ΣfEE

HELLENIC ASSOCIATION OF PHARMACEUTICAL COMPANIES

ANNUAL

GENERAL ASSEMBLY OF SFEE

March 20, 2015

ΣfEE
HELLENIC ASSOCIATION OF PHARMACEUTICAL COMPANIES

GENERAL ASSEMBLY OF SFEE

March 20, 2015

CONTENTS

BoD of SFEE

President:	**Konstantinos M. Frouzis** *Vice President & General Manager of Novartis*
Secretary General:	**Vasilis Niadas** *President of Cana*
Treasurer:	**Nicolas Varelas** *Managing Director of Galenica*
Vice Presidents:	**Pascal Apostolides** *Managing Director of AbbVie* **Costantinos Evripides** *Chief Executive Officer of Genesis Pharma* **Marcos Gerassopoulos** *Managing Director & General Manager of Sanofi* **Nikos Kefalas** *Managing Director of Janssen-Cilag* **Konstantinos Panagoulias** *Vice President of the BoD of Vianex* **Olympios Papadimitriou** *General Manager of Novo Nordisk*
Members:	**Spyros Filiotis** *Vice President & General Manager of Pharmaserve-Lilly* **Roberto Greco** *Vice President & Managing Director of GSK* **Marios Katsikas** *President & Managing Director of Rottapharm* **Marios Kosmidis** *General Manger of Win Medica* **Nikos Ragousis** *Managing Director Leo Pharmaceuticals* **Stavros Theodorakis** *Managing Director of Chiesi Hellas*

ΣfEE
HELLENIC ASSOCIATION OF PHARMACEUTICAL COMPANIES

ANNUAL GENERAL ASSEMBLY OF SFEE MEMBERS

INVITATION

The Hellenic Association of Pharmaceutical Companies of Greece (**SFEE**)

Invites its members to the

ANNUAL GENERAL ASSEMBLY

Which will be held

on Friday, March 20, 2015 at **10:00**

in the ***Olympia B*** Hall of the ***CARAVEL*** Hotel.

Cocktails will be served after the meeting

Konstantinos M. Frouzis
President of SFEE

AGENDA

Friday, March 20, 2015
Caravel, Olympia B

ANNUAL GENERAL MEETING OF SFEE's MEMBERS	
09:30 – 10:00	**Arrival – Registration**
10:00 – 10:10	**1. Election of Chairman and Secretary of the General Assembly**
10:10 – 10:30	**2. Introduction-Speech of the President of SFEE:** K. Frouzis
10:30 – 11:40	**3. Review (7' Speeches):** ▪ Pricing Issues: N. Kefalas ▪ Reimbursement-List-EOPYY: A. Apostolidis ▪ EOF Issues-Clinical Trials: Ol. Papadimitriou ▪ Hospital & Growth Issues: K. Panagoulias ▪ Debts of the State: K. Evripides ▪ Ethics & Transparency: M. Gerassopoulos – Y. Chryssospathis ▪ Documentation Issues & Data Monitoring: V. Niadas
11:40-12:00	**4. Questions/Discussion:** Companies-Members of SFEE
12:00 – 12:30	**5. Issues for Approval:** ▪ Amendment of the Code of Ethics of SFEE: Y. Chryssospathis ▪ Financial Review 2014 & Budget for 2015: N. Varelas
12:45-14:30	**6. Elections for New Board of Directors** ▪ Election Committee ▪ Voting ▪ Results
14:30	**7. Closure of the General Assembly:** K. Frouzis

Please confirm your participation at the following e-mail:
jenny.papadonikolaki@sfee.gr

The constituent meeting of the new BoD will take place on Monday 23 March 2015 at 10:00 at SFEE premises.

ΣfEE
HELLENIC ASSOCIATION OF PHARMACEUTICAL COMPANIES

To the

General Directors

Re: Annual General Meeting

Halandri, February 26, 2015

Dear Colleagues,

We herewith attach the invitation containing the Agenda for the annual Ordinary General Meeting of our Association which will be held on **Friday, March 20, 2015 at ώρα 10.00 π.μ. at the *CARAVEL* Hotel, Hall Olympia B**, according to article 9 par. 1 of the Articles of Association.

In 2015, the three-years term of this Board of Directors expires, as well as the term of office of the Disciplinary Board and of the Auditors. Consequently, elections will be held in the General Meeting for the appointment of 15 new members of the Board of Directors, 3 new members of the Disciplinary Board and 2 new Auditors of the Association.

- According to article 12 paragraph 1 clause 3, the right to run for member of the Board of Directors lies only to: the Manager of the LLC, General Partnership and the President or the General Manager or the Managing Director of S.A., regardless on his/her nationality who is also the legal representative of the S.A. and binds the company.

- Those wishing to be elected as members of the above bodies of SFEE, must state their nomination in writing to the General Secretary of SFEE Mr. Vasilis Neiadas, **until March 10, 2015**. They must also attach a brief curriculum vitae (around 400 words), as well as a letter where they will quote a message showing the reasons for which they wish to participate in the Board of Directors of the Association, which will be distributed to the members of the Association before the General Meeting, so that everyone will have a better picture of the nominees.

- According to article 4 par. 1 of the Articles of Association, the right to participate and vote in the General Meeting is vested with the Companies-Members who have performed their financial obligations (annual contribution) to the Association. To that end, Γwe kindly request the members who have not settled their financial obligations to do so before March 20, 2015. **The companies-members who have paid their contribution for the year 2014 are deemed to have performed their financial obligation towards the Association**.

280 Kifissias Avenue & 3 Agriniou Str, 152 32 CHALANDRI, ATHENS
TEL. 210 6891101 – FAX 210 6891060
e-mail: sfee@sfee.gr
www.sfee.gr

- **Each company-member is represented in the General Meeting by the legal representative thereof or in case he/she is impeded, by the authorised substitute thereof** (article 3 par. 3 of the Articles of Association). Persons absent or impeded can be represented in the General Meeting by another representative of a member of SFEE or by an officer of their company, by virtue of written authorisation, as defined in Article 9 par. 3 of the Articles of Association. According to the same article, each representative may represent a maximum of two absent or impeded ordinary members of the Association.

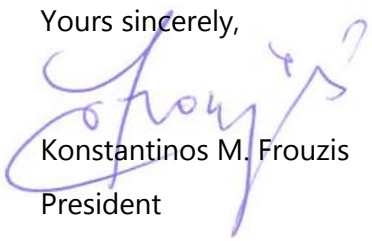
- According to article 9 par. 5 of the Articles of Association, the General Meeting will be at quorum if at least half (½) of the members entitled to vote are present. In any different case, a new General Meeting will be convoked with the same Agenda on the respective day and time of the following week, i.e. on Friday March 27, 2015..

Dear colleagues,

This year is critical for the industry and our country. **Unity and dedication to the mission** of our Association, to the Boards and Committees is required.

On behalf of the Board of Directors of SFEE, I invite you all **to participate in person** in the General Meeting, thus declaring your presence and rallying, protecting the interests of patients, companies and of our employees.

Yours sincerely,



Konstantinos M. Frouzis
President

280 Kifissias Avenue & 3 Agriniou Str, 152 32 CHALANDRI, ATHENS
TEL. 210 6891101 – FAX 210 6891060
e-mail: sfee@sfee.gr
www.sfee.gr

Our Key positions

Konstantinos Frouzis,
President of the BoD
Annual General Assembly of SFEE
March 20, 2015

Athens

OUR KEY POSITIONS (2012-2015+)

(1/3)

- **State Payments: limit our financial exposure; offsetting process**
- **Sustainable drug budget in EOPYY**
  - Uninsured
  - Patients' needs ≅ orders → No CB!
- **Sustainable Hospital budget for drugs**
  - Stop "STEREITAI"
  - ALL 1A in Hospitals
  - Tenders 50-30-20
- **Patients' access to innovative drugs/therapies and increase penetration of Gx/off patent**

OUR KEY POSITIONS (2012-2015+)

(2/3)

- **Correct prices (as per Law) for all drugs**
  - Stable reference pricing for all branded drugs
  - Avoid IRP negative impact out of GR
  - Pricing to allow Gx launches after 2012
- **Reimbursement:** regular, predictable but under conditions / "HTA" concept
- **Rationalized prescribing; Mandatory:**
  - Therapeutic / diagnostic guidelines
  - Registries, for severe diseases
- **Copayment: affordable for patients (variable)** but not on the companies' shoulders

ΣfEE

OUR KEY POSITIONS (2012-2015+)

(3/3)

- **Control of ALL health care cost** centers allows the sustainability of the overall System
- **Code of compliance / disclosure**
  - No compromises; state / EOF needs to align with us
- **Support Development in GR**
  - Increase **investments** and **Clinical trials** in GR under certain conditions & incentives.
  - Promote Innovation concept: **SFEE Innovation project**
- **External orientation of the Association:** Communicate regularly our positions
- Maintain **regular alignment** with **EFPIA**
- Go for a **Stability Part MoU with GoG**

ΣfEE

Communication Committee

Review of Activities
2012-2014

Konstantinos Frouzis
President of SFEE

Annual General Assembly of SFEE
March 20, 2015

2012-14 Workstreams: Key Activities

Internal Communication

- Weekly Report
- Daily Press Updates
- Web Monitoring Reports
- Media & Political Intelligence Reports
- Comm Support of SFEE Committees
- Internal Perception Surveys
- New Years's Events
- New Site Launch

Press Office & Media Relations

- Media Presence (Articles &Interviews)
- Press Conferences
- Events
- Strategic Partnerships
- Publications/Brochures
  - Facts & Figures
  - "Medicines 2013: A journey without compass"
- SFEE's Profile
- Social Media Activation
- Issues Management

CSR Strategy & Activation

- Build and Implement CSR Strategy
  - SFEE Innovation Project
  - SFEE Bank of Medicines
  - SFEE Business Days
  - Promotion of Members CSR Activities in www.sfee.gr
  - ΔΙΑΦΑΝΙΑ – Code of Ethics/ Disclosure Code
  - Bionian Cluster Event
  - Museum of Cycladic Art Event

Public Affairs

- Networking and Meetings with key KoLs
- Participation in Major National Conferences
- Luncheons with major journalists and chief editors
- Major SFEE Event during the European Presidency

2012 - 2014 Public Relations & Publicity Report

- Over 120 f2f meetings with Key stakeholders (Ministers, HAs, Ambassadors, MPs, Opposition Party MPs, Brussels MGP, etc.)
- 2013-2014: Over 6.000 clippings mentioning SFEE - Increase by 40% of the publicity volume in comparison to 2013 and by 60% in comparison to 2012
- 60 Press Releases and 46 Non Papers resulting to over 4.000 references per category in all media
- Over 250 published Articles & Interviews (Newspapers, Web, TV, Radio)
- 110 Weekly Reports, 97 Media & 87 Political Update Reports & 24 General News Reports
- 1.010 Daily press updates - 890 Web monitoring reports
- 1020 Facebook posts, 300 Tweets, 60 YouTube, 30 LinkedIN posts

Annual General Assembly, March 2015

2014 Events-Activities CSR Report

SFEE's Corporate Social Responsibility Programme

- ►SFEE Innovation Project Ceremony
- ►Innovation Project Day Event - Health Innovation Poll & One to One Pitches (4/6/2014)
- ►Roadshows in 5 Major Cities (June-Sept. 2014)
- ► Mentoring Team Activation
- ► SFEE Business Day Workshop (29/5/2014)

Annual Events – Code of Ethics - Conferences

- ►25 Participations in Major National Conferences
- ►Code of Ethics Month (Nov. 2014)
- ►Disclosure Code Event (Oct. 2014)
- ►Clinical Trials Event (May 2014)
- ►Event on IOBE Growth Strategy Study (May 2014)
- ►New Year's Reception

Media

- ►2 Press Conferences on Disclosure Code and following Extr. General Assembly of Sept. 2014
- ►7 business, 4 luncheons – with 25 major chief editors and journalists
- ►AMNA Strategic Partnership (Athens Macedonian News Agency)

Publications/ e-tools

- ►New Site Launch
- ►Social Media Activation
- ►Blog Activation
- ►2 Disclosure Code Videos and Leaflet
- ►Info Material for MReps
- ►2 Innovation Project Concept Videos

Internal Survey

30 F2F meetings with member companies

Annual General Assembly, March 2015

2015 Proposed Strategic Objectives & Workstreams

Objectives	Strategies to apply	Work Streams
Enhance SFEE's Corporate Image, Positioning and Caring for Health Care Sustainability	○ Adapt Health & Growth Strategy by EFPIA to the Greek environment and SFEE positioning ○ Develop more compelling datasets to measure success of healthcare policies and benefits of innovation ○ Alliance building -Close Partnerships btw the Industry and the NHS and key Institutions/ KoLs ○ More Extrovert Approach on Issues Management & Regular media contacting	▪ Vision & Mission Brochure for the Public incorporating H&G Strategy ▪ Media Workshops & Training based on specific datasets that substantiate relevant specific messages ▪ PR activities, Events & Awareness and Social Media Campaigns ▪ Promote Strategy in Main Health Conferences ▪ Issue e- Newsletter incl. policy papers ▪ Enrich CSR Strategy/Actions – Promote Members' Social Profile
Strengthen Internal Alignment	○ Revisit Cooperation among Committees, Set Operation Guidelines and promote Transparency ○ Activate Strategic Planning Committee ○ Communicate Main Positions of SFEE, Create Policy Papers ○ Organize Workshops and Training Sessions for Members	▪ Internal Survey - Interviews with each SFEE member company ▪ Edit Operation and Governance Guidelines ▪ Social media community engagement ▪ Issue Strategic Committee Monthly Report incl. SFEE's main positions ▪ SFEE Blog Activation ▪ Disclosure Code Comms Plan ▪ Create SFEE Intranet to use as internal info exchange center

2015 Proposed Strategic Objectives & Workstreams

Objectives	Strategies to apply	Work Streams
Promote Value of Innovation as Driver for Growth and Progress	○ Demonstrate the value of medicines and research -new medicines bring benefits and hope to patients ○ Patients must be at the center of decision-making about health (alliance building) ○ Build a Strong Emotional Counter-Argument to the Talk about Costs ○ Effective message delivery to the key decision making centers and public at large	▪ Formal Meetings with Government and Public authority representatives ▪ Brochure on Innovative medicine for the Public ▪ Identify and Activate Advocates & Ambassadors to promote messages ▪ Press Conferences & Events ▪ Media Workshops & Training ▪ CSR Program: SFEE Innovation Project ▪ Systematic and integrated mix of PR/ Advertising methods - Social media campaigns ▪ Find the right data (i.e. OECD, EFPIA, SFEE, McKinsey, Research reports) and package data in the right way, for the right customer at the right time

Communication Committee & Corporate Social Responsibility Working Group

Konstantinos Frouzis | Novartis	Natalia Toubanaki | SfEE
Manolis Mitakis | Boehringer Ingelheim	Vicky Karra | Genesis
Maritina Mantzavinatou | Janssen-Cilag	Stathis Kontodimas | Leo
Manolis Alexandrakis | MSD	Kely Stavropoulou | Novartis
Loukia Theofanopoulou | Novo Nordisk	Antonis Fousteris | Pfizer
Efstratia Variami| Pharmaserve-Lilly	Konstantinos Kotzias | Pharmathen
Kimon Malataras | Roche	Panayiotis Nikakis | Shire
Zoe Magklara | SfEE	

Annual General Assembly, March 2015

Pricing & New Medicines Committee 2012-2015

Nikos Kefalas
Vice President SFEE
March 20th, 2015

Athens

Key achievements (1/2)

- Substantial development in the pricing process, in respect to transparency and prediction (3 price bulletins with NEW drugs in 2014!)
- Legislation that supports the patent use and not data protection use for the definition of off-patent.
- Finalisation of SFEE pricing proposal
- Corrections of prices being at the EU lowest price
- Predictability for the introduction of new products

Key achievements (2/2)

- Strong presence in MoH Price Committee
- Continuous and close monitoring of developments in pricing periods and changes of legislation
- Build close and trusted collaboration with several meetings at EOF and MoH for pricing issues and submission of proposals and letters
- Several committee meetings within SfEE for alignment / update / exchange ideas / shape arguments

Developments/Outlook 2015

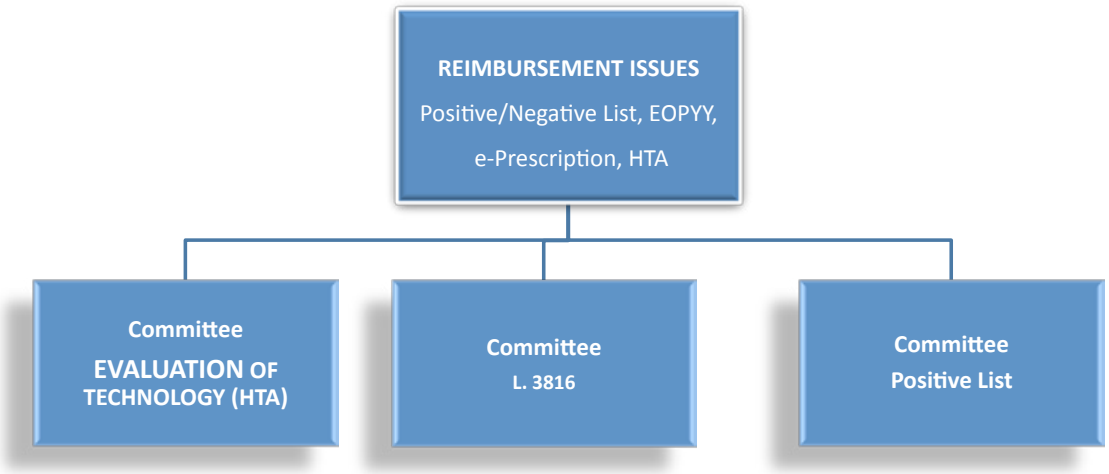
- Imminent repricing expected in April 2015
- Pending price approvals for new drugs (since 10/2014)
- Discussion on new pricing system and possible changes, according to the average of 3 lowest in Eurozone
- Possible differentiation of actual reimbursement price
- SFEE play important role as contributor in discussions with MoH and submit proposals in alignment with PEF and SAFEE.
- Support local manufacturing

Review of Actions Reimbursement Committees 2012-2014, and Proposals Moving Forward

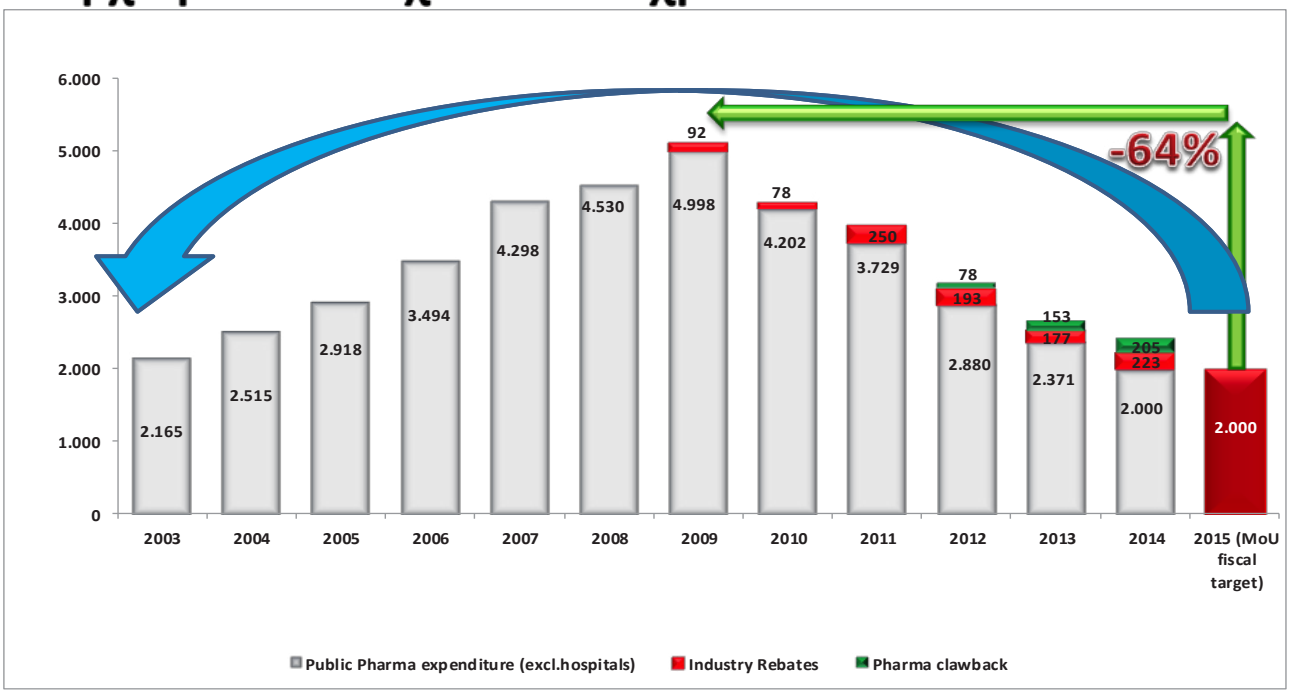
Pascal Apostolides
Managing Director, AbbVie Pharmaceuticals
Vice President, SFEE
President of Pharma Committee, AmCham

Athens, 20 March 2015

Reimbursement Committees



Η περικοπή της φαρμακευτικής δαπάνης οδηγεί τη χώρα τουλάχιστον 12 χρόνια πίσω



Πηγή: ΣΦΕΕ, ΙΟΒΕ- Γεγονότα και Στοιχεία, 2012-2014

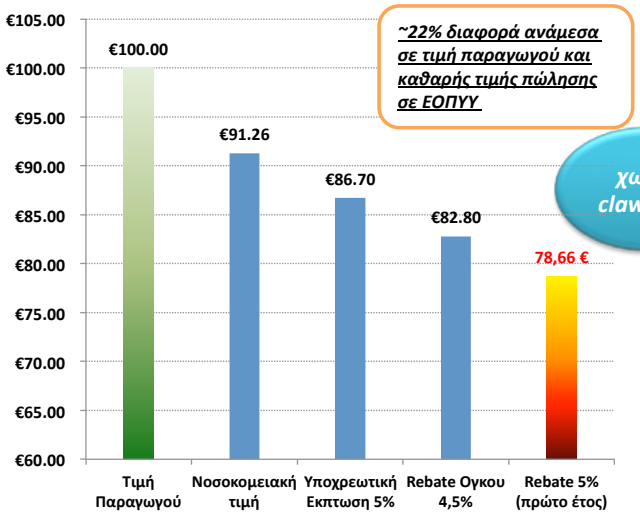
Total financial burden from rebates & clawback (2012-2014)

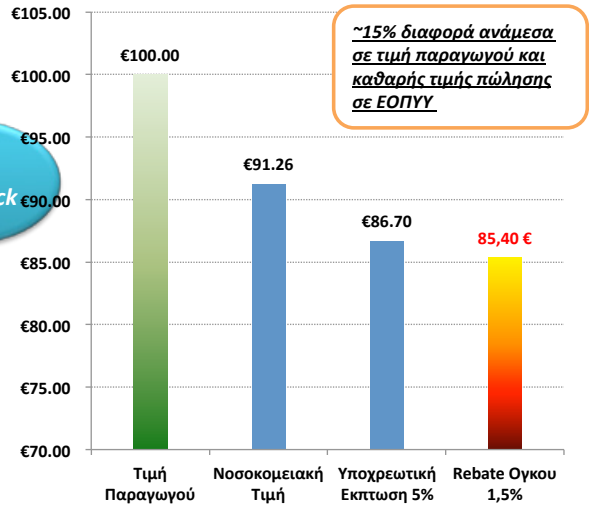
Year	Pharma Industry Rebates	Pharma Industry Clawbacks	Total financial burden (a)	Target of Public Pharma Expenditure (b)	% Contribution of Pharma Industry to Public Pharma Expenditure (a/ b)
2012	€193 MM	€78 MM	€271 MM	€2,880 MM	***9.4%***
2013	€177 MM	€153 MM	€330 MM	€2,371 MM	***13.9%***
2014	€223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

Εκπτώσεις και επιστροφές (rebate) φαρμάκων του ν.3816



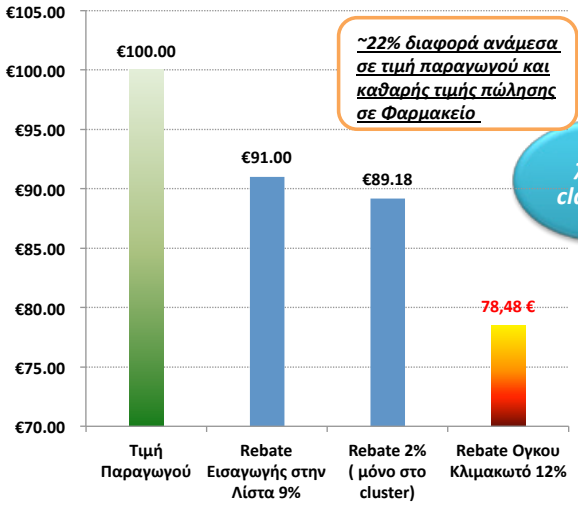


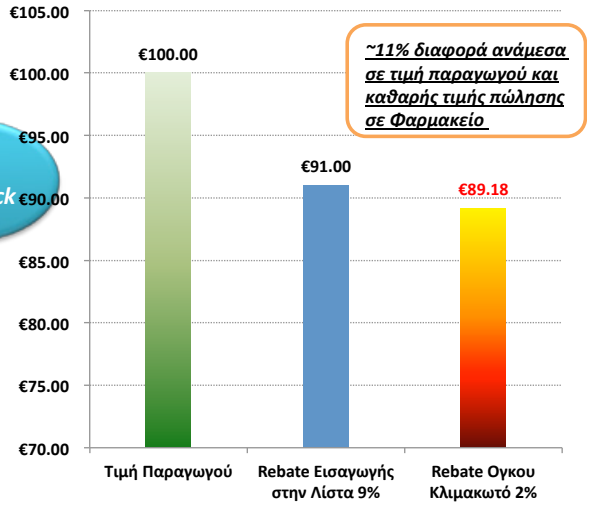
1ο έτος κυκλοφορίας, >€4,5ΜΜ πωλήσεις το τρίμηνο

Ωριμο προϊόν, <€2,5ΜΜ πωλήσεις το τρίμηνο

Η διαφορά τιμής πώλησης και τιμής παραγωγού μπορεί να κυμανθεί από ***15%*** εώς ***22%***, εξαρτημένη από τον όγκο πωλήσεων τριμήνου και το αν το φάρμακο είναι στο πρώτο έτος κυκλοφορίας του.

Εκπτώσεις και επιστροφές (rebate) συνταγογραφούμενων φαρμάκων κοινότητας





Μόνο του στο cluster, >€2,0ΜΜ πωλήσεις το τρίμηνο

Οχι μόνο του στο cluster, <€400Κ πωλήσεις το τρίμηνο

Η διαφορά τιμής πώλησης και τιμής παραγωγού μπορεί να κυμανθεί από ***11%*** εώς ***22%***, εξαρτημένη από τον όγκο πωλήσεων τριμήνου και από το αν το φάρμακο είναι μόνο του στο cluster της Θετικής Λίστας

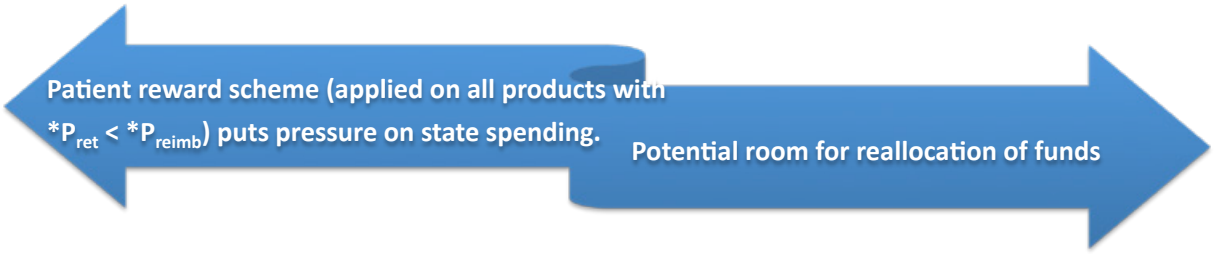
Patients have access to new innovative treatments for therapeutic categories that had no or limited alternative

- 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)

43 Medicines in L.3816 & 31 retail medicines

Total of 74 new medicines included in the new reference list

Επίδραση της εφαρμογής της θετικής λίστας στο 2014



- Evaluated changes in co-payment algorithm & reference price estimation between **March 2014 & August 2014**, to assess the burden to all stakeholders (EOPYY, Pharma Companies, 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).

*P ret = retail price
*P reimb = reimbursed price

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).

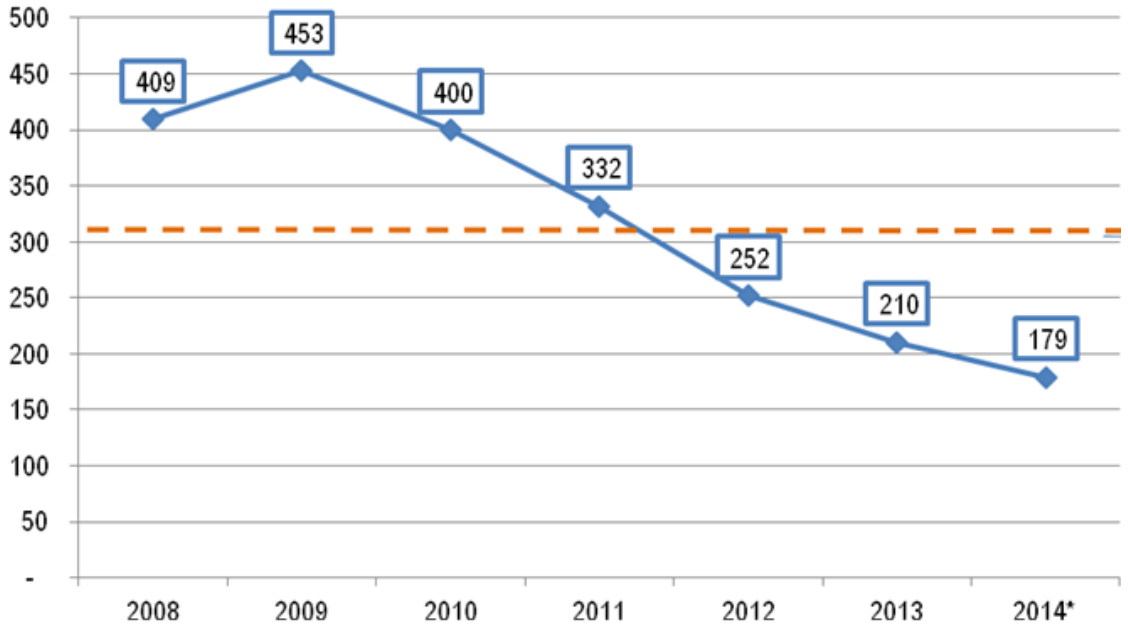
2015 Onwards – Moving ahead

- Mandatory implementation of therapeutic protocols for top 20 therapies in value
  - So far: Osteoporosis, Dislipidemia, Gout, Diabetes I & II and Rheumatoid Arthritis
- Implementation of patient registries in order to assess actual prevalence of the disease and subsequent impact to healthcare system
  - Hep.C patient registry is completed and training for physicians & experts staff is underway
  - Hep.B, Acute Myeloid Leukaemia & MS are the next diseases to follow

2015 Onwards – Moving ahead

- Demand & establish upper limit of clawback of **max. 3%** of pharma expenditure that should be eliminated with implementation of structural reforms.
- Demand the extraction of VAT, third party withholdings (ΕΚΑΣ, ΜΤΠΥ) and vaccines from pharmaceutical expenditure.
- Demand & establish pharmaceutical expenditure to cover the uninsured population, as current per capita is 50% less than the EU average *(next slide)*

Δημόσια κατά κεφαλή δαπάνη στην Ελλάδα 2008-2014, κάτω από τον μέσο όρο της ΕΕ για το 2012-2014



Πηγή: Σύστημα Λογαριασμών Υγείας 2009-2011. ΕΟΠΥΥ 2012

2015 onwards – Moving ahead

The Chinese use two brush strokes to write the word 'crisis'.

One brush stroke stands for danger; the other for opportunity.

In a crisis, be aware of the danger - but recognize the opportunity.

John F. Kennedy

ΣΑΣ ΕΥΧΑΡΙΣΤΩ ΘΕΡΜΑ!

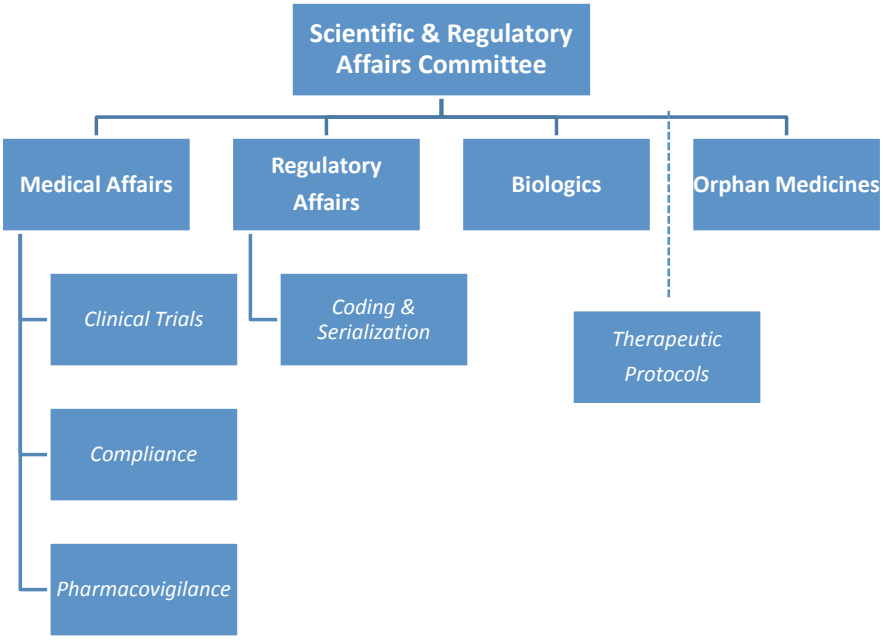
PASCAL APOSTOLIDES
BSc,B.A., PGrad.Dipl.,MSc
Managing Director
AbbVie Pharmaceuticals S.A.

Cell: +30 6945 853700
E-mail: pascal.apostolides@abbvie.com

Scientific & Regulatory Affairs Committees 2012-2014

Olympios Papadimitriou
Managing Director Novo Nordisk
Vice President SFEE

Scientific & Regulatory Affairs Committee



Medical Affairs Committee

Clinical Studies

- **Interventional Studies**
  - –SFEE positions re clinical research communicated to MoH & Proposal with changes in GG390/21.02.13
  - – Collaboration labs SFEE - EPLO & stakeholders: MoH, Ministry of Finance, Ministry of Development
    - EOF, YPE, Hospitals, Researchers, Academia etc
  - – Study on clinical research investment from NSPH 2012 VS. 2010: presented in ISPOR 2014
  - – SFEE Event in NSPH about CTs, in May 2014 with the participation of all stakeholders
  - – Increased publicity & acceptance within government officials
- **Non-Interventional Studies**
  - – Proposal on institutional & legislative framework required
- **«Delon» Registry**
  - – Access to the public for non-interventional studies : 56 studies uploaded

Training

- **Patient Education Programs**
  - – Proposal for adaptation within the code of ethics of SfEE of responsibilities and practices for patient education programs
- **Continuous Education Program SFEE - DEREE**
  - – Clinical Research
  - – Pharmacovigilance
  - – GCP for researchers
  - – Patient Centricity
  - – Medical Affairs

Medical Affairs Committee

Suggested Priorities for 2015

- **Clinical Studies**
  - – Event on International Clinical Studies Day, May 2015
  - – Evaluate Investment of Pharma Industry in Clinical Studies through an independent body (Medicines, diagnostic tests, research expenses, fees for professionals involved such as CROs, physicians etc.)
  - – Preparation on the Implementation of the New European Regulation (working committees with stakeholders; Action plan for attracting Clinical studies and investment)
- **Therapeutic Protocols**
  - – Workshop on the establishment of a transparent institutional framework on TPs.
- **Biologics**
  - – Collaboration with the respective working team for an Educational Workshop on Biologics

Regulatory Affairs Committee

- Agreement over the method of implementation of **Regulation 712** in order to accelerate the use of variations before the issuance of the official decision.
- **Public access** to the approved **SPC_PIL** through an online database set up by EOF – Q1 2015
- Preparation of proposal for **fees reduction** based on payment per active substance/brand and not per SKU – 2015
- **Coding & Serialization** project
  - update re counterfeit medicines; Follow-up with partners to keep members & authorities updated on the progress of the project.
  - The project will be implemented in Greece **by 2023;** monitoring system through authenticity tags already in place. However, pharma companies **supplying products to the EU** have to comply by **2017**.

Orphan Drugs Committee

- Updated **Position paper** re policy framework necessary for P&R approval of orphan drugs.
- **Stakeholder call plan execution** to sensitize authorities on rare diseases & access problems patients face to incorporate our position in the **National Action Plan for Rare Diseases.**
  - President of Committee of National Action Plan for Rare Diseases
  - General manager of KEELPNO & Scientific Coordinator
  - EOPYY President & Director of Pharmaceutical Services
- Collaboration with Mrs. Michelakaki for the update of **Orphanet with national data**
- **Press Conference** re barriers in access of orphan drugs during the **World Rare Disease Day** (Prof. Bouros & General Secretary of Public Health Mr. Avgerinos)

Biologics Committee

- Rx of biologics based on brand name (GG3057/18.11.12)
- Collaboration with authorities to ensure that biosimilars and biologics are **not interchangeable** resulting in EOPYY circular 36/88/13 & GG64/16.01.14.
- Advisory Board of all stakeholders (physicians, hospital pharmacists, MoH, EOPYY, EPY/YPE, EOF) on biologics differentiation and added value that could result in **a consensus paper;** proposed to take place in 2015
- **Day Conference on Biologics** with the support of pharma industry & MoH hospice to provide a holistic view on biologics (regulatory, clinical and economic perspective) within Q2 2015

Committee on Growth & Added Value
&
Hospitals Committee

Konstantinos Panagoulias,
Vice President of SFEE
Annual General Assembly of SFEE
March, 2015
Athens

Committee on Growth

A Growth Strategy for the Pharmaceutical Industry towards 2020 in collaboration with IOVE

- 2 Pillars
  - Clinical Trials/R&D
  - Production, Exports
- Proposal of specific measures per Ministry or stakeholder
  - The role & organization of EOF
  - Clinical Trials
  - Legislation on Growth & Innovation
  - Incentives and Funding

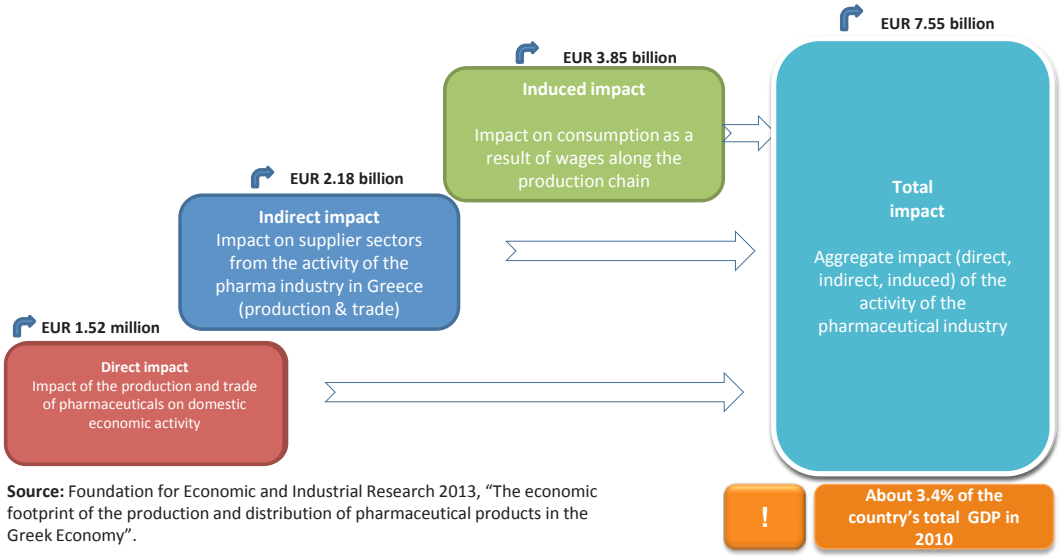
- Contribution in the National Economy
- Multipliers

The Footprint of Pharma Industry

- Expertise on subsidized programs IMI2, HORIZON, NSRF

Subsidized programs

V. Contribution of the pharma industry to the economy: impact on Gross Domestic Product



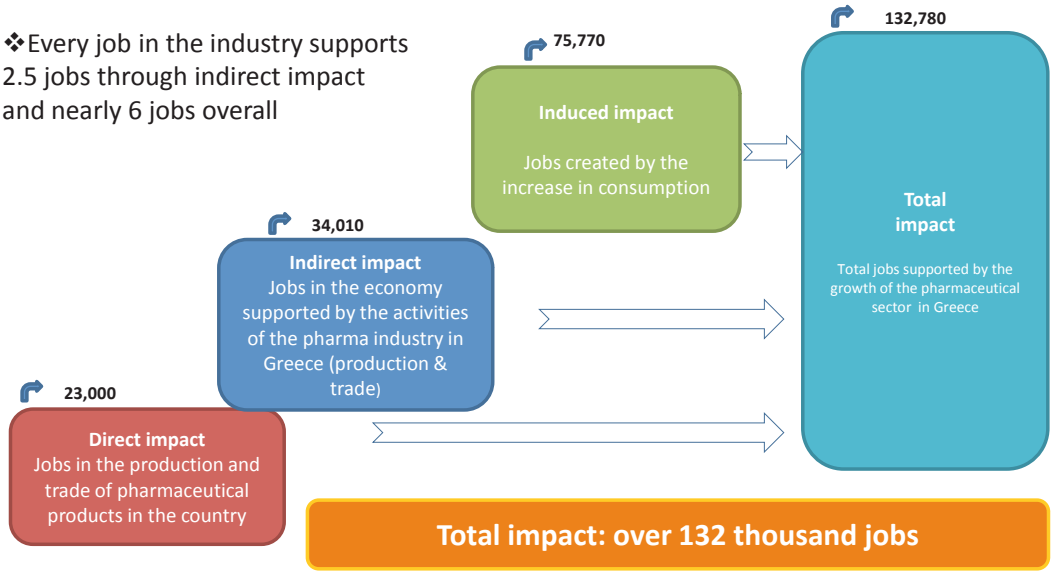
Source: Foundation for Economic and Industrial Research 2013, "The economic footprint of the production and distribution of pharmaceutical products in the Greek Economy".

- Every euro of value added in the production and distribution of pharmaceutical products leads to:
  - EUR 2.6 of value added through indirect impact; and
  - EUR 5.3 of value added if induced impact is also included.
- In terms of GDP, the multiplier is equal to 2.4 and 5 respectively

3

V. Contribution of the pharma industry to the economy: effect on employment

- Every job in the industry supports 2.5 jobs through indirect impact and nearly 6 jobs overall



Source: Foundation for Economic and Industrial Research 2013,
"The economic footprint of the production and distribution of pharmaceutical products in the Greek Economy".

4

Hospitals Committee

Monitoring Hospitals Budget

- Increase to 700-800 mil €
- Ratio 50:50 with other supplies as in EU

Study on the improvement of hospital environment & measures proposals

Payments

- Improving Lags
- Promoting Off-setting
- Provisions on the legalization of hospital supplies

High Cost Drugs (L.3816/2010 ∫ 1[A])

- Should be prescribed and provided by hospitals

Tenders-EPY

- Formatting a functional framework for tenders
- More than one Lowest Bidders

Contacts with Task Force

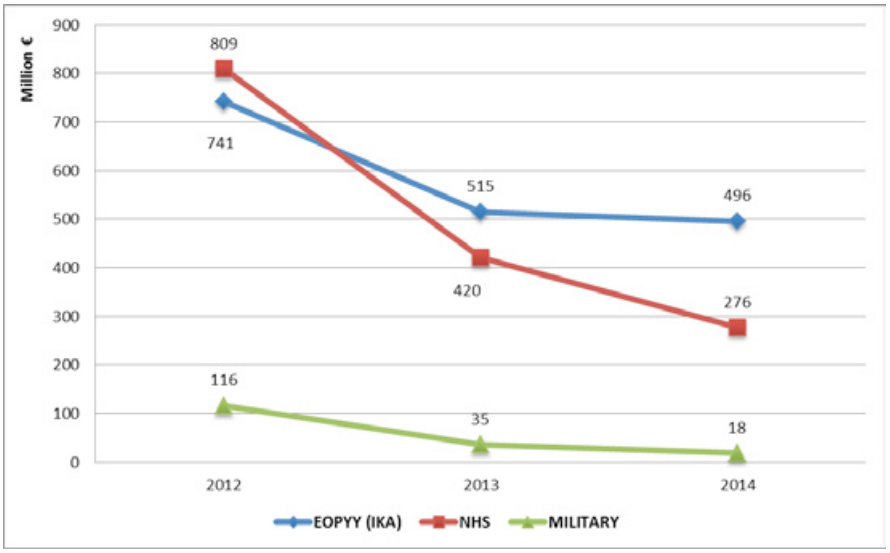
Arrears Payments

Costantinos Evripides,
Vice President of SFEE
Annual General Assembly of SFEE
March, 2015
Athens

Summary of outstanding Debts for 2014

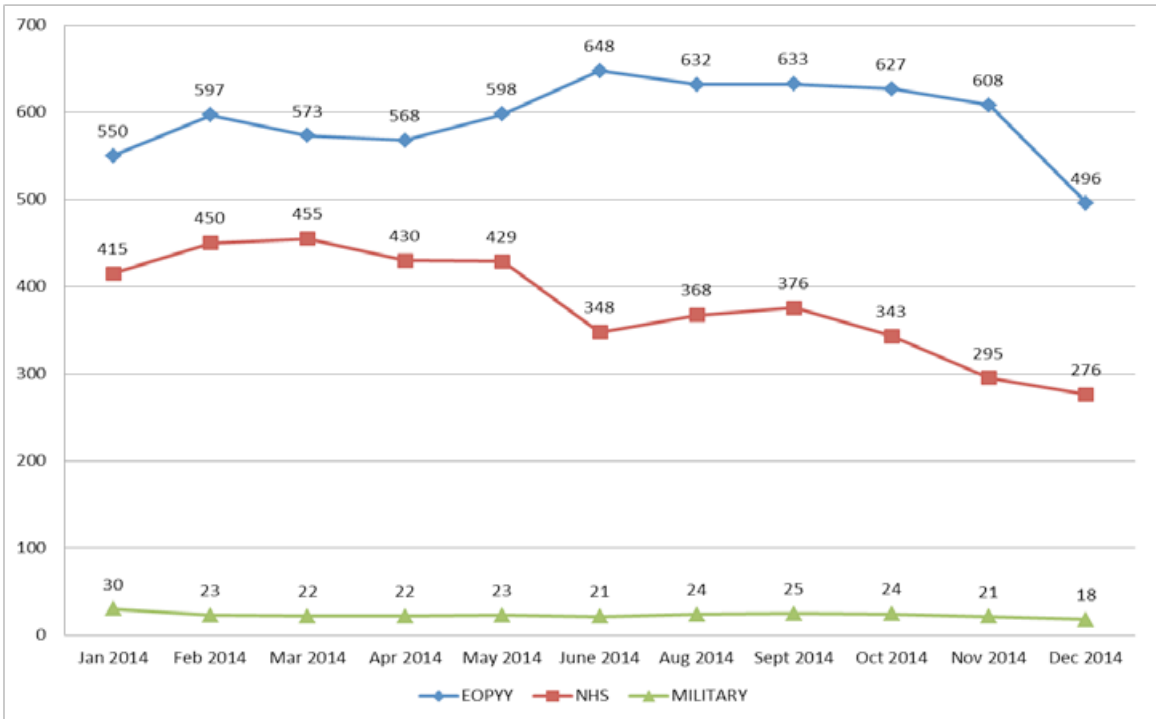
	Debts (until 31/12/2012)	2013 Debts (until 31/12/2013)	2014 Debts (until 31/12/2014)	Total
EOPYY (IKA)	~ 2.1 mio	~ 0.84 mio	~ 493.1 mio	**~ 496.1 mio**
NHS	~ 8.97 mio	~ 63.4 mio	~ 203.6 mio	**~ 276.0 mio**
MILITARY	~ 0.3 mio	~ 2.8 mio	~ 14.6 mio	**~ 17.7 mio**
TOTAL	**~ 11.4 mio**	**~ 67.1 mio**	**~ 711.4 mio**	**~ 789.9 mio**

Evolution of debts 2012-2014
(incl. arrears of previous years)

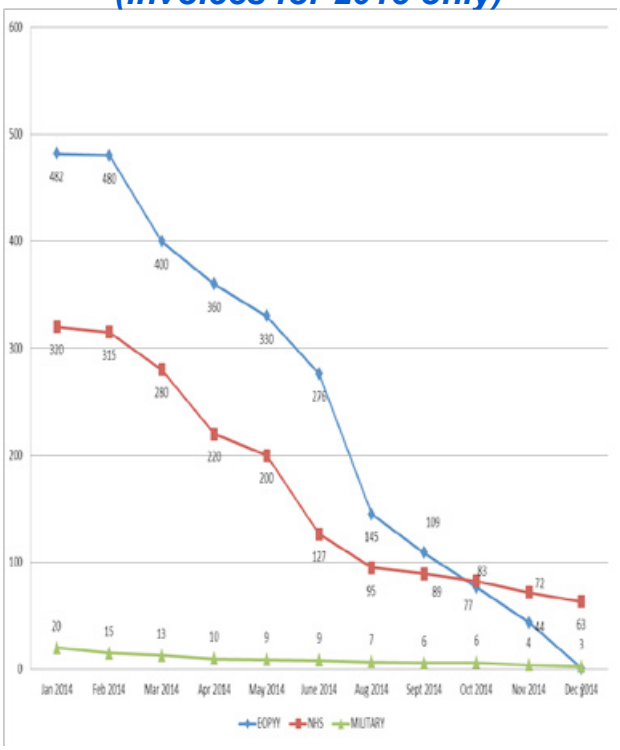


Unsettled payments	2012	2013	2014
Total	1,7 bln	970 mio	790 mio

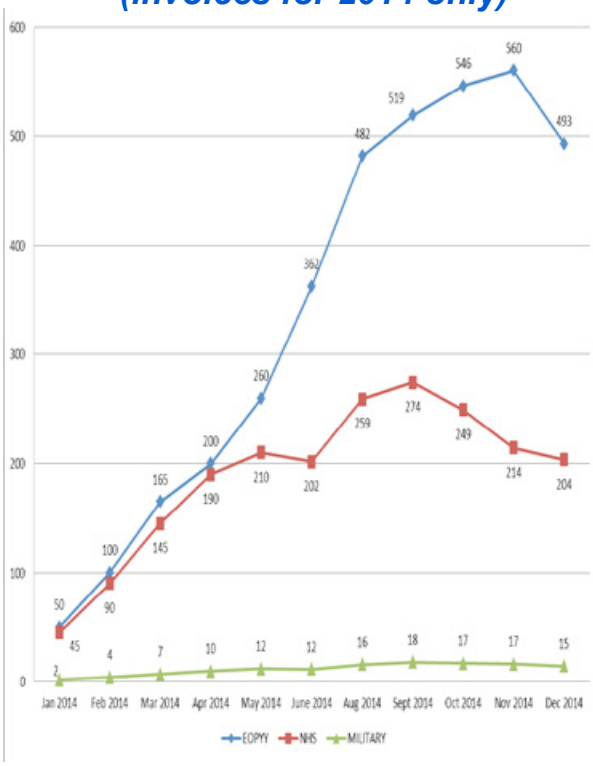
Monthly Evolution of Payments
Unsettled Debts 2012 – 2014 (incl. arrears)



95% of 2013 debts settled (invoices for 2013 only)

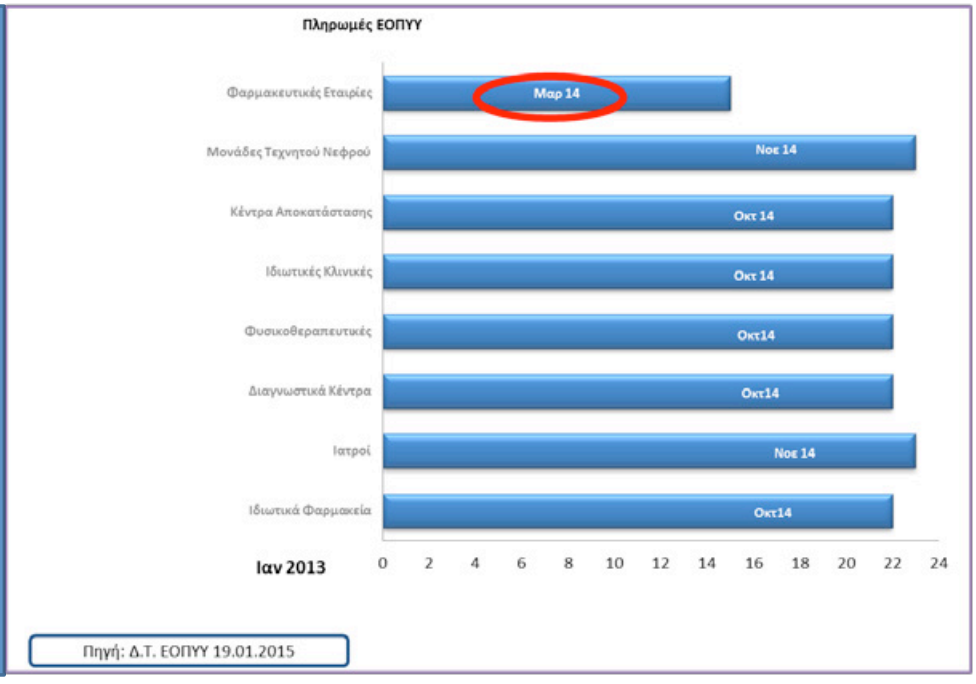


40% of 2014 debts settled (invoices for 2014 only)



EOPYY payments in 2014
Payments remain unbalanced among suppliers…
7-8 months difference

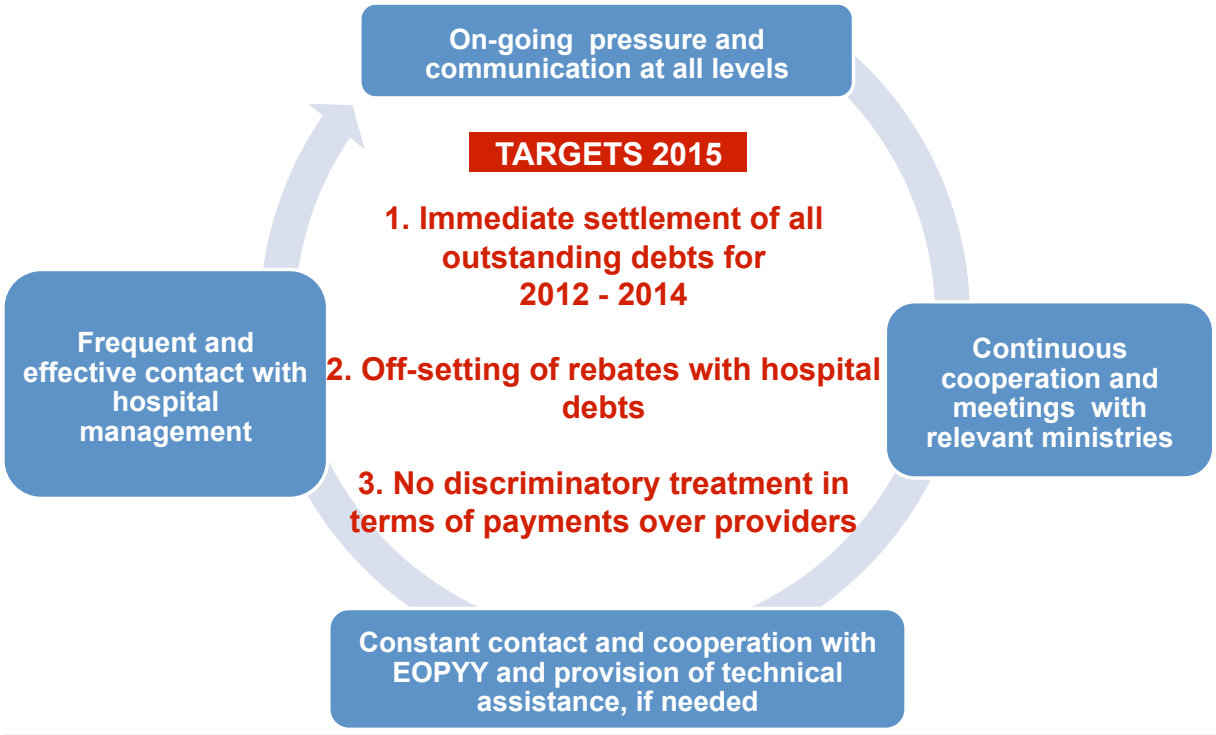
Payments should not be executed in a discriminatory way



SFEE High Priority Issues For Debts

- Immediate settlement of all outstanding debts
- Expansion of the off-setting mechanism to all companies' obligations to the State & prioritization of settlements (e.g. Papageorgiou)
- Implementation of EU-Directive 2011/7, according to which the debts of the State must be settled within 60 days
- Non-discriminatory-favorable payments from EOPYY to its other suppliers

ACTIONS AND TARGETS 2015



COMMITTEE FOR DOCUMENTATION AND DATA MONITORING 2015

Vassili Niadas, SfEE Secretary General & Committee President

Annual General Assembly of SFEE

March 20, 2015

THE COMMITTEE MEMBERS

- M. Himonas, Z. Vostitsanou, D. Theodoratou, J. Papadonikolaki, SfEE
- A. Angeli, AstraZeneca
- M. Bokaris, Sanofi
- Ch. Martakos, Lilly
- I. Palaka, Amgen
- I. Roubou, Novartis
- R. Siaterli P. Karabela, GSK
- A. Vernadaki, Abbvie
- And we need more

CONCLUSIONS from 2014

- Variability of environment in 2014 and delays in decision-making responsible for outdated information
- Monthly bulletin of financial/market indicators
- Improved distribution of information to the BoD and members
- Improved utilization of material from third-party studies

ORGANISATION & NEEDS 2015

- Focus around four thematic units:
  - Contribution of medicinal products to Economy, public Finance and Development
  - Developments in pharmaceutical market & economy
  - Measures and impact thereof on welfare and Health
  - Hospitals and other cost centers of Health
- Improve alignment between the Board's strategic needs for documentation and the Committee. Make **swift** decisions.
- Flexibility to order special reports (eg "The state of the pharma industry" for negotiations with the Unions)
- Improved distribution of outcomes to the BoD and SfEE members when such distribution is not legally restricted
- Encourage other Committees to commission their own research, and align with the Documentation Committee

TWO MESSAGES

- TO THE BOARD
  - **Define** SfEE's needs of documentation with clarity and speediness for better coordination with the Committee's duties
- TO SfEE MEMBERS
  - Encourage your top managers from market access, health economics, public/government affairs, pricing or reimbursement to join the Documentation Committee

CODE OF ETHICS	SUGGESTED MODIFICATIONS	REASON TO MODIFY
1ST AMENDMENT	**ADVERTISEMENTS ON PRINTED MATERIALS OF POSITIVELY EVALUATED (BY SFEE) CONFERENCES**	**EXPLANATORY NOTE**
BEFORE: **Article 5, page 9** Article 5. Advertisements Advertisements may only appear in professional publications, namely publications sent or delivered exclusively to health scientists and nursing personnel. Scientific journals and publications of the health sector, printed material of conferences, medical/ pharmaceutical books etc, fall under this category. A loose insert in such a publication (for instance, separate leaflets distributed through the medical press) is not considered abbreviated advertisement.	**AFTER:** **Article 5, page 9** Article 5. Advertisements Advertisements may only appear in professional publications, namely publications sent or delivered exclusively to health scientists and nursing personnel. Scientific journals and publications of the health sector, printed material of **POSITIVELY EVALUATED** conferences, medical/ pharmaceutical books, etc, fall under this category. A loose insert in such a publication (for instance, separate leaflets distributed through the medical press) is not considered abbreviated advertisement.	The insertion of the phrase **«POSITIVELY EVALUATED»** is suggested, so that it is clarified that the advertisements in conferences' printed materials should take place in materials of **positively evaluated** conferences by the SFEE evaluation committee. Otherwise, it is no worthy rejecting a positive evaluation due to infringement of code provisions, yet allowing the written advertisement.

1

2nd AMENDMENT	**ANY OFFER OF MEDICAL, DIAGNOSTIC INSTRUMENT, SCIENTIFIC TEXTBOOK, ELECTRONIC CONNECTION ETC. OVER 15€ IS CONSIDERED TO BE A DONNATION – Completion of the gap in the existing threshold between article 14 and 16.**	**EXPLANATORY NOTE**
BEFORE: **Article 16.3. page 17** As of 1st January 2014 this category includes various medical or diagnostic instruments, scientific textbooks, electronic aids (mainly electronic connections to databases, supportive software and computers, books) exceeding € 100 in value.	**AFTER:** **Article 16.3. page 17** As of 1st January 2014 this category includes various medical or diagnostic instruments, scientific textbooks, electronic aids (mainly electronic connections to databases, supportive software and computers, books) exceeding € 15 in value (including VAT).	Correction of the amount in € because nowhere in the Code is there a provision stipulating that transfers of value up to a 100 € are allowed- the provision of article 16.2. – in its previous version- was contradictory to the provision of article 14.2.
3rd AMENDMENT	**DEFINITION OF SCIENTIFIC EVENTS ABOUT TOPICAL HEALTH AND MEDICINAL ISSUES ORGANISED BY ADVERTISING OR OTHER COMPANIES – MANDATORY EOF APPROVAL – THRESHOLDS TO GRANTS LIKE THE TYPE "A" CONFERENCES**	**EXPLANATORY NOTE**

2

BEFORE: **No provision.** **INSERTION:** **NEW ARTICLE (insertion of paragraph "H" in ARTICLE 17 page 23.)**	**AFTER:** **ARTICLE 17, Page 23** **H. Conferences on Health / Medicinal Issues organized by advertising or other services' supply companies.** Conferences organized in Greece by advertising or other services' supply companies, which undertake the whole cost of the organization, without promotional purposes, aiming through the participation of different stakeholders (i.e. HCPs, patients, members' of pharmaceutical companies, public officers), to the general information of the public and exchange of views about topical health and medicinal issues. The organization of such conferences presupposes the EOF approval procedure in line with the current circular in force regulating scientific conferences. The pecuniary level of the grants should be proportionate to the duration of the conference, according to the thresholds of type A conferences (N.B. article 19A).	**Harmonization with EOF circular** "Pursuant to article 31 par. 3 of the L. 1316/83 "organization or granting of conferences or seminars or any other relevant means of information referring to issues of EOF's competence by pharmaceutical industries or companies or through any advertising or any other services' supply companies, could be allowed solely prior to EOF approval".
4th AMENDMENT	**CONFERENCES' EVALUATION BY COLOURS**	**EXPLANATORY NOTE**
BEFORE:	**AFTER:**	**Filling in of the relevant gap.**

3

No provision. **INSERTION:** **INSERTION AT THE END** **OF THE INTRODUCTION OF ARTICLE 18 (PRIOR TO 18.1.)**	**The SFEE Evaluation Committee evaluates the conferences and having first applied the criteria of the Code, distinguishes the conferences by the following color distinction:** **BLUE: MISSING ELEMENTS, CANNOT BE EVALUATED.** **GREEN: IN FULL HARMONISATION WITH THE CODE PROVISIONS** **WHITE: INFRINGES ONE OR MORE OF THE CODE PROVISIONS, THE COMPANY MAY PARTICIPATE AT THEIR OWN RESPONSIBILITY** **PURPLE: EXCLUSIVELY FOR INTERNATIONAL CONFERENCES, AT THE DISCRETION OF ANY PHARMACEUTICAL COMPANY**	
5th AMENDMENT	**INVOICING BY THE PCO ONLY IN SPECIAL CIRCUMSTANCES WHERE THE SCIENTIFIC INSTITUTION/ ASSOCIATION IS NOT BY ITS LEGAL NATURE ENTITLED TO ISSUE AN INVOICE**	**EXPLANATORY NOTE**
BEFORE:	**AFTER:** **ARTICLE 18.5 page 25 (new subparagraph A):**	**Clarification- Insertion**

4

ARTICLE 18.5 page 25 **INSERTION** ---------- If the scientific organizing entity is not competent or in view of its may not due to the nature of its legal form issue such receipts, it is entitled – under a valid contract signed with the Professional Conference Organizer, that should be explicitly mentioned in the EOF approval – to assign to the Professional Conference Organizer the entire financial management of the conference.	**If the scientific organizing entity is competent or it is by nature of its legal form able to issue receipts and invoices, the invoicing of the full range of services of the conference to the pharmaceutical company shall be done solely by the scientific organizing entity.** If the scientific organizing entity is not competent or in view of its may not due to the nature of its legal form issue such receipts, it is entitled – under a valid contract signed with the Professional Conference Organizer, that should be explicitly mentioned in the EOF approval – to assign to the Professional Conference Organizer the entire financial management of the conference.	
6th AMENDMENT	**SAME LIMITS ON HOSPITALITY LEVEL (MEALS & OVERNIGHT STAY) APPLICABLE TO FOREIGNERS PARTICIPATING IN CONFERENCES IN GREECE *(HOST COUNTRY PRINCIPLE)***	**EXPLANATORY NOTE**
BEFORE:	**AFTER:**	**Harmonization with the EFPIA code**

Article 19, page 27 **Scientific Events held in Greece** The cost of meals per participant should not exceed EUR 70 (incl. VAT) per day in Greece. Accommodation costs must not exceed EUR 140 (incl. VAT) in Greece. In this price (EUR140) breakfast is included. **Scientific Events held abroad** The cost of meals in scientific events held abroad should not exceed EUR 70 (excluding VAT) per day and the accommodation cost EUR 250 (excluding VAT) per day in 4-star hotels.	**Article 19, page 27** **Scientific Events held in Greece** The cost of meals per participant should not exceed EUR 70 (incl. VAT) per day in Greece. Accommodation costs must not exceed EUR 140 (incl. VAT) in Greece. In this price (EUR140) breakfast is included. **The above mentioned meals' and accommodation limits apply also for foreign HCPs who participate in scientific events held in Greece.** **Scientific Events held abroad** The hospitality cost (meals and accommodation) of scientific events held abroad, should be in line with the thresholds of the country where the event takes place, if and in case the meals' cost does not exceed EUR 70 (excluding VAT) per day and the accommodation cost does not exceed EUR 250 (excluding VAT) per day in 4-star hotels.	**provision.**
7th AMENDMENT	**CLARIFICATION OF THE DEFINITION OF INTERNATIONAL CONFERENCES – organization by a foreign scientific institution a mandatory pre-requisite**	**EXPLANATORY NOTE**

BEFORE: **Table of page 28:** **Completion of the definition of International Conferences** *The organizer is a foreign scientific institution/ association or the foreign scientific institution/ association is a co-organizer with a Greek scientific institution/ association, as mentioned on the EOF approval.	**AFTER:** *International/ Worldwide scientific events that take place in Greece organized by a foreign scientific institution/ association or co-organized with a Greek scientific institution/ association **(not when the organizer is a Greek scientific institution/ association acting under the auspices of a foreign institution).**	**Clarification.**
8th AMENDMENT	**SFEE AUSPICES**	**EXPLANATORY NOTE**
BEFORE: **No provision.**	**AFTER:** **Article 19 D. SFEE Auspices [New***]** SFEE may offer their auspices to any scientific event of whatever nature, as long as it fulfils the code harmonization requirement and the specific scientific event generally promotes the interests of the pharmaceutical sector. In cases of doubt, the SFEE	***NEW ARTICLE*** ***to fill in the relevant gap.***

7

	BOD will issue the final judgement.	
9th AMENDMENT	**1. HONORARIA THROUGH ELKE/ELKEA OR NOT, pursuant to the currently existing Law provisions-** **2. NEW PARAGRAPH TO ARTICLE 22: ADVISORY BOARDS, INVESTIGATORS MEETINGS & CONSULTANT MEETINGS WITHOUT EOF APPROVAL.**	**EXPLANATORY NOTE**
BEFORE: **Article 22.** *Provision of Consulting Services or similar collaborations between HCPs and the Pharmaceutical Industry.* **22.3. a.** Any honorary fee shall be deposited to the entities foreseen by the legislation in force, which shall transfer it to the beneficiary after the appropriate deductions and, at the end of the year, issue a relevant income certificate for tax purposes. In any case HCP fees must be paid as	**AFTER:** **Article 22:** **22.3. a.** Any honorary fee shall be deposited to the entities foreseen by the legislation in force, which shall transfer it to the beneficiary after the appropriate deductions and, at the end of the year, issue a relevant income certificate for tax purposes**, or (the honorary fee) could be directly deposited to the beneficiaries' (HCP) account as long as the latter is entitled by the law, as currently in effect, to invoice directly.** In any case HCP fees must be paid as described above and not through third parties (e.g. scientific societies). **22.3. b. The meetings held with a small number of**	**1. Harmonization with the Law currently in effect (issuance of services' invoice).** **2. INSERTION OF A NEW PARAGRAPH –b- to article 22.3.**

8

described above and not through third parties (e.g. scientific societies).	**participants in order that the participants advise on scientific issues (advisory boards), get informed about new facts concerning clinical trials to which they participate as investigators (investigator meetings) or contribute with their acknowledged experience on scientific issues, elaborate epidemiological facts, that is diseases and therapeutic accesses etc (consultant meetings) and which are organized by the Medical Affairs' department of a company, do not need the EOF approval to the extent that the scientific element supersedes the sociable element.**	
10th AMENDMENT	**MODIFICATION OF ARTICLE 23: PATIENTS EDUCATION & TRAINING PROGRAMS**	**EXPLANATORY NOTE**
BEFORE: **Article 23 Patient Education and Support Programs** The key requirements that must be met are: i. Observance of the Pharmacovigilance obligations ii. Observance of the law on sensitive personal data. iii. The purpose and description of the program must	**AFTER:** **Article 23. Patient Education and Support Programs** **a. Definition- Purpose- Framework** The patient education programs do not constitute Clinical Trials – they have clearly educative/ non-interventional character – and there is no patient personal data collection, further to the necessary information for the compliance with the legislative	***[Provision prepared by the Committee of Medical Affairs Managers]*** **Definition, Clarifications, Prerequisites, Methodology.**

be consistent with the SPC, and the program must not be promotional iv. The use of printed instructions to the HCPs participating and the patients must comply with the applicable laws and the circulars of EOF on medical information and advertisement. v. The Medical affairs departments of the companies must be responsible for the approval and/or supervision of programs Programs may be implemented by means of outsourcing to third-party providers, authorized by the Data Protection Authority.	framework on pharmacovigilance. These programs aim at enhancing the compliance of a potential patient to his/hers prescribed therapy and the amelioration of their quality of life and they are applicable mainly to special medicines which entail the need for specific handling either during the setting title procedure or instructions at the manual use. The provision of education and support of nursery care by third parties is dictated by a social need and contributes, in parallel, to the right and safe therapy of the patients. The performance of medical/ nursery actions, including the medicines' allowance at home, does not fall within the scope of this present provision. Any direct or indirect communication between a patient and his familiars and the pharmaceutical company dealing with the trade/ allocation/ promotion of a drug, is forbidden within the framework of these education programs – as described above, apart from cases of reporting side effects in line with the relevant provisions of the law. The patients' programs, as defined above, are not allowed to be applied by companies dealing with the	

	trade/ allocation/ promotion of drugs for human use. Nevertheless, these companies may solely finance these programs. The execution of these programs is assigned exclusively to HCPs, HCOs or Health Services' Companies in order to safeguard the independent and right provision of education and support services. Programs entailing medical technology products are explicitly excluded from this present. **b. Conditions- Methodology** The education programs have as their object the familiarization of the patients and may include: ● Education of the patients/ or those nursing them to the use of the drug within the framework of the SPC and the product information leaflet (PIL) and supervision at home concerning the drug allowance. ● Education on the typical instructions in relation to the management of the disease. ● Provision of materials and services within the framework of compliance with the therapy, as for instance, leaflets and or reminder programs for the uptake of the drug. ● Anything relevant to the replacement of the drug either reminder or facilitation to its delivery at home. ● Centers for patients' information. ● Medicines that their allowance must be observed by a specialist doctor or / and at a hospital environment are	

	explicitly excluded. ● All the above must be advised by the therapist doctor. ● The written consent of the patient or his attorney at law is mandatory. Goods and Services of medical and educative character delivered to the patient must bear the company name of the grantor pharmaceutical company. The intervention of a pharmaceutical company in these activities must become known to those interested HCPs and/ or to the administrative personnel participating in these services. Moreover the patients should be as well fully informed – through their written consent- about the support of the pharmaceutical company to the services provided to them. The consent is collected by the provider company during the first visit. The consent forms and the patients' data are kept by the provider in a way compliant with the provisions of the law concerning sensitive personal data. The consent form may be retired at any given time and unconditionally, by the patient's initiative. The contract between the provider and the pharmaceutical company should contain the provisions of the laws about the protection of sensitive personal data and pharmacovigilance. The pharmaceutical company and their employees should not have access to personal data and files which may lead to the reveal of the identity of specific patients or be associated with	

	specific patients, apart from the case of reporting side effects. The curating doctors who advise the participation of the patient to such a program do not receive any fee or any other indirect grant. The rest of the HCPs (i.e. nurses, dieticians, pharmacists etc) acting by the grant of a pharmaceutical company are not allowed to be involved in the promotion of specific products. The HCPs and the HCOs and in particular providers of support/ education and training should safeguard that all the information referring to patients must be at all times kept confidential and in compliance with the legislation of personal data. All the printed materials drafted to be used for education purposes should not be used for promotional reasons. It is not acceptable that these materials promote prescription, sales or allocation of the drugs of the grantor company. Nor is it as well acceptable that these materials make critical judgements about competitive products, as this might be deemed as a promotional activity. All the relevant materials addressed to the public should be approved by the Supervisory Committee of Medicinal Information and Advertisement Printed Materials distributed by pharmaceutical companies, along with the provisions of the existing legal framework.	

	Competences: HCPs acting on behalf of an institution/ or health services' provider company, that could be granted by a pharmaceutical company are competent to substantiate these programs. The education programs are advised by the curating doctor to his/her patient. They cannot be substituted by financial remuneration or other reward in kind. The participation to these programs is not obligatory for the patients and it is not a prerequisite for the patients' social security coverage nor relevant to the level of the coverage care and the drugs for the confrontation of the disease. These programs, as well as any other supportive documentation of these programs, are subject to the approval of the division of pharmacovigilance of EOF, in case they consist part of the distribution license of the drug and they are included in the risk management program of the product. In no other circumstances are they subject to EOF approval. The HCO providing these services according to their articles of association, the organization of their personnel, their education and their quality control procedures should have a license issued by the competent authority or collection, elaboration, use and retain of sensitive personal data as well as any other	

	form of accreditation (i.e. ISO 9001). Moreover, their personnel should be consisted by Health Practitioners or individuals with relative to the program specialties (nurses, dietitians, psychologists e.t.c.) Before the setting off of any of such programs, the grantor company must keep a file containing the following documents: 1. In depth description of the program with the relevant scientific documentation, either from the SPC or from the disease and bibliography, or by the technical need. 2. Cooperation contract with the company providing the program services. The contact will include an analytical description of each party obligations. 3. Compliance with the legislation about protection of personal data of those participating in the program. 4. All the supportive documents that will be used during the application of the program.	
11th AMENDMENT	**NO OBLIGATION TO CONSENT**	**EXPLANATORY NOTE**
CHAPTER B DISCLOSURE CODE **BEFORE:**	**CHAPTER B DISCLOSURE CODE** **AFTER:** **Article 1 par. 1.01., page 34**	**Harmonization with the Disclosure Law (4316/2014). The consent is not**

15

Article 1 par. 1.01., page 34 A condition for the disclosure is the written consent of the Recipient. If the recipient does not consent to the disclosure of the transfer of value, the pharmaceutical company shall make an aggregate disclosure. The recipient may on serious grounds revoke in writing his/her consent once given.	According to the above stipulated, any Pharmaceutical Company should disclose on their website and on the EOF website platform, within six months' by the end of each calendar year at the latest, individually by name every transfer of value granted to third parties. The supervision of the above obligation falls within the competence of EOF.	**mandatory. The supervision falls within EOF competence.**
12th AMENDMENT	**DISCONNECTION OF DONNATIONS FROM PROMOTION**	**EXPLANATORY NOTE**
BEFORE: **CHAPTER B** **ARTICLE 4.02.** **Definitions used in Chapter B for the disclosure of Fees of HCPs and HCOs by pharmaceutical companies.** **Donations and Grants**	**AFTER:** **CHAPTER B** **ARTICLE 4.02.** **Definitions used in Chapter B for the disclosure of Fees of HCPs and HCOs by pharmaceutical companies.** **Donations and Grants**	

16

Collectively, means donations and grants (either cash or benefits in kind), for the promotion of prescription and non-prescription medicinal products.	Collectively, means donations, **under the meaning of article 16 of this present Code,** and grants (either cash or benefits in kind), for the promotion of prescription and non-prescription medicinal products.	
13th AMENDMENT	**Correction to the Definition of Service & Consultancy**	**EXPLANATORY NOTE**
BEFORE: **CHAPTER B** **Article 4:** **SERVICE AND CONSULTANCY** **Service and Consultancy:** Education/ training (in house for company employees or externally to other HCPs), advisory boards (non-medical: commercial advisory boards or pharmaco-economics expert panels), speeches/lectures, general consultancy (regarding medical information brochures, preparation of programs for informing HCPs and /or the public on diseases). The above term includes: education, market research, article authoring,	**BEFORE:** **CHAPTER B** **Article 4:** **SERVICE AND CONSULTANCY** **Service and Consultancy:** Education/ training (in house for company employees or externally to other HCPs), advisory boards/**Committees** (~~non-medical: commercial~~ **any type of** advisory boards or pharmaco-economics expert panels), speeches/lectures, general consultancy (**i.e.** regarding medical information brochures, preparation of programs for informing HCPs and /or the public on diseases). The above term includes: education, market research, article authoring, translation, ~~planning/ co-organization of scientific events~~.	**Deletions.**

translation, planning/ co-organization of scientific events.		
14th AMENDMENT	**INSERTION OF CLARIFICATION-** **DELETION OF subparagraph C.**	**EXPLANATORY NOTE**
BEFORE: **CHAPTER C, ARTICLE 4, PARAGRAPH A** 4.Sanctions A. The First Instance Committee, if, after examining the allegation/ complaint, judges that there is a violation of any of the articles of the Code, may impose to a member company that fails to comply with the provisions of the Chapter A of the Code the following sanctions, which shall be enforced after the deadline for filing an appeal has elapsed without any action or after the decision on the appeal, unless the respondent has accepted the	**AFTER:** **4.Sanctions** A. The First Instance Committee, if, after examining the allegation/ complaint, judges that there is a violation of any of the articles of the Code and taking into account the **type of the violation, the number of violations, the gravity and the relapse** may impose to a member company that fails to comply with the provisions of the Chapter A of the Code, the following sanctions, which shall be enforced after the deadline for filing an appeal has elapsed without any action or after the decision on the appeal, unless the respondent has accepted the violation or part thereof: a) A financial penalty of up to EUR 25,000. b) Correction of the non-compliant promotional material	**Insertion of aggravating criteria for penalties. Removal of –d- to –a-. Deletion of –c-.**

violation or part thereof: a) Prompt publication of the decision on SFEE's website. b) Correction of the non-compliant promotional material and obligation of the pharmaceutical company concerned to send the corrected material to its addresses, accompanied by a letter stating the amendments; c) Publication of the decision text, depending on its subject, in relevant scientific journals that are addressed to HCPs; d) A financial penalty of up to EUR 25,000.	and obligation of the pharmaceutical company concerned to send the corrected material to its addresses, accompanied by a letter stating the amendments; c) Prompt publication of the decision on SFEE's website. ~~c) Publication of the decision text, depending on its subject, in relevant scientific journals that are addressed to HCPs;~~ ~~d) A financial penalty of up to EUR 25,000.~~	
15th AMENDMENT	**GENERAL RULE: STRICTER RULE APPLIES**	**EXPLANATORY NOTE**
CHAPTER C, page 41 **No provision.**	**Article 8 (*NEW)** **General Provision**	**We introduce an interpretation tool to facilitate the application of the rules each time in effect.**

	In case of conflict of Laws between the provisions of this present Code and the Greek laws, the stricter rule applies.	

PATIENTS' ASSOCIATIONS CODE

1st AMENDMENT	AMENDMENT OF ARTICLE 7	EXPLANATORY NOTE
BEFORE: "A pharmaceutical company cannot be the sole grantor of a program organized by a patients' association, except from the cases of diseases that there is no other alternative (i.e. a unique medicine available for the disease) as well as in the cases of rare diseases".	**AFTER:** **"A pharmaceutical company cannot be the sole grantor of a Patients' Association and all the actions that this association may organize on an annual basis, except from the diseases that there is no other available funding. Patients' Associations active in rare diseases are explicitly excluded".**	**Several protestations by patients' associations.**

Financial Review 2014 & Budget for 2015

Nikos Varelas,
Treasurer of the BoD

Annual General Assembly of SFEE
March 20, 2015

Athens

2014	BUDGET	REVIEW
REVENUES		
REVENUES FROM MEMBERSHIP FEES	1.973.000	2.073.631
OTHER REVENUES	27.000	21.780
TOTAL REVENUES	**2.000.000**	**2.095.411**
EXPENSES		
OPERATING EXPENSES	1.355.400	1.189.031
COMMITTEES EXPENSES - OTHER EXPENSES OF SFEE	776.900	636.372
TOTAL EXPENSES	**2.132.300**	**1.825.402**
NOTES		
RESERVES	1.216.126	1.216.126
DIF.REVENUES-EXPENSES	-132.300	270.009
FEES COLLECTION OF PREVIOUS FISCAL YEAR	197.018	171.225
OUTSTANDING FEES OF PREVIOUS FISCAL YEAR	-197.300	-227.355
NEW RESERVES	**1.083.544**	**1.430.005**
COMPENSATION TO SALARIED STAFF	-200.000	-200.000
NEW RESERVE 31/12/2014	**883.544**	**1.230.005**

BoD BUDGET 2015

REVENUES

REVENUES FROM MEMBERSHIP FEES	1.972.000
OTHER REVENUES	28.000
TOTAL REVENUES	**2.000.000**

EXPENSES

OPERATING EXPENSES	1.273.600
COMMITTES EXPENSES - OTHER EXPENSES OF SFEE	672.500
TOTAL EXPENSES	**1.946.100**

NOTES

RESERVES	1.230.005
DIF. REVENUES-EXPENSES	53.900
FEES COLLECTION OF PREVIOUS FISCAL YEAR	253.148
OUTSTANDING FEES OF PREVIOUS FISCAL YEAR	-197.200
NEW RESERVES 31/12/2015	**1.339.853**
COMPENSATION TO SALARIED STAFF	-200.000
NEW RESERVES 31/12/2015	**1.139.853**

1/4 REVENUES= 500.000

* New BoD can reallocate Committees budget upon their needs

2014 REVIEW & BUDGET 2015
revised 16-3-2015

	ACTUAL 2013	BUDGET 2014	ACTUAL 2014	BUDGET 2015
REVENUES				
Interest	31.146,67	20.400	17.539,06	15.400
Rental Income	600,00	600	600,00	600
New member companies fees	12.000,00	6.000	0,00	12.000
Fees of current fiscal year	1.667.569,60	1.775.700	1.846.275,84	1.774.800
Outstanding fees of current fiscal year	191.017,68	197.300	227.355,14	197.200
TOTAL FEES OF FISCAL YEAR	**1.858.587,28**	**1.973.000**	**2.073.630,98**	**1.972.000**
RETURN OF DOWNPAYMENT FOR AUDI Q5	0,00	0	3.641,40	0
TOTAL REVENUES	**1.902.333,95**	**2.000.000**	**2.095.411,44**	**2.000.000**
EXPENSES				
1* Employee remuneration - third parties	760.919,51	838.200	735.985,45	867.700
2* New recruitments	35.885,60	44.600	46.975,20	0
3* Office Rent	120.745,80	117.500	117.482,40	110.100
4* Office Expenses	96.704,80	118.600	98.410,72	104.300
5* IT infrastructure	27.011,12	23.500	14.492,14	23.500
6* E.F.P.I.A. fees	46.445,00	46.500	46.445,00	38.800
7* Travel expenses	23.491,82	24.500	18.677,83	20.000
8* Other expenses	128.131,08	142.000	110.561,95	109.200
OPERATING EXPENSES	**1.239.334,73**	**1.355.400**	**1.189.030,69**	**1.273.600**
9* Communication Committee Expenses	424.365,76	439.400	359.071,46	317.000
10* Data Monitoring Committee Expenses	168.544,58	148.900	122.785,09	104.600
11* Growth Committee Expenses	27.911,70	44.550	39.254,72	15.000
12* Regulatory Affairs Committee Expenses	5.412,00	20.160	19.587,02	20.000
13* Reimbursement List-EOPYY Committee Expenses	18.450,00	18.450	18.450,00	47.450
14* Pricing Committee Expenses	6.150,00	6.150	6.150,00	12.300
15* Code of Ethics Committee Expenses	6.248,40	35.700	28.566,75	50.800
16* Appeals to CoS + Special Assignments	49.490,33	53.990	41.490,41	103.000
17* Unforeseen expenses	754,81	9.600	1.016,08	2.350
OTHER EXPENSES OF SFEE COMMITTEES	**707.327,58**	**776.900**	**636.371,53**	**672.500**
TOTAL EXPENSES	**1.946.662,31**	**2.132.300,00**	**1.825.402,22**	**1.946.100,00**
NOTE				
RESERVES	1.334.395,72	1.216.126	1.216.126,00	1.230.005
DIF. REVENUES-EXPENSES	-44.328,36	-132.300	270.009,22	53.900
FEES COLLECTION OF PREVIOUS FISCAL YEAR	117.076,32	197.018	171.224,85	253.148
OUTSTANDING FEES OF PREVIOUS FISCAL YEAR	-191.017,68	-197.300	-227.355,14	-197.200
NEW RESERVES	**1.216.126,00**	**1.083.544**	**1.430.004,93**	**1.339.853**
COMPENSATION TO SALARIED STAFF		-200.000	-200.000,00	-200.000
NEW RESERVES FINAL		**883.544**	**1.230.004,93**	**1.139.853** 1/4 revenues=500.000

The reserve is created to address any potential risks of non-liquidation of claims as well as future compensation to personnel resignation

OPERATING EXPENSES (BREAKDOWN)

	EMPLOYEE REMUNERATION - THIRD PARTIES	2014 REVIEW	BUDGET 2015	NOTES
1*	Remuneration & contributions	709.595		10 employees 12montn basis & 6 employees 2-7month basis (2014)
	Remuneration & contributions		839.700	14 employees 12month basis (2015)
	Kalavros legal fixed annual fee	22.140	22.140	
	Third parties	4.250	5.860	
	TOTAL	**735.985**	**867.700**	
	NEW RECRUITMENTS	**2014 REVIEW**	**BUDGET 2015**	**NOTES**
2*	Remuneration & contributions for new recruitments	33.285		Recruitment 19/5/2014 Payroll for Market Access Officer
	Payments to Headhunters	13.690		General Manager & Market Access Officer
	TOTAL	**46.975**	**0**	
	OFFICE RENT	**2014 REVIEW**	**BUDGET 2015**	**NOTES**
3*	Office Rent	113.400	106.200	9450 X 3 + 8650 X 9 (8% REDUCTION 4/2015)
	Stamp Duty	4.082	3.900	
	TOTAL	**117.482**	**110.100**	
	OFFICE EXPENSES	**2014 REVIEW**	**BUDGET 2015**	**NOTES**
4*	Furniture & other equipment	1.745	7.000	NEW OPEN PLAN 5000
	Telephony & Teleconference	12.285	12.500	
	Mobiles cosmote	13.894	13.894	
	Post	2.652	3.000	
	Repairs & maintenance	17.878	24.500	FAST.INTERNET 8000
	Utilities - electricity - security	48.049	41.500	ABOLITION OF SECURITY SERVICES 4/2015 (950 X9)
	Sundry	1.908	1.906	
	TOTAL	**98.411**	**104.300**	
	IT INFRASTRUCTURE	**2014 REVIEW**	**BUDGET 2015**	**NOTES**
5*	IT Iinfrastructure	14.492	12.900	
	Server & Router		10.600	NEW SERVER
	TOTAL	**14.492**	**23.500**	
	E.F.P.I.A. FEES	**2014 REVIEW**	**BUDGET 2015**	**NOTES**
6*	Annual fees	46.445	38.800	FEES REDUCTION
	TOTAL	**46.445**	**38.800**	
	TRAVEL EXPENSES	**2014 REVIEW**	**BUDGET 2015**	**NOTES**
7*	Travel Expenses	18.678	20.000	
	TOTAL	**18.678**	**20.000**	
	OTHER EXPENSES	**2014 REVIEW**	**BUDGET 2015**	**NOTES**
8*	Car Leasing	26.111	22.900	
	Travel Allowances of employees	14.685	20.800	2 extra
	President Travel Allowances	13.436	6.000	
	Group Insurance	5.369	5.500	
	Subscription to Legal site	902	1.000	
	Subscription to magazins & newspapers	1.815	2.000	
	SEV fees	2.000	2.000	
	General Assembly and BoD meetings	17.835	19.000	EXPENSES FOR THE 2 GAs 13000
	Provisions/ Supplies	6.082	7.000	
	Brochures & stationery	9.398	10.000	
	Publications	1.041	1.000	
	Personnel Services	8.431	8.500	
	Bank Expenses	634	1.000	
	Other Expenses	2.823	2.500	
	TOTAL	**110.562**	**109.200**	

OVERALL TOTAL	1.189.030	1.273.600

OTHER COMMITTEES EXPENSES (BREAKDOWN)

9*	**COMMUNICATION COMMITTEE (Mr. FROUZIS)**	**2014 REVIEW**	**BUDGET 2015**	**NOTES**
	SFEE Brochures	4.969	4.000	
	New Year's event	9.985	10.500	
	Public Relations	21.441	27.000	
	Internal com.-Donations - Other	50.717	22.000	
	Web - Social media	11.888	16.000	
	Dinners with journalists -Press Releases - Media Training	8.040	24.000	
	Press Room	38.650	30.000	
	Advertisements	136.495	115.000	
	Corporate Social Responsibility (CSR)	76.886	68.500	
	TOTAL	**359.071**	**317.000**	
10*	**DATA MONITORING COMMITTEE (Mr. NIADAS)**	**2014 REVIEW**	**BUDGET 2015**	**NOTES**
	IOVE Contract	68.880	55.000	
	IMS Contract (4 DELIVERABLES)	36.900	25.000	
	F+F	7.005		
	Other Reports		24.600	
	IKPI Report (transfer from 2013)	10.000	0	
	TOTAL	**122.785**	**104.600**	
11*	**GROWTH COMMITTEE (Mr. PANAGOULIAS)**	**2014 REVIEW**	**BUDGET 2015**	**NOTES**
	Communication of IOVE Report	29.171		
	Other Reports		10.000	
	TEAYFE Report	6.550		
	Remuneration for labor issues consultant	3.534	5.000	
	TOTAL	**39.255**	**15.000**	
12*	**REGULATORY AFFAIRS COMMITTEE(Mr. PAPADIMITRIOU)**	**2014 REVIEW**	**BUDGET 2015**	**NOTES**
	ESDY Footprint Report (from 2013)	14.760		
	Clinical Trials		20.000	
	Clinical Trials Event 22/5/2014	4.397		
	Improvement of the web platform for Clinical Trials	430		
	TOTAL	**19.587**	**20.000**	
13*	**REIMBURSEMENT-EOPYY COMMITTEE (Mr. APOSTOLIDES)**	**2014 REVIEW**	**BUDGET 2015**	**NOTES**
	Evaluation of New Reimbursement List	18.450	18.450	
	Policies of Innovation Management in Greece (+PIF)		29.000	
	TOTAL	**18.450**	**47.450**	
14*	**PRICING COMMITTEE (Mr. KEFALAS)**	**2014 REVIEW**	**BUDGET 2015**	**NOTES**
	Pricing Study	6.150	12.300	
	TOTAL	**6.150**	**12.300**	
15*	**CODE OF ETHICS COMMITTEE (Mr. GERASSOPOULOS)**	**2014 REVIEW**	**BUDGET 2015**	**NOTES**
	Improvement of web platform for congresses	1.476	1.476	
	Cooperation with Audit Company (E&Y)	11.070	33.270	1 SEM..2014 + 2 SEM. 2015
	Events for the promotion of CoE & Disclosure	8.573	8.573	
	Upgrade of CoE	197	230	
	CoE Logo	3.690	3.690	
	Disclosure Code	3.561	3.561	
	TOTAL	**28.567**	**50.800**	
16*	**APPEALS TO CoS + SPECIAL ASSIGNMENTS**	**2014 REVIEW**	**BUDGET 2015**	**NOTES**
	CoS Appeals 2014 (KALAVROS)	10.905	29.000	8 APPEALS FROM 2014 (actual)
	New CoS Appeals 2015 (KALAVROS)	0	19.000	5 NEW APPEALS (est.)
	CoS Discussions on old appeals (KALAVROS)	711	13.000	
	Other Legal Assignments	24	2.300	
	Translations	20.340	21.000	
	1st & 2nd Degree Committee of CoE	9.200	15.000	
	Other Assignments	310	3.700	
	TOTAL	**41.490**	**103.000**	
17*	**UNFORESEEN**	**2014 REVIEW**	**BUDGET 2015**	
	Unforeseen Expenses	1.016	2.350	
	TOTAL	**1.016**	**2.350**	
	OVERALL TOTAL	**636.371**	**672.500**	

ΣΥΝΔΕΣΜΟΣ ΦΑΡΜΑΚΕΥΤΙΚΩΝ ΕΠΙΧΕΙΡΗΣΕΩΝ ΕΛΛΑΔΟΣ — ΣfEE — HELLENIC ASSOCIATION OF PHARMACEUTICAL COMPANIES

Έκθεση Ελεγκτών

Σε εκτέλεση της εντολής που ανέθεσε η Γενική Συνέλευση στις 23 Μαρτίου 2012 στον κ. Γ. Μαγαλιό και το Δ.Σ. στις 5 Νοεμβρίου 2013 στον κ. Χ. Δάκα, μετά την παραίτηση του κ. Χ. Καρτάλη, συνήλθαμε σήμερα την 11η Μαρτίου 2015 ημέρα Τετάρτη και ώρα 14:00 μ.μ. στα γραφεία του Συνδέσμου επί της Λεωφ. Κηφισίας 280 & Αγρινίου 3 και διενεργήσαμε οικονομικό έλεγχο, δια την περίοδο από 1ης Ιανουαρίου έως 31ης Δεκεμβρίου 2014.

Από τον έλεγχο του βιβλίου του Ταμείου-Διαφόρων Πράξεων και των λοιπών στοιχείων της οικονομικής διαχείρισης και από την έκθεση του Ορκωτού Λογιστή διαπιστώσαμε ότι η όλη διαχείριση των οικονομικών πόρων του Συνδέσμου κατά την περίοδο αυτή έχει καλώς.

Κατόπιν αυτού προτείνουμε στη Γενική Συνέλευση την έγκριση του οικονομικού απολογισμού του έτους 2014 και την απαλλαγή του Διοικητικού Συμβουλίου από κάθε ευθύνη.

Χαλάνδρι, 11 Μαρτίου 2015

Οι ελεγκτές

Χ. Δάκας

Γ. Μαγαλιός

Λ. Κηφισίας 280 & Αγρινίου 3, 152 32, Χαλάνδρι, Αθήνα, Τηλ.: 210 68 91 101 – Fax: 210 68 91 060
Web site: www.sfee.gr – e mail: sfee@sfee.gr
280, Kifissias Ave. & 3, Agriniou str., 152 32, Halandri, Athens, Greece, Tel. : (+30) 210 68 91 101 – Fax : (+30) 210 68 91 060

ΣΟΛ
ΟΡΚΩΤΟΙ ΛΟΓΙΣΤΕΣ
Crowe Horwath

Εμπειρία • Γνώση • Αξιοπιστία

Αθήνα, 10 Φεβρουαρίου 2015

Προς
τη Γενική Συνέλευση
του Συνδέσμου Φαρμακευτικών
Επιχειρήσεων Ελλάδος (ΣΦΕΕ)
Κηφισίας 280 & Αγρινίου 3
Χαλάνδρι

ΕΚΘΕΣΗ

Ελέγχου επί της οικονομικής διαχειρίσεως χρήσεως 2014

Ο έλεγχός μας διενεργήθηκε σε εκτέλεση της προσυμφωνημένης εντολής που μας ανατέθηκε στις 31 Ιανουαρίου 2015 από τη Γενική Διεύθυνση του Σ.Φ.Ε.Ε.

Κατά τον έλεγχό μας εφαρμόσαμε τις ελεγκτικές διαδικασίες που κρίναμε κατάλληλες στα πλαίσια των αρχών ελεγκτικής που ακολουθούμε.

Τέθηκαν υπόψιν μας τα τηρούμενα βιβλία και στοιχεία και παρασχέθηκαν οι πληροφορίες και επεξηγήσεις τις οποίες ζητήσαμε.

Αντικείμενο του ελέγχου μας, όπως προαναφέρθηκε ήταν η οικονομική διαχείριση του ΣΦΕΕ χρονικής περιόδου 1/1-31/12/2014 όπου διαπιστώθηκε ότι έχει καλώς.

ΣΟΛ
ΟΡΚΩΤΟΙ ΛΟΓΙΣΤΕΣ
Crowe Horwath

ΑΘΗΝΑ - ΚΕΝΤΡΙΚΟ:
ΦΩΚΙΩΝΟΣ ΝΕΓΡΗ 3, 112 57 ΑΘΗΝΑ
ΤΗΛ: 210 86 91 100
FAX: 210 86 17 328, 210 86 18 016
e-mail: solaeoe@otenet.gr
site: www. solae.gr ΑΡ.Μ.30ΕΛ 125

ΘΕΣΣΑΛΟΝΙΚΗ:
ΒΑΛΚΑΝΙΚΟ ΚΕΝΤΡΟ (ΚΤΙΡΙΟ ΑΛΕΞΑΝΔΡΟΣ)
ΓΙΑΝΝΙΤΣΩΝ 31 & ΠΑΤΡ. ΚΥΡΙΑΚΟΥ
546 27 ΘΕΣΣΑΛΟΝΙΚΗ
ΤΗΛ: 2310 544 150/1 - FAX: 2310 544 152
e-mail: solthes@otenet.gr

ΚΕΡΚΥΡΑ:
Λ. ΔΗΜΟΚΡΑΤΙΑΣ 7
49 100 ΚΕΡΚΥΡΑ
ΤΗΛ: 26610 42 037
FAX: 26610 82 087
e-mail: solcorfu@hol.gr

ΠΑΤΡΑ:
ΑΜΕΡΙΚΗΣ 44
264 41 ΠΑΤΡΑ
ΤΗΛ: 2610 431 938
FAX: 2610 436 867
e-mail: solpatra@otenet.gr

ΛΑΡΙΣΑ:
ΚΟΥΜΑ 34
412 23 ΛΑΡΙΣΑ
ΤΗΛ: 2410 555461-2
FAX: 2410 555463
e-mail: solarisa@hol.gr

ΗΡΑΚΛΕΙΟ ΚΡΗΤΗΣ:
ΕΘΝ. ΑΝΤΙΣΤΑΣΕΩΣ 47
71 306 ΗΡΑΚΛΕΙΟ
ΤΗΛ: 2810 280 104
FAX: 2810 280 686
e-mail: solkriti@hol.gr

ΙΩΑΝΝΙΝΑ:
ΣΑΛΑΜΑΓΚΑ 1, - 453 32 ΙΩΑΝΝΙΝΑ
ΤΗΛ: 26510 70293, 70876 - FAX: 26510 70351
e-mail: solioan@hol.gr

ΚΑΒΑΛΑ:
ΜΗΤΡΟΠΟΛΕΩΣ 8β (5ος όροφος), 654 03 ΚΑΒΑΛΑ
ΤΗΛ: 2510 620801, FAX: 2510 620802

ΡΟΥΜΑΝΙΑ:
BUCHAREST, DRAGOS VODA Str, No 53
DISTRICT 2, code 020747, camera 1,
TEL: 0040 213166816

ΣΟΛ ΟΡΚΩΤΟΙ ΛΟΓΙΣΤΕΣ Crowe Horwath.

SOL CERTIFIED PUBLIC ACCOUNTANTS Crowe Horwath.

Η έκθεσή μας καταρτίστηκε αποκλειστικά για εσωτερική χρήση. Σημειώνεται ότι ο έλεγχος βασίστηκε στη νομιμότητα των παραστατικών και στις αποφάσεις της Διοίκησης χωρίς να εξετάζεται η σκοπιμότητα των δαπανών.

Συνοπτικά παραθέτουμε στο τέλος της έκθεσης τους λογαριασμούς όπως αυτοί συντάσσονται και εμφανίζονται (σε ευρώ) στον Οικονομικό Απολογισμό 1/1 – 31/12/2014 και στον Ισολογισμό – Αποτελέσματα Χρήσεως της 31/12/2014 του Σ.Φ.Ε.Ε.

Επί των ανωτέρω διευκρινίζουμε:

1) Τα έσοδα της χρήσης 2014 εμφανίζονται, στον Οικονομικό Απολογισμό (2.039.281,15 – 17.539,06 τόκοι – 600,00 έσοδα ενοικίων – 3.641,40 επιστροφή εγγύησης αυτοκ/του) € 2.017.500,69 ενώ στα Μικτά Αποτελέσματα Εκμετάλ/σης του Ισολογισμού € 2.073.630,98. Διαφορά επί πλέον στα Μικτά Αποτελέσματα Εκμεταλ/σης του Ισολογισμού € **56.130,29** η οποία οφείλεται:

   α) στη λογιστική καταχώρηση των εισφορών συνδρομητών που δεν είχαν εισπραχθεί μέχρι 31/12/2014 και κατά συνέπεια δεν συμπεριλήφθησαν στα έσοδα του Οικονομικού Απολογισμού € **253.148,02** και

   β) στην είσπραξη εισφορών προηγουμένων χρήσεων € 171.224,85 που συμπεριλαμβάνονται στα έσοδα του Οικονομικού Απολογισμού της 31/12/2014 πλέον οφειλόμενων εισφορών € 25.792,88 ενώ είχαν καταχωρηθεί στα Αποτελέσματα της χρήσεως 31/12/2013, € **197.017,73**.

2) Τα χρηματικά διαθέσιμα του Ισολογισμού και του Οικονομικού Απολογισμού της χρήσεως 2014 ανέρχονται σε € **1.527.600,36** τα οποία συμφωνούν με το σύνολο των κονδυλίων του Αποθεματικού Καταστατικού € 352.041,31, των λοιπών αποθεματικών € 4.077,48, του Αποτελέσματος εις Νέον (πλεονάσματος) της προηγούμενης χρήσεως € 1.099.665,76 και του πλεονάσματος της παρούσας € 67.253,42 **(Σύνολο= € 1.523.037,97)**,

ΣΟΛ ΟΡΚΩΤΟΙ ΛΟΓΙΣΤΕΣ Crowe Horwath.

ΣΟΛ ΟΡΚΩΤΟΙ ΛΟΓΙΣΤΕΣ Crowe Horwath.

SOL CERTIFIED PUBLIC ACCOUNTANTS Crowe Horwath.

αφού στο σύνολο (λογιστικό υπόλοιπο) αυτό προστεθούν τα κονδύλια:

Υποχρεώσεις Προμηθευτών	150.359,37
Υποχρεώσεις Φόρων	41.703,41
Υποχρεώσεις Ασφαλ. Οργ.	31.479,80
Υποχρεώσεις Πιστωτών	74.016,07
Υποχρεώσεις Λογ. Διαχ. Προκ.& Πιστ.	36,78
ΣΥΝΟΛΟ	**297.595,43**

και αφαιρεθούν τα κονδύλια:

Λοιπές Μακροπρόθ. Απαιτήσεις	39.885,02
Απαιτήσεις από Πελάτες	253.148,02
ΣΥΝΟΛΟ	**293.033,04**

ΥΠΟΛΟΙΠΟ € 1.527.600,36

3) Κατά πάγια τακτική α) τα έξοδα ιδρύσεως - Α΄ εγκατάστασης και τα στοιχεία του παγίου ενεργητικού αποσβένονται στη χρήση κτήσεώς τους κατά 100%, ανεξαρτήτως ποσού, β) δεν σχηματίζεται πρόβλεψη για αποζημίωση του προσωπικού λόγω εξόδου για συνταξιοδότηση.

Με τιμή

ΣΟΛ ΟΡΚΩΤΟΙ ΛΟΓΙΣΤΕΣ Crowe Horwath.

ΔΗΜΗΤΡΙΟΣ Β. ΛΑΜΠΡΙΝΟΣ

Ορκωτός Ελεγκτής Λογιστής Α.Μ. ΣΟΕΛ 13741

Σ.Φ.Ε.Ε.

