Can EU citizens afford their medicines? The financial crisis and access to medicines in Europe"
High Level Meeting. The European Parliament

PANEL I: *"What can be done to reduce cost and increase equity in access?"*

Brussels, Thursday the 16th of May 2013

Joan Rovira, Professor Emeritus

University of Barcelona

Content

- Main impact of the crisis on health services access in Spain
- Options for a EU price regulation approach that ensures A2M, appropriate incentives to innovation and a fair contribution to the investment in biomedical R&D by EU countries

Main impact of the crisis on health services access in Spain

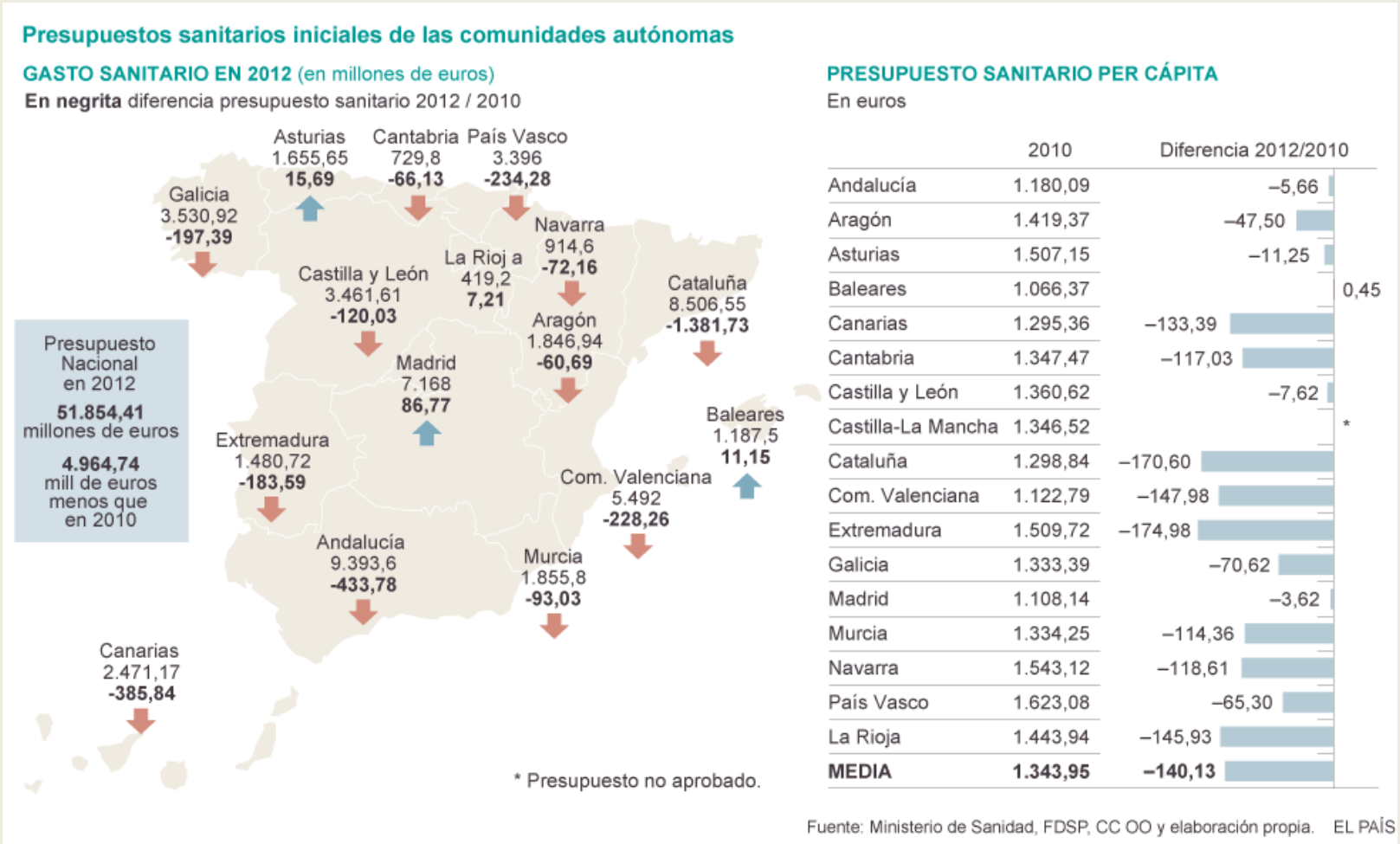
Main measures

- Royal Decrees 4/2010 and 8/2010, mainly aimed at reducing public expenditure on pharmaceutical and other health products.
- Decree Law 16/2012. It reduces overall health benefits, but specifically affects access of some disadvantaged population groups to health care
- Overall cuts in health care budgets (aprox 10% of previous level between 2010 and 2012).
- Introduction of new co-payments for medicines and other health care services.

