



Greece structural reforms of the last 8 years Council of State views - analyses new challenges

Dimitra Lempesi

Legal Counsel

ΣφΕΕ

ΣΥΝΔΕΣΜΟΣ ΦΑΡΜΑΚΕΥΤΙΚΩΝ ΕΠΙΧΕΙΡΗΣΕΩΝ ΕΛΛΑΔΟΣ

Our NEW pharma law history started back in 2010.....

Reimbursement List

L. 3816/2010, Art. 12:

- The POM medicines are classified in reimbursed (positive list) and non – reimbursed (negative list)
- The companies had to work and persuade for the introduction of their products in the positive list. There used to be a list until 2006 which has been then abolished and reinstated.

10 Amendments

Amended by Laws:

- 3984/2011,
- 4025/2011,
- 4052/2012
- 4316/2014,
- 4249/2014,
- 4446/2016,
- 4461/2017,
- 4472/2017,
- 4512/2018

Still in 2010...

L. 3845/2010 1st Memorandum of Understanding

Generic penetration up to 60% by means of:

- a. INN prescription
- b. generic substitution by pharmacists
- c. closed budgets
- d. prescription and expenditure limits by physician
- e. Mandatory therapeutic protocols

→ *by 31.3.2012 EOF had to have classified all brand products by ATC and incorporated into the 160 therapeutic protocols. Today more than 20 ready.*

Court Ruling phase 1

- a. INN prescription, **constitutional** STE 3802/2014
- b. generic substitution by pharmacists, **constitutional** STE 3802/2014 *

Stemming from the L. 3845/2010 (1st Memorandum), Ministerial Decision No. EMP4/17.11.2012, exempted a small amount of prescriptions (15%) from the mandatory INN system. The exemptions referred to very particular cases of patients, mostly suffering from chronic diseases. Physicians found to be in excess of the 15% limit would be facing penalties. The medical association challenged the MD. STE 3802/2014 ruling rejected their petition.



Finally in 2010.....

Law 3892/2010 articles 1-5

**Mandatory electronic
prescription administered
by HDIKA A.E.**





New Year 2011 has come and together with it, we had the historic law 3918/2011

- Creating one national organization for the provision of health services (ΕΟΠΥΥ), art. 17.
- The Pricing and Reimbursement became the sole competence of the Minister of Health (no market decrees anymore), art. 40.
- **Bi –annual** price bulletins, art. 40.
- 50% of drugs in hospitals to be generics, art. 2
- System of **rebates**, art. 35

Rebates
Article 35
has been totally replaced
three (3) times!
by laws 4472/2017,
4486/2017 and
4489/2017
unified rebate equation
(all belonging to the
corpus of Memorandum
III- and renewals)

Court Ruling

STE 3450/2015 Section D

Rebate is a lawful *retroactive reduction of prices* given that companies are capable to control the volume and predict their sales.

Constitutional, based on 668/2012 Plenary, ruling that the Memorandum of the Greek Government with the Institutions are lawful.

Forced by the Law of Necessity (Emergency) of the Greek Economy.

In accordance with the public interest.



2012 Out-patient claw-back

L. 4052/2012
art. 11
**out-patient
claw-back for a
three –year
period
2012-2015**

STE 2439-2441, 2443-2445/2015 joint cases. Outpatient claw-back is a **lawful retroactive reduction of prices** so long as companies are capable to control the volume and predict their sales and the measure is TEMPORARY for a limited duration of 3 years which might not be exceeded.

Based on 668/2012, Plenary, law of necessity.

Court Ruling phase 2

In the meantime, L. 3845/2010 Amended by L. 4052/2012 (art.21 par. 5 case B' and C') **4213/2013** and L. 4262/2014 (art. 54) in order to include Directive 2011/24/EU on cross boarder health care and the rights of patients

Stemming from the Laws above a new MD No. 53768/2014 extended the ceilings as well as the expenditure and prescription limits by physician, de facto annulling the margin of 15% off INN for many a cases of patients.

