

**Shaping the Future of Healthcare in Greece: CARING, CURING,
SECURING**

**Pharmaceutical pricing: Impact of the Greek
pricing decisions on other Member States and
the Transparency Directive**

20.3.2012, Athens

Dr. Alexander Natz

Agenda

I. Situation in Greece

II. Pricing and Reimbursement in the EU

III. Transparency Directive

IV. Conclusion

EUCOPE: The perspective of innovative mid-sized pharma companies

EUCOPE represents

- 900+ mid-sized companies via EMIG, SwedenBio, IML, BPI, BioDeutschland
- Board represents **often family owned pharma companies** from Sweden, the UK, Bulgaria, Italy, Greece, Germany, the Netherlands and Austria
- Companies such as: B. Braun, SigmaTau, Grifols, Celgene, Alexion, Ferring ...
- Innovative often family owned companies

EUCOPE Positions

- <http://www.eucope.org/en/positions/>
- Especially **mid-sized innovative pharma companies** are **disproportionally affected** by price cuts, late payment and reference pricing due to the dependence on their “home markets”

Some general remarks

The pharmaceutical industry is different from other industries as it ...

- ... **invests significantly** in R&D to tackle new challenges for society
- ... is faced with large public purchasing groups and is **dependent on government spending** (price cuts, international reference pricing, tenders ...)
- However, different from other industries pharma companies **cannot decide to stop supply certain markets** for legal and ethical reasons
- The **industry is taking its part** to solve the situation in Greece
- **However, what the industry cannot afford is importing the Greek prices to other countries due to international reference pricing** (Germany just recently decided to reference to 80% of EEA countries incl. Greece)

Greece: The pharmaceutical industry ...

- ... **fully understands** the need for countries such as Greece, Ireland, Portugal and Spain to **take measures to control public spending** and that **all sectors of industry have to contribute**
- ... **has contributed 7 billion EUR via discounts and price cuts** in just 5 Member States only (Greece, Italy, Ireland, Portugal and Spain)
- ... needs predictable and reliable circumstances to plan market access
- ... is faced with to problems such as late payment not only in Greece due to its dependence on public spending
- **However, tenders are no solution as they delete competition** in competitive markets as the data of the European Commission in the pharma sector inquiry on the example Netherlands shows

I. Situation in Greece

Impact of austerity measures (SCRIP 13.03.2012)

A screenshot of the SCRIP website showing an article about the impact of austerity measures in Greece. The page includes a navigation menu, social sharing options, and the main text of the article.

SCRIP Newly launched
CLINICAL RESEARCH

ASK THE ANALYST FREE
"Could you please
market perspective t

Home Therapy Sector Generics Business
Pricing & Reimbursement Regulation Healthcare Policy Pharmacovigilance

