European Industrial Pharmacists Group

2012 General Assembly

The current state of the Pharmaceutical Industry in Portugal

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Agenda

1. **Introduction**
2. **Pharmaceutical Industry in Portugal**
3. **The Fundamental Pillars of the Healthcare System**
   - Access
   - Sustainability
4. **Facing Global Challenges – Europe**
5. **Conclusions**

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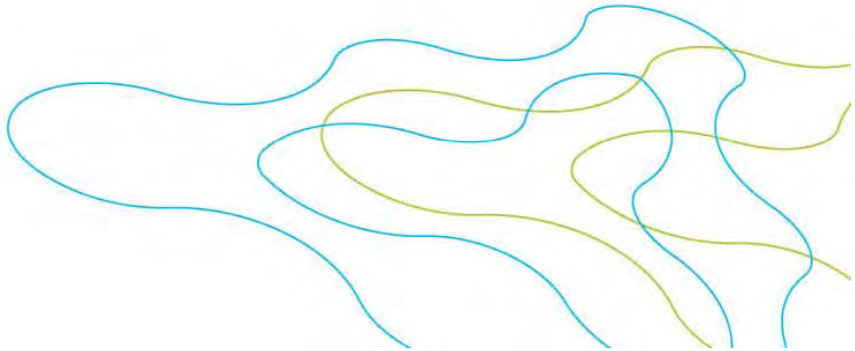

INTRODUCTION

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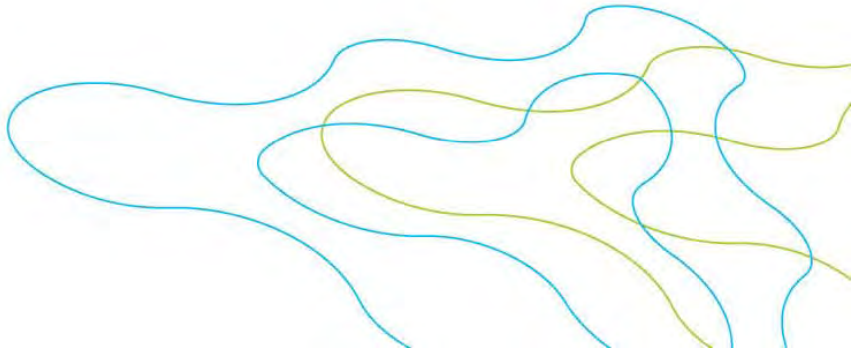

Aperto nas contas públicas em ano de eleições

EM 2009, O GOVERNO terá de cumprir o compromisso orçamental com Bruxelas e lidar com a crise.

Bruno Faria Lopes

"Hoje, os portugueses podem olhar para a situação orçamental do Estado português e dizer: as contas estão em ordem. A crise orçamental está resolvida", disse o primeiro-ministro, José Sócrates, no final de Março deste ano, após ter anunciado a descida da taxa máxima do IVA de 21% para 20%. Quatro meses depois, o agravamento da situação económica portuguesa e a falta de margem do Governo para actuar com um estímulo fiscal confirmam a opinião da maioria dos economistas: a situação de urgência nas contas públicas foi ultrapassada, mas a somber do défice orçamental e o peso da despesa pública continuam a ser um problema.

É neste cenário de crise económica e pressão acrescida sobre as contas públicas que o Governo está a preparar o Orçamento do Estado para 2009, ano em que também irá a eleições legislativas.

Segundo o Programa de Estabilidade e Crescimento (2009-2011), no próximo ano o compromisso com Bruxelas implica que se chegue a um défice de 1,9% do PIB. Depois de ter revisto em baixa a meta para o défice orçamental pelo segundo ano consecutivo – de 2,6% para 2,2% em 2008 – o ministro das Finanças ainda não se pronunciou sobre que objectivo irá Portugal assumir perante a Comissão Europeia. Bruxelas, entretanto, começou a fazer pressão sobre os Estados-membro para chegarem ao défice zero em 2010.

Com a crise económica a pressionar a receita fiscal – algo bem visível no primeiro semestre deste ano, que acabou com as contas controladas, mas com sinais claros de risco – é certo que não haverá margem para abrir os cofres do Estado para ajudar a economia. ■

O caminho da redução do défice

A meta mais urgente – colocar o défice abaixo de 3% – foi atingida, mas a situação das contas públicas não está resolvida

*Valores em % do PIB

Fonte: PEC 2007-2011

É num cenário de crise económica e pressão acrescida sobre as contas públicas que o Governo está a preparar o Orçamento do Estado para 2009

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The Current State of the Healthcare Sector

- The **financial crisis** in the public field – structural vs cyclical
- **Excessive deficits** (>3% GDP) in most EU countries
- **Public Expenditure** is growing in all countries and health is a key aspect of governance
  - ***Pharmaceuticals always easy and disproportionate target***
- Risk of frequent **short term measures** based on price cuts
- Healthcare systems in Europe want to keep **basic premises of solidarity and equity**

Need for long term measures – **models linked to "valuable" innovation and "responsible" patient access** – broader societal benefit

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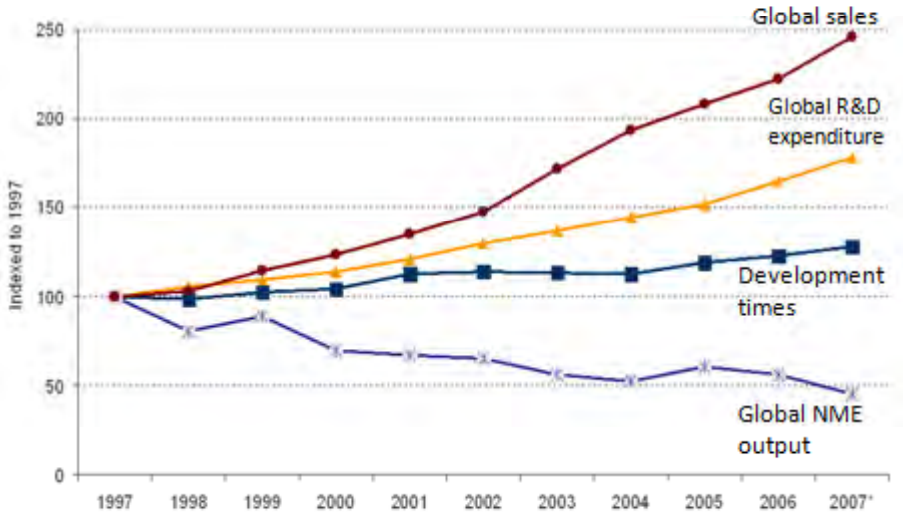
Innovation: brings added value

Innovation make significant contributions to the economy and society:

- Highly-skilled **job creation**
- Increased **scientific knowledge**
- Growth in the **Gross Domestic Product**
- **Fundamental innovation** brings significant value in terms of health gains survival rates and quality of life providing reduction of costs related with diseases
- Also **incremental innovation** provides relevant contribution to health but especially to the medicines chain and R&D processes.



Innovation in Healthcare acts as investment …

… and the pharmaceutical industry must be an integral part of the System

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Clinical Trials: Potential Investiment

Comparative Study EU vs PT

Countries	No. of active clinical trials	No of planned Centres	Nº of planned recruited patients	Investment (Million €)
Portugal	147	461	3.917	58,755
Austria	188	596	6.502	97,530
Belgium	328	1.024	12.996	194,940
Czech Republic	218	967	15.433	231,495

Source: APIFARMA Survey, 2009
Sample: 10 pharmaceutical companies with a large representation in conducting clinical trials in Portugal

PT is the country with less potencial for conducting Clinical Trials comparing to:

Belgium ↓ **55%**

Czech Republic ↓ **32%**

Austria ↓ **22%**

… and loses over 136 million EUR (*vs* Belgium)

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Clinical Trials: Potential Investiment

Pilot Study 2012 – Results

Results (16 companies):
(Studies conducted from 2007 to 2011)

Number of STUDIES (Phase II, Phase III and Phase IV)

- Studies conducted : **734**

Number of PATIENTS

- Planned patients: **5.745**
- Patients included: **4.046**

Patients NOT included: **1.699**

=> **29,5%** of the planned patients

INVESTIMENT

- Average value of investment per patient**: 14.893 €**
- Total planned investment: **85 Million EUR**
- Real investment: **60 Million EUR**

Potential investment losses 25 Million EUR

=> **29,4%** of the planned investment

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Source: APIFARMA Survey, 2012
Sample: 16 pharmaceutical companies

Pharmaceutical Industry in Portugal

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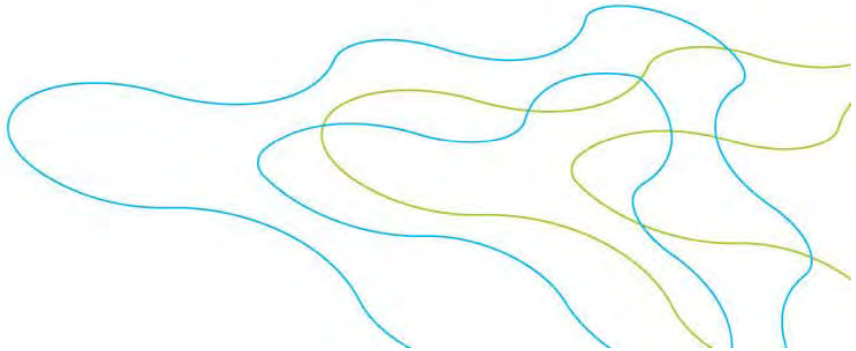

Pharmaceutical Industry Sector

Number of associated companies	120 *(Source: Apifarma ; 2011)*
Areas of intervention	• Innovative medicines • Generic medicines • Prescription medicines • Biotechnology • Vaccines • *In vitro* diagnostics • Veterinary medicines • Research and clinical trials
Market Clinic	• 2,074 EUR million • 251 million packs *(Source: IMS Health ; value at Ex-factory price; 2011)*
Hospital Market	• 1,000 EUR million *(Source: Infarmed ; 2010)*
Investment in R&D	• 68 Million Euros 2,5% of total R&D investment 5,2% of the industry's investment in R&D *(Source: MCTES / IPCTN08; 2009)*
Employment	• 9,511 workers (Year: 2010) (Δ 2008-2010 ↔ - 7%) *(Source: Apifarma)*
Production	• 1.679 million EUR *(Source: Apifarma ,estimate; 2010)*
Exportation	• 501 million EUR *(Source: AICEP / INE; 2010)*

