ΘΕΣΕΙΣ

Innovation and Value in Health & Pharmaceutical Care
Economist Conference

ΣfEE's round table on Pharmacovigilance

ΣfEE's Code of Practice Regarding Relationships of Pharmaceutical Companies with Patient Associations

ΣΥΝΔΕΣΜΟΣ ΦΑΡΜΑΚΕΥΤΙΚΩΝ ΕΠΙΧΕΙΡΗΣΕΩΝ ΕΛΛΑΔΟΣ

ΣfEE

HELLENIC ASSOCIATION OF PHARMACEUTICAL COMPANIES

#72

MARCH 2009

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Our Philosophy

Dionysios Filiotis
PRESIDENT OF ΣfEE
President & Managing Director of
PHARMASERVE LILLY S.A.C.I.

Trust is a commodity of the highest importance and value. As with all business functions and transactions, human relationships - public and private - must rest on solid ground upon which mutual trust is based. The continuous open and honest dialogue between all interested parties is the main condition that must be met in order for trust to be established. There is no doubt that dialogue and the establishment of a climate of trust between the State and pharmaceutical companies are necessary to protect and promote public health.

The future of public health is one of the most important issues that every modern state and society has to face. In our country, it is clear that significant progress has been made in this area, but it is also an indisputable fact that many mistakes have been made and in many cases the appropriate practices have not been applied. The road to a better future requires a bold break with the past. It behooves both the State and the pharmaceutical companies to adopt a new and radical understanding and attitude regarding communication which by Greek standards may be considered innovative but which is widely established in other developed countries. Our country will achieve real progress only if a tradition and culture of dialogue and continuous consultation among all key sectors of the economy can truly prevail.

Before passing legislation, the State must consult the institutional representatives of the various business sectors and create the conditions for reaching consensus. Thus public officials will acquire complete and well-rounded knowledge of all issues and will protect the State and its citizens from passing legislation and ministerial decrees, circulars and guidelines that create confusion, make citizens angry, provoke negative reactions, undermine development and lead the economy and the business sector into crisis. The establishment of consultation procedures with a view to reach the required consensus will not only ensure the implementation of all decisions made but will also guarantee a climate of transparency and mutual trust. Legislative provisions adopted behind the back of institutional representatives lead to decisions that cannot be implement-

"The establishment of consultation procedures with a view to reach the required consensus will not only ensure the implementation of all decisions made but will also guarantee a climate of transparency and mutual trust"

ed in practice, disorientate business from their original aim which is creativity, promotion of innovation and the attainment of the optimum level of effectiveness. Arbitrary legislative surprises must end for good since we cannot walk into the future using methods of the past.

The real issue Greece is facing in this new era is a new philosophy for taking action based on mutual trust and constructive collaboration between the State and all stakeholders without ulterior motives and arrogance, with no winners and losers. The Hellenic Association of Pharmaceutical Companies is systematically working towards and actively participating in the establishment of a continuous dialogue with the State on all issues regarding the pharmaceutical sector, always keeping in mind what is in the best interest of the citizens, the State and the sector in general. These efforts will continue with the objective of achieving substantial progress in all issues critical to the sector as well as ensuring high quality public health in our country.

Dionysios Filiotis
President of ΣfEE

Interview with Androulla Vassiliou

EU Commissioner for Health

The interview is based on the speech given by the Commissioner A. Vassiliou as keynote speaker at the Economist Conference

Androulla Vassiliou
COMMISSIONER DG HEALTH & CONSUMER PROTECTION

ΘΕΣΕΙΣ: **To what extent can the financial crisis we face have a negative impact on social Europe, on social security and specifically on the health system in Europe?**

Answer: You are referring to a subject of great concern for the College of Commissioners.
We are preparing specific proposals which will be submitted to the Council of Europe. We address a plea to the Council of Europe to pay specific attention on this sector, so that public health systems do not collapse because of the financial crisis.

ΘΕΣΕΙΣ: **Do you believe that the dialogue among the stakeholders of the sector at a European level is a necessary prerequisite for the optimum operation of the pharmaceutical market?**

Answer: It is important to have a unique pharmaceutical European market which will balance the need to ensure the competitiveness of the pharmaceutical industry with the need for access of European citizens to effective medicines.
The provision of healthcare of the highest possible level requires coordination and dialogue among the stakeholders of the sector.

ΘΕΣΕΙΣ: **What is the position of the EU concerning direct access of patients to medicines? Which are the achievements at EU level in research and innovation from the Public Health's side of view?**

Answer: As you know, we have to maintain a very delicate balance between providing high quality of public healthcare, ensuring at the same time industry competitiveness and the implementation of cost containment policies.
The EU supports some basic common values and principles for health care. Social protection should ensure that all citizens have access to high quality health care independent of their ability to pay.
Hence, solidarity and the fair allocation of resources are two key principles inherent to healthcare systems. Yet these principles do not always ensure access to health care. Significant unmet health care needsremain, not only within the EU, but even more dramatically, worldwide

ΘΕΣΕΙΣ: **To which extent does the EU support innovation and according to your opinion how important is the role of pharmaceutical companies in the fight to confront diseases and the promotion of Public Health?**

Answer: In 2004 WHO held a Conference regarding its report "Priority Medicines for Europe and the World", which was an initiative of the Dutch Presidency of the European Union, at that time. The WHO report identified a list of priority areas of public health for research and development in the field of pharmaceuticals, such as HIV/AIDS, pandemic influenza and antimicrobial resistance.

This report by WHO has influenced also the actions undertaken by the EU. One such example is the IMI initiative, namely the "Innovative Medicines Initiative" to boost the discovery and development of better medicines for patients, and to enhance Europe's competitiveness by ensuring that its biopharmaceutical sector remains a dynamic high-technology sector. The IMI is a unique partnership between the European Community, represented by the European Commission, and the European Federation of Pharmaceutical Industries and

Associations (EFPIA). This initiative has benefited from a tremendous financial input - the IMI initiative will manage 2 billion έ which comes from industry and the EU's 7th research framework programme.
Another area of priority for the EU is the possibility of a pandemic of influenza. The threat of an outbreak of pandemic influenza remains a very real concern. In light of the enormous scale and impact of such an event our responses and preparedness planning need to be comprehensive and involve all sectors concerned in a coordinated way. This is not an easy task. The European Commission has responded by playing an important role in helping Member States to improve EU wide coordination of prevention and implementation of control measures for certain communicable diseases. We are also working closely with the WHO, to help Member States prepare for an eventual influenza pandemic.
Medical interventions will be the key pillar of defense. For the development of new interventions I call on the industry to be more active and proactive. The European Commission is also vigorously supporting research and action in the area of pandemic influenza, both via the EU Framework Programme and the Health Programme.The Framework Programme is the most significant EU programme. The current Programme runs from 2007 to 2013 and over that period over έ50 billion euros will be available. In line with the priorities of the WHO report, the European Union is also aiming to implement specific strategies to contain antimicrobial resistance. Through the EU Public Health Programme we have funded projects:

- to increase and enlarge the quality of surveillance
- to develop tests for assessing the microbial resistance
- to follow up the use of antibiotics among the EU population in each Member state.

One of the most recent projects being developed is addressing the economic burden of human diseases related to antibiotic resistant strains of bacteria.
Our services are also supporting cooperation between the competent agencies of the European Center for Disease Prevention and Control (ECDC), European Medicines Agency (EMEA) and European Food Safety Authority (EFSA). A joint ECDC-EMEA working group has been set up to study the extent of antimicrobial resistance and the availability of effective therapeutic agents in the forthcoming years.
On a global level the EU has significantly increased its funding in the fight against HIV/AIDS, TB and Malaria.
One of the main initiatives of the EU is the established partnership with developing countries for the conduct of clinical trials. The purpose of this initiative is to accelerate the development of new vaccines and medicines for HIV/AIDS, malaria and tuberculosis by supporting clinical trials in Africa in partnership with developing countries. Besides that in Africa is being developed one of the largest programmes on clinical trials. An unprecedented and genuine North/South partnership is created, focused on the real needs of developing countries. The European Commission has so far contributed around 200 million έ to this project, and the participating Member States have contributed the same amount in the form of co-funding. Since 2003, the EDCTP has committed funding to 74 projects that include clinical trials, and support of research networks. In the area of other infectious diseases, the 7th Framework Programme will build on the significant progress accomplished so far. Since 1997 **j** 70 million have already been offered to fund 55 research projects. Such projects so far have covered a range of relatively little-known diseases.
Another vital aspect is the focus and efforts in relation to health systems research. The EU also funds global initiatives and international partnerships such as:

- the Global Fund to Fight Aids, Tuberculosis and Malaria;
- the Global Alliance for Vaccine Initiative;
- the International AIDS Vaccine Initiative; and
- the International Partnership for Microbiocides.

ΘΕΣΕΙΣ: **The pharmaceutical industry, which contributes decisively in the development of new medicines, must make a return on investment in order to continue its innovative course against the fight of diseases. Do you agree with this?**

Answer: The pharmaceutical industry clearly needs to make a return on investment, not least to finance and secure its long term work in innovation.

On the other hand, it is important that public investment leads to clear benefits in decreasing health care costs and lost working days. To address these challenges, health care officials have the responsibility not only to encourage research and innovation, but also to issue guidelines to help make the best decisions on where to allocate public funds. They must also of course ensure that the new innovating pharmaceuticals and other technologies are integrated effectively into efficient and high quality health systems.

Significant progress in the regulatory framework has been made to facilitate research and innovation and to address the objectives of the enhancement of public health, reward for innovation and cost containment. One such example is the regulatory framework on orphan drugs. The European Union's current regulation on orphan drugs has provided solid incentives for the research, development and marketing of medicines for rare diseases. The Commission is working on an initiative on rare diseases which aims to improve the availability of information about them and to pull together expertise across the European Union so that all patients can have access to it.

Another example is our recent regulation on paediatric medicines which covers the development and authorisation of medicines for paediatric use. Studies show that over 50% of children's medicines may not have been tested specifically for children. Therefore, it is important to ensure the highest quality research so that medicines used for children are specifically authorised for such use, and to ensure availability of high quality information about these medicines.

ΘΕΣΕΙΣ: **Has the EU undertaken other initiatives to this end?**

Answer: A third regulatory initiative relates to patent provisions. The European Commission has been an active member of the WHO Inter- Governmental Working Group which produced a draft Global Strategy and Plan of Action on public health, innovation and intellectual property. The Global Strategy was adopted by the World Health Assembly in May 2008. It aims to give incentives to innovation and access to medicines, as well as to focus on more needs-driven research and development. By working together with stakeholders, such as representatives of industry and civil society, to implement this Global Strategy, we should help deliver tangible improvements on availability, affordability and access to medicines worldwide. At the same time we can encourage an optimal environment for pharmaceutical innovation.

Measures have also been taken to help health care officials in their dual objective of providing better access to health care while at the same time trying to contain public expenditure. Health care officials and policy makers need to shape new approaches to make the best use of the public funds available.

Existing products and new technologies should be subject to health technology assessment to make sure that interventions which bring real therapeutic added value for patients are made available.

The EU has undertaken two initiatives to promote the development of health technology assessment. First - the European network on Health Technology Assessment (EUnet HTA), which has developed generic tools for adapting health technology assessments made by one country to be used in other countries.

Second - the Pharmaceutical Forum, which was set up in 2005 as a three year process to find solutions to public health issues regarding pharmaceuticals, while ensuring industry competitiveness and the sustainability of national health-care systems. The Pharmaceutical Forum has come up with a series of recommendations on delivering fair pricing and reimbursement decisions on pharmaceutical products by Member States.

ΘΕΣΕΙΣ: **What kind of initiatives will the EU undertake regarding counterfeit medicines?**

Answer: Mr. Filiotis during his speech has asked the EU to take measures for the fight against counterfeit medicines and it is a great pleasure for me to inform him that the European Union is working on a pharmaceutical package on medicines, including the issue of counterfeit medicines. Concluding I would like to underline the fact that our wish is to jointly achieve together with all the stakeholders even greater progress in covering the healthcare needs, so as to provide the highest quality of healthcare for citizens.