ΙΣΟΛΟΓΙΣΜΟΣ ΤΗΣ 31ης ΔΕΚΕΜΒΡΙΟΥ 2014 (1η ΙΑΝ. 2014 - 31η ΔΕΚ. 2014)

ΕΝΕΡΓΗΤΙΚΟ

	Ποσά κλειόμενης χρήσεως 2014			Ποσά προηγούμενης χρήσεως 2013		
	Αξία Κτήσεως	Αποσβέσεις	Αναπ. Αξία	Αξία Κτήσεως	Αποσβέσεις	Αναπ. Αξία
Β. ΕΞΟΔΑ ΕΓΚΑΤΑΣΤΑΣΕΩΣ						
1. Έξοδα ιδρύσεως & Α' εγκατ/σεως	40.750,14	40.750,14	0,00	36.525,40	36.525,40	0,00
Γ. ΠΑΓΙΟ ΕΝΕΡΓΗΤΙΚΟ						
II. Ενσώματες ακινητοποιήσεις						
3. Κτίρια & τεχνικά έργα	489.621,84	489.621,84	0,00	489.621,84	489.621,84	0,00
4. Μηχ.- τεχν. εγκατ. & λοιπός μηχ. εξοπλισμός	1.635,90	1.635,90	0,00	1.635,90	1.635,90	0,00
6. Έπιπλα & λοιπός εξοπλισμός	263.184,90	263.184,90	0,00	251.172,13	251.172,13	0,00
	754.442,64	754.442,64	0,00	742.429,87	742.429,87	0,00
III. Συμμετοχές & άλλες μακροπρόθ. χρηματοοικονομικές απαιτήσεις						
7. Λοιπές μακροπρόθ. Απαιτήσεις			39.885,02			42.640,82
Σύνολο παγίου ενεργητικού (ΓΙΙ+ΓΙΙΙ)			39.885,02			42.640,82
Δ. ΚΥΚΛΟΦΟΡΟΥΝ ΕΝΕΡΓΗΤΙΚΟ						
II. Απαιτήσεις						
1. Πελάτες (Συνδρομητές)			253.148,02			197.017,73
11. Χρεώστες διάφοροι			0,00			3.450,00
			253.148,02			200.467,73
IV. Διαθέσιμα						
1. Ταμείο			2.586,60			1.316,36
3. Καταθέσεις όψεως & προθεσμίας			1.525.013,76			1.549.478,61
Σύνολο κυκλοφορούντος ενεργητικού (ΔΙΙ+ΔΙV)			1.527.600,36			1.550.794,97
			1.780.748,38			1.751.262,70
ΓΕΝ. ΣΥΝΟΛΟ ΕΝΕΡΓΗΤΙΚΟΥ (Β+Γ+Δ)			**1.820.633,40**			**1.793.903,52**

ΠΑΘΗΤΙΚΟ

	Ποσά κλειόμ. χρήσεως 2014	Ποσά προηγ. χρήσεως 2013
Α. ΙΔΙΑ ΚΕΦΑΛΑΙΑ		
IV. Αποθεματικά κεφάλαια		
2. Αποθεματικά καταστατικού	352.041,31	352.041,31
Λοιπά αποθεματικά Συνδέσμου	4.077,48	4.077,48
	356.118,79	356.118,79
V. Αποτελέσματα εις νέον		
Υπόλοιπο πλεονάσματος εις νέον	1.166.919,18	1.099.665,76
Σύνολο ιδίων κεφαλαίων (ΑΙV+ΑV)	1.523.037,97	1.455.784,55
Β. ΠΡΟΒΛΕΨΕΙΣ ΓΙΑ ΚΙΝΔ. & ΕΞΟΔΑ		
2. Λοιπές προβλέψεις	.....	.....
Γ. ΥΠΟΧΡΕΩΣΕΙΣ		
II. Βραχυπρόθεσμες υποχρεώσεις		
1. Προμηθευτές	150.359,37	163.668,88
5. Υποχρεώσεις από φόρους-τέλη	41.703,41	47.634,72
6. Ασφαλιστικοί Οργανισμοί	31.479,80	34.577,70
11. Πιστωτές διάφοροι	74.016,07	89.846,63
12. Υποχρ. Λογ. Διαχείρ. προκατ/λών & πιστ.	36,78	2.391,04
	297.595,43	338.118,97
ΓΕΝ. ΣΥΝΟΛΟ ΠΑΘΗΤΙΚΟΥ (Α+Β+Γ)	**1.820.633,40**	**1.793.903,52**

ΑΠΟΤΕΛΕΣΜΑΤΑ ΧΡΗΣΕΩΣ 31ης Δεκεμβρίου 2014 (1 Ιανουαρίου - 31 Δεκεμβρίου 2014)

		Ποσά κλειόμ. χρήσεως 2014		Ποσά προηγ. χρήσεως 2013
Ι. ΑΠΟΤΕΛΕΣΜΑΤΑ ΕΚΜΕΤΑΛΛΕΥΣΕΩΣ				
Κύκλος Εργασιών (Συνδρομές)		2.073.630,98		1.870.587,33
ΜΕΙΟΝ: Κόστος πωλήσεων		0,00		0,00
Μικτά αποτελ/τα (πλεον/τα ή ελλείμ/τα) εκμεταλ/σεως		2.073.630,98		1.870.587,33
ΠΛΕΟΝ : Άλλα έσοδα εκμεταλ/σεως		600,00		600,00
Σύνολο		2.074.230,98		1.871.187,33
ΜΕΙΟΝ: 1. Έξοδα διοικητικής λειτουργίας	2.024.034,60	2.024.034,60	1.943.771,65	1.943.771,65
Μερικά αποτελ/τα (πλεονάσματα) εκμεταλ/σεως		50.196,38		-72.584,32
ΠΛΕΟΝ:4. Πιστωτικοί τόκοι & συναφή έσοδα	17.539,06		31.146,67	
ΜΕΙΟΝ: 3. Χρεωστικοί τόκοι & συναφή έξοδα	0,00	17.539,06	0,00	31.146,67
Ολικά αποτελ/τα (πλεον/τα ή ελλείμ/τα) εκμεταλ/σεως		67.735,44		-41.437,65
ΜΕΙΟΝ: ΕΚΤΑΚΤΑ ΑΠΟΤΕΛΕΣΜΑΤΑ				
ΠΛΕΟΝ: 1. Έκτακτα & ανόργανα έσοδα	16,41		174,76	
ΜΕΙΟΝ: 1. Έκτακτα & ανόργανα έξοδα	498,43		210,01	
ΜΕΙΟΝ: 3. Έξοδα προηγούμενων χρήσεων	0,00	-482,02	110,71	-145,96
Οργανικά & έκτακτα αποτελέσματα (πλεονάσματα)		67.253,42		-41.583,61
ΜΕΙΟΝ: Σύνολο αποσβέσεων παγίων στοιχείων	16.237,51		27.936,65	
ΜΕΙΟΝ: Οι από αυτές ενσωματωμένες στο λειτουργικό κόστος	16.237,51	0,00	27.936,65	0,00
ΚΑΘΑΡΑ ΑΠΟΤΕΛ/ΤΑ (ΠΛΕΟΝ/ΤΑ ή ΕΛΛΕΙΜ/ΤΑ) ΧΡΗΣΕΩΣ		**67.253,42**		**-41.583,61**

ΠΙΝΑΚΑΣ ΔΙΑΘΕΣΕΩΣ ΑΠΟΤΕΛΕΣΜΑΤΩΝ

	Ποσά κλειόμ. χρήσεως 2014	Ποσά προηγ. χρήσεως 2013
Καθ. Αποτελ.(πλεον/τα ή ελλείμ/τα) χρήσεως	67.253,42	-41.583,61
(+) Υπόλ. Αποτελ. (πλεονασμ.) προηγ. χρήσεων	1.099.665,76	1.141.249,37
Σύνολο	1.166.919,18	1.099.665,76
Υπόλοιπο πλεονάσματος εις νέον	1.166.919,18	1.099.665,76

Χαλάνδρι 31 Ιανουαρίου 2015

Ο Πρόεδρος του Δ.Σ.

Κ. Φρουζής
Α.Δ.Τ. ΑΒ 346667

Ο Ταμίας του Δ.Σ.

Ν. Βαρελάς
Α.Δ.Τ. Ρ 033564

Ο Γεν. Διευθυντής

Μ. Χειμώνας
Α.Δ.Τ. ΑΚ 067877

Η Λογίστρια

Ε. Γραββάνη
Α.Δ.Τ. ΑΚ 748769

ΣΟΛ ΟΡΚΩΤΟΙ ΛΟΓΙΣΤΕΣ Crowe Horwath

Σ/ΕΕ HELLENIC ASSOCIATION OF PHARMACEUTICAL COMPANIES

ΟΙΚΟΝΟΜΙΚΟΣ ΑΠΟΛΟΓΙΣΜΟΣ 1/1/2014 ΕΩΣ 31/12/2014

ΥΠΟΛΟΙΠΟ 31/12/2013			**1.550.794,97**
ΔΑΠΑΝΕΣ 2013 ΜΗ ΠΗΡ/ΣΕΣ, ΠΛΗΡ/ΣΕΣ 2014			-334.668,97
ΕΣΟΔΑ =2.039.281,15			
ΤΟΚΟΙ	17.539,06	17.539,06	
ΕΣΟΔΑ ΕΝΟΙΚΙΩΝ	600,00	600,00	
ΣΥΝΔΡΟΜΕΣ 2013	171.224,85		
ΣΥΝΔΡΟΜΕΣ 2014	1.846.275,84	2.017.500,69	
ΕΓΓΡΑΦΗ ΝΕΩΝ ΜΕΛΩΝ	0,00	0,00	
ΕΠΙΣΤΡΟΦΗ ΕΓΓΥΗΣΗΣ AUDI Q5	3.641,40	3.641,40	
ΣΥΝΟΛΟ ΕΣΟΔΩΝ			**2.039.281,15**
		ΣΥΝΟΛΟ (Α)	3.255.407,15
ΕΞΟΔΑ =2.025.402,22			
ΑΜΟΙΒΕΣ & ΕΙΣΦΟΡΕΣ ΠΡΟΣΩΠΙΚΟΥ	709.595,20		
ΑΜΟΙΒΕΣ ΤΡΙΤΩΝ	26.390,25		
ΚΟΣΤΟΣ ΝΕΩΝ ΠΡΟΣΛΗΨΕΩΝ	46.975,20		
ΕΝΟΙΚΙΑ ΓΡΑΦΕΙΩΝ	117.482,40		
ΕΞΟΔΑ ΓΡΑΦΕΙΩΝ	98.410,72		
ΜΗΧ/ΚΟΣ ΕΞΟΠΛΙΣΜΟΣ ΓΡΑΦΕΙΩΝ	14.492,14		
ΣΥΝΔΡΟΜΕΣ E.F.P.I.A.	46.445,00		
ΕΞΟΔΑ ΤΑΞΙΔΙΩΝ	18.677,83		
ΔΙΑΦΟΡΑ ΕΞΟΔΑ	110.561,95		
ΕΞΟΔΑ ΛΕΙΤΟΥΡΓΙΑΣ		1.189.030,69	
ΕΤΑΙΡΙΚΑ ΕΝΤΥΠΑ	4.969,20		
ΕΚΔΗΛΩΣΗ NEW YEAR	9.984,90		
ΔΗΜΟΣΙΕΣ ΣΧΕΣΕΙΣ	21.440,66		
INTERNAL COM.-ΔΩΡΕΕΣ - ΔΙΑΦ.ΕΞ.ΠΡΟΒ.	50.717,19		
ΔΙΑΔΙΚΤΥΟ - SOCIAL MEDIA	11.888,18		
ΓΕΥΜ. ΔΗΜ/ΦΩΝ -ΣΥΝ. ΤΥΠΟΥ - MEDIA TRAINING	8.039,86		
ΓΡΑΦΕΙΟ ΤΥΠΟΥ	38.650,00		
ΔΙΑΦΗΜΙΣΤΙΚΕΣ ΚΑΤΑΧ/ΣΕΙΣ	136.495,22		
ΕΤΑΙΡΙΚΗ ΚΟΙΝΩΝΙΚΗ ΕΥΘΥΝΗ (Ε.Κ.Ε.)	76.886,25		
ΕΞΟΔΑ ΠΡΟΒΟΛΗΣ		359.071,46	
Ι.Ο.Β.Ε. (ΣΥΜΒΑΣΗ)	68.880,00		
ΔΙΑΦΟΡΑ ΕΞΟΔΑ Ι.Ο.Β.Ε.	0,00		
ΔΙΑΦ. ΕΞΟΔΑ ΤΕΚΜΗΡ/ΣΗΣ	53.905,09		
ΕΞΟΔΑ ΕΠΙΤΡΟΠΗΣ ΑΝΑΠΤΥΞΗΣ	39.254,72		
ΕΞΟΔΑ ΕΠΙΤΡ. ΕΠΙΣΤ. & ΡΥΘΜ. ΘΕΜΑΤΩΝ	19.587,02		
ΠΑΛΑΙΕΣ ΠΡΟΣΦΥΓΕΣ	710,94		
ΝΕΕΣ ΠΡΟΣΦΥΓΕΣ & ΕΙΔΙΚΕΣ ΑΝΑΘΕΣΕΙΣ	40.779,47		
ΕΞΟΔΑ ΕΠΙΤΡ. ΛΙΣΤΑΣ - ΕΟΠΥΥ	18.450,00		
ΕΞΟΔΑ ΕΠΙΤΡ. ΤΙΜΟΛΟΓΗΣΗΣ	6.150,00		
ΚΩΔΙΚΑΣ ΔΕΟΝΤΟΛΟΓΙΑΣ	28.566,75		
ΑΠΡΟΒΛΕΠΤΑ	1.016,08		
ΛΟΙΠΑ ΕΞΟΔΑ ΕΠΙΤΡΟΠΩΝ - Σ.Φ.Ε.Ε.		277.300,07	
ΑΠΟΖΗΜΙΩΣΗ ΑΠΟΛΥΣΗΣ ΜΑΓΓΑΛΟΥΣΗ	200.000,00		
		200.000,00	
ΣΥΝΟΛΟ ΕΞΟΔΩΝ			**2.025.402,22**
ΜΕΙΟΝ ΔΑΠΑΝΕΣ ΜΗ ΠΛΗΡΩΘΕΙΣΕΣ			-297.595,43
		ΣΥΝΟΛΟ (Β)	1.727.806,79
ΥΠΟΛΟΙΠΟ: ΣΥΝΟΛΟ (Α)-ΣΥΝΟΛΟ (Β)=			**1.527.600,36**
ΣΕ ΛΟΓ/ΜΟ ΟΨΕΩΣ	165.013,76		
ΣΕ ΤΑΜΕΙΟ	2.586,60		
ΣΕ ΠΡΟΘΕΣΜΙΑΚΕΣ ΚΑΤΑΘΕΣΕΙΣ	1.360.000,00		
		1.527.600,36	
ΑΝΑΛΥΣΗ ΔΑΠΑΝΕΣ ΜΗ ΠΛΗΡΩΘΕΙΣΕΣ			
ΥΠΟΧΡΕΩΣΕΙΣ ΣΕ ΠΡΟΜΗΘΕΥΤΕΣ	150.359,37		
ΥΠΟΧΡΕΩΣΕΙΣ ΣΕ ΠΙΣΤΩΤΕΣ	74.016,07		
ΥΠΟΧΡΕΩΣΕΙΣ ΣΕ ΧΡΕΩΣΤΕΣ	0,00		
ΥΠΟΧΡΕΩΣΕΙΣ ΣΕ ΛΟΓ.ΠΡΟΚΑΤ.& ΠΙΣΤΩΣΕΩΝ	36,78		
ΥΠΟΧΡΕΩΣΕΙΣ ΑΠΟ ΦΟΡΟΥΣ-ΤΕΛΗ	41.703,41		
ΥΠΟΧΡΕΩΣΕΙΣ ΣΕ ΑΣΦ. ΟΡΓΑΝΙΣΜΟΥΣ	31.479,80		
		297.595,43	

SFEE's legal actions

20/3/2015

Petitions for Cassation before the Council of State

MD	Issue
MD No ΓΠ/οικ 56432/ΦΕΚ/Β/1753/2014	Re the Coverage for uninsured citizens – No hearing date is yet scheduled
MD No 52768/ΦΕΚ/Β/1796/2014	Re the minimum percentile prescription limits for active substances to the extent it relates with the prescription targets of the physicians – No hearing date is yet scheduled
MD No ΓΠ/οικ 61771/ΦΕΚ/1907/Β/2014	Re the provision for the pricing of medicinal products. It does not permit increases of prices in case of re-pricing – No hearing date is yet scheduled
MD No ΔΥΓ 3/ΓΠ οικ 70519/ΦΕΚ 2243/Β/2014	Re the imposition on pharmaceutical companies in the form of a rebate, to pay the difference between the insurance price and the retail price of a medicinal product – No hearing date is yet scheduled
Prices Bulletin, August 12	Petition for the cassation of the Prices Bulletin dated August 12, 2014 – No hearing date is yet scheduled
MD ΔΥΓ 3Α/478/30-4-2013 Price Bulletin (with new generics and corrections)	Hearing Date: 29-9-2015
ΚΥΑ ΔΥΓ 3ατ /ΓΠοικ 59716 (ΦΕΚ871/Β/8.5.2009)	Re 3% rebate (art. 35 of the L. 3697/2008)- FIRST TIME IMPLEMENTED. Hearing Date: 9-6-2015.
MD ΔΥΓ3(α)οικ/19389 - Amendment of the MD ΔΥΓ3α/οικ104774/2012/ΦΕΚ3356/Β/17.12.2012	Re Positive List –Reference Prices Estimation- Hearing Date: 31-3-2015
MD ΔΥΓ3(α)οικ13833/ΦΕΚ235/Β/7.2.2013	Re Review of List of L. 3816/2010- Hearing Date: 21-4-2015

Notes