SHARE Email to a colleague Contact the Editor

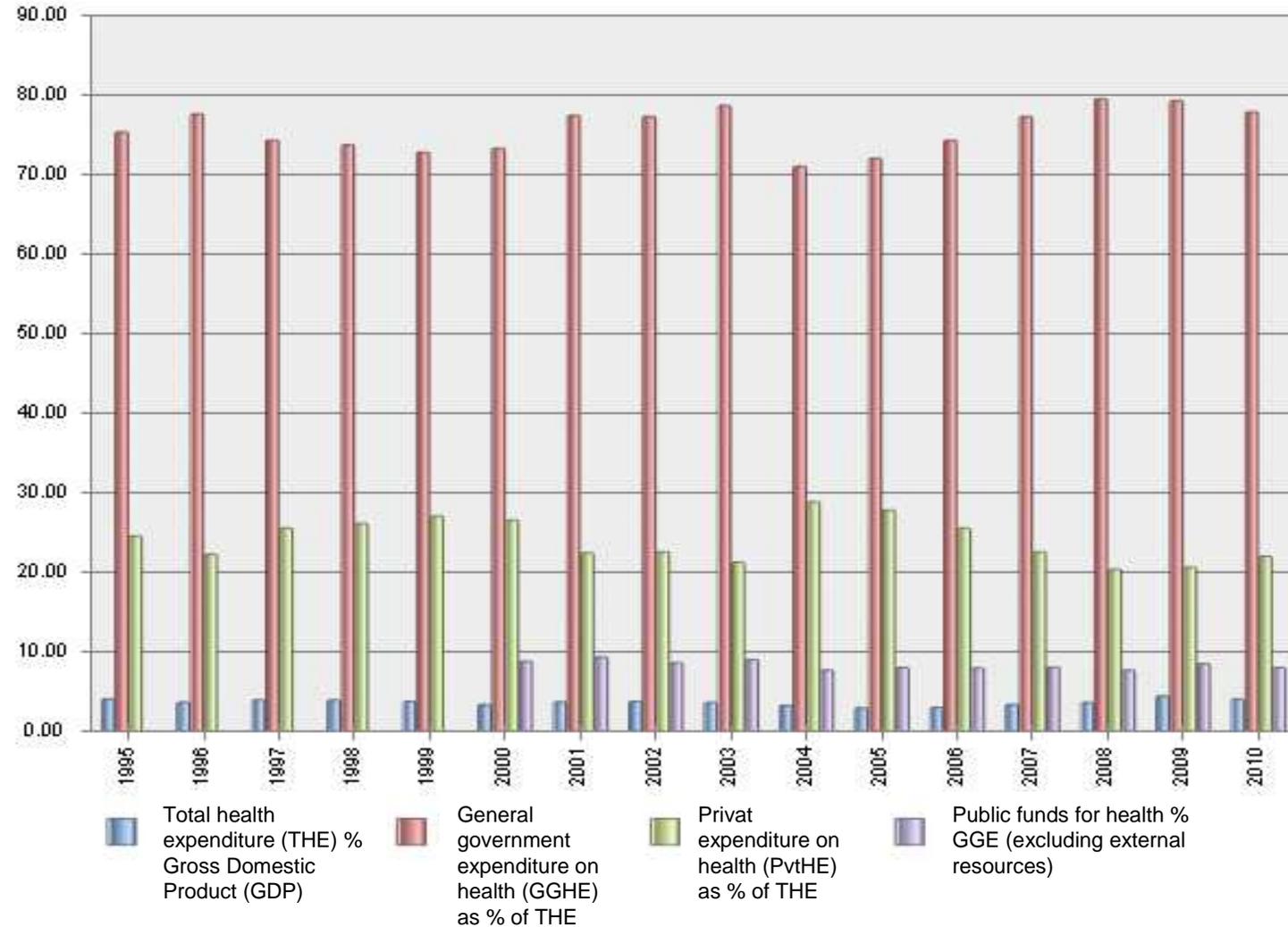
Greek cuts could drive business melt-down and drugs shortages, industry claims

13 March 2012
Eleanor Malone

The Greek pharmaceutical market faces "dramatic consequences" of upheavals designed to cut the drugs bill and avoid a sovereign debt default. The consequences, says the SFEE (the Hellenic Association of Pharmaceutical Companies), could include companies going out of business, large job losses, distribution chains being disrupted and serious shortages of medicines. SFEE has issued double warning about a recent new law and the outlook for the government bonds pharma firms were forced to accept in lieu of cash payments for debts owed to them by public hospitals (scripintelligence.com, 13 March 2012).

EUCOPE (the European Confederation of Pharmaceutical Entrepreneurs) points out that some commonly used drugs, such as those for hypertension, kidney diseases, cancer and painkillers, have already been in short supply, while of around 12,000 pharmacies in the country, 800 are about to close and 200 have severe operational difficulties, thanks to delayed payments from social security funds leaving them unable to pay their suppliers and in the position of having to demand patients pay in cash for medicines.

Greece – Health expenditure (in relation) from 1995 – 2010 / WHO



Source: Data from WHO – Database, available under:
<http://apps.who.int/nha/database/DataExplorer.aspx?d=1>

Greek austerity measures in 2010 / 2011

➤ September 2010

- **Prices** of 97% of drugs in the Greek market **were reduced by an average of 20% (price cuts)**
- Those cost-saving measures **did not tackle a major problem of prescription fraud and overly high generic pricing**

➤ June 2011

- Announcement that by widening the use of electronic prescribing and further drug price cuts **another € 2.1 bn of healthcare spending will be cut during 2011–15**