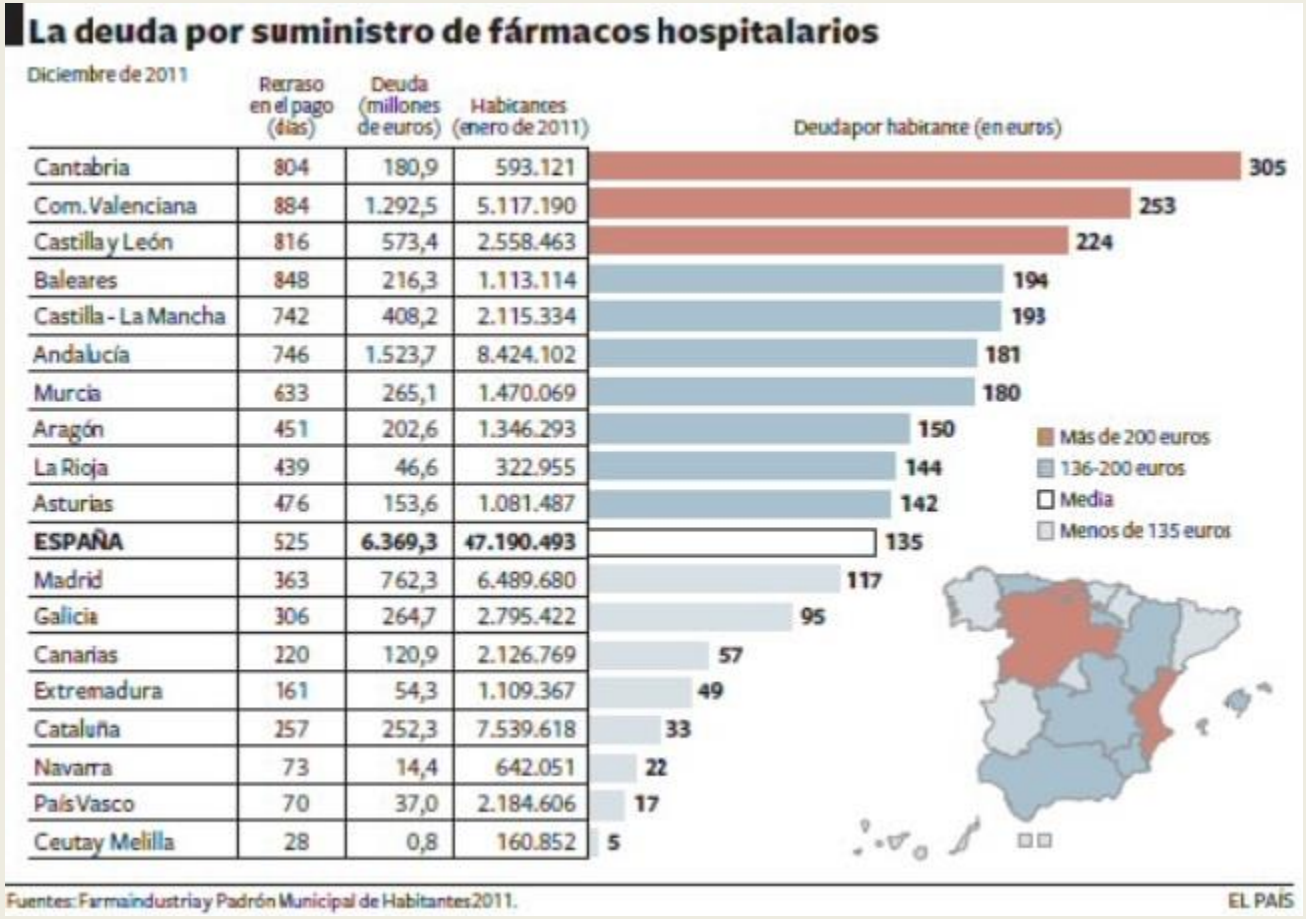
Out-Patient Pharmaceutical Expenditure in Spain

Year		In million Euros	Annual growth rate
2005		10.051,33	5,63
2006		10.636,06	5,82
2007		11.191,07	5,22
2008		11.970,96	6,97
2009		12.505,69	4,47
2010		12.211,10	-2,36
2011		11.135,40	-8,78
2012		9.770,77	-12,25

