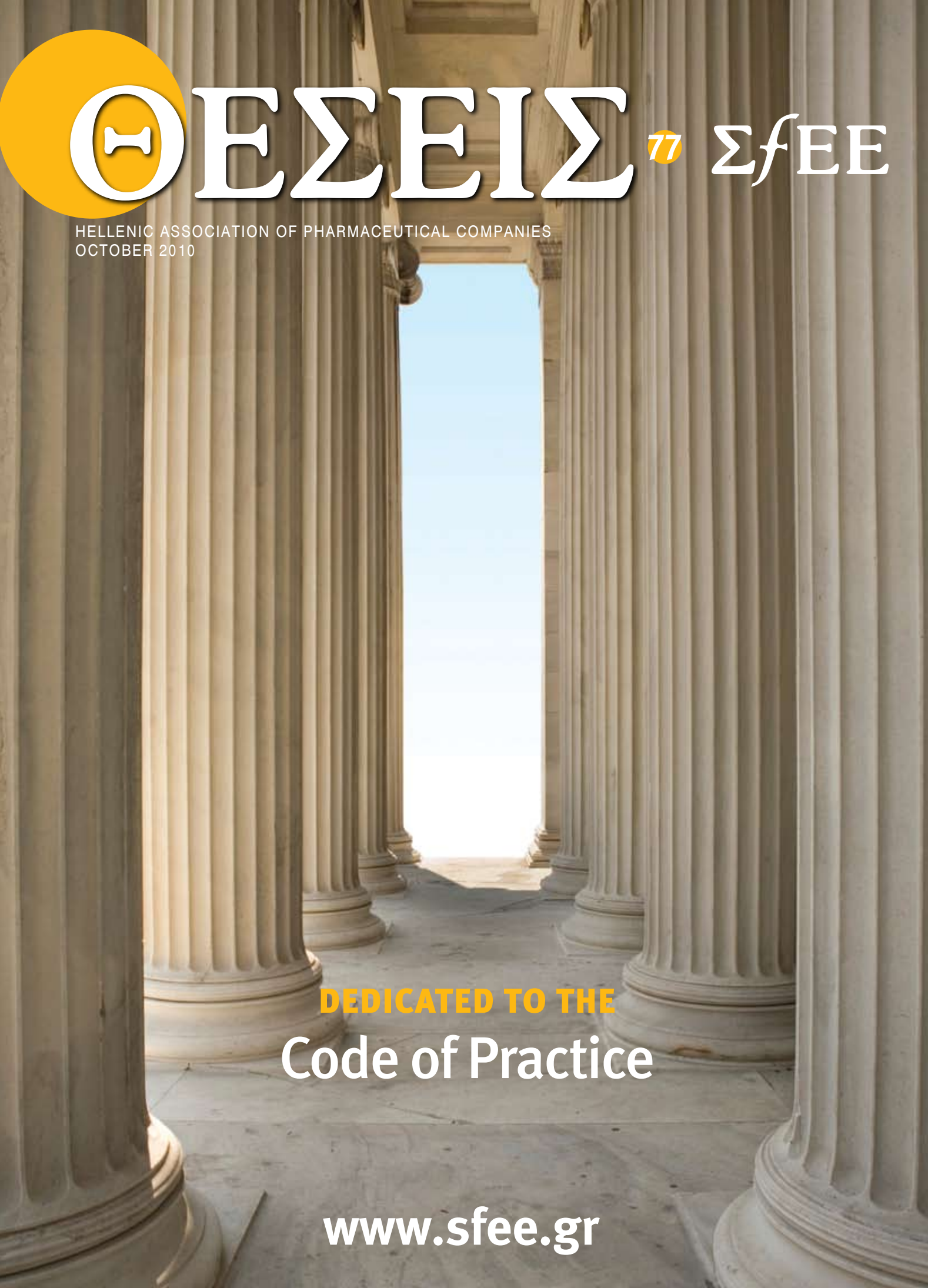

ΘΕΣΕΙΣ 77 SfEE

HELLENIC ASSOCIATION OF PHARMACEUTICAL COMPANIES
OCTOBER 2010

DEDICATED TO THE
Code of Practice

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"Only branded medicines - original or essentially similar- guarantee therapeutic efficacy, safety and quality."

Direct access of all citizens to all branded medicines -original or essentially similar- that are prescribed under the exclusive responsibility of the attending physician and are administered under the responsibility of the pharmacist through the extensive distribution network throughout the country with strict adherence to the Code of Practice.

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HELLENIC ASSOCIATION OF PHARMACEUTICAL COMPANIES

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Code of Practice: The primary concern of every profession

There can be no doubt that code of practice is the cornerstone, not only of a business's healthy contribution to society, but of civilization itself. Our code of practice is constructed from clear principles of self-regulation and rules of ethically correct professional conduct. It endows the existing statutory framework governing and regulating our actions, activities and conduct with the necessary moral seriousness. However, the notion of code of practice is not merely a moral concept; it also demonstrates a high degree of business intelligence.

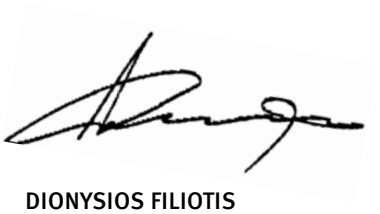
The Code of Practice determines the rules and recommended practices for the provision of comprehensive, integrated scientific information. Adherence to the Code, particularly in the sensitive field of health and medicine, operates as a safety valve for correct business strategy and provides a guarantee that the patient will receive the most appropriate care. It thereby ensures correct treatment and guarantees efficient management of the health system as a viable, competitive and indispensable pillar of the welfare state.

SFEE has shown Greece the lead in promoting principles and rules of ethics, demonstrating great determination in recent years to promote the implementation of a comprehensive Code of Practice for the pharmaceutical sector. As adopted and implemented by our members, SFEE's Code of Practice has endowed our sector with new authority and status, increasing the respect we enjoy from society, the state and other parts of the business community. SFEE attaches great importance to implementing the Code of Practice. This is not simply an aspiration – it is a commitment on

the part of the entire sector. It is significant that the overwhelming majority of pharmaceutical companies demonstrate a high level of commitment to the promotion of public health. Cases of unfortunate and reprehensible practices in the health sector are rare; an unfortunate and regretful exception. Implementation of the Code of Practice is monitored with unceasing vigilance and every effort is being made to inculcate the principles of professional ethics and to raise awareness of their value.

SFEE's positions– from the price of pharmaceutical products to the streamlining of IT infrastructure for social insurance funds and public hospitals– reflects our faith in the Code, since our positions on these issues are determined by the principle of promoting the common good, for the public, the state, the pharmaceutical industry and those working in it. We have made SFEE a force for stability, a pillar of the health system, and this has earned us the position of authority and respect we enjoy in our consultations with the state and our other partners in the sector.

The challenge of achieving lasting relevance and viability, and the maximum good over the long term, must be met through an emphasis on the contribution of a business, and by extension the sector it belongs to, to the progress of society as a whole. Adherence to our Code of Practice will, therefore, safeguard the future of our sector and advance our collective endeavours to provide the Greek people with medical and pharmaceutical care of the highest quality. Our Code has always been, and will continue to be, the compass by which we chart the future development of our sector and its contribution to the general good of society.

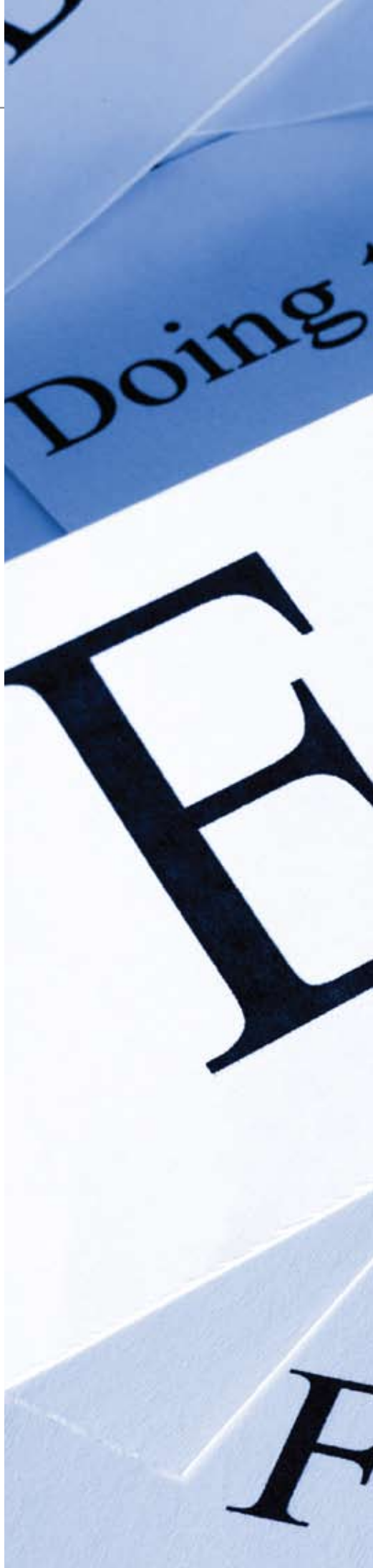


DIONYSIOS FILIOTIS
President of SFEE

President and Managing Director of
PHARMASERVE - LILLY S.A.C.I.

CODE OF PRACTICE: Hellenic Association of Pharmaceutical Companies (SFEE)

SFEE Code of Practice commits all members to implement specific practices, methods and conduct of high European standards in terms of the quality of services. In combination with the remarkable efforts of health professionals, the SFEE Code of Practice shields public health of negative phenomena and practices, and is setting a series of high standards for medicines in Greece.




the Right
Ethics
ard
Value

The President of SFEE Mr. Dionysios Filiotis speaking at the Athens Concert Hall

> "The Code of Practice is a living text, which we constantly update in line not only with all the requirements of the Greek environment, but also of the European experience. This is an ongoing effort, with the overriding objective being to reassure the general public that pharmaceutical enterprises are self regulated and promote public health"

Placing Deontology at the heart of how medicines are prescribed lies at the core of SFEE's vision for public health, and demonstrates our unwavering position that medicines one of the most sensitive equitable goods in society. Our clear-cut views about unimpeded access to quality medicines and treatments as part of a modern healthcare system and a flawless distribution network are based on the joint decision to self-regulate the sector, through an express commitment to comply with the principles and rules contained in the Code of Practice,» stressed the President of SFEE, Mr. Dionysios Filiotis.

Actions to publicise the Code of Practice

SFEE's Code of Practice is one of the most cutting edge, well-rounded Codes of Practice at European level, and is constantly being supplemented and updated. It is fully in line with the national and European law, and the Code of Practice of the European Federation of Pharmaceutical Industries and Associations (EFPIA).

«The Code of Practice is a living text, which we constantly update in line not only with all the requirements of the Greek environment, but also of the European experience. This is an ongoing effort, with the overriding objective being to reassure the general public that pharmaceutical enterprises are self regulated and promote public health,» stressed Mr. Dionysios Filiotis. That constant effort is confirmed by the ongoing series of actions taken to widely publicise the Code of Practice and ensure strict compliance.

Major event to publicise the Code of Practice

SFEE's most important initiative was the major event to publicise the Code of Practice organised by SFEE on Monday 29 October 2007 at the Athens Concert Hall.

That event was held under the auspices of the Ministry of Health & Social Solidarity, and was attended by leading personalities, politicians, members of the academic community and more than 3,000 people who were given a detailed briefing about the principles, philosophy and content of SFEE's Code of Practice.

SFEE plans to organise a new major event at the Athens Concert Hall in April 2011 to stress its unwavering decision to implement the Code of Practice in all cases without exception.

«Code of Practice Day» - Three page pamphlet of the Code of Practice

SFEE decided to publicise the provisions of the Code of Practice to the bodies concerned to ensure that they are fully briefed and properly implement it.

The decision was thus taken in 2007 designate a day each year as «Code of Practice Day».

On that day, medical sales representatives of all pharmaceutical companies which are members of SFEE present the Code of Practice during their visits to physicians nationwide; their main tool being the «Three page pamphlet of the Code of Practice» setting out all the basic provisions of the Code.

