Review of Actions taken within 2012 – 2014
Reimbursement Committees

Paschalis Apostolides
Managing Director AbbVie
Vice President of SFEE

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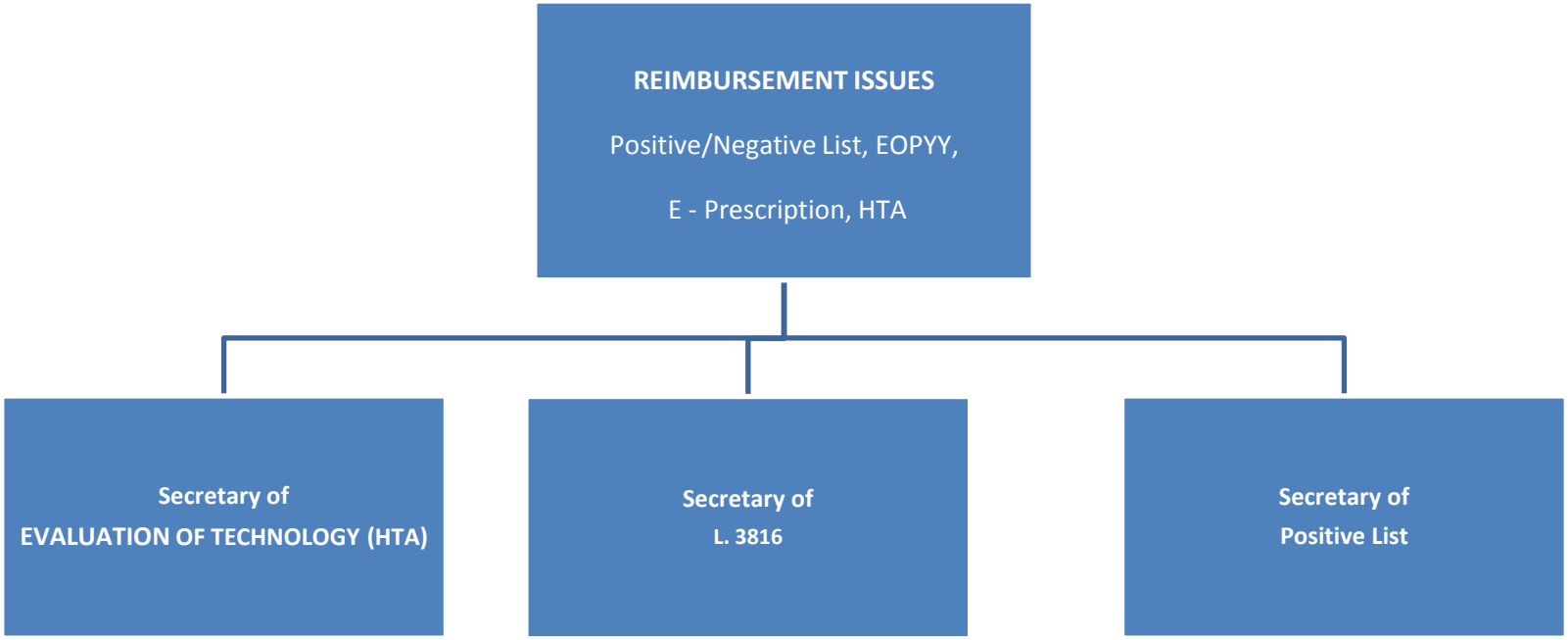
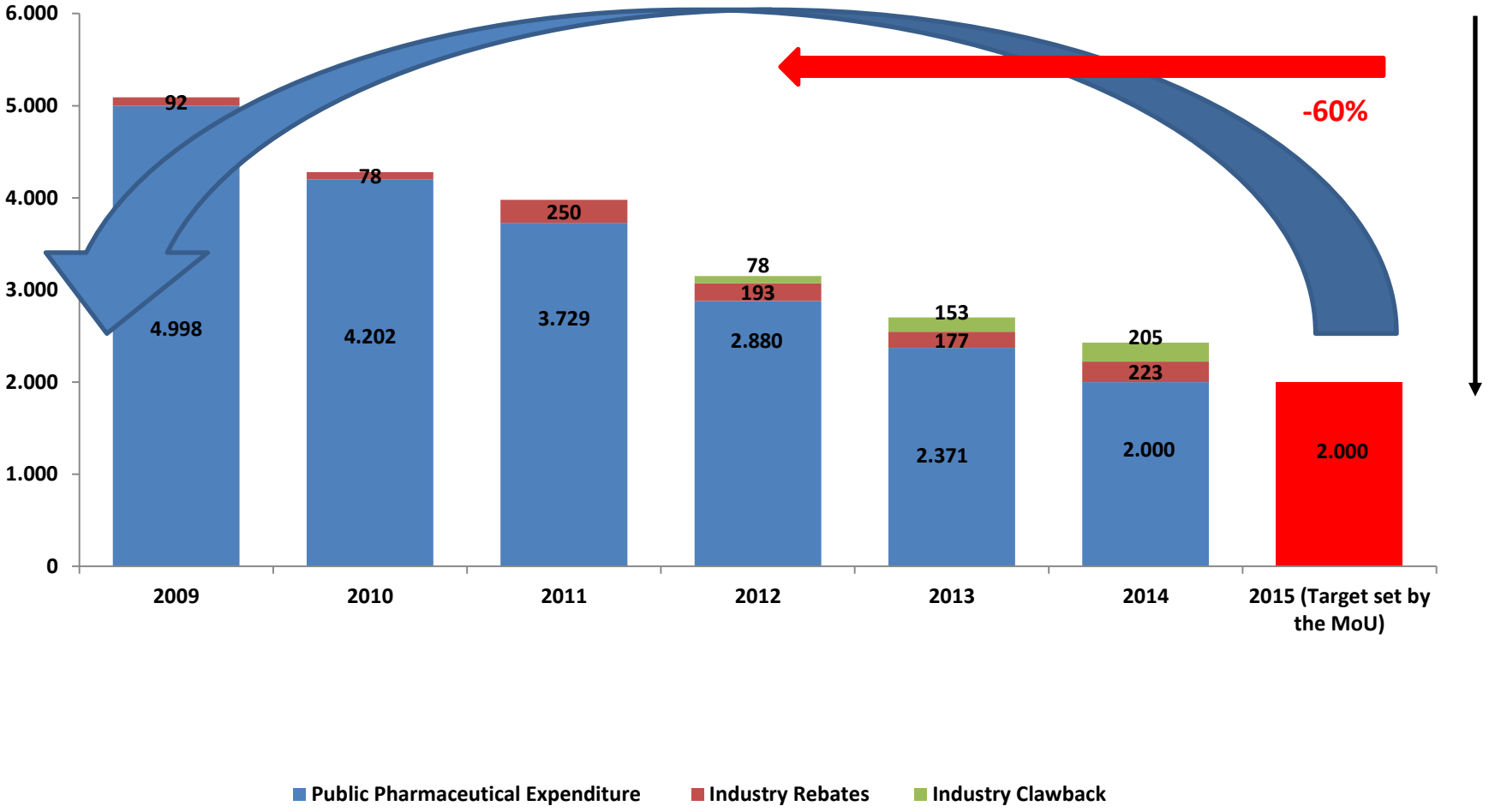
Reimbursement Committees



