en los análisis de evaluación económica

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VALUE IN HEALTH

The Economic Value of Innovative Treatments over the Product Life Cycle: The Case of Targeted Trastuzumab Therapy for Breast Cancer

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University of Washington, Seattle, WA, USA

ABSTRACT

Objective: Pharmacoeconomic analyses typically project the expected cost-effectiveness of a new product for a specific indication. This analysis develops a dynamic life-cycle model to conduct a multiindication evaluation using the case of trastuzumab licensed in the United States for both early-stage and metastatic (or late-stage) human epidermal growth factor receptor 2 (HER2)-positive breast cancer therapy (early breast cancer [EBC]; metastatic breast cancer [MBC]), approved in 2006 and 1998, respectively.

Methods: This dynamic model combined information on expected incremental cost-utility ratios for specific indications with an epidemiologically based projection of utilization by indication over the product life cycle—from 1998 to 2016. Net economic value was estimated as the cumulative quality-adjusted life years (QALYs) gained over the life cycle multiplied by a societal valuation of health gains ($/QALY) minus cumulative net direct treatment costs. Sensitivity analyses were performed under a range of assumptions.

Results: We projected that the annual number of EBC patients receiving trastuzumab will be more than three times that of MBC by 2016, in part because adjuvant treatment reduces the future incidence of MBC. Over this life cycle, the estimated overall incremental cost-effectiveness ratio (ICER) was $35,590/QALY with a total of 432,547 discounted QALYs gained. Under sensitivity analyses, the overall ICER varied from $21,000 to $53,000/QALY, and the projected net economic value resulting from trastuzumab treatment ranged from $6.2 billion to $49.5 billion.

Conclusions: Average ICERs for multiindication compounds can increase or decrease over the product life cycle. In this example, the projected overall life-cycle ICER for trastuzumab was less than one half of that in the initial indication. This dynamic perspective—versus the usual static one—highlights the interdependence of drug development decisions and investment incentives, raising important reimbursement policy issues.

Keywords: cost-utility analysis, economics, modeling, pharmaceutical pricing, product life cycle.

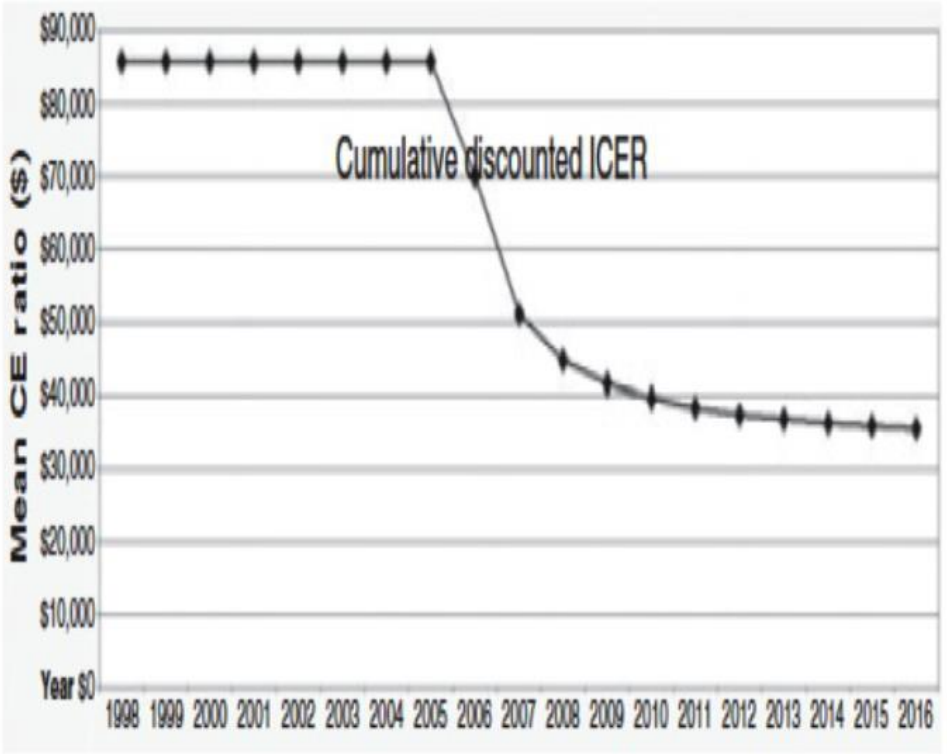

Figure 2 Cumulative, discounted life-cycle incremental cost-effectiveness ratio (ICER) for trastuzumab (1998$).