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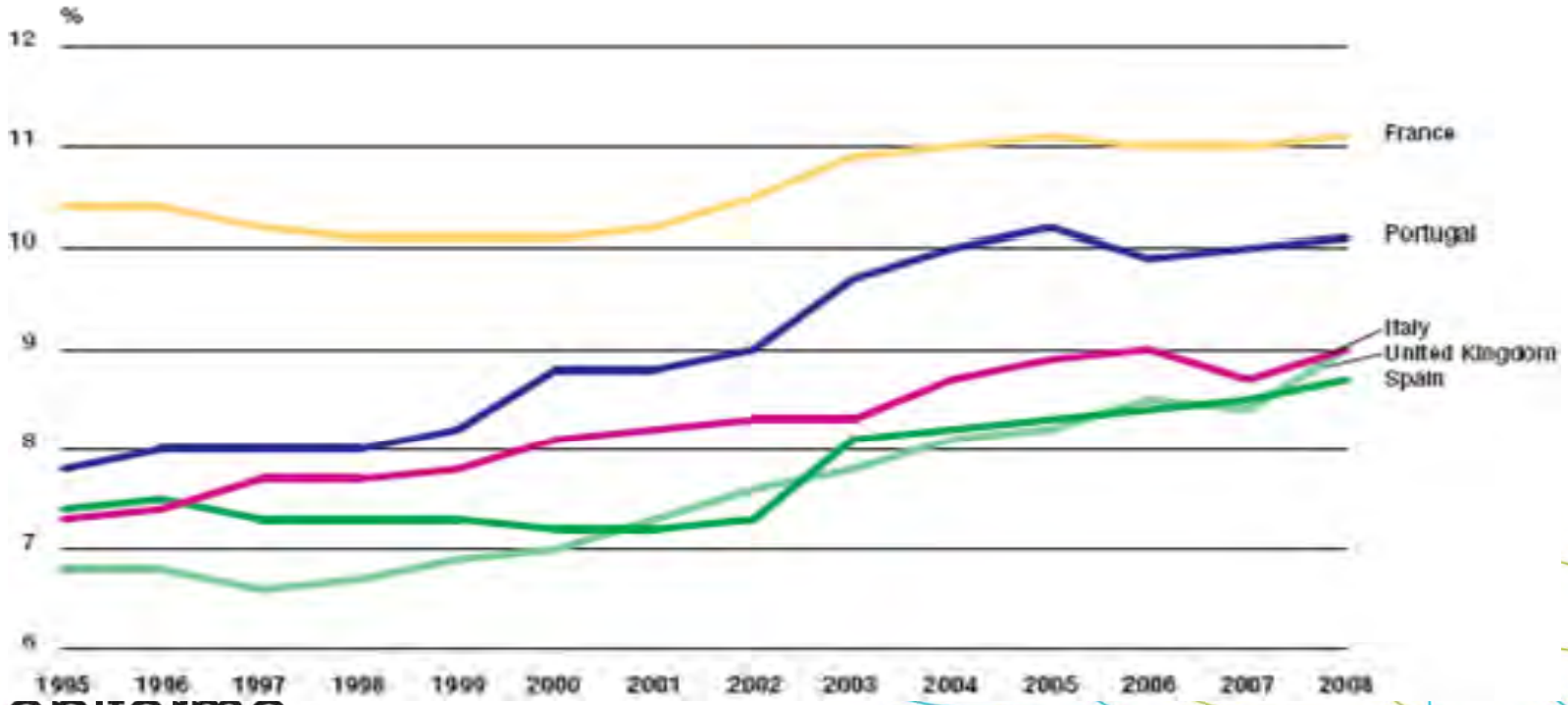
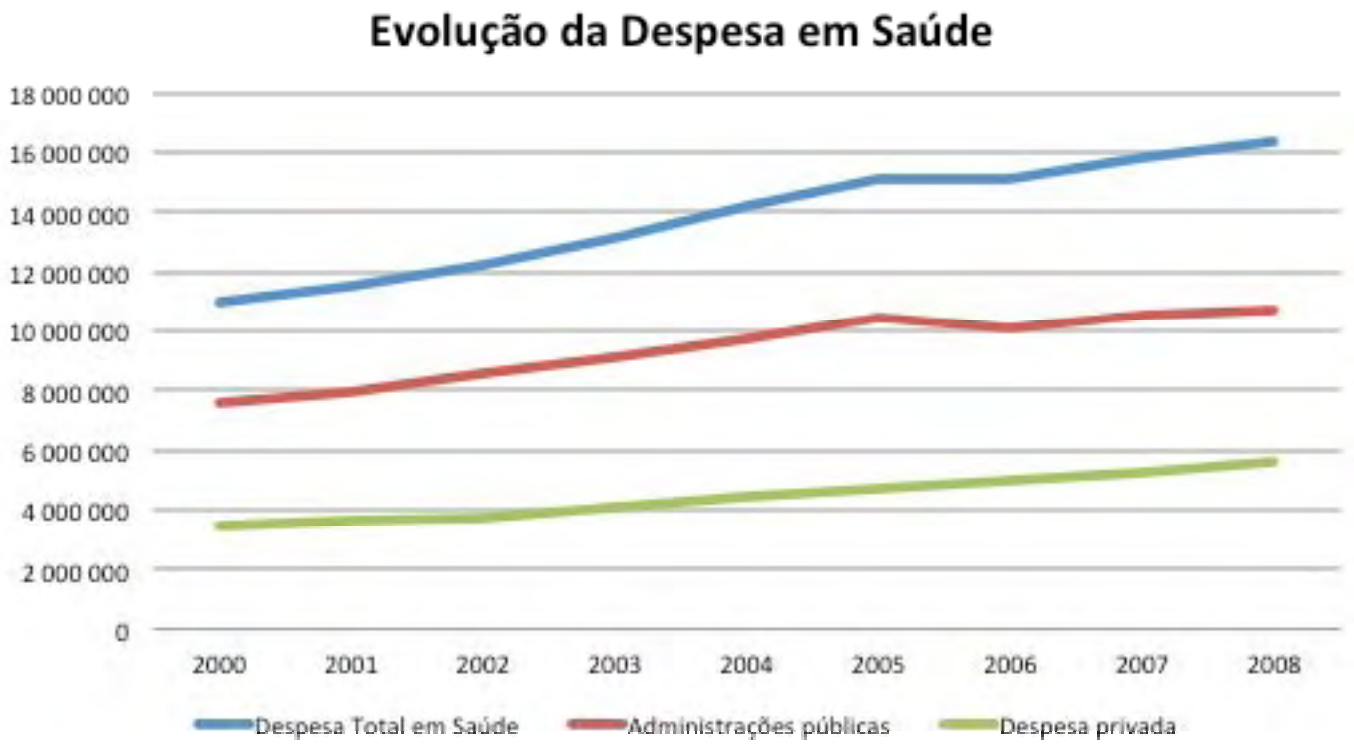
E a Sustentabilidade?

A evolução das despesas de saúde em percentagem (%) do PIB em Portugal e países seleccionados, 1995-2008



Fonte: INE–BP, INE, PORDATA; WHO REGIONAL OFFICE FOR EUROPE, 2011

A sustentabilidade



Fonte: INE
Conta satélite da saúde

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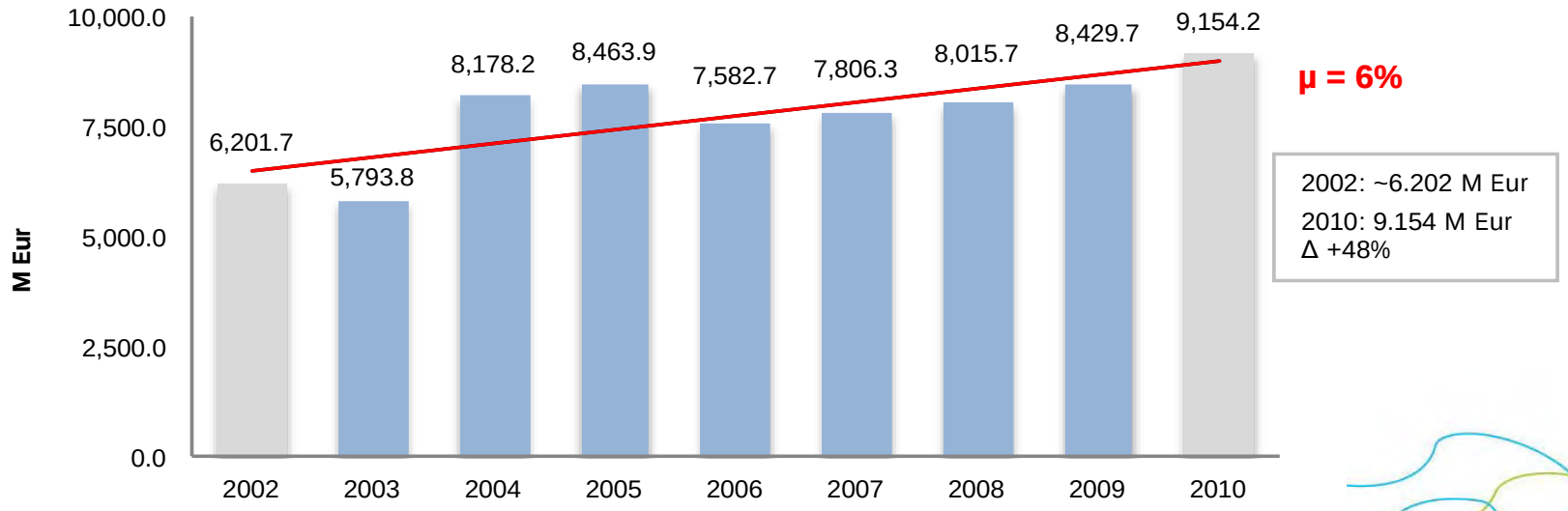
Evolução da despesa pública de saúde

A Despesa Pública do SNS ascende a **9.154** M Eur e apresenta um ritmo médio de crescimento anual de 6%, de 2002 a 2010

Evolução da Despesa Pública do SNS - 2002 a 2010



Fonte: ACSS

Os hospitais representam, no seu conjunto, 55% do orçamento do SNS

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The fundamental Pillars of the Healthcare System

Access - Sustainability

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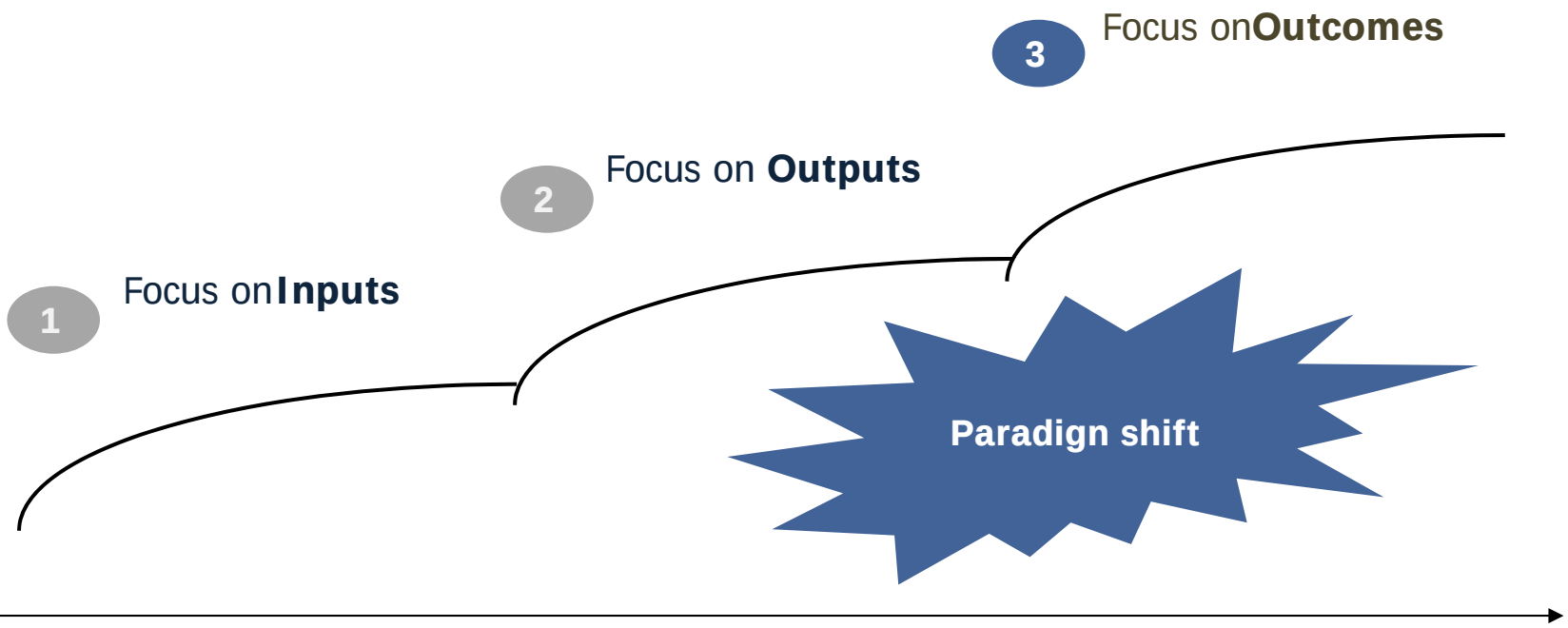
Health Policy

Paradigm shift



2000

- Better access
- Reduction of waiting lists
- Better coverage of Portuguese territory

2010

- Better level of service
- Better healthcare
- Risk sharing

2020

- Personalised Medicine
- Sustainability
- Focus on Patients
- Integrated diseases management

