ΘΕΣΕΙΣ

"The Truth about (Public) Pharmaceutical Expenditure"

ΣΥΝΔΕΣΜΟΣ ΦΑΡΜΑΚΕΥΤΙΚΩΝ ΕΠΙΧΕΙΡΗΣΕΩΝ ΕΛΛΑΔΟΣ

SfEE

HELLENIC ASSOCIATION OF PHARMACEUTICAL COMPANIES

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ΣfEE represents **64 pharmaceutical companies** operating in Greece.
ΣfEE members account for **90%** of the pharmaceutical market share in Greece.
ΣfEE is a member of EFPIA.

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The clarification of a "misunderstanding"

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Misunderstandings are common in public dialogue. However, clarifications should be made with the use of strong arguments and objective data, before these misunderstandings are magnified and become a harmful "deceptive truth.

"I will speak boldly, stating from the beginning the following simple and unquestionable truth: **The true public pharmaceutical expenditure is about 1/3 of the figure presented in several mass media as "pharmaceutical expenditure.**"

What has happened? Many media report the official estimate of the National Organisation for Medicines (EOF), that "pharmaceutical expenditure" in 2006 exceeded 6 billion euro. However, there is a serious mistake in the interpretation of this estimate, as EOF records and publishes the amount of "total pharmaceutical sales" at retail prices (which include wholesaler and pharmacist's profit, as well as VAT). Moreover, total pharmaceutical sales include expenditure which does not at all constitute a burden for the state (an argument analysed in SFEE's Press Release sent to all mass media, which is presented on page *5).

There is, therefore, confusion in public dialogue, between "total pharmaceutical sales" and "pharmaceutical expenditure," as the latter is mistakenly identified with the former. Such confusion has a multiple negative effect, as it sets the public dialogue on a false foundation and leads towards erroneous arguments and conclusions.

Let's examine closely the "misunderstanding" and see how it could be easily resolved: Public pharmaceutical expenditure is **only a part of pharmaceutical sales,** as total pharmaceutical sales include six (6) figures:

1. The public pharmaceutical expenditure, which is incurred by social insurance*
   (part of it, however, returns to public funds, through 9% VAT)

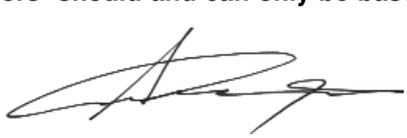
"Medicines sales to hospitals are included in hospital expenditure therefore if included in pharmaceutical expenditure as well, they would be double counted"

2. The medicines sales to hospitals
   (at Hospital Price: Wholesale Price minus 13%)
3. The sales of medicines which are legally re-exported *(parallel exports)**
4. The sales of medicines to either Greek citizens or tourists, which are paid out-of-pocket
5. The sales of medicines dispensed to Greek citizens or foreigners insured at private insurance companies, which are covered by the latter
6. Patient's co-payment, which is not reimbursed by social security funds

** Pharmaceutical expenditure covered by social security includes a considerable amount of waste.*

It should be noted that pharmaceutical sales to hospitals are included in **hospital expenditure;** therefore, if included in pharmaceutical expenditure as well, they would be double-counted. It should also be stressed that points 3, 4, 5 and 6 do not, of course, constitute public pharmaceutical expenditure -on the contrary, they provide public funds with revenue, through VAT, income and salary taxation, and payments to insurance funds.

If all these factors are taken into account, it becomes clear that pharmaceutical expenditure is about 1/3 of total pharmaceutical sales. **As a result, designating "pharmaceutical sales" as "expenditure" is a detrimental mistake, since it is obvious that a rational policy and wise decision making for pharmaceuticals - as well as for all other sectors- should and can only be based on objective and reliable data.**