The Panhellenic Medical association (PIS) challenged this MD.

STE Plenary session **1749/2016** said that art. 21 of the L. 4052/2012 (Memorandum II) is ***anti-constitutional by content*** and that its content had to be defined by a presidential decree and not a ministerial decision as art. 21 did not provide for a sufficient authorization basis.
It did not explicitly annul the provision.

There have been though press releases saying that in reality the INN prescription system becomes ineffective.....

2015 hospital claw-back

Data protection vs. patent protection

L. 4336/2015 3rd MOU

- **EXTENDS (!) out-patient claw-back for another three years 2015-2018, art. 2**
- **Initiates hospital claw-back** for the same three year period 2015-2018, art. 2
- abolished patent protection and replaced it with data protection period in order to define the end of the protection period for the originators (incentives), art. 15.
- The price is set as a median price of ex-factory three lowest in Europe until the data protection period expires. Then, a percentage of the price at it has been defined after several repricing at the time point of expiry of data protection. Same for off-patent and generics.

Court Ruling New Phase

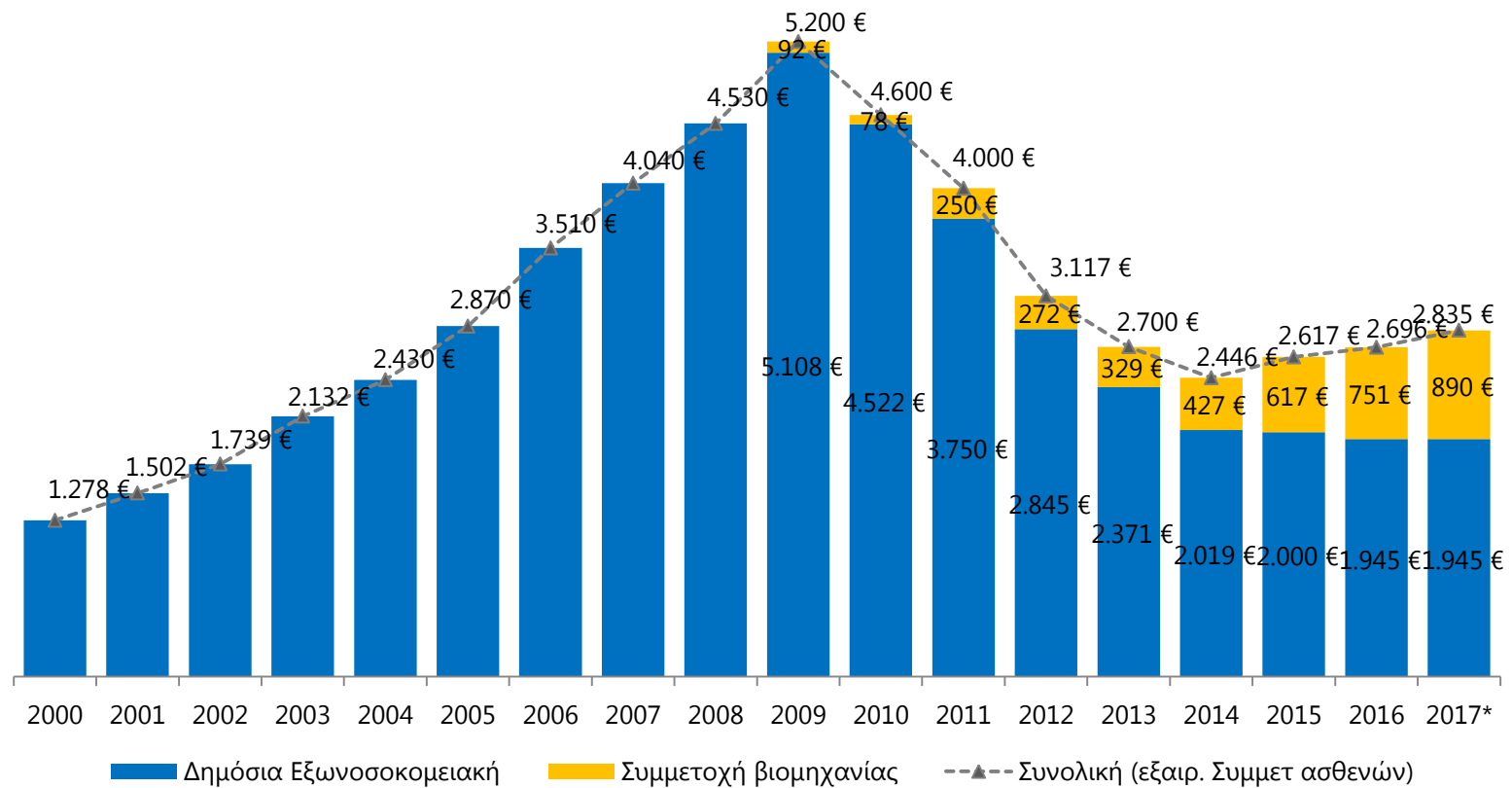
1. *Some companies sought recourse to the Court for a second time, following the new Law 4336/2015 extending the obligation for another three years.*