Key provisions

SFEE's Code of Practice covers the provision of scientific information on prescription medicines. It covers all activities undertaken, organised or carried out by a pharmaceutical company or authorised by it to promote the prescribing, supply or administration of medicinal products of companies that are members of SFEE.

In short, it sets out the regulatory framework which governs relations between pharmaceutical companies and healthcare professionals based on the principles of responsibility, ethics and transparency.

SFEE's Code

Documentation, accuracy, balance, objectivity, clarity. Those are the keywords that can be used to summarise the Code.
The Code consists of 2 Sections and 1 Annex. Section I contains the substantive provisions of the Code while Section II relates to the procedure to control implementation of the Code. The Annex contains EFPIA «Guidelines for Internet websites available to healthcare professionals, patients and the public in the EU» which provide guidance to member associations and companies with respect to the content of websites containing information on medicinal products subject to prescription.
The Code covers:

- **promotion of medicinal products to persons qualified to prescribe or supply medicinal products;**
- **visits by medical sales representatives to persons qualified to prescribe or supply medicinal products;**
- **sponsorship of meetings to promote medicinal products and/or scientific congresses attended by persons qualified to prescribe or supply medicinal products and in particular payment of their travel and accommodation expenses;**
- **the provision of information directly or indirectly to the general public;**
- **advertising in magazines or by direct mailing;**
- **the activities of medical sales representatives and all printed materials used;**
- **hospitality provided at professional or scientific events and meetings to promote medicinal products;**
- **the distribution of medical information documentation;**
- **other promotional activities (participation in events, use of audiovisual materials, films, DVDs, videos, electronic media, interactive data systems, etc.).**

The Major Event to publicise the Code of Practice of SFEE October 29, 2007 Athens Concert Hall

«SFEE's Code of Practice concerns us all: businesses, healthcare professionals, healthcare providers and every individual Greek patient. Only by means of overall effort and only by taking a responsible approach can we ensure that a high level of medical information is provided, which will in turn ensure a high level of health care,» stresses SFEE.

Implementation of the Code seeks to provide a reassurance to all that medicinal products are prescribed based on their advantages to cover the specific needs of each individual patient. In other words the Code fosters respect for patients, and builds trust in the quality and therapeutic efficacy of medicinal products.

Establishing citizen trust

Implementation of the Code of Practice establishes citizen trust in healthcare professionals and pharmaceutical companies. SFEE ensures that the Code of Practice is regularly updated and improved. In 2008 SFEE adopted the Code of Practice on relations between pharmaceutical companies and patients' associations, along the same lines as the corresponding EFPIA Code, in order to promote mutual respect and transparency in relations between pharmaceutical companies and patients' associations.

Emphasis on implementing the Code

From its actions to date, SFEE has demonstrated that the Code is much more than just words on paper. Every possible means is used to promote the Code of Practice, ensure that it is properly complied with.

SFEE puts special emphasis on the implementation of the Code of Practice. This is no simple decision; it expresses the will of the whole pharmaceutical industry. Implementation of the Code has a strong moral dimension, a dimension of responsibility towards society and the scientific community. SFEE holds an equally strong belief that this is correct business practice. «We believe that the pharmaceutical sector and the pharmaceutical companies must fully respect implementation of the Code and remain constantly vigilant. We are consistent in our responsibility towards Greek society. Our day-to-day conduct and actions prove this, and we shall continue to respect the same principles in the future,» stressed Mr. Filiotis.

The implantation of the Code of Practice and the immediate, thorough examination of reports or denunciations for violations by the members of SFEE are assured by the First-Degree and Second –Degree Committees for the implementation of the Code. Desiring to place stronger emphasis and a new dimension on the strict implementation of the Code, SFEE has decided that, apart from the Chairman of the Second-Degree Committee, the Chairman of the First-Degree Committee for the Implementation of the Code of Practice should be a honorary Vice President of the Supreme Court, thus reinforcing the implementation of the Code with the prestige of high ranking judges of the supreme Court.

«The Code makes SFEE a force for responsible practices and progress»

Nikolaos Theodoropoulos,
Honorary Hellenic Supreme Court Judge, Chairman of the Second-Degree Committee for Implementation of the Code of Practice

«Next to the well-developed statutory structures which govern actions and forms of behaviour in society, there is the concept of self-regulation and self-control generated by the principles and rules of ethics.

Ethics derives from the very sense of justice that lies within the very core of our conscience and tells us what is right and wrong, what is fair and unfair, what is good and bad.

In highlighting the importance and seriousness of ethics, by adopting special specific principles and rules of conduct, SFEE and the pharmaceutical companies which are its members have become a force for responsible conductsand progress in Greek society».

Compliance with the Code of Practice

The Committees controlling the implementation of the Code of Practice called the "Code" on the promotion of prescription only medicinal products are:
a) The First Degree Committee for the implementation of the Code, which deals with reports/complaints registered at SFEE's secretariat.
b) The second Degree Committee for the implementation of the Code, deals with reports/ complaints, upon application for referral filed by the interested party and provided a decision of the First Degree Committee was previously issued.
c) The Disciplinary Council of SFEE deals with cases of pharmaceutical companies referred to it upon request of the Second Degree Committee, with the question of deletion of a company from the membership of SFEE.

«A significant contribution to building healthy relations»

Professor Yannis Tountas,
President of the National Organisation for Medicines (EOF)

«SFEE's Code of Practice is a significant contribution to building healthy relationships in terms of communication and collaboration between pharmaceutical companies and the health. In Greece, and internationally, we frequently discover non-transparent prescribing practices, with material rewards being provided in direct or indirect ways, which is something that increases pharmaceutical spending.

However, the Code on its own is not sufficient. All the stakeholders involved in producing, distributing and marketing medicinal products need to assume their responsibilities and, of course, above all the State itself needs to play its role. Aware of its responsibility in this regard, the National Organisation for Medicines recently took the initiative to publish a new circular relating to the approval of sponsored scientific events. The new circular attempts to put in place objective criteria and transparent procedures which will ensure that approved events are of scientific nature, and that their budgets are prudently implemented.

It also attempts to clarify what promotional expenses, which in Community law must relate to specific promotional activities for medicinal products aimed at persons who prescribe or supply prescription medicines. The Organisation's new circular thus seeks to ensure harmonisation with the Community legislative framework.

Moreover, the fact that applications to the Organisation for approval of subsidised scientific events more than doubled within one year makes it necessary to evaluate whether all those events are really necessary.

The same holds true for honoraria to physicians participating in domestic conferences, but especially so in international conferences abroad. Without denying the importance of support required to constantly update and inform healthcare professionals, the new circular puts in place provisions that will prevent such forms of support being abused.

In the current difficult fiscal situation that Greece finds itself in, and for as long as is necessary, scientific events abroad organised by Greek organisers will be approved only in a few exceptional cases where pre-existing international obligations exist or there is a substantive financial contribution from local joint organisers».

«The aim is to safeguard health and healthcare service users»

Dr. Emmanuel G. Kalokerinos,
President of the Greek Medical Association

«For a long time, putting in place a Code of Practice was a primary concern of the board of the Greek Medical Association, which managed to achieve agreement between the European partners under my chairmanship of the Comité Permanent des Médecins Européens (1995-1998).

SFEE Code is in line with the Code of the Greek Medical Association and that of the European Federation of Pharmaceutical Industries and Associations, and is now playing an important role in resolving a number of problems which had built up over time relating to ambiguities, overlaps and, above all, lack of a jointly acceptable, official regulatory body.

That problem no longer exists, since full and proper implementation of the Code of Conduct is a badge of honour for associations and individuals to achieve the maximum degree of protection for the health of users of healthcare services, which is a top priority in Europe.

I feel particularly happy about this as President of the Pan-Hellenic Medical Association».

«The Code of Practice is the thread linking profit to ethical prestige»

Konstantinos Evripidis,
Vice President of SFEE

«Compliance with the rules and principles in the Code of Practice ensures and guarantees the prestige and credibility of enterprises; an issue of inestimable value which cannot be measured in normal accounting terms. The Code of Practice is the thread linking profit with moral prestige, business performance and social responsibility. The Code of Practice must lie at the very «core' of every pharmaceutical company. Our mission is to work for a healthy society and that mission can only rest of solid principles which promote quality, efficiency and respect for citizens. SFEE is a pioneer among stakeholders in terms of adopting and implementing modern principles and rules of conduct».

«Moral perfection and ethics are necessary»

Christodoulos Stefanadis,
Prof. of Cardiology, Dean of the School of Medicine / Athens National & Capodistrian University

«The «Code of Practice» is a set of moral principles that must guide professional practice, vocations or scientific research. Its prime importance in the modern age is clear. There is confusion about the concept of ethics, and all ethical principles are constantly being violated to such a degree that virtue and morality risks being characterised as out-fashioned or even hypocritical.

More than ever moral perfection and ethics are necessary in science and scientific research because moral superiority helps in putting aside self interest, dishonesty, opportunism. Ethics and codes of practice provide exactly the moral foundation needed for scientific contributions not just to generate an intellect inflated by knowledge, but to generate virtue. Therefore the concept of ethics and the drafting of codes of practice are timely nowadays, especially in the sensitive field of health.

SFEE's Code of Practice does not seek to replace the provisions of the Civil or Penal Code as sources of law, but to facilitate their application by offering a set of simple rules for how scientists in the field of health can abide by the law, by setting out the human rights of healthcare professionals and patients, and formulating new concepts and definitions for socially and scientifically targeted activities; it thus becomes a document that is widely accepted by society. In this sense, the drafting of the Code is a valuable contribution to healthcare professionals and to society as a whole, and demonstrates both the important role SFEE plays in the pharmaceutical sector in Greece, and the wider social role it performs».

«Responsibility within Ethics»

by Evangelos Moutsopoulos,
member of the Academy of Athens

«In paragraph 7 of his Critique of Practical Reason (1784), Kant sets forth his view on the categorical imperative which requires that we always behave, within the context of freedom of conscience, in such a way that our every act be a model of universal acceptance to be followed. The universality which that imperative entails is nowadays based on the value of responsibility to man and to civilisation in general. The corruption which plagues our societies has quite literally eroded that value, with the risk of it becoming value-less. Consequently, it is not strange that societies themselves have begun a healthy and responsible reaction to this status, by developing the neglected field of morality and ethics in order to meet specific criteria to assist one's conscience when evaluating the actions one is about to take. One area in particular where such developments have taken place is bioethics, since it covers vital issues relating to the physical and mental health of the members of each society. I consider it a blessing that global institutions are closely collaborating with the authorities in each country, and that in Greece the National Bioethics Committee, even if only advisory in nature, reports directly to the prime minister. This committee is comprised of lawyers, doctors, biologists, theologians and philosophers. I happen to have direct insight into the multiple activities it engages in. The problems which constantly arise and which are brought for consultation cover a wide-ranging number of areas, from welfare and medical practice to the issue of informed patient consent. The Committee also deals with pharmaceutical processes. All these issues and the consultations concerning them, seek to protect individuals, and for that reason the resulting legislation is noticeably detailed, even exhaustive one might say, since it is developed to cover specific cases as is appropriate for any serious piece of legislation. Particular regard is given to the responsibility the State has to citizens, to that which attendant doctors have to patients and that which industries have to society as a whole.

In the healthcare sector in particular, the recommendations of the Code of Ethics of the Royal Society of the UK for its members have applied since August 2007: 1. Make patient care your first priority, 2. Make professional judgements in the interests of patients and the public, 3. Respect others, 4. Encourage patients to participate in decisions relating to their care, 5. Deepen your professional knowledge and com-

petences, 6. Be honourable and reliable, and 7. Assume responsibility for your professional activities.

