



Committee for the Dialogue with Patients

Key activities 2012-2014

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In 2012 we joined forces....



Objectives

1. **Strengthen** trust between Pharmaceutical Industry & Patient Advocacy Groups
2. **Share** best practices at local and EU level – participation of Patients in HTA Committees/ EMA Scientific Committees etc.
3. **Reinforce dialogue** between Patient Advocacy Groups
4. **Explore** the patient's experiences, needs, narratives, emotions
5. **Update** patients on new legislation
6. **Provide training proactively or on a as needed basis**
7. **Collaborate** closely in order to reinforce the creation of one legal entity (eg. PanHellenic Patient Federation of Chronic Diseases) as a result of joining forces to advocate for their rights



Therapeutic categories related to Associations which participate at the committee

1. HIV/AIDS
2. Hepatitis
3. Cancer
4. Thalassemia
5. Kidney Disease
6. Crohn disease
7. Osteoporosis
8. Rheumatoid Arthritis
9. Psoriasis/ Psoriatic Arthritis
10. Rare Diseases
11. Multiple Sclerosis
12. Diabetes
13. Cystic Fibrosis
14. Alzheimer disease & Related Disorders

Key outcomes 2012-2014

- *Sessions on :*

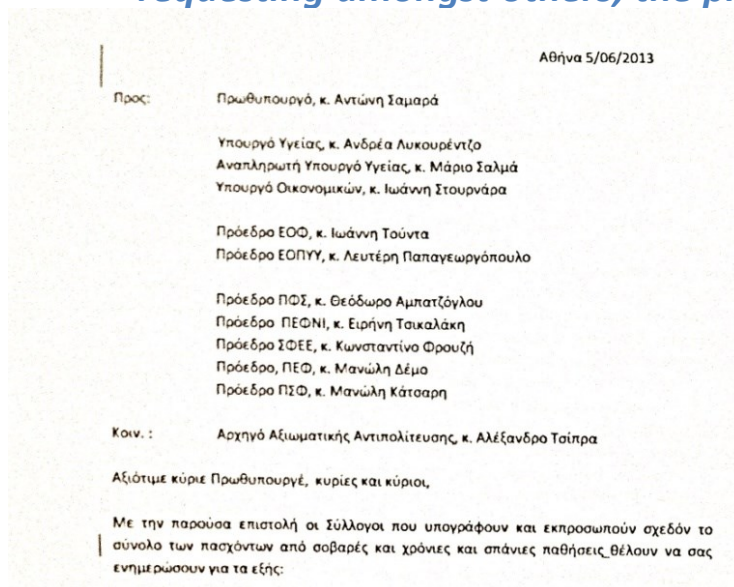
- Innovative medicines and access challenges
- Update on Health care environment and new laws
- The legislature framework of Biomedical research
- Best practice sharing between patient advocacy groups on fund raising/ successful awareness and screening campaigns

- *Training on :*

- Communicating with media
- Health Technology Assessment
- Pricing & Reimbursement

Key outcomes 2012-2014

Letter sent on 5/6/2013 to the Prime Minister, Ministry of Health, EOF, EOPYY, PEFNI & Industry Associations co-signed, for the 1st time, by 9 Patient Advocacy Groups requesting amongst others, the pricing of new & innovative medicines



Τέλος ζητούμε την κυκλοφορία των καινούριων φαρμάκων τα οποία αν και έχουν πάρει έγκριση πάνω από δύο χρόνια , εντούτοις δεν έχουν δοθεί στην αγορά, παραβαίνοντας έτσι το Κοινοτικό Δίκαιο.