Reduction in health care budgets

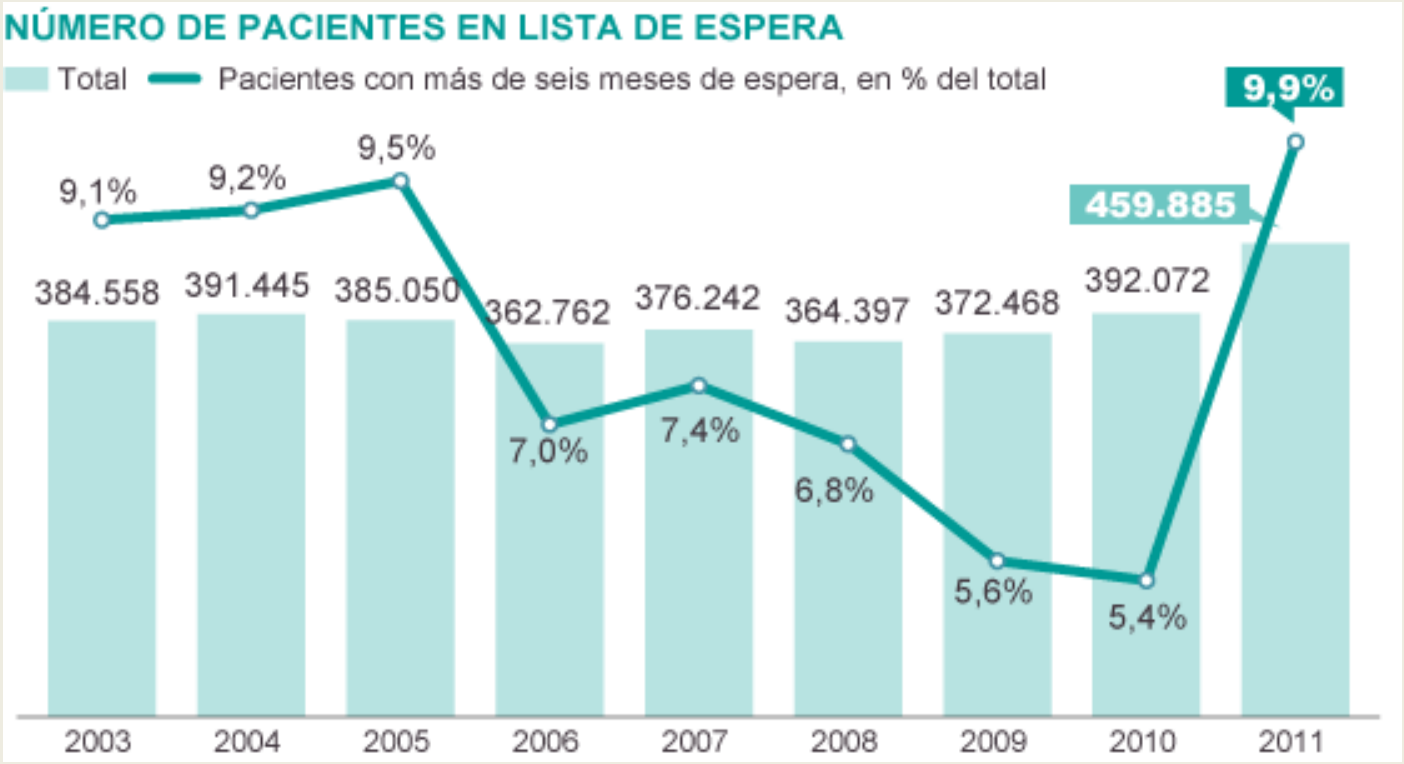


NHS payment delays and debt to health products suppliers



Font: Farmaindustria, Padró Municipal d'habitants 2011, El Pais 28/01/2012

Evolution of patients in waiting list



536.991 9,4%

Not comparable because a new region was added in 2012

Waiting time (months)	--	8,6	8,5	6,2	6,3	5,8	5,0	4,0	5,7	9,8
										2012

Source: Sistema Nacional de Salud

Royal Decree 16/2012

Urgent measures to guarantee the sustainability of the NHS and to improve the quality and safety of its services

The following groups are excluded from NHS-provided health care benefits

- 1. Irregulars immigrants with no work permit.
- 2. EU and EES + Switzerland which are not residents in Spain, and their dependent relatives.
- 3. National and foreign citizens with residence permit, aged over 26 and not having received in the past unemployment benefits, with and income above a level to be determined.

Emergency care up to discharge is however provided to everyone, as well as comprehensive care to those aged under 18 years.