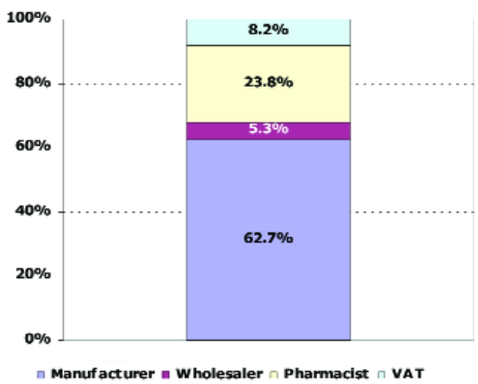
Dionysios S. Filiotis
President of ΣfEE

The Truth about (public) Pharmaceutical Expenditure

Press Release

During recent months, a prevailing confusion exists between the terms "pharmaceutical expenditure" and "total pharmaceutical sales". More specifically, "pharmaceutical sales", the data recorded by the National Organisation for Medicines (EOF), have been incorrectly designated as "pharmaceutical expenditure." First, it should be clarified that the data provided by EOF describe total pharmaceutical sales, at retail prices, which include the wholesaler's profit, the pharmacist's profit and VAT. Specifically, the structure of a medicine's Retail Price is the following:

Pharmaceutical Retail Price Structure (R.P. =100)



EOF records, on a monthly basis, **the sales of medicinal products** from companies to Hospitals and Wholesalers/ Pharmacies. Contrarily, **public expenditure on medicinal products** -according to OECD International Classification of Health Accounts, with which our country is harmonised- describes the expenditure on medicinal products dispensed to outpatients, which is covered by Social Insurance Funds. **Therefore, pharmaceutical expenditure is only a fraction of total pharmaceutical sales.**

To be more precise, it should be noted that **pharmaceutical sales** comprise:

A) public expenditure on medicinal products, which is incurred by social insurance funds (part of it, however, returns to public funds, through 9% VAT)
B) medicines sales to hospitals (at Hospital Price: Wholesale Price minus 13%)
C) sales of medicinal products which are re-exported (parallel exports)
D) sales of medicinal products to either Greek citizens or tourists, which are paid out-of-pocket
E) sales of medicinal products dispensed to Greek citizens or foreigners insured at private insurance companies, which are covered by the latter
F) patients' co-payment, which is not reimbursed by social security

As far as point B is concerned, it should be noted that pharmaceutical sales to hospitals are included in hospital expenditure; therefore, if included in pharmaceutical expenditure as well, they would be double-counted.

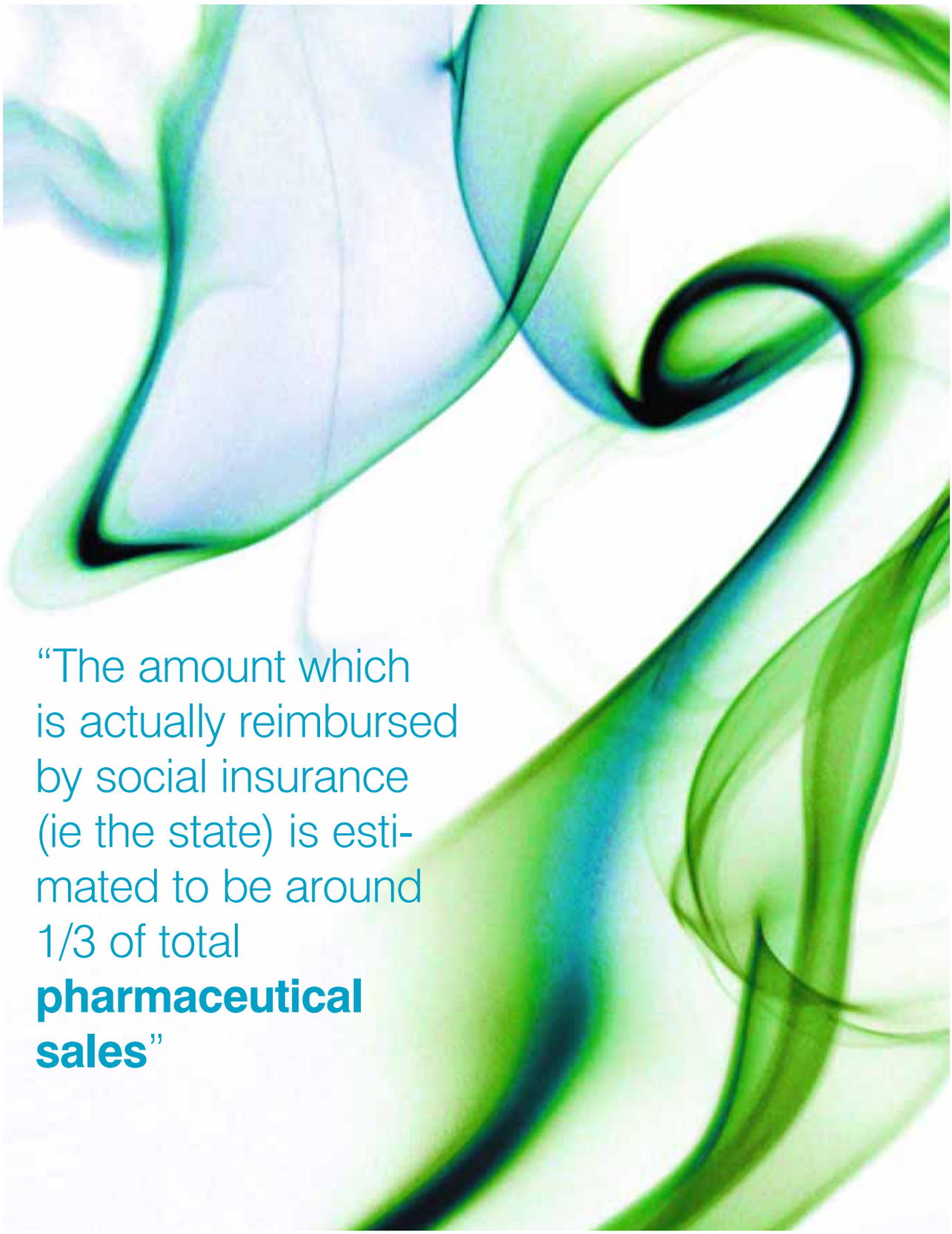
As far as points C, D and E are concerned, it should be stressed that these sales do not constitute public pharmaceutical expenditure -on the contrary, they provide public funds with revenue, through VAT, income and salary taxation, payments to insurance funds, and others.

