

Policies beyond the crisis & lessons learned

The Greek case

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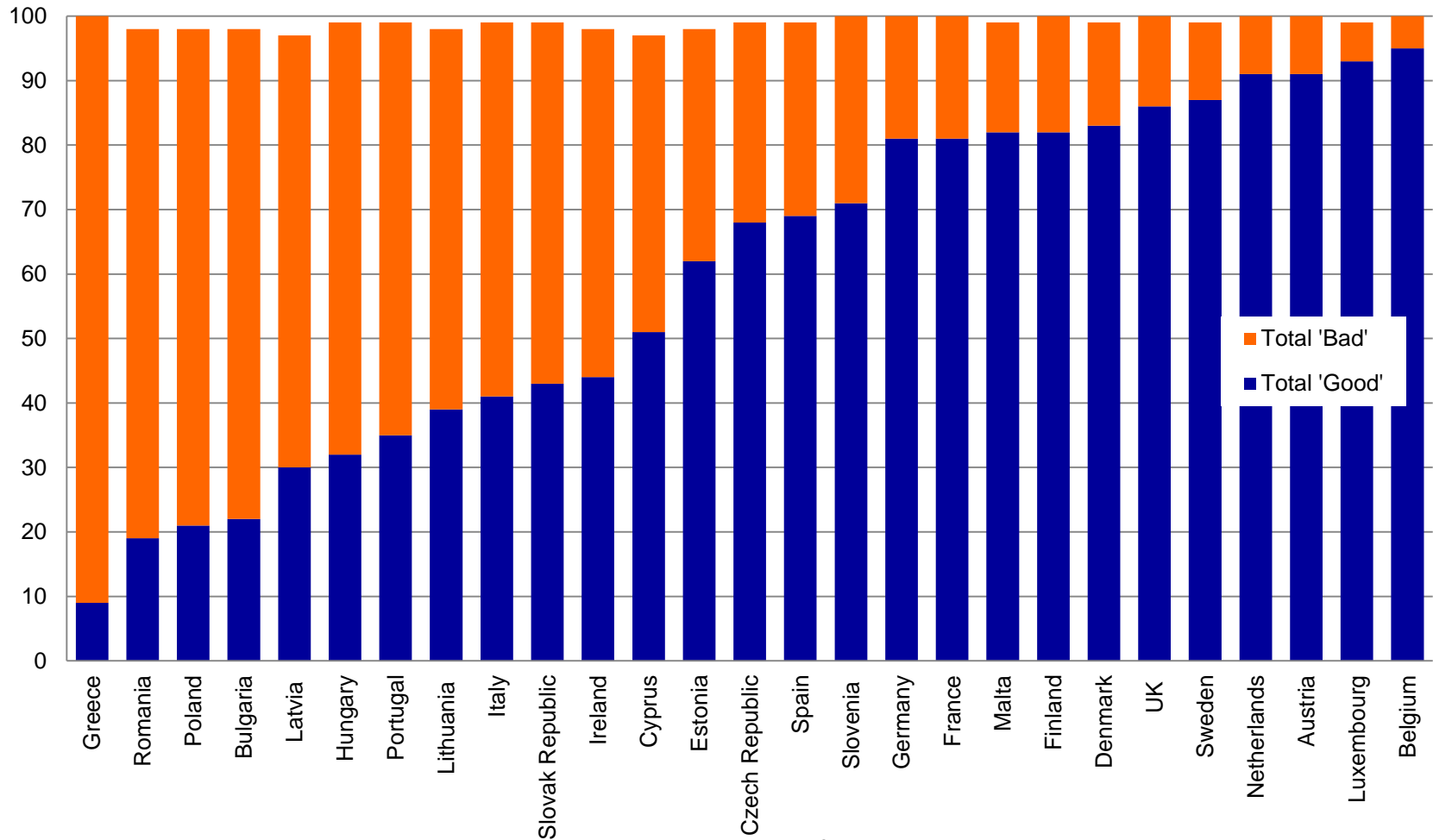
3rd PPRI conference, Vienna, 13 October 2015

Outline

- How did we get there?
- Priorities for reform
- Progress made: pharmaceutical policy
- Lessons learned

How did we get there?

Satisfaction with health care provision

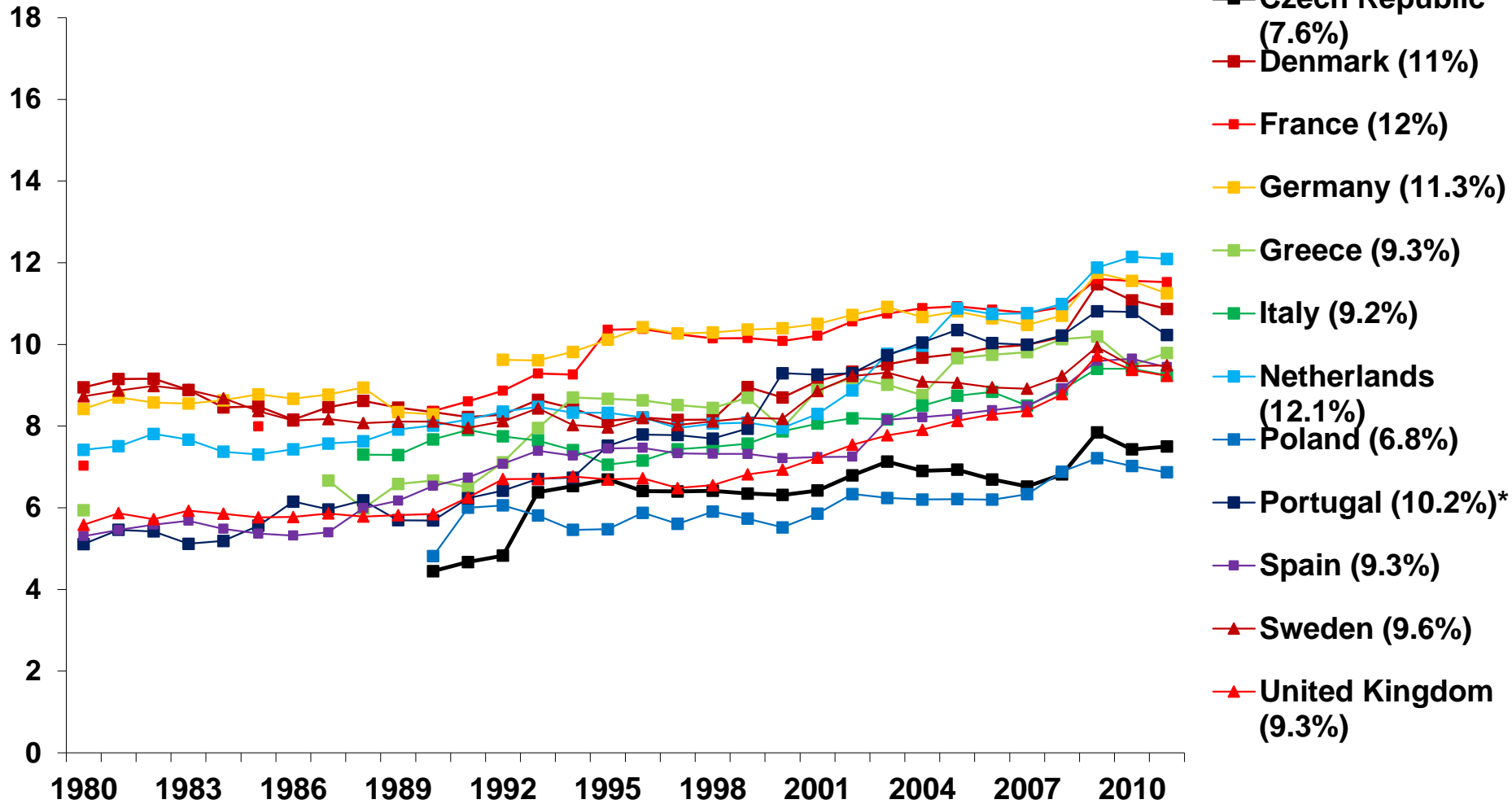


Note: Depicts how Europeans perceive the current situation of healthcare provision in their country. Possible answers included: “very good”, “rather good”, “rather bad”, “very bad”, “don’t know”. We summarised positive and negative responses under “total bad” and “total good”.