Enferm Infecc Microbiol Clin. 2012;30(8):441–451

ELSEVIER DOYMA

Enfermedades Infecciosas y Microbiología Clínica

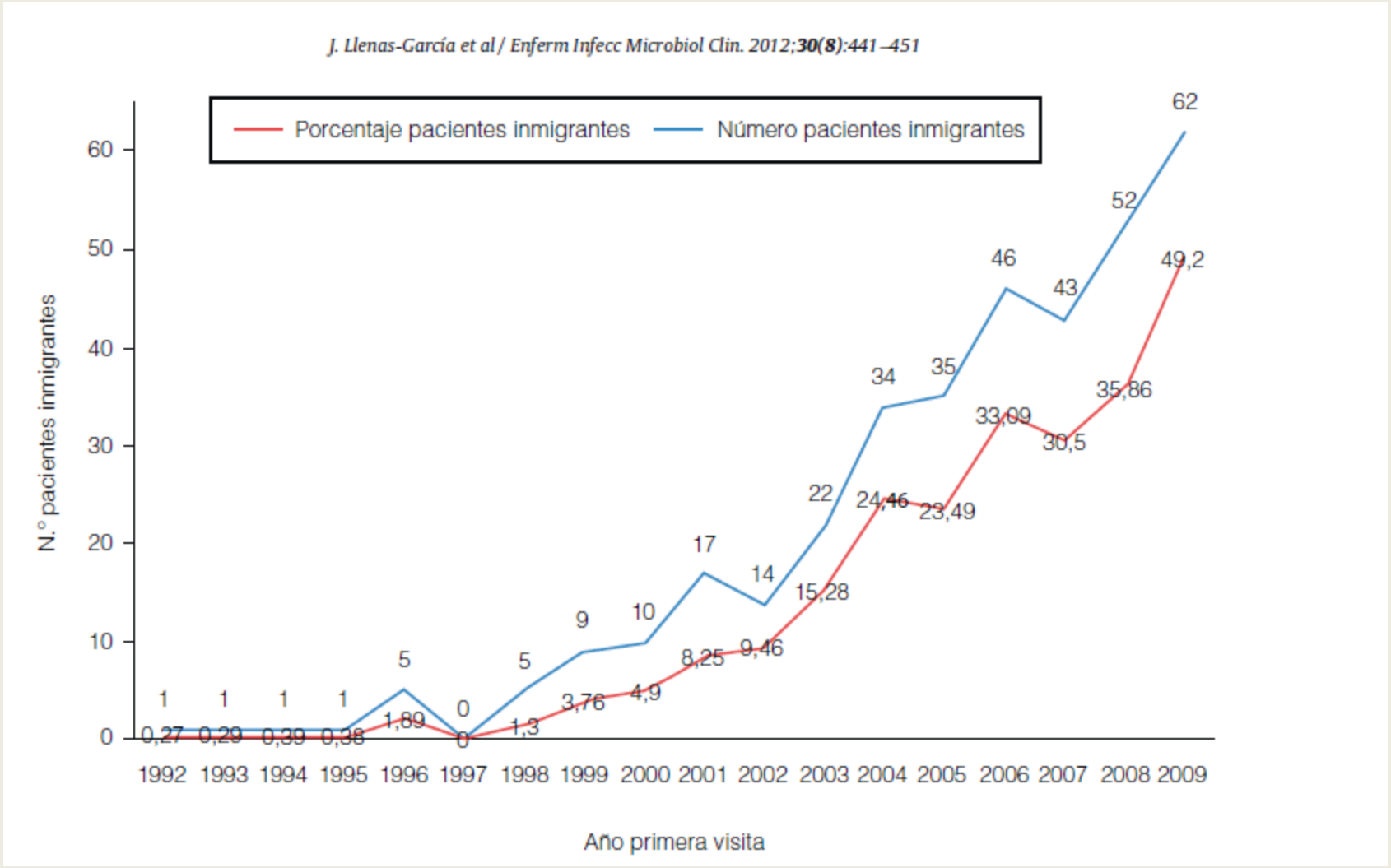
www.elsevier.es/eimc

Original

Características clínico-epidemiológicas de los pacientes inmigrantes con infección por el VIH: estudio de 371 casos

Jara Llenas-García[a,*], Rafael Rubio[a], Asunción Hernando[b], Silvana Fiorante[a,b], Diego Maseda[a], Mariano Matarranz[a], José Ramón Costa[a], Beatriz Alonso[a] y Federico Pulido[a]

[a] *Unidad VIH, Hospital Universitario 12 de Octubre, Madrid, España*
[b] *Departamento de Especialidades Médicas, Universidad Europea de Madrid, Madrid, España*


J. Llenas-García et al / Enferm Infecc Microbiol Clin. 2012;30(8):441–451
Porcentaje pacientes inmigrantes
Número pacientes inmigrantes
N.° pacientes inmigrantes
Año primera visita
1992 1993 1994 1995 1996 1997 1998 1999 2000 2001 2002 2003 2004 2005 2006 2007 2008 2009
1 1 1 1 5 0 5 9 10 17 14 22 34 35 46 43 52 62
0,27 0,29 0,39 0,38 1,89 0 1,3 3,76 4,9 8,25 9,46 15,28 24,46 23,49 33,09 30,5 35,86 49,2

Estimated effects and implications of Royal Decree 16/2012

- It has been estimated that between 2.700-4.500 HIV+ patients would be left unattended, resulting in 324-580 additional infections per year.
- The potential direct treatment costs “saved” (8,500€ per person-year) likely to be overcome by the additional expenditure in emergency care.
- The measure implies the abandonement of the present model of universal care as a right for the whole population (established by the 1986 Health Bill), and the return to the previous model of employment-based insurance
- Some regions and groups of health professionals do not comply with the new rules