100

¿Los medicametos biológicos y biosimilares se pueden tratar de forma idéntica en las evaluaciones económicas?

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ClinicoEconomics and Outcomes Research

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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

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.

Targ Oncol (2012) 7:227–231
DOI 10.1007/s11523-011-0192-7

REVIEW

Biosimilars and market access: a question of comparability and costs?

Steven Simoens · Gilbert Verbeken · Isabelle Huys

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Abstract This article discusses specific issues related to the market access of biosimilars. Biopharmaceuticals are complex molecules produced by living cells. Copies of these medicines, called biosimilars, are not identical to their reference medicine and therefore specific regulatory requirements apply. When considering the use of biosimilars, the question of the degree of comparability between a biosimilar and the reference biopharmaceutical needs to be considered for registration, pricing and reimbursement purposes in addition to the cost issue. To date, many key concepts (like clinically meaningful differences) remain undefined and the question of the degree of comparability is not yet resolved.

biologics or biopharmaceuticals, obtained using living organisms like bacteria or yeasts. These compounds have revolutionized the treatment of many diseases such as anemia and diabetes. Since the early 1980s, legal protection through patents became available for these biological products allowing the original developer to recoup investment costs by a 20-year period of exclusivity. Examples are the first recombinant DNA products like insulin or human growth hormone. As the exclusivity periods and patent terms for the earliest biological products expire or are about to expire, copies of the original biologics (called "biosimilars" in Europe or "follow-on biologics" in the United States) are developed, requesting approval from the medicines agencies to rely on the safety and efficacy data

Hasta la fecha si analizamos las diferentes evaluaciones llevadas a cabo por diferentes agencias de evaluación:

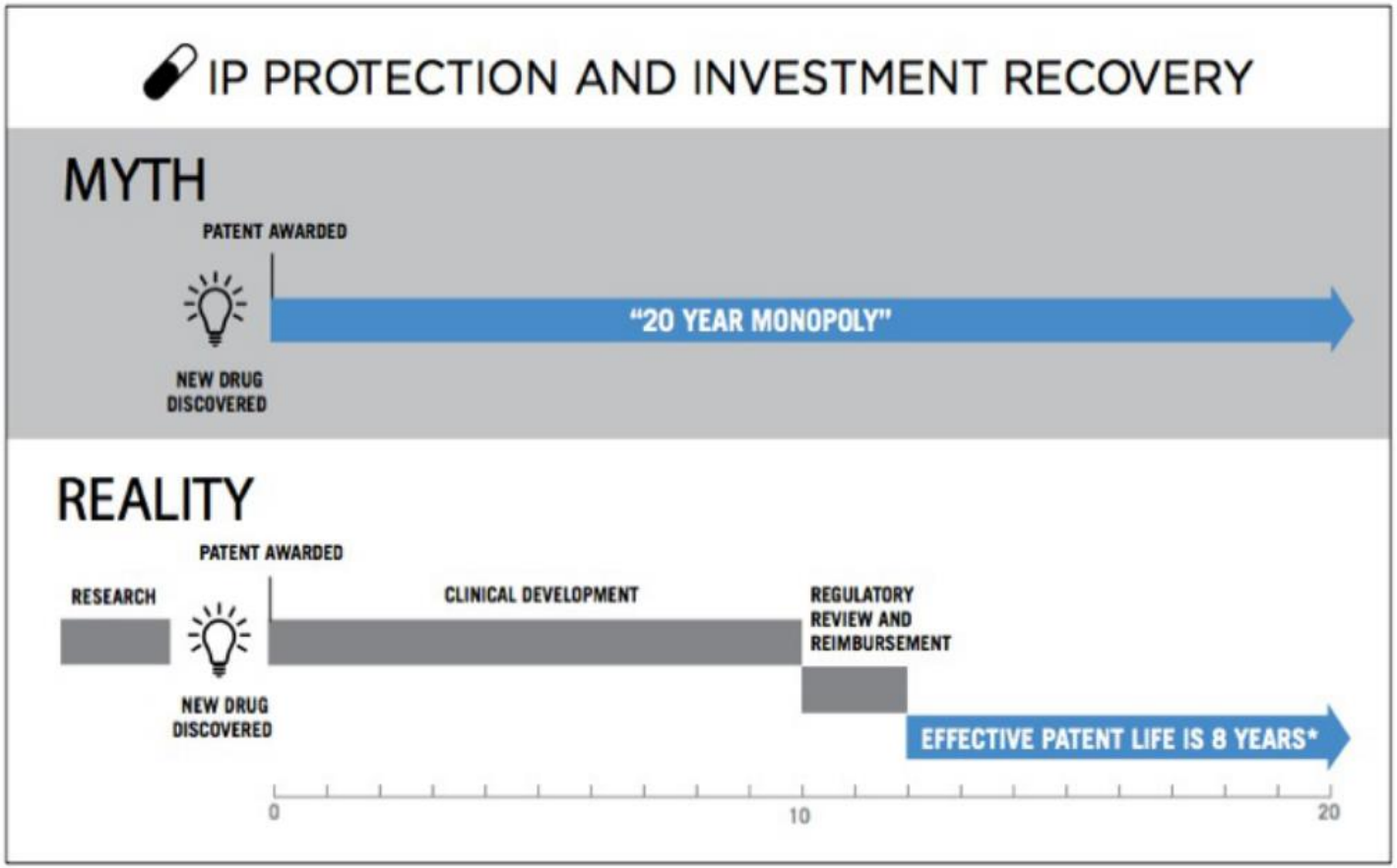
- tanto en el caso de la anemia (Scottish Medicines Consortium, 2010),
- como en el de la neutropenia febril (Scottish Medicines Consortium, 2009)
- o en el de la hormona de crecimiento (National Institute for Health and Clinical Excellence, 2010)