Source: Eurobarometer, 2012.

Health Care Spending as a Percentage of GDP, 1980–2012

Percent



* 2011

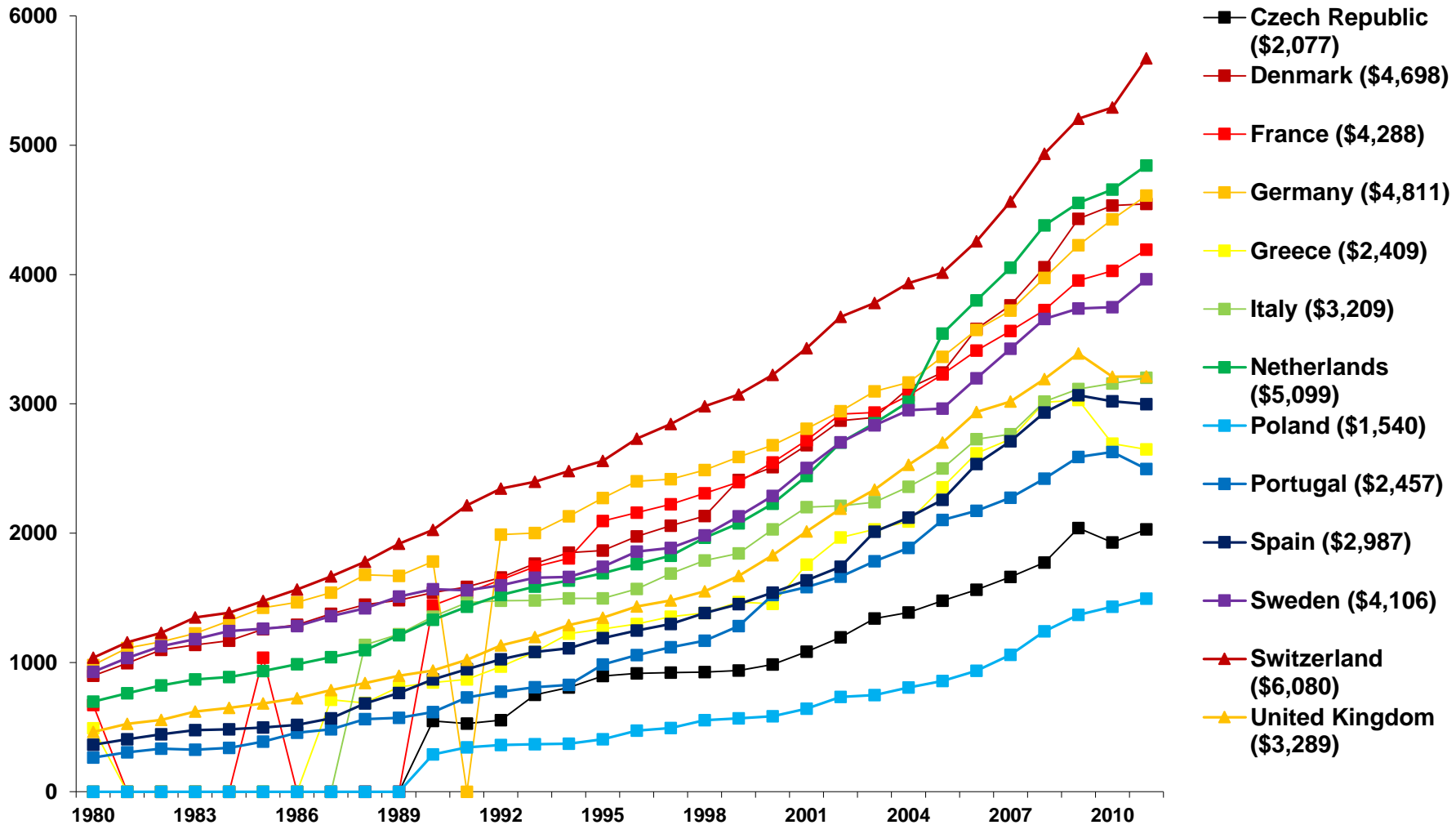
GDP refers to gross domestic product.

Source: OECD Health Data 2014.

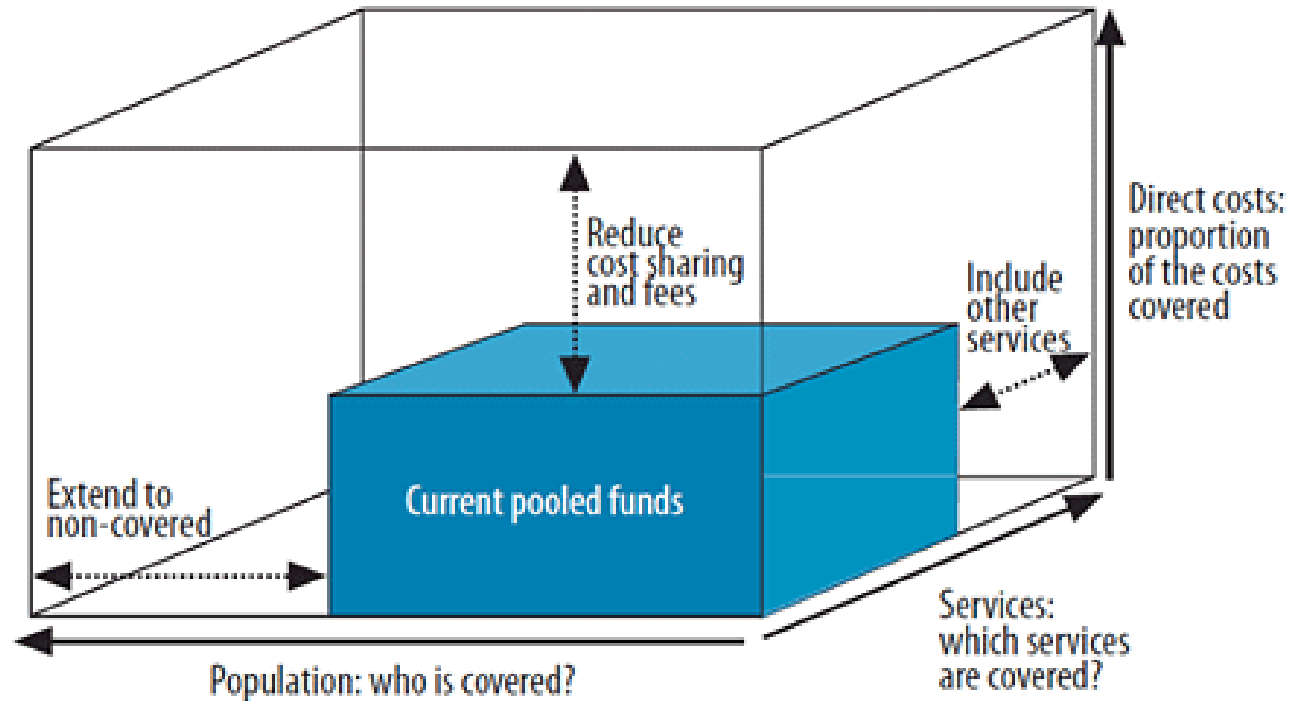
Average Health Care Spending per Capita, 1980–2012

US\$ purchasing power parity (PPP)