Pharmaceutical Expenditure & Rebates Evolution (2012-2014)



**Latest data EOPYY, January 2015*

Pharmaceutical Expenditure & Rebates Evolution (2012-2014)

- Continuous reduction in the public pharmaceutical expenditure for the past 4 years has led to an overall 60% reduction (2009-2014).
- As a result:
  - Delays in pricing of innovative medicines in order to achieve savings from the 2 annual re-pricing cycles
  - Delays in the reimbursement of innovative medicines in order to further reduce public expenditure
  - Huge hurdles in the uptake of new potentially life-prolonging and life-saving medicines
  - Numerous changes in rebates/clawback/cost sharing among stakeholders (co-pays)/inclusion criteria for the positive list and changes in calculation of positive list therapeutic reference price
  - Increased rebates and clawback - **solid proof that the €2bn is an unsustainable fiscal target**
  - Coverage of increased uninsured population creates an important issue for the government, (allocation of €350M for the uninsured, included in the target)

Changes in Rebates (2012 – 2014)

- Rebate for inclusion in the **positive** list **9%**
- Additional rebate for active substances **solely grouped** in a cluster **+ 2%**
- Additional rebate for inclusion of **new active** substances in the RL for the 1st year + **5%**
- **Scaled rebate** set in May '12 based on 3-month sales volume starting from €400.000 **per SKU** from 2%-8%. Scale was changed in both volume sales & respective % contributions in Jan '14 starting from **€100.000** per SKU from 2%-12%. In Aug '14, the basis of calculation for volume rebate was changed based on **brand** sales.
- L.3816 medicinal products **discount** over hospital price was initially set at **5%** for all products at **SKU level**. In Jan'14 this was increased to **5 + 1.5%**, which was changed again in Aug' 14 at a **brand level** based on 3-month sales (%)
  - **5 + 1.5%** up to €2.5 mio
  - **5 + 3%** from €2.5 - €5 mio
  - **5 + 4.5%** for over €5 mio
- Rebate of **50%** for **MAH (co-pay)** for unique medicinal products, in cases where the Ret. Price > Reimb. Price. As of 01.03.15, this has changed to **30% for MAH,** for any additional difference above 6€. Patient co-pay should not exceed the €50 threshold. However, implementation has been postponed.
- Additional rebate for L.3816 products supplied directly to private pharmacies; MAH should pay the difference between the purchase & the price if sold to EOPYY pharmacies.

Rebates L.3816/2010 Example

On-patent product with an ex-factory price of €100 which is at the first year of circulation and with term sales of above €5MM

Ex-factory: ***100€*** (which already is one of the lowest prices in Europe)

- minus 8,74% (hospital price): ***91,26€***

-minus 5% (national mandatory discount) : ***86,70€***

-minus 4,5% (term volume rebate): ***82,80€***

-minus 5% rebate (first year of circulation): 78,66€

All rebates shape a selling price which is ***22%*** lower than the ex-factory price of the product

- *This case study has not taken into account clawback or L.3816 additional rebate in case it is directly sold to pharmacies, which will further increase the difference between Ex-factory and net selling price.*
- ***In general terms, the reduction can range from 14% to 22% depending on sales and years of circulation.***

Rebates Retail Channel (Reimbursed, not L.3816/2010)

- A unique on-patent product with an ex-factory price of 100€ and term sales of above €2MM

Ex-factory: ***100€*** (which is one of the lowest prices in Europe)

- minus 9% (Inclusion in List Rebate) : ***91€***

-minus 2% (alone in cluster): ***89,18€***

-minus 12% (Term Volume Rebate): ***78,48€***

All rebates shape a price which is ***22%*** lower than the ex-factory price of the product

- *This case study has not taken into account clawback, participation of MAH in co-pay (50%-50%) or if1st year of circulation extra rebate of 5%, which will further increase the difference between Ex-factory and net selling price.*
- ***In general terms the reduction can range from 11% to 22% depending on sales and years of circulation.***

Clawback

- A controlling mechanism to sustain the public outpatient expenditure at the €2bn on an annual basis
- It is distributed across pharma companies based on their Market Share
- It is calculated on a semester basis
- Clawback is estimated after deduction of
  - 9% rebate
  - Escalating Volume rebate
  - Pharmacy rebate
  - Invoice discount for Pharmacy
  - L.3016/2010 1A products (hospitals only)
  - Patient Copayment
  - Wholesaler margin returned to EOPYY for direct sales
  - VAT
  - Discounts by MAH after agreement with EOPYY
- Clawback is steadily growing on an annual basis despite all measures and efforts to control the expenditure

Total financial burden from rebates & clawback (2012-2014)

Year	Pharma Industry Rebates	Pharma Industry Clawbacks	Total financial burden (a)	Target of Public Pharma Expenditure (b)	% Contribution of Pharma Industry to Public Pharma Expenditure (a/b)
2012	€193 MM	€78 MM	€271 MM	€2,880 MM	***9.4%***
2013	€177 MM	€153 MM	€330 MM	€2,371 MM	***13.9%***
2014	€223 MM	€ 205 MM	€428 MM	€2,000 MM	***21.4%***

Constantly increasing clawback and rebate burden . Solid proof that the €2bn target is unsustainable

Latest EOPYY data, January 2015
Discounts over hospital price are not included here

Reimbursement List I:
Criteria for the inclusion of new medicinal products

- Between 2009-2012, there were **no approvals** for inclusion in the RL
- In **October 2012**, new criteria for inclusion in RL were published. These referred to efficacy, safety, quality & cost-effectiveness of the respective medicinal products (GG2912/30.10.2012).
- **Main criteria included** :