2. *Hospital Claw-back, constitutional, **STE 3047/2017,***

temporary measure based on the law of necessity (668/2012).

3. *Abolition of Patent protection system, award is awaited...*

Out-Patient Pharma Expenditure (2000-2017)



Conclusions!

10 Major structural reforms

1. Ministerial decrees for Pricing and Reimbursement
 - Bi-annual price bulletins
 2. EOPYY
 3. HDIKA
 4. Mandatory Therapeutic Protocols
 5. re-introduction of Reimbursement List
 6. Generic penetration, mostly by INN prescription
 7. 50% of hospital pharma provisions generics
 8. system of rebates
 9. system of claw-backs
 10. data protection period for pricing
- New HTA system (L. 4512/2018) voted, not yet applied....*

General Conclusion

- ***Very difficult business environment...***
- ***Unpredictable***
- ***Strict***
- ***With Limited profitability***
- ***Demanding hard efforts to keep up with our business model and our business standards***

Challenges

Greece

- Will claw-back still exist after 2018;
- Will the patients have faster access to new medicines given the new HTA system (Efpia, W.A.I.T. indicator) ?
- Will the patent system in pricing will be reinstated?
- Will we reach up to the 60% generics penetration?
- **AND, ARE WE FINALLY DONE WITH THE RESTRUCTURING OF THE SYSTEM?**

Europe

- Patients' rights in cross-border Healthcare
- E-health
- Telemedicine
- Digital Single Market
- Big Data



Cross-border possibilities for Citizens eHealth Digital Service Infrastructure

- E-prescription
- E- Patient summary



Digital Single Market Priorities



Would you rather?



Conclusions Europewide

Cross-border Healthcare Directive



1. Directive 2011/24 has been a major step –we saw that is affected also the Greek Court Ruling 1749/2016- it explicitly put the patient in the pattern
2. Digital market: The knowledge travels not the patient:
 - Treat and diagnose patients: exchange clinical data on patient cases at a distance.
 - Develop and exchange expertise through the network and across Europe
 - Networking, research and training
 - Virtual patient management software for the networks.
 - Responsibility moves more to the patient
 - The role of the doctor is changing substantially: guiding treatment and coaching.
3. **Key legal issues in cross-bordering telemedicine:** Licensing (does the telemedicine provider needs to be registered/ licensed in the MS), Data Protection, Reimbursement, Liability, Relevant Jurisdiction and applicable law.
4. **We do not know the impact of GDPR in health big data**
5. Health competence is largely with the member states (principle of subsidiarity 168TFEU). **They have the will and the means to work together.**
6. EU Voluntary co-operation, funding and legislation (Benelux-A, Valetta, Visegra..).
7. Digital Single Market **strategy**
8. European infrastructure! (like EMVO!!! And others)

✓ **major changes ahead in Health Sector!!!!**

Would you rather?



Life moves fast forward...
And pharma industry has the future answers!



Thank you!