\$US PPP

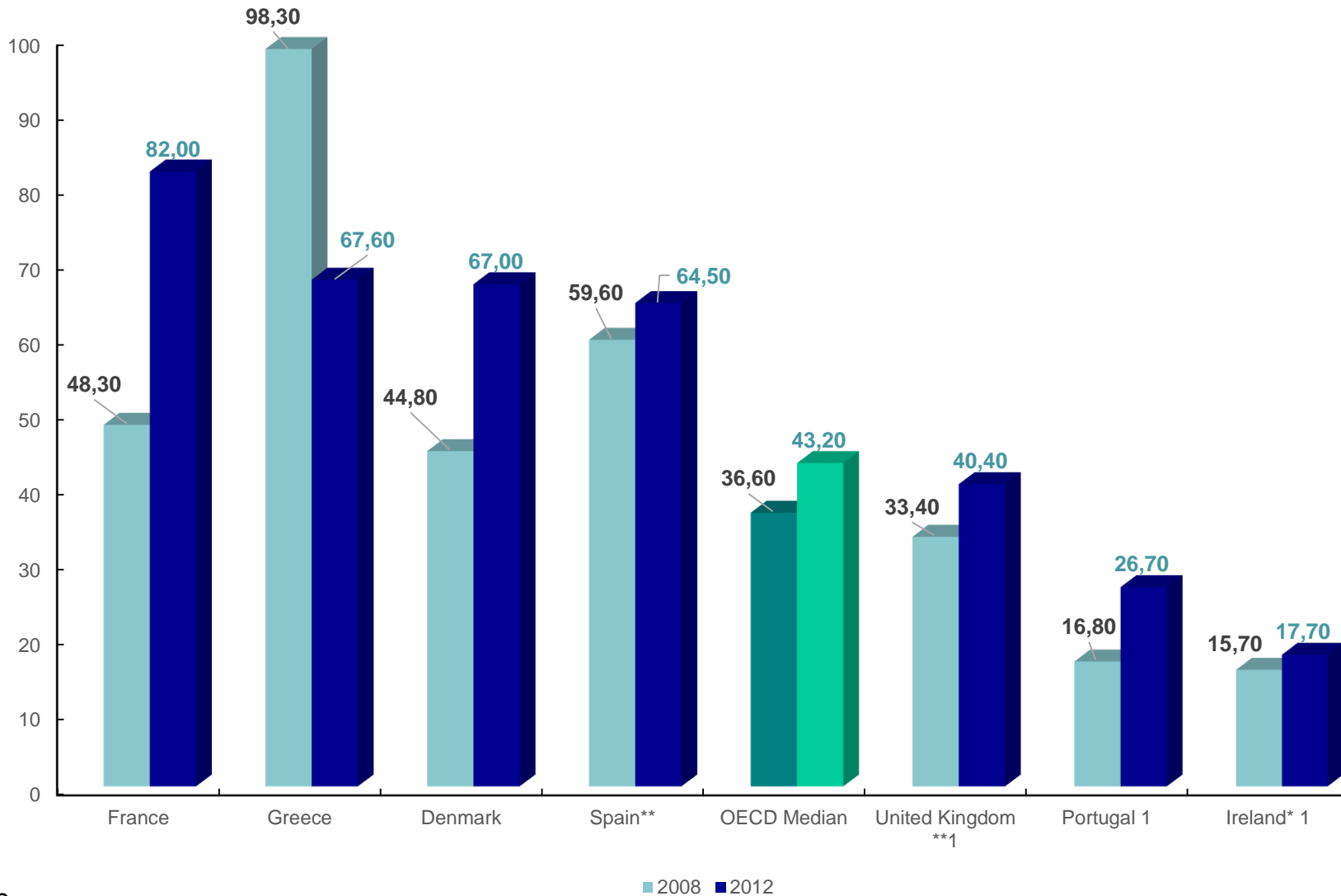


Three dimensions to consider when moving towards universal health insurance



Three dimensions to consider when moving towards universal coverage

Magnetic Resonance Imaging (MRI) Exams per Million Population, 2008⁸ and 2012



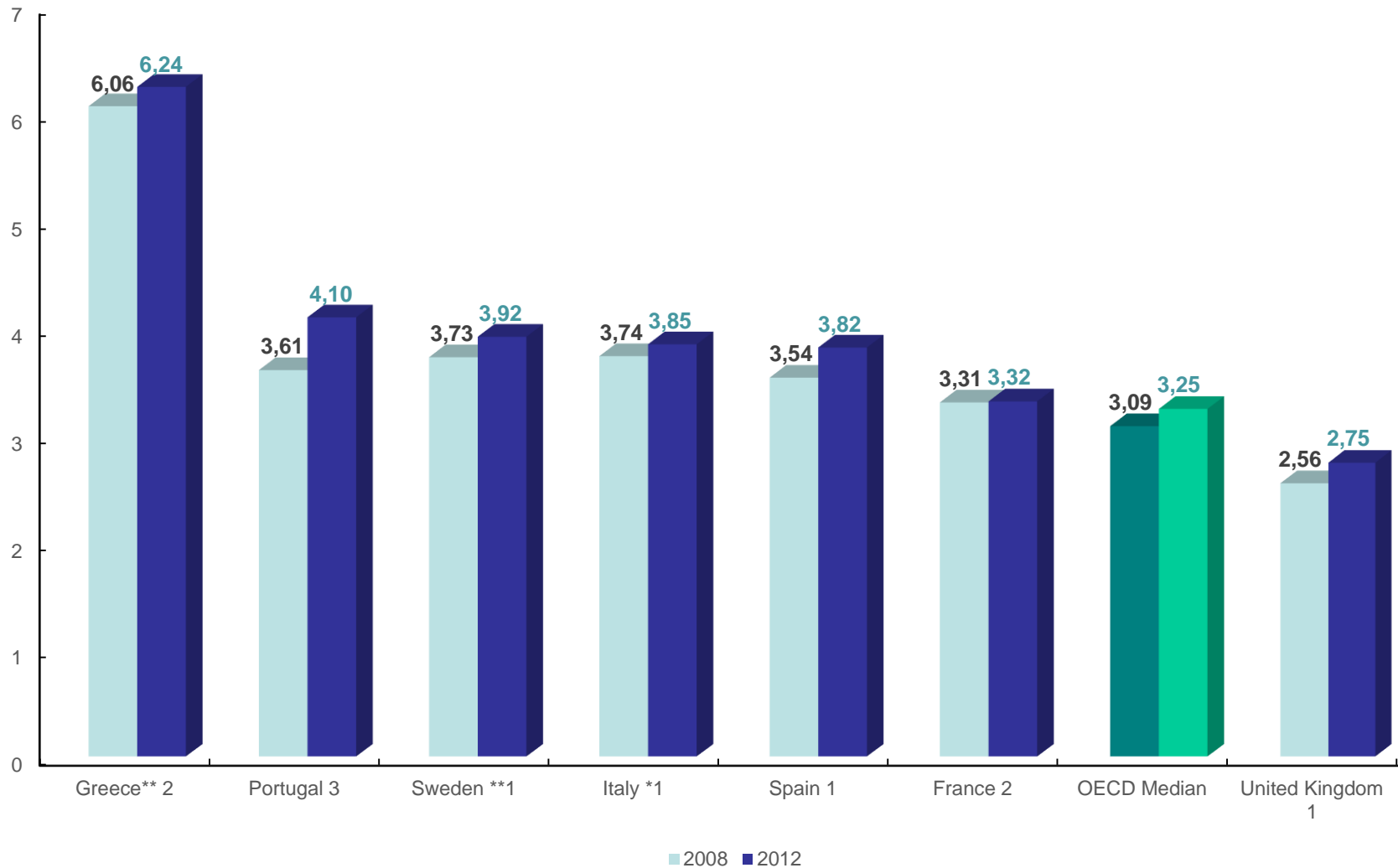
* 2009

**2010.

1. Data refer to exams in hospital only.

Source: OECD Health Data 2014.