As a result, pharmaceutical expenditure, which is incurred by social insurance, is much lower than total pharmaceutical sales.

Therefore, the amount which is actually reimbursed by social insurance (ie the state) is estimated to be around 1/3 of total "pharmaceutical sales". This is the "real pharmaceutical expenditure" and is estimated on the basis of both the aforementioned and the following:

It is clear that pharmaceutical sales describe t**he pharmaceutical sector's supply-side, rather than the demand-side.** Therefore, the proper way to present these sales is by estimating them at ex-factory prices, which is the usual case, rather than at retails prices. Presenting pharmaceutical sales at retail prices (sales which include medicines that will never reach the domestic retail market due to parallel exports), creates an overwhelmingly inflated picture of pharmaceutical expenditure. Moreover, the increase in sales at retails prices includes the effect of the rise in VAT in April 2005, which, of course, should not be attributed to a change in the pharmaceutical market per se.

Consequently, **sales of medicianl products in terms of value, reached j 3.8 billion in 2005** (Table 1). The rate of increase for the same year was 10%.



"The amount which is actually reimbursed by social insurance (ie the state) is estimated to be around 1/3 of total **pharmaceutical sales**"

Table 1: Pharmaceutical Sales in Value (at ex factory prices)

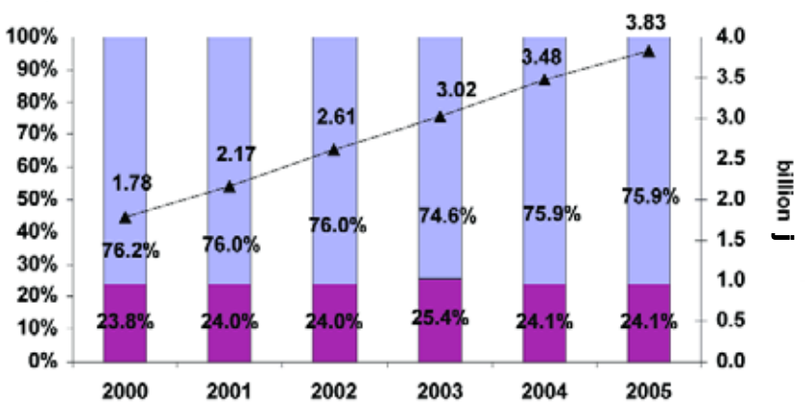
Year	Hospitals (Hospital Price)		Wholesalers-Pharmacies (Net Price[1])		Total	
	thousand €	% of change	thousand €	% of change	thousand €	% of change
2000	423.274	-	1.358.873	-	1.782.147	-
2001	522.504	23%	1.652.265	22%	2.174.769	22%
2002	626.286	20%	1.983.592	20%	2.609.878	20%
2003	767.984	23%	2.252.925	14%	3.020.909	16%
2004	837.497	9%	2.638.165	17%	3.475.662	15%
2005	921.387	10%	2.907.646	10%	3.829.033	10%