Likewise, the Professional Ethics Committee established in parallel with and collaborating with the Bioethics Committee makes judgements on all ethical problems. The concept of what is ethical has also been a quasi-synonym for what one ought to do, in other words what is suitable for the process of giving effect to some value. However, what is ethical also contains within it a sense of vital necessity; of a debt, an obligation, a duty, and the responsibility which that debt entails for the person asked and even obliged to fulfil it. Developments in ethics and in deontology are occurring in parallel with those in the field of bioethics. Nevertheless, the concepts that these sectors represent are not equivalent. Bioethics falls within the more general sphere of ethics and deontology and is related to responsibilities of a very specific nature which require delicate balances to be drawn. Deontology specifies rules of behaviour towards others, in other words society as a whole, and also specifies the degree of responsibility for anyone who violates even one of those rules. One can easily understand how crucial rules of this type are, in a time when easy, effortless enrichment, coupled with a demotion of morality and cultural sensitivity, has been transformed into a dominant value.

Since that mentality would appear to be spreading rapidly as some sort of epidemic (if not pandemic), it is vital for ethical institutions to bolster themselves so that the rules which they adopt be stricter and that those responsible everywhere for breaking the rules receive exemplary punishment; otherwise the dynamics of this terrible situation are such that even those few who are still seeking to withstand it (perhaps because they developed suitable antibodies in their own moral universe at an early age) will be dragged down along with the rest. Modern societies have become debased in many ways on multiple levels. The constantly increasing number of mass media has brought to light offences which remain completely unpunished. It is vital that those who manage the fate of societies recover their sense of responsibility to society; otherwise Kant's categorical imperative runs the risk of operating in the opposite direction: in other words there is a risk of one's vile acts becoming a model for universal acceptance to be followed...».

ΣΥΝΔΕΣΜΟΣ ΦΑΡΜΑΚΕΥΤΙΚΩΝ ΕΠΙΧΕΙΡΗΣΕΩΝ ΕΛΛΑΔΟΣ
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LEANDROS RAKINTZIS

Inspector General for Public Administration

Mr. Leandros Rakintzis, Inspector General for Public Administration attributes the critical situation which forced Greece to turn to the International Monetary Fund to maladministration and corruption. «If we didn't have corruption, which costs Greece € 20 billion a year, we wouldn't now have a € 300 billion deficit,» says the Inspector General, who acknowledges that some improvements have been made, but he admits that development of e-governing and streamlining of IT infrastructure will further improve the situation.

«The economic crisis may only intensify small-scale corruption»

You have been the Inspector General for Public Administration since September 2004. What makes your report for 2009 different from that for previous years?

The report for 2009 shows that the phenomena of corruption and maladministration are not as severe as they were in previous years. That is encouraging because we will gradually be able to reorganise the public administration. It is a fact that civil servants are now starting to be more careful, and above all, they are trying to do their job. The problem with the public administration is not the corrupted employees, but the indifferent employees.

In which sectors exist the greatest maladministration and corruption problems?

So far it was in the urban planning offices, but now it is in local government and the National Health System. «Unfortunately, god has given so much money to Greece that we don't know how to handle it». Yet we have a massive deficit. So, while the country and people are rich, the state is not, and it is very difficult to perform its functions.

What problems have you found in the healthcare sector?

In 2009 I carried out some inspections in person, the most interesting of which are shown in the findings of my report. The findings relating to the healthcare sector have to do with medical certificates used before the courts, and the pharmaceutical expenditure on treatments for people suffering from thalassaemia. Around 3,000 people in Greece suffer from thalassaemia. They all receive blood transfusions and follow a life-long course of iron-chelating therapy. Very expensive medicines are used in these cases which are covered by the IKA (Social Insurance Institute) Fund and other social insurance funds. However, cases of induced prescribing have been identified.

I also carried out inspections at hospitals where I found that certificates are being issued to individuals for hospitalisation, medical tests and follow-up at outpatient clinics so that these certificates can be used in the courts. It is very easy to obtain a medical certificate in order to secure a postponement of a court hearing. In the majority of such cases the certificate is either false or forged. However, relying on those certificates the courts postpone hearings. An expert is only sent when there are a lot of postponements. However, it is rare for these certificates to be found to be false.

What factors have led to this phenomenon emerging?

Many. The civil servants themselves, politicians, the organisational chart, the very structure of the

state, our legal culture, and citizens themselves who often condemn corruptions but turn to it in practice.

Do the inspections generate results?

Inspections have two objectives. Discouragement and prevention. The sanctions imposed lead to general prevention, in the sense that other civil servants become afraid and start doing their jobs. Inspections are necessary and unfortunately only random inspections have been carried out. There are not enough inspectors to carry out scheduled inspections and that is why they carry out only random inspections.

Can the economic crisis worsen corruption?

In a sense it could. On the other hand, when there is no money or economic activity, there is no reason to turn to extravagant acts of corruption. In short, the economic crisis may intensify small-scale corruption but no large-scale corruption can develop.

> “Streamlining of the IT infrastructure of the healthcare sector is one of the key points in eliminating waste of resources and in organising the system”

Is corruption responsible for the situation we are in today?

It is a vicious circle. Clearly, if we didn't have corruption which costs € 20 billion a year, if we didn't have so much corruption over the last 15 years, we wouldn't now have a € 300 billion deficit.

What changes have you proposed to reduce cases of maladministration?

To improve the public administration I have proposed:

a. reintroduction of the restriction on use of local employees as civil servants or functionaries in critical or important sectors of the state such as justice, the police, the coast guard, the tax offices, cadastral offices, planning departments, and so on.
b. the allocation of competences and human resources per body or service based on real needs using rational criteria, so as to avoid «overcrowding» of certain better paid positions, which is achieved using various methods such as transfers, secondment, etc.
c. rotation in positions of responsibility.
d. privatisation of those sectors of the state which do not meet the imperium and fiscus requirements, but allowing the state to retain a regulatory or supervisory role in those sectors.
e. preparation of new salary-scales for employees based on meritocratic criteria, and connecting pay with productivity.
f. evaluation of public entities and their human resources, based on targets set, as part of strategic programmes to be prepared.
g. a reduction in bureaucracy by constantly simplifying bureaucratic procedures such as cases being handled using one's-man-job or one-stop-shop systems where that is feasible, and by fully developing and implementing e-governing. It would also be useful for the state to have trust in its citizens and not raise various bureaucratic barriers in its efforts to protect itself.
h. constant improvements to the transparency of administrative actions, especially online.
i. disciplinary boards with capable employees trained for that purpose, so as to make more objective decisions.
j. trade union representatives limiting themselves purely to their trade union-related duties.
k. improving inspection and self-regulatory mechanisms and systems in central and local government, with more substantive and efficient control over level 1 and 2 local government authorities by the Regions and the introduction of controls over municipal enterprises.
l. incentives for really worthy employees by supervisors. More responsible evaluation reports. Almost all employees receive excellent evaluations, making it impossible for career advancement boards to select those employees who really are excellent.

m. supervisors within departments exercising the powers as disciplinarers instead of carrying out pointless administrative examinations under oath which result in nothing.
n. promoted employees should be sent to another department because in many cases it is difficult for them to impose their will on former colleagues who were previously at the same level.
o. the State and public law legal entities pay third parties huge amounts as compensation for acts or failures to act, intended or negligent, of their employees during the course of their duties. The existing legislation according to which the relevant amounts are paid by the responsible employees must be implemented.

All these proposals need to be implemented at the same time. If they are implemented at the same time, the situation will improve.

Is every complaint addressed to your office investigated?

Every complaint that is specific enough in terms of its facts, so that it can be checked out, is investigated. Vague complaints are not investigated.

Approximately how many complaints are received every year?

The inspectorates receive around 4,500 to 5,000 complaints per year.

THE GENERAL INSPECTORATE

The Inspector General for Public Administration was established by Law 3074/2002 and officially began operating in 2003. The Inspector General's mission is to ensure efficient running of the public administration, to monitor and evaluate the work of public administration inspectors and to identify cases of corruption and maladministration which result to disciplinary procedures being initiated against employees who have committed disciplinary or criminal offences.

Your report mentions that the number of named complaints has risen. Why is that happening?

People are no longer afraid to submit complaints. That is a very encouraging message.

Do you think that the shift to the digital age will change things?

It will help a lot, because it will cut the «umbilical cord' between citizens and civil servants.

In the healthcare sector in particular, what role will computerisation play? The Hellenic Association of Pharmaceutical Companies (SFEE) has been stressing for years that computerisation of the healthcare system is the only way forward.

Streamlining of IT infrastructure in the healthcare sector will be one of the key points in stopping waste of resources and in organising the system.

There are currently 14 inspectorates and investigative bodies. Are there any overlaps in what they do? How can they be coordinated?

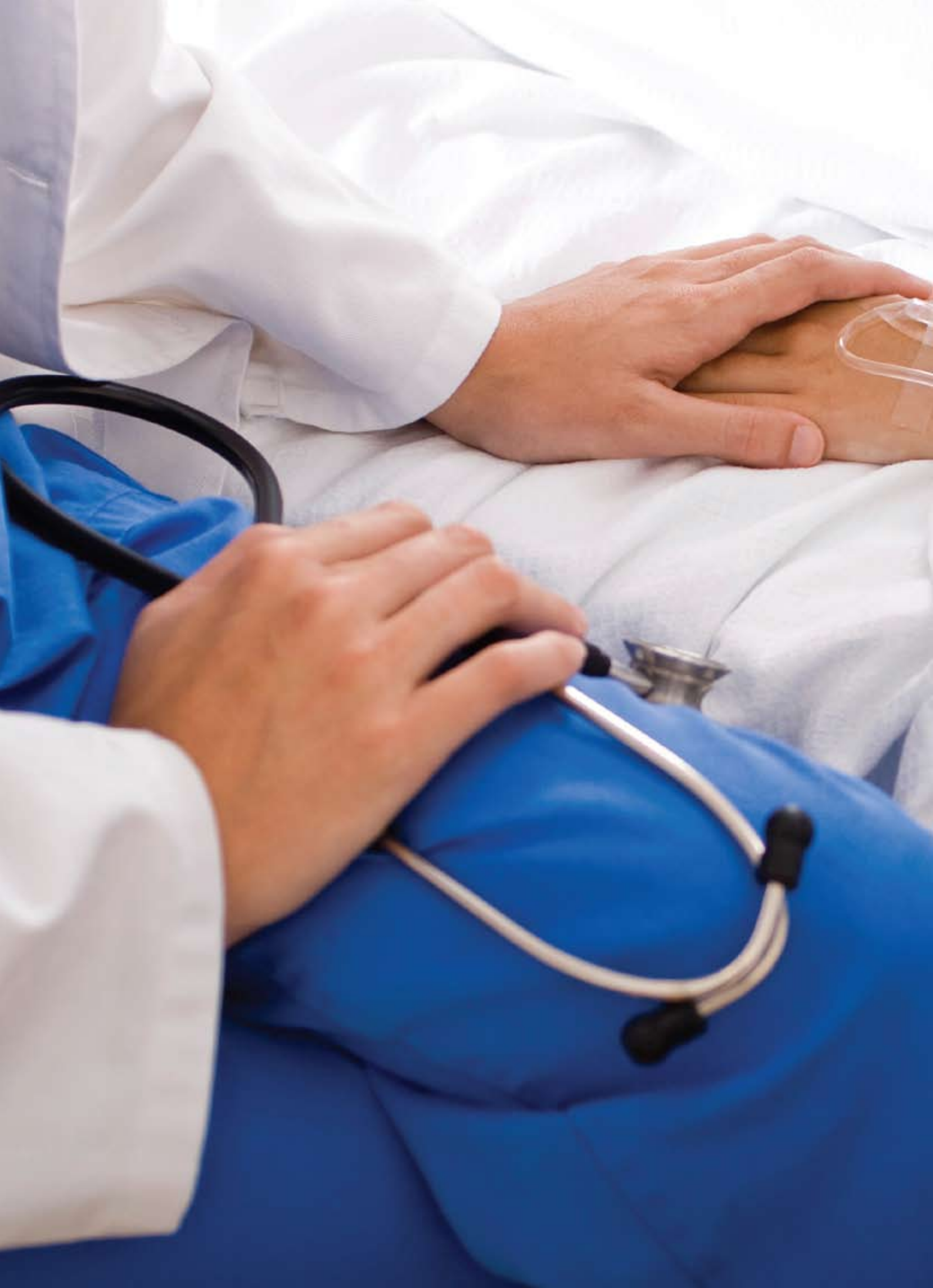
The inspectorates and investigative bodies need to be unified into a single body. The State will decide the format that it will take. Until the inspectorates are unified, I fill the gap by establishing joint inspection committees, by selecting someone from each inspectorate. It has been noted that the findings from these joint committees are better documented and entail time and cost savings of 75%.