→ Postponed to January 2012

New Greek austerity measures in 2012 – Structural reforms

➤ February 2012

- "Troika" established a € 130 bn rescue package for Greece incl. **a cut from the country's already reduced pharmaceutical budget by € 1.076 bn**
- **Measures according memorandum of understanding** between the Troika and the Greek government include price controls and claw-backs that are designed **to force a greater level of generic prescribing, reduce opaque and suspect prescriptions to combat fraud and increase patient co-payments**
- **Additional measures might be introduced if necessary.** (prescription budget for each doctor / average costs of prescription per patient / further cuts in prices and profit margins / increases of co-payment) So there is **a thread that** - if the government fails to implement the structural reforms (combat fraud / increase the use of generics) – **“emergency measures” will punish patented medicines especially**

New Greek austerity measures from Feb. 2012 in detail (I)

- **Quarterly automatic claw-back from companies' turnover**
- **There is foreseen a stipulation of a quarterly rebate from 2012/15 that will yield € 250 mill. plus if spending (after tax) retroactive to 1.1.2012 exceeds € 240 mill. per month**
- **A number of the most expensive medicines will be selected to be sold in hospitals or national health service pharmacies**
- **Costs associated with outpatient distribution margins will be reduced**
- **Pricing and reimbursement**

Pricing → mechanism based on the 2 EU countries with the lowest prices

Update → of a complete price list every quarter / update of neg. and OTC lists

Government → must remove drugs from the positive reimbursement list if other countries have found them to be ineffective or not cost-effective

New → medicines will only be admitted to the positive reimbursement list if they have already been included in such lists by two-thirds of EU countries

New Greek austerity measures from Feb. 2012 in detail (II)

➤ Generic prescribing

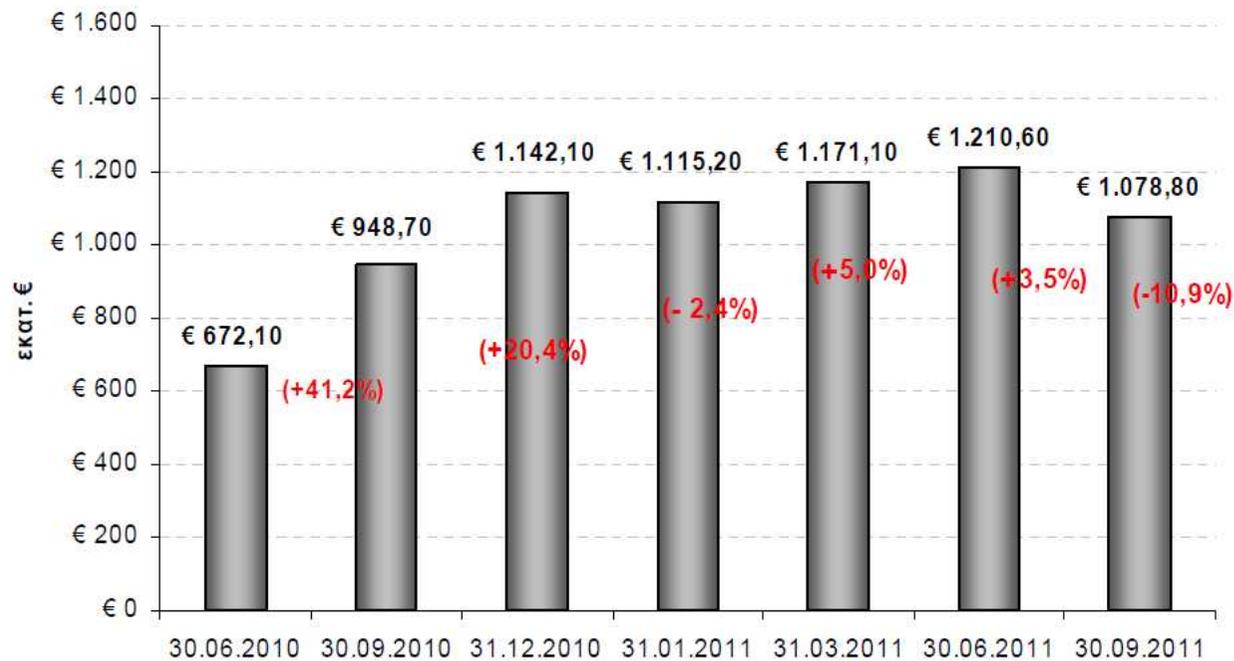
- **Adjustment of the profit margins of pharmacies and wholesalers**
- Imposing **flat fees on pharmacies** for expensive drugs
- **Prices** of generics and off-patent medicines **will be capped to 40% and 50% of patented products**
- Doctors have to prescribe international non-proprietary name / compulsory generic substitution by pharmacies
- Simplification of the **procedures to speed up the entry of cheaper generics**
- Requirement that **at least 40% of the volume of medicines used in public hospitals have to be generics** that price below similar branded products and off-patent medicines