Source: EOF-IFET and IOBE calculations
Data include parallel exports

Moreover, by presenting sales data in this way, we are being more precise in estimating the share of hospital sales on total sales, which when estimated by using the retail price, is much lower due to the fact that sales to wholesalers/ pharmacies include wholesaler and pharmacist profit.

Therefore, in order to calculate pharmaceutical expenditure, we must subtract 24% (hospital sales) out of total sales (Diagram 1), and from the remaining € 2.9 billion, we should subtract parallel exports (for which no official data exist). Accordingly, pharmaceutical expenditure which is incurred by insurance funds is estimated to be about 1/3 of total pharmaceutical sales.

Diagram 1: Breakdown of Pharmaceutical Sales to Hospitals and Wholesalers/ Pharmacies



Source: EOF-IFET and IOBE calculations
Data include parallel exports

In summary, it is evident that in Greece, pharmaceutical sales data are entirely different from pharmaceutical expenditure data.

As pharmaceutical expenditure is only a fraction of total pharmaceutical sales, and as long as all other parameters are taken into consideration, it is accurate and valid that the burden of pharmaceuticals to Social Insurance Funds is actually much smaller than the one arising when we incorrectly designate "sales" as "expenditure.

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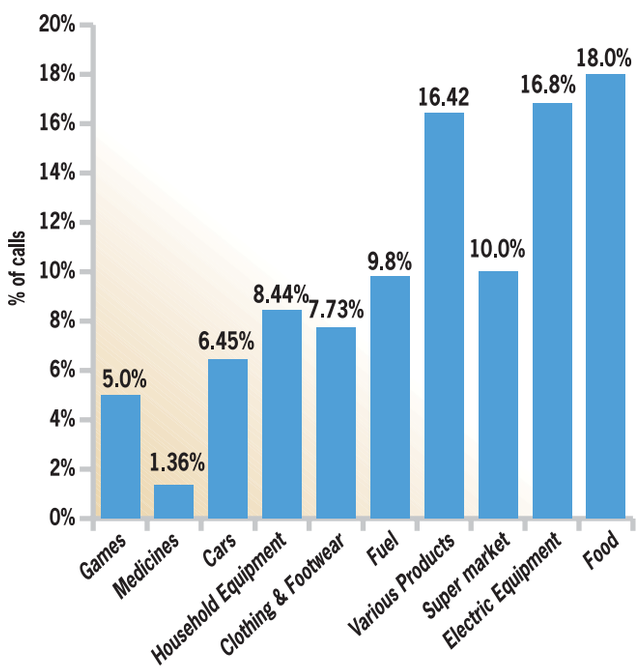
The high quality of medicines and the responsibility of the pharmaceutical sector in Greece are substantiated

According to data presented by Deputy Minister of Development Mr. G. Vlachos on January 15, complaints regarding medicines made to the Department of Consumer Affairs in 2007 accounted for only 1.36% of the 51.107 written and oral (through telephone) complaints made to the department. This percentage places the pharmaceutical sector with the lowest number of consumer complaints.

The result demonstrates the high quality of marketed medicinal products and the high sense of responsibility characterizing all professionals involved in or related to the pharmaceutical sector: pharmaceutical companies, production units, the market control mechanisms of the National Organisation for Medicines (EOF) and, in particular, the pharmacists and the medical and hospital personnel of our country. In addition, this result demonstrates the efficiency of our country's system, in which only branded medicinal products are marketed, being prescribed with the exclusive responsibility of a physician. This ensures that only high quality medicines are marketed and that public health is protected.

A result of this policy is this exceptionally low percentage of complaints lodged against the pharmaceutical sector. Surely, this achievement does not constitute a cause for relaxation, since our goal is even greater success in this area. Our goal is for citizen complaints against medicines to fall to zero.

