



ΣfEE

ΣΥΝΔΕΣΜΟΣ ΦΑΡΜΑΚΕΥΤΙΚΩΝ ΕΠΙΧΕΙΡΗΣΕΩΝ ΕΛΛΑΔΟΣ

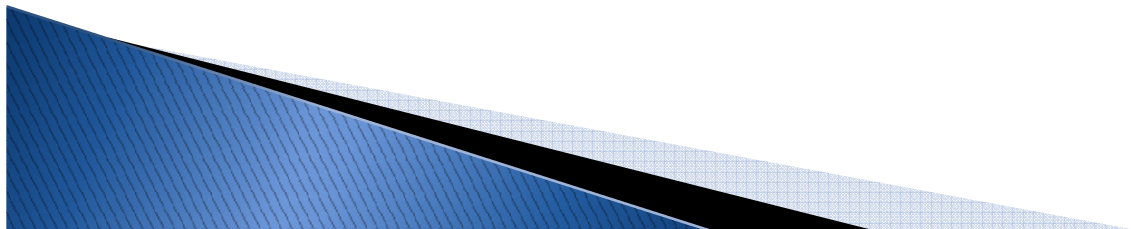
SfEE's Extraordinary General Assembly

**"SfEE's Actions and Positions regarding the critical issues
faced by the companies of our sector"**

September 25, 2012

Agenda

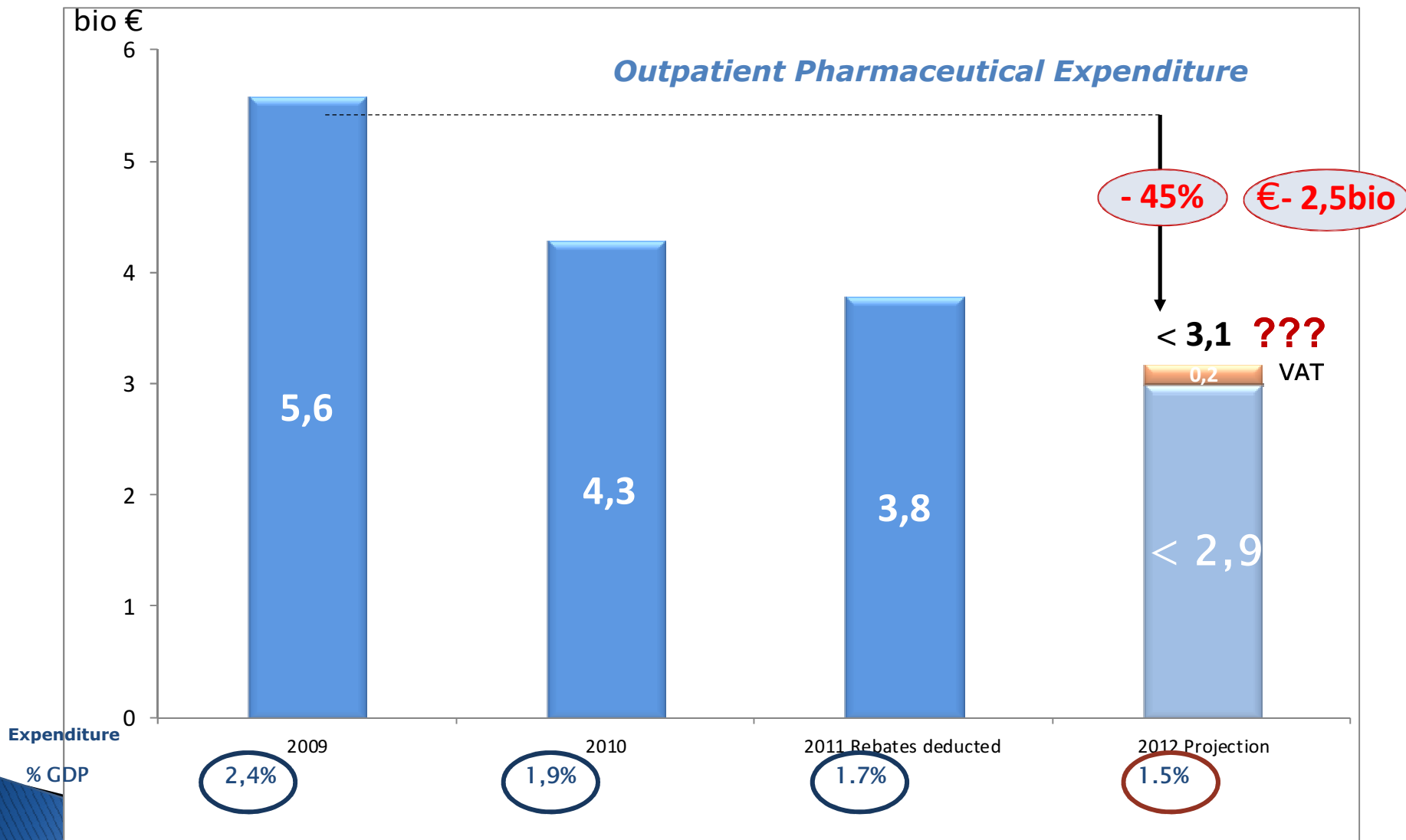
1. Claw Back, Rebates: EOPYY's Expenditure
2. Outstanding Debts – PSI - Offsettings
3. "September" Re-pricing – New Medicinal Products
4. Reimbursement System (Reimbursement Price & Brand name)
5. Stability Pact 2012-2014
Government – Pharma industry