➤ Controlling prescribing

- **Compulsory e-prescription system** to monitor prescriptions effectively
- **Individual doctors and pharmacies will be punished if they fail to follow compulsory prescription guidelines** (Doctors will potentially lose the right to prescribe reimbursed drugs)

Hospital and pharmacy debts (2010 / 2011)

- But despite the price cuts, Greek **hospitals and pharmacies struggled to pay their bills**
- Data from SFEE member-companies regarding **pharmaceutical debts of public hospitals** for the invoices issued from 01.01.2010 to 30.09.2011



Source: SFEE's Report on public hospitals' debts towards SFEE's member-companies, p. 3, available: http://www.sfee.gr/files/story/Report_Hospital_Debts_ENG_31-12-2011.pdf.

Expenditures in the health sector in Greece (2010 / 2011)

- The following figures from 2010 / 2011 **project the expenditures in the health sector:**

	2010	2011	Decline in %
Pharmaceuticals	EUR 7.20 bn	EUR 6.48 bn	-10.1% 
Healthcare	EUR 22.87 bn	EUR 21.64 bn	-5.4%
Medical devices	EUR 959 mn	EUR 886 mn	-7.6%

Source: ResearchandMarkets - **Greece Pharmaceuticals and Healthcare Report Q1 2012**, available under:
http://www.researchandmarkets.com/reports/2024260/greece_pharmaceuticals_and_healthcare_report_q1

➔ **Pharmaceutical companies bear the highest burden in %**

- **Figures on the state's pharmaceutical spending gives an even clearer picture:**

	2010	2011	2012
Pharmaceutical spending	EUR 5.6 bn	EUR 4.1 bn	Around EUR 3.1 bn

Source: ana-mpa, available: <http://greece.greekreporter.com/2012/02/03/pharmaceutical-spending-to-fall-to-2-88-billion-euros-in-2012/>.

Countries that reference Greece's drug prices

- Greece's drug prices are often referenced elsewhere



→ **Direct impact**

→ **Indirect impact**

Source: Grafic map: <http://www.abload.de/img/europakarte4emw.png>
data on countries: Sukkar, SCRIP, 23.12.2010

Conclusion – Situation in Greece

- **Greek price cuts have a huge impact on the pharmaceutical industry not only in Greece but also in other EU Member States due to international reference pricing**
- **The pharmaceutical sector is disproportionately affected by these measures**
- **Other Member States should refrain from referencing to prices with countries with austerity measures!**
- **The late payment issue needs to be tackle not in Greece only**

II. Pricing and Reimbursement in the EU

National price changes and impacts on other countries

	Country	2010 Price reduction mechanisms
PRICE CUTS	Belgium	•15% cut in drugs reimbursed >12 years
	Germany	•Mandatory rebate increased from 6% to 16%
	Greece	•21.5% temporary price cut of average
	Portugal	•6% price cut on all products
	Italy	•12.5% cut in generic prices
	Spain	•7.5% temporary price rebate
	UK	•1.9% price cut
REIMBURSE CHANGES	Denmark	•Removal of IVF reimbursement
	Sweden	• Reimbursement price dependent on health technology assessments
PRICING REFORMS	France	• Introduction regional health agencies resulting in greater purchasing power for hospital drugs
	Ireland	• Reference pricing; generic price cuts
	Netherlands	• Injectables included in reference pricing
	Portugal	• Centralised hospital drug purchasing system • Change in reference pricing rules

