



THEODORE TRYFON

There is no room for other measures

“The pharmaceutical policies, which were implemented during the crisis, forced us into a continuous crisis management, the result of which was to significantly restrict our possibilities for growth strategies”, points out Mr. Theodore Tryfon, President of the Panhellenic Union of Pharmaceutical Industries (PEF), while making it clear that the Greek Pharmaceutical Industry cannot endure any new measures. Mr. Tryfon lists the problems caused by the erroneous policies of the last few years, and submits PEF’s proposals which can bring forth a breath of new life to the National Health System (ESY).

What are the main problems that were caused in the Greek pharmaceutical industry, by the policies implemented in the drug sector during the last 5 years?

The Greek Pharmaceutical Industry suffered the consequences of erroneous policies that were implemented in the drug sector during the last 5 years – policies which led a dynamic industrial sector, one with an annual contribution of €2,8 billion to our country’s GDP, to a financial impasse. Specifically:

- Within the context of our per-memorandum obligation to decrease pharmaceutical expenditure, crushing reductions were unilaterally

implemented in the already low prices of established Greek drugs – primarily regarding generics, which constitute the basic product of Greek pharmaceutical production. A characteristic example is the following paradox: Greek drugs, while representing 18% in volume and 25% in value of the pharmaceutical expenditure, were subjected to much larger reductions in their prices, compared to more expensive drugs.

- The financial burden that the Greek pharmaceutical industry faced, in the form of direct and indirect taxation, reached 55%, thereby creating an absolutely stifling fiscal framework for an

industrial sector which faces high operating and financial costs, and has limited access to funding resources.

Unfortunately, we have reached a point where we estimate that 50% of drug revenues go to rebates and clawback.

- The absence of an organized policy which would encourage the use of Greek Drugs, prevented an increase in market penetration of domestically produced pharmaceuticals. Instead of implementing activities aimed at comprehensively informing Greek doctors, pharmacists and patients, about the safety and affordability of Greek generics, we saw police-like legislative regulations implemented, which

brought forth absolutely no result.

- Unlike imported generic drugs, which receive marketing authorizations for the Greek market in much shorter periods of time, the domestic pharmaceutical industry faces significant delays in the marketing authorization of its new drugs. This fact undoubtedly creates conditions of unfair competition at the expense of Greek drugs.

constituting a reduction of 70% of the original price. And we say nominal value, because of the subsequently imposed rebate and clawback which must also be taken into account. It should be noted that all rebates range on average, between 12,5 and 13,5%, while clawbacks are at 10%. These facts are proof of the unsustainable conditions for many generics which as a result cannot be marketed at these prices, thus constituting a severe blow to

In what regards the public pharmaceutical expenditure cap, the situation does not seem to be changing. On the other hand, the pressure of new drugs is constantly growing. It is possible that certain new measures might be required, in the near future. Can the Greek pharmaceutical industries afford new measures?

Under the circumstances that I just described, the Greek pharmaceutical industry – an industry representing 27 modern production units in our country, holding 60% of employment positions in the sector and 100% of new investments, while ranking second in exports, has been driven to the limits of extinction. Is this what we want?

The pharmaceutical policies which were implemented during the crisis, have forced us to a constant “crisis management”, where as a result, our possibilities for growth strategies were significantly restricted.

Certainly there is no room for new measures; unless our objective is to have expensive, imported drugs dominate in the market, and to have a complete deindustrialization in our country.

However, such an eventuality will have dramatic consequences, not only for the Greek pharmaceutical industry’s sustainability, but for the Public Health as well. The consecutive price reductions in cost-effective Greek drugs will lead to their withdrawal from the market,



PEF speaks of reductions in the prices of generics, in the area of 45-65%. If one combines this with the rebates and clawbacks, where do we stand today compared to 2008?

The problem lies mostly in new generics, that is, those that were given marketing authorizations after 2012. The price of these drugs is nominally specified at 32,5% of the drug reference product’s price, for the period during which it was an original drug, thus,

the Greek pharmaceutical industry. In this context, the resulting withdrawal of affordable Greek drugs from the market paves the way for their substitution by expensive, imported drugs. Such an outcome will impede the patients’ access to necessary pharmaceutical treatments, with incalculable consequences for the Public Health. In parallel, the current framework causes an abrupt decline in the country’s social insurance revenue.

as their production will be considered unprofitable. As a consequence, the market will be monopolized by expensive, imported drugs, a fact, which in turn, will impede the patients' access to necessary therapies, especially amidst a period of limited income. You realize, therefore, that ethical issues are also raised.

In any case, it doesn't make sense not to exploit the dynamics of a sector which for 50 years now, develops significant technical know-how, while according to domestic and international studies, ranks among the nine growth forces that will lead our country out of the crisis.

We will continue to function as a responsible social partner; in this context, we want the sustainability of the social insurance funds. We are in favor of adopting fair measures which will take into account the proportional participation of each cost center in the shaping of expenditure. In such a direction, the fragmentary reductions which were implemented in previous years, must yield to cost-volume agreements.