Dionysios Filiotis
PRESIDENT OF ΣfEE
President & Managing Director of
PHARMASERVE LILLY S.A.C.I.

Mr. D. Filiotis letter to Professor G. Papastamkos,

MEP, New Democracy Party

To
Professor George Papastamkos
Member of the European Parliament

Halandri, 22 December 2008

Dear Mr. Papastamkos,

Please accept my congratulations on your speech before the European Parliament in which you made a thorough presentation of the consequences of counterfeiting and tampering and shed light on the legal, financial and of course ethical aspects of this problem.

The extent of the problem is made evident by the fact, mentioned also in your speech, that in the pharmaceutical sector in particular, the confiscation of counterfeit medicines in 2007 increased by 51%, compared with 2006. The recent announcement of the confiscation of 34 million medicinal products at the external borders of the EU, within two months (mid-October to mid-November), highlights your point. Furthermore, according to the WHO announcement, 10% of the medicinal products marketed worldwide are counterfeit.

Nevertheless, we should stress the fact that Greece is at the forefront of medicine safety and authenticity issues and is fully protected against counterfeit medicines, due to a number of decisions and initiatives undertaken by the State in cooperation with the pharmaceutical sector.. The implementation of the authenticity tag, the double barcode and the unique serial number guarantee, the authenticity and quality of medicines.

In an era of counterfeiting, questionable therapeutic value and safety, it is a well-established fact that only branded medicines can guarantee quality, safety and therapeutic

effectiveness. This is the reason why in Greece we only allow the marketing and prescription of branded medicines, original or essentially similar.

The Prescribing of medicines remains the sole responsibility of the treating physician and is a second powerful "branding", a second guarantee for the quality of the prescribed medicine. We have thus established a "double branding" and "double responsibility" system, ensuring that counterfeit products will never reach patients.

We should therefore be proud of this system, not forgetting that it is our duty to maintain, protect and reinforce it. In view of this effort to reinforce the system, we obviously support the ban of the repackaging of medicines, since this further protects the marketing of authentic medicines in Europe.

I would also like to add that we - physicians and pharmaceutical companies - all have a great responsibility toward human life. Observing this responsibility is always our main concern, as made evident by the effective use of medicines and the high level of public health in our country.

Again, please accept my congratulations for your substantial and apt speech at the European Parliament Plenary.

Sincerely yours,

Dionisios Filiotis
President of the Hellenic Association of
Pharmaceutical Companies

ΣfEE ΘΕΣΕΙΣ #72 MARCH 2009

The new Board of Directors at EOF

The newly appointed EOF's Board of Directors comprises five members:

President

V. Kontozamanis

Vice President A'

D. Patargia-Angelou

Vice President B'

Professor H. Giamarelou

Members

Professor D. Raptopoulos

Professor N. Zakopoulos

The Hellenic Association of Pharmaceutical Companies wishes the new Board a successful term of office.

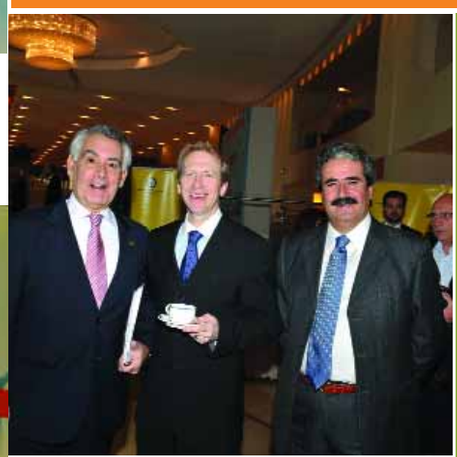
From left to right: Mr. T. Zervakakis, Mr. D. Speckhard, Ms. Amdroulla Vassiliou, EU Commissioner for Health, Mr. D. Filiotis and Ms. Margaret Doyle, Conference Chair, Economist Conferences

From left to right: Ms. M. Doyle, Mr. T. Zervakakis, Mr. D. Avramopoulos - Minister of Health, Mr. D. Filiotis, Ms. K. Karella - General Manager Pfizer Hellas, Mr. P. Apostolides - General Manager Abbott Laboratories Hellas, Mr. V. Kontozamanis - President of EOF, Mr. A. Kypraios - General Manager Genzyme Hellas.

The Economist Conference on «Innovation & Value in Health & Pharmaceutical Care» was held with great success. Among the speakers were the most eminent personalities of the sector including the EU Commissioner for Health Mrs. Androula Vasiliou, the Minister of Health Mr. D. Avramopoulos and Mrs. Georgette Lalis Director Consumer Goods, DG Enterprise and Industry, European Commission.

6th Biennial Summit

INNOVATION & VALUE in HEALTH & PHARMACEUTICAL CARE

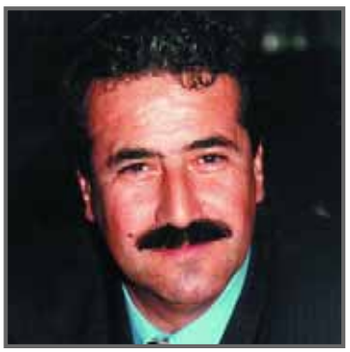


From left to right: The President of ΣfEE, Mr. D. Filiotis, the US Ambassador to Greece, Mr. D. Speckhard, the President of PhRMA L.A.W.G. Greece, Mr. T. Zervakakis, Vice-President of ΣfEE

Mr. D. Filiotis with Ms. Georgette Lalis, Director Consumer Goods, DG Enterprise and Industry, EU.

Economist Conference - The 6th Biennial Summit "Innovation and Value in Health & Pharmaceutical Care"

Speech by Mr. T. Zervakakis, President of PhRMA L.A.W.G. Greece, Vice President of ΣfEE



Takis Zervakakis
Vice President of ΣfEE
President of PhRMA L.A.W.G., Greece

6th Biennial Summit
INNOVATION & VALUE in HEALTH & PHARMACEUTICAL CARE

Ladies and gentlemen, Health Commissioner, Mrs. Vassiliou; Ambassador Speckhard, President of ΣfEE, Mr. Filiotis; Director General, Madamme Lalis, dear colleagues.

As you all know time flies. I remember we had started this interesting discussion, a few years ago, as part of the Economist Conference, with PhRMA. We have happily reached our sixth conference.

It would, therefore, be useful to think back and reflect on whether the issues we have discussed during these conferences have been progressed and to what extent. We should also reflect on whether we have succeeded in improving the provision of health care services, and, therefore, the health of the Greek citizens.

I would like, first, to briefly introduce PhRMA, by focusing especially to the topic of "Research and development of new medicines".

PhRMA represents American research and development pharmaceutical and biotechnology companies. There is an enormous amount of work conducted on research to develop new medicines, which aim to offer patients important treatment solutions for their needs and a better quality of life.

PhRMA's primary mission is the development of new medicines for patients who are in need of new therapy options. Today, PhRMA is celebrating 50 years since its foundation and aims to excel in the area of research and development of new medicines. There exist more than 500,000 employees and 80,000 researchers in the United States alone who have been carrying out research for many years.

What is the primary and most important element of this activity? I would like to stress that this effort is truly a costly one, both in financial resources and in time.

It is true, that pharmaceutical research is time-consuming and, although significant funds are also required, it is important to consider the associated risks, as well as the changes we have been witnessing in recent years, with regard to the ease by which medicines will eventually reach patients. Today, it takes approximately 10 to 15 years for a medicine to reach the market. (slide 1)

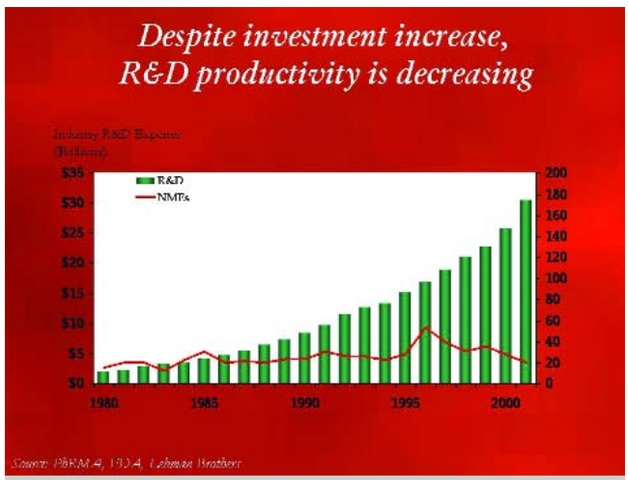
The research carried out is of great importance, with 80,000 researchers participating in the United States alone. This, however, must continue, by investing in the research and development of new medicines. The investment in research and development increased from 2 billion dollars in 1980, to 31 billion in 2002.

Investments have increased 15-fold within 20 years, but interestingly enough the amount of discovered medicines, as well as their development rate, appears not to have been proportionate to the amounts of dollars spent during this period. In 1980, 20 medicines were developed, a number which is equal to the number of medicines developed in 2002, despite the 15-fold increase in investment. This means that the development of new medicines is extremely difficult. (slide 2)

It is worth bearing in mind that in 2007 approximately 60 billion dollars were spent on research and development; 45 billion, or 75% of this investment, was spent by PhRMA and American companies. (slide 3)

Today, over 2,000 new medicines are under development. Only a few of these medicines will eventually be at the physician's and patient's disposal.

These 2,000 medicines are being tested in clinical trials and a considerable amount of effort and work is dedicated to their development. However, there is room for significant improvement, considering that today a human being dies from cancer every four seconds. This is the situation. Despite the excellent work carried out at the level



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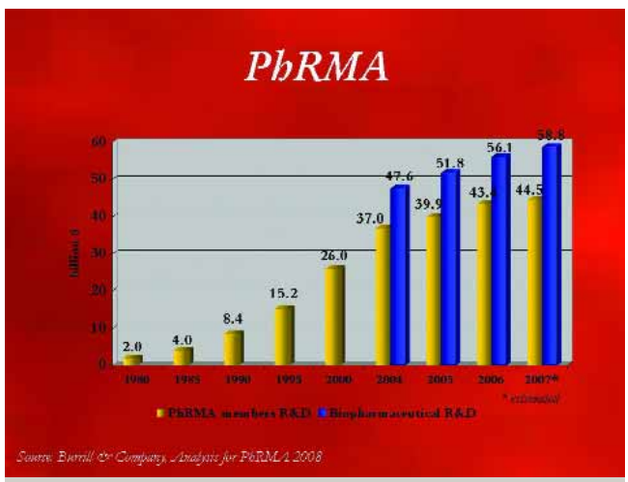


Slide 3

6th Biennial Summit
INNOVATION & VALUE in HEALTH & PHARMACEUTICAL CARE

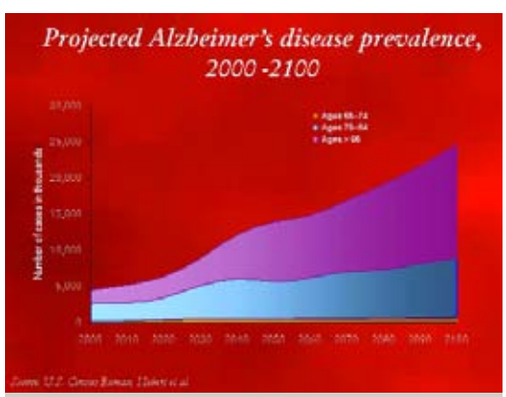
of research and development of new medicines, a human being dies from cancer every four seconds. A human being dies from stroke every six seconds, from AIDS every 11 seconds and from diabetes every 30 seconds. It is also worth mentioning that a human being dies from Alzheimer's disease every 90 seconds. (slide 4)

A lot of work is still needed; there is still room for improvement, to reach more acceptable levels of success. The frequency of Alzheimer's disease increases with age. Onset is less common in persons aged between 65 and 74. Onset frequency increases in persons aged from 75 to 84 years, while the greatest risk of developing Alzheimer's disease is larger for persons aged 85 years and more. This debilitating disease should concern us all, the pharmaceutical industry, the medical community, the State in finding ways to improving its management. (slide 5)