Source: Graham Foxon, Ferring AG

External reference pricing in selected countries



Source: WHO/HAI Project on Medicine Prices and Availability, Working Paper 1: External Reference Pricing, May 2011, p. 17 , available under:
<http://www.haiweb.org/medicineprices/05062011/ERP%20final%20May2011.pdf>

Example Netherlands: Price reductions through tenders

Price reductions since 01.06.2008 for the six top-selling products according to European Commission:

Product	Preferred supplier	Price in May	Price in June	Change
Omeprazol tablets/capsules 20 mg	Ratiopharm	€ 0.36	€ 0.05	-88%
Alendroninezuur tablets 70 mg	Centrafarm	€ 4.99	€ 0.36	-93%
Omeprazol tablets/capsules 40 mg	Centrafarm	€ 0.65	€ 0.09	-86%
Paroxetine tablets 20 mg	Ratiopharm	€ 0.37	€ 0.07	-82%
Simvastatine tablets 40 mg	Actavis	€ 0.27	€ 0.04	-84%
Pravastatine tablets 40 mg	Focus Pharma	€ 0.54	€ 0.13	-76%

Source: European Commission, Pharmaceutical Sector Inquiry, Final Report, 8.7.2009, para. 376.

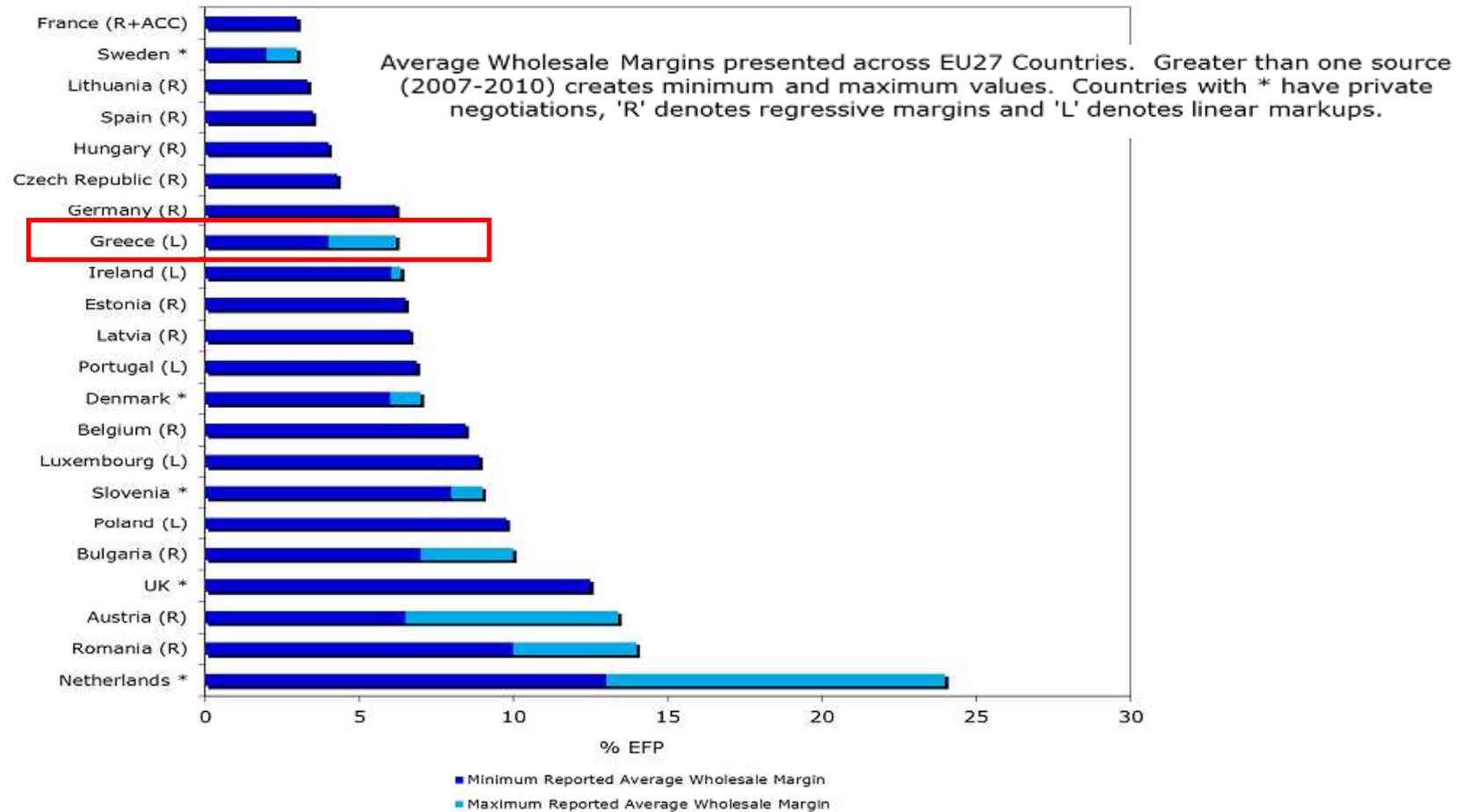
Brand prices per unit in EU countries, DDD-adjusted, in €, 2005