Sources of information

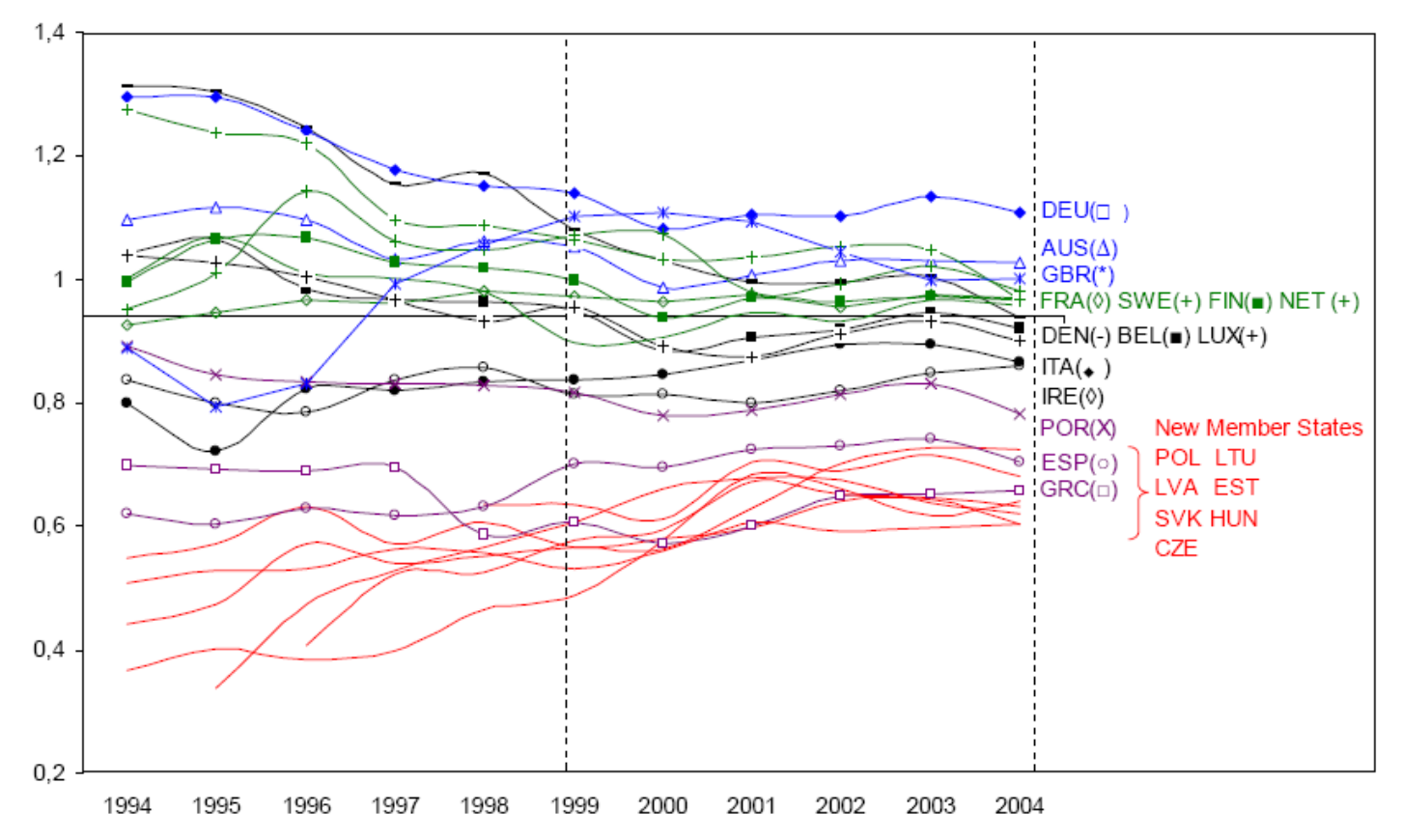
- The Observatory on the Impact of the Crisis on Health of the Andalusian School of Public Health provides a systematic repository of the literature and sources of information on the impact of the crisis on health in Spain and elsewhere:
- http://www.easp.es/es/content/recursos/impacto-de-la-crisis-en-la-salud

Options for a EU price regulation approach that ensures A2M, appropriate incentives to innovation and a fair contribution to the investment in biomedical R&D by EU countries

