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Annual Report 2009

Executive Summary

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IOBE's Annual Report 2009 on the Greek Pharmaceutical Market includes a description and analysis of the demand and supply-side of the sector, the trends of external trade, the regulatory framework and the global environment of the pharmaceutical market.

Demand for Pharmaceuticals in Greece

Analysis of the pharmaceutical sector's demand-side includes, on one hand, the description of its determinants (demographics and epidemiological data) and, on the other, the description of the pharmaceutical expenditure evolution (public and private).

According to OECD data, in 2006 the Greek population exceeds 11.1 million persons, of which 50.5% are female and 49.5% are male. Moreover, according to data by the National Statistical Service of Greece (ESYE), the total number of births and deaths in 2007 amounted to 111,900 and 109,900, respectively.

The average *life expectancy* at birth in the Greek population is 79.6 years (82 years for females and 77.1 years for males). Apart from the increase in life expectancy, another significant factor which contributes to the increase of pharmaceutical expenditure over time is the ageing of the population. An index which measures the changes in the ageing structure of the population is the *Old Age Dependency Ratio*, which calculates the percentage of people between 0-14 years old and from 65 years and over, to the total of the economically active population group (people between 15-64 years old). This index exhibits an increasing trend over time, as the life expectancy increases while the number of births does not. Greece's index (48.9) is lower than Europe's average and is at about the same level with USA's and Australia's. Nevertheless, it is important the fact that half of the population supports the other half, and this percentage tends to go up in the following years, making therefore this relation more unfavorable.

The *main causes of mortality* in Greece in 2007 were cardiovascular diseases, malignant neoplasms and cerebrovascular and respiratory diseases. The above mentioned four categories are responsible for 78.4% of total deaths, while there is a relatively high death-rate which is responsible for "incidents vaguely determined".

Pharmaceutical expenditure is a proxy for demand in the pharmaceutical sector, and – according to the OECD System of Health Accounts- it *includes only expenditure for*

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pharmaceuticals dispensed to outpatients. According to ESYE's provisional data, the pharmaceutical expenditure in Greece in 2007 *reached* €4.5 *billion, accounting for 21.6% of total health care expenditure and 2% of GDP.* Indeed, pharmaceuticals in Greece are only a small portion of health care costs (almost one fifth over time) and represent a social good, as 86.5% (average of 2000-2007) is covered by social insurance (Diagram 1).



Diagram 1 Public and Private Pharmaceutical Expenditure

It is estimated that the *public pharmaceutical expenditure* (i.e. the amount compensated by the Insurance Funds), is roughly equal to half of the total pharmaceutical sales (hospital sales are also included). Also, it is noted that for the first time in the history of the Greek State, the public pharmaceutical expenditure was officially announced through ministerial decision and it appeared that in 2006 it was ≤ 3.22 billion and in 2007 it was ≤ 3.83 billion.

Health expenditure exhibits a long-term increasing trend like pharmaceutical expenditure as a subclass of it. The **evolution of pharmaceutical expenditure** in Greece is connected with the increase in the consumption of medicinal products, as a result of socio-economic and demographic factors. More specifically, the ageing of the population, the high number of immigrants who possess legal authorisation of residence and work in our country (provided that they are covered by the public insurance funds or by private insurance companies) and the development of the pharmaceutical science - which contribute in the marketing of new active substances and in the import of new technology, are factors which lead to the increase of pharmaceutical expenditure.

As it is proved in a recent study of IOBE concerning the over time evolution of prices of medicinal products over the period 1997-2008, *the total decrease in prices of the top 100 medicinal products in terms of value (for 2008) amounted to 6.6% during the last decade*. Moreover, concerning the top 100 medicinal products in terms of value, their weighed - by their market share in the total market - price change decreased by 2.21% and their weighed - by the packages sold (i.e. quantity) - price change decreased by 4.95%.