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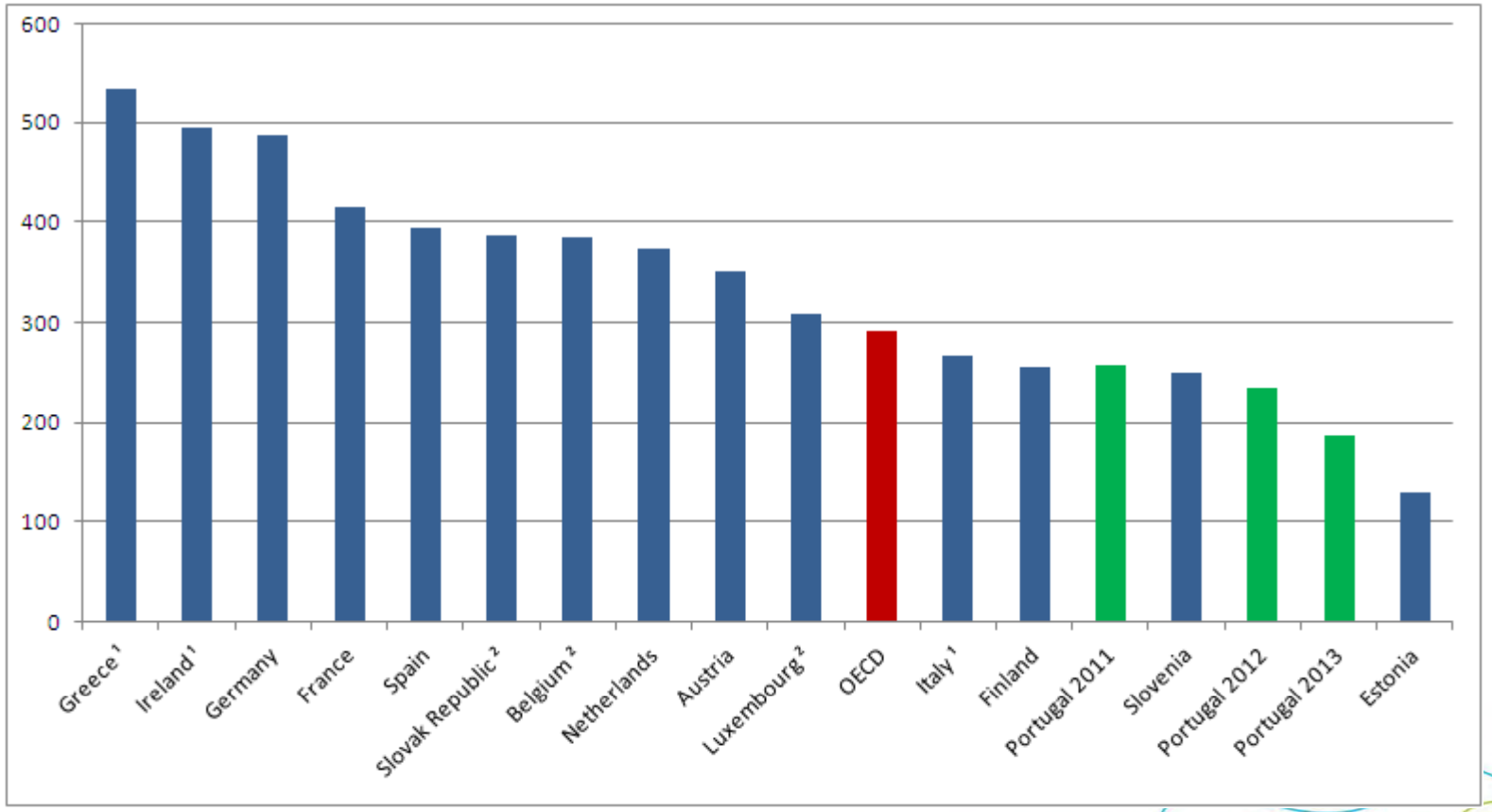
Public Expenditure on pharmaceuticals per capita

ambulatory/hospital



Source: *OECD Health Data 2011.* 1. Cannot be separated and includes medical non-durables. 2. Prescribed medicines only. 3. Total medical goods.
Euro zone countries OCDE Indicators 2009 (or nearest year) Portugal 2010,2011 Infarmed Reports Ambulatory; 2013 Target MOU for 2013

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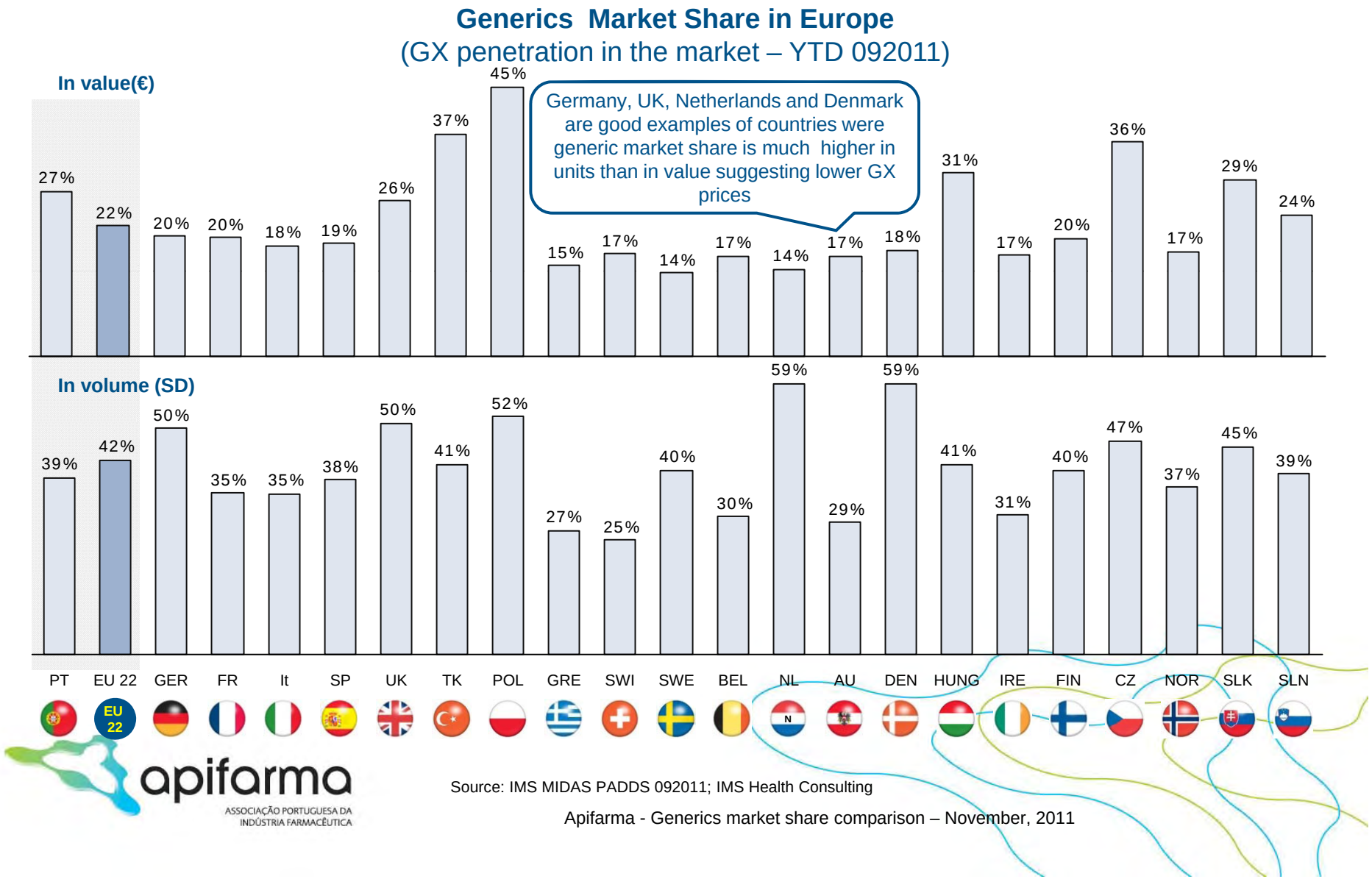
Generics market share varies significantly among the countries both in value and in units showing different country dynamics



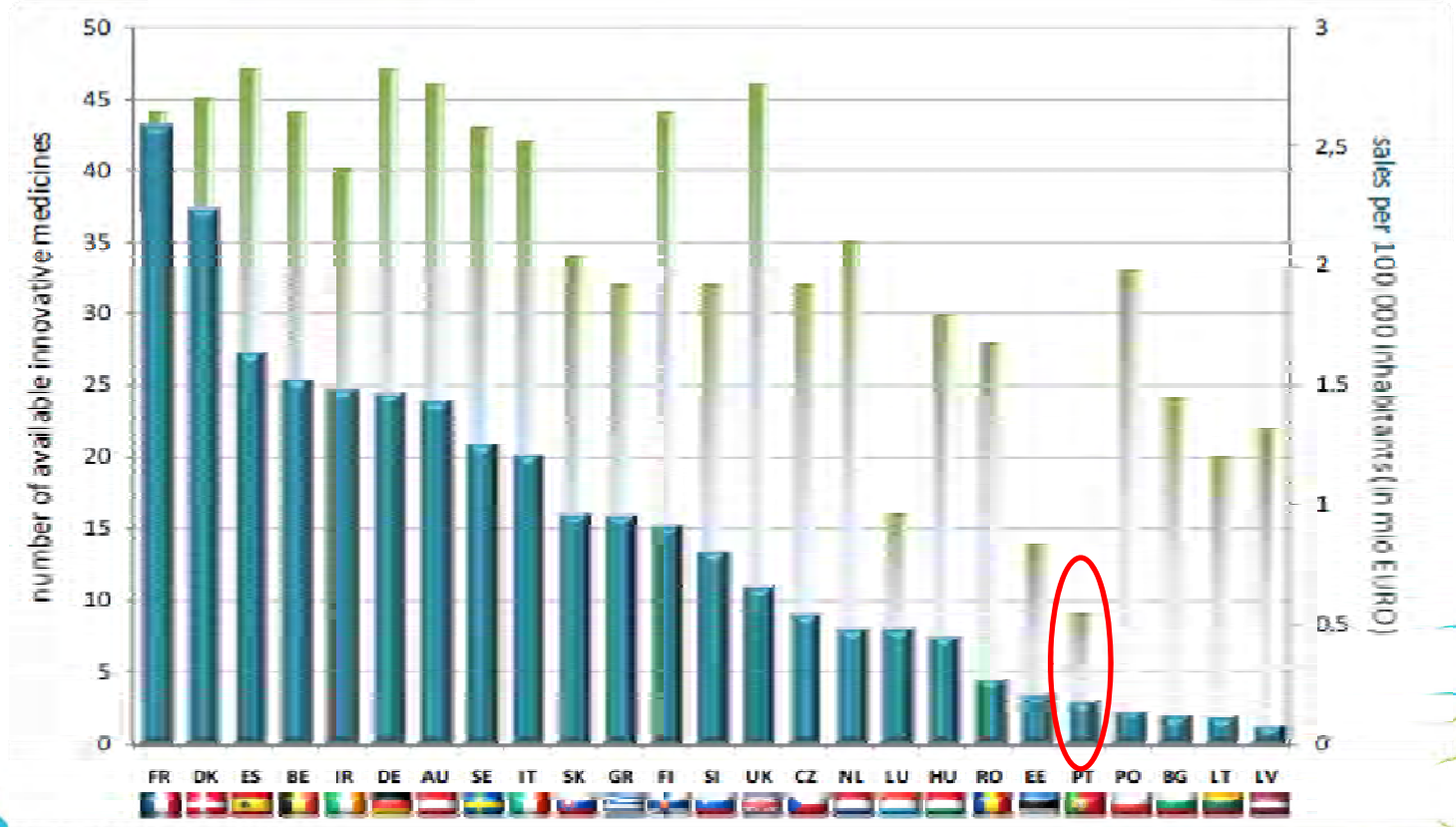
Source: IMS MIDAS PADDS 092011; IMS Health Consulting