Pharma Industry:

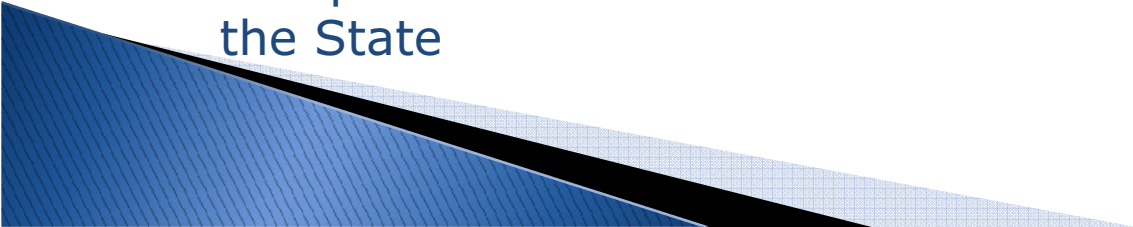
Contribution to Savings: **€2,5 bio** in 3 years!

(Additionally: **€1.8 bio** Outstanding Debts & **€1 bio** bonds' "haircut")



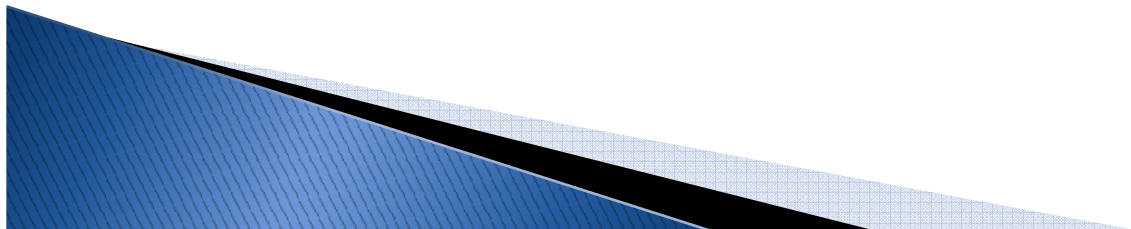
* GDP 2012/2009 ≥ -20%!