In this year's report you mention numerous objections to disciplinary decisions. Clearly, you consider that they were lenient...

Either they were lenient or the first instance boards had made a mistake.

What is that leniency due to?

It's due to the composition of the disciplinary boards. They consist of two trade union representatives and three colleagues of the employee being accused. It is very difficult to prosecute an employee who is a colleague of yours. The Ministry of Interior is planning to address this by establishing general disciplinary boards, not specific ones. I don't know when it will be implemented...



CLINICAL RESEARCH

Investment in the future

Everything indicates that 2011 will be a turning point for research and innovation, since the European Commission recently approved the largest amount it has ever approved in its history, namely € 6.4 billion for R&D.

With this extra financing for research and innovation, the European Commission is seeking to bolster Europe's competitiveness and the endeavour to address major challenges such as climate change, food safety, health and an ageing population. A significant part of this immense sum by EU standards so far, in fact € 700 million, will be allocated to the health and new pharmaceuticals sector. Of that figure, around € 200 million, almost 1/3 of the total amount allocated to the sensitive health sector, will be invested in clinical trials with a dual aim of making the development and introduction of new pharmaceuticals to the market, faster and safer. The European Commissioner for R&D, Màire Geoghegan Quinn, considers that investments in research and innovation are the only smart way to emerge from the crisis and move towards sustainable and socially equitable development. Moreover, the € 6.4 billion package is expected to create more than 165,000 jobs in Europe.

As part of this € 6.4 billion financing package, the Innovative Medicines Initiative (IMI) received € 1 billion, which will be added to financing of the same level provided by the European Federation of Pharmaceutical Industries and Associations.

IMI: the Innovative Medicines Initiative

The objective of the IMI is to accelerate the discovery and development of new, effective, safer medicines for illnesses such as cancer, inflammatory and infectious diseases, by overcoming any difficulties in the process of developing those medicines and by utilising new methods and tools to optimise this process.

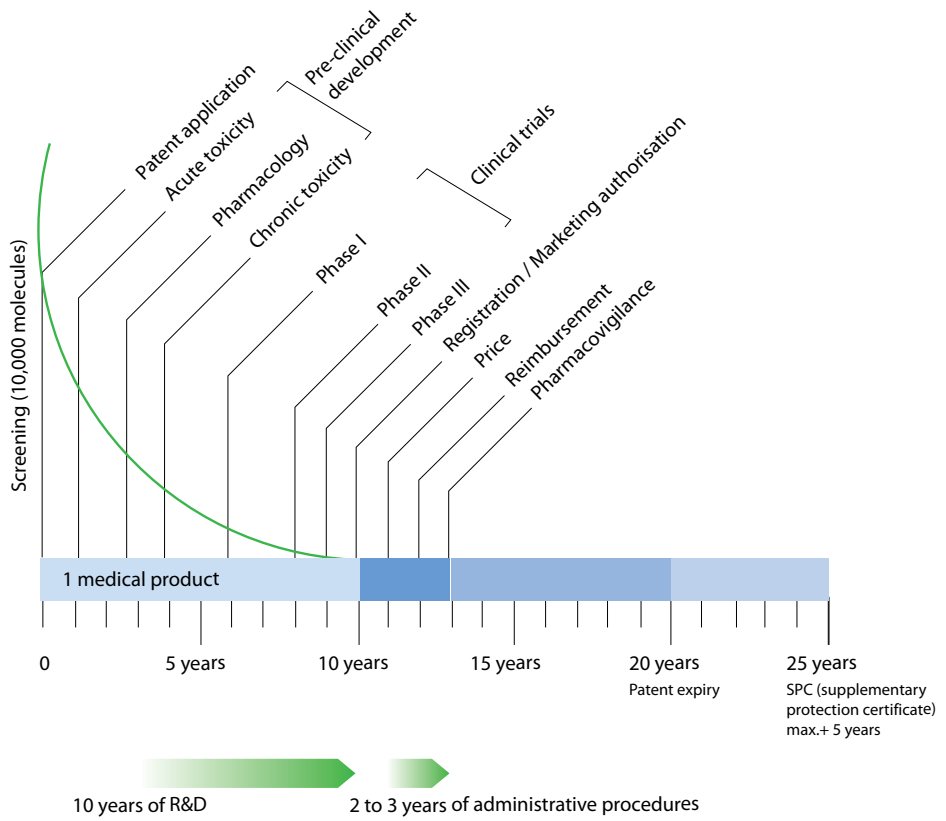
«IMI represents an innovative attempt to solve complex problems associated with the need to modernise and improve the drug development process. IMI brings together industry and the academic communities to develop appropriate tools that will support the discovery of innovative medicines,» explains the European Commissioner. The IMI will also finance research programmes to improve data exchanges between industry and the scientific community, which is a major aspect of knowledge management. Prof. Michel Goldman, IMI Executive Director, has stated that through the IMI, the pharmaceutical industry is building new research models which are based on collaboration and transparency. That is why an attempt is being made as part of the I initiative to attract and collaborate with scientists / scientific bodies from all over Europe which will work together with the pharmaceutical enterprises. Through such partnership, the participants will share not just scientific knowledge and innovations, but also the costs and risks associated with developing a new medicine.

Table 1 shows the allocation of approximately € 281 million to 15 research programmes following the Initiative's first call in 2008. The response to the second call for expressions of interest in 2009 was also immense, with 124 expressions of interest by 1,118 participants for research into rapid diagnosis of infections, inflammatory diseases and oncological bio-indicators. Research in these fields is considered to be of the utmost importance for the most efficient possible, safest and rapid process of discovering new medicines today. Other equally important objectives of the IMI are timely treatment of illnesses and greater accuracy when it comes to the administration of medicines by healthcare professionals.

According to Mr. Goldman, we are wasting a lot of time because we cannot find the patients for which a given molecule may be effective. That is very important for diseases such as cancer, for example, and Mr. Goldman stresses that a lot is invested in this field.

> "The European Commissioner for R&D, Màire Geoghegan Quinn, considers that investments in research and innovation are the only smart way to emerge from the crisis and move towards sustainable and socially equitable development"

PHASES OF THE RESEARCH AND DEVELOPMENT PROCESS



Source: *EFPIA 2010*

The difficulties in developing new medicines

It is estimated that for every 100,000 new molecules investigated, only 10 finally reach the market as medicines and only 2 of them are profitable for the company producing them.

R&D for a new medicine is an investment entailing high business risk since it requires 12-13 years to get from lab to market, and the cost is around € 1 billion.

According to recently available data, the pharmaceutical industry in the EU-27 invests the highest percentage of all investments by all industrial sectors in research and the new innovative medicines (19.3%) (Diagram 1). Compared to other production sectors, the pharmaceutical sector is constantly seeking out innovative ideas to develop and to create new, effective medicines.

It is worth stressing in relation to the increase in investments in the development of new medicines that while US companies were spending USD 5.5 billion on R&D into medicines and pharmaceutical products in 1980, that figure had reached USD 17 billion in 2003. The switch from chemistry to molecular biology when developing medicines played a major role in this.

TABLE 1 INNOVATIVE MEDICINES INITIATIVE ONGOING PROJECTS

Acronym	EFPIA Coordinator	Budget (M€)
SAFE-T	Novartis Pharma	35,9
PROTECT	European Medicines Agency	29,8
SUMMIT	Boehringer Ingelheim	28,4
PHARMA-COG	GSK	27,7
IMIDIA	Sanofi-Aventis	25,4
NEWSMEDS	Lundbeck	24,0
U-BIOPRED	Novartis Pharma	20,6
EUROPAIN	AstraZeneca	18,2
PROactive	Chiesi Farmaceutici	16,7
MARCAR	Novartis Pharma	13,3
E-TOX	Novartis Pharma	12,9
EMTRAIN	AstraZeneca	7,7
EU2P	F.Hoffman – La Roche	7,2
Pharma Train	Eur. Federation of Courses	6,6
SafeSciMET	F.Hoffman – La Roche	6,3

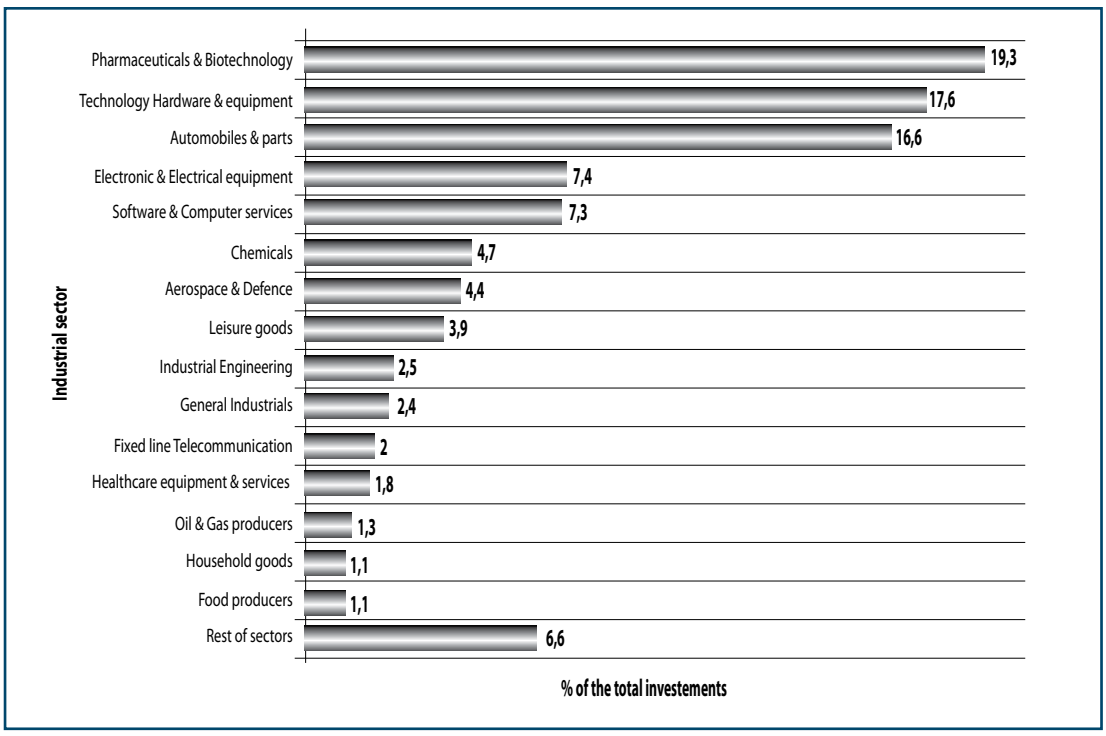
The most common causes for stopping the development of a potential medicine are listed below:

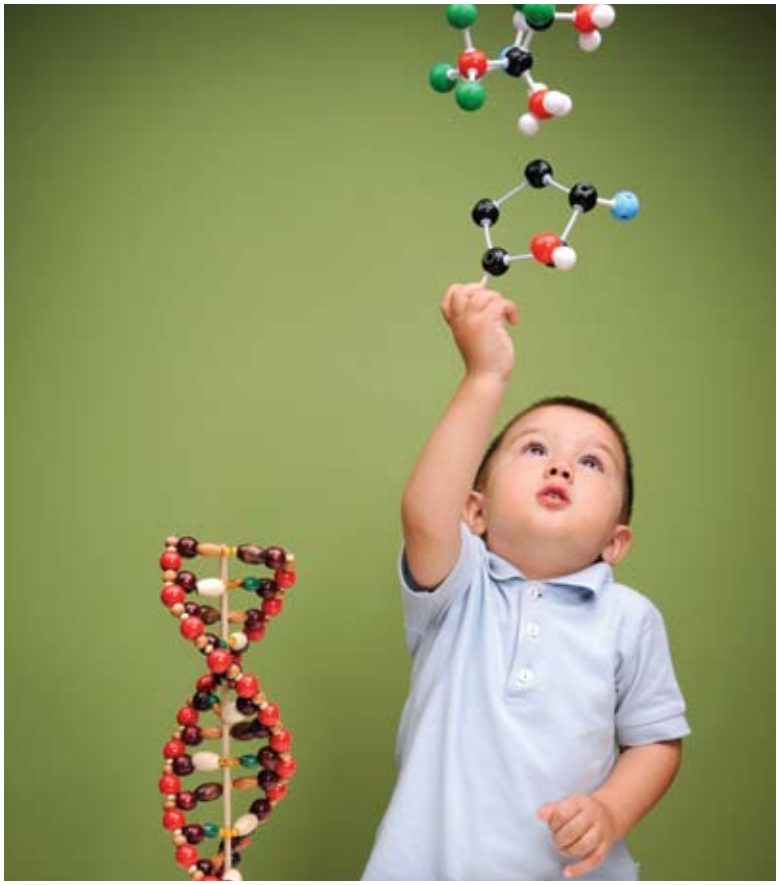
- Lack of efficacy (25% likelihood), when the potential medicine does not have the expected clinical results,
- Toxicological findings in preclinical testing (20% likelihood) when the potential medicine has adverse effects in animal models,
- Safety-related findings on the medicine being tested (12%) during clinical trials.

