
Greece

Capital: Athens
Population: 10.8 million (2013 estimate)
GDP:* €182.1 billion (2013), €193.7 billion (2012)
Currency: Euro
Language: Greek (official)



Summary

Greece finds itself in one of its most challenging periods in its post-war history. The economic developments in Greece, triggered by the recent financial crisis, have created a new environment for all sectors. The government has made progress in carrying out widespread economic reforms. Many of these reforms aim to simplify the investment framework, and the government is aggressively seeking to attract foreign investment to drive the country's long-term economic recovery. After six years of recession, Greece is expected to return to positive growth rates (+0.6%) in 2014. Business confidence dropped sharply through the crisis, but after Greece and its international creditors reached agreement on a large disbursement of assistance (over €50 billion) for the country in early 2013, sentiment along with several economic indexes improved and this trend continues in 2014 to date. Access to the international capital markets has improved, as demonstrated by two successful senior bank bond issuances for the first time since 2009 and the successful share capital increases by all four core banks, validating investors' renewed trust in the Greek economy.

Amidst the above developments, Greece's geographic location continues to make the country an excellent business gateway into Southeastern Europe. The continuously growing demand for medical equipment in Greece, as well as in many of the developing Balkan states, provides strong prospects for companies in the medical equipment field in Greece and neighboring Balkan countries. The Greek market for medical equipment had experienced stable annual growth of 12.7 percent in the previous years, which is expected to resume, following the expected overall market recovery. One of the prime characteristics of this market is its high level of imports.

Spending in 2011 of 21.80 billion euros (\$30.31 billion) was reduced to 20.34 billion euros (\$25.83 billion) in 2012 in both the public and private healthcare sectors. The government is finalizing the merger of many hospital units and attempting a twenty-four hour operation standard within all public hospitals, with a greater level of transparency in hospital financial transactions and hospital procurement. Healthcare expenditures as a share of GDP in Greece have been reduced to 6.3% annually in 2012. This expenditure is comprised of approximately 60% government-provided care and 40% private care. Preference for private healthcare has been higher in Greece than in most E.U. countries during the recent years, although this is changing, given the economic situation and Greek citizens' ability to pay for private care. Still, healthcare is the number one concern since more than 25% of the population is over 60 years old.

Market Entry

General

As a member of the E.U., Greece applies the E.U. common tariff schedule on products imported from non-E.U. countries. All products, regardless of origin, are subject to the value-added tax (VAT) which is 23 percent for most products and 11 percent for pharmaceutical products. A further increase is under debate, as a result of the government's intention to raise more funds to fight the budget deficit. According to sources*, the projected expenditure on Pharmaceuticals for Q4 in 2012 was US\$ 7.5 bn, on Healthcare US\$26 bn and finally on Medical Devices US\$775mn.

Medical Equipment & Devices Sector

While duties are applied to parts of medical products and disposables, U.S. medical equipment receive duty-free treatment. Within the E.U., medical device legislation has been harmonized through the European Union's Medical Devices Directive 93/42/EEC. This enables a manufacturer who has approval in one E.U. country, to gain access to Europe's entire market without having to obtain approvals from each additional country. All low risk devices, which are in conformity with the requirements of the directive, must carry a CE mark. Higher risk classified products, in addition to the CE mark, must carry the identification number of the certifying organization that performed the conformity assessment and issued the approval. National implementation of the Medical Device Directive requires instructions for use in the national language. However, technical manuals and promotional material may be in English, French or German. Representatives in Greece can assist U.S. companies to meet these standards, if the U.S. firms have not already done so, in an effort to enable them to gain access to E.U.'s entire market. Other Directives they follow under the European Legislation are Data Protection Directive (95/46/EC), Electronic Signatures (1999/93/EC), Patient Rights in Cross border healthcare (2011/24/EU), Medical Device (90/385/EEC),(93/42/EEC),(98/79/EC), Electronic Commerce (2000/31/EC).

OTC & Dietary Supplements Sector

All the details pertaining to the introduction of a new food supplement to the Greek market are outlined in the Greek Government Gazette #935 of November 13-1995 and in the E.U. Directive 2002/46/EC of the European Parliament. An American company interested in entering the Greek market is advised to find a local agent/distributor in order to expedite procedure normally encountered during the registration-approval process. The National Organization for Medicines (EOF) is the official authority for granting authorization to the sale of medicines and drugs in Greece.

In 2012, a plan to merge the National Organization for Medicines with the Hellenic Food Authority and other similar organizations was proposed to the Greek Government by appointed consultants. With this merger, the new centralized agency would resemble the U.S. FDA and contribute towards a more immediate regulatory process.