SfEE's Position on Claw Back

- ▶ SfEE is **totally opposed** to the payment of the legislated clawback, because:
 - It is a serious disincentive for the implementation of structural reforms and therefore any excess must be calculated **after all measures and reforms** have been implemented following the deadlines provided by the MoU and applied to **all partners of the pharma sector**
 - The calculation must be based on the sales reimbursed by SSFs in **ex-factory prices**
 - The **hospital use only products** distributed by EOPYY (L.3816) must be **exempted** by the calculation
 - **VAT should not be calculated** as public expenditure!
 - Whatever the excess, this should be calculated on a **yearly basis**
 - Companies should be allowed to offset the clawback with debts of the State
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Sfee's Positions – Actions on Outstanding Debts

- ▶ Payment of the entire amount of outstanding debts owed by the State to the pharmaceutical companies within 2012
- ▶ Determine a concrete plan of payments of the outstanding debts of public hospitals and social security funds to the pharmaceutical companies
- ▶ If the “bridge” loan is granted within September or October (EOPYY + Hospitals) debts Q1 2012 should be paid

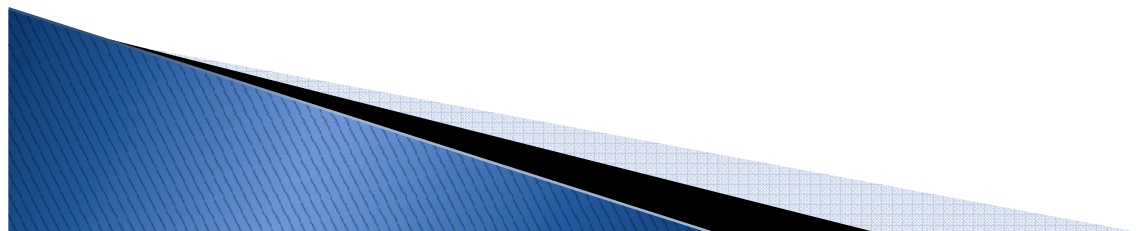


SfEE's Positions – Actions on Off-setting

SfEE has already sent the Ministry of Finance a concrete legislative and regulatory proposal for the expansion of the offsetting mechanism of outstanding debts of pharma companies towards the State with outstanding debts of the latter to them

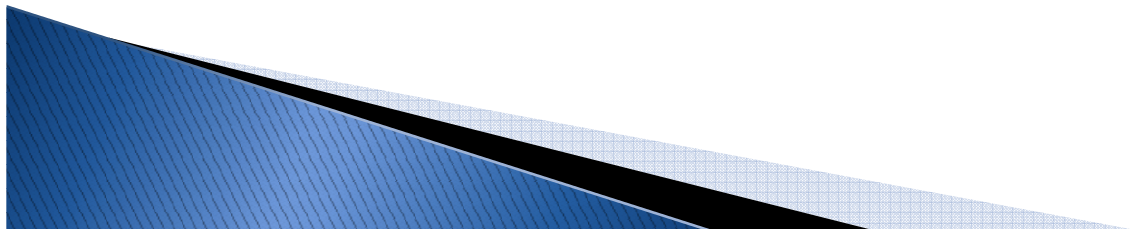


Within the next 2-4 weeks establish an offsetting mechanism of all public outstanding debts towards the pharma companies with debts of the latter towards the State



SfEE's Positions – Actions on PSI

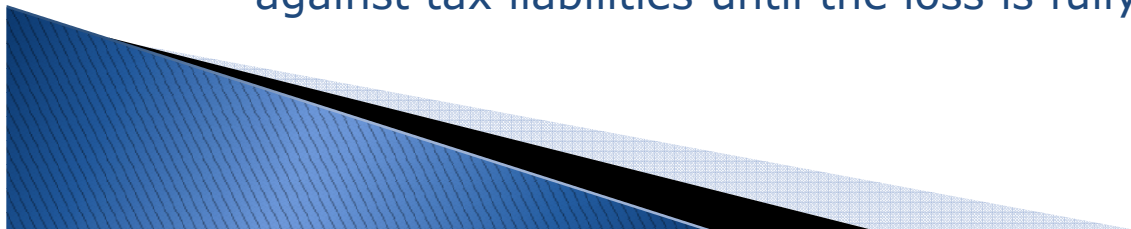
- ❑ In the context of the upcoming recapitalisation of the Greek Banks a provision must be foreseen for the pre-PSI bonds, which were offered by pharmaceutical companies as collateral to secure their borrowing from banks
- ❑ Immediate payment by EOPPY and public hospitals of their debts to pharmaceutical companies for amounts up to the equivalent of the haircut on the pre-PSI bonds they held
- ❑ Prompt payment of reimbursed medicinal products under Law 3816/2010 within one month from their supply