Number of Practicing Physicians per 1,000 Population, 2008 and 2012 9



1. Data refer to practising physicians. Practising physicians are defined as those providing care directly to patients.

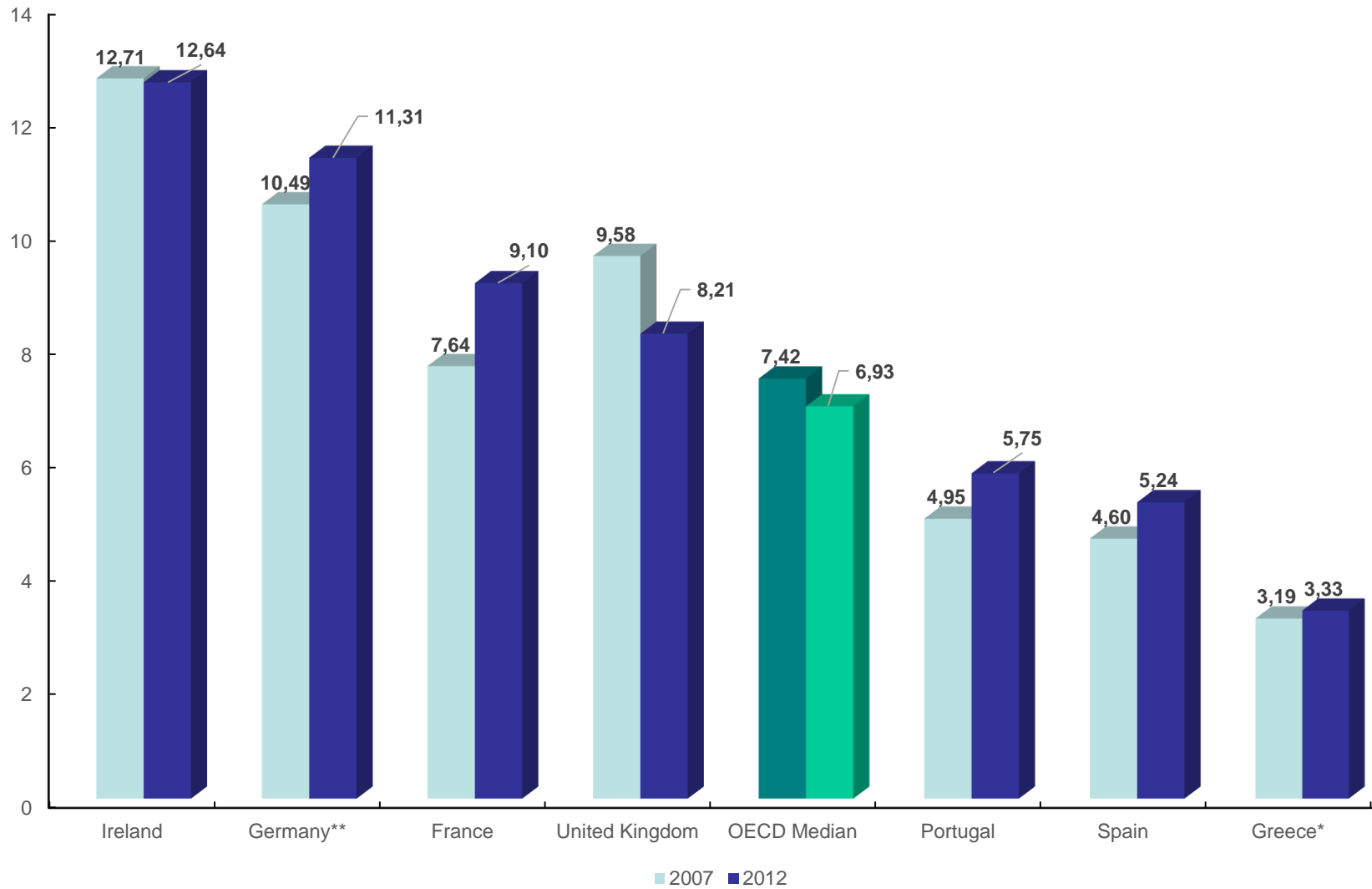
2. Data refer to professionally active physicians. They include practising physicians plus other physicians working in the health sector as managers, educators, researchers, etc. (adding another 5-10% of doctors).

3. Data refer to all physicians who are licensed to practice.

*2009

**2011

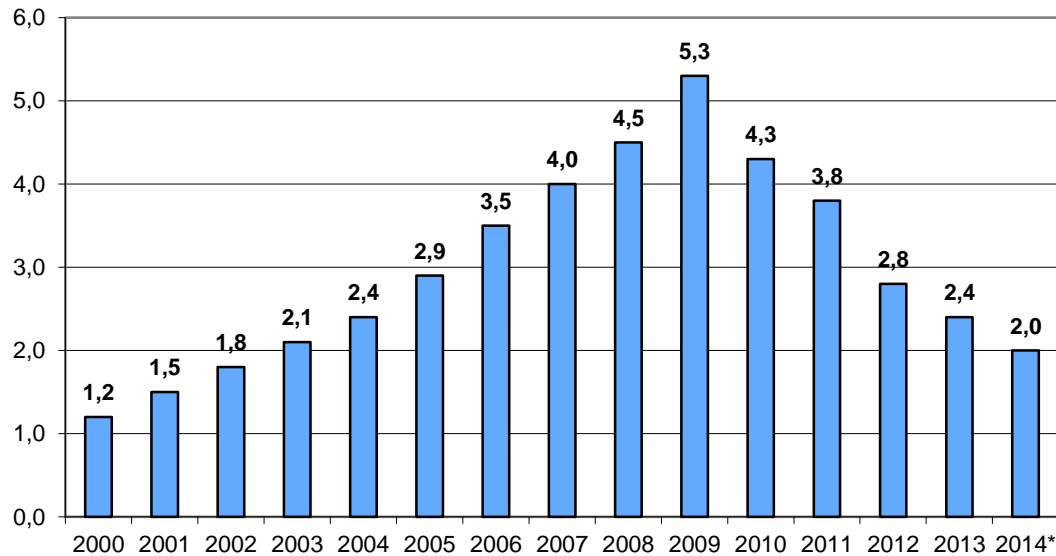
Number of Nurses per 1,000 Population, 2007 and 2012



*2009

**2011

Public pharmaceutical expenditure in Greece 2000-2014 (in € billion)**



Note: * 2014 figures are estimates.