In the field of diabetes, marked improvement has been shown although its diagnostic prevalence is expected to double in the next twenty years. (slide 6)

I believe we can agree that a lot of work has been done, and allow me to be specific, by presenting the investment realized on behalf of PhRMA on the research and development of "orphan" drugs. (slide 7) The progress achieved in the field of AIDS is a good exam-

Slide 4



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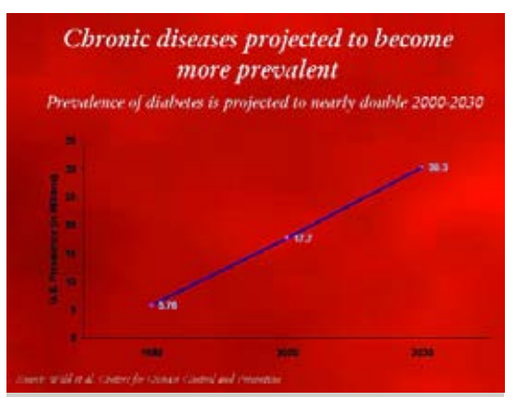


Slide 6

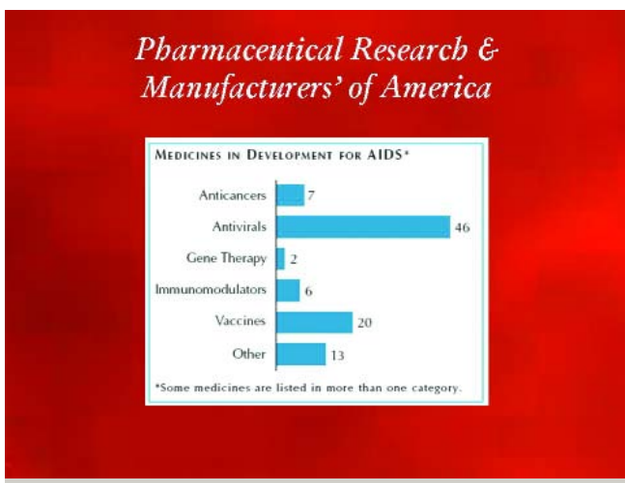
ple. We once regarded people infected with this disease a lost cause. This is no longer the case. The great therapeutic achievements realized to date allow patients living with AIDS to pursue a better quality of life. However, as one colleague of mine once said, the greatest room in this world is the room for improvement. (slide 8)

Today's meeting, ladies and gentlemen, is the sixth meeting at which we are taking part. We want to believe that we have engaged in a constructive dialogue so that the State responds to a greater extent to our needs.

It is also important to know that our Greece-based colleagues have equally contributed to the achievement of our goals and efforts, as PhRMA International is a giant, global Association.

I thank all my colleagues who work in these companies and who have willingly supported and continue to support this Conference. I also thank my colleagues from PhRMA's Subcommittee, who have organized this conference and have managed to attract and invite our esteemed and important speakers. (slide 9)

Thank you very much and I hope that today's discussion will be constructive.



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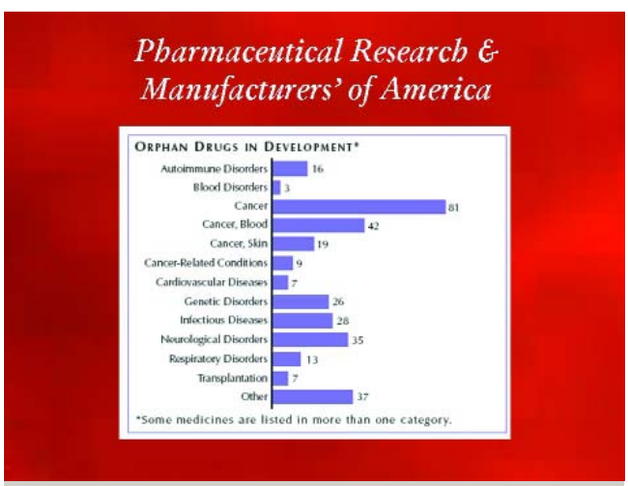

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Dionysios Filiotis
PRESIDENT OF ΣfEE
President & Managing Director of
PHARMASERVE LILLY S.A.C.I.

Economist Conference - The 6th Biennial Summit "Innovation and Value in Health & Pharmaceutical Care"

Speech by Dionysios Filiotis President of ΣfEE

Health Commissioner of the European Union, Mrs. Androulla Vassiliou; Madam Lalis, Director General of the European Union on Consumer Products; United States Ambassador Mr. Speckhard, Mr. President of PhRMA, Chairwoman Mrs. Margaret Doyle, Professor, dear colleagues, ladies and gentlemen.

Taking part in one of the most important conferences organized in our country is both an honor and an opportunity for the Hellenic Association of Pharmaceutical Companies to express its views and positions on issues of particular interest to us.

Dear friends, the global pharmaceutical industry has developed and offered to the world, most of the new, effective, revolutionary and innovative medicines. It constitutes a powerful pillar for the development of the global economy and the welfare of society. It must, therefore, be encouraged to carry on its work.

The progress realized in Greece during the last 30 years has been impressive. Today, the citizens of our country, even those residing in secluded villages, have direct access to all branded medicines-original or essentially similar-whose quality is assured through the authenticity tag, the double bar code, and the unique serial number.

In addition, all medicinal products marketed in Greece are among the least expensive in the 27 member States of the European Union.

At this point, I would like to stress that although we are not faced with the problem of counterfeit medicines in Greece, we place particular emphasis on the fight against them.

It is without a shadow of doubt that counterfeits are multiplying internationally and pose a threat to society. Therefore strict measures should be taken. In this context we urge the European Commission to present a legal proposal banning the repackaging and relabeling of medicinal products.

The repackaging of medicines is the gate through which counterfeits enter the legal European Union supply chain. This practice must come to an end. Pharmaceutical companies in Greece work systematically for the achievement of these goals.

At this point, dear friends, it is necessary to highlight that direct access to all medicines, especially those that are new, requires provision of credible information; pharmaceutical companies discover, develop, produce and distribute new medicines but also contribute significantly in training health professionals on these new products.

We perform a particularly significant social task which renders us in a position to acknowledge that in the sensitive area of medicines, ethics constitutes the cornerstone upon which rests every business development effort.

Having established and implemented the Code of Ethics in our country, we have followed the example of the most developed European countries. We are aware that one of the most crucial elements is the non-tangible component called trust, and we ensure that our relationship with health professionals, the State and society is always characterized by trust.

Certainly, ethics has two aspects. The second requires that the State takes ethically sound decisions on crucial problems that can be resolved. The State ought to be equally sensitive and take ethically sound choices on pharmaceutical market issues. In a range of issues, from hospital debts to pharmaceutical companies up to the lagging in the technological streamlining of the system's IT infrastructure, we have witnessed practices that endanger the viability of the system as well as citizens' direct access to medicines.

I believe that a new sense of elevated responsibility and a more responsible decision-making process must be fostered. An environment where dialogue and collaboration between the State and pharmaceutical companies will help overcome impediments and will lead to the progress required today. The new era in Greece dictates a new philosophy, the philosophy of "acting," which should be based on mutual trust and constructive cooperation.

Although many remain pessimistic, I am certain that we will achieve these goals, just as we have set many more milestones en route to the streamlining of the pharmaceutical industry. This is the route we must follow to face today's economic crisis. The ethical management, along with the incorporation of the technological streamlining and innovation within the healthcare system, constitutes a long term vision that will ensure that our country continues to offer its citizens long-term, direct access to all medicines and treatments.

Dear friends, time will not wait. This is the time to seize the opportunity and to proceed with those improvements that will empower Greece and render it a country to invest in innovation, technology and new knowledge. The Greek pharmaceutical market is mature and pharmaceutical companies are ready to utilize our era's opportunities.

We must work consistently and confidently to safeguard our achievements, upon which to build the future we deserve. Together with the State, citizens and scientists, the Greek business community can achieve miracles. It has been proven that pharmaceutical companies, one of the most dynamic sectors globally, can be at the forefront of a new effort for progress in healthcare as well as for the country's progress.

Mrs. President of the Conference, ladies and gentlemen, I wish you all the greatest success at this conference, which you have superbly organized, with foresight and intelligence. Thank you very much.

Georgette Lalis
Director ENTR/F
European Commission

Does Fostering Pharmaceutical Innovation and Competitiveness in the EU Benefit the European Patient?

Speech by Georgette Lalis, Director DG Enterprise and Industry, European Commission
Representative Parts of the speech

6th Biennial Summit
INNOVATION & VALUE in HEALTH & PHARMACEUTICAL CARE

Progress in life sciences and especially in biotechnology, has led to the development of new medicines and enabling tools for the diagnosis and treatment of diseases. Additionally, the completion of the human genome project has made it easier to associate specific genes (or gene combinations) to a disease, and thus to identify novel drug targets.

These developments pose at least 3 challenges on which I want to elaborate:

1. patient safety,
2. availability, access, and affordability of quality medicines, and
3. transparency/information

Recent events linked to adverse reactions and the upswing in detected counterfeit medicines demonstrate that the safety of medicines remains a major public health issue. There is an urgent need to address the potential dangers for public health brought about by the globalisation of the value chain. New markets (China, India, Brazil, Russia, Indonesia, Mexico and Turkey) have already become centres in producing Active Pharmaceutical Ingredients (APIs) and prime sources for European imports of those substances. **A growing number of medicines are now developed simultaneously in multi-centre studies in different continents. Ingredients and finished products are more and more sourced through international distribution channels.** This makes the task of authorities (evaluation of trials, inspection of sites) more difficult and resource-intensive.

The Commission "Report on Community Customs Activities on Counterfeit and Piracy" for 2007 revealed that medicines seized by customs authorities increased by 628% in just two years (2005-2007). Not only so-called 'lifestyle' products are affected, but also essential treatments against life-threatening diseases. **It is a vivid reminder that action against counterfeit is urgently needed.**

The Commission has prepared two legislative proposals within its Pharma Package in order to rationalise and strengthen the EU framework on safety monitoring (pharmacovigilance) and to address the topic of counterfeit drugs. Various measures are proposed, ranging from product-related measures, (such as obligatory safety features and traceability), to strengthened obligations and reporting mechanisms for the whole supply chain including API manufacturers and distributors.

But measures aimed only to the EU market are not enough anymore. Global industry requires global cooperation of regulators and global monitoring. As scarce resources have to be used efficiently, intensifying the **regulatory cooperation with the US, Japan and Canada** within ICH and existing confidentiality arrangements remains our priority. Our field of cooperation will extend to **mutually agreed mechanisms for joint inspections** in third countries.

At the same time, we are **intensifying biliateral cooperation** with targeted third countries that are important trade partners. New mechanisms of exchange of information on illegal distribution channels and counterfeiting as well as on clinical trials and the manufacturing of API's, are being established with **Russia, India and China.**

2. Availability, Access and Affordability

These 3 issues are of extreme importance if we want the innovative medicines that our societies need to be available and accessible to EU patients at an affordable price.

Let me start with the **supply of medicines.** There is an ongoing debate in the WHO and other international fora on what are the priority medicines for combating diseases in the world.

But this is only one part of the question. The other part is whether MS's public health budgets are capable of coping with such innovative drugs? The **sustainability** in financing of an ever more modern (and probably more costly) health care sector is a concern which requires our undivided attention.

To make future innovative drugs **accessible to the patients** of Europe, we need to ensure that:

1) Development and marketing costs must be brought down by industry

Attrition rates are too high. **Fewer substances overcome the costly and time-consuming pre-MA requirements.** We hear more and more about the benefits of personalised drugs and therapies. It is fair to say that such drugs will be extremely efficient thus saving lives of patients and money for the sickness funds. However with the existing development models and rate of attrition we also know that they will necessarily be more costly as fewer will have to bear the developments costs. At EU level, industry and the Commission have created a partnership, the Joint Initiative called IMI, in order to foster research in new pathways for the development of innovative drugs. We place our hopes in biomarkers to reduce costs and failure rate.