SfEE's Positions – Actions on PSI

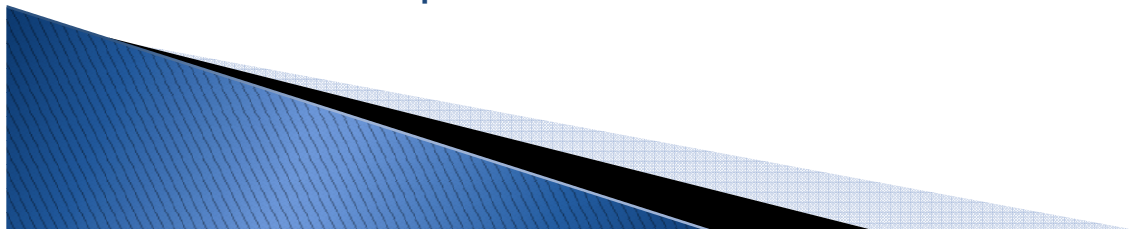
□ Ways to address the negative net balance sheet position:

- Exemption of these pharmaceutical companies from any rebates and claw backs up to the amount of the haircut
- Offsetting the amounts of monthly VAT due against the amount of VAT included in the haircut of 53.5%, which, having already been paid to the State through regular monthly VAT returns, it was paid once again indirectly, through the PSI; this double payment is totally unfair and unreasonable
- Offsetting allowed with income tax liabilities
- Calculation of the net worth of pharmaceutical companies without taking into account the impact of the haircut
- Carrying forward, for tax purposes, the losses caused by the 53,5% haircut in the context of the PSI, so that they can be offset in any year starting from 2011 and up to the maturity of the new bonds issued during the exchange
- Offsetting the loss likely to result from the sale of the new bonds against tax liabilities until the loss is fully offset



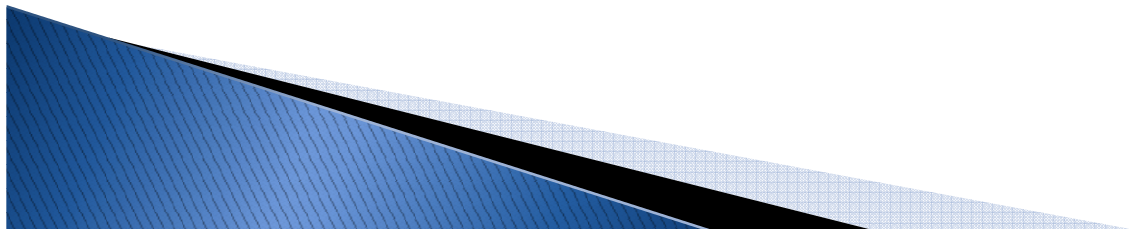
Pricing of Medicines: September Re-pricing

- Reliable, fair and transparent pricing system – Publication of all data on the internet and publication of the draft Price Bulletin
- **On patent**: Re-pricing based on the average of the 3 lowest prices in the EU (provision for the exclusion of several countries and of re-pricing of several categories of medicinal products: orphans, vaccines, blood derivatives, antiretroviral, OTC, products of the negative list)
- **Off-patent/Generics/On-patent with Retail Price < 10 Euro**: Horizontal cuts & set as the lowest limit the average of the 3 lowest prices in the EU
- Submit verification sheet & prices crosscheck of all products by the companies, excluding orphans, vaccines, blood derivatives, OTC, antiretroviral medicines, based on the IDIKA and negative list file
- No publication of the hospital price in the Price Bulletin
- Implementation of Legislation on the profit of pharmacists regarding medicinal products of L.3816