las agencias consideraron que los ensayos clínicos demostraban misma eficacia y las tres evaluaciones se realizaron mediante un AMC, recomendando en los tres casos el uso del medicamento biológico biosimilar frente al medicamento biológico innovador

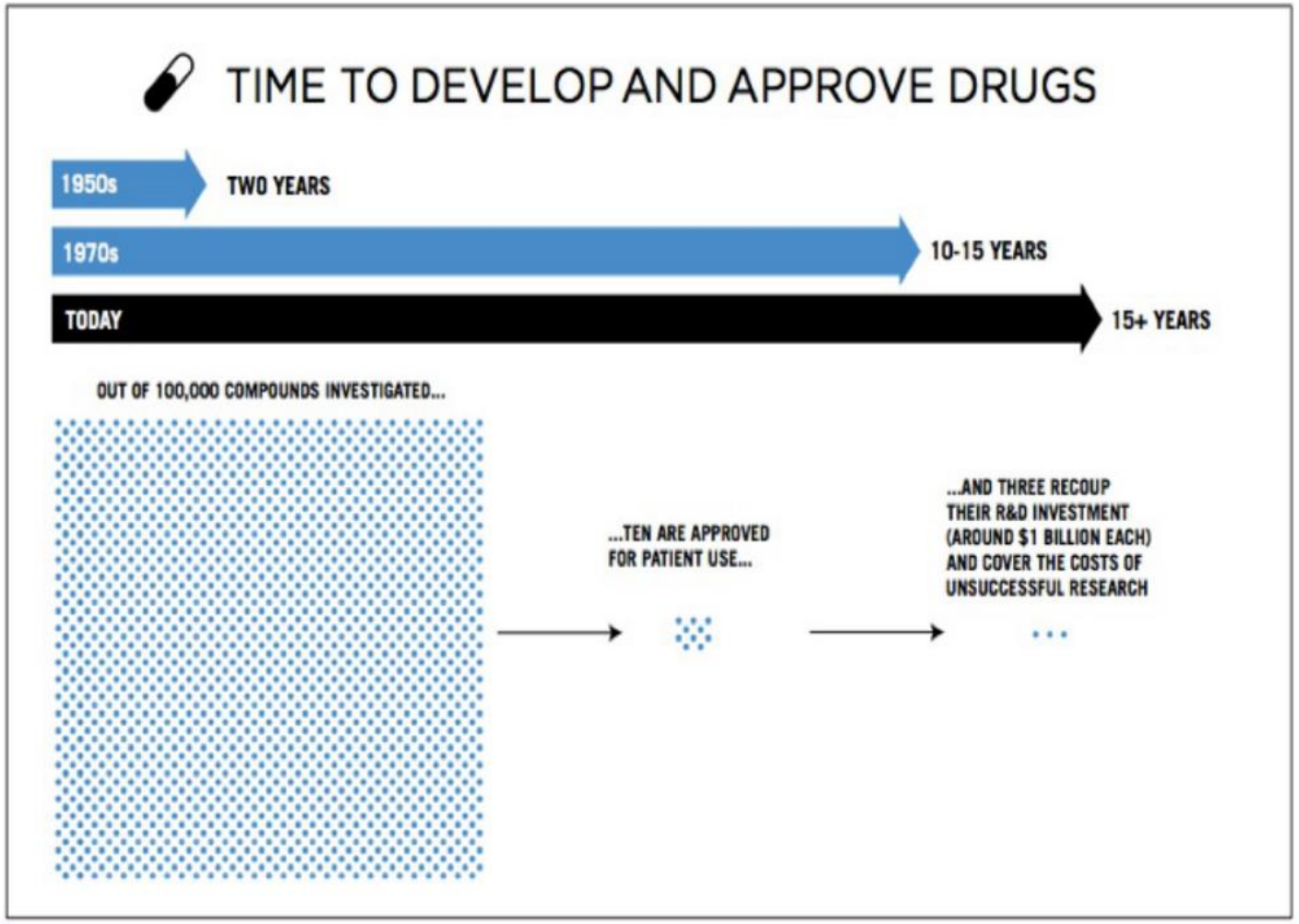

Comenzamos...
Analizando el peso de los biológicos en el mercado farmacéutico
Aspectos claves:
Algunas conclusiones
Cambio de mentalidad
Aspectos claves