2) **Regulators, policy makers and payers have to review their pricing and reimbursement systems to reward innovation and promote the use of generics and OTC.** The EU has a single market - though not perfect - for market authorisation but a fragmented market as far as pricing and reimbursement is concerned. The combined effect of the different national systems with parallel trade is detrimental to industry and to patients as well. The global benefit a drug is creating should be taken into account for deciding its reimbursement and design of intelligent cost-containment measures is of paramount importance for the future.

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3) Finally, and I realise that this point is debatable, we **might have to engage in a societal debate on the notion of risk-benefit.** No medicine is safe and the samples we have from the phase 3 clinical trials are not enough to ensure the best possible risk-benefit assessment. At the same time, our society seems to become increasingly risk- averse when at the same time patients affected by a disease expect the drug as soon as possible on the market. It is clear that increasing safety via regulatory requirements increases costs. Should we make a wider use of risk management plans, phase 4 studies combined with a robust pharmacovigilance system? The debate is open.

There are however another **two** important aspects of the availability of innovative drugs.

The first is of particular relevance to our discussions today. It is the fact that some Member States that represent **small markets** experience shortages in drugs especially with products of low volume, low price and specialised products intended to treat severe and/or rare diseases."

We have started by trying to understand the reasons, and then develop solutions within the relevant network of the Heads of Medicines' Agencies, and finally within the Pharmaceutical forum.

A series of recommendations were formulated by simplifying the MRP to allow MS who wish to do so to rely completely on another Agency or by waiving the language barrier. Other solutions, notably those linked to the economic aspects of the supply of drugs in these MS have to be tackled by them. I refer here to the way the wholesaling of drugs is organised, the way public procurement is designed, finally the pricing and reimbursement regimes.

For issues related to pricing and reimbursement the Pharmaceutical Forum has proven an interesting experience. A common set of Guiding Principles has been adopted by that Forum to support future national pricing and reimbursement policies. The positive experience of information exchange and cooperation between Member States and with stakeholders should be strengthened at EU level. More efficient market mechanisms and, in particular, price competition for non-reimbursed medicines, would provide, in this sector, more patients choice at a more affordable cost. Recommendation 6 of the G10 group was again endorsed by the Forum that stipulates that Member States should, remove price controls on medicines that are neither purchased nor reimbursed by the State.

Further development of **health technology assessments** will also offer valuable support to national authorities to strike a balance between containing pharmaceutical expenditure and ensuring a fair reward for valuable innovation and access to the best available medicines. Cooperation among authorities and dialogue with stakeholders will be a prerequisite to achieve such a balance.

The results of the Pharmaceutical Forum show what can be achieved through dialogue and cooperation among stakeholders. We will be able to progress only through close co-operation, i.e. a genuine partnership between the Commission, the Member States, the industry and all players concerned.

3. Information and Transparency

As outlined in the Commission White paper on Health Strategy, patients are becoming more involved in the decision-making regarding their health. They have a right to more quality information on available medicines, the grounds on which they have been authorised and how they are monitored.

Public authorities and health care professionals have a crucial role in providing patients with relevant and impartial information. The Pharmaceutical Forum endorsed recommendations to enhance the generation, access and dissemination of good quality information on diseases and treatments. The use of quality principles and the increased cooperation among all partners for developing patient information should lead to tangible improvements for citizens.

On this basis, the Commission considers that the role of industry in this context should be clarified. As you know advertising is prohibited in Europe for prescription drugs. The provision of information by industry on prescription drugs is not harmonised at EU level and industry is therefore facing different legal systems in the 27 MS.

The Commission has presented a legislative proposal to rationalise the availability and improve the quality of information to patients within the EU on prescription-only medicines, while maintaining the prohibition of advertising.

I come now to the last issue that is dear to my heart and to patients and consumers equally. It is the question of transparency. For a long time this industry was perceived as being keen not to disclose information that might harm the commercial value of its drugs. I speak in the past because I think that a lot has happened these recent years. It is fair to say that if patients are to take risks on drugs they need to know these risks in order to make an informed decision. They need to be confident that full light has been made to the results during the premarket phase but also in the post market life of a drug. It is therefore of paramount importance that in parallel to what one or the other company may decide to do to improve the situation, we as Commission will place mandatory obligations on the national regulatory agencies, the sponsors and market authorisation holders. We started with the paediatrics regulation, we continue with pharmacovigilance (publication of the opinion of the pharmacovigilance committee, patient reporting and patient participation in hearings) and will go on in a couple of years with the revision of the clinical trials directive. When doing so, we feel we can only but help industry improving its image.

Ladies and gentlemen,

Policy makers and industry together, we have to make further progress towards a single and sustainable market in pharmaceuticals, we have to take on the opportunities and challenges of globalisation and we have to make science deliver the best for European patients. Finally we have to restore the EU's role as the natural home for pharmaceutical innovation.

Thank you for your attention.

Dimitris Avramopoulos
MINISTER OF HEALTH
& SOCIAL SOLIDARITY

Economist Conference - The 6th Biennial Summit "Innovation and Value in Health & Pharmaceutical Care"

Speech by Mr. Dimitris Avramopoulos Minister of Health & Social Solidarity

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Ladies and gentlemen,

The design and implementation of an integrated policy for medicines has been our top priority ever since we took office at the Ministry of Health and Social Solidarity.

This policy was and still remains the primary parameter determining our goal to improve public health economics and to safeguard transparency of their management. To this end we reduced the bureaucratic structures of the NHS (National Health System), thus rendering it more functional and efficient.

Moreover, we established for the first time a procurement system, exclusively for the health sector, which is gradually implemented. Starting January 1rst, 2009, the Health Procurement Committee (HPC), which is the central procurement authority, will conduct tenders for the procurement of public health units

Thus we will be able to save 500 million Euro annually. The benefits from the implementation of this system are, at this early stage, already tangible and amount to millions of Euro. This year during the period of its operation we saved 50 million Euro, and we have managed, to reach an agreement with orthopedics suppliers for the reduction of orthopedic product prices by 30% to 40%, in 2009 provided payments are settled in due time. This is ensured by the financing system foreseen by law for the HPC.

In parallel to our awareness campaign on prevention, and the fight against primary public health risk factors, we create the appropriate structure for the prevention of diseases, which otherwise would have been a great financial burden for social security funds.

In this regard, the draft law on antismoking policy, adopted by the Parliament is an illustrative example and consists an important contribution for the protection of public health, and the containment of expenditure for the treatment of smoking-related diseases.

We implement our plan for the creation of new, modern health units and the procurement of the relative equipment with transparency, taking under consideration the cost-benefit ratio.

We create the best possible employment conditions for hospital personnel and realize the most significant reform ever since the establishment of the NHS, signing the first collective employment agreement with hospital physicians.

Following the accomplishment of our reform activities which aim to constrain unreasonable expenditure with the view to reinvest the sums contained, in the health sector, we undertake initiatives for the containment at first of the pharmaceutical expenditure.

We refer to the expenditure which is unreasonably born by Social Insurance Funds and which all the stakeholders wish to eliminate.

To this end, we aim to establish therapeutic clusters, under the responsibility of the National Agency for Medicines (EOF), in which will be classified all original medicinal products and branded essentially similar products marketed in Greece.

This measure in combination with the establishment of diagnostic-therapeutic protocols by the Central Board of Health (KESY) will discourage the prescribing of medicines for out-of-label diseases and will help save approximately 100 million Euro annually.

Our legislative proposal also provides for a 3% rebate on the retail prices of prescribed medicines, which is to be reimbursed by the pharmaceutical industry to social security funds. Based on our estimates, this will lead to savings of approximately 100 million Euro annually, which will be used to implement our policies for the upgrade of the public health units in our country.

The publication of the joint ministerial decision indicating the high cost medicines for hospital use, and the provision for their administration through private hospital pharmacies, will lead to the containment of resources amounting to 70 million Euro annually The specific list comprises 90 medicinal products and will be updated on a regular basis.

With the establishment of a new type of safety tag (bar code), which is a pioneer initiative at EU level, we have drastically tackled the unacceptable trade of safety tags, which is linked with parallel exports.

This illegal practice is essentially an act of plundering of public money and an insult to the State, as well as a great concern for social security funds.

We are determined to confront and eliminate this phenomenon, as we believe that the loss incumbent to public funds amounts to hundreds of million Euro annually.

We modernize the management and operation model of EOF, by making it more flexible, and proceed with the streamlining of its IT infrastructure. We reinforce EOF Committees, since this is necessary for the optimization of the Agency's effective operation.

We place special importance on the conduct of clinical trials as a premium opportunity for taking benefit of our great scientific potential to foster research and development of innovative and effective therapies and reinforce the Greek pharmaceutical industry, upon which to base the development of our national economy.

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Apart from this legislative framework that streamlines and simplifies the conditions for the conduct of clinical trials, we reinforce the competent Committee, which monitors and approves clinical trials.

By undertaking the necessary initiatives at European and International level we encourage the collaboration of Greek pharmaceutical companies with their foreign pharmaceutical counterparts, and organizations, so as to ensure the required outward-looking nature of our economic and productive policy.

The sector of medicines is of crucial importance, for the implementation of health policy as well as for the reinforcement and enhancement of our economic policy, in a development perspective.

Sound choices, targeting, and planning ensure, on one hand, efficient, high quality financially beneficial solutions for the health of citizens savings of financial resources to be reinvested in the health sector and create employment positions and development prospects for our researchers and scientists.

The Ministry of Health and Social Solidarity and our government have an enduring and permanent interest in the implementation and achievement of these goals.

This is why we are engaged in an open, honest, and systematic dialogue with all the stakeholders of the pharmaceutical sector for the enhancement of public health and the protection of the interest of society

Dear friends,

The improvement of the quality of life has contributed to the prolongation of life expectancy and transformed social relationships globally.

The World Health Organization is bound by a new philosophy, which is based on social consent, social participation in the management and organization of health systems, and the creation of healthcare systems which will be financially and socially efficient and accessible to all citizens, of all classes.

In Greece, rising social needs combined with demographic changes, rapid developments in technology, the rise in the need and demand for health services, disease prevalence, are calling for new health policies that will emphasize:

- prevention
- provision of better information to citizens
- improved access to health services
- greater responsiveness to patient needs
- improved efficiency of the system,
- optimum administrative practices and clinical excellence

The demographic changes we are witnessing are due to the increase in life expectancy which leads to an increase in healthcare needs.

Greece ranks third among the OECD member-States in the percentage of persons aged 65 and over.

The National Health System is faced with three important challenges; the aging of country's population; the increasing efficiency of healthcare which is more costly and patients demand for high quality healthcare services..

To face these challenges we have set three long-term goals:

- equal access to healthcare for all citizens
- high quality standard of supplied healthcare
- viability of the health system

Greece faces these challenges and strategies, through structural reforms, whose goal is the maintenance and enhancement of citizen's health.

The Country places particular emphasis on the medicines policy, within a framework of an integrated policy on disease management, by setting strategic goals in the area of technology evaluation, monitoring it's effect at the level of provided healthcare services, strategic planning and investment and, finally, monitoring the cost-effectiveness of the supplied services.

Our planning, decisions, and actions take into account the total cost and benefit to society, the health system and the pharmaceutical industry.

The value inherent in research, development and use of an innovative medicine is undisputable.

We should at all times estimate citizens' healthcare needs and promote innovation, as long as it delivers on its promises and meets the safety, quality, and efficacy criteria.

Health has never represented expenditure to us, but we consider it a productive investment for society, in the sense that the individual, the healthy individual, who trusts the State, is more useful and productive.

Today, it is a fact that the state financial resources allocated on health, and medicines in particular, are not a few.

The government is reforming the system of pharmaceutical healthcare, to enhance public health, to ensure equal patient access to safe, effective and cost-efficient medicines, to improve the quality of life of patients, to establish financial stability, resource efficiency and the economic sustainability of the social insurance system.

In recent years, we have demonstrated at the Ministry of Health that we take an integral approach at the healthcare system, by considering the total cost for society, for the health system and for social insurance, so as to ensure that citizens have access to every available treatment at the lowest possible cost.