We constantly hear about measures for generics. Was there an increase in the prescriptions' volume, after all?

Currently, what is observed is an increase in their penetration for certain therapeutic categories something which in fact is very positive, but, is far from the intended objective, so

much for the social insurance funds, so much as for the patients.

However, what is important is that today, the Greek insured patient has begun to be aware of the quality and reliability of Greek pharmaceuticals, and to examine the cost of his/her participation in the pharmaceutical treatments. From the alternative choices of domestically produced drugs, the patient can understand that he/she should direct himself/herself towards domestically produced drugs which are both quality and cost-effective.

Besides, Greek pharmaceuticals are present in Greek households for 50 years now. Therefore, you realize that millions of Greek pharmaceutical packages have been used these past 50 years by Greek patients, thus, subconsciously giving these products the recognition they deserve. Therefore, the trust in generics, especially those which are domestically manufactured, is indeed boosted; yet, significant steps are still required in order for us to achieve the goal.

You have stated that during the last two years, the budget for Health is at very low, unattainable, levels; that is, almost 30% below the European average. What sort of problems does this create, and what do you consider a rational amount to be given to the Drug sector?

It is crystal clear that the shooting rise of the pharmaceutical expenditure in 2009, made necessary the adoption of measures in a direction so as to curtail it. Still, the memorandum target for a public pharmaceutical expenditure at 1% of the GDP threatened the sustainability of both Greek public Health as well as the pharmaceutical market. In addition, while one would expect the attainment of such a goal to be included in the framework of an overall policy of substantial restructuring (that is, rationalization of the pharmaceutical market), through promotion of the required structural measures, the Troika's unilateral rationale was based on an 'accounting' perception of this specific extent.

Within this context, a policy of violent and horizontal reductions was adopted – reductions which completely ignored the patients' needs and the particularities of the Greek Healthcare System. Furthermore, it does not make good use of the proposals that were put forward by the Greek Pharmaceutical Industry (PEF) – proposals which ensure a coverage of 70% of the pharmaceutical needs of PHC, and 50% in hospital care, and without any additional cost for the State. Under these circumstances, we were led to the following:

- The objective of restricting pharmaceutical expenditure has

brought about opposite results in the public health and national economy, to the results sought by the competent authorities. The 60% reduction of this specific amount, drove our country, like you said, to the lowest per capita public pharmaceutical expenditure in the EU (€179 versus €320, which is the average per capita expenditure in Europe); this had dramatic consequences for the public Health, but also for public revenues. In fact, according to a research recently conducted by the University of Peloponnese, for every €100 million reduction in pharmaceutical expenditure, the State loses €47 million from public revenues, as well as 350 highly-trained jobs.

- In order to limit health expenditure, there was a unilateral focus on dramatic reductions in pharmaceutical expenditure; as a consequence, other cost centers, which significantly participate in the formation of the overall health cost,

were affected to a much lesser extent.

- It led to an indirect market share reinforcement of expensive, imported drugs, at the expense of domestic production. In fact, during the last few years, in spite of the constantly shrinking pharmaceutical expenditure, a 23% increase in the market share of expensive drugs has been observed. Therefore, it is obvious that it is essential to redefine in a realistic manner, the budget's limits for pharmaceutical healthcare; for us, this would entail the following prerequisites:
 - Determining the pharmaceutical expenditure for drugs at €2,3 billion, instead of the current €2 billion. This has also been emphasized by the political leadership.
 - Forming a separate, closed budget for high-cost drugs (HCD).
 - Separating the social welfare policies in the drug sector, from the closed pharmaceutical expenditure budget.



You have spoken about the Troika's interventions, which afflicted the Greek Pharmaceutical Industry. What is it exactly that you refer to?

During the memorandum, the domestic drug production sector suffered a dramatic blow, in terms of pricing and taxation, but also by means of a series of financial burdens – the most representative example being, the successive annual rebates and clawbacks, as well as the “haircut” of Greek government bonds, with which orders of the Greek pharmaceutical industry had been paid, by the PSI. The situation worsened further by the complete lack of a government policy encouraging the use of generics. The suffocating framework that was formed for the domestic pharmaceutical industries, significantly limited their possibilities for growth strategies, thereby rendering

visible the risk of their extinction.

In this context, our sector's proposals were ignored – proposals, according to which, and with no additional cost for the State, we are committed to:

- Cover 70% of primary healthcare and 50% of hospital care with reliable, branded and cost-effective drugs.
- Immediate realization of new investments in equipment, cutting-edge technology, research and technical know-how.
- Reinforcement of employment with at least 2,000 new recruitments, thus, considerably increasing indirect employment.

It is therefore evident, that the Greek Drug was “sacrificed” on the altar of cost-cutting, and of the market's monopolization by expensive, imported drugs. It is demonstrated clearly by the result itself, that the Troika's interventions failed to yield the ‘fiscal therapy’ and reformation of the pharmaceutical healthcare sector. The healthcare crisis continues to wreak havoc in our country, threatening the citizens' health as well as the sustainability of the country's social insurance funds. By obsessively persisting on measures that had no possibility to succeed in Greece, indirectly, the Troika

drove one of the last productive fields of the country to significant shrinkage, with no benefit for the social insurance funds, by merely redistributing the market shares within a closed budget.