Productos biológicos aspectos económicos
SiES
Instituto Max Weber

Debemos valorar el valor social y no los ICER

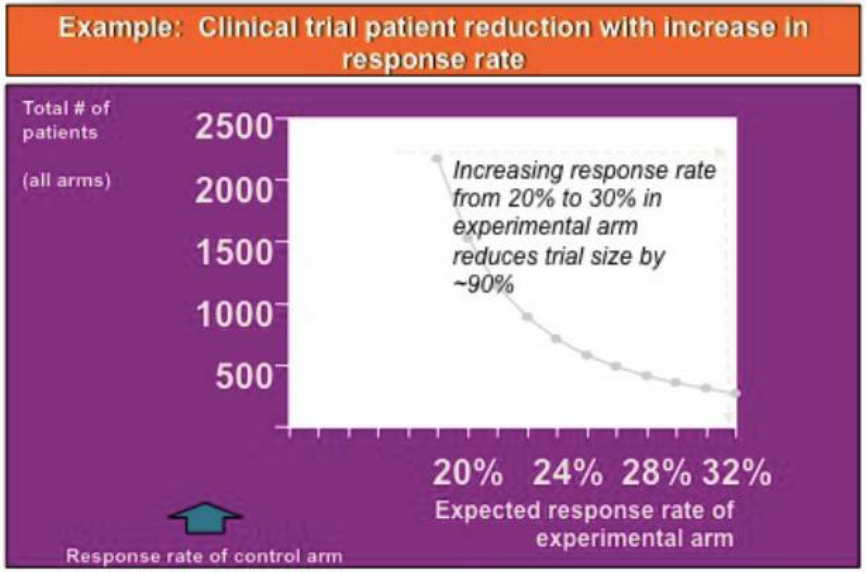

Fomentar la investigación
Favorecer la competencia
Desinvertir



* *Average year for market entry (Grootendorst and Di Matteo, "The Effect of Pharmaceutical Patent Term Length on Research and Development and Drug Expenditures in Canada," Healthcare Policy, 2007 February; 2(3): 63-84); the number can vary.*