Present situation

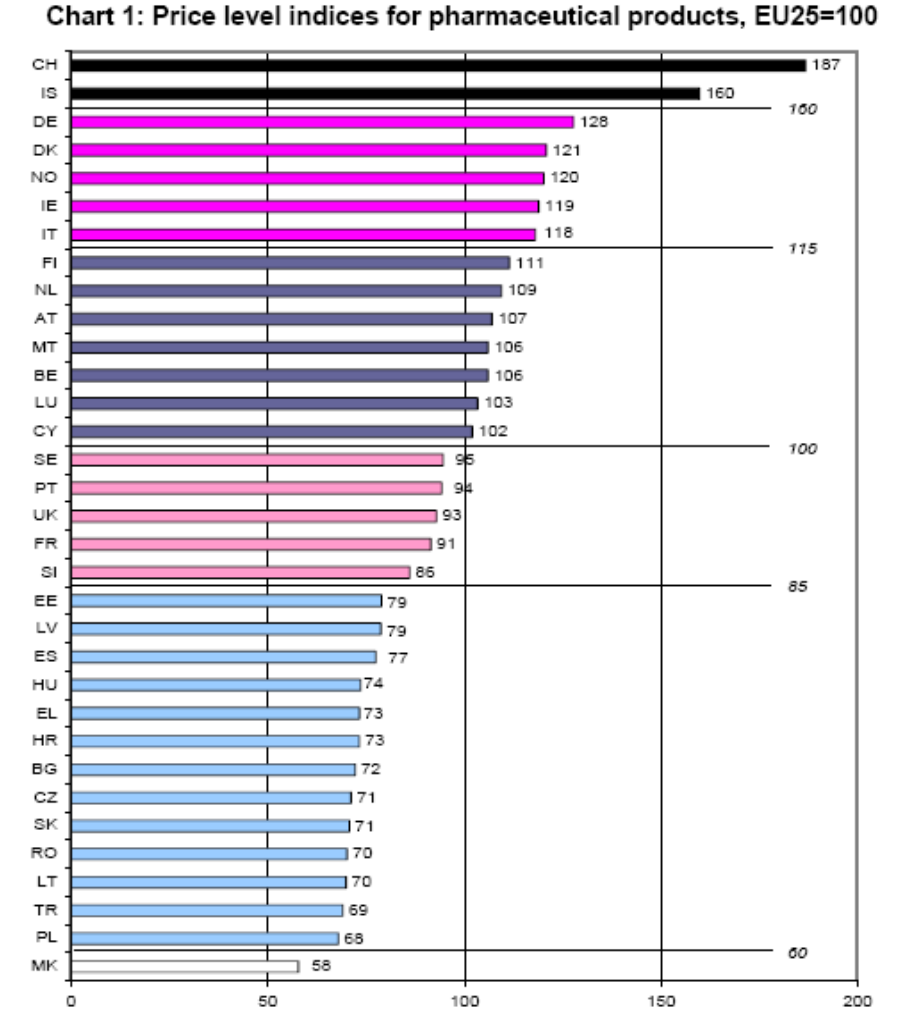
- Two main approaches in the EU to regulate the price of new products under market exclusivity:
  - P&R remains a responsibility of national authorities
  - External/international reference pricing
  - Value based pricing (cost-effectiveness criterion)
- The effects on the structure of medicine prices in the EU are:
  - Price convergence; higher income countries likely to obtain lower actual prices (non-affordability/inequity)
  - Delays in launching (or absolute unavailability of certain drugs) in some lower income countries
  - Non-disclosure and hence no reliable information on actual transaction prices, rendering ERP unpredictable and unaccountable; probably useless.

Price Convergence UE 25 (1994-2005)



Fuente Commission staff working document, accompanying the communication from the commission. "Economic reforms and competitiveness. Key messages from the European Competitiveness Report 2006" (com (2006) 697 final)