Our social sensitivity is further associated with the obligation to protect public funding and to negotiate the resources invested in pharmaceutical care.

Vasilis Kontozamanis
President of National Drug Organization (EOF)

Economist Conference - The 6th Biennial Summit "Innovation and Value in Health & Pharmaceutical Care"

Speech by Mr. V. Kontozamanis President of the National Organization for Medicines (EOF)

We often hear that health expenditure is an investment. This has been demonstrated beyond any doubt by the previous speakers.

This round table is asked to answer the question whether we can support this investment.

It is certain that a return on every investment is expected.

The pharmaceutical industry invests on a new therapy and anticipates a return its investment while, for the State an investment is measured from whether it ensures equal access of patients to new medicines, at the lowest possible cost, leading to the containment of total expenditure.

That is, a return on innovation requires the strike of a suitable balance between the need for return on investment and access to a truly innovative social commodity.

The pharmaceutical market is global, which means that the cost for research and development may be allocated accordingly at an international level. The cost is born by the producer, from the moment production initiates, and of cource the price of the product cannot be based on the marginal production cost.

On the other hand, society needs the development of new medicines, since it leads to the improvement of health outflows. The State must in this instance promote and reward innovation. The issue of innovation in pharmaceutical care is a never ending discussion for the parties involved.

The term "innovation" is commonly applied upon entry into the market of a new pharmaceutical product. This entry, however, is not in itself sufficient to determine the extent of innovation. I believe we all agree on this. We must, therefore, render a stricter definition of innovation, always bearing in mind that innovation ought to correspond to patient needs.

The technological developments in the health sector have undoubtedly transformed the healthcare environment. The provision of healthcare services is of a much higher level and the quality of life of patients has been ameliorated. New medicinal products are vital for the contemporary medicine, they save lives, and cure diseases. But not all medicines are innovative.

To measure the extent of innovation of a medicinal product we must take into consideration the availability of a preexisting treatment and , the size of the therapeutic and economic effect of the new medicine.

Reward of innovation is related to the existence of pricing and reimbursement systems, which balance a) the timely market entry of innovative products b) the containment of expenditure and finally c) the creation of a dynamic and competitive market that promotes research and development.

Ladies and gentlemen, Health is priceless, but costly. The associated cost must result from the minimization of financial inflows and the maximization of health outflows, since the financial resources available are not abundant.

The benefit associated with the use of a new medicine ought therefore, to be substantial. It is necessary that the extra money spent should produce further treatment benefit.

It is hence commonly accepted that there is difference between a «commodity» and the «value» of this commodity. It is commonly accepted that a health service should be provided depending on the incurred benefit and not on how much it costs. The provided benefit is focused on three issues: Clinical efficacy, better quality of life for the patient and whether the provided service reduces the consumption of health resources.

In Greece we fortunately have access to all available pharmaceutical treatments. We know that direct access to pharmaceutical care leads to an increase of expenditure, but unfortunately we are not aware of the benefits derived in health and financial terms.

We must take advantage of the fact that Greek citizens probably enjoy best access to pharmaceutical care.

We ought to maintain and improve the health of citizens and not merely manage disease and sickness.

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We have, unfortunately up to this day, been trying to answer the question of whether pharmaceutical expenditure is high or low, while we also persist in «demonizing» overconsumption. This distracts us from the essence of the problem, which concerns the increase of expenditure in relation to the consumption of daily doses of medicines.

We find it easier to discuss about the cost and not about the cost-benefit relationship. Social insurance funds ought to evaluate the increase of expenditure in relation to the system's economic efficiency and clinical efficacy, and the equal access of patients in high quality health services.

We should estimate the real needs of patients in healthcare.

I have repeatedly mentioned, and will do so again, that in this country we are ignorant of the potential existence of under consumption, in a therapeutic category because using exaggerations is to the benefit of political conflict.

We should focus on completing the streamlining of the system's IT infrastructure, not in order to facilitate the quicker settlement of prescriptions, but to finally obtain the necessary data that will allow us to make decisions on health policy issues and to assess their results. We must put an end to the waste of resources

Finally, we must engage in the continuous evaluation of innovation.

This is a continuous process. At this point I must stress the importance of the Competent Authorities on every issue regarding medicine.

The approval of a medicine is based on the evaluation of the risk-benefit ratio, where the proven benefits are greater than the known risks, and the ratio is favorable, leading to the granting of a marketing authorisation.

Despite the comprehensive understanding of a medicine at the time of approval, after its approval there may occur unforeseen or undetected adverse events.

Hence the aim of the competent Authorities is not merely the improvement of bureaucratic mechanisms, associated with the evaluation of medicines, pricing, and reimbursement by the social insurance system. Our work is not concluded with the approval of a product. Our aim is to protect the health of citizens by ensuring high quality standards and safe use of medicines. To this end, at the National Organization for Medicines we have proceeded with the change of our organizational structure, by emphasizing pharmacovigilance and market surveillance.

Speaking of innovation, we must not forget innovators. I am referring in particular to the Greek pharmaceutical industry, which demonstrates an outward looking nature; it is competitive and produces innovative products. We should support people who innovate in this country and have a vision. The country needs it.

Dear friends, the future is here. It is our duty to proceed at a faster pace and keep apace with European developments, to the benefit of public health, economy and society.

Thank you very much.

Prof. Fotis Pavlatos

Professor F. Pavlatos:

When the practice of medicine meets poetry

When a young doctor, Fotis Pavlatos, crossed over to the opposite shore of the Atlantic in 1962 and went even further, to the Pacific shore to attend the University of San Francisco, he could not dream of how his career would evolve.

In a very short time, together with his professor, John H. Karam, he became one of the most esteemed members of the international scientific community. The discerning researcher from Cephalonia effectively contributed to the perfection of the «overnight dexamethasone test» method, which would become known internationally as the “Pavlatos examination”.

A brilliant career had already begun and continued in Greece where he returned in 1965 to accept a lecturer position at the Athens General Hospital’s First University Clinic.

It was here that he began his work in endocrinology and diabetology where he would treat many patients and would earn their gratitude.

Later he became a university professor and trained thousands of medical students and doctors employed by his and other hospitals until 1992, at the twilight of his brilliant university career.

When Professor Pavlatos enters an auditorium, a revered silence settles over the audience because everyone knows that he is going to present a High Level lecture; one that combines scientific precision with the highest level of speech and expression.

But mainly everyone will feel the dedication for the patient that distinguishes him. Indeed for professor Pavlatos the respect for his patient has always been his highest priority.

His patients and his homeland have always been a top priority. This is his personal poetic touch in all things and that is how this sensitive endocrinologist expresses himself.

His life is characterized by the highest sense of ethics, profound knowledge and sound judgment. He is the quintessential medical and teaching role model.

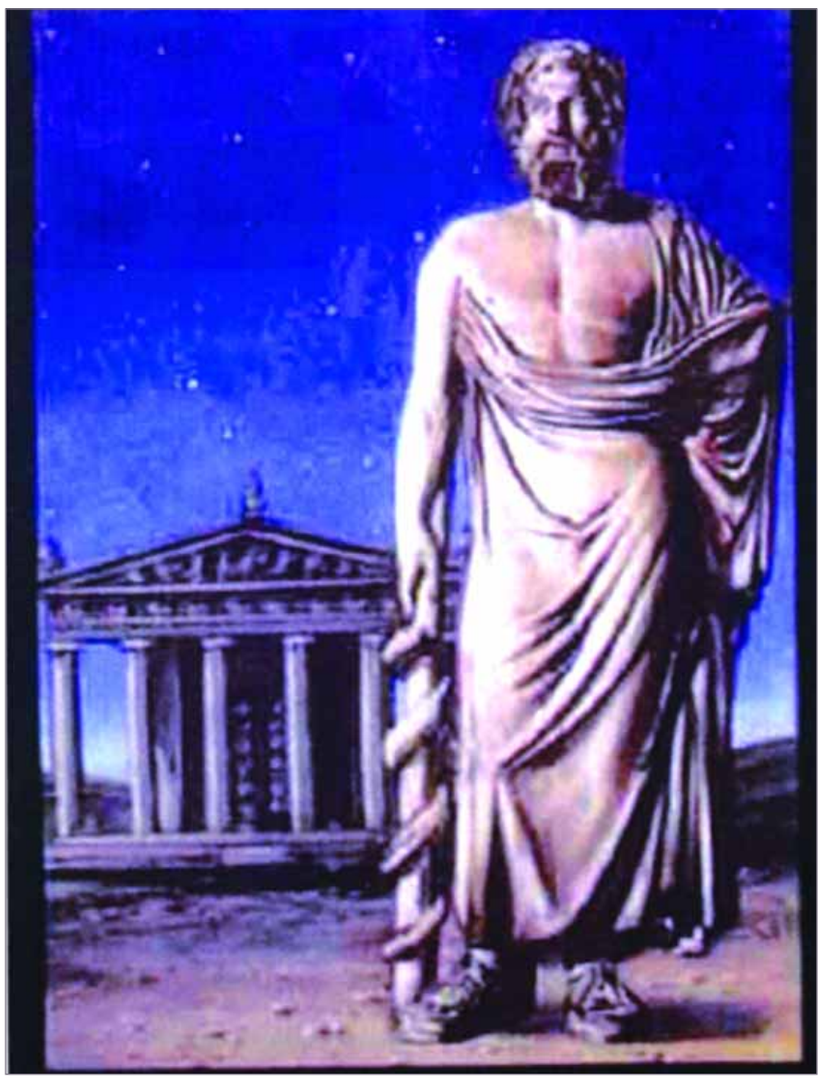
With a life full of “hardships”, this great Greek Nobleman never refuses to offer his advice and help with a smile and gentleness to whoever asks for it.

Professor, it is an honor and a privilege for us to hear you address us as your friends.

Greece owes you a great deal and we all share the greatest respect for you

Dionysios Filiotis

ASCLEPIOS



To
The President of the Hellenic Association of Pharmaceutical Companies
Mr. Dionisios Sp. Filiotis
15th Km, National Athens-Lamia Road
145 64 Kifissia

Maroussi, 5 December 2008

Dear Mr. Filiotis,

First, I would like to thank you for your letter on the recent Congress in Crete and assure you that my focus - as I believe is the case for all of us - always encompasses that sensitive health sector, aside from my other important duties as a mayor. In any case, this is a public sector that we have served for many years, and sometimes on different sides, but we always shared a sense of cooperation and development.

It was in this framework that as early as 2005, we established the **Local Administration Authorities' Intermunicipal Health and Social Solidarity Network, aiming at Prevention and the Promotion of health. We have so far offered our services to 130 Municipalities, members of the Network, from all over the country.** These services pertain both to the timely and scientific education of our citizens on issues related to their health, as well as to the development of prevention programs, in cooperation with other institutions.

It was very recently, during the Convention of the Central Committee of Greek Municipalities and Communities, held in the Interbalkan Health Centre in Thessaloniki, that we had the opportunity to brief 150 Mayors, mainly from Northern Greece, on the Intermunicipal Network, in the presence of the Minister of Health and Social Solidarity, Mr. Dimitrios Avramopoulos.

The Hellenic Association of Pharmaceutical Companies and its members have offered their unwavering support, assisting our efforts both to scientifically educate our citizens and in our National Congresses. This is why we believe that now is an appropriate moment to present our progress and the results of our activities to your members, so that they may all be informed of our work and, above all, our cooperation prospects.

Therefore, if you agree to it, we can organize a presentation to all the members of your association interested in the Local Administration Authorities' Intermunicipal Health and Social Solidarity Network, in the Town Hall or in any other venue of your preference.

Sincerely yours,
The Chairman of the Board of the Intermunicipal Health and solidarity Network
George Patoulis
Maroussi Mayor

ΣΦΕΕ ΘΕΣΕΙΣ #72 MARCH 2009

The Intermunicipal Health and Solidarity Network

Responding to the very important initiative of the President of the Intermunicipal Health and Solidarity Network Mr. G. Patoulis SFEE decided to co-organize with the IHSN on March 19 a Conference entitled:

"Corporate Social Responsibility and prevention programs"

The Conference aims to promote the development of prevention programs.