With continuous vigilance, with the support of tested and successful policies, and with a constructive cooperation by all healthcare professionals, we will succeed in strengthening even more the pharmaceutical sector as one of the country's top sectors in the highly vital and sensitive area of responsibility and respect toward citizens.



Source: Ministry of Development

George Vlahos
Deputy Minister of Development

Interview with the Deputy Minister of Development Mr George Vlahos

QUESTION:

It is acknowledged internationally that new medicines increase the average life expectancy as they add more healthy, creative, and productive years to people's lives. At the same time, they reduce the need for surgery and consequently hospitalization time. Do you agree that the cost of new medicines is counterbalanced by their benefit to society through the saving of resources they bring about in other branches of the health system?

In recent years the rapid development of scientific research has contributed to the discovery of new medicines for a number of diseases. New options are created for the improvement of therapies, the fighting of disease, and finally the improvement of the quality of life.

Given that the ultimate commodity in contemporary society is human life, it is obvious that the introduction of new medicines, that prove to offer solutions to problems, can only provide added value.

It is clear that the cost of new medicines is an issue of concern to the whole of society. And it is clear and acceptable that companies, expect financial benefits from the circulation of a new medicine, so that they may support research and development. Nevertheless, we must know that we refer to specific societies with specific characteristics and possibilities.

We, as representatives of the State, try, through the institutionalized pricing procedure, to establish a proper balance between the need every company has to be competitive and the need of the Greek citizen to have at his/her disposal medicines at accessible prices.

Regarding the savings of resources within the health system, it is a very serious issue with many aspects of concern to the government. This is why there are certain initiatives from the ministries concerned that aim to ensure transparency and the principles of rational management in health economics.

However, in general, targeted therapies and the application of prevention policies may ensure the containment of expenses and mainly may help citizens avoid painful inconveniences.

QUESTION:

As medicinal products in Greece are among the least expensive in the European Union of 27, do you agree that the real financial problem of the system originates from waste of resources, which results from the lack of technological modernization and streamlining of the health system?

Greece, and the ministries concerned, have already proceeded with a major program of rationalizing NHS finances, including supply procedures. Through the introduction of new technologies and absolute respect for the principles of transparency, we are working to ensure the expenses of the national budget-which are constantly increasing-benefit the citizen.

QUESTION:

Do you believe that the concept of deontology in the health sector should include the attitude and the obligations of the State? In other words, do you believe that the eradication of waste, in addition to economic and technocratic approaches, should include a moral approach? Is this, therefore, part of the sum of deontologically correct choices that lead to modernization and the armoring of the system against every sort of negative practice and attitude?

The principles of our policy have a universal application. We do not function à la carte and on the basis of what suits us. We have planned and are implementing our policy on the basis of strategic axes, such as the unhindered access of patients to medicine, the improvement of the citizen's daily contact with health services, the profitable use of available resources, the viability of the insurance system, and the support of local production of medicines. The stable support of these principles is nonnegotiable.

QUESTION:

In addition to the abolishment of the cost estimate, what do you believe should be the incentives the State must provide to the pharmaceutical sector to reinforce local production? Do you believe that the pharmaceutical sector should be included in the high technology sectors?

The provision of some incentives for the development of local production and research in Greece may be examined, with the aim of financially supporting the Greek pharmaceutical industry. But this is something that must go through the dialogue process with involved bodies. It is a standard principle of the Ministry of Development to engage in dialogue, to exhaust it with all those involved, without prejudice, in order to achieve the best possible results.

“However, in general, targeted therapies and the application of pro-active policies may ensure the containment of expenses and primarily help citizens avoid hardships”

QUESTION:

The abolition of the positive list and the issue of new price bulletins every 90 days, as stipulated by European legislation, was the decisive step toward ensuring direct access to all medicines and stabilizing the growth rate of pharmaceutical expenditure, since old and established medicines are not replaced by newer and more expensive ones. Do you believe a wider political consensus must exist in favor of this very simple truth?

A. It is by now well established that for the past four years our policy has met a wider political consent. It is known to all that the issue of price bulletins every 90 days, as provided for in the EU directive 89/105, has been achieved, as well as the simultaneous updating of pharmaceutical data through the Internet at the local as well at Community level.