Price Convergence



PRICE

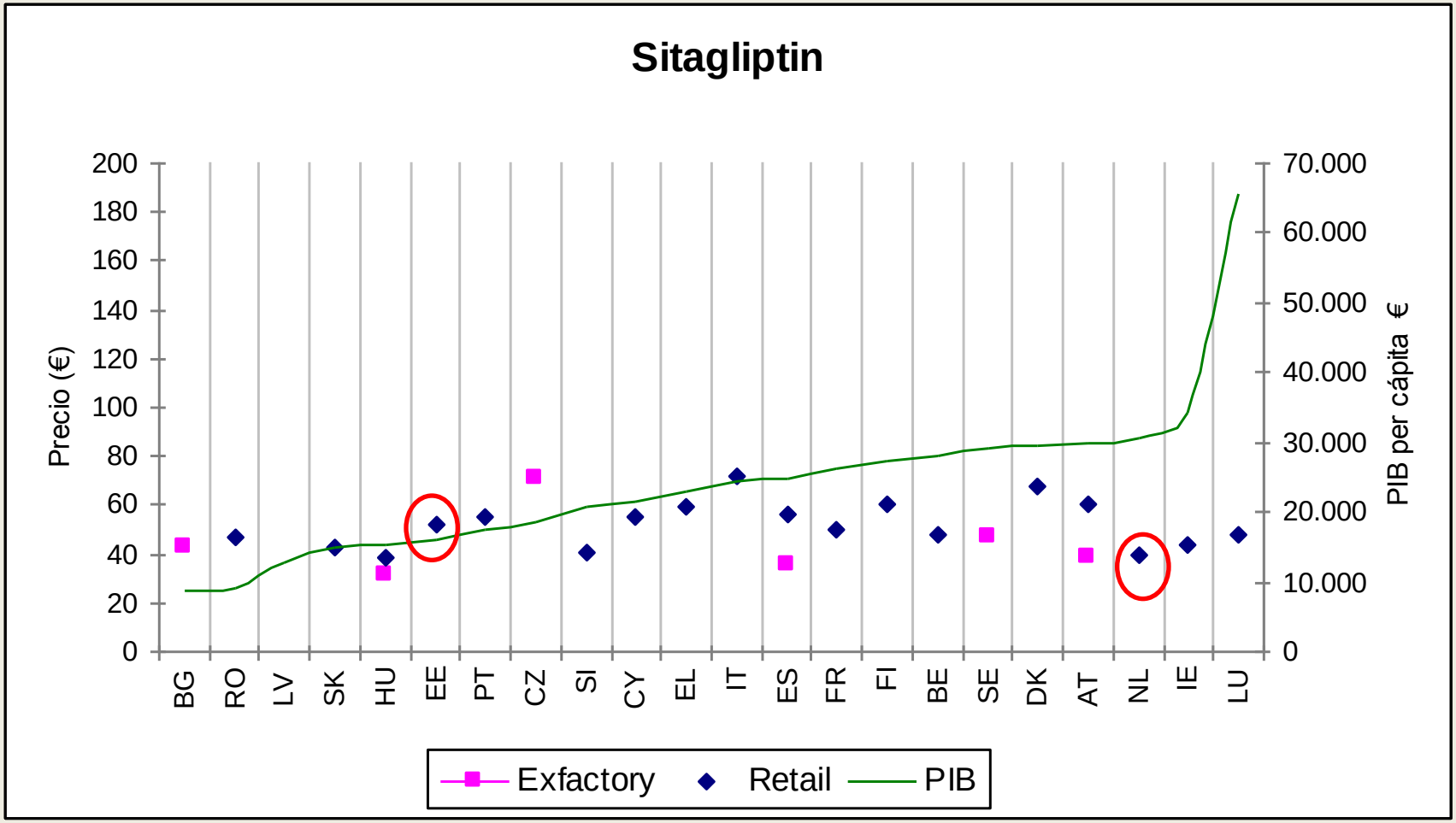
X 2

GDP PER CAPITA

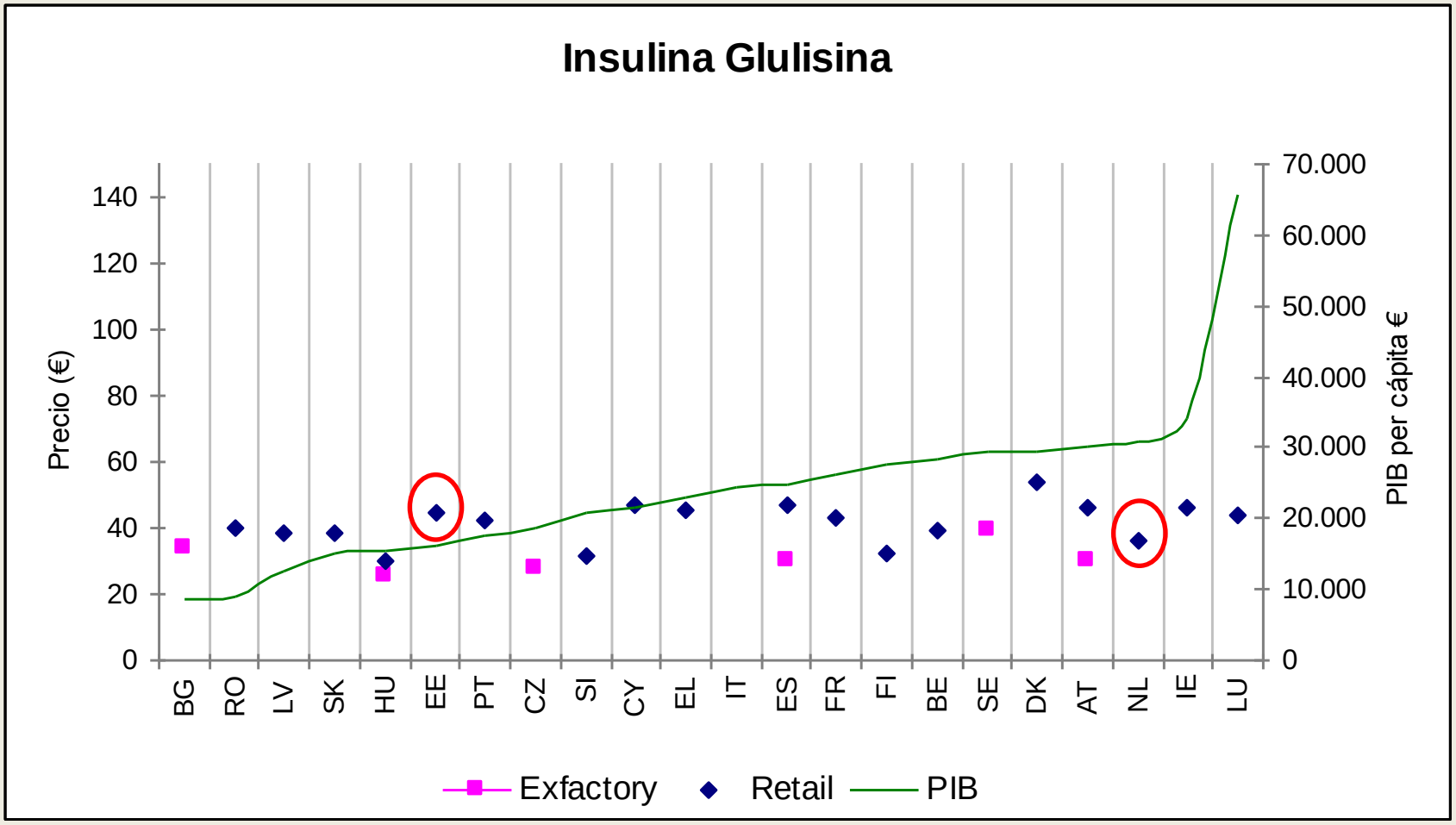
X 17

SO, WHAT ABOUT AFFORDABILITY?

Source: Eurostat-OECD 2007



Fuente: Elaboración propia con datos oficiales de las web de los Ministerios de Salud



Fuente: Elaboración propia con datos oficiales de las web de los Ministerios de Salud

Assumptions, principles and requirements of a fair an efficient EU price regulation system

- (Biomedical) Innovation is a global public good.
- All (EU) citizens should have an equitable access to health care and to medicines, including innovations.
- (Private) innovators require appropriate incentives, mainly, the possibility of recovering the total R&D investment and earning a risk-adjusted profit.
- Patents and other IPR link the incentive to the high monopolistic prices that can be often set by the IPR holder on the commercially successful products.
- A consensus is required on what would be the fair contribution of each country in exchange for universal access to biomedical innovation.

Option 1: Delinking incentives to innovate from marketing exclusivity and monopoly rights

- Determination of needs-based, social priorities in biomedical innovation
- Determining the annual budgets/resources for biomedical innovation (at national or international level)
- Distribution of the innovation budget among innovations according to (therapeutic/social) added value
- Production under generic competition from market launch

Option 2: introducing appropriate price regulation of products under exclusivity

- Determination of needs-based, social priorities in biomedical innovation
- Countries can apply VBP, using an EU-wide agreed national ICER threshold, related to their GDP per capita.
- Countries not able or willing to independently apply VBP, use ERP based on a basket of countries that use VBP, and adjust the resulting basket price by the relative GDP per capita of the country/basket.
- Lower actual prices in lower income countries implemented by means of discounts/rebates on national consumption in order to limit spillover effects of ERP and parallel trade.

Option 2 (cont)

- Objective and transparent discounts could be accorded (for transaction size, annual volume of sales, paying conditions, etc)
- Total cost of innovation might be open-ended or adjusted a posteriori by rising/lowering ICER threshold structure