Current Market Trends

Medical Equipment & Devices

The Greek market for medical equipment was estimated in 2010 to have increased by 5.4 percent compared to the previous year. It is estimated that the Greek market for medical equipment in 2010 reached \$1.569 billion, out of which around 95 percent was supplied by imports. The greater share of the companies' revenues is recorded in their business with the public sector (at around 80 percent) but this slightly changed due to the revised company focus toward the private healthcare sector, given its ability to pay for the products it buys in a reasonable time frame. As of 2012, approximately 13,000 individuals are employed in the Greek pharmaceutical and medical supplies fields. Medical Devices and Diagnostics total market value reached 1.2 million euro in 2012 and faced a decline of approximately 10% from 2011 as a repercussion of the economic crisis. However, for 2013 onwards this decline has been stabilized from 10% reduction with signs of positive prospects thereafter.

Health IT

Health Information Technologies (e-Health) consists of hardware and software systems used by healthcare professionals to gather, file, classify, have access to, and electronically exchange healthcare information including administrative, clinical and other supportive systems. eHealth is one of six prioritized markets in the European Commission's Lead Market Initiative, a public-private dialogue to promote innovation and an open market. The Commission's eHealth Action Plan 2012-2020 sets out the following goals and asks member states to work closely together with EU institutions to: 1) achieve wider interoperability of eHealth services; 2) support research, development and innovation in eHealth; 3) facilitate uptake and ensure wider deployment; 4) promote policy dialogue and international cooperation

on eHealth at global level 5) improve legal and market conditions for developing eHealth products and services. As stated in the European Action Plan, the development of e-Health aims to improve the implementation of digital systems for monitoring and home care for the elderly and chronically ill, in disseminating the use of telemedicine technology for diagnostic and therapeutic purposes, to enhance the safety and quality of cross-border health services, promoting innovation to create new products and services that can contribute to the sustainability and efficiency of health systems, and generally improve the quality of life of Europeans citizens. In addition, the development of e-health services can contribute decisively as a major engine of growth and competitiveness in European industry and technology.

In terms of e-Health, Greece scores below the E.U. 27 average regarding availability of Information and Communication Technology (ICT) infrastructure (computers and Internet) and the use of ICT for e-Health purposes. Although Greece was lagging behind the E.U. in internet penetration and broadband, the aim of the National Digital Strategy was to reach the E.U. average by 2010, and the recent government efforts through its National Digital Strategy (2007-2013), including related investments of over \$665 million have already led to considerable improvement. In particular, Greece is quickly catching up to the above-mentioned E.U. average (20 percent). According to the National Telecommunications and Post Commission, by the end of March 2012, the market grew by 8.1% year-on-year.

Although the use of ICT technology for use in healthcare appeared in the 1980's, ICT solutions have not yet been strongly adopted in healthcare practice in Greece. This is mainly due to the rather late development of an e-Health strategy. However, the successful Conference under the Greek Presidency [E-Health Forum 2014] shows that e-governance together with private business initiatives may change the scenery, This moves Greece towards the real development of the Greek eHealth ecosystem that will bring the country closer to the goals of the EU Action Plan 2012-2020 for eHealth while at the same time it attracts the interest of the industry and other stakeholders. The eHealth Forum 2014 served as the meeting point for the six Actions Groups of the European Innovation Partnership on Active and Healthy Aging (EIP on AHA). The Forum brought together the High Level eHealth Conference and Exhibition, the eHealth Network Meeting and many more events, and become a true forum for the exchange of experience, mutual support, good practices and innovation.

The first preparatory meeting for the eHealth and the Greek eHealth Ecosystem took place in July 20, 2013, thus reinforcing the strong commitment and investment in the deployment of eHealth solutions and the dissemination of good practices. Therefore, the required infrastructure, including standards, a national health portal, insurance smart cards, electronic information systems, etc., will start becoming available in the upcoming years. eHealth facilitates the values of equity and solidarity by enabling the access to high quality services and safer care for all, including numerous groups of citizens with chronic diseases and the elderly. At the same time it serves as the backbone for necessary structural and functional reform and for addressing the issue of shortage of financial resources.

Greece considers that ICT solutions and eHealth could lead to valuable, sustainable outcomes for the society, promote the wellbeing of the European Union citizens and build a solid base for the delivery of cross-border healthcare through interoperable services. Regardless of the recession, Greece aims at driving eHealth forward. The Greek Presidency through the eHealth Forum encouraged the development of visionary policies and looked into maximizing health and economic benefits and the potential for employment through new technologies.