Under those circumstances, it is an issue of vital importance for the pharmaceutical industry to be able to predict the likely failure of medicines as soon as possible. That could significantly increase research productivity and accelerate the discovery and development of more effective and safer medicines. Other major challenges facing scientists include developing medicines for rare diseases, creating innovative, effective antibiotics, and the need for strategies to combat the tolerance of certain microbes to treatment. Furthermore, the search for ways to answer the challenges posed by demographic changes and the ageing population is also important.

> “According to recently available data, the pharmaceutical industry in the EU-27 invests the highest percentage of all investments by all industrial sectors in research and the new innovative medicines (19.3%)”

Ranking of industrial sectors by overall R&D intensity





THE BENEFITS OF CLINICAL RESEARCH

For the national economy: Foreign investments flowing into Greece
- **New jobs in the health sector**
- **Human resources utilised in specialised sectors.**

For the National Health System:
- **Research know-how is acquired**
- **Better organisation and equipment**
- **Revenues**

For patients:
- **Rapid access to new treatments**
- **Improved treatment for various conditions diseases**
- **More treatment choices**
- **Increase in life expectancy**
- **Better quality of life**

For healthcare professionals:
- **New medicines available**
- **Ability to choose the most suitable treatment in each case**
- **Answers to specific scientific questions**
- **Extended knowledge and understanding of various diseases**
- **More experience in treating and handling various diseases**

«Health is one of the most important challenges facing society»

EXCLUSIVE INTERVIEW FOR «ΘΕΣΕΙΣ»

Mark English, the European Commission Spokesperson for R&D made the following comments exclusively to «ΘΕΣΕΙΣ». «As far as the health research sector is concerned, we have placed major emphasis on innovation and Small/Medium Enterprises (SMEs). In general, our objective is to include SMEs in health research, and more than € 200 million will be spent on 10 projects focused on SMEs. At the same time, the emphasis being placed on clinical trials is also clear, for which a budget of € 200 million has also been set aside. In effect, we are introducing large-scale, strategically important programmes to answer questions relating to immunology and epigenetics. Important efforts are also being made concerning diabetes, where major international partnerships have been developed, and in relation to studies of the brain».

In the interview which follows (on pages 34-39) Mr. English presents the EU's plans and decisions relating to research, science and innovation exclusively to «ΘΕΣΕΙΣ».

«IT IS OUR OBLIGATION AND OUR DUTY TO ENCOURAGE AND PROMOTE CLINICAL TRIALS IN OUR COUNTRY»

Konstantinos A. Dimopoulos,

Chairman of the National Ethics Committee, Professor Emeritus and former Chancellor of the University of Athens

«T he National Ethics Committee applauds and encourages initiatives to establish and codify rules in the area of bioethics and ethics in general, particularly in the field of clinical trials – which is the Committee's main area of competence and responsibility.

The National Ethics Committee takes the view that rules and regulations are not enough; there is always the danger that they might be circumvented, or even suppressed or revoked. Just as necessary, indeed essential, as the existence of rules is that those working in the health sector, and particularly those involved in ensuring the efficacy of a medicinal product, should see their work as a sacred duty, a choice they have consciously taken.

We are all aware that the discovery and use of new medicines have contributed in curing serious diseases, in prolonging life expectancy and, above all, improving our quality of life. This is why we are grateful to the great researchers who, through their hard efforts, have promoted the discovery of new medicinal products.

Clinical trials must be carried out so as to ensure the efficacy and safety of a new medicine. The conduct of clinical trials is a valuable opportunity to promote research often published in journals of international standing. At Clinical trials are an alternative source of funding, which may help researchers meet some of their needs for technological equipment, or personnel with specialised knowledge.

We note with satisfaction that major pharmaceutical enterprises trust in Greek scientists and Greek clinics and hospitals to carry out a large number of clinical trials. This fact confirms the trust of foreign research centers in Greek scientists and their skills in carrying out high quality research.

We consider it our duty to simplify and reduce to a minimum the time-consuming procedures followed in the past, in order to make it easier for clinical trials to be conducted in Greece.

It is our belief that the very few cases in which the necessary ethical principles were not observed should not be allowed to serve as a pretext or justification for delays and postponements of trials the vast majority of which are conducted by highly respected and experienced scientists with a great sense of responsibility and a profound respect for the human personality.

SFEE's positions

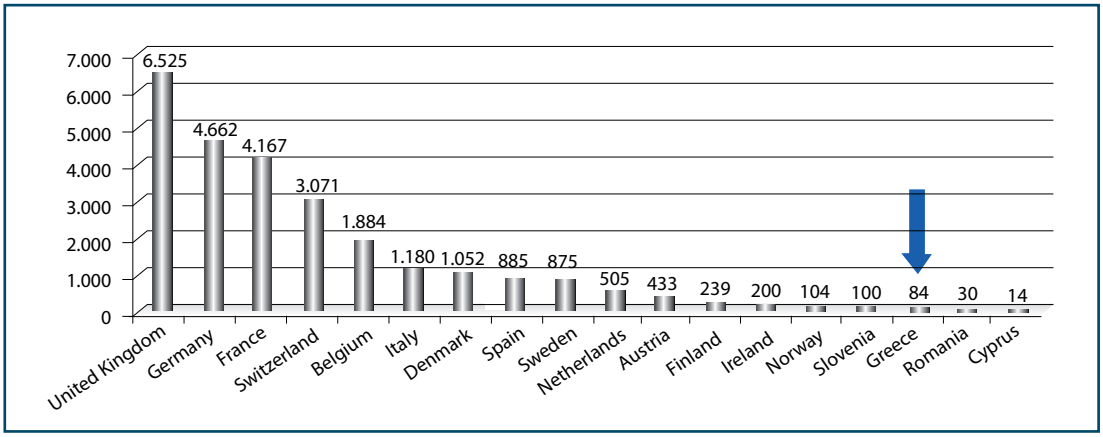
It is the unwavering position of the Hellenic Association of Pharmaceutical Companies that, «the clinical research sector is exceptionally important for the social welfare state, and for the country's economy. Clinical research creates specialised jobs, and imports international know-how and incorporates it into the Greek development model. With suitable economic, tax and development incentives, and by developing links between universities and research, impressive results can be achieved.

Attracting investments in research, with an emphasis on clinical trials being held in Greece, participation of Greek researchers in international partnerships and networks such as the European Clinical Research Infrastructure Network (ECRIN) and the adoption of incentives for research such as those in the context of the Innovative Medicines Initiative (IMI) are the way forward, and are a path which Greece must go down. Greece has also the qualifications and is in the vanguard in terms of academic training for its researchers, the level of experience of the public authorities and the various committees of the National Organisation for Medicines and the National Professional Ethics Committee, in evaluating, approving and monitoring clinical trials. Greece can become a centre for the conduct of clinical trials of international importance, thereby generating major benefits for public health and the national economy».

The data presented at the Pharma Money Conference 2010 show that Greece is well behind in pharmaceutical research and loses around € 200 million every year due to bureaucracy! At the same time, other countries of the EU-27, such as the Czech Republic, Romania and Hungary have made remarkable progress in this sector. All speakers at the Conference called upon the government to shorten time-consuming procedures which are strangling the prospects for the growth of clinical research in Greece. Today around 250 clinical trials are being held in Greece, with a total budget of only € 40 million approximately, which is mainly being invested by the 30 largest pharmaceutical industries worldwide.

> “Greece can become a centre for the conduct of clinical trials of international importance, thereby generating major benefits for public health and the national economy”

PHARMACEUTICAL INDUSTRY R&D IN EUROPE **EFPIA 2007 FIGURES**



Mr. John Hondrelis, Sr Manager Clinical Operations & Regulatory Affairs in Pharmaserve-Lilly S.A.C.I., pointed out that that amount could be quadrupled if authorisations could be obtained in good time from the competent authorities. According to data presented at the conference, the pharmaceutical industry invests more than USD 50 billion worldwide on R&D for medicines. Around 1/3 of that amount relates to clinical trials, which create new jobs and promote the transfer of know-how. It is indicative that worldwide, for each new job in the clinical research sector, 3.7 jobs are created in other sectors.

Greece is not lagging behind either in terms of potential in this field or in terms of human resources. The expertise exists, as does the highly trained staff as well as a high degree of know-how. However, better organisation of the structures involved is needed as well as a single operating framework for them as part of the ongoing effort to bring Greece into line with the EU.

It is SFEE's unwavering position that, «modern clinical research into cutting-edge science means savings in the time and money required to develop new pharmaceutical substances, with the result that citizens can have immediate access to all innovative medicines and benefit from new treatment options without delay. New innovative medicines and new treatments lead to better public health, which is a necessary structural element of public health, economic growth and a prosperous society. We believe that in difficult times, and in areas where there is intense competition among countries for research activities related to Health, such as the clinical trials, close collaboration between all players is required, so as to find consensual solutions which will highlight our country's dynamism in this field and will make Greece a reliable European partner». ■

MARK ENGLISH

EU Spokesperson for Research, Innovation and Science

«Investments in research and innovation are vital if Europe is to maintain its position as a provider of excellent healthcare and a global leader in medical research», declares Mark English EU Spokesperson for Research, Innovation and Science

«Europe must respond to the challenges»

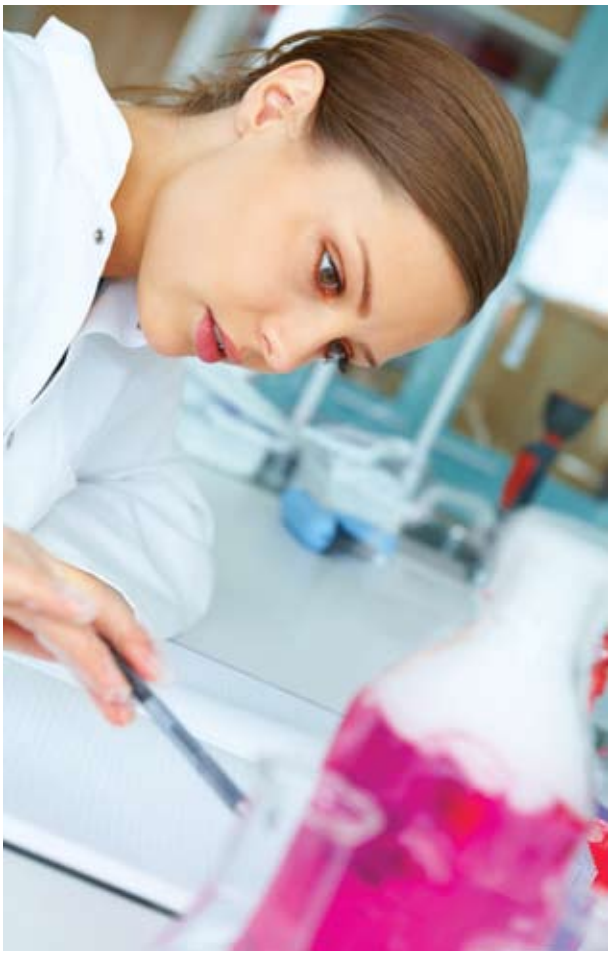
Mr English, FTP7 is aiming to improve the health of the European citizens. In which ways will this be achieved?

With a budget of €6.1 billion for the period 2007–2013, the Health theme of the Seventh Framework Programme for Research and Technological Development (FP7) represents over 9% of the total EU FP7 budget. This provides a significant drive for the improvement of the health of both European citizens and global health and also for the competitiveness of European health related industries and businesses.

By funding transnational collaborative research projects, FP7 Health brings together excellent teams of innovative researchers from different European and associated countries as well as other international partners, working in universities, research centres, hospitals, small and medium enterprises and large industries and associations, all cooperating on ambitious objectives that would be impossible to achieve alone or in a single country. The participants in these projects enjoy the benefits of working co-operatively in a consortium composed of partners with a complementary range of skill sets and areas of expertise. This means that they are able to tackle significantly larger objectives than would be possible if working alone, by virtue of increased financial or human resources, access to samples or infrastructures and so on. Furthermore, projects can feature partners with expertise not only in knowledge creation and research but also in knowledge exploitation and innovation. Thus, there is the opportunity for teams to develop and diversify their science and technology-based knowledge in various domains as well as the ability to undergo staff exchange and training.

Our current research priorities are listed in the attached «work-programme» (the document which indicates the topics for which we invite the research community to submit applications for funding to undertake research). This year's work-programme has some novel features, including an emphasis on the participation of small and medium sized enterprises and on the funding of clinical trials. These are explained in greater detail in the accompanying documents available from the links provided below.

With the publication (19 July 2010) of our 2011 work programme and its corresponding calls for research proposals we describe research topics which span the continuum from basic to translational research. The deadlines



for submitting proposals through the online application system are 13 October and 20 November, dependent on application type, and the work programme has a budget of €681 million.

Eight (of a total of 51) topics aim to support clinical trials to verify the safety and efficacy of various treatments and to promote the translation of research into clinical practice, each of which may result in several projects receiving up to €6 million. Successful projects will target results increasing therapeutic options for patients and will stimulate the implementation of best practice in Member States. Topics address issues as diverse as regenerative medicine, brain-related diseases, human development and ageing, antimicrobial drug resistance, cancer, cardiovascular diseases, diabetes and obesity, and off-patent medicines for children.

Ten further topics require that at least 15% or 30% of the EU grant is allocated to small and medium-sized enterprises (SMEs) and two of these topics will support ambitious «high impact» research initiatives in immunisation and in epi-genomics with up to € 30 million EU funding, addressing the spectrum of research from knowledge generation to translational research and product development, as well as education and training. The remaining topics address our efforts on a more limited set of subjects than in previous years including research to tackle lifestyle-related and global health issues. Subsequent years will see investment directed elsewhere to ensure full and effective coverage of the FP7 Health programme.

We believe that the calls respond to the needs of the research community, will support efforts to embed the economic recovery by focussing on research intensive, SMEs, and will in the long term lead to developments, discoveries and treatments that will benefit all European citizens. In that way they are in line with the priorities of the Commissioner for Research, Innovation and Science, Máire Geoghegan-Quinn, who has highlighted supporting innovation as her priority and identified health and the ageing population among the major societal challenges to be addressed by the full package of 2011 work programmes (also dealing with, inter alia climate change, energy and food security and with a total budget of € 6.4 billion*).

How will the drug development process be facilitated and modernised?

The drug development process is undoubtedly a very complex, costly and time consuming endeavour. It has been estimated that it on average takes some 15 years and costs more than 1 billion EUR to develop a new drug. A major problem is the failure of a drug at the late stages of clinical trials when a large investment in research already has been made and when patient expectations have been raised. The Innovative Medicines Initiative, IMI, aims at resolving some key problems in the

drug development process by supporting the more rapid discovery and development of better medicines for patients. In doing so it will enhance Europe's competitiveness by ensuring that its biopharmaceutical sector remains a dynamic high-technology sector.

IMI has had a successful start with over 250 expressions of interest, bringing together over 2400 applicants for its first two calls. 15 projects under the first call are ongoing with over 400 participants from 22 countries, including 155 academic and research organisations. They are receiving about 110 million € of IMI funding and about 132 million € of pharmaceutical industry in-kind contribution. The projects funded address areas such as liver toxicity, pharmaco-vigilance, in silico prediction of drug toxicity, pain, diabetes, depression and schizophrenia, Alzheimer's, asthma and the development of research training networks. (Fact sheets can be found on the IMI website).

> "The Innovative Medicines Initiative, IMI, aims at resolving some key problems in the drug development process by supporting the more rapid discovery and development of better medicines for patients"

The IMI published its second Call for Proposals on 27 November 2009. The evaluation process is in progress. The selected projects are expected to kick off end of 2010 or beginning of 2011. Topics include cancer biomarkers, inflammation, diagnostic tools for infectious diseases, and development of new tools for knowledge management. An IMI budget of about € 78 million is available. (Details are again on the IMI website).

Finally, the IMI expects to launch its third Call for Proposals in late 2010. Topics are expected to include immunological safety and or drug-induced toxicity in various organs. An IMI budget of about €98 million is foreseen http://www.imi-europe.org/Pages/default.aspx

How many ongoing clinical trials are there in Europe?

Thanks to the European legislation requiring that all applications for interventional clinical trials on medicinal products be registered in the EudraCT database, we have exact figures on the number of new trials launched every year in Europe since the introduction of said database. Because each trial will last a different period of time (sometimes they can be quick such as in the case of Phase I trials or they can last for many years), it is not possible to give a figure for the number of clinical trials ongoing at a given point in time.

The figures are: 2007: 5028 CTs; 2008: 4818 CTs; 2009: 4491 CTs. Of the trials started in 2009, 933 (or 21%) were multinational clinical trials. Interestingly, this relatively small proportion of clinical trials accounted for 70% of the patients to be recruited, demonstrating the importance of multinational clinical trials.

No detailed information on the number of trials started in a year is readily available for other types of clinical trials, such as surgery or radiotherapy trials or trials on medical devices, let alone observational studies. However, the project ICREL (Impact on clinical research of European legislation) funded in 2008 with an EU contribution of € 1M has gathered data on this issue for the years 2003 and 2007. According to the ICREL report, more than 900 clinical trials were approved with medicinal products in 2007 an increase of 21% over 2003. Trials testing surgical procedures decreased from more than 700 in 2003 to less than 500 in 2007, whereas trials on radiotherapy increased (from more than 400 to more than 600). More than 5000 trials were approved testing other interventions in both 2003 and 2007 and around 9000 observational studies were approved in both years. The report is available at http://www.efgcp.be/icrel/. (data are in table 63 on page 139; detailed information is in a statistical annex to the report, available at the

mentioned website).

The EudraCT database will become publicly accessible soon. A final release date had to be postponed because of some technical difficulties in the database migration (see news on release version 8 of EurdaCT). The internet address for the database is https://eudract.ema.europa.eu/."

What are the challenges that Europe has to face concerning the health of its citizens?

The importance of the health theme in Europe 2020 has been emphasised by both President Barroso and Commissioner Geoghegan-Quinn, with an acknowledgement that R&D and innovation policies should be refocused on the challenges facing our society, such as climate change, energy and resource efficiency, health and demographic change. Every link should be strengthened in the innovation chain, from «blue sky» research to commercialisation. Investments in research and innovation are clearly vital if Europe is to maintain its position as a provider of excellent healthcare and a global leader in medical research.

FP7 Health investments address these challenges by supporting a range of research activities and initiatives focusing on health biotechnology, translational research, the optimisation of healthcare delivery to citizens and support to other EU policies. Their combined aim is to improve the health of European citizens, to increase the competitiveness and innovative capacity of European health related industries and business and to address global health issues. By comparison with earlier framework programmes, health research in FP7 is characterised by greater emphasis on translating basic knowledge into clinical applications, including the rigorous scientific validation of results, a prerequisite for regulatory approval of new products. Besides the disease-oriented priority areas, some overarching issues such as child health, the ageing population and gender related medical aspects are identified as strategic targets, as is support to innovative small and medium enterprises.

FP7 has also seen the establishment of the IMI joint undertaking as an autonomous body, with a further €1bn contribution from FP7-Health and €1bn in kind from EFPIA (the European Federation of Pharmaceutical Industries and Associations) and its member companies. IMI represents an innovative attempt to solve complex problems associated with the need to modernise and improve the drug development process. While investment in European pharmaceutical research and development has decreased dramatically in the last decade, the total costs from research to market for a single drug are increasing. Bringing together industry and the academic communities to develop pre-competitive tools aiding drug develop-

ment, IMI provides a large pool of expertise to industry and early stage validation of work to academia, with the aim that Europeans should benefit from improved pharmaceuticals and a flourishing industry.

Cooperation between member states and the European Commission has also seen the launch of the Joint Programming pilot initiative on Neurodegenerative Diseases (in particular Alzheimer's disease). This initiative recognises the impact that neurodegenerative diseases will have on an ageing European society and

> "While investment in European pharmaceutical research and development has decreased dramatically in the last decade, the total costs from research to market for a single drug are increasing"

aims to allow member states to join forces to establish a strategic research agenda to tackle the scientific, clinical and societal challenges that these diseases present.

Cooperation with international partners is also a feature of FP7, with the recent coordinated FP7-Africa-2010 call for proposals addressing research aspects of the Africa-EU strategic partnership. A number of health research projects will be funded, each of which will feature a minimum of two partners from African countries. Cooperation with other regions of the world has also included Russia, India and may in future feature Brazil, China, the Mediterranean, Latin America and elsewhere.

Excellence, support for innovation and responses to society's grand challenges are all clearly reflected in these projects and initiatives, and will continue to be supported as the health programme of FP7 progresses. Future calls for research proposals are likely to see a strategic focusing of funds, annually, on a more limited set of areas, for example, on the effects of lifestyle on health or on supporting clinical trials to verify the safety and efficacy of various therapies, and will enable a critical mass of resources to be directed at specific topics. Many more topics will be designed with the participation of innovative small and medium-sized enterprises in mind, which will significantly increase their involvement.

Greater emphasis will be put on large-scale integrating projects, for example, in the field of personalised medicine. Building on approximately € 1bn of investment in groundbreaking research in FP6, 7 and in other programmes, results from the «-omics» disciplines will be studied with the aim of understanding how individual genetic and epigenetic variation is linked with disease, and of better tailoring medical treatments to individual patient needs.

Such investments in research and innovation are clearly vital if Europe is to maintain its position as a provider of excellent healthcare and a global leader in medical research. FP7 will continue to be in the forefront of efforts to support these goals.

Which illnesses is the European health research targeting?

European health research supports investigation into a wide range of illnesses, as well as «blue sky» research which, while not directly investigating particular diseases, may nevertheless contribute to the general state of knowledge, contributing to developments in these areas.

FP7, and previous programmes, have seen considerable efforts on brain and brain related diseases, other diseases of ageing, the major poverty related diseases of HIV/AIDS, malaria and tuberculosis, new and re-emerging epidemics (e.g. zoonoses), neglected infectious diseases, major diseases such as cancer, cardiovascular disease, diabetes and obesity, and rare diseases, as well as research to tackle microbial drug resistance. ■

For further information on specific project funding please see: http://www.healthcompetence.eu/converis/publicweb/area/1

ANDREW WITTY
GSK CEO and President of EFPIA

« We need shared understandings of value»

«I want this industry to be able to play its part in transforming the lives of patients and supporting the economic strength and competitiveness of Europe» declares Andrew Witty, CEO GlaxoSmithKline & President of European Federation of Pharmaceutical Industries & Associations (EFPIA)

What do you want to achieve for the European pharmaceutical industry during your presidency?

I want this industry to be able to play its part in transforming the lives of patients and supporting the economic strength and competitiveness of Europe.