- In the absence of EU-wide agreement on the fair distribution of R&D costs (i.e. national ICER thresholds or income-related price differential) countries might decide to apply it individually (or by clusters). If the right holders do not accept marketing the product at the maximum price set, countries could make use of compulsory licenses.

Comparison between Options 1 and 2

- Theoretical advantages of Option 1 include: more direct link between priorities and incentives, less incentive/ability for manufacturers to promote excessive (inefficient) use of innovations, incentives to early reductions in costs of production, less interventionist approach, easier to control expenditure, …
- Exclusive or complementary options?
- Relative political feasibility (Radicality, retrosprectivity, likely opposition by big pharma and developed countries)

Two examples showing that effective regulation of prices is and will not be welcome by big pharma

Australia was the first country to apply CEA to P&R of pharmaceuticals. Impact of the Australia—US Free Trade Agreement on Australian Medicines Regulation and Prices *Journal of Generic Medicines: The Business Journal for the Generic Medicines Sector January 2010 7: 18-29,*

Comment of most recent 301 Report, linking price regulation and IP

"The value of IP protection should not be undermined by discriminatory market access barriers, including discriminatory government pricing and reimbursement policies. We welcome USTR's recognition of market access barriers faced by U.S. pharmaceutical companies and their efforts to eliminate them in many countries in order to provide for affordable health care today and support the innovation that assures improved health care tomorrow."

PHRMA STATEMENT ON 2013 SPECIAL 301 REPORT WASHINGTON, D.C. (May 1, 2013)

Main recommendations

- Universal affordable access to socially-needed biomedical innovation should be the main goal.
- To promote a broad debate and consensus on the fair distribution of the cost of biomedical R&D among EU countries and beyond.
- To require full transparency at all levels: efficacy and safety, transaction prices, authorisation and P&R procedures and decisions, negotiation of trade agreements, financial links between the industry and the prescribers, etc.
- To support simultaneously more radical changes of the business model (delinking prices from incentives for innovation) and better use of P&R approaches and competition policies for products under market exclusivity.