Best Prospects for U.S. Firms

Health IT

Below are some of the existing or upcoming areas of opportunity:

Hospital procurement based on Electronic Data Interchange Systems (EDI)
Information system for transactions between hospitals and insurance companies

Smart health insurance cards
Information system for the national ambulance service
Information system for organ transplantation coordination and control
National blood-bank information system
Primary care information system
Medical libraries information system
Clinical information systems such as radiology information system; Nursing information system; Computer assisted diagnosis; Surgery training and planning system
E-care & telemedicine such as disease management, and remote patient monitoring,
Development of information systems to improve the services provided by welfare and mental health providers to the elderly and people with special needs.
e-Prescription and e-Referral, e-Labs systems(inclusive of provisions for appropriate accreditation, testing and certification).

OTC & Dietary Supplements

The regime for over-the-counter medicines (OTCs) and dietary supplements, including vitamins is highly restrictive. Greece is among the few EU countries that both set prices throughout the vertical production chain for OTCs (ex-factory, wholesale and retail prices) and restrict their distribution to licensed pharmacies only. The joint restriction severely limits competition in the market, leading to under-investment in the sector and poor availability of OTCs and dietary supplements for consumers. The OTC healthcare market in Greece is characterized by consolidation of global supplies, with multiple foreign brands active in the market. This market condition does not seem likely to change, as multinationals are only becoming stronger and traditional Greek firms are moving towards importing rather than manufacturing medicines. The trend of health and wellness in Greece has favored companies in nutritionals, herbal/traditional products and in OTC healthcare, for example vitamins and dietary supplements.

A recent contributor to the sector's positive growth is the ongoing trend towards self-medication as many Greek people are now avoiding a visit to the doctor for economic reasons. Also, further to the recent removal of non-prescription products from the public reimbursement plan, and their relevant transfer to official OTC status, there is opportunity for OTC market development in the future. Availability without prescription from the Greek public reimbursement scheme, supports the development of a real OTC market in the longer term.

During the past couple of years, weight management in Greece encompassed a shift away from meal replacement slimming and move towards weight loss supplements and OTC. Dynamic new product launches within weight loss supplements and the positive performance of GlaxoSmithKline's Alli (example of an OTC obesity brand) were the main reasons for the shift towards weight loss supplements and OTC respectively. Weight loss supplements recorded the fastest value growth in weight management in Greece during the past couple of years, increasing in value by 13%.

The Greek vitamin and dietary supplement market has grown significantly during the last decade, creating investment opportunities. Consumption of vitamins and dietary supplements has increased as people learn of potential beneficial effects through advertisements and their doctors. Vitamins and dietary supplements increased in value by 2% in 2011 and onwards, including those which are normally associated with health and beauty and skin health as well as anti-ageing and anti-stress products and products which boost immunity and energy levels.

Dietary supplements and herbal/nutritional products remain under the supervision and control of the National Drug Administration (EOF) with very few exceptions (e.g. herbal nutritional supplements). Consequently, the majority of these products can only be sold through pharmacies, are not eligible for reimbursement and their prices are set according to a reference price system. Cosmetics also fall under the supervision of the EOF following the European Regulation No. 1223/2009, which is common for 31 European countries, as well as the REACH regulation on chemicals No. 1907/2006.

Main Competitors

In the Greek market, there are approximately 300 active companies in the medical device field. These companies are mainly importers and distributors of scientific and medical equipment which also provide after-sales services. Key suppliers of medical equipment to Greece are the United States, Germany, and Italy, and to a smaller degree, the Netherlands, France, United Kingdom, and Luxemburg. The E.U. has acquired a major share of the Greek market due to geographic proximity, product quality, established marketing arrangements and favorable tariff treatments. Domestic manufacturing in this sector is not highly developed. Consequently, the supply capability of Greek companies is largely limited to low-value products such as syringes, bandages, gauze and various small medical devices. The medical equipment market in Greece is highly competitive because of the number of diverse importers. The structure of the public healthcare sector and especially the bureaucratic process of the existing tender system make it imperative for U.S. suppliers to have local partners. Competitive strategies focus mostly on pricing, exchange rates, and payment terms, particularly when dealing with the public hospitals. Leasing is also an option, especially for large, high-tech, expensive equipment. The most active and profitable sub-sectors for foreign suppliers include surgical equipment and supplies, electro medical equipment, IT healthcare systems and telemedicine technology. Specifically for IT healthcare, there is significant demand for products that increase the patient's safety through reduction of medical errors, while improving health information management.

Relevant U.S. company presence in the Greek market includes: 3M, Abbott, Alcon, Bard, Baxter, Boston Scientific Hellas, Carestream, Edwards Lifesciences, GE Medical Systems, Johnson & Johnson, Medtronic, Stryker, and Teleflex Medical. It should be noted that the actual share of U.S. imports was much higher than the estimated 18 percent because a large amount of the medical equipment was produced by the European subsidiaries of U.S. firms and are registered as having originated in the E.U.