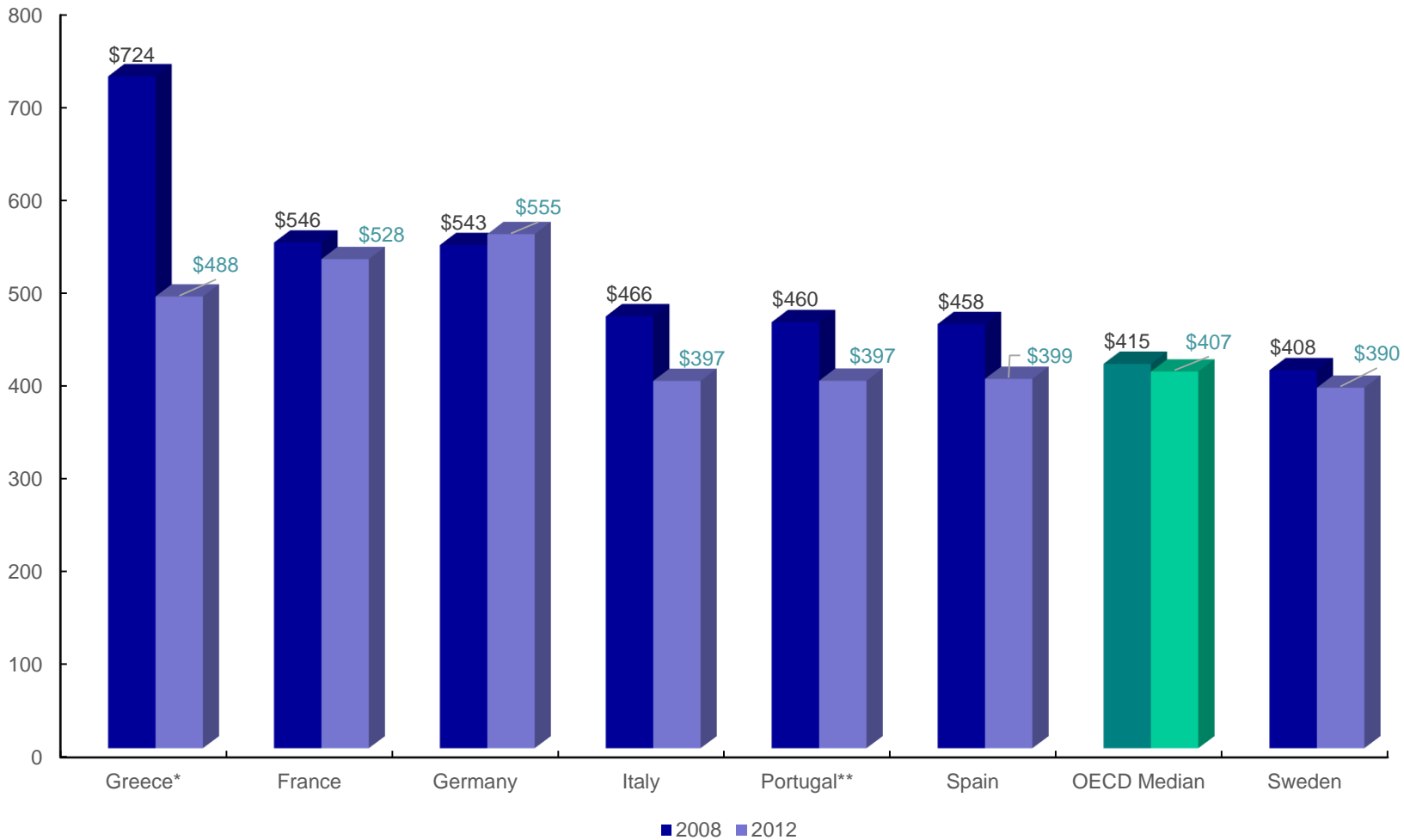
** Rebates to the government have been accounted for.

Source: Foundation for Economic and Industrial Research, General Secretariat for Social Security, own calculations.

Pharmaceutical Spending per Capita, 2008 and 2012

US\$ purchasing power parity

Dollars (\$US)

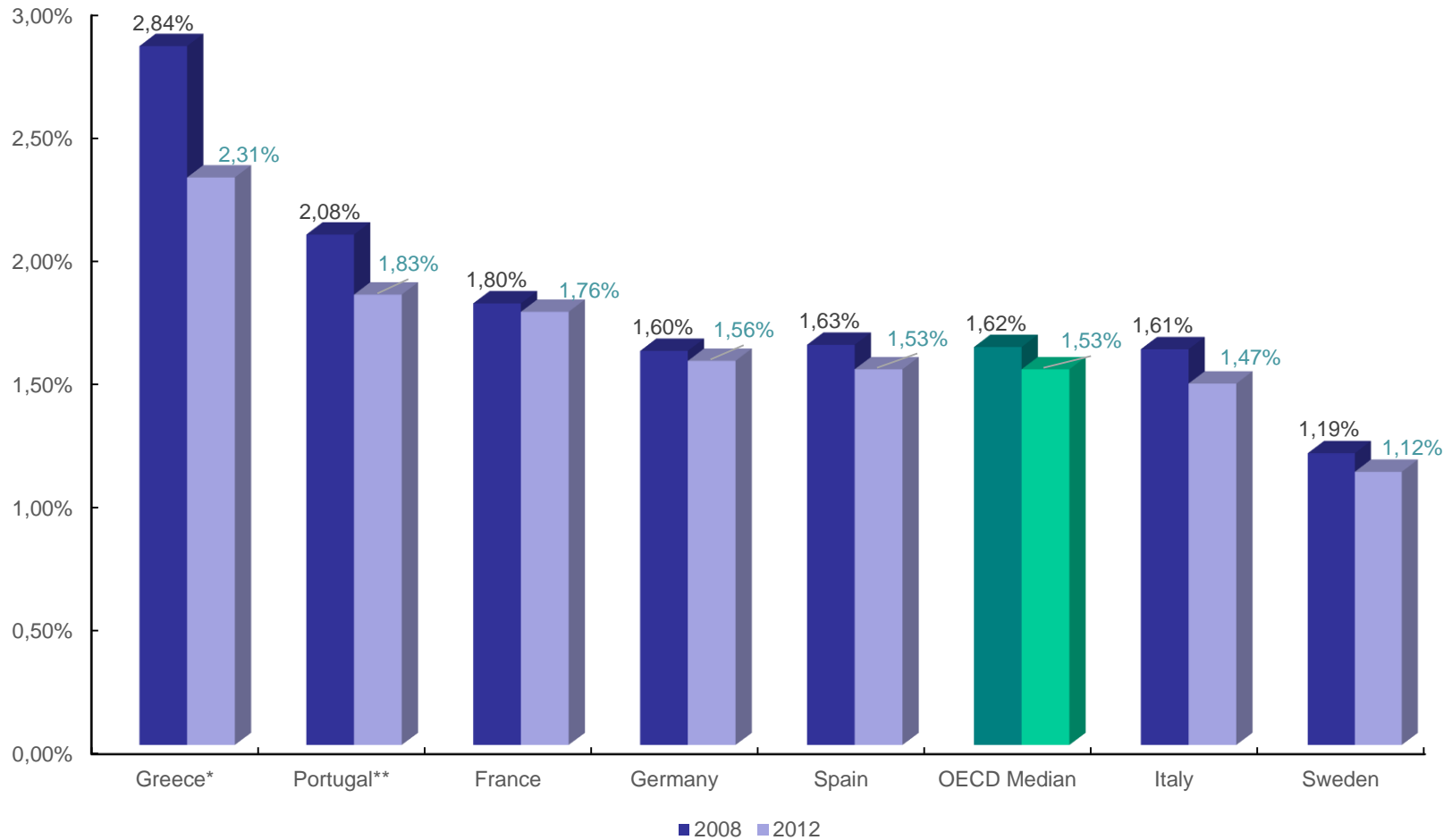


*2009

**2011

Pharmaceutical Spending as a Percentage of GDP, 2008 and 2012

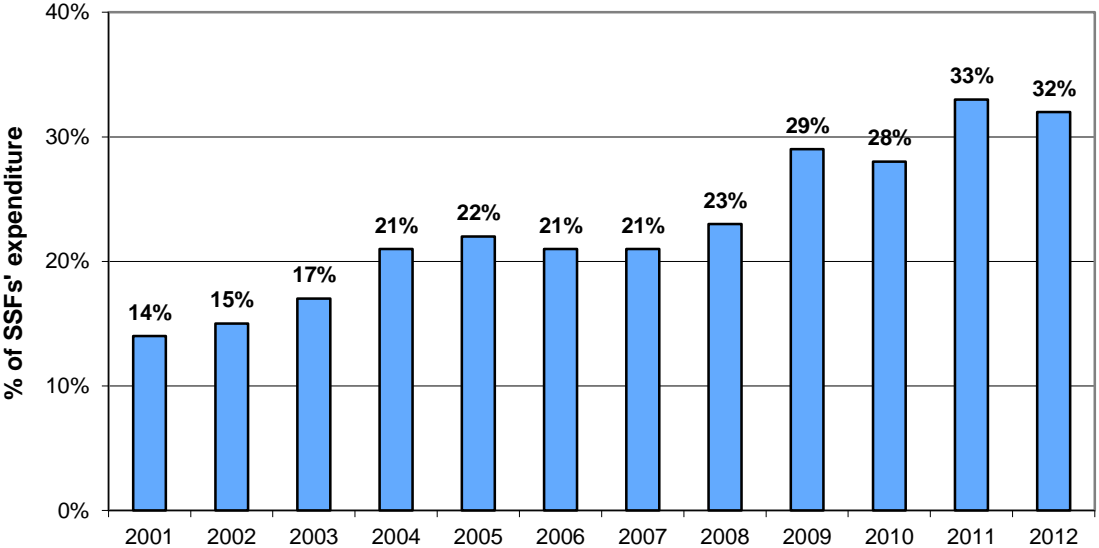
\$US PPP



*2009

**2011

Government Budget subsidies to the Social Security Fund (SSF) as % of SSFs' expenditure



Source: Hellenic General Accounting Office, 2011.