Apifarma - Generics market share comparison – November, 2011

Access to the Market of Innovative Medicines

Patients ACCESS to Innovative Medicines in Portugal is the LOWEST

Sales per 100.000 inhabitants vs. Number of available innovative medicines - 2009



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Source:Ministerial Conference "Innovation and Solidarity on Pharmaceuticals" Brussels –23 & 24 September 2010

Access to the Market of Innovative Medicines

Portugal is the country where the DELAYS ARE LONGER

Study* reveals:

- **Probability of the financing decision occurred within the legal timelines:**
  - ❑ 0% regarding hospital medicinal products (Δt=70 days)
  - ❑ < 10% regarding ambulatory medicinal products (Δt=110 days)

- **Median time from funding application to decision:**
  - ❑ Ambulatory – **292 days**
  - ❑ Hospital – **481 days**

- **Specific Groups** (*Median time - days*)
  - ❑ Medicinal products for exclusive in-hospital use – **634 days**
  - ❑ Orphan medicinal products – **718 days**
  - ❑ Oncologic medicinal products – **743 days**
  - ❑ New therapeutic indications – **890 days**

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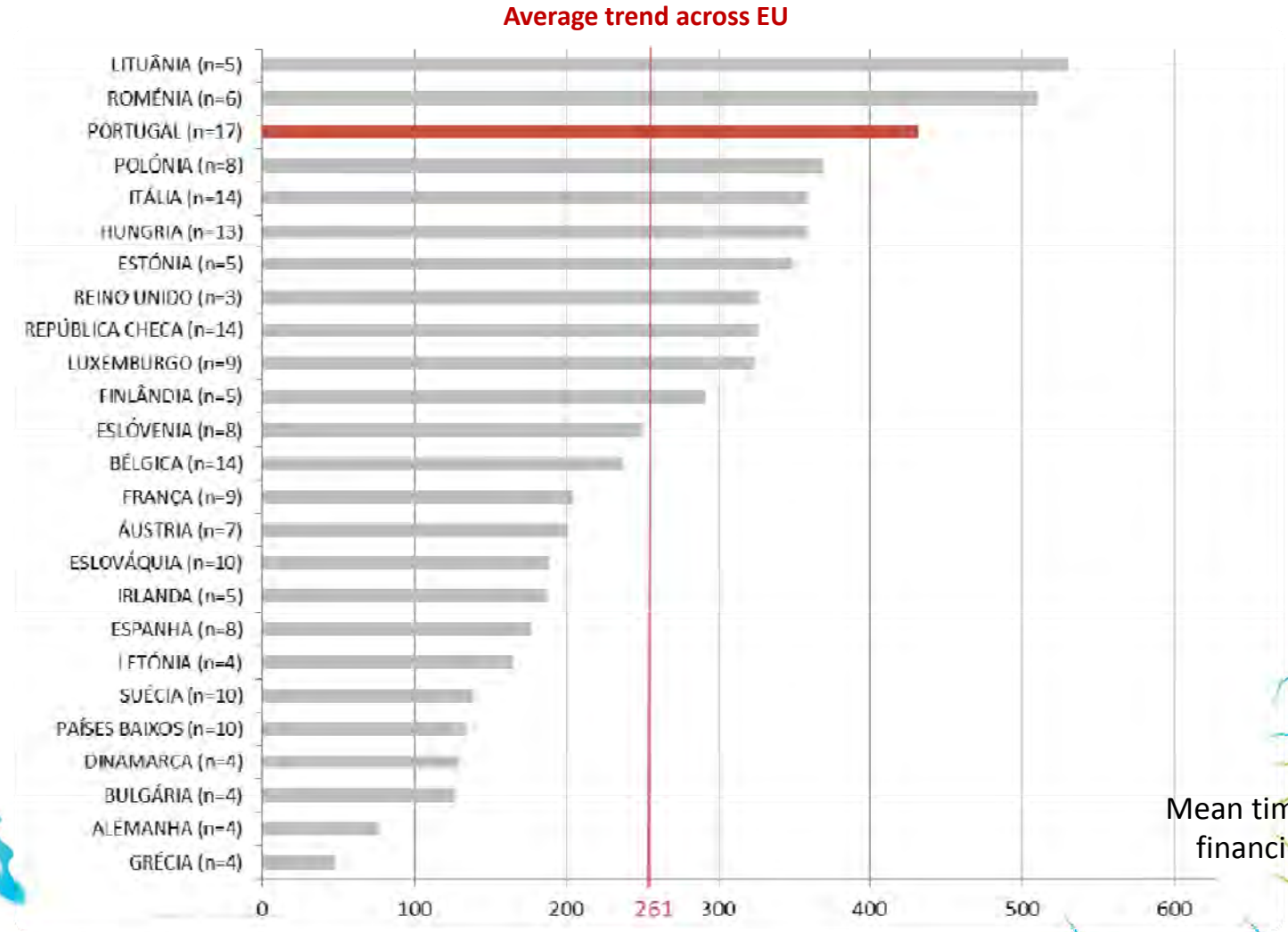
* Retrospective study concerning the evaluation processo of public financing of medicines in Portugal 2007-2011. EXIGO Consultants, Nov. 2011

Access to the Market of Innovative Medicines

European Comparison:



Sustainability of NHS – Social and Economical Framework

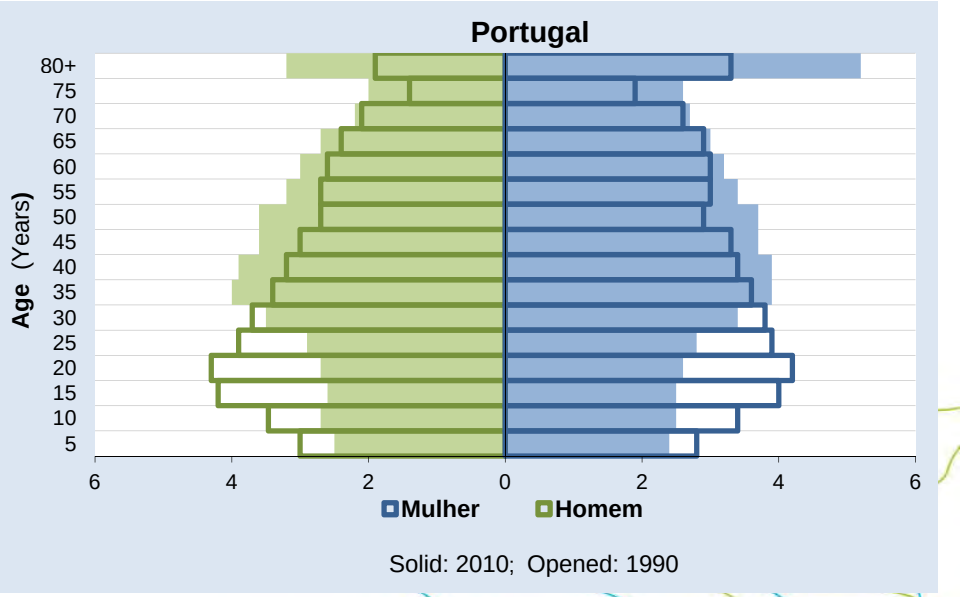
- **Macroeconomic context:**
  - Global economical and financial crisis
  - Additionally Portugal is overcoming an excessive deficit situation

- **Social context:**
  - Ageing population
  - Increase in chronic diseases
  - Growing societal demand for improved health care.

Pressing Health expenditure

Indicator	2011	2012 F
Real GDP Growth (Δ%)	-1,6%	-3,3%
Unemployment Rate (%)	+12,7%	+14,4%
Public Deficit (% GDP)	-5,9%	-4,5%
Consumer Price Index (Δ%)	+3,7%	+3,2%

Source: INE, FMI, Apr.2012



Source: Eurostat 2011

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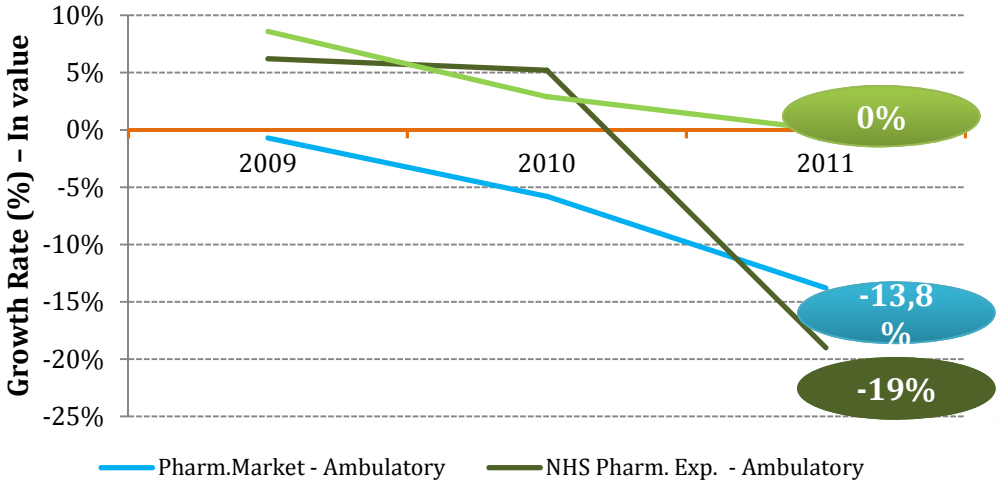
Sustainability of NHS – Pharmaceutical Market

Pharmaceutical Market and NHS Expenditure are declining

- The Outpatient Pharmaceutical Market is in a strong downward trend, with losses in 2011 of:
  - € 493 million (-13,8%, year on year)
- NHS expenditure with medicines are controlled and in decline
  - € 312 million (-19% year on year in the outpatient market)



Outpatient Market	2009	2010	2011
H.V. (%)	-0,7%	**-5,8%**	**-13,8%**
Δ(M€) in Retail Price	-27,4	-218,4	-493,0

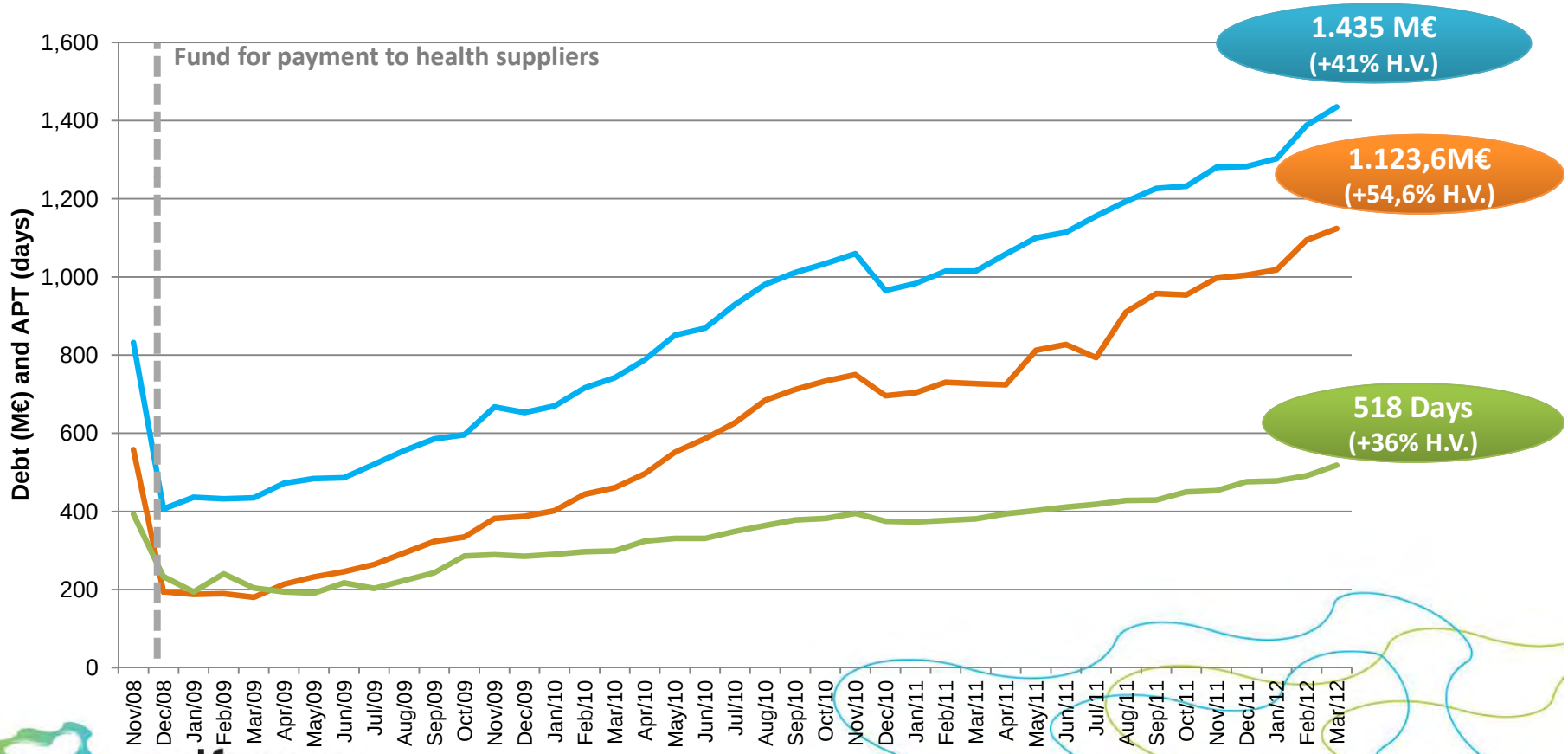
NHS Expenditure		2009	2010	2011
Outpatient		1559	1641	1328
	%GDP	0,92%	0,95%	0,78%
	H.V. (%)	6,2%	5,2%	**-19,0%**
Hospital		973	1000	1000
	%GDP	0,58%	0,58%	0,58%
	H.V. (%)	8,6%	2,9%	0,0%
Total (%GDP)		1,50%	1,53%	1,36%

