

**CHARLES UNIVERSITY IN PRAGUE**  
**FACULTY OF PHARMACY IN HRADEC KRALOVE**

**Department of social and clinical pharmacy**

**PHARMACIES IN GREECE**

*(Diploma thesis)*

**Lékárny v Řecku**

Tutor of Diploma thesis:

RNDr.Jana Kotlarova,Ph.D.

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**Georgios Zacharakis**

## **STATEMENT**

I declare that this thesis is my original authorial work, which I wrote alone. All literature and other sources which I used, are listed in the reference and are not previously published.

20.8.2014

**Georgios Zacharakis**

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## **LIST OF ABBREVIATIONS**

<b>AMKA</b>	Social Insurance Number (in gr)
<b>ATC</b>	Anatomical therapeutic classification
<b>DILOF</b>	Distribution Account membership Pharmaceutical Thessaloniki (in gr)
<b>DOATAP</b>	Interuniversity National Academic Recognition and information(in gr)
<b>ECB</b>	European Central Bank
<b>EOF</b>	National drug Organization(in gr)
<b>EOPPY</b>	National Organization providing Health(in gr)
<b>EU</b>	European Union
<b>FEK</b>	Official Gazzette(in gr)
<b>FKA</b>	Foundation for Economic and Industrial Research(in gr)
<b>FSA</b>	Pharmaceutical Association of Athens(in gr)
<b>FSTH</b>	Pharmaceutical Association of Thessaloniki(in gr)
<b>IKA</b>	Social Insurance Institute(in gr)
<b>IMF</b>	International Money Fund
<b>MYSYFA</b>	Over the counter drugs(in gr)
<b>NHS</b>	National Health System
<b>OECD</b>	Organization for economic Cooperation and development
<b>OTC</b>	Over the counter drugs
<b>PD</b>	Presidential Decree
<b>PFS</b>	Panhellenic Pharmaceutical Chamber
<b>PILs</b>	Patient Information Leaflets
<b>SFEE</b>	Hellenic Association of Pharmaceutical Companies(in gr)
<b>SPCs</b>	Summaries of Products Characteristics
<b>UK</b>	United Kingdom
<b>VAT</b>	Value Added tax

## **INTRODUCTION AND AIM OF DIPLOMA THESIS**

It is fact that one of the significant sectors of the economy with many strategic benefits, which are identified either in the sense of mature capabilities either in the sense of good times and potential growth prospects is the pharmaceutical industry and more specifically, the production sector of pharmaceutical and chemical products for medical purposes.

However, it should be noted that there is a direct function of the industry with the applied pharmaceutical and insurance policy, given the particