

INTERVIEW OF MR. THEODORE TRYFON

Mr. Theodore Tryfon was born in the beautiful island of Mytilini, Lesvos. He completed his primary and secondary education at the prestigious "Athens College". He graduated in economics at the University of Southampton, UK, while his post graduate studies (MBA) were completed at city of London business school, UK. His professional horizons started at Colgate Palmolive, and subsequently at Merrill Lynch. Mr. Tryfon was also actively involved in the family business upon completion of his academic endeavors. His active role in the pharmaceutical sector began in 1992, at ELPEN Pharmaceutical CO.INC. Today, after 21 dynamic and productive years at ELPEN, together with the Managing Director, Mr. Konstantinos Pentafragas, is at the helm of the ELPEN Group of Companies which include: ELPEN, AENORASIS, and WINMEDICA. The ELPEN Group of Companies has a turnover of 175 million euros in Greece, and 22 million euros from foreign business interests. The Group is reknown for its dynamic manufacturing activities, for its unique for Greek standards privately-owned research department, as well as its strategic business development investment projects, both locally and internationally. Mr. Tryfon has been an active member of the board of directors of EBEEA-ATHENS Chamber of Commerce and Industry, and of SEB-HELLENIC Federation of Enterprises. For 8 years he was an effective and respected president of PEF-Panhellenic Association of Greek Pharmaceutical Industries.



Theodore Tryfon

Vice President of ELPEN Pharmaceutical Co.Inc. / Vice President of Panhellenic Association of Greek Pharmaceutical Industries (PEF)

"Greek Generics are Among the Safest in Europe"

Greece's Pharma-Health sector is moving forward toward the expansion of the practice of prescribing generics. The Vice President of the Panhellenic Association of Greek Pharmaceutical Industries (PEF) interviewed by "Pharmaceutical World" magazine, argues that the level of pharmaceutical expenditure, taking into account today's circumstances in Greece, should definitely not fall below 2,5 billion euros. He clearly states that horizontal cutback measures regarding drug prices are clearly condemned to absolute failure if these measures are not accompanied by the analogous adjustments and the rationalization of drug prescribing.

Moreover, he reveals that in the European Union there is a dubious activity whereby certain companies are producing a multitude of studies regarding generics, which are of questionable quality.

ELPEN Group of Companies

ELPEN is one of the oldest, absolutely Greek pharmaceutical companies in Greece. Ever since its founding, ELPEN has won over the trust and loyalty both from professionals in the Pharma sector as well as from the actual citizens of the country. Where do you attribute this?

It is a basic fact that from ELPEN's point of inception from the founder Mr. Dimitrios Pentafragas, his main focus was to apply a deeply anthropocentric method of running his company. The factors which distinguish ELPEN and which we, the new generation, plan to continue and develop even further, is the company's intense dedication to the quality of our manufacturing procedures, and our absolute focus on producing products equal in quality on an international level...

Furthermore, we invest in the proper and effective infrastructure of our company, thus enabling it to function based on the current European standards and criteria, while at the same time maintaining our Chairman's quest to create a company based on direct communication, the pleasant and effective collaboration between staff members, as well as a favorable and enjoyable working environment for all the employees working at the ELPEN Group of Companies.

In this ultra-competitive environment whereby sources of funds for the healthcare sector are continuously diminishing, your company continues to invest in research?

It is absolutely clear that for ELPEN its value is exceedingly important. Ever since the mid-90's, our company has invested large sums for research, and has done so during difficult years for ELPEN, where funding was virtually non-existent and cashflow very inhibited. Investments in research continued analogously to the company's turnover per annum with the pinnacle being reached this past decade whereby our Chairman Mr. D. Pentafragas, through extensive research and huge investiture, patented his original asthma device, the ELPENHALER®! This unique device created for the administration of medicaments for use in Asthma and COPD, is distinguished among other inhaler devices, and herein lies the innovation, as it offers the rare possibility for the user to actually check the air flow and distribution of the medicament. This was a huge challenge for the inventor, Mr. D. Pentafragas, who managed to overcome great obstacles and to successfully achieve success and obtain many marketing authorizations, where other multinationals have failed.

Has ELPENHALER® won over European buyers?

As of this year our product has been granted marketing authorization in many western European countries. Nevertheless, by virtue of the device's design and the indications, it cannot be offered in national tenders, in any country worldwide. Therefore, it is promoted by means of direct medical information and training. This poses a huge challenge as a large number of medical representatives is required, which we face either on our own or via collaborations with foreign companies, in Germany, Sweden, Hungary, etc.

What are the collaborations that were made with other companies?

The possibility of collaboration with ELPEN is threefold. One possibility can be a collaboration in terms of third-party manufacturing, either from a Greek or foreign company, at our manufacturing plant in Greece.

A second possibility relates to the promotion and medical information for products whose marketing authorization is owned by other companies. This type of collaboration primarily involves original products for which we share marketing rights (co-marketing), or products for which we are granted exclusive marketing authorization solely for the territory of Greece.

The third collaboration relates to the many long-standing collaborations we enjoy for the promotion of our own products in foreign markets. We enjoy mutually beneficial collaborations with multinationals such as Novartis, Bayer, Pfizer, Lundbeck, Hospira, Italfarmaco.

Are studies carried out for the pharmaceutical products which you manufacture?

We have created a fully-equipped department for product development studies and the writing of their dossiers. Bioequivalence studies are carried out for reasons of transparency and infrastructure, in hospitals abroad with strict adherence, from our side, to the study's protocol.

We give a great significance to the assurance of proper developmental procedures of all our generic pharmaceuticals, in what regards the proper selection of the raw material (active ingredient) used in the manufacturing process, and most importantly, in choosing the analogous analytical methods which will ultimately prove that our final product is indeed bioequivalent with respect to the reference product. As you can understand this is an extremely complex endeavour.

It is for this reason that I am always extremely cautious

It is a matter of huge social responsibility that the Greek pharmaceutical companies have all chosen to maintain their manufacturing plants in Greece under huge economic strain, when there are extremely tempting promises of a 50% decrease in manufacturing costs.

with companies which produce final product dossiers, companies which seem to have sprouted-up like mushrooms all over Europe. For us insiders who have a deep knowledge of how complex and costly it is to actually develop a final product dossier, which in our case demands a team of 15 highly-specialized scientists, we manage to produce and with great difficulties, a mere 5-6 product dossiers per year. So, how is it ever possible for CRO companies from Portugal or Holland to produce 20-30 dossiers? I have valid doubts as to whether the European or Greek regulatory mechanisms can exercise any control over such dubious work.

What is your position on current prescribing methods?

Much has been said about the ethical code which must be adhered to by all pharmaceutical companies.

I can securely state that as far as ELPEN is concerned, we are proud of the fact that for many decades we maintain one of the most orthodox marketing departments in Greece, focusing on strategic medical representation and information/training of the medical community in the country. Our information tactics are primarily based on communication based on trust and respect, as opposed to relying on material incentives. We have opted for a longterm relationship with the medical community rather than using traditional, short-term marketing methods with doctors. Our moral compass is profoundly based on the superior quality of our products.

Moreover, we have given great significance to providing accurate, detailed medical information regarding studies, indications, etc.

What are your actions in the sector of social responsibility?

Up until the time period before the financial crisis, our company was hesitant to display our concerns about

social issues because we had our own private reasons for wanting to participate in social crises.

During the last few years, many factors have changed dramatically in terms of the huge socio-economic crisis which has befallen our country, resulting in massive problems in our society on so many different levels. The problems are not only financial in nature, and so, things need to be exposed and said as they really are.

We are extremely proud of the fact that we have decided to preserve the 805 job positions in our Group of companies, and it is noteworthy to say that we are in fact among the top employers in the country today! We are proud that we are able to face and overcome the massive taxation of our companies in Greece, and of the fact that we have chosen to maintain our manufacturing plant in Greece, keeping in mind that there are a myriad of available cheaper solutions if we were to move to adjacent countries to Greece. This fact alone, in and of itself, encompasses our huge commitment and endowment to the sector of social responsibility in Greece.

It is a matter of huge social responsibility that the Greek pharmaceutical companies: ELPEN, Vianex, Pharmathen, Demo, Uni-Pharma, Galenica, etc, have all chosen to maintain their manufacturing plants in Greece under huge economic strain, when there are extremely tempting promises of a 50% decrease in manufacturing costs.

It is an undisputed fact that every responsible business must be aware of the fact that we are all part of a community and the better this community's prospects the more favorable it will be to our businesses. The more one gives back to the community the higher the probability of reciprocity.

At ELPEN there is an organized department focusing on matters of social crises within the weaker social groups of our country, on crises suffered by isolated regions of

our country like in small faraway islands, and on the prosperity of our traditions, our culture, and spirit of athleticism... all of which synthesize our Greek society.

The Politics of Pharmaceuticals

Let us proceed with more general questions regarding the politics of the pharmaceutical sector. Do you believe the measures applied in order to rationalize expenditure are serving a practical means to an end?

As seen in recent years, healthcare costs indeed skyrocketed out of control. The inflation observed within all sectors of the healthcare system: doctors, pharmacists, pharma wholesalers, the pharmaceutical industry, as well as the severe lack of government regulation, created a system of resulting demand in the pharmaceutical market, which in turn contributed to an increase in healthcare expenditure. This fact was indeed foreseen and pointed out a decade ago, by the Panhellenic Association of Pharmaceutical Companies (PEF). We predicted the imminent dangers and saw that we were all headed towards the proverbial 'brick wall': the suspension of all payments. This abrupt cease of payment was primarily due to the voluminous hospital debts and increasing debts of social security funds towards pharmaceutical companies. It was quite unfortunate that payments were done by means of Greek government bonds which unfortunately were included in the PSI conundrum brought upon by the current economic crisis, thus losing all their value.

Therefore, the sure thing is that a drastic intervention needed to take place. In reality there was never an organized political plan covering the pharmaceutical sector, no planning nor application.