During the Conference will be presented examples of collaboration between pharmaceutical companies - members of SFEE and the Intermunicipal Health and Solidarity Network.

Hellenic Association of Pharmaceutical Companies:

A Report On Hospital Debts Towards ΣfEE's Member-Companies

Pending Payments on 31.12.2008
Athens, January 2009

The Hellenic Association of Pharmaceutical Companies (ΣfEE) collected and analysed all the available data relating to pharmaceutical debts of public and private hospitals to its member-companies. The analysis resulted in the overall amount due per hospital, as well as the average length of payment delay. The main points resulting from the analysis of the tables are the following:

- On 31.12.08, the **total amount of hospital debt** towards ΣfEE's pharmaceutical companies was **j 2.68 billion.** This figure shows a remarkable increase (39.3%) compared to the respective figure on 31.12.2007 (**j** 1.92 billion) (Diagram 1). If the rate of increase remains unchanged, it is anticipated that by the end of the first semester of 2009 hospital debts will exceed **j** 3 billion.

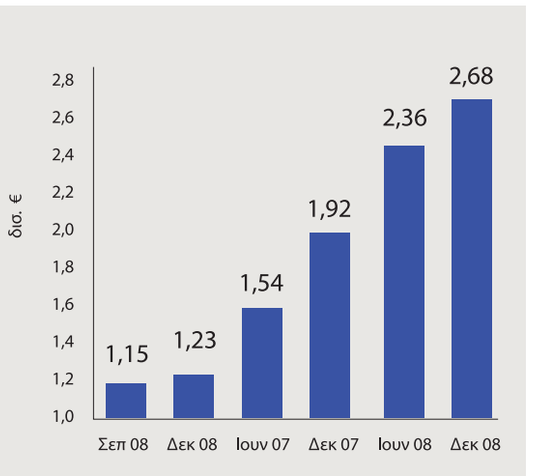


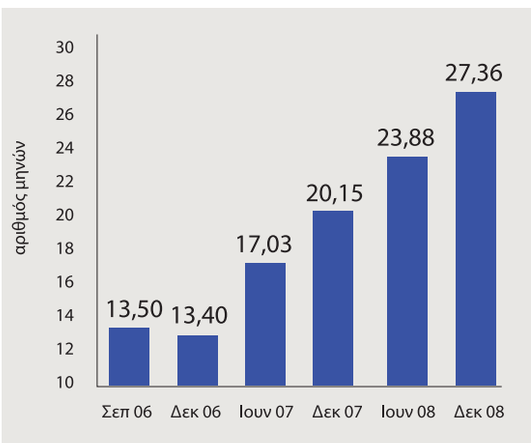
Diagram 1

Evolution of Hospital Debt for Pharmaceutical Products

- The **average length of payment delay was 27.36 months** (820.89 days), i.e. hospital debts are - on average- pending since October 2006. The average length of payment delay also presents significant increase compared to the respective delay on 31.12.07 (20.15 months) (Diagram 2).

Diagram 2

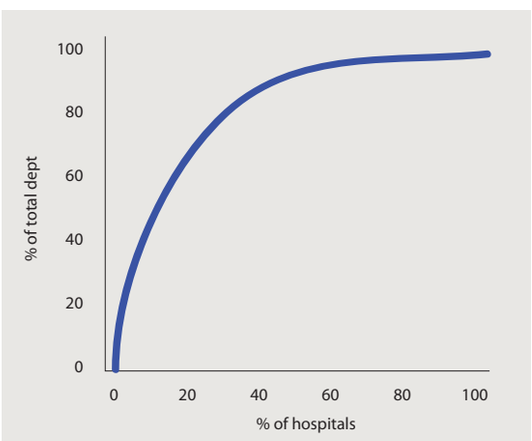
Average Length of Payment Delay of Hospital Debts to Pharmaceutical Companies



- Finally, there is a **high degree of concentration** of debts to a small number of hospitals. The **top ten** hospitals with the highest levels of debt (jointly **j** 882.6 million) account for 32.9% of total debt. As presented in Diagram 3, 20% of hospitals are responsible for 67.1% of total debts.

Diagram 3

Inequality Distribution Diagram of Hospital Debts



** The overall payment delay is a weighted average of the respective delays. Companies which were not included in the Ministry's Settlement are excluded from the estimation.*

"Pharmacovigilance and Public Health: The Stakeholders and their contribution to the safe use of medicines"

PRESS RELEASE

Based on the definition given by World Health Organization, Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse events caused by medicines. The main principle is derived by the Hippocratic dictum "ωφελείν ή μη βλάπτειν" (English translation "to benefit or to not harm") and its main goal is to ensure and promote public health through the continuous monitoring of the safety data of all medicines that are marketed or under clinical investigation, ensuring the patient's right for safe, qualitative and effective medicines.

Health Professionals have the obligation to report to National Organization for Medicines (EOF) all adverse drug reactions that are becoming aware of, by completing the "yellow card".

In practice, information on the occurrence of adverse drug reactions originates either from Health Professionals (physicians, dentists, pharmacists, nurses) or from patients themselves and is reported to National Organization for Medicines (EOF) and/or to those Pharmaceutical Companies which are Marketing Authorization Holders of the concerned medicines.

The reporting of adverse drug reactions contributes to the enrichment of our knowledge towards medicines so that we can take appropriate measures for a more accurate and safe use. By continuous surveillance of the medicines benefit / risk ratio, the benefit of the patients is ensured.

On the occasion of the 4th Annual Congress for the Management of Economics and Health Policy, the Hellenic Association of Pharmaceutical Companies (ΣfEE), is organizing a round table with subject «Pharmacovigilance and Public Health: the stakeholders and their contribution to the safe use of medicines", where the following topics will be presented:

- The regulatory framework and EOF's role
- Clinical Practice and experience
- Prescription practice and adverse drug reactions reporting
- Awareness and continuous update of Health Professional regarding Pharmacovigilance activities by ΣfEE.

With the undivided support of Academicians, the contribution of eminent delegates from Regulatory Authorities and Hospital's area, we aim at the collaboration and co-responsibility of all relevant Parties (Regulatory Authorities, Health Professionals, patients and all pharmaceutical companies-members of ΣfEE).

Having a global and shared responsibility attitude towards Pharmacovigilance, our goal is to highlight the importance the Safety of the medicinal products should hold, for ensuring the highest quality Health services for the Greek citizen.

On the occasion of the round table's organization, ΣfEE published the Pharmacovigilance Manual which will be distributed to Health Professionals and uploaded to ΣfEE website. This manual outlines ΣfEE's position that Drug Safety is a responsibility of all stakeholders.

Dr Barbara Baroutsou

Round Table ΣfEE

"Pharmacovigilance and Public Health: The Stakeholders and their Contribution to the Safe Use of Medicines"

On December 3, 2008 in the context of the 4th Panhellenic Congress on Health Management, Economics and Policies, the Hellenic Association of Pharmaceutical Companies (ΣfEE) held a round table discussion on "Pharmacovigilance and Public Health: The stakeholders and their Contribution to the Safe Use of Medicines", attended by 150 officials.

ΣfEE aims to raise awareness and foster the cooperation of all stakeholders in Pharmacovigilance, keeping with its ethical, scientific, social and legal duty to safeguard public health.

The following speakers participated in the round table discussion:

1) The executives of the National Organization for Medicines, **Ms. G. Terzi** (Head of the Adverse Drug Reactions Department) and **Mr. L. Klironomos,** officer of the ADR Department,
2) Dr. **M. Theodorakis**/Internal Medicine Lecturer of the Therapeutic Clinic of the University of Athens Clinic and Vice-Chairman of the National Pharmacovigilance Committee,
3) Ms. **B. Tsiantou**/Health Economist and Researcher in the National School of Public Health,
4) Ms. **E. Giannoula**/Pharmacovigilance Manager (Roche Hellas S.A.), representing the Pharmacovigilance Group of the Hellenic Association of Pharmaceutical Companies.

The round table discussion was moderated by the undersigned Dr. B. Baroutsou/Internist - Medical Director Sanofi Aventis, Head of the Pharmacovigilance Group of ΣfEE.

Speakers acknowledged the joint responsibility of all the parties involved (health and regulatory authorities and pharmaceutical companies - Marketing authorisation holders and sponsors of clinical trials) share in monitoring the safety of the marketed medicines as well as of those under research.

The participants unanimously agreed on:

- Raising awareness, training and motivating health professionals to use the yellow card and familiarize themselves for reporting ADR's,
- The emphasis that should be placed on correct prescription practices, in order to eliminate adverse reactions,
- the need to contain resources of the health system.

According to the study conducted by the National School of Public Health, presented during the round table discussion, it has been recorded that only 40% of health professionals fills in and submits a yellow card to the National Organization for Medicines, when faced with an adverse reaction.

Adverse events are the 5th most common cause of admissions in the E.U., while it has been estimated that the direct cost from prolongation of hospitalisations per person due to an Adverse Event amounts to approximately to 2,800 euros.

On the occasion of the round table, ΣfEE made public and distributed to delegates:

1) its position on the safe use of medicines,
2) the Pharmacovigilance Manual, compiled by the editorial subgroup of the Pharmacovigilance Group of ΣfEE,
3) the Association's poster and
4) a press release.

All this material has been posted on the Association's website. At the same time, the manual and the Association's poster will be mailed to all health professionals in 2009.

The Hellenic Association of Pharmaceutical Companies has systematically and greatly contributed in raising awareness and providing continuous education on Pharmacovigilance issues to health care professionals, by means of:

- Its close cooperation with the National Organization for Medicines,
- The development of a special glossary and poster on Pharmacovigilance,
- Designing research, collecting and processing statistical data, and
- Organizing or participating in lectures in hospitals, congresses or meetings.

The positive reception of this scientific initiative of the Association encourages the undertaking of joint actions by the Pharmacovigilance stakeholders during 2009.

We address our warmest thanks to the Congress Organizing Committee, the speakers, the members of the Pharmacovigilance working party and the Association's executives, for contributing in the success of the round table.

The position of ΣfEE

on the Safe Use of Medicines

Pharmacovigilance is the science and the activities relating to detection, assessment, understanding and prevention of adverse drug reactions.

As adverse drug reaction is defined any untoward medical event which occurs in a patient after the administration of a medicinal product.

Other special issues which must be recorded and reported in order to improve the safety profile of the drugs are:

- Any information regarding a pregnant woman taking a medicinal product. The Drug exposure in Utero during pregnancy should be reported even if it is not developed any adverse event
- Lack of efficacy cases (it occurs when the drug used have different action from the expected action described in the Summary of Product Characteristics)
- Drug interaction cases (Adverse drug reaction (ADR) derived from the interaction between two or more medicinal products)
- Drug abuse/misuse/overdose cases

All adverse drug reactions, serious and non-serious, derived spontaneously or from clinical studies, **are important** and are described in the section concerning the ADRs in the Summary of Product Characteristics and in Patient's Information Leaflet. After the drug marketing authorisation, the safety data continues to be collected and recorded into the product Periodic Safety Update Report. The Marketing Authorisation Holders, through this document, notify the Competent Authorities about ALL the safety information coming to their attention from the product worldwide experience.

Drugs can be more safe and effective thanks to the attempt and collaboration of all the participants of the Public Health, which are:

Healthcare Professionals (physicians, pharmacist, dentists, nurses): Through the daily practice and/or drug research (pre-marketing and post-marketing studies), healthcare professionals can significantly contributed to the correct and safe use of drugs following the approved drug instructions, be compliant with the clinical trial protocol (for the physician involved in clinical studies), monitoring adequately patients through the daily clinical practice and reporting all the suspected adverse drug reactions arising from the drug use.

A suspected adverse drug reaction can be reported to:

- The local Health Authorities (National Organisation for Medicines, EOF), through the **YELLOW CARD** (http://eof3.eof.gr/web/guest/yellowgeneral)
- The Marketing Authorisation Holder responsible for the medicinal product or the sponsor of a clinical study, if the adverse drug reaction concerns an investigational medicinal product.