  A) Fast track approvals from FDA & EMA

  B) Orphan drugs & vaccines,

  C) Therapeutic effectiveness & reduction in the cost of treatment

  D) Substitutions of forms or strengths that would not put burden on pharma expenditure &

  E) Date of application

- In **September 2013**, criteria changed and SSF reimburse medicinal products with MA after 01.01.12 **if** they are reimbursed in the 2/3 of EU member-states in which **they are marketed** or in at least 12 EU member-states following HTA evaluation. (GG2219/9.9.2013). By priority
  - Medicinal products whose retail price was lower than the reference price of their category were included
  - Orphan drugs & life-threatening disease medicinal products also are included
- In **March 2014**, aforementioned criteria changed and SSF only reimburse **only those products** that are reimbursed in the **2/3 of EU member – states** or in at least 12 EU member-states following HTA evaluation (GG73/24.03.2014)

Patients have access to new innovative treatments for therapeutic categories that had no or limited alternative

- During 2012-2014, more than **2.550 SKUs** have been included in the list (original & Gx)
- During 2014 only, **74 new active substances** have been included in the list (38 out of 74 were L.3816 products)
- 3 positive list amendments in 2014 (Feb, May, Dec)

Active substances included in RL (2014)

Reimbursement List II:
Changes in the calculation of the reference price

- **Reimbursement price = reference price * # of daily doses of the pack.**
- In Oct'12, the reference price was set as the **lowest cost of daily treatment** (CDT) between on-patent, off-patent & the average CDT of Gx (GG2912/30.10.12)
- However, after strong deliberations with the authorities, this was changed on Dec'12 and the reference price was set as the **lowest between the weighted average of the** CDT for original products & the respective CDT for generics . (GG 3356/17.12.12)
- In Dec'13, the reference price of each group was set as the lowest between the weighted average of CDT for originals & the **average of the three cheapest generics** of each group with a **market share in volume greater than 4%** in the said group, provided that it granted prices lower than the existing system. (GG 3117/B/09.12.2013)
- Finally, in May 2014, the reference price was set at the lowest between the weighted average of CDT or originals & the **weighted average of CDT for Gx that have 20% of market share in terms of sales** in the cluster during the past 6-months.

IMS Positive List Study

- Evaluated changes in co-payment algorithm & reference price estimation between **March 2014 & August 2014**, to assess the burden to all stakeholders (EOPYY, MAH, patients).
- **Findings suggested that**
  - Overall impact on state spending resulted in **savings** of ~€70M vs. Mar '14, mainly due to changes in **new list and reference pricing** (~ €61M).
  - If broken down by **product type**, the state faces **savings** of ~€82M from **originals**, in contrast to **expenses** of ~€11M from **generics**, due to the "patient reward scheme" set.
  - Highest contribution to state savings arises from **No longer protected products** (~€43M) out of the overall savings.

Therapeutic Protocols & Patient Registries should be fully, universally & mandatorily implemented

Therapeutic Protocols

- Based on GG3117/9.12.2013, EOPYY and HDIKA should have embedded until June 2014 the therapeutic protocols of at least 20 of the most costly treatments in the e-prescription system
- So far, the following TPs have been uploaded & implemented in the system:
  - Osteoporosis
  - Dislipidemia
  - Gout (Ουρική Αρθρίτιδα)
  - Hyperuricaemia
  - Diabetes Type I & II
- RA, axSpA & PsA are uploaded in MoH site but not yet active in e-prescription.

Patient Registries

- Benchmarking with EU practices for registries already undertaken by respective working committees as a basis for potential proposals for future use.
- Meanwhile, an Agreement for the development & implementation of Therapeutic Registries for Patients Diseases was signed by the MoH & EOPYY in cooperation with the University of Athens & the University of Peloponnese (EOPYY Press Release, 24.2.2014).
- Hepatitis C is completed and training for physicians & expert staff is underway.
- Acute Myeloid Leukaemia & Multiple Sclerosis are the next to follow.

Achievements

- Reimbursement of new products **after 3 years of no approvals**.
- Improvement of algorithm for estimation of reference price of the reimbursement list towards a **more equitable system** (weighted based on volume sales).
- Actions for receiving sales data from EOPYY/HDIKA so as to be able to estimate, verify rebates, c/b etc.
  - Set up of online application from EOPYY / HDIKA (07.11.14) to allow official sales data exchange already initiated.
  - Set-up of draft agreement between EOPYY & MAHs (pending due to change of government).