Priorities for reform (2009 – 2015)

Three key areas of focus

- **Financing mechanism**
 - Consolidation of different insurance funds/schemes into a single fund; principle of money follows patient
 - Contracting, reimbursement mechanisms
 - Taxation and social insurance or single mode of financing?
- **Primary health care**
 - Key pillar for reform, significant gap in health system structure
 - General practitioner not a specialty
- **Pharmaceutical care**
 - Major problem with significant overspend
 - Prices of drugs a problem, volume an even greater problem
 - Resistance to create oversight mechanisms that would promote efficiency (online Rx system)

Health Reform Support Programme (HRSP)

- Several pillars, including
 - Primary Health Care
 - Hospital Management
 - Hospital Financing
 - Public Procurement
 - Pharmaceuticals
 - Reform of Public Administration
- Involvement of WHO and GIZ (the German Development Agency)

Pharmaceuticals Pillar: Key Highlights

- 1. Institutional strengthening and/or establishment of strong institutions with clear remit, roles and responsibilities, ToRs, tasks and background support**
- 2. Inter-connectivity across and within institutions and functions**
- 3. Comprehensiveness and linkages as part of national drug policy**
- 4. Increased reliance on and inclusion of modern tools (for the Greek setting) and techniques to achieve objectives**
- 5. Capacity-building/training to strengthen and improve skills in a variety of new tools**

Objective of the P&R Pillar

- **Outline, propose and help implement changes that lead to an:**

- **Effective;**
- **Stable;**
- **Predictable;**
- **Robust;**
- **Transparent;**
- **Sustainable, and**
- **Administratively simple**

... Pricing and Reimbursement system that guarantees

- **Access to prescription medicines for ALL citizens**
- **Availability and Affordability of prescription medicines for the ENTIRE population AND the health care system**
- **Safeguard the introduction of new therapies in a timely fashion and the fast uptake of generics upon patent expiry**

Progress with Pharma Sector Reform

Delivery of the pharmaceutical pillar

1. Create a National Drug Policy document
2. Overhaul the system of pricing
3. Overhaul the system of reimbursement
4. Work on prescribing, incentives, generics policy, and clinical guidance >>> *eliminated*
5. Work on dispensing and overall distribution >>> *eliminated*
6. Help rationalise the system of cost-sharing >>> *partly eliminated*

Delivery included both technical assistance, local presence and extensive capacity-building

1. A National Pharmaceutical Policy

Health Reform Support Programme HRSP
Pillar of Pricing & Reimbursement

National Pharmaceutical Policy for Greece
Striving for safe, efficient, rational and cost effective use of medicines

Panos Kanavos and David Taylor
with the assistance of
Anna Szerb, Nicholas Petersdorf & Peter Lauper
London School of Economics

3rd Draft

December 2014



Objectives :

- A strategic document that showcases the role of the Minister of Health as a steward of the health system & the pharmaceutical sector and delegates responsibility for policy implementation to key institutional stakeholders, based on WHO principles
- The document promotes a number of objectives:
 1. Universal access to essential medicines for all and at affordable prices for the health system
 2. Robust regulation is key in ensuring safety, efficacy and quality and should be a product of strong co-operation among all relevant stakeholders
 3. Physicians and pharmacists have a responsibility to prescribe and dispense drugs rationally, while patients have an equally important role in contributing to appropriate, adequate, and cost-effective care
 4. Pharmaceutical manufacturing and research and development activities are vital for the prosperity of Greece's population and economic growth
 5. Effective care, a thriving industry, and an affordable health system will rely upon investments in human and physical capital to research new therapies, evaluate novel and existing treatments, and monitor patient safety

1. A National Pharmaceutical Policy

Key Findings And Recommendations :

Actions for Objective 2:

1. Quality assurance has to be the responsibility of all the stakeholders in the pharmaceutical supply chain
2. Adherence to EU pharmacovigilance regulation needs to be enforced
3. Regulatory decisions need to build on substantial co-operation between all the stakeholders

Actions for Objective 3:

1. Expand and continuously update the e-prescribing system; integrate this IT database with e-diagnosis and patient record databases currently in development
2. Prescriptions made according to international prescribing protocols, with the view of engaging in INN-based prescribing (leverage e-prescribing)
3. Promote generic substitution for out-patient drugs and control spending on in-patient drugs
4. Educate on the favourable evidence-base (in terms of safety and efficacy) of generic drugs to meeting patient' needs; foster collaborative doctor-patient relationships in order to make prescribing more efficient
5. Monitor the activity of physicians and pharmacists in order to ensure generic prescribing and substitution

Actions for Objective 4:

1. Cooperation between suppliers and purchasers of medicines in order to obtain fair prices for both parties
2. Institute and enforce profit controls throughout the supply chain in order to obtain fair pricing and to control costs
3. Promote pharmaceutical companies for both economic progress and the viability of the health system

2. A Pricing Policy – External Price Referencing

**Health Reform Support Programme
HRSP
Pillar of Pricing & Reimbursement**

External Price Referencing for Pharmaceuticals: European Best Practices and Options for Greece

**Panos Kanavos, Anna-Maria Fournier, Sotiris Vandoros,
and David Taylor**
London School of Economics and Political Science

DRAFT – FOR CONSULTATION ONLY

February 2015



www.gppra-procology.gr



www.mun.who.int

Co-financed by Greece and the European Union



www.nydra.gr



www.mps.gr

Objectives:

- Taking into account the views and perspectives of key stakeholders including governmental bodies, key purchasers and pharmaceutical manufacturers;
- Simplify the current external price referencing (EPR) system and reduce its administrative burden;
- To rationalise the basket size and the extent of re-pricing and, therefore, avoid having an overtly complex system;
- To ensure that Greece does not overpay for new medicines in relation to (some of) its neighbours;
- To achieve reasonable prices, in relation to its ability to; and
- To contribute towards the principle of *macroeconomic* efficiency (overall budget constraint) by means of exerting pressure on price
- Make a number of policy recommendations for a new EPR system

2. A Pricing Policy – EPR Recommendations

| Variable | Current system | Option 1 “Mixed Basket” | Option 2 “Eurozone Basket” | Option 3 “Eurozone Basket with Launch Prices” |
|-------------------------------|--|--|---|--|
| Basket countries | All EU | <ul style="list-style-type: none"> Similar population size to Greece or larger Candidates include: Belgium, Finland, Poland, Czech Republic, Portugal, Austria, Spain, Italy | <ul style="list-style-type: none"> Similar population size to Greece or larger Candidates include: Belgium, Finland, Portugal, Austria, Spain, Italy | <ul style="list-style-type: none"> Similar population size to Greece or larger Candidates include: Belgium, Finland, Portugal, Austria, Spain, Italy |
| Price from basket | Lowest | Lowest | Average | Average |
| Re-pricing | Twice annually | Annually | Annually | <ul style="list-style-type: none"> Launch prices only No formal re-pricing |
| Wealth adjustment | None | Very likely, depending on countries selected for basket | Very likely, depending on countries selected for basket | Very likely, depending on countries selected for basket |
| Relationship to reimbursement | Derived price is reimbursed subject to discounts and clawbacks | <ul style="list-style-type: none"> Launch prices form basis of negotiation for reimbursement Objective is to deliver best possible discount If re-pricing reveals price reductions higher than 20% there will be an automatic re-negotiation of terms of reimburse- | <ul style="list-style-type: none"> Launch prices form basis of negotiation for reimbursement Objective is to deliver best possible discount If re-pricing reveals price reductions higher than 20% there will be an automatic re-negotiation of terms of | <ul style="list-style-type: none"> Launch prices form basis of negotiation for reimbursement Objective is to deliver best possible discount Re-pricing is activated only if it yields price reductions of $\geq 20\%$ in basket countries in which case an automatic re- |