Current Demand

There are two major sources of demand for medical devices: (1) Public Health Institutions (hospitals, health centers, and regional clinics) and (2) Private Health Institutions (hospitals, clinics, diagnostic centers, and professionals). Demand from consumers represents a small but increasing segment of the market. Research shows that demand for medical equipment from public hospitals represents approximately 80 percent of the total demand, making public sector hospital payment delays a serious concern. There are ongoing public and private initiatives to reduce the mismanagement of public capital and delay of payments, which the new government claims is at the top of its agenda. Additionally the Greek government has agreed to start paying off debt to hospital suppliers and to maintain the uninterrupted flow of medical supplies and consumables the public hospitals but this is still enroute.

During the past year, progress has been made in the electronic processing of prescriptions which leads to better drug control within the public sector. Doctors are now required to electronically prescribe medication. With this change the government has started to regulate the budget for pharmaceuticals accordingly.

The challenges within the public sector have created an opportunity for the private sector to grow in importance. The involvement of the private sector in health care delivery is extensive and has been growing rapidly since the early 1990s. The current number of private hospitals is 146 with a total capacity of 38,628 beds and 140 hospitals in the public sector with 37,027 beds accounts for 95.9 percent of the total healthcare infrastructure. Most of these facilities are general and maternity hospitals. There are also 170 private clinics in the country with another 15,028 beds. (BMI, source 6) The private hospital sector accounts for 39% of all health services provided in Greece, trying to capture opportunities in new areas, such as Medical Tourism.

The market leaders in the private Healthcare Sector in Greece are the Athens Medical Group, Euromedica, Hygeia Group, and IASO Group. These medical business groups have grown tremendously from the past decade. These companies continuously seek to increase their stake in the market, however, because of the current economic situation, operate under financial pressure. Already, they have established facilities in Greece, and some neighboring countries such as Albania and Cyprus. The private health care sector is averaging an annual growth of 13-15 percent. General and diagnostic clinics have averaged 16.8 percent and 8.4 percent annual growth, respectively. In terms of primary health care, there are more than 25,000 private practitioners and laboratories, and approximately 250 diagnostic centers in Greece, most of which are equipped with, "big ticket" medical technology. Private practices, labs and diagnostic centers are also contracted through social insurance funds to provide health care services to their beneficiaries. Remuneration is on a fee-for-service basis. Rehabilitation services and services for the elderly (geriatric homes, etc.) are predominantly offered through the private sector. Finally, the private sector through its digital strategy, together with the Ministry of Health are following an ongoing development /adaptation of Hospital Information Systems applications, to comply with the newly introduced and evolving, requirements on DRGs, billing, and reporting.

Registration Process

There is no requirement for an FDA certification since it is not accepted by the EU Legal framework. Every product even if it has an FDA Certification should comply with the European standards. More particularly, companies interested in exporting to Greece should apply through the importing company to the National Organization for Medicines (EOF), indicating the country and the laboratory that produced the pharmaceutical as well as precise details about its active ingredient, etc. The company importing the U.S. pharmaceuticals should also have a specialized license to import pharmaceuticals obtained by EOF. The exporter and/or the product should also comply and be certified with the Good Manufacturing Practice (GMP) by a member state of the EU. This can be based on the Compilation of Community Procedures on Inspections and Exchange guidelines as described in the Outline of a Procedure for Coordinating the Verification of the GMP Status of Manufacturers in Third Countries. Additional documentation, such as the license to produce the pharmaceutical product by the FDA should be provided. Finally, relevant fees will be applied for the procedure.

There are no import restrictions for medical devices. However, there is a requirement for CE Certification (European Conformity) according to the European Law which can be provided by the authorities of any EU country and is accepted by the member countries of the EU. According to the Council Directive 93/42/EEC as amended by Directive 2007/47/EC, a manufacturer from a third country, who does not have a registered place of business in EU seeking a CE Certification should designate a single authorized representative in the European Union.

Barriers

There are no real barriers for entry in the Greek market. However, the situation with public sector hospital payment arrears has been an issue, particularly amidst the Greek economic crisis. Many companies have witnessed long delays in the payment of accumulated debts by the Greek public sector. However, the DIRECTIVE 2011/7/E.U. of the European Parliament and of the Council of 16 February 2011 on combating late payment in commercial transactions has placed some increased pressure on the Greek government in proceeding with the normalization of payments in the future. Despite this directive and given the financial crisis, there continues to be public sector debt.

Trade Events

Name of event: Medic Expo 2015

Location: Athens, Metropolitan Expo

English language website: <http://www.medicexpo.com/>

Date: February, 2015

Available Market Research

- ❖ Euromonitor International
- ❖ Business Monitor International
- ❖ Hellenic Republic Ministry of Health
- ❖ Morgan Stanley Risk Analysis
- ❖ Iatrikesexelixeis.gr
- ❖ European Commission

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