I would like to point out the following: with the abolition of the list we managed to achieve direct access by citizens to every available medicinal therapy. Furthermore, we put an end to the harassment of citizens, who either paid out of their own pocket for the medicine not included in the list, or tried to find ways to obtain it,. Moreover, we tried to financially assist the insurance funds and to cover all medicines. These are efforts that citizens recognize and appreciate.

ΣΦΕΕ ΘΕΣΕΙΣ #67 FEBRUARY 2008

Implementation of New Pricing Policy

Assessment and Expectations

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REVIEW

We are at "the day after" since the adoption of the new model of the Pricing Decree of medicinal products in our country. Its implementation is still recent, and therefore the entire procedure is under evaluation. The assessment of the results of the 3rd and 4th Price Bulletins (3/2007 and 4/2007), which were issued in the beginning of October and at the end of November, is before us. Some delays in the issue of Price Bulletins, mainly during 2005-6, have been noted since the commencement of the implementation of the new legislative framework. Nevertheless, it is worth noting that the last five price bulletins have been published at regular intervals, one every three months, as provided for in the community legislation and the pertinent circular of the Ministry of Development.

This gives us reason to be optimistic that the targets will be met, with the adoption of this particular pricing scheme, aiming to ensure sufficiency of medicinal products in the market and the proper service of Greek patients.

For its part, SFEE cooperates with all involved bodies and works with the State to ensure access of all citizens to every necessary medicine at the lowest possible cost. At the same time SFEE focuses on the benefits the patient will have from the improvement of the total performance of the health system. We also support the improvement of the health system through research development of new medicines and the qualitative upgrading the quality of existing medicines.

In short, SFEE is developing a new philosophy for a timely and proper pricing policy, combined with the system's technological streamlining and upgrading. These two initiatives not only can contain but even reduce pharmaceutical expenditure as a percentage of GDP, achieving at the same time a vertical improvement in the quality of health care.

To reach conclusions about the operation and the purpose the new method of pricing serves, we must remember the needs that led to its implementation and to evaluate whether and to what extent the original targets have been met.

Harmonization with the legislative framework of the EU was adopted to smooth out and if not to solve the problem of delay in patient access to new medicines. The problem has its roots in a set of "traditional" causes. A basic cause is the bureaucratic mechanisms related to price determination and approval of re-imbursement from Social Security Funds. Another basic cause is that sometimes new medicines were not marketed in Greece due to the fact that until today medicines in Greece had the lowest price in Europe. The exclusion of medicines from the reimbursement list was another cause. Last, responsible for the lack of medicines in the Greek market are parallel exports, due to price differences, as well as the withdrawal of medicines due to low prices.

It should be kept in mind that, with the new pricing system, the price of a medicine, which is manufactured, packaged or imported into our country, results from the average of the three lowest prices of the said medicinal product in the EU. The price is determined after taking into consideration the lowest price in two of the States, which were EU members before 1/5/04 (including Switzerland) and in one of the 10 new states that joined the EU on 1/5/04.

For the essentially similar medicinal products containing the same active substance and having the same pharmaceutical form, their price is set at 80% of the selling prices of the equivalent branded original. On the other hand, the prices of branded original medicines are reduced by 20% following the expiration of the patent of their active substance, and the new price remains stable for the following four years. It is also very important to note that this price reduction comes into effect one year after the marketing of one or more essentially similar medicines if, according to EOF, the new medicine or medicines prove to have achieved an in-market market share of 5%. As becomes evident with the new pricing system, the prices of off-patent original medicines and non-branded medicines end up at the same level.

Finally, regarding the pricing of original medicinal products manufactured by Greek pharmaceutical companies and for which research has been carried out on active substances or pharmacological form with a Greek patent (without a respective similar medicine in another country), pricing will be based on cost estimates. The cost estimate will include expenses of production and packaging for every form and every pack size, and also expenses of Administration-Distribution. All these costs are calculated by taking into consideration data- updated every two years-of the sector's average expenses, the materialization of new investments, the cost of research and development of the active substance, and potential know-how expenses.