INN name	Norway	Belgium	Germany	Sweden	Denmark	UK	Nether Lands	Spain	Portugal	Italy	Greece	France	Ireland	Austria
Atorvastatin	0.78	0.86	1.37	1.04	0.72	1.01	0.95	0.96	0.91	0.63	0.55	0.91	0.89	0.97
Pravastatin	1.25	1.08	1.63	1.00	0.98	1.67	1.04	1.58	1.11	0.91	0.66	1.07	1.55	0.92
Simvastatin	1.43	1.28	1.06	N/a	0.81	1.25	1.12	1.19	0.82	0.74	0.62	0.80	1.13	0.96
Captopril	0.48	0.62	0.28	0.21	0.46	0.58	0.54	0.26	0.56	0.30	0.38	0.61	0.50	0.77
Enalapril	0.25	0.29	0.20	N/a	0.22	0.59	0.30	0.19	0.28	0.28	0.19	0.46	0.41	0.24
Quinapril	N/a	0.76	0.45	0.49	0.37	0.38	0.88	0.19	0.36	0.37	0.27	0.53	0.75	0.43
Ramipril	0.32	0.51	0.48	0.31	0.17	0.60	0.69	0.21	0.28	0.24	0.18	0.40	0.35	0.36
Losartan	0.83	0.93	0.80	0.85	0.63	0.97	0.87	0.63	0.77	0.69	0.58	0.92	0.77	0.47
Valsartan	0.82	0.59	0.80	0.82	0.60	0.88	0.86	0.45	0.72	0.62	0.39	0.87	0.75	0.77
Clozapine	0.20	0.27	0.25	0.18	0.19	0.92	0.28	0.13	0.28	0.29	0.11	0.30	N/a	0.10
Olanzapine	4.80	5.60	5.78	5.37	3.81	5.48	5.19	3.57	3.90	3.60	3.30	4.83	6.07	5.28
Risperidone	3.98	4.23	5.54	4.08	2.68	5.21	5.47	2.87	3.22	2.93	2.25	3.65	5.03	5.23
Lansoprazole	1.37	2.01	1.84	1.15	0.85	1.33	1.93	1.07	0.90	1.53	1.05	1.68	1.66	1.57
Omeprazole	1.89	2.24	1.77	1.83	N/a	1.60	2.09	0.43	1.66	1.50	0.84	1.86	1.77	1.57
Pantoprazole	1.33	2.01	2.32	1.16	0.83	1.33	1.88	1.27	1.34	1.28	1.10	1.65	1.40	1.57
Citalopram	1.02	1.08	1.12	0.66	0.75	0.90	1.18	0.73	N/a	0.75	0.68	0.90	0.97	0.97
Fluoxetine	0.97	1.04	1.16	0.85	0.78	1.51	1.38	0.53	0.69	0.56	0.65	0.93	0.90	0.61
Paroxetine	N/a	1.31	1.16	0.90	0.91	0.93	1.11	0.80	0.86	0.77	0.69	0.90	0.90	0.56
Sertraline	1.08	1.22	1.11	1.12	0.82	0.85	1.31	0.72	0.76	0.87	0.55	0.84	1.36	0.88

Notes: DDD is Defined Daily Dose.