2. A Pricing Policy – Orphans & Biosimilars

Health Reform Support Programme HRSP

Pillar of Pricing & Reimbursement

**Pricing and Reimbursement Proposals for
Orphan, Biosimilars and OTC
pharmaceuticals in Greece**

Panos Kanavos and Anna-Maria Fontrier

London School of Economics and Political Science

DRAFT – FOR CONSULTATION ONLY

May 2015



www.ygeia-aronika.gr



www.euro.who.int



www.cpaefn.gr



www.mpsa.gr

Co-financed by Greece and the European Union

Objectives:

- To outline and discuss pricing and reimbursement policies for orphan medicinal products and for biosimilars and their treatment in other EU Member States
- To propose ways and models that enable the coverage of orphan medicinal products in Greece from a pricing perspective and propose amendments to the current legislative framework
- To address the issue of substitutability for biosimilars as well as the issue of their pricing and reimbursement
- Create Specific legislation for orphan and biosimilar drugs
- Determine the criteria for de-listing certain products as well as the terms of their coverage by the health care system
- Improve Access and Availability of orphans and biosimilars

3.Reimbursement Rules and Criteria - HTA

**Health Reform Support Programme HRSP
Pillar of Pricing & Reimbursement**

**The Future of Health Technology Assessment in
Europe and its Application to Greece – Evidence,
Policy Options and Recommendations**

Panos Kanavos and Anna-Maria Fontrier
London School of Economics

DRAFT FOR COMMENTS ONLY

January 2015



Objectives:

- Greece does NOT have a system of value assessment of new medicinal products that suits its own needs: Help create one!
- Propose a detailed model of HTA implementation and its key parameters; based on that offer a number of options as to how HTA could be implemented in the short- and the longer-term
- Assess the value of new technologies more effectively in order to make sound reimbursement decisions
- Improve the capacity of institutional stakeholders in their negotiations with manufacturers in order to achieve better reimbursed prices, esp for expensive products
- Create Capacity-Building for HTA in the country as well to enable local experts undertake HTA

3. Reimbursement Rules and Criteria - HTA

Key Policy Options for Greece:

Option 1: HTA is not an explicit process or function in Greek health care decision-making, but cost-effectiveness evidence from other settings will be taken into account when considering reimbursement decisions. Such cost-effectiveness evidence can be leveraged from available recommendations elsewhere in the European Union. The role of clinical cost-effectiveness evidence in this context is advisory and will contribute to decision-making, albeit in an implicit manner.

Option 2: Capacity-building in and use of HTA by tasking existing institutional stakeholders to develop capacity and share the responsibilities in HTA. Based on this option, all new in-patent products as well as line extensions will undergo clinical benefit assessment and will have their budget impact assessed, in addition to an appraisal of cost-effectiveness evidence. The stakeholders responsible for this will be the National Medicines Organisation (responsible for clinical benefit assessment), and EOPYY (responsible for (a) commenting on cost-effectiveness evidence submitted by the manufacturer and (b) providing budget impact analysis). The Negotiation Committee (NC) will conduct negotiations with manufacturers in order to ensure that uncertainties are minimised and the best possible reimbursement prices are secured

Option 3: Establish an independent HTA agency or institute, which will conduct HTAs based on the principles of “summary evaluation approach”. Accordingly, an independent HTA agency/institute will adopt a “*summary evaluation approach*” for all new (in-patent and line extension) products and once HTA experience and capacity have been built the remit of technologies appraised can be expanded to include medical devices and other health care technologies. Selection criteria for negotiation remain the same as in the previous option and will include budgetary, epidemiological, clinical and cost-effectiveness. The role of the NC remains the same.

Option 4: Establish an independent HTA agency or institute based on the principles of a “consultative approach”. Accordingly, an independent HTA agency/institute will adopt a “*consultative approach*”, whilst also considering expanding the remit of the technologies to include medical devices and other health care technologies. If a consultative model is adopted, then a small number of technologies can be evaluated in any given year and selection criteria for these will include budgetary, epidemiological, clinical and cost-effectiveness; the same technologies will undergo negotiation for inclusion into the positive list. The role of the NC remains the same and a better coordination will need to take place between what technologies the independent HTA agency/institute appraises and which technologies are subsequently subjected to negotiation.

Current formularies and respective decision-making committees

| <i>Formulary</i> | <i>Description of formulary</i> | <i>Decision-making Committee</i> |
|--|--|---|
| Positive list | Drugs reimbursed by the EOPYY | Positive and Negative List Committee |
| Negative list | Drugs that can be prescribed but are not reimbursed by the EOPYY (e.g. lifestyle drugs) | Positive and Negative List Committee |
| OTC list | Products that can be sold only in pharmacies | |
| High-cost pharmaceutical products list | Drugs that are considered high cost (with a price exceeding EUR 200) and reimbursed by the EOPYY | High-cost Pharmaceutical Products Committee |

Consolidate all lists into a single positive list with clear and transparent criteria for inclusion

3.Reimbursement Rules and Criteria – The Negotiation Committee

Objectives:

- Strengthen the role of the NC as a key stakeholder in co-determining pharmaceutical reimbursement on behalf of EOPYY
- To improve on the process of conducting reimbursement negotiations with manufacturers for risk-sharing and managed entry agreements
- To offer the operating principles of a Negotiation Committee based on how similar committees operate in key EU countries
- To put together an operating manual, including staff levels for the Negotiation Committee

Health Reform Support Programme HRSP
Pillar of Pricing & Reimbursement

Strengthening the role of the Negotiation Committee in
the context of pharmaceutical reimbursement in
Greece: Guiding Principles