Source: National Statistical Service of Greece (ESYE), National Accounts *: provisional data

According to the same study, *the average price of the medicinal products marketed in* **2008** (approximately 12 thousand medicinal products) *increased by* **1.32%** (average for one decade) *from the time they were launched until December 2008*. Specifically, for every medicinal product it was calculated the change in its price from its launch up to the publication of 2008 Consolidated Price Bulletin.

The Supply- Side of the Greek Pharmaceutical Sector

In 2007 Greece has 150 *pharmaceutical wholesalers*, which places it in the third position among European countries in the number of pharmaceutical wholesalers; France has only 9 and Germany 16. In addition, Greece has the highest number of *pharmacies* in Europe per 100,000 inhabitants (i.e. 94.2 pharmacies per 100,000 inhabitants).

The change of law regarding the pricing system of medicinal products, took place in November 2005 (Law.3408/05, FEK. 272 A') and the first Price Bulletin (P.B) was published in April 2006. However, the gap that was created in the publication of P.B. (from 11/2004 until 4/2006), had as a result the P.B. that were published in 2006 to include a great number of new medicinal products (1,952). In other words, 2006's P.B. included medicinal products which launched in the market with a delay of up to 1.5 year. As a result the total pharmaceutical sales in 2007 increased by 29.7% compared to 2006, while the Mean Annual Growth Rate (MAGR) of sales for the period 2000-2007 was 17.5%.

Total sales in 2007 reached €5.5 billion (at ex-factory prices), 72.5% of which include sales to wholesalers and pharmacies (and therefore include parallel exports), while the remaining 27.5% refers to sales towards hospitals.



Diagram 2 Pharmaceutical Sales in Value and Shares of Sales towards Hospitals and Wholesalers / Pharmacies

Source: National Organization for Medicines and IOBE calculations Data include parallel exports

Pharmaceutical sales in 2007 included sales of branded original products at 87% and branded essentially similar products at 13%. The first therapeutic category in terms of sales in 2008 was cardiovascular disease (23.8% of total sales), followed by sales of medicines for

the central nervous system (16%) and for the alimentary tract and metabolism (12.6%) (Source: Hellenic Association of Pharmaceutical Companies, SFEE).

Domestic pharmaceutical *production* in 2007 fell by 1% compared to 2006 and reached €704 million. The MAGR for the period 2000-2007 is 11.1%.

Based on ESYE's Annual Industrial Surveys, productivity in the pharmaceutical sector in 2006 was €57,160 per employee (increased by 12.5% compared with 2005), while *investment* in the sector exhibited an increase of 56.7% compared to 2005. In 2006, 5,726 persons were employed in the production of pharmaceuticals, accounting for 35.7% of employees in the chemical industry.

The *capacity utilisation rate* in the pharmaceutical industry reached 82.2% while the respective rate of the total manufacturing sector was 75.9% (IOBE's Business Trend Survey's).

Employment in the pharmaceutical industry reached 13,500 employees. Employment's evolution is extremely ascending over the last six years, while in the other sectors it decreases or remains stable. Moreover, according to IOBE's research findings, the mean annual employment in the pharmaceutical sector exhibits an increasing trend during the years 2002-2007, with a MAGR of 4.2%. Among the employees with Highest Level of Education, most of the staff is specialised in Economics and Chemistry, while Biology, Pharmacy, Business Administration, Marketing and ICT (Informatics Computer Technology) training are also frequent scientific specialties among University Graduates.

The Business Confidence Index in the pharmaceutical sector is higher than the respective index for the total manufacturing sector. Particularly, in 2008 the average Business Confidence Index in the pharmaceutical sector reached 107 units, while the Index for the total manufacturing sector was 92 units. However, the Index in the pharmaceutical sector after a period of relative stability presented a decreasing trend in the last trimester of 2008, as it moved to a level lower than the average.

Finally, the Pharmaceutical Price Index presents a lower annual rate of increase than the Health Price Index and the Consumer Price Index. In particular, the annual change of the Pharmaceutical Price Index reached 1% in 2008, while the Health Price Index and the Consumer Price Index increased by 3.6% and 4.1%, respectively.