Sources: (1) IMS Health; (2) Infarmed I.P.(Hospital Data 2011 provisory)

Sustainability of NHS – Hospital Debt

• Regarding hospital market the debt level to the Pharmaceutical Industry overcomes a year free funding of the NHS Hospital medicines expenditure

• Hospital debts higher than ever and lack of bank financing



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Medicines + Diagnostics

Source: Survey APIFARMA, Mar.2012

Sustainability of NHS - Memorandum of Understanding

- Memorandum of Understanding (MoU), as off May 2011, stated:

"Generate additional savings in the area of pharmaceuticals to reduce the public spending on pharmaceutical to **1,25 per cent of GDP by end 2012 and to about 1 per cent of GDP in 2013 (in line with EU average)"**

European Average Public Pharmaceutical Expenditure %GDP - Outpatient

	2008 i)	2009 ii)
EU average	1,0%	1,0%

Source: OCDE Health Data, Jul.11 - i) Data from 20 countries; ii) Data from 17 countries

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Note: Figures obtained based on the public data indicators available in official databases (ex.: OCDE, Eurostat), which are restricted to Outpatient market

➢ Average public expenditure on medicines in the EU % GDP (OCDE)

• According to OECD publications of the Public Expenditure on medicines in the EU average, in the different markets is:

Average Public Expenditure	Outpatient	Hospital	Total
EU	1,02%	0,26%	1,28%

Source: Health at a Glance Europe 2010, OCDE – pg.110
Total Outpatient Expenditure is 1,7%, inclusion of Hospital would add another 15% to pharmaceutical; public purse covers on average in European countries around 60% of total pharmaceutical outpatient expenditure

• There are important differences between countries, from Bulgaria, whose funds cover only 20% public expenditure on medicines to Germany, where the value exceeds 80%.

• There are also significant disparity within the therapeutic range covered by each market, for example in some countries medicines for HIV / AIDS and biological DMARD are included in the outpatient market.

• APIFARMA's survey (Aug.2011) to their European counterparts (21 countries) showed that in the majority of the situations there is no public official database for hospital pharmaceutical expenditure

Sustainability of NHS – 2012 State Budget

• The 2012 State Budget proposed by the Portuguese Government based on the MoU objectives for the health care system, namely for the pharmaceutical expenditure, states that:

"Public expenditure (outpatient and inpatient) on drugs should correspond to 1,25% of GDP in 2012"

	Outpatient	Hospital	Total	Δ (%)
PT 2010	0,95% (1.640 M€)	0,58% (1.000 M€)	1,53% (2.640 M€)	
PT 2011	0,78% (1.328 M€)	0,58% (1.000 M€)	1,36% (2.328 M€)	
PT2012	---	---	1,25% (2.115 M€)	-20% (-525M€)

1,25% GDP

• The overall savings from 2010 to 2011 ascended to 312 M€ (-10% in overall), and the effort asked for the 2012 is a further 213 M€, which amount to 525 M€, a fifth of the 2010 market, endangering the health sector proper functioning

• The **NHS outpatient costs**, as % of GDP, are **already below the EU average**

➢ Global Impact in the NHS 2010 - 2012

- **Impact of Savings 2010 - 2012 NHS**

Year / Total Expenditure	Total (M€)	Δ (%)
2010	2.641	
2011	2.328	
2012 OE	2.115	-20% (-525M€)
2012 M.H.	2.042	-23% (-598 M€)

Puts into question:
-Public Health
-Sustainability of the Pharmaceutical Industry

- Would put Portugal in terms of public spending *per capita* on drugs in the tail of Europe, alongside countries such as Estonia and Poland

Sustainability of NHS – HM Objectives for 2012

- **Total NHS Expenditure 2011: 2.328 M€ (Infarmed)**
  - Outpatient 1.328 M€ (-19%)
  - Hospital 1.000 M€ (0%) (provisional data)

Objectives 2012	M(€)	Var. Rate (%)	Δ(M€)	%PIB*
State Budget 2012 (1,25% GDP)	2115	-9%	-213	1,25%
M.H.	2042	**-12%**	**-286**	1,21%

The objectives of the HM go far beyond the objectives included in the 2012 State Budget 2012 and those contained in the MoU

NHS Expenditure		
Outpatient (M€)		1180
	%GDP	0,70%
	Var. Rate (%)	-11,1%
Hospital (M€)		862
	%GDP	0,51%
	Var. Rate (%)	-13,8%

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* GDP calculated based on government forecasts for the 2012 State Budget and the data available at the time of 2012 State Budget

Sustainability of NHS

Recent changes in the Pharmaceutical Sector - LEGISLATION

- **Margin** methodology changes (wholesale, pharmacies) - introducing price ranges with fixed value plus regressive margins

- New countries for **external reference pricing** (Spain, Italy and Slovenia)

- **Price annual review** (April) according to the new reference countries

- New price difference for **generics price** – 50% lower than the original or 75% (for products below 10 Euro)

- Created the possibility to have **reference price and clusters by ATC level 4**

- **e-prescribing** as prerequisite for reimbursement

- Continued **generics promotion**

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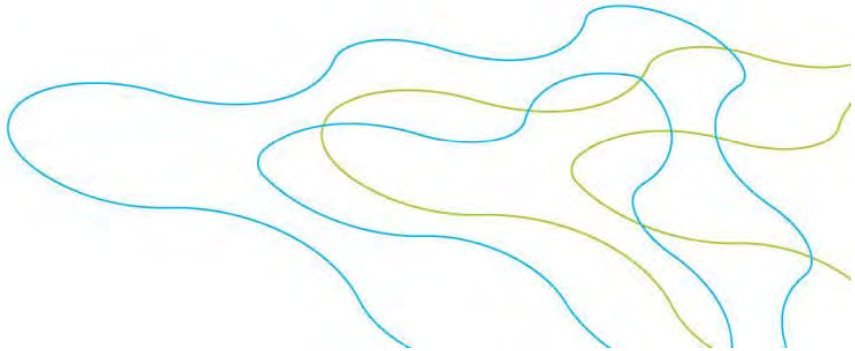

Sustainability of NHS
Agreement Ministry of Health - APIFARMA

APIFARMA's Objectives:

- Alignment with the total public expenditure EU average, i.e. 1,25% of GDP in 2013, regarding GDP forecasted

- The Outpatient Pharmaceutical Market is in a strong downward trend over the past years with lost of more than 493 M€ only in 2011 and more is expected for 2012

- Simultaneously Portuguese NHS pharmaceutical expenditure is controlled and in declining

  - The total NHS costs, as% of GDP, are going to be in 2012 below the European average, despite the unfavorable evolution of the GDP indicator, and decreasing at a faster rate than most other European countries (OECD data).

	2012	2013
Public Expenditure (%GDP)	1,25%	1,25%
Total Public Expenditure (M€)	2.115	2.161

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Δ This way the approach to the European average as stated in the MoU with "Troika" is more suitable and feasible

APIFARMA's Objectives:

- The objectives of maximum growth of expenditure on medicines, for the years 2012 and 2013, must be fixed taking into account the evolution of public expenditure on pharmaceuticals being in alignment with the European average spending of European countries, based on OECD indicators .

- Monitoring the public expenditure on pharmaceuticals, creating a Steering Committee between the Ministry of Health and APIFARMA enabling it to collect and evaluate the indicators produced within the Observatory of Medicines & Healthcare Products of INFARMED and to analyze in due time the evolution of expenditure, allowing the upstream adoption of measures if justified and avoiding administrative measures downstream.

- Definition of a pay-back if the expenditure exceeds the goals of maximum growth of the market for outpatient and hospital care.

- Pharmaceutical industry is available to collaborate with the Ministry of Health in the definition of programs allowing the access of disadvantaged patients to drugs.

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Sustainability of NHS and Pay-Back

- Overall, it should be fixed for the years 2012 and 2013 a total reduction of expenditure on pharmaceuticals of the National Health Service (NHS) to the reimbursement of outpatient drugs and hospital drugs corresponding to 1.25% of GDP for each year .
- Pharmaceutical Industry is committed to collaborate with the Portuguese Government in the effort of the sustainability of public expenditure on pharmaceuticals in the years 2012 and 2013, upon payment of a contribution to be provided by the companies that will join the Protocol.
- If the growth of spending on outpatient and hospital pharmaceuticals is higher in the year 2012 and 2013 than 1.25% of GDP, the Pharmaceutical Industry shall make payment of a contribution equivalent to the difference.

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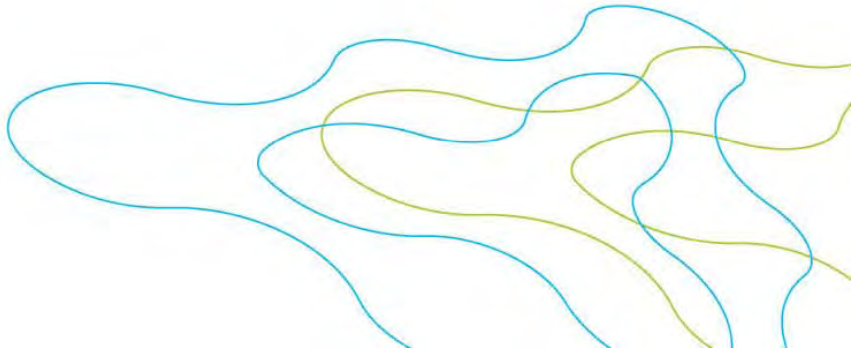

Sustainability of NHS
Current and Future Challenges

- Previsibility and Co-responsability for the sustainability of the medicines expenditure
- Hospital debts
- Centralized purchase and Procurement Central
- (New) Price methodology
- Financing model (New Reimbursement methodology)
- Patents
- Public tenders
- Access to new drugs and innovation
- Attracting more clinical research to Portugal

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➢ Patents

- Ministry of Health undertakes to make all efforts with the Ministry of Justice to implement the installation of the Intellectual Property Court.

- The Ministry of Health is committed to make all efforts with the Ministry of Justice for the establishment of a mechanism for monitoring and assess the implementation of Law of Compulsory arbitration.

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➢ Public Tenders

- Public tenders launched by NHS should be guided by the principle of transparency, proportionality and must respect the rules of market competition.