SfEE's Positions - Actions: Price Bulletin with New Medicinal Products

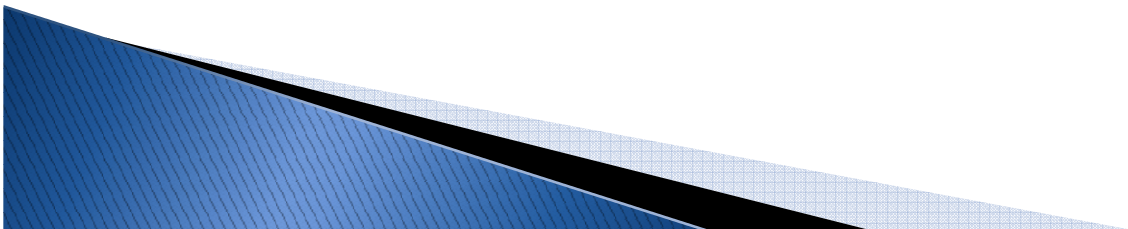
- ▶ A Price Bulletin including all new medicinal products should be immediately issued, according to the EU Directive 89/105 based on which Price Bulletins should be issued every 90 days
- ▶ SFEE has already proceeded with legal actions against the non issuance of the Price Bulletin
- ▶ SFEE constantly demands the immediate issuance of a Price Bulletin with new medicinal products to all relevant stakeholders, in order to achieve patient access to new treatments
- ▶ Remove from the Price Bulletin all medicinal products introduced arbitrarily in the April 2012 Bulletin
- ▶ Deliberations between SFEE and the Government for the gradual reimbursement of new medicinal products that are priced, based on specific criteria



Expansion of the existing pilot reimbursement system (Reimbursement Price)

In collaboration with PEF, SFEE is in deliberations with the Government to immediately expand the pilot reimbursement system that will secure:

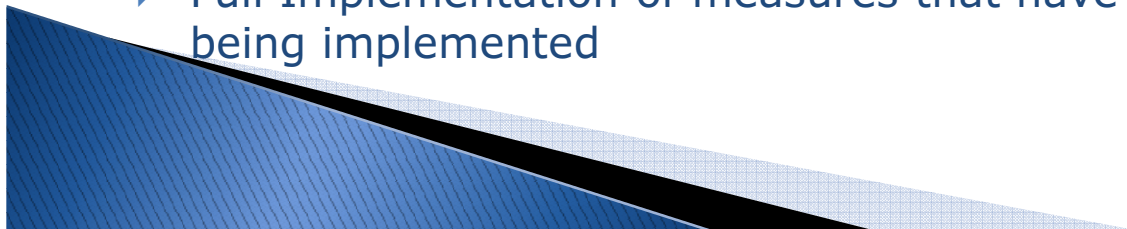
- Prescription by brand name with the responsibility of the doctor
- A specific and fair reimbursement price



Immediate Implementation of Structural Reforms

E-prescribing & Therapeutic Protocols

- ▶ **Full implementation of e-prescribing** will contribute in:
 - Saving of resources
 - Reaching targets and improving the functioning of the system
 - Reliable monitoring of allocation of pharmaceutical expenditure, in order to obtain substantiated data as a tool for developing and setting sound health and pharmaceutical policy
 - Combat of illegal trafficking of fake prescriptions
- ▶ **Full computerization and technological modernization is the only effective and safe solution for:**
 - Rationalization of health expenditure and volume reduction
 - Control of supplies and expenditure by government
 - Objective and substantiated calculation of the expenditure throughout the supply chain from the insurance funds
- ▶ **Implementation of Diagnostic & Therapeutic Protocols of DRGs and the patients' co-payment rates**
- ▶ Full Implementation of measures that have been instituted and are not being implemented



What is immediately required:

- ▶ **YES** to structural and implementable reforms
NO to horizontal measures like clawback
 - ▶ The most important reform:
e-prescription = **Transparency**
 - ▶ **All partners and cost centers in the health sector** should contribute in the savings in order to secure their viability
 - ▶ **EOPYY's Financement** to secure payments within 2012
- ▶ A Stability Pact for 2012-2014 (Government-Pharma Industry) with commitments and obligations from both parties, within October 2012