Βασικό μας ζητούμενο είναι η άμεση κάλυψη του θεραπευτικού κενού που έχει δημιουργηθεί, καθώς και η διασφάλιση της απρόσκοπτης πρόσβασης όλων των Ελλήνων πολιτών, σε μοναδικές και πολύτιμες για τη ζωή μας θεραπείες, για ασθένειες όπως , ο καρκίνος κάθε μορφής, η θαλασσαιμία (μεσογειακή αναιμία), η δρεπανοκυτταρική νόσος, η οξεία σκλήρυνση, η ηπατίτιδα C, η οστεοπόρωση, η σκλήρυνση κατά πλάκας-πολλαπλή σκλήρυνση, το AIDS, η πνευμονική υπέρταση, η κυστική ίνωση, οι σοβαρές ρευματικές παθήσεις, οι πρωτοπαθείς ανοσοανεπάρκειες, τα μεταβολικά νοσήματα, η ψωρίαση και ψωριασική αρθρίτιδα καθώς και διάφορες άλλες σπάνιες παθήσεις.

Επικαλούμαστε την τήρηση της νομοθεσίας με βάση την οποία πρέπει να εκδίδονται Δελτία Τιμών με νέα φαρμακευτικά ιδιοσκευάσματα κάθε 90 μέρες [άρθρο 10 παρ. 3 της Υπουργικής Απόφασης ΔΥΤ3(α)/οικ.ΓΥ/151 (ΦΕΚ 545/Β/1.3.2012) σε συμμόρφωση με την Κοινοτική Οδηγία 89/105] κάτι που έχει καταστρατηγηθεί καθώς είναι πλέον ευρέως διαπιστωμένο ότι δεν έχει εκδοθεί Δελτίο Τιμών με νέα φάρμακα τα τελευταία 2,5 χρόνια. Αυτό στερεί από εμάς τους Έλληνες ασθενείς την πρόσβαση σε απαραίτητες καινοτόμες θεραπείες κυριολεκτικά ζωτικής σημασίας .

Άλλωστε, η εισαγωγή νέων θεραπειών και η αποζημίωσή τους στην Ελλάδα είναι στόχος του Μνημονίου σύμφωνα με την τελευταία έκθεση της Ευρωπαϊκής Επιτροπής (Second Economic Adjustment Programme - Second Review May 2013).

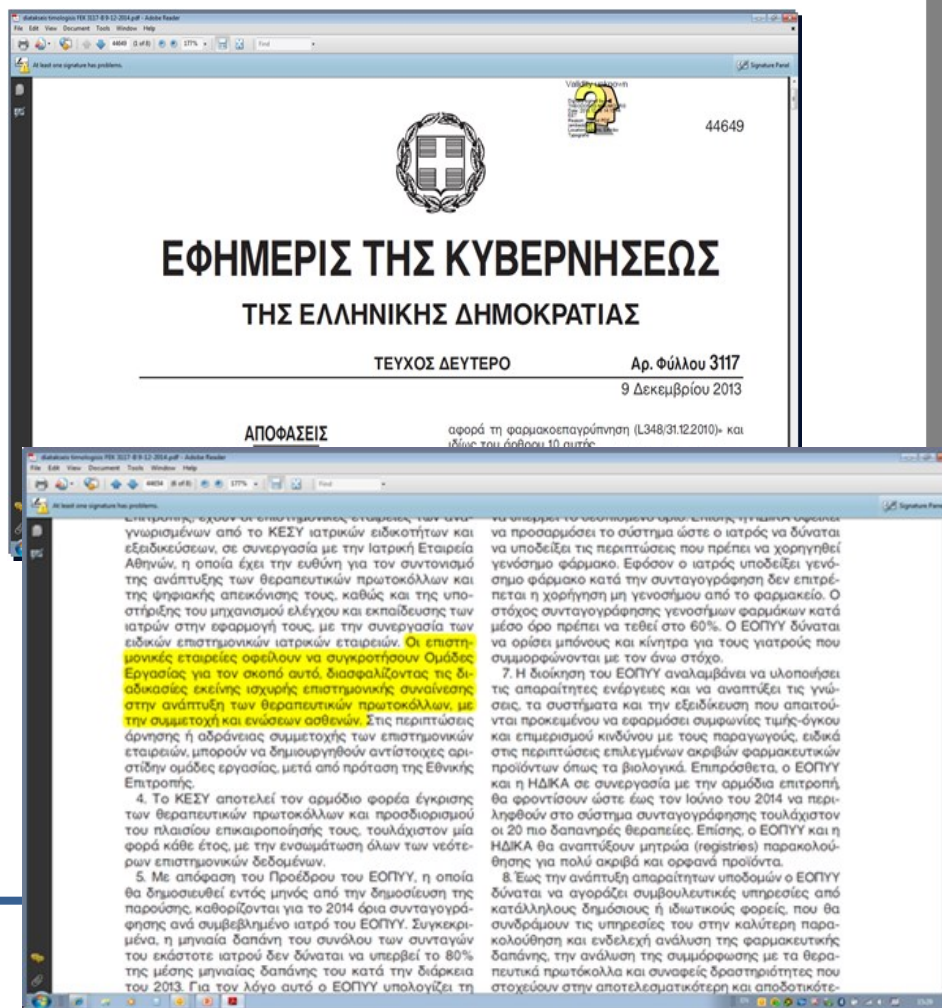
Υποθέτουμε ότι ένας από τους λόγους μη εισαγωγής νέων φαρμάκων στην αγορά είναι οι πιθανές αρνητικές συνέπειες στη φαρμακευτική δαπάνη, δεδομένων μάλιστα και των στόχων που έχουν τεθεί με το Μνημόνιο. Υποστηρίζουμε όμως ότι οι νέες σύγχρονες θεραπείες, τις οποίες και στερούμαστε, δύνανται αντίθετα να μειώσουν τη δαπάνη πόρων σε άλλα σημεία του συστήματος υγείας καίριας σημασίας, όπως τα νοσοκομειακά κόστη, που προκύπτουν από συχνά περιττές ακριβές εξετάσεις, περιττές επεμβάσεις και άλλα. Αυτό έχει επιπτώσεις αφενός μεν στην αποδοτικότητα των ασθενών στην κοινωνία, αφού δε θα είναι σε θέση πλέον να εργαστούν, αφετέρου δε στη ψυχολογική τους επιβάρυνση η οποία μπορεί και να χειροτερέψει την κατάσταση της υγείας τους.

Following that, new medicines were included (after over 2 years) in the price bulletin issued in August 2013 & included in the positive reimbursement list of February 2014

Key outcomes 2012-2014

For the first time patients are actively involved by legislation in decision making and in particular , in therapeutic protocols committees (Dec 9th, 2013)

From vision to reality



Key outcomes 2012-2014

1. Creation of 1st Patient's in Power Conference in Nov 2012: the first congress in which patients were involved in all stages as co-organizers, speakers and audience. The Conference was a unique opportunity for patients and patient organizations across diseases to meet and discuss with the other “partners in healthcare” issues of concern to all.
2. The 2nd & 3rd Patients in Power Conference, took place in Nov 2013 & 2014 respectively. The problems of healthcare access, pre-existing and accumulated during the four years of extreme austerity were amongst the key issues of discussion.

**Patients in
POWER
Conference**

**UNDER THE AUSPICES OF MINISTRY OF
HEALTH**



Next steps

✓Finalization (within 1st quarter of 2015) of the Code of Interaction between Patient Organizations and Pharmaceutical Companies following updates that have been made in 2014 by the SFEE committee in alignment with both the Code of EFPIA and the SFEE Code of Ethics

Continue :

✓Strengthening the constructive dialogue between SFEE & Patient Advocacy Groups

✓Training and empowering Patient Advocacy Groups

✓Encouraging Patient Associations to collaborate and work as a team through :