The External Trade of the Pharmaceutical Sector

Based on Eurostat data, Greek trade flows of pharmaceuticals exceeded €4.2 billion in 2007, exhibiting an average annual increase of 8.1% for the years 2005-2007. Pharmaceutical imports increased by 13.9%, reaching €3.35 billion. Pharmaceutical exports exhibited an increase of 4.2% in comparison with 2006, reaching €942.3 million. The country's trade balance for the pharmaceutical sector is negative throughout the period under examination and exhibits an increasing trend (from €2 billion in 2006 to €2.4 billion in 2007) (Diagram 3).



Diagram 3 Evolution of Imports, Exports and Trade Balance

Πηγή: Eurostat

The 81.7% of total imports derives from the EU-25 countries, and the remaining 18.3% derives from the extra-EU countries. Similarly, exports are mainly directed to the EU-25 (92.8%). Germany holds the first position in Greece's commercial transactions in the field of pharmaceuticals, as it has the largest share of both exports and imports for 2007.

The Regulatory Framework of the Greek Pharmaceutical Sector

In Greece, all marketed prescription medicines are reimbursed by Social Insurance. The reimbursement system includes three co-payment rates for pharmaceuticals (25%, 10%, 0%), based on disease severity and the socio-economic characteristics of the insured.

With the article 35 of Law 3697/09 (FEK.194A'/09) the Insurance Funds cover the expenditure of the prescription medicines up to the Reference Price (the Retail Price decreased by 3%), decreased by the co-payment rate of the insured. The expenditure concerning the 3% burdens exclusively the pharmaceutical industry or the holders of medicines' market authorisation. In other words, according to the new Law the pharmaceutical companies return the 3% of the Retail Price of pharmaceutical expenditure to the Insurance Funds (rebate).

Regarding the pricing system, a price must be assigned to a pharmaceutical product, in order to be marketed, by the Ministry of Development, based on the system of "2+1" (three lowest prices in European countries). In 2008, five Price Bulletins were issued, that is to say that the bulletins were issued in an interval smaller than 90 days (i.e. according to the national and Community legislation a price bulletin is issued every 3 months).

Finally, one of the major problems of the domestic pharmaceutical industry, which is directly related to the regulatory framework of the pharmaceutical market, is *hospital debt* towards pharmaceutical companies. According to SFEE's report, the total amount of debt in December 2008 was €2.68 billion, exhibiting an increase of 39.3% compared with December 2007 (€1.92 billion). The average payment delay amounted to 27.36 months.

The International Environment of the Pharmaceutical Sector

According to IMS Health, the global pharmaceutical environment in 2008 showed a marginal improvement. *Global market sales* reached \$773 billion, marking an increase of \$58 billion compared with 2007 –however the rate of increase was reduced to 4.8% from 6.6% in 2007.

North America (USA and Canada) holds the largest share of sales in the global market (40.3% in 2008), followed by the European market (32%) and by Asia, Africa and Australia (11.7%). The highest rate of increase was noted in Asia, Africa and Australia (15.3%), while Latin America although it is the market with the lowest share of global sales (6%), it exhibits high rate of increase (12.6%).

One of the characteristics of the global pharmaceutical market is the significant shift of demand from mature to developing markets, as the growth rates in mature markets gradually moderate, while developing markets, with low shares of global sales, continue to exhibit two-digit growth rates.

Finally, the fact that the global pharmaceutical market –although to a lesser extent than many other industries- is affected by the impact of the economic crisis, sets the perspectives for the following years very worrying (IMS Market Prognosis). Moreover, in 2009 the global pharmaceutical market is expected to grow only 2.5% -3.5% and apart from the impacts of the economic crisis, the pharmaceutical market is going to face a large number of patents of the leading pharmaceutical products, which will expire by 2012.