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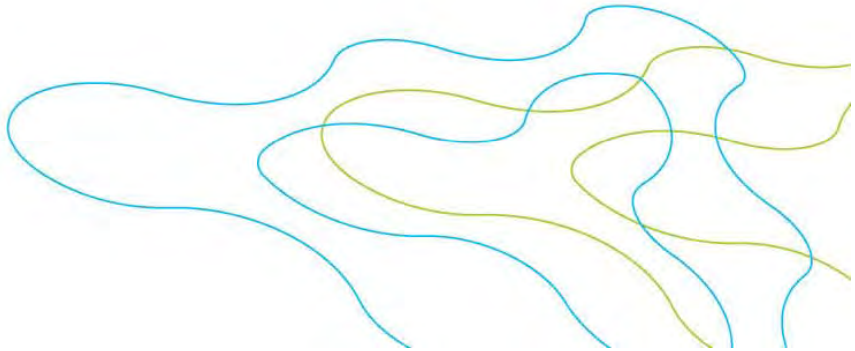
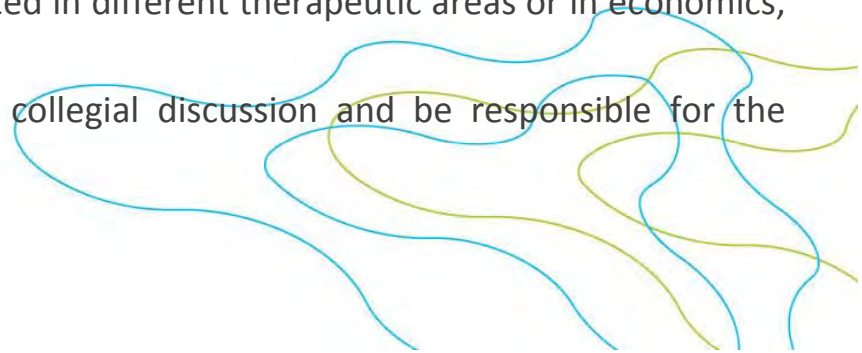


➢ Improving Access to Innovation

- Government should be committed in improving the therapeutic innovation through **reimbursement of new drugs for outpatients and through real access to new pharmaceuticals for use in hospitals**.
- Ensure compliance with the timelines of evaluation and decision making in law (legislation & **Transparency Directive**).
- Improvement of the reimbursement system through the adoption of the following steps: **assessment, appraisal, contract and decision**.
- Implementation of an innovative system of **contractual agreements** based on shared management of risk between pharmaceutical companies and NHS.
- Recognition of the **specificity of certain therapeutic groups**, including orphan drugs and those for certain populations (e.g. Life-saving treatments and Oncology).
- The institution of effective procedures which ensure that, prior to a final appraisal being issued, companies have a right to an **adversarial process** in the event of technical and scientific disagreements.
    - Possibility of a re-evaluation by a second expert, or by means of the mandatory intervention of a specific Commission, composed of experts specialized in different therapeutic areas or in economics, as well as representatives of all interested parties.
    - Such Commission would be the forum for prior collegial discussion and be responsible for the issuance of the final appraisal.



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➢ Development of clinical trials in Portugal

Recognising the strategic importance of health research and R&D for the national economic development:

- Valuing the clinical research activities on the evaluation indicators and financing the activities on the healthcare units
- Valuing the clinical research on programmes to support investigation promoted by public funds
- Creating a Partnership /public-private Platform for the Clinical Research and for promoting the clinical trials with a single coordination
- Setting goals and objectives in a medium term, taking into account the public and private contribution, through a Council or another appropriate mechanism, which ensures the participation of all entities involved

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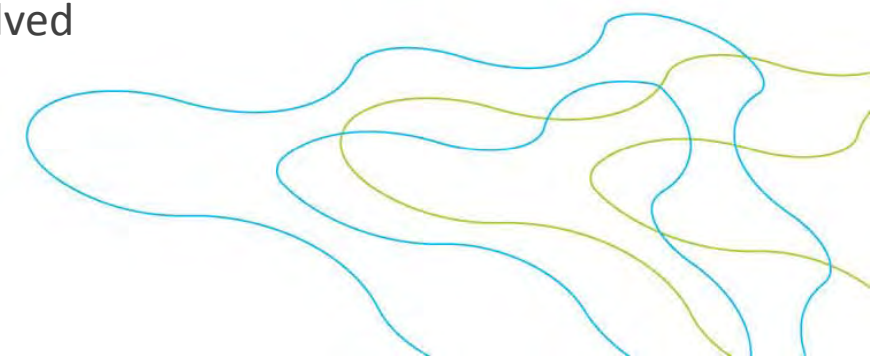


➢ Development of clinical trials in Portugal (Cont.)

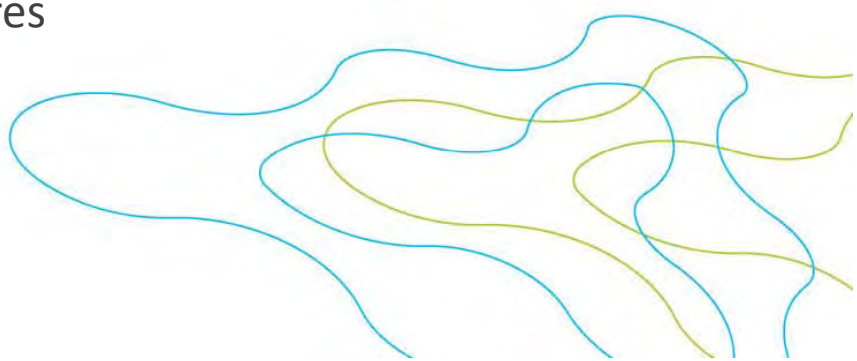
• Enhancing the **Clinical Trials Platform**, ensuring the creation of an electronic system in a '*one stop shop*' model for the registration and monitoring the clinical trials

• Creating a fund to support clinical research – **National Programme that supports Clinical Research** – to be defined between Health Ministry and APIFARMA

• Acceptance of a **single opinion from the Ethics Committee** with a view to better define and streamline the approval process

• Implementation of a Platform which defines a framework for the **development of epidemiological studies** in Portugal

• Creation of a **pharmacoepidemiological network** bringing together academic institutions and public and private research centres



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Facing Global Challenges
- Europe -

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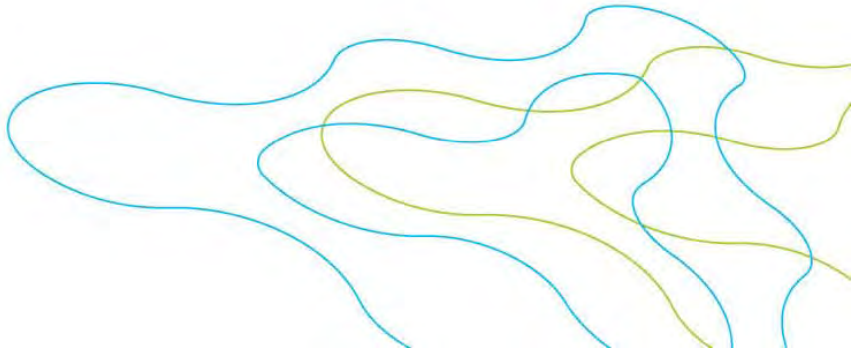

Challenges for the Europe's Pharmaceutical Sector

- Europe has been **losing ground in pharmaceutical innovation**
- Shortcomings in the **availability of medicines** have been identified
- The industry is becoming more and **more globalised**.
- **Scientific breakthroughs** revolutionize the way medicines are developed and prescribed

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Ongoing and Future Initiatives

EU Policies	• **EU Clinical Trials Directive** – Commission plans to make it a Regulation • **Falsified Medicines Directive** – Commission priority: Delegated Acts • Implementation of the **New Pharmacovigilance Legislation** (July 2012) • **Information to Patients** – still no progress in the Council • Enhanced cooperation in the area of **Unitary Patent Protection** • Revision of the **EU Transparency Directive** • Update of the **priority list of the Water Framework Directive** – proposal to include 3 active pharmaceutical ingredients (*diclofenac, estradiol, ethinylestradiol*)
Partnerships (*examples*)	• Science delivering for European patient – **Innovative Medicines Initiative** • **European Innovation Partnership on Active and Healthy ageing**: Commission calls for commitments and issues a communication

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CONCLUSIONS

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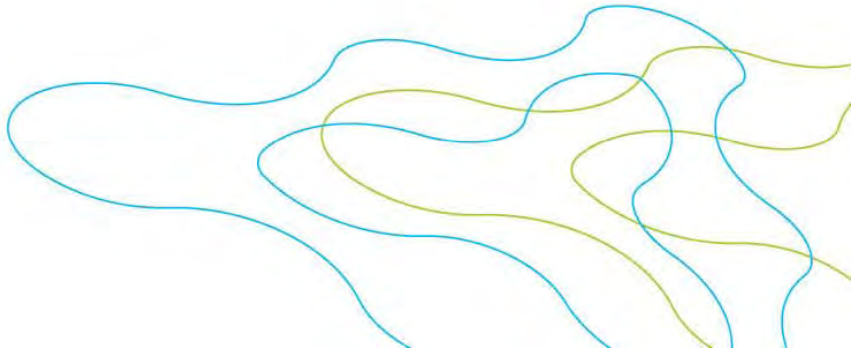

Prevention

Therapeutic value

Reduction of morbi-mortality

Reduction of diseases costs

Reduction of disabilities

Higher productivity

Loer loss of working days

Health Gains/Outcomes

Increase of Quality of Life

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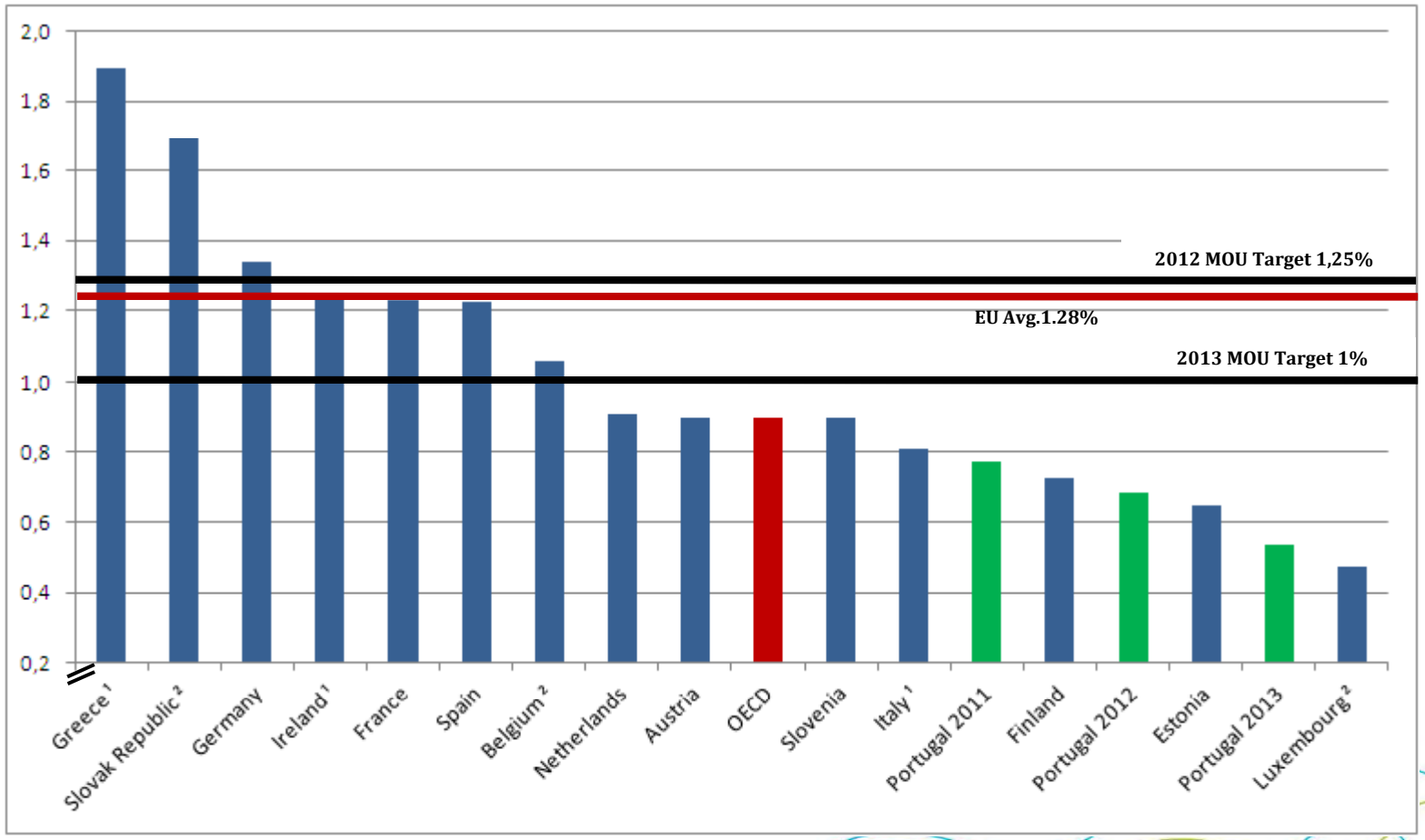
Public expenditure on pharmaceuticals as a share of GDP
and Portugal public expenditure on pharmaceuticals as share of GDP in ambulatory