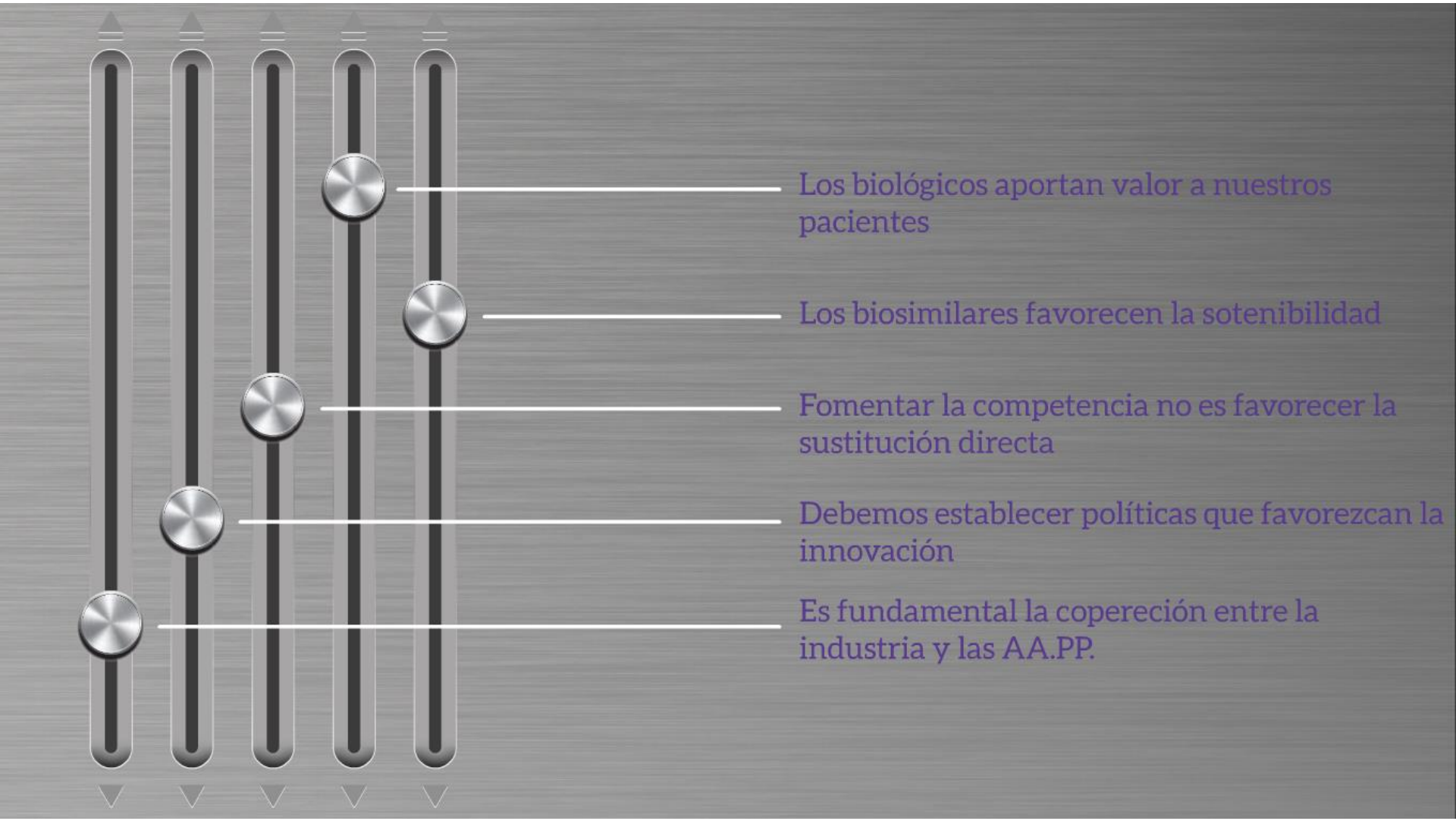

TIME TO DEVELOP AND APPROVE DRUGS
1950s
TWO YEARS
1970s
10-15 YEARS
TODAY
15+ YEARS
OUT OF 100,000 COMPOUNDS INVESTIGATED...
...TEN ARE APPROVED FOR PATIENT USE...
...AND THREE RECOUP THEIR R&D INVESTMENT (AROUND $1 BILLION EACH) AND COVER THE COSTS OF UNSUCCESSFUL RESEARCH

Using Pharmacogenetics to Improve Drug Safety and Efficacy



- Reducción de un 50% de pacientes en Fase II
- Reducción de un 10% de pacientes en Fase III
- Reducción de un 20% en la duración de los estudios Fase III
- Ahorros de hasta 500 millones $ por fármaco comercializado

Ginsburg y cols, Arch Intern Med, 2005


Los biológicos aportan valor a nuestros pacientes
Los biosimilares favorecen la sotenibilidad
Fomentar la competencia no es favorecer la sustitución directa
Debemos establecer políticas que favorezcan la innovación
Es fundamental la copereción entre la industria y las AA.PP.

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