Health Authorities (National Organisation for Medicines - EOF, European Medicines Agency - EMEA): They are responsible to implement the legal framework/regulations regarding pharmacovigilance and monitor the compliance of the Marketing Authorisation Holders with European Guidelines and legislation regarding Pharmacovigilance.

They actively follow and evaluate the reporting of adverse drug reactions in order to ensure the correct and safe use of medicinal products.

They continuously evaluate the ratio risk - benefit of medicinal products and maintain the marketing authorisation for the drugs with more benefits than risks.

The Marketing Authorisation Holders must maintain:

- A Pharmacovigilance System for the collection, evaluation, and reporting of safety data to Regulatory Authorities for the products under their responsibility.
- A Risk Management System for the detection, designation, prevention or minimization of the risks related to the use of medicinal products and the appraisal of the effectiveness of these interventions. The Competent Authorities must approve and monitor the Risk Management System.

The procedure of expedited and/or periodic reporting of adverse drug reactions to the Competent Authorities is accomplished within strict submission timelines in order to monitor systematically and promptly the drug safety data and to prevent immediately possible risks either in pre-marketing either in post-marketing period.

Consumers (patients, friends or patients' relatives). They can report possible adverse drug reactions to Healthcare Professionals and/or Competent Authorities and /or Marketing Authorisation Holders.

The patient's safety and wellbeing must be a priority for all participants in the sector of Health. The Hellenic Association of Pharmaceutical Companies supporting the culture and enhancement of continuing Pharmacovigilance training, with the assistance of specialised scientists (representatives of companies participating in ΣfEE), collaborates with the Authorities, healthcare professionals and investigators in order to emphasize the importance of safety for medicinal products in a health system with high level services to the citizens.

Yellow card to EOF. Red card to risk!

The Safety of Medicines is everyone's Responsibility

The safety of medicines is our fundamental concern. With respect to our ethical and legal obligations, we align with the Health Authorities and encourage Health Care Professionals to complete the special, confidential form of EOF, the "Yellow Card". We strive for safer medicines and support every effort undertaken by the competent authorities and the scientific community for the promotion of public h ealth.

Help make medicines safer. Complete the "Yellow Card".
Report:

- **ALL** Adverse Events for New Medicines [N] (marketed up to one year)
- **SERIOUS** adverse events for Known medicines (marketed more than one year)

ΣfEE
HELLENIC ASSOCIATION OF PHARMACEUTICAL COMPANIES

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

ΣfEE's Code of Practice regarding the Relationship between pharmaceutical companies and patient organizations

Scope

This Code covers the relationship between pharmaceutical companies which are members of ΣfEE and the patient associations which operate in Greece.

Patient organizations are defined as non-profit organizations representing and/or supporting the needs of people who suffer from medical conditions.

Article 1

Promotion of medicinal products

In the application of this Code, the provisions established by national and community Laws prohibiting the advertising of prescription only medicinal products sold to the wider public are valid.

Article 2

Written contract

Any financial support provided by pharmaceutical companies to patient organizations must be covered by a written contract. The contract must describe the activities undertaken by the contracting parties and the amount of the funding. Every pharmaceutical company must implement a procedure for the authorization of this type of contracts.

A template of a written contract is included in Annex I.

Article 3

Use of logos and proprietary material

For a pharmaceutical company to use a patient organization's logo and proprietary material, the Organization's written authorization is required. The pharmaceutical company must clearly mention, in its request to the patient organization, the specific purpose and the way in which the logo and/or the proprietary material shall be used.

Article 4
Control of publications

Pharmaceutical companies financing in any way patient organizations are prohibited from influencing the text concerning the material they are financing in a way favorable to their commercial interests. This does not prevent the companies from correcting any inaccuracies they may detect in the above-mentioned text.

Article 5
Transparency

a. All pharmaceutical companies are encouraged to issue, once yearly, a list of patient organizations to which they offer financial support and/or considerable indirect non-financial support. The list must include a short description of the type of support.

b. Pharmaceutical companies must ensure that competent health authorities have access to the list mentioned in paragraph a) of this article.

Article 6
Sponsorship by a Pharmaceutical Company

A pharmaceutical company may not demand to be the sole sponsor of a patient organization or of one of the Organization's major programmes.

Article 7
Events and hospitality

All events intended for patient orgnanizations and organized or sponsored by or on behalf of a pharmaceutical company must be held in an appropriate venue, that is conducive to the main purpose of the event, avoiding venues which are "luxurious" or "well reputed" for their entertainment facilities. Hospitality must not include the financing or organization of recreational events.

All forms of hospitality provided by a pharmaceutical company to patient organizations and their members shall be reasonable and secondary to the main purpose of the event, whether the event is organized by the patient organization or the pharmaceutical company.

The hospitality extended during the event, is limited to travel expenses, meals, accommodation and registration fees.

A pharmaceutical company is not allowed, to directly or indirectly (through its parent company or other third company to which it is continually or temporarily associated with by any lawful relationship), organize or sponsor an event held outside the country where it is located (international event) unless:

a. the majority of the guests come from abroad in relation to the country where the pharmaceutical country is located and, considering the countries of origin of most guests, it is deemed more reasonable to hold the event in another country or

b. the specific nature of some facilities (e.g. research labs, production facilities etc) which are part of the objective or the theme of the event are located outside the country and thus it is considered more reasonable to hold the event in another country.

CONTROL PROCEDURE FOR THE ENFORCEMENT OF THE CODE ON THE RELATIONSHIPS BETWEEN PHARMACEUTICAL COMPANIES AND PATIENT ORGANIZATIONS

Article 1

Competent authorities for the control of the enforcement of the Code provisions on the relationships between pharmaceutical companies and patient organizations are the authorities in charge for the observance of the SFFE Code of Practice.

Article 2

Should a ΣfEE member pharmaceutical company violate the terms of this Code, the procedure for submission of a complaint/report as provided for in articles 2 and 3 of the Control Procedure in the ΣfEE Code of Practice, is followed.

Article 3

SANCTIONS

A. Matters concerning articles 1 to 6 of this Code

- The First Degree Committee for the observance of the ΣfEE Code of Practice , after considering the submitted report/ complaint and if it judges that there has been a violation of articles 1 to 6 of the Code concerning relationships between pharmaceutical companies and ΣfEE's patient organizations, can impose the following sanctions on the member company-r of ΣfEE, which has not observed the above mentioned provisions of the present Code:

  a. The immediate publication of the First Degree Committee judgment condemning the pharmaceutical company , n the ΣfEE journal "Theseis" (Θέσεις) .

  b. The correction of the promotional material and the obligation of the indicted pharmaceutical company to send the corrected material to the same recipients accompanied by a relevant letter referring to the modifications.

  c. The publication of the text of the First Degree Committee judgment, as the case may be, depending on the subject, in scientific journals intended for healthcare professionals.

The above mentioned sanctions (b) and (c) are imposed if the deadline for the referral of the report/complaint to the Second Degree Committee, as provided for in article 2.14 of the ΣfEE Control Procedure on Implementation of ΣfEE's Code of Practice, expires and no action has been taken.

The Second Degree Committee may impose on the ΣfEE member company which has not complied with the judgment of the First Degree Committee the sanctions cited in article 4.1 A of the Control Procedure of ΣfEE's Code of Practice. The Second Degree Committee may, apart from the above sanctions, impose a fine of 15.000 **j** . The cited fines shall be deposited by the violating pharmaceutical company in a special bank account of ΣfEE, within a maximum of 30 working days from the date of issuing the judgment.

B. Matters concerning article 7 of this Code

The First Degree Committee for the observance of ΣfEE Code of Practice, may, after considering the submitted report/ complaint, and if it judges that there has been a violation of article 7 of this Code, impose via its judgment a fine of up to 3.000 **j** to the ΣfEE member company.

The cited fines shall be deposited by the indicted pharmaceutical company in a special bank account of ΣfEE.

After the issuance of the judgement by the First Degree Committee, the opposed parties reserve their right to submit, within 30 working days of notification of the judgment to them by ΣfEE Secretariat, an application to refer the case to the Second Degree Committee according to article 2.14 of the ΣfEE Code of Practice Control Procedure. The above-mentioned action suspends the claim for the aforementioned fine.

The Second Degree Committee may impose a fine of up to 15.000 **j** to the non compliant pharmaceutical ΣfEE member company.

The cited fines shall be deposited by the violating pharmaceutical company in a special ΣfEE bank account.

If the fines imposed by the First Degree Committee are not paid and if a report referral has not been submitted to the Second Degree Committee within the deadlines set according to article 2.14 of the ΣfEE Code of Practice Control Procedure, the Second Degree Committee then decides to impose a fine, ex-officio, to the ΣfEE member company, to which the First Degree Committee had previously imposed a fine.

Should the ΣfEE pharmaceutical member company fail to comply with the judgment of the Second Degree Committee again, the latter shall refer the matter to the ΣfEE Disciplinary Board which may decide to expel the said company from ΣfEE.

ANNEX Proposed content of written contracts between pharmaceutical companies and patient organizations

When pharmaceutical companies offer financial support, considerable indirect support and considerable non-financial support to patient organizations they must sign a written contract in accordance with article 2 of this Code.

Below follows a template including the key points of a written contract. The objective of this contract is to describe clearly, what has been agreed upon, considering the requirements set by the EFPIA Code of Practice concerning the Relationships between pharmaceutical companies and patient organizations.

- Title of the project
- Names of participating parties (pharmaceutical company, patient organization and, where required, third parties involved in the project in order to help.)
- Type of project (i.e. whether the contract concerns general grants for operational expenses, specific meetings, sponsorships, leaflets, information campaigns, educational programmes, etc.)
- Objectives
- Agreed role of the pharmaceutical company and the patient organization
- Timeframe
- Amount and type of financial support
- Description of the considerable indirect / non-financial support (e.g. donation of a PR agency's time, free of charge training programmes.

All contracting parties are fully aware that the sponsorship must be clearly acknowledged.

Reception to celebrate the New Year at ΣfEE's Premises

The Hellenic Association of Pharmaceutical Companies (ΣfEE) held on Wednesday, January 21st a reception to celebrate the New Year at the Association Premises, in the presence of the EOF President, Mr. Vasilis Kontozamanis and EOF Vice - President Mrs. D. Patargia, the ΣfEE member - companies' CEOs as well as other distinguished guests.

The President, Mr. Dionysios Filiotis during his speech referred to the ΣfEE accomplishments, emphasizing the Association's vision and how highly appreciated it is in the broader pharmaceutical sector. He particularly pointed out that ΣfEE members' credibility, high sense of professionalism and integrity are the foundations for defending ΣfEE's views during the contacts and negotiations with the State authorities for promoting and resolving issues of concern to the industry. He pointed out that only branded original medicinal products or branded essentially similar medicinal products guarantee quality, safety and efficacy. He stressed the importance of cooperation with other highly esteemed institutions, e.g. IOVE, which, conduct surveys and market research documenting the Association's Vision and Positions.

Among other things, the President emphasized the significance ΣfEE attributes to the streamlining of the IT infrastructure of the healthcare system, since this is critical for eliminating the extreme waste of resources and for radically reducing operating expenditure. He strongly emphasized the ΣfEE's Code of Practice and the activities for promoting it, e.g. the establishment of the Greek Code of Practice Day on November 24th 2008. He stressed his confidence that Code of Practice is a significant step, reinforcing the credibility of the Pharmaceutical Industry. An equally significant achievement for 2008 is the establishment of the ΣfEE SOPs Manual and the establishment of a new Portal, which will be a gold standard for the industry.

The President, Mr. Filiotis, emphasized that ΣfEE and he personally will keep working with the sole purpose of serving the common interest of Greek citizens, the Greek State and pharmaceutical companies. On this occasion, he thanked ΣfEE member companies for their contribution to this common goal.