By

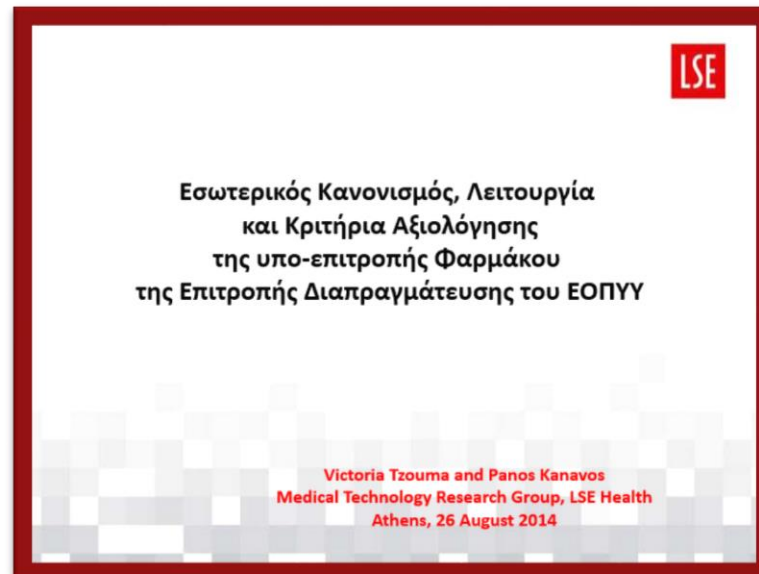
Panos Kanavos, PhD

Medical Technology Research Group, LSE Health

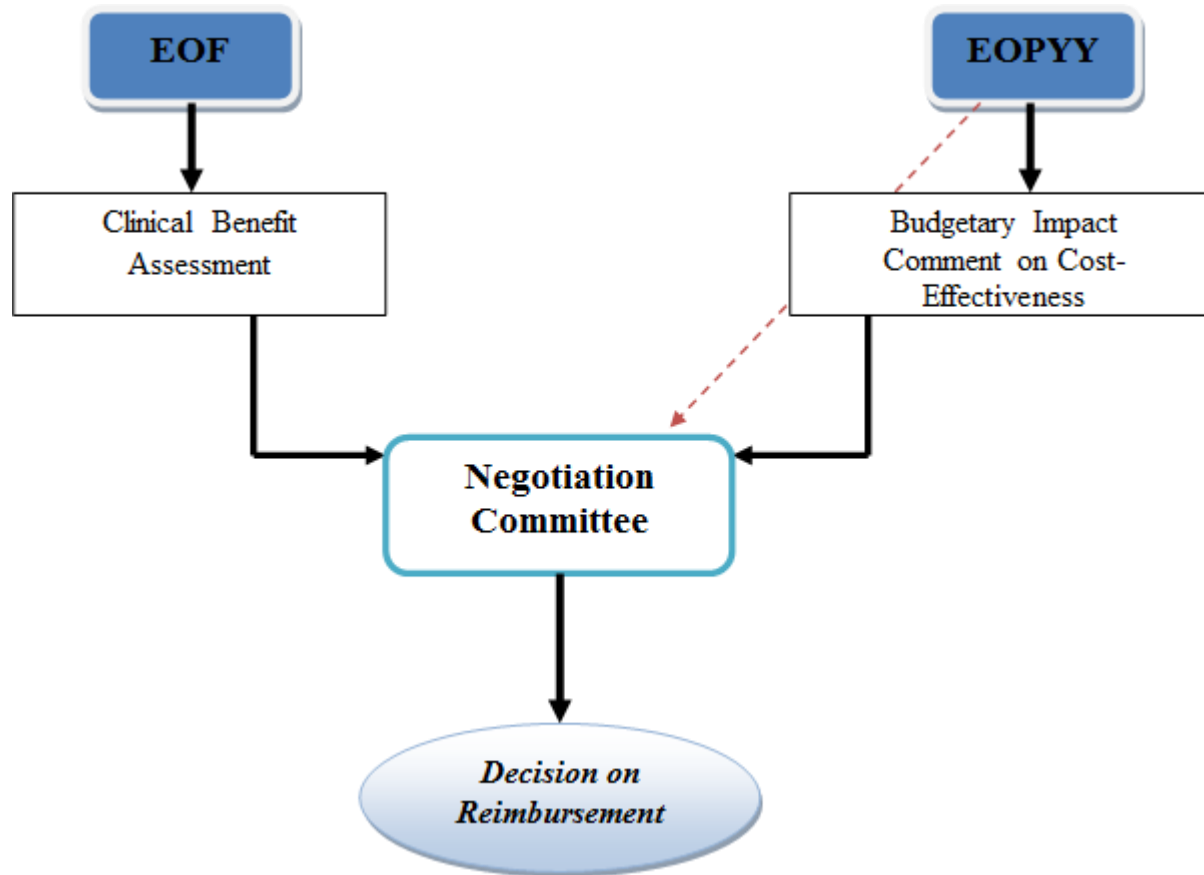
London School of Economics

Final draft

November 2014

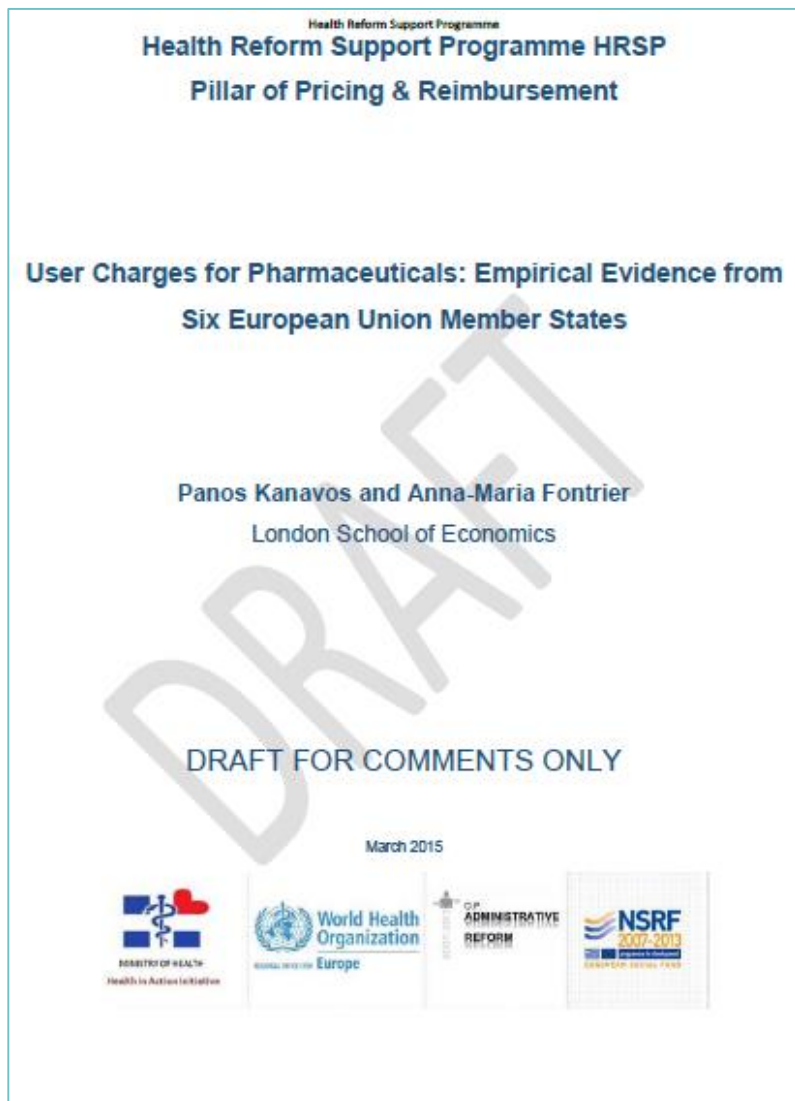


3.Reimbursement Rules and Criteria – Links to HTA and The Negotiation Committee



BUT, significant interference and lobbying by one of the competent authorities, coupled by political interference

4. Cost-Sharing



Objectives:

- Review the current legislation in Greece regarding pharmaceutical co-payments
- Present data on the extent of the “effective co-payment” in Greece compared with other EU Member States;
- Discuss the advantages and limitations of different types of cost-sharing mechanisms (flat fee, co-insurance, deductible, differential co-pay, reference pricing)
- Define criteria for exemptions (based on age, disease, income), present evidence on their implementation in different systems and for different types of patients and present their advantages and limitations;
- Make brief recommendations about how cost-sharing could be re-structured in Greece

Lessons

Lessons learnt

1. Lack of continuity
 - Politics as a deterrent
2. Lack of (political) support
 - Civil service (fiercely) opposed
3. Institution building needs to take precedence
 - ...so that any programme includes them in policy-making
4. Priority on tactical rather than strategic objectives
 - Dealing with day-to-day 'crises' overrides everything else
5. Political involvement
 - Constant firefighting with ministerial decisions distracting from programme's key objectives
6. Powerful vested interests & stakeholder influence
 - The power of lobbies
7. Piecemeal action w/o adequate thinking
 - The Negotiation Committee
8. Insist that a programme of reform is implemented as conceived and approved