Pharmaceutical innovation delivers life-transforming healthcare, increased competitiveness, and more efficient healthcare systems. But the challenge of getting medicines to patients across Europe is real. Health services everywhere face enormous challenges. Payers struggle to cope with rapid demographic change, the pace of technological change, and unbridled demand. All of these challenges are compounded by the current financial crisis.

We need to support the development of strong and sustainable industrial base able to research, develop and deliver medicines and vaccines in Europe. I want our Industry to contribute effectively to an economy based on knowledge and innovation for the benefit of patients.

As policymakers seek new approaches for reducing the level and growth in health care spending, we have a unique opportunity to make sure that the right issues are addressed.

In June you called for a new dialogue between governments and the pharmaceutical industry. What are your hopes for this dialogue?

All stakeholders need to change the way they think and act. Industry must demonstrate that we are genuine partners to governments and their agencies.

We must deliver new medicines and vaccines that address unmet need and have demonstrable value. We know that any pharmaceutical innovation is only as good as the added value it brings to the patient. We understand the budgetary constraints impacting Governments, and recognise the increasing desire of governments to identify value in innovation to make difficult funding decisions. We accept that we will only be rewarded for added value.

We must behave ethically. We must continue to look to improve our practices and increase the transparency of what we do to build confidence that our approach is ethical and appropriate.

We must be a source of ideas and solutions to governments, including on increasing funding and more efficient use of budgets. We should collaborate openly with healthcare authorities, HTA assessors and payer bodies to find sustainable solutions for patient access.

Which basic conditions do you think are required by pharmaceutical companies in Europe to launch innovative products and do we have these conditions in Europe?

We must ensure that the current financial crisis does not lead to long-term ramifications that will make it even more difficult to deliver new treatments to patients. Across-the-board price cuts, and measures like international reference pricing, simply compound the current challenges.

Industry has to understand the type of added value that matters to patients and will be funded by payers. The govt is the customer - the signals that payers give through their funding decisions, and the manner in which they welcome and conduct dialogue on and decision-making in value in innovation, have a crucial bearing on us.

> “We must behave ethically. We must continue to look to improve our practices and increase the transparency of what we do to build confidence that our approach is ethical and appropriate”

Ultimately, governments have a responsibility for shaping the industry they end up with, for defining the type of innovation worth paying for, and for the challenges in ensuring medicines reach the patients that need them.

The govts of Europe need to take a strategic decision about the value they place on innovative medicines and the presence of the R&D-based industry.

We seek an environment that incentivises and rewards therapeutic progress, while accepting the need to maintain core characteristics like equity, public funding and heavy regulation.

We need a strategic agenda for health and for the development of new medicines. This should be set with industry to ensure that unmet need is addressed and disease prioritisation is clear.

We need a shift in focus from cost to value. Let’s stop looking at medicines expenditure simply as a cost. What matters is whether a medicine works, responds to patient needs and if so, that it is rewarded. Reward can come in different forms - price-setting or readjustment, unrestricted access for the patient population defined as needing new therapy, and speed of access.

We need shared understandings of value. A key goal for industry is to better understand and predict what authorities expect in terms of therapeutic added benefit and what is deemed worth paying for. Gaining shared understandings will require better dialogue between industry and authorities, prior to the marketing authorisation.

Because of the challenges of providing data at time of launch, evaluation must be flexible. Medicines should be treated on clinical effectiveness as «innocent until proven guilty», rather than «guilty until proven innocent», which is invariably the case at present.

Without some give on all these issues by both industry and payers, there is a possibility that many medicines will not be used within healthcare systems.

Recently EFPIA released a leadership statement on ethical practices, e.g. restricted product sampling and new standards for sales representatives and congresses. What is your strategy as president of EFPIA and CEO of a global pharmaceutical company to align the industry behind this new set of principles?

The Leadership Statement agreed in June is a tangible demonstration of the importance that I, and my fellow CEOs, attach to self-regulation as a means of raising standards across the industry. Going forward, Guidance will be developed by EFPIA to support improved practices in the five areas highlighted in the Statement. Member Associations will be asked to implement the Guidance within 1 year of its issuance. As a CEO, I will also be working to ensure that GSK fully embraces the new Guidance in a timely and comprehensive way.

How do you see the patients’ role within the healthcare system?

Patients, or more accurately their representatives, must be at the heart of decision-mak-

ing. They should be given the ability to make choices, and the information to choose wisely. They should be involved in choices about access, allocation of funding and assessments of value. They should also have a louder voice in the development and registration of new medicines, in HTA, and in the allocation of healthcare resources by governments.

What can be improved for the cooperation between patient organisation and pharmaceutical industry and other partners in the healthcare system?

If we are to move forward, we need to create an equilibrium between the needs of different stakeholders. This doesn't exist currently. The challenge is to find a policy approach that delivers fast access to medicines for patients, enhanced competitiveness, balanced healthcare budgets, and reward for innovation. «Health for all» is something that must be achieved collaboratively by all parties at all levels: local, national and European.

As a necessary step towards this equilibrium patient organisations are becoming increasingly influential and I welcome this development. All stakeholders, including governments, are realizing that the voice of the patient needs to be heard equally alongside that of others. The industry has done a lot of great work with patient organisations and must continue to support them appropriately and ethically ensuring their credibility is not compromised and respecting their independence. In the June Leadership statement EFPIA is calling on companies to fully disclose all details of funding to patient groups to achieve the highest level of transparency.

More and more people seem to buy pharmaceuticals on the internet not realising the danger of possibly counterfeited products. How does the pharmaceutical industry deal with the rising number of counterfeit pharmaceuticals and what can be done to prevent them from entering the European market?

The European industry fully recognises the public health threat posed by internet as a source of counterfeit medicines. The World Health Organization has stated it believes that approximately 50% of medicines sold on-line from unauthorised sources are counterfeit.

> “Gaining shared understandings will require better dialogue between industry and authorities, prior to the marketing authorisation”

However, the proliferation in counterfeit medicines available via the internet is only part of the problem. Fundamental concerns also exist around the lack of regulatory oversight of safe diagnosis, good prescribing practices and effective pharmacovigilance associated with the internet. Tackling all these issues effectively is a significant task and one the industry believes needs to be tackled, initially via a thorough assessment of the problem as it relates o European patients. Here we hope the European Commission will act and table a proposal for action.

In the meantime, the industry will continue to support the draft Directive on falsified medicinal products which is currently looking to tighten the existing European supply chain, and so help minimise the chances of counterfeit medicines reaching patients via legitimate supply channels. Here we believe the most effective solution lies via the introduction of a harmonised approach to product coding, authentication and traceability across Europe (ie. serialisation) based on the use of 2D data matrix, GSI coding standards and Point of Dispense verification. ■

KYRIAKOS SOULIOTIS
President of the Board of the Civil Servants Healthcare Organisation (OPAD)

«Waste of resources must be dealt with»

A strong supporter of electronic prescribing and streamlining of IT infrastructure of the health system, Mr. Kyriakos Souliotis, Lecturer in Health Policy at the University of the Peloponnese and President of the Board of the Civil Servants Healthcare Organisation (OPAD), stresses, «Institutions react on attempts to make progress and change habits».

Mr. Souliotis, which are the main problems faced by the Civil Servants Healthcare Organisation which you chair.

The Organisation's problems can be classified in two categories: (a) structural / organisational problems and (b) financial / administrative problems. Unfortunately, the Organisation has been set up and is being run along purely bureaucratic lines, which does not leave room for sweeping changes and interventions, in order to improve the management of financial resources and to provide better levels of service to insured persons.

Furthermore an extremely serious understaffing problem, creates an environment where any attempt to rationalise the system runs head long into a deeply-rooted attitude of 'it's not possible' or 'no provision exist for this'.

The second category of the problems faced by the Organisation relates to the inability to contain health expenditure, which coupled with late payments, has led to an expansion of the deficit leaving very limited choices available both to the Organisation's management team and to supervisory bodies.

The Organisation's expenditure augmented from € 850 million in 2004 to € 1.7 billion in 2008. What was the cause of this rise?

The data generated by the investigative study we carried out is indeed indicative since it shows a continuous trend of rising healthcare expenditure per insured person even though the com-

pensation amounts remained relatively stable over the entire period examined.

The «relaxation» of measures to contain expenditure which was the practice of health insurance funds over recent years had a direct impact on social budgets.

In addition, an inter-regional comparison of the relevant figures shows that the Organisation's increase of health expenditure is related to the growth in the number of physicians, diagnostic centres, etc. which in turn affects demand for services, often without the latter actually meeting the real needs of the population.

In any case, the ratio of OPAD insured persons per physician, which is on aver-

age 107, indicates first an excessive supply of medical services and second reflects the inability to control transactions and consequently the relevant expenditure.

What steps will you take to address this problem?
Since I have taken up responsibility of the management of the Organisation, I have set an important goal the Organisation: to implement a valid system for recording and processing data relating to healthcare issues (expenditure, medical examinations, medicines, etc.) in order to take decisions based on reliable evidence and to ensure the greatest possible degree of transparency in how the Organisation operates..

However, in parallel with depicting the real financial, organisational and operational status of the Organisation – a process which has been completed – measures have also been taken to rationalise the operation of the Organisation and to contain healthcare expenditure. For example:

> “Monitoring healthcare expenditure in real time would greatly assist management teams and the competent bodies of social security funds since it would highlight the areas in which expenses are rising”

- In June 224 inspecting physicians and dentists were recruited nationwide. The Organisation was assisted in that task by a special committee which evaluated the short-listed candidates. Using selection criteria made it possible to reduce the percentage of non-specialised physicians from 85% to below 50%.

- In an effort to reduce the Organisation’s operational expenditures, we are currently renegotiating rents for the buildings housing the various services of the Organisation and the Municipal / Community Employees Health Fund (TYDKY) nationwide and those negotiations are about to be completed. Reduction of 20% has already been agreed in most cases, and similar reductions are being made with all the Organisation's supply arrangements.

- Maximum prices were set for the first time on special materials used in medical interventions and surgical procedures at associated private clinics, which have brought expenditure down by 50%.

- Adjustments to the framework governing the coverage of medical expenses incurred abroad are being made with the Ministries of Finance and Health, and that process is about to be completed. This is necessary because ambiguities were found in the existing framework, constantly raising the cost.

- The regulation benefits for insured persons will also be reformed by the end of 2010.

- Finally, an online system was developed to monitor lab test requests, which is expected to generate cost savings of 30% of expenditure on such tests. The system is currently being implemented on a pilot basis at more than 700 private physician's surgeries and the number of participants is constantly increasing. Our goal is that the system will be used both for tests and for medicines by the beginning of 2011. That is why we are collaborating directly with three other large social insurance funds (the IKA, OGA and OAEE Funds) as part of a wide-ranging attempt to develop synergies to ensure the viability of the social insurance system.

> "Human resources have been trapped in logic of denial, one might even say fear, of new technologies, even though all international and domestic best practices show spectacular results"

For some time now the Hellenic Association of Pharmaceutical Companies (SFEE) has been stressing that an electronic prescribing system and streamlining of IT infrastructure for social insurance funds and public hospitals is the only way forward for rationalising expenditure. What is your opinion?
Monitoring healthcare expenditure in real time would greatly assist management teams and the competent bodies of social security funds since it would highlight the areas in which expenses are rising.

I consider that the sense that one is being monitored, especially at sectors where expenditure is incurred, namely physician's surgeries, will make a decisive contribution to the containment of expenditure.

Why we are so far behind on this issue even though everyone believes in the immense benefits that it would have for the healthcare sector?
The issue is complex; In my opinion it is primarily a matter of will, not just political will but also administrative will. There are many players involved in this complex game and I am not just referring to those who have reason to be «concerned» about the implementation of an electronic data recording and auditing system.

Institutions themselves – many of which are anachronistic – act as a brake on attempts to make progress and to change habits. Human resources have been trapped in logic of denial, one might even say fear, of new technologies, even though all international and domestic best practices show spectacular results. I consider that the partnership approach which the four largest social insurance funds in the country are gradually adopting will make a decisive contribution to addressing such problems.

The IKA Fund has already begun to use the electronic prescribing system. What is the situation with OPAD?