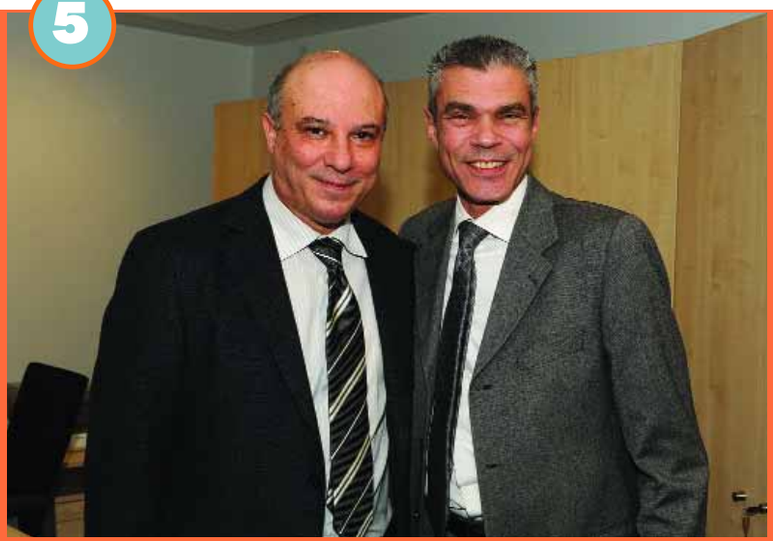
Mr.F. Mangalousis, Director General of ΣfEE, Mrs. D. Patargia, Vice President of EOF, Mr. V. Kontozamanis, President of EOF, Mr. D. Filiotis, President of ΣfEE, Mrs. S. Mela, Scientific Director of ΣfEE, Mr. V. Niadas, (CEO Cana) Vice President of ΣfEE, Mr. Y. Chryssospathis, Legal Counsel of ΣfEE, Mr. T. Zervakakis, (CEO Wyeth) Vice President of ΣfEE

1. *The President of ΣfEE, Mr. D. Filiotis presenting Mr. D. Chandras, Vice-President of the Association of Greek Self Medication Industry and Head of BU OTC, Novartis Hellas, the New Year's golden coin, which he won. Looking on is Mr. G. Dokios, Director General of the Association of Greek Self Medication Industry.*

2. *Mr. D. Filiotis, Mr Th. Coletis President of PEF, Mr. E. Adamou President of the Association of Wholesalers, Mr. M. Katsikas Member of the Board of ΣfEE*

3. *Mr. A. Galanopoulos President of the Pharmacists Cooperative, Mrs C. Karella (CEO Pfizer), Secretary General of ΣfEE and Dr. Leo Crassaris Honorary President of ΣfEE*

4. *Mr. A. Avgerinos President of the Panhellenic Association of Pharmasists, Professor N. Houlis, Mr. M. Katsikas (CEO Faran)*



5. *Mr. K. Evripides (CEO Genesis), Vice President of ΣfEE, Mr. A. Kypraios, (CEO Genzyme)*

6. *Mr. P. Cardoso, (CEO Galderma), Mr. V. Niadas, Mr. P. Meyer, President and CEO Astra Zeneca*

7. *Mr. G. Sykianakis, (CEO Menarini) President of ΣfEE's Committee for the Implementation of the Code of Practice, Dr. Leo Crassaris and Mr. D. Filiotis*

8. *Mr. C. Schiever, (CEO Schering Plough), Mr. A. Marinopoulos, (Famar), Mr. P. Marinopoulos, (CEO Famar)*

European Cervical Cancer Prevention Week

GlaxoSmithKline, Vianex and the Intermunicipal Health and Social Solidarity Network

Under the Auspices of the Ministry of Health and Social Solidarity

Within the framework of the official inauguration of the 3rd European Cervical Cancer Prevention Week, the Association of Volunteers against Cancer (AVC) "AGKALIAZO" and the ECCA (European Cervical Cancer Association) presented the most important developments for preventing cervical cancer, as well as the benefits from HPV vaccination in preventing cervical cancer.

A campaign for raising public awareness, which will last throughout the Cervical Cancer Prevention Week (18 -24 January) and for the whole month, included the distribution of information leaflets to municipalities and hospitals, as well as private institutions, a meeting in Thessaloniki and a TV awareness commercial. This awareness campaign is conducted under the auspices of the Ministry of Health and is supported by GlaxoSmithKline and VIANEX, with the kind cooperation of Alpha Bank and the Intermunicipal Health Network.

During a press conference held for the campaign, the ECCA representative, **Mr. Theodore Agorastos,** a Professor at the 1st Obstetrics and Gynaecology Clinic of the Aristotle University, at the "Papageorgiou" Hospital in Thessaloniki, stated: **"The core message for the campaign this year is that Cervical Cancer cases can be reduced by 94%, by applying the vaccination and Pap Test program".**

Mrs. Skourta, Chairman of AVC, stated that: **"Last year, we managed something very important, that is the inclusion of the HPV vaccines in the National Vaccination Program and the commitment of social security funds to providing them free of charge to girls and young women, aged 12-26. However, we also ask social security funds to better inform their members of the vaccination option, and ask the state to implement organized screening programs, so the women in our country may feel secure against this form of cancer".**

Y. Skourta - *President of the Group of Volunteers against Cancer (AGALIAZO),*
Th. Agorastos - *Professor of Obstetrics Representative of ECCA,*
D. Avramopoulos - *Minister of Health and Social Solidarity,*
F. Palli-Petralia - *Minister of Employment and Social Protection,*
E. Diakomanolis - *Professor of Obstetrics, Athens University, President of the European Society of Cervical Pathology*

St. Fotiou - *Professor of Obstetrics Athens University,*
G. Patoulis - *President of the Intermunicipal Health and Solidarity Network,*
Th. Agorastos,
E. Diakomanolis,
Ev. Paraskevaidis - *Professor of Obstetrics Ioannina University, President of the Greek Society of Cervical Pathology*

Transparency as the fundamental principle of relations with Patient Associations

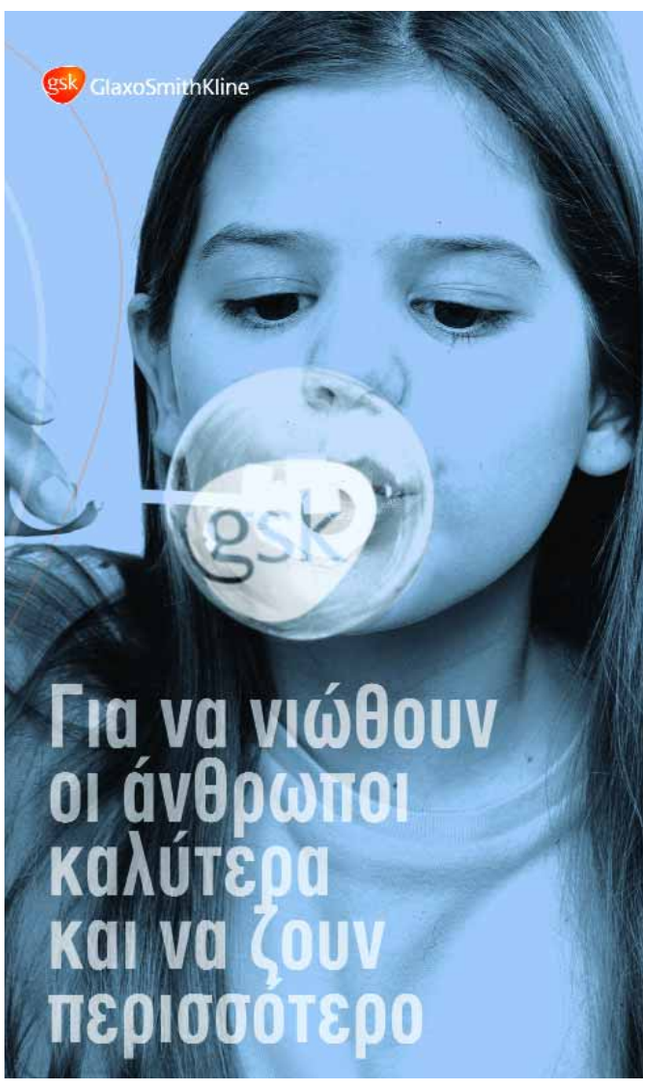
Lena Lyberopoulou
Director Government Affairs
and Communications
GlaxoSmithKline Hellas

Through its social responsibility plan, GlaxoSmithKline places special emphasis on its cooperation with associations who support patients with various diseases, mainly focusing on understanding the needs of patients and their disease, in order to support their positions and strengthen discussions between interested parties to achieve better benefits for patients.

For 4 years now, GlaxoSmithKline follows the "Code of Practice on Relations with Patient Associations" which highlights the need for these associations to enjoy independence, mutual respect and transparency. This Code was then adopted by the pharmaceutical sector in whole with the EFPIA Code. In Greece, it was adopted by the Hellenic Association of Pharmaceutical Companies in July 2008.

In adherence with its Code which binds its relations with patient associations, GlaxoSmithKline publishes an annual report on the financial support it provides on each association and project basis, while the financial support to patient associations may not exceed 25% of the financing they receive annually.

In 2008, the Greek GlaxoSmithKline branch supported 6 different patient associations with a total of 36,500_, thus contributing to their work and promoting public awareness for various health issues, such as the prevention of cervical cancer and osteoporosis.



The Mayor of Maroussi, Mr. George Patoulis, and the Business Unit Director for Roche (Hellas), Mr. Dimitris Palakas.

ROCHE 2008 Children's Walk

One Organization, One Day, One Purpose

For the 6th year in a row, on December 1st, 14,000 employees from Roche and 100 affiliates from around the world took part in AIDSWALK, this year renamed as the CHILDREN'S WALK, thus actively contributing to the lives of thousands of children worldwide.

To this end, employees from Roche affiliates around the world this year collected money not only for children in Malawi, who were deprived of their parents because of the AIDS epidemic, as well as for local institutions that aiming at improving quality of life for children. In Roche (Hellas), the employees themselves decided on the charity that would benefit from 50% of the amount donated. This was the Association of Parents of Children with Neoplasmatic Diseases "FLOGA" (www.floga.org.gr), an association of parents whose children suffer from cancer. Throughout its 26 years of operation, the Association has made an important contribution, targeting to offer children better psychological and social care.

How did the Walk work?

Once more, more than 100 employees from Roche Hellas walked together, passing through Mitropoleos and Ermou streets, to end their walk at the Maroussi City Hall, where the Mayor, Mr. George Patoulis, had arranged for refreshments and light food to be offered. In his short address to those present, the Mayor congratulated the Roche (Hellas) employees on their initiative. On the other hand, Mr. Dimitris Palakas, Business Unit Director with Roche (Hellas), warmly thanked Mr. Patoulis for hosting the event in the City Hall premises. During this year's Roche Children Walk, Roche (Hellas) employees collected money for the children of the "FLOGA" Association, while an equal amount was matched by the company and donated to the Malawi orphans, thus contributing in meeting their needs for food and education

“Less Paper... More Life”
sanofi - aventis

Dr. Marcos Gerassopoulos
Managing Director
sanofi-aventis Greece & Cyprus

Sanofi-aventis , with a high sense of social responsibility has decided to put an end to the reckless damage of the environment. The company is changing the means of communicating with health professionals, by dramatically reducing the quantity of printed promotional material, which will no longer be distributed to physicians.

To replace printed material, Sanofi-aventis has decided to adopt new technologies, and has developed a special section on its Greek website www.sanofi-aventis.gr, which may only be accessed by health professionals and includes detailed information (SPC, PIL, medical information documents, useful bibliography, etc.) on the company’s pharmaceutical products, thus providing an additional information tool to the medical community.

In this way the company ensures that physicians obtain timely, detailed and complete information, while at the same time it’s been achieved the saving of vast quantities of paper, for which valuable natural resources are required.

"I am truly proud of our initiative to change the way, in which we provide information on our pharmaceutical products to the Greek medical community.

We dare to be different. We are the first pharmaceutical company that has been innovative and has proven its sensitivity for the environment.

I hope that this initiative will inspire others to undertake similar actions, because the future of the environment is in our hands.”