Source: *OECD Health Data 2011*. 1. Cannot be separated and includes medical non-durables. 2. Prescribed medicines only. 3. Total medical goods.
Euro zone countries OCDE Indicators 2009 (or nearest year) Portugal 2010,2011 Infarmed Reports Ambulatory; 2013 Target MOU for 2013

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Final Reflection

- The **sustainability and budgetary control** is essential
- **Health Expenditure** should be viewed as an **Investment**
- The **strategic nature of the Pharmaceutical Industry** should be reaffirmed in order to promote the stability and predictability of the sector
- **Balanced policies** are needed instead of policies focused on cost reduction /access limitations
- Consequences of avoiding health expenditures in a short-medium term:
  - Restrictions on patients access to medicines and diagnostics, namely to the innovation
  - Limitation on the companies growth, specially the national ones (more dependent from the national market)

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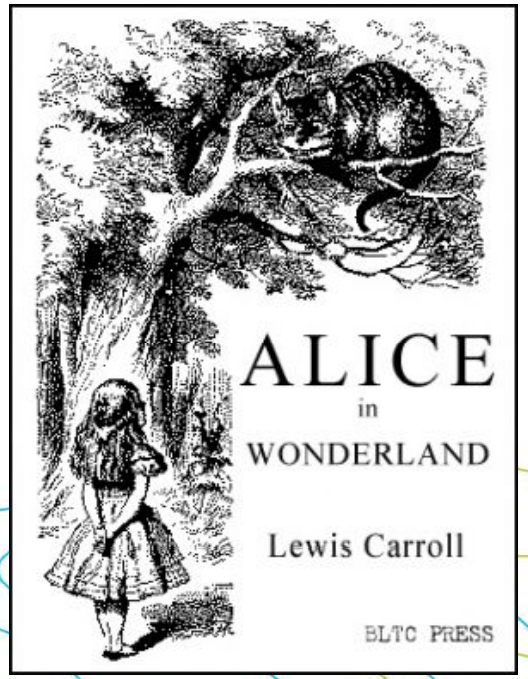
Source: Study"10 anos de Política do Medicamento em Portugal", Prof. P. Pita Barros at al, GANEC, Nova School of Business & Economics May 2011

If you don't know where you are going, any road will get you there.



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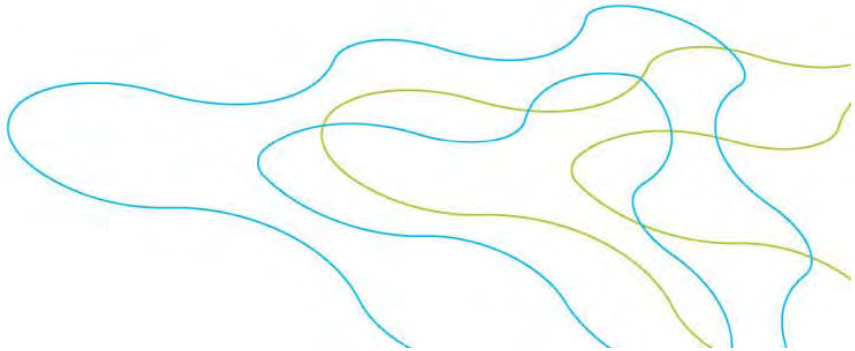

Thank you for your attention

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BACK UP

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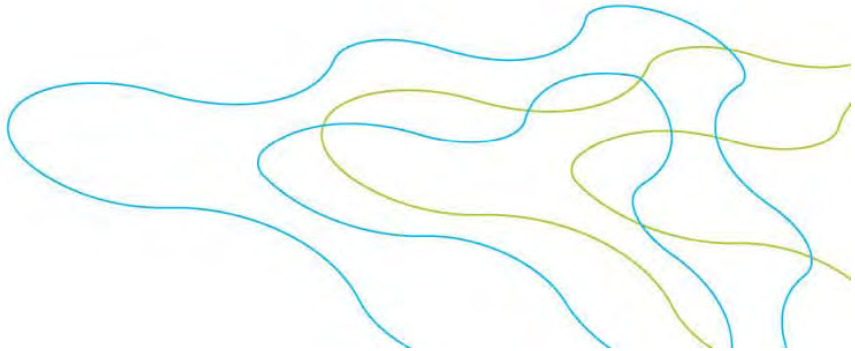

2012 Health Agenda - Portugal

Price Methodology	• Maintenance of the same logic and the stability principle
Reimbursement System and Access to Innovation	• Maintenance of the same logic • Eligibility conditions for reimbursement: avoidance of double demonstration of added therapeutic value and economic advantage • Fixing caps based on objective and transparent criteria (epidemiologica data..)
Intellectual Property – patent litigation	• Transitional measures for arbitration while the Industrial Property Court is not effectively installed
INN prescription	• Prescription limitation to what is economically favourable to the government • INN prescription is also applied to non-reimbursed medicines subject to medical prescription (?) • Patients' access to the most appropriate therapy is limited, both in terms of innovation and in terms of generic medicines
Rational Use of Medicines	• Introduction of therapeutic guidelines for prescribing medicines based on the latest scientific evidence and its suitability to the clinical practice • This can not constitute a mechanism that may limit, delay or prevent access to the innovative medicines (clinical and economic added value)

Ongoing and Future Initiatives - Europe

EU Policies	• **EU Clinical Trials Directive** – Commission plans to make it a Regulation • **Falsified Medicines Directive** – Commission priority: Delegated Acts • Implementation of the **New Pharmacovigilance Legislation** (July 2012) • **Information to Patients** – still no progress in the Council • Enhanced cooperation in the area of **Unitary Patent Protection** • Revision of the **EU Transparency Directive** • Update of the **priority list of the Water Framework Directive** – proposal to include 3 active pharmaceutical ingredients (*diclofenac, estradiol, ethinylestradiol*)
Other initiatives EU 2020 Strategy – *Innovation Union*	• **European Innovation Partnership on Active and Healthy ageing**: Commission calls for commitments and issues a communication • **Horizon 2020 – Programme for Research and Innovation (2014-2020)**

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EU Policies

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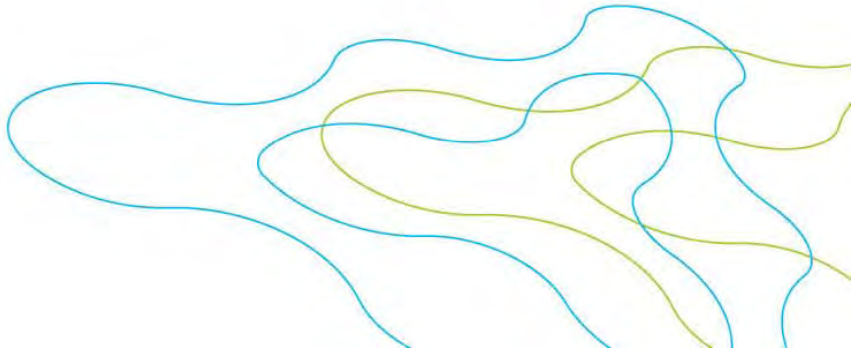

➢ EU Clinical Trials Directive

KEY ISSUES

- **Submissions and assessments in multinational trials**
  - Submission (single EU-portal?)
  - Assessment
  - Decision (dual decision?; one decision?)
  - How many Member Sates involved?
  - What in case of disagreement?
  - Who coordinates?
  - What areas are assessed jointly (scope)?
- **Adapting regulation to risk**
- **Global cooperation and capacity building**
- **Inspections**
- **Transparency**

Commission plans to make it a Regulation

Adoption of legislative proposal in mid-2012

Submission to European Parliament and to the Council

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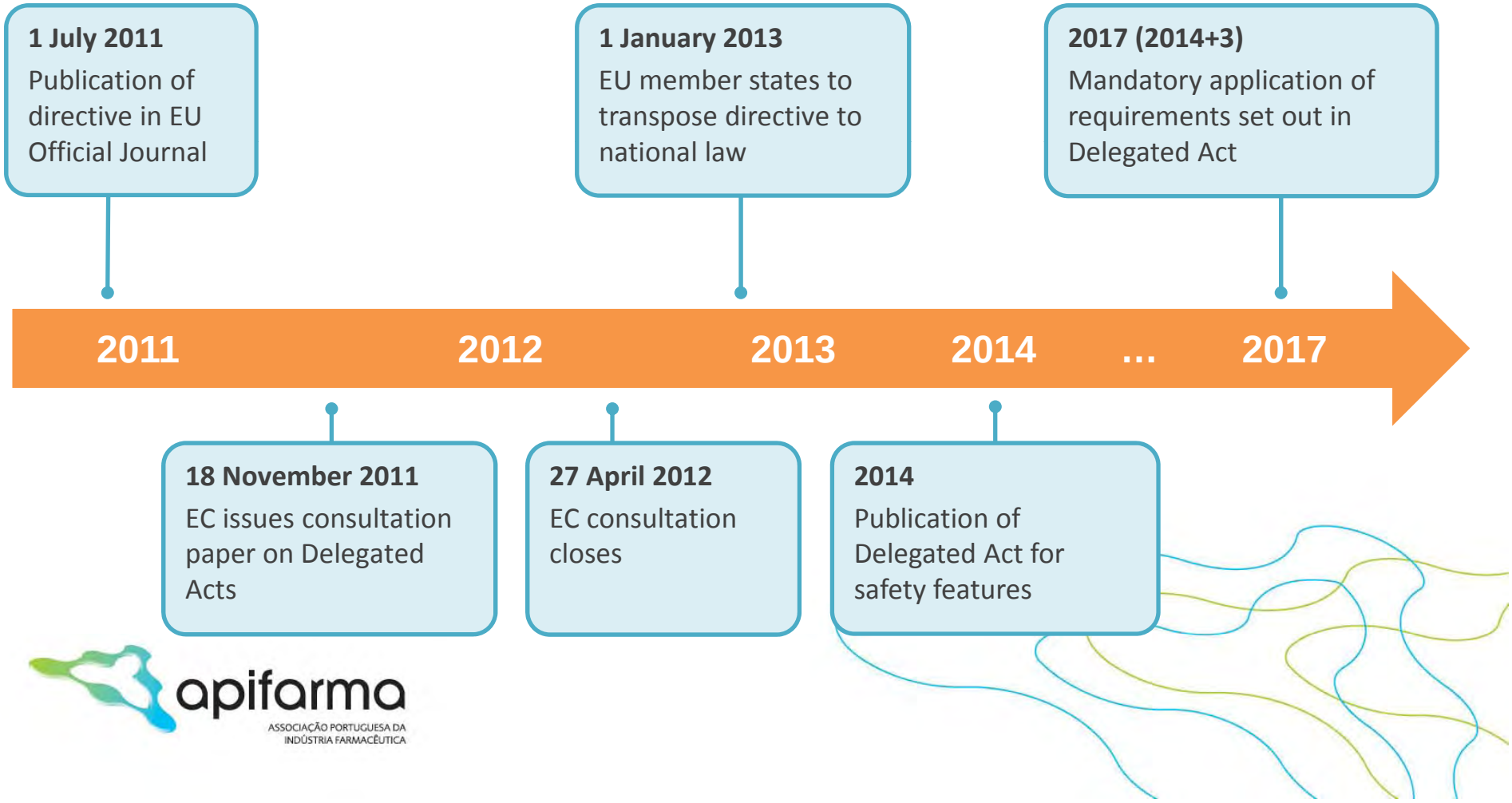
➢ Falsified Medicines Directive

Schedule towards pan-European medicines verification is tight



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➢ Falsified Medicines Directive (Cont.)