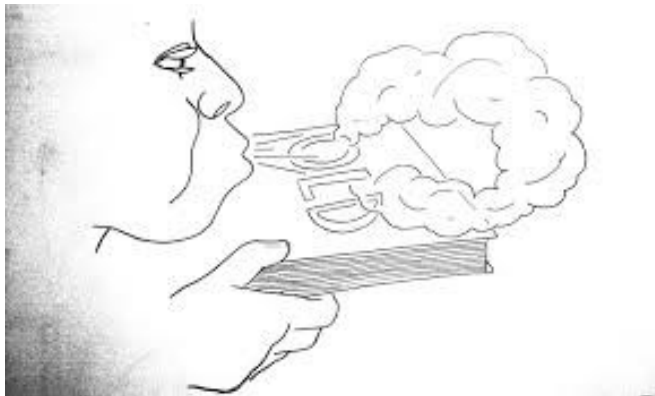
- ❖sharing best practices
- ❖creating a common agenda
- ❖joining forces to advocate for their rights
- ❖Strengthening their voice demanding a patient-centered health care system
- ❖ being considered by policy makers as key partners in healthcare

The ultimate goal for 2015 is the reinforcement of Patient Advocacy Groups for the creation of one legal entity (eg. Pan-Hellenic Patient Federation of Chronic Diseases) as a result of joining forces to advocate for their rights and be included in committees that are formed by government bodies



Code of Ethics (CE) Committee 2012-2015

2002-2012: no renewal in the code



2012 Need for self-regulation:

Planning the future - Setting the foundations

- Donations
- Scientific events
- Consulting services
- Market research
- Procedure for the Control of Implementation (verification process)
- Communication Awareness Campaign



2013 Implementation of our plan:

Building our relation with the HCPs and HCOs

- Alignment of companies / members
- Tension - Discussion -Information
- Harmonization with EOF
- Conference Evaluation Platform
- Disclosure of donations
- Non-interventional studies registry
- Disclosure code
- The strategic role of Code of Ethics Committee



2014 Establishment of Code of Ethics in daily practice:

Shaping our home

- Commitment – Higher Participation of SFEE members in the Code of Ethics Committee
- Alignment between HCOs - PCO agencies
- Monitoring of Code of Ethics implementation by an independent company
- **Adoption of Disclosure Code by the State (law)**



Scientific events Evaluation Committee

Active participation and commitment

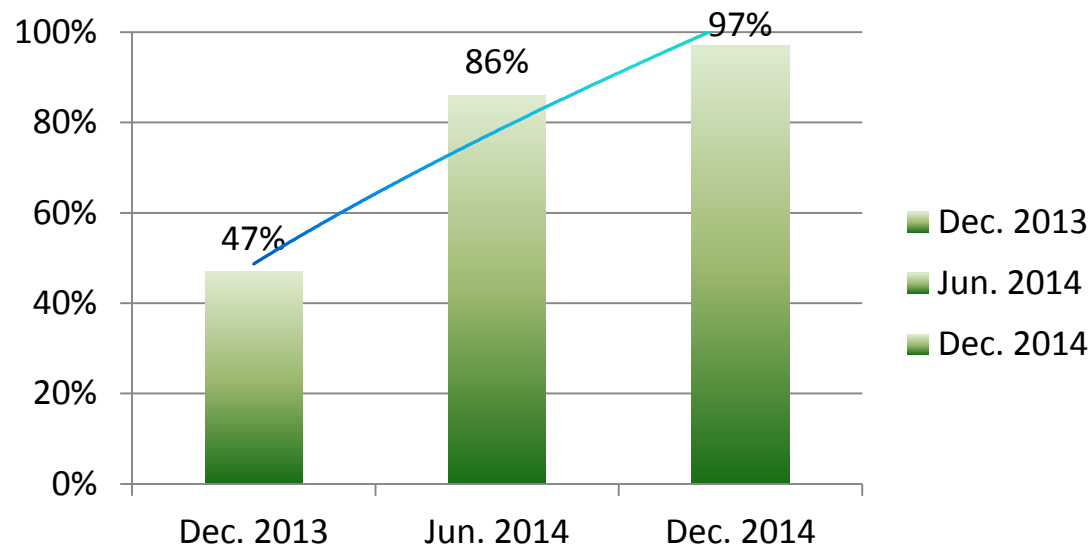
- More than **110** Committee meetings
- More than **400** hours of conference evaluation by the Code of ethics Committee
- More than **4,000** clarification emails
- More than **80** meetings with EOF, HCOs, PCOs



Conference evaluation:

Increasing Compliance with Code of Ethics

- SFEE's congress evaluation committee has evaluated **1690** conferences since September 1, 2013.