During the first few days, after assuming its duties, the new leadership of the Health Ministry on many occasions emphasized that “Greece can become the Switzerland of the South in drug production”. How do you judge the government's intentions relative to the Greek drug, and what do you actually expect in practice?

I think that in this case, the numbers themselves provide the answer. Being in the position of the second most dynamic export pole in our country, with 27 ultramodern production units, with 50 years of supreme technical know-how, and with annual investments of €30 million in more than 80 research programs, the Greek Pharmaceutical Industry represents a business sector which must actively participate in the country's plans for productive reformation.

These facts certainly allow a margin for plenty of optimism. However, as long as there is a continuation of the unilateral, “accounting” perception of previous years, the sector's growth potential is increasingly downgraded. In this context, it is deemed as necessary to provide the required incentives, with the

implementation of a specific taxation policy being the first step towards such a direction. In parallel, it is essential to formulate a new pharmaceutical policy model, with stable market regulation, with the objective to achieve the release of growth investments.

The Greek Pharmaceutical Industry has the potential to unfold its role as a social partner; for this reason, it is required to establish an atmosphere of dialogue with the government, in order to not only cover the pharmaceutical needs, but also to activate the procedures that will encourage the sector's growth, to the benefit of the country's economy.

Consequently, cooperation is of the outmost necessity, as well as an environment of mutual trust, in place of the unjust, horizontal measures that were implemented in previous years.

Having the honor and responsibility to represent the Greek Pharmaceutical Industry (PEF), I want to believe in the prospect of an effective collaboration with the new political leadership – one that will aim at establishing growth rates for our country. Towards this direction, providing the necessary incentives to multinational industries will play a substantial role, in order to encourage investments in production and research.

PEF'S POSITIONS ON THE DRUG SECTOR'S POLICY

1. Drawing up a sustainable budget for drugs, one which will approach the European Union's average, in terms of per capita drug expenditure, taking into consideration the needs of the uninsured population, as well as the participation of other cost centers (aside from drugs) in the formation of the overall expenditure.
2. Restrict the arbitrary, horizontal, rebate and clawback for domestically produced drugs, within the context of an effort to stabilize the Greek Pharmaceutical Industry sector.
3. Restore the mistakes that were observed during these last years in the pharmaceutical pricing lists, leading to distortions in the market. This grave confusion of re-costing experienced in previous years must cease, as it has thrown the spotlight on the pricing issue, focusing in a unilateral manner, on drug prices and imposing exhausting reductions in the cost-efficient Greek drugs.
4. Control and evaluate the effectiveness of expensive drug treatments, aiming for reimbursement through the social security system, of truly innovative drugs.
5. Implement a policy for domestically produced generics, through public awareness activities, in order to encourage their use to Greek patients, and to increase Greek pharmaceutical market penetration.
6. Promote a series of reforms for the control of consumption, and the promotion of proper drug use.
7. Participation of the domestic pharmaceutical industry in the country's plan for productive reconstruction.
8. Establish a new policy model on drugs, with stable rules and market incentives.
9. Reinforce the Drug Directorate of EOPYY.
10. Staffing and reinforcement of EOF(National Drug Agency).

PRESCRIBING BASED ON THE ACTIVE INGREDIENT

"Prescribing based on the active ingredient has been a measure which did not yield any results in terms of fiscal savings. On the contrary, it created distortions, essentially removing the 'identity' of Greek drugs. By excluding prescriptions based on brand name, the perceived value of every drug was diminished, a value which is unique for patients and doctors. In parallel, this particular measure was not accompanied by the provision of appropriate incentives for doctors, pharmacists and patients, in a manner whereby the use of generics would become their conscious choice. Within this context, it has undoubtedly been a counter-incentive for the expansion of their use".

DRUG PROCUREMENT TENDERS

"The tendering procedure model for drug procurement adhered to in hospitals, led to their unconditional surrender to drug importers. In fact, during the last three years, the tenders that were held by the Committee for Health Procurement, had the lowest price as a sole criterion, while simultaneously committing to the fact that each drug's procurement would be done from a single supplier. This gave the possibility to specific multinational pharmaceutical companies, which have a tradition in strategic 'price dumbing', to offer degrading drug prices, in order for them to be distinguished as the lowest bidder. They followed this tactic even when they knew beforehand, that they were **unable** to supply the National Health System with the required amount of drugs. Undoubtedly, these conditions established a context of monopolistic hostage, per active ingredient, thus destroying domestic competition and contributing to our country's absolute deindustrialization".

For 50 years now, we are constantly growing in order for you to grow along with us!

It is time to introduce ourselves!

For 50 years now, you trust us and we continue to create reliable Greek drugs. We are in every Greek household, as well as in 60 countries, and we are constantly growing in order for you to grow along with us!

The leading Greek pharmaceutical company: ELPEN