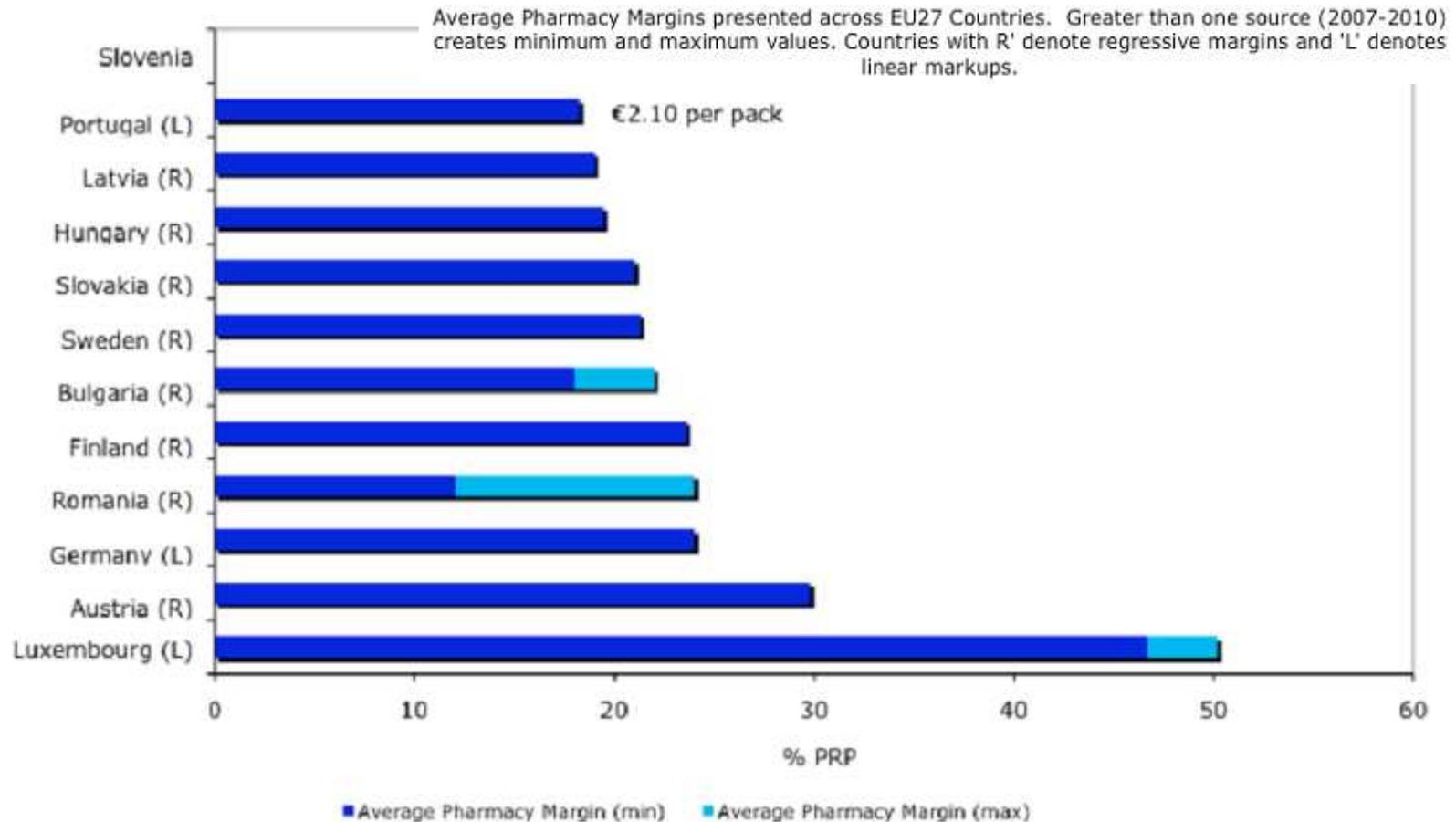
Source: EP Study - Differences in Costs of and Access to Pharmaceutical Products in the EU, March 2011, p. 85

Avg. wholesale margins as a share of retail prices in selected EU MS



Source: EP Study - Differences in Costs of and Access to Pharmaceutical Products in the EU, March 2011, p. 51

Avg. pharmacy (retail) margins as a share of retail prices in selected EU MS



Source: EP Study - Differences in Costs of and Access to Pharmaceutical Products in the EU, March 2011, p. 52