Commission priority: Delegated Acts

Safety Features:

- Technical specification
- How it should be verified
- Set up of Repositories System
- Criteria for establishing White List / Black List

L 174/74 EN Official Journal of the European Union 1.7.2011

DIRECTIVE 2011/62/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 8 June 2011
amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products
(Text with EEA relevance)

EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL
Health systems and products
Pharmaceuticals

Brussels, 18/11/2011
Sanco.ddg1.d.3(2011)1342823

DELEGATED ACT ON THE DETAILED RULES FOR A UNIQUE IDENTIFIER FOR MEDICINAL PRODUCTS FOR HUMAN USE, AND ITS VERIFICATION

CONCEPT PAPER SUBMITTED FOR PUBLIC CONSULTATION

Public consultation → Impact assessment → Consultation of member states → Adoption

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➢ New Pharmacovigilance Legislation

Biggest change to the legal framework for human medicines since 1995

Why? Promote and protect public health – effective risk minimisation and optimisation of use of medicines

What? Regulation (EU) No. 1235/2010 and Directive 2010/84/EU

When? By July 2012

How? **Implementing Measures**, **Good Vigilance Practice** but also **new processes, existing processes to be amended**, new IT tools/functionalities to be developed and implemented

Focus on consensus building and collaboration to support a **harmonised approach** to implementation across the EU network

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➢ New Pharmacovigilance Legislation (Cont.)

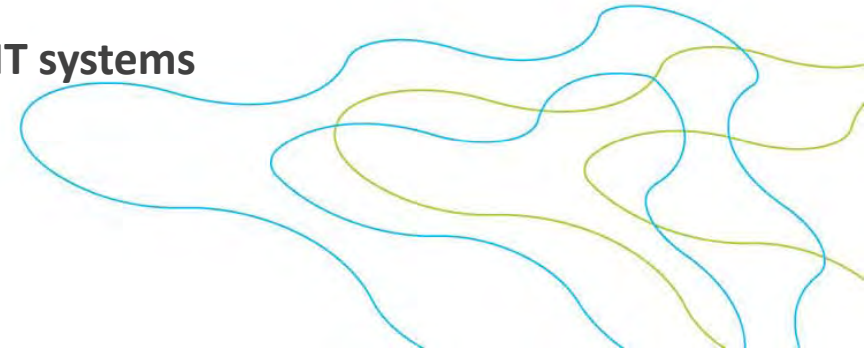
Implementation Plan - 4 main areas of activity

1. Collection of key information on medicines

- **Risk Management Plans**
- **Periodic Safety Update Reports** (B/R evaluation; single EU assessment)
- **Post-Authorisation Studies** (Safety and Efficacy)
- Electronic submission of **core medicine information** by pharmaceutical industry and start validation of received information (Article 57)

2. Analysis and understanding of data and information

- **EudraVigilance and signal detection**
- Finalise business requirements for **enhanced IT systems**



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➢ New Pharmacovigilance Legislation (Cont.)

3. Regulatory action to safeguard public health

- **Scientific Committee and decision-making:**
  - Establish the new Committee (PRAC)
  - Revise the mandate of the current CMD(h)
- **Strengthening referral procedures** (Urgent Union procedure)
- **Additional monitoring** (list of medicines with additional monitoring status)

4. Communication /Transparency

- **Online publishing of information**
  - CHMP and PRAC agendas, minutes, recommendations, opinions
- **Coordination of Member States' safety announcements for NAPs**
- **Public hearings**
- Continued **development of detailed guidance** on all aspects of the new pharmacovigilance legislation through GVP modules

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NAP: *nationally authorised product*

➢ New Pharmacovigilance Legislation (Cont.)

Challenges for the Pharmaceutical Industry

- **ADR's reporting** (patient reporting; processing suspected non-serious adverse reactions reported within 90 days)
- **PhV System Master File** (PSMF on site and PSMF summary in the MA)
- **Renewal application** (updated content)
- **Risk management plan** (all new applications; proportionate to risks)
- **Periodic Safety Update Reports** (frequency as condition to the MA - risk proportionate)
- **Post-Authorisation Studies** (need for national regulation for observational studies; additional budget)
- **Additional monitoring** (black symbol and statements in SmPC and PL)

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➢ Information to Patients

Context and Timelines

• **Dec. 2008:** EC launches its proposals on "information to the general public on prescription medicines" = a left-over from pharma review 2001, G 10, EU Pharmaceutical Forum and the most controversial part of the pharmaceutical package

• **Jun. 2009:** Council decide to freeze their debate until Parliament comes up with an opinion

• **Nov. 2010:** After a lengthy debate with 500 amendments, European Parliament concluds its first reading with an overwhelming majority

• **11 Oct. 2011:** Health Commissioner Dalli presents his "modified proposals", (broadly in line with the Parliament position) and also including a few new elements on pharmacovigilance

• **25 Oct. 2011:** Polish EU Presidency put the modified proposals on the agenda of the Council Working Group (national government representatives): Many MS still seem skeptical/reluctant to discuss ITP at all. It is decided to focus on pharmacovigilance first

• **10 Feb. 2012:** The split proposals, otherwise unchanged, were published in Feb. 2012

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The Council **still has not reached a consensus** on whether to proceed with the Commission's revised legislative proposal

➢ Information to Patients (Cont.)

Industry supports:

- Establishment of a **legal framework** for companies to provide high-quality, non-promotional information to patients, who seek such information
- Application of **quality criteria** to distinguish information from advertising and ensure patients can receive more helpful and non-promotional information on medicines
- **Robust control systems** to be complemented by a **EU-wide code of practice**, which would outline quality assessment procedures, incl. pre-approval of information by registered doctors and pharmacists
- **Unnecessary, disproportionate and costly bureaucracy** with no additional benefit for the quality of information should be avoided
- **No backward steps** for Member States with well-functioning information systems, which are based on self-/co-regulatory mechanisms and where industry is involved

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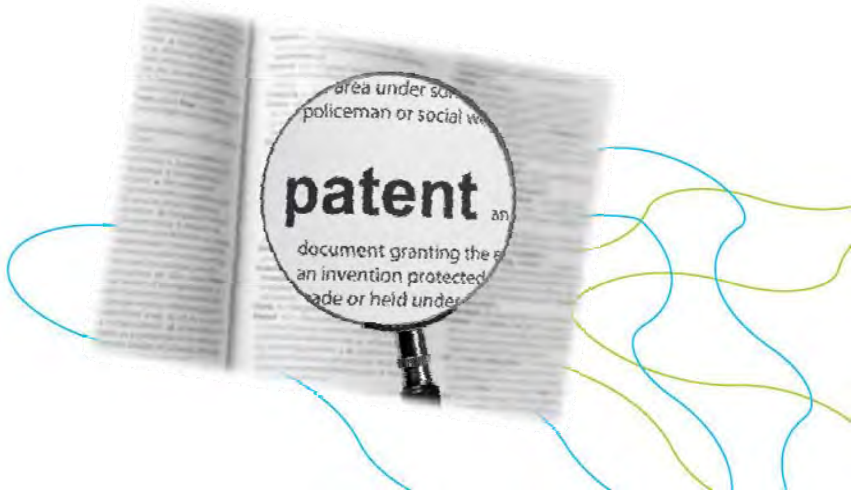
➢ European Unitary Patent Protection

The European Union is moving towards finalising a Unitary Patent system

The rationale is **to increase the competitiveness** of the European economy by:

- reducing the cost of EU wide patent protection
- reducing the cost of translation fees
- reducing the costs of infringement cases by setting up an EU patent litigation system



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➢ European Unitary Patent Protection (Cont.)

The proposed architecture:

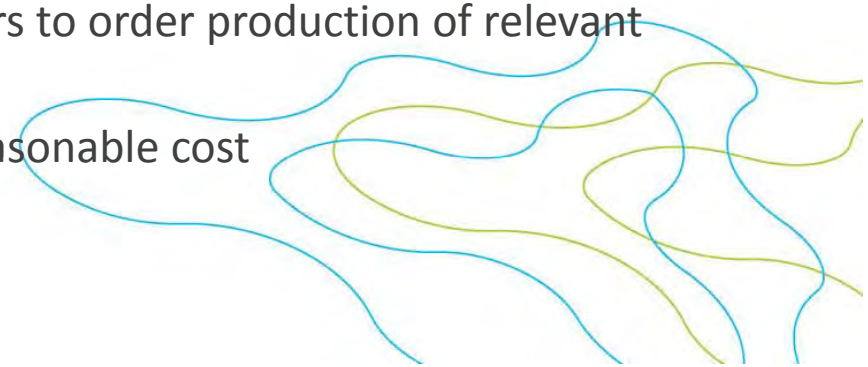
- Unitary patent rights should only be granted once the unitary court is in place
- Structure: central division & regional and local divisions
- Issues of infringement should not be separated from issues of validity

Substantive law

- It should be possible to grant or obtain licences on a country by country basis;
- Provisions defining acts of infringement and defences should be dealt with exclusively in the international agreement;
- Need for clarification that supplementary protection certificates can be based on a unitary patent

Rules of procedure

- Rules will determine how cases are actually dealt with by the courts
- Court with sufficient powers, such as the powers to order production of relevant documents and cross-examination of witnesses
- The new system must deliver high quality at reasonable cost



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➢ Revision of the EU Transparency Directive

Faster access of patients to new medicines

Proposal 1st March 2012 – What's new?

- Clarification of scope **(Art 1, 11 and 12)**
- Definition of HTA **(Art 2)**
- Shorter time-limits **(Art 3 and 7)**
- Remedy for failure to meet time limits **(Art 8)**
- Reimbursement groups **(Art 10)**
- No reassessment of MA criteria **(Art 13)**
- No interference of IPR with P&R procedures **(Art 14)**
- Increased dialogue tools **(Art 15 and 16)**

Improving access to medicines is a complex challenge ...

Europe must continue to *incentivize and reward innovation*

Industry wants to make sure that products are available, but this requires *solidarity among Member States*

EU 2020 Strategy
- Innovation Union -

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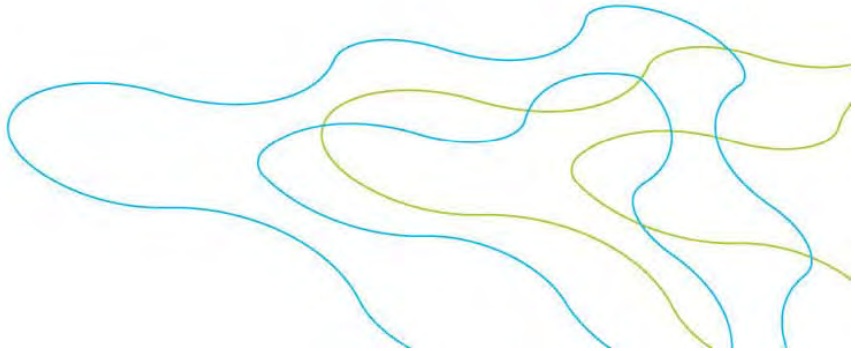

➢ Innovation Union

- The Innovation Union is one of the key elements of the EU2020 strategy
- IU Communication highlights underinvestment, poor framework conditions and fragmentation as causes of EU underperformance
- Initiatives:

European Innovation Partnerships (EIP's)

  - Challenge-driven, integrated, stream-lined approach to deployment of innovation
  - Active and Health Ageing is the first EIP

Horizon 2020

  - €80 billion programme for investment in research and innovation
  - It brings together all EU research and innovation funding under a single programme

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