Under the huge burden and pressure exerted upon us by the Troika, theoretically, we painstakingly used up all the possibilities and approaches toward the planning of a sound political framework for the pharmaceutical industry. Unfortunately, thus far not much has been achieved nor materialized.

Was it in fact necessary for these specific measures to be applied?

Many of the measures taken were in fact necessary. Obviously, an intervention needed to be made regarding drug prices, and equally important, it was necessary for the positive list to be reintroduced. Today's drug list is headed in the right direction with products being organized into similar drug categories, nevertheless, its application must be associated with the analogous therapeutic protocols and the close vigilance of Doc-

tor's drug prescribing methods, otherwise it will never be effective.

Nobody is claiming that pharma policies introduced in other countries should not be applied to Greece. It is obvious that one must take into consideration and be aware that when these measures were taken, important parameters were also taken into account. One must firstly apply therapeutic protocols, a pharmacoeconomic evaluation of new therapies, the drug list, the budget allocated for doctors, information and training of patients, and after all these considerations one can apply the mechanism of action of the active ingredient, which of course cannot be effective on its own.

It has been stated that pharmaceutical expenditure must be set at 1% of the country's GNP. Is it your belief that this is adequate?

GNP as an index is an erroneous consideration. Surely there must be a set ceiling which of course will be dependent on the course of the country's GNP. If it is in continuous freefall then the country must ensure that certain social services must be provided to its citizens. I believe that the per capita expenditure would be a more feasible index, meaning the amount of money the healthcare system must and is able to spend for every insured person. In what regards Greece's population, based on data and the variety of pharmaceuticals in the market, I believe that approximately 2,5 billion euros in pharmaceutical spending (excluding hospital expenditure) is in fact realistic and remains within the boundaries of what a country and a society like Greece's can feasibly finance.

All of this granted that the participation percentage for the insured is not increased. If we were to go to a model whereby the insured's participation is greater, then healthcare expenditure may even decrease to 2 billion euros. Nevertheless, in the case of an increase in private participation it is a prerequisite that we absolutely ensure the viability of the portion of the population that is extremely economically weak. Also, planning must be made which will allow for greater incentives for the use of cheaper medicaments.

What do you believe is the Greek Pharmaceutical Industry's gravest problem?

The problems are multifaceted. One basic problem is the lack of a stable government framework. We are faced with non-stop regulatory or other interventions which in turn alter the given facts, continuously and abruptly. All these changes do not necessarily imply that anything productive or desirable has resulted.

Moreover, in our sector up until today, instead of there being a modernization of the system, instead of the



therapeutic protocols working smoothly and efficiently, likewise for the drug list and the correct supervision of drug prescribing methods, we have unfortunately focused solely on the decrease of prices of the older drugs, products which are primarily manufactured by Greek pharmaceutical companies. When on average drug prices have decreased by 20-25%, the pharmaceuticals manufactured by the Greek Pharma Industry, the off-patent and generics have decreased by 60%. Nevertheless, regardless of this one-sided focus on drug prices, we have yet to substantially gain, in terms of sales by volume.

The pharmacist, as well as the physician and patient, have only recently begun to comprehend the fundamental importance of using generics in order to ensure the viability of our healthcare funds.

Which do you believe is the strategic direction which should be followed by the Greek Pharmaceutical Industry?

We support a model which includes a system of drug refunds based on the therapeutic categories with a set reference price, offering incentives to companies, whose pharmaceutical products are priced below the reference price, thus ensuring a small price, the reference price, for older drugs. Moreover, this model allows for a rebate volume system, in which for any company that produces a larger than predicted expenditure, it will be obliged to pay an extra, gradual rebate. A system like this would allow for a way in which to address the healthcare expenditure, while maintaining the limits within the confines set by the Troika, granted that all other measures are put into effect.

There is another section of companies which support the model of deregulation of drug prices. This model serves the purposes of multinationals and companies marketing original, patented, expensive pharmaceutical products, most especially medicaments intended for hospital use. In this model, the older drugs will be sold cheaply so as to ensure that the new drugs respectively, obtain a very high price. We will therefore end up having two categories of drugs: the very cheap ones, and the very expensive ones.

If the former model is applied, the Greek Pharmaceutical Industry can in fact obtain a large portion of the generics market. This would allow companies to invest in foreign markets whereby more assets would be obtained, thus creating a healthy, dynamic business model of development for the Greek economy by providing employment opportunities, research, and reciprocity.

If the latter model is applied, it is clear that we the Greek pharmaceutical industry will be mobile only in foreign markets, unfortunately becoming "agents" for multinational interests, within our own country!

The decision therefore is clearly a political one. It involves the future of pharmaceutical healthcare in Greece.

I must stress the fact that it would undoubtedly be a national fiscal crime for the Greek government to allocate 2 billion euros for pharmaceutical costs, when ultimately this amount would simply end up being exported.

An overall united political stance must be planned and executed so as to ensure that at least 30% of the low-priced drug market remains in Greek hands, thus achieving the objective of benefitting the national economy and our already very burdened society.