The management teams of the four large social insurance funds are coordinating and planning joint, non-overlapping actions. In that context, at OPAD we have already begun pilot implementation of an online system to monitor requests for lab tests and the OAEE Fund is expected to implement a similar system for pharmaceuticals on a pilot basis. At present, the systems are being tested and improved before being implemented universally by all funds.

> “I am personally in favour of a system of pre-purchase of insurance rights by Social Insurance Funds so that the NHS acquires liquidity and negotiating power in order to achieve better prices”

The system already in place at the IKA Fund operates retroactively and we are preparing a collaborative plan to examine whether it can be used to handle prescriptions from OPAD.

What objective difficulties does the whole venture face?

There are several difficulties, but the venture is so important that we must overcome them. Adjustments will be needed to the legislative framework, to infrastructure, to training, and everyone will need to put in a lot of work. In addition, the supply side will need to support this entire effort which is to the benefit of everyone. In any case, the threat to the viability of the social insurance funds is a threat to the entire healthcare sector.

When we talk about health expenditure, most people focus on medicines, but medicines only accounts for 20% of the public expenditure. Why do you believe that medicinal products are being targeted and how can the other 80% of expenditure be effectively controlled?

I have dealt with this issue over recent years at the university and as part of my research. It is true that all studies do show that inflationary tendencies appear in all categories of healthcare services and not just in medicines.

However, I do not think that we can talk about «targeting» here. In any case, the reality is such that «preferences» are not possible in relation to which type of expenditure will be curtailed. Waste of resources need to be dealt with, no matter where it is found. However the solution is well-known and common to all healthcare services: electronic control, guidelines, diagnostic and treatment protocols, awareness raising among the parties involved in cost issues, market research and transparency in supplies.,

What else needs to be done to put the healthcare sector in order?
I think the time has come for massive changes in the financing system. I consider that traditional «fee-for-service» models which are being used must be replaced with fixed budget systems on all levels. All parties involved must adopt logic of discipline within specific financial limits, as is the case in all healthy productive structures.

Will the problem of hospital debts also be dealt with in that way?
That is precisely the issue I was referring to when answering your previous question. Following a change in the financing system, the cash flow will be direct, and it will operate in a deflationary manner.

I am personally in favour of a system of pre-purchase of insurance rights by Social Insurance Funds so that the NHS acquires liquidity and negotiating power in order to achieve better prices.

However, there is also the issue of social insurance contribution evasion which is also of vital importance for the social security system. The efforts being made are significant.

In a nutshell, rationalising health insurance / healthcare services is a complex, ongoing process but one which is absolutely necessary in the unfavourable economic climate we have to cope with. Collective efforts and synergies are needed, both from the State and its Institutions, and on the market side to achieve this objective. ■

YANNIS STOURNARAS
Prof. of Economics / University of Athens and
Director General of the Foundation for Economic and Industrial Research (IOBE)

«Credibility is easily lost and hard won»

«The Memorandum and the measures it entails are a great opportunity to address the two major problems of the Greek economy, namely high public debt and low competitiveness, and to redefine Greece's development model». Yannis Stournaras, Professor of Economics at Athens University and General Director of the Foundation for Economic & Industrial Research is quite optimistic in his assessment of how the Greek economy will develop. Professor Stournaras considers that «it is vitally important to make savings in public health expenditure and in particular in the procurement of materials and prescribing, instead of constantly focusing on the prices of medicinal products.»

A recent survey conducted by the Foundation for Economic & Industrial Research states that, «for the first time in modern history, the economic policy of the years to come has been set out in such a clear and binding manner that leaves no space for deviations or delays». Do you believe that the implementation of the Memorandum is a necessity for solving Greece's financial problems?

The political system could not offer the Greek economy and society the «cure» it needed because of the political cost that no government was willing to shoulder. Consequently, the Memorandum and the measures it entails are a great opportunity to address the two major problems of the Greek economy, namely high public debt and low competitiveness, and to redefine Greece's growth model. If the measures contained in the Memorandum are effectively implemented, both in terms of the fiscal and structural measures, the developments will probably be significantly more favourable than the scenarios outlined in the Memorandum, in relation to both the size of public debt and the rates of economic growth.

How would you rate the implementation of the Memorandum's requirements so far?
At present, the programme appears to be going well. Despite the errors and delays noted, the implementation of the economic policy has begun to build up pace and acquire substantive content, while there are encouraging initial results, with the exception of revenues and the introduction of structural changes, which are happening slowly even though the process is underway. I would say that those are the two sticking points. If improvements are made there, I believe that everything will go well. Now, as far as the debt is concerned, I don't believe it will ever reach 150% - the macroeconomic scenario presented by the Troika is extremely pessimistic. The assessment conducted by the Foundation for Economic & Industrial Research's estimate it at 135-136% of GDP, and there are numerous opportunities for improving the situation, such as privatisation and utilisation of the state's real estate assets, revenues from which could be used to pay off part of the public debt. The issue is that our creditors need to be persuaded about that possibility.

"The global economic and financial crisis exposed Greece's vulnerabilities, highlighting the longstanding structural problems of the Greek economy. This brought the problems of the Greek economy to the fore, causing an acute blow to the trust of the international markets and leading to reductions in the country's credit ratings and increases in the interest rates"

Are you optimistic that the markets will have renewed trust in us by the end of the three coming years?
The global economic and financial crisis exposed Greece's vulnerabilities, highlighting the longstanding structural problems of the Greek economy. This brought the problems of the Greek economy to the fore, causing an acute blow to the trust of the international markets and leading to reductions in the country's credit ratings and increases in the interest rates. Time will be needed to restore Greece's credibility for investors. Credibility is easily lost and hard won. At the end of the year we will be able to see the reaction of the financial markets to the progress achieved in the economic adjustment programme.

What opportunities do you see for reducing the deficit and debt and for increasing GDP over the coming years?
I can single out four areas where action is needed. Firstly, the immediate opening up of markets and professions is required. As a result of the countless restrictions imposed by the regulatory framework of the public sector, the profit margin in the services sector in Greece is estimated to be 15% higher than the corresponding margin in the Euro Area. It is expected that removing these restrictions, will result in a convergence with the Euro Area's profit margin and will increase GDP by approximately 10% over the next 5, critical, years.

Secondly, the utilisation of the state's real estate assets should become a priority. In Greece, there is a large public sector property which has not been recorded or valued, but rough estimates consider its value to be close to the level of public debt. In this context, the state could generate revenue from its real estate, as approximately 1/3 of its value could be utilised immediately. Today,

with public debt acting as a noose around Greece's neck, selling off real estate or unused assets to pay off the public debt must be a priority.

Thirdly, emphasis must be placed on bolstering the capital adequacy of banks. Today, the issue in the banking sector is neither mergers nor privatisations, but adequate capitalisation of the banks, so that they can persuade the markets to open up to them, and thereby improve their liquidity to be able to lend money to their customers. Second generation stress tests need to be carried out, to ensure that banks are on the right path, while banks that can't secure adequate capital from their shareholders should make use of the Financial Stability Fund.

Fourthly, public expenditure savings are needed, especially in the health sector. Evidence indicates that the major waste of resources in the health sector is related to the procurement of special materials, the lack of measurement, accounting books or IT infrastructure for public hospitals, as well as to the absence of evaluation and control over physicians' prescribing patterns. The waste of resources in terms of procurement, especially for consumables not covered by contracts or non-transparent supply procedures for medical technologies, amounts to approximately € 2 billion per year. This figure arises simply by comparing the cost of these materials in Greece with the respective cost in the rest of the Euro Area. This is a market worth around € 6 billion per year, with profit margins for the companies importing these goods in excess of 200%.

Why do you think that pharmaceutical products are constantly being targeted?

Total healthcare expenditure amounts to 9.7% of GDP and just 1/5 of that expendi-

> "In Greece, there is a large public sector property which has not been recorded or valued, but rough estimates consider its value to be close to the level of public debt"

ture relates to pharmaceutical products. Of the € 21 billion of total healthcare expenditure, government measures focus on the € 4.5 billion related to the public pharmaceutical expenditure due to the legal framework which makes it easier to intervene in that sector. Contrary to the prices of medical devices and consumables which are not controlled by the State, pharmaceutical prices in Greece are set by the State and are set low. Yet the intervention which takes place is one-dimensional and does not look at pharmaceutical expenditure as a whole, since it only deals with the price and not with the quantity of prescribed medicine.

To what can the rise in public pharmaceutical expenditure over recent years be attributed?

It is true that pharmaceutical expenditure in Greece has been rising over the last decade. Based on the most reliable, ex post, data from social insurance funds, public pharmaceutical expenditure in Greece is rising by half a billion euro per year.

The results of the recent survey conducted by the Foundation for Economic & Industrial Research (Review of changes in pharmaceutical prices over time: 1997-2008) showed that there are other factors that play a dominant role in the increase of pharmaceutical expenditure, such as lack of streamlining of IT infrastructure for social insurance funds and public hospitals and prescription control, and not the prices of medicinal products per se.

Specifically, if one compares the evolution of the Pharmaceutical Price Index (PPI) to that of the General Consumer Price Index and the price indexes for other healthcare products and services, one sees that the change in PPI is much smaller compared to the change of the Healthcare Price Index,

PHARMACEUTICAL PRODUCTS ARE CONSTANTLY BEING TARGETED

Total healthcare expenditure amounts to 9.7% of GDP and just 1/5 of that expenditure relates to pharmaceutical products. Of the ¤ 21 billion of total healthcare expenditure, government measures focus on the ¤ 4.5 billion related to the public pharmaceutical expenditure due to the legal framework which makes it easier to intervene in that sector. Contrary to the prices of medical devices and consumables which are not controlled by the State, pharmaceutical prices in Greece are set by the State and are set low. Yet the intervention which takes place is one-dimensional and does not look at pharmaceutical expenditure as a whole, since it only deals with the price and not with the quantity of prescribed medicine.

the Hospital Care Price Index and the General Consumer Price Index. In other words, it is clear that the prices of medicines are rising at a slower rate than the prices of other healthcare products and services, and other goods, such as food and housing, where demand is inelastic just like demand for medicinal products.

Consequently, one must not attribute the rise in pharmaceutical expenditure to changes in the prices of medicinal products.

How do you think that healthcare and pharmaceutical expenditure in Greece can be rationalised?

The introduction of a double-entry accounting system at hospitals and the streamlining of IT infrastructure in social insurance funds and public hospitals must become a priority. Streamlining of IT infrastructure is necessary to ensure effective control of overall healthcare expenditure and to combat waste of resources. International experience shows that this can lead to overall savings for the state budget of up to € 2 billion per year, over time. In addition, the introduction of a uniform accounting and IT system for hospitals in the NHS will improve centralised control over spending and monitoring of the procurement of medical supplies. As far as medicinal products are concerned, waste of resources can be limited by introducing a system of electronic prescribing. The adoption of such measure will enable monitoring of the prescribing habits of physicians and the extent to which these habits match the real needs of patients. Electronic prescribing is expected to improve the quality of services provided, assist in faster handling of patients and reduce medical errors.

Moreover, the government will have to exploit the opportunities which arise to make cost savings and to identify new resources. Over the years to come Greece may well have the fortune of welcoming the affluent war generation pensioners, the so-called baby boomers, who want to live in the countries of the European South because of their mild climate, natural beauty and cultural heritage. However, it is not possible with the current regulatory framework which governs both public and private healthcare to design and implement a suitable development policy for this sector. A different approach than the current one is needed; a realistic, outward-looking approach which will involve the private sector in the development planning.

In a nutshell, at present, Greece has the opportunity to emerge from the vicious cycle of excessive debt and recession through systematic and continuous structural and fiscal reforms. The problem is that the clock is ticking. ■

> “The results of the recent survey conducted by the Foundation for Economic & Industrial Research (Review of changes in pharmaceutical prices over time: 1997-2008) showed that there are other factors that play a dominant role in the increase of pharmaceutical expenditure, such as lack of streamlining of IT infrastructure for social insurance funds and public hospitals and prescription control, and not the prices of medicinal products per se.”

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