E&Y example 1

Conference evaluation:

- Green
- duration 3 days
- costs within Code limits
- Without recreational program

E&Y evaluation:

- Actual 1-day program
- 1st day excursion
- 3rd day... visit to a museum
- Presence of accompany memebtrs in all conference activities

E&Y example 2

Conference evaluation:

- Green
- lasting 2 days
- costs within Code limits
- Without recreational program

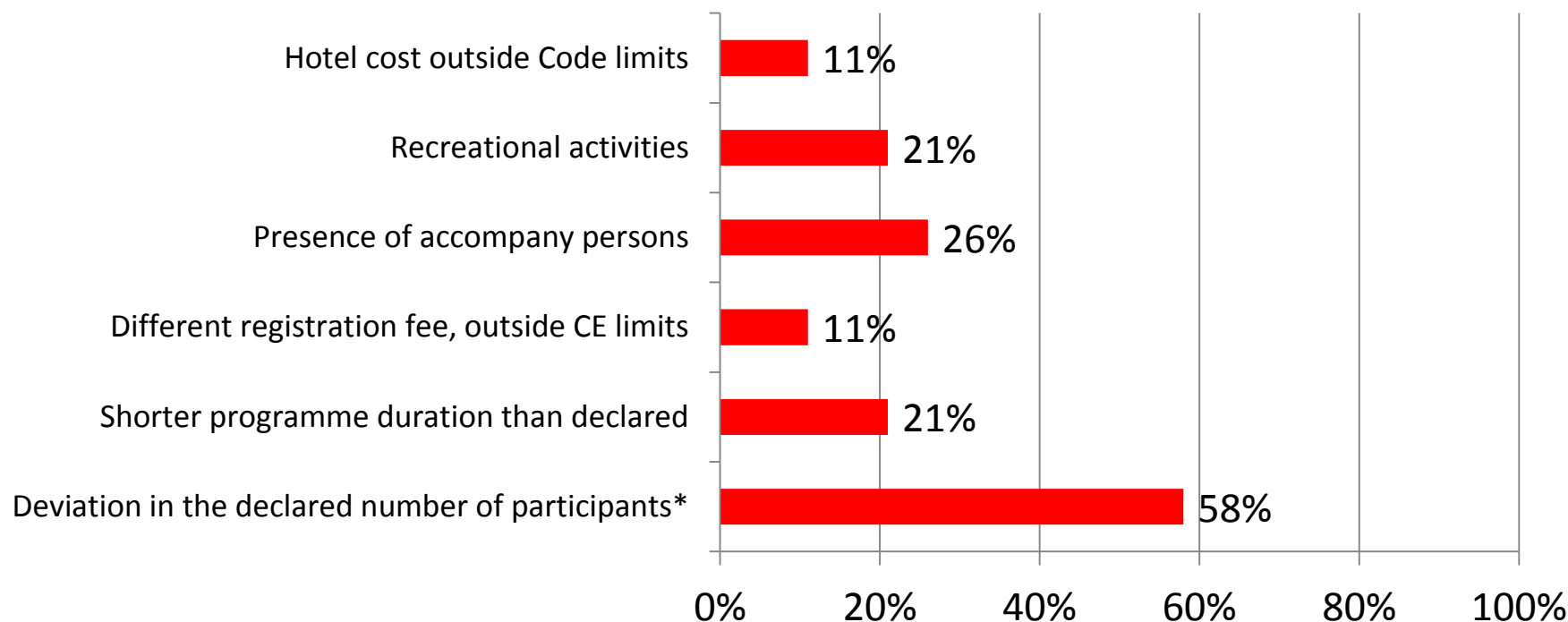
E&Y evaluation:

- Different sponsorship package & Different registration fee higher than allowed
- participation less than 1/3 of those initially declared

Outcome of E&Y verification

5/19 outside of Athens - Thessaloniki

% inspected



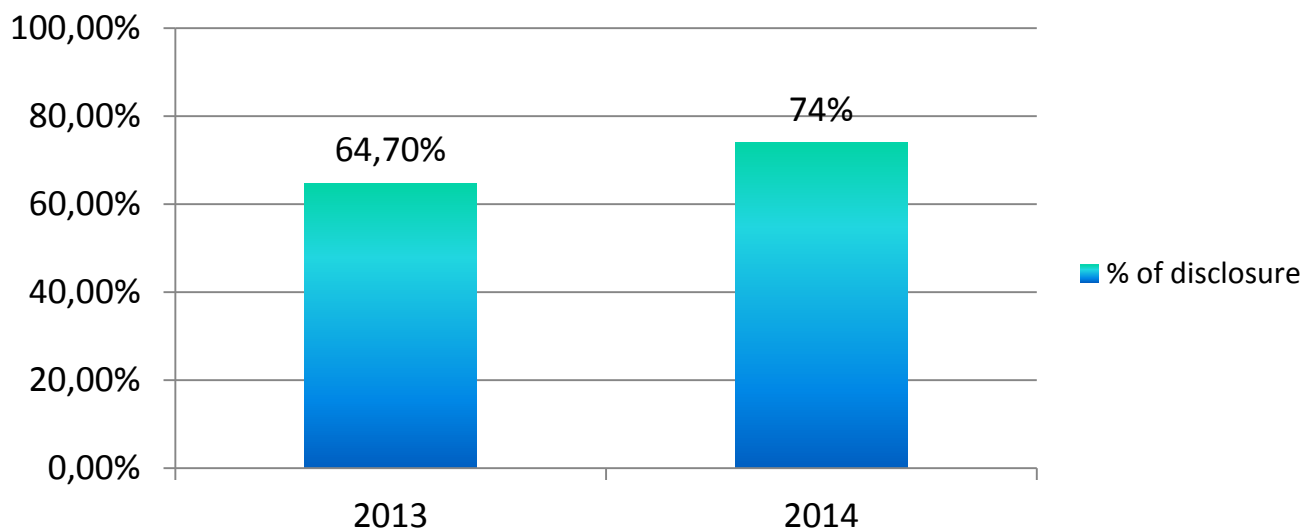
Limitation to conference expenses

example: pan-hellenic conference

	2009	2010	2014	% Reduction 2009-2014
STAND price	32.000	20.000	12.00	37%
SATELLITE SYMPOSIA	17.000	14.000	9.000	53%
Final programme, cover	10.000	3.000	3.000	30%
Coffee break	10.000	4.500	2.000	20%
Accommodation DIVANI CARAVEL	270	210	140	52%
HILTON	300	220	140	47%

Transparency in Donations

The amount of companies disclosing donations is increasing



Complaints regarding Code of Ethics violation

- 14 complaints about Code of Ethics violations have been examined by the primary SFEE committee
- The final decisions imposing sanctions shall be disclosed at SFEE site



2015 Collection of disclosure data:

Continue our work

- Disclosure data platform (EOF)
- Interpretative EOF circular regarding Disclosure
- Update of Code of Ethics - Continuous improvement
- Transparency in all our actions
- Updating of HCPs and HCOs
- Point for improvement: possible sanctions to PCOs & HCOs failing to comply with code of ethics



2016 Transparency in action:

Opening our home

- Getting ready to respond to challenges
- Protect our home
- Continue good practice
- Improve constantly our environment