SFEE POSITION

SFEE's position, based on these considerations, was, and still is, that the new regulations are in general a step in the right direction. However, reservations exist regarding the ability of their proper implementation with consistency and continuity and not only on a temporary basis. The association's position remains that the most objective pricing of a medicine can be achieved when the price is defined as the average of the prices of all Eurozone countries, excluding, for the time being, the newly joined former "eastern countries," whose health systems possibly need more time to harmonize with the standards of the other member states.

In spite the change in the pricing system, Greece continues to have the lowest prices in Europe. Moreover, medicine remains among the very few commodities with the lowest price average compared with prices in other European countries. At this point it is worth noting that the noise which created about excessive increases in prices in fact contradicts the official data of the Ministry of Economy and Finance. Even after the revision of the Market Decree for pricing, based on 2+1, recent data from the Ministry of Economy and Finance show that the annual surcharge on the CPI (Consumer Price Index) - between August 2006 and August 2007- was only 0.3% or 0.003 percentage units.

It must be pointed out that the implementation of the new Market Decree was received positively by all parties involved as a procedure that is transparent, objective, and impartial, solving many of the chronic problems of the sector regarding pricing of medicines.

24 MONTHS AFTER IMPLEMENTATION - PENDING ISSUES TO RESOLVE

Certain problems have emerged, as expected with the implementation of a new procedure. During price controls/carried out by the competent authorities the following issues have been noted, regarding:

A) The determination of the ex-factory price of medicines in European countries, due to the different approach in the calculation of price between competent authorities and companies. This verification of prices by the authorities involves both hospital and community medicines.

B) The pricing of medicines in the case of the introduction of an additional new form, is not clear (different strength or pack size).

C) The delays in determining the prices of new medicines due to the lack of EOF code number or timely approval of method of distribution (blue box), which is dictated by EOF.

PROPOSED SOLUTIONS

SFEE and the relevant departments of the Ministry of Development have, for some time, established contact, in an effort to solve problems on the basis of an honest and good-faith dialogue. Many of the issues noted have either been contained or solved. Specifically, the following changes have been approved:

A.

1) The Ministry's responsible departments are willing to accept invoices from abroad, authenticated by a Public Authority (Ministry of Exterior, Embassy, Consulate etc.) regarding the content of the invoice, in cases where the invoice is the only proof of the company's claimed price.

2) There is no need for authentication of invoices in cases where there is additional proof of the company's claims regarding requested prices (MIMS catalogues, Rote Liste, L'Informatore Farmaceutico, etc., or website prices of an official public authority).

3) Regarding the verification of ex-factory prices in other European countries (community and hospital medicines) there has not been found, to date, a mutually accepted solution, but efforts are still in progress in a climate of sincere cooperation.

B.

In the cases that a new price is requested for an additional similar form (different strength, or pack size) it must be noted that:

i) When the existing strength has been priced on the basis of the old pricing system, the reduction or increase is effected on the basis of the table of paragraph 445A of the market decree (with upper limit 12%), whereas

ii) When the existing strength has been priced on the basis of the prices of European countries (2+1), then equally the requested price of the new strength will be set on the basis of the (2+1) price regulation.

Regarding requested prices for new pack sizes, they will be reduced or increased with an upper limit of 12%, on the basis of the tables of paragraph 445A of the Market Decree.

C.

Regarding delays in accepting pricing requests due to lack of EOF code number or timely approval of the blue box, the competent departments of the Ministry of Development are willing to accept companies' requests provided that the EOF code number of the medicinal product and the blue box approved by EOF, will be submitted promptly and officially (before the meeting of the Pricing Committee). Also, in EOF's recently issued circular (dated 19.12.2007), it is clarified that the supply of EOF's code number and the approval of the blue box for centrally approved medicines will be effected at the same time with the issue of a single administrative act.

EPILOGUE

The positive climate in the health sector, as well as the earnest participation of the State during recent years for the improvement of the sector's institutional framework, prove that we are moving in the right direction regarding the reduction of delays in patients' access to new medicines.

The cooperation of the State with SFEE, as well as all the other pertinent stake holders, may shape a stable institutional environment, where the terms of operation of the State's mechanisms and of the pharmaceutical companies will be clear and transparent and will not be subject to continuous changes. Such a framework is feasible and will contribute mostly in building a healthier, faster, secure and better-organized system, which offers faster access of medicines to patients and a higher quality of service.