External price referencing in EU Member States, 2010 (I)

	AT	BE	BG	HR	CY	CZ	DK	EE	FI	FR	DE	GR	HU	IE	IT	LV	LT	NL	NO	PL	PT	RO	SK	SI	ES	SE	CH	UK
AT		✓			✓	✓		✓	✓			✓	✓	✓		✓			✓			✓	✓	✓			✓	
BE	✓		✓		✓	✓		✓	✓			✓	✓	✓		✓		✓	✓			✓	✓		✓			
BG						✓		✓								✓						✓	✓					
CY	✓					✓		✓				✓				✓							✓					
CZ	✓		✓	✓				✓				✓	✓			✓	✓			✓		✓	✓					
DK	✓	✓			✓	✓		✓	✓			✓		✓		✓			✓			✓	✓				✓	
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FI	✓	✓				✓		✓				✓		✓		✓			✓				✓					
FR	✓	✓	✓	✓	✓	✓		✓	✓			✓	✓	✓	✓	✓		✓			✓		✓	✓	✓		✓	
DE	✓	✓			✓	✓		✓	✓	✓		✓	✓	✓	✓	✓		✓	✓			✓	✓	✓	✓	✓	✓	✓
GR	✓	✓	✓		✓	✓		✓	✓				✓			✓				✓	✓	✓	✓		✓			
HU	✓		✓			✓		✓	✓			✓		✓		✓	✓			✓		✓	✓					
IE	✓	✓				✓		✓	✓			✓	✓			✓			✓			✓	✓		✓			
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LV	✓		✓			✓		✓	✓			✓					✓			✓			✓					
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RO			✓			✓		✓								✓							✓					

Source: EP Study - Differences in Costs of and Access to Pharmaceutical Products in the EU, March 2011, p. 80

Conclusion – Pricing and Reimbursement in the EU

- **Each MS has its own measures to control spending** including price cuts, external reference pricing, tenders etc.

MS have the right to take such measures in view of promoting the financial stability of their health insurance system

*Art. 168 (7) (1,2) TFEU: “**Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them.**”*

However, basic conditions of procedural transparency must be met. These conditions are laid down in the Transparency Directive 89/105/EEC.



III. Transparency Directive

Transparency Directive – State of play today

- The **Transparency Directive 89/105/EEC** lays down three major requirements with respect to individual pricing and reimbursement decisions:

→ Decisions must be made within a **specific timeframe** (90/180 days)

For example: Price approval within a time limit:

“In the absence of such a decision within the abovementioned period or periods, the applicant shall be entitled to market the product at the price proposed.” (Art. 2 (1)(4))

Decisions must be **communicated to the applicant and contain a statement of reasons based on objective and verifiable criteria**

Decisions must be **open to judicial appeal at national level**



Transparency Directive – The new Commission proposal (I)

Commission proposal – Published on 01 March 2012



Source: Commission proposal, available at:
http://ec.europa.eu/enterprise/sectors/healthcare/files/docs/transpadir_finalprop01032012_en.pdf.

Transparency Directive – The new Commission proposal (II)

The Commission proposal includes the following aspects:

- **Voluntary contractual agreements and cost containment measures under public procurement law** remain excluded from the directive
- **HTA agreements fall in the scope of the directive**
- **Demand-side-related measures** (incentives to physicians such as me-too lists) **are in the scope of the directive** (see ECJ, ABPI case C-62/09)
- **Time limits for pricing and reimbursement** are reduced for both generic (15/30 days) and innovative medicinal products (60/120 days) with longer time-limits in cases with a HTA procedure (90/180 days).
- Art. 8 introduces a **remedies procedure** in case of non-compliance with the time limits related to the inclusion of medicinal products in health insurance systems. A designated **an independent body on national level can adopt interim measures, award damages** to the applicant and **impose a penalty payment**



IV. Conclusion

Conclusion: The pharmaceutical industry ...

- ... **fully understands** the need for countries such as Greece, Ireland, Portugal and Spain to **take measures to control public spending** and that **all sectors of industry have to contribute**
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Thank you for your attention!

Dr. Alexander Natz, LL.M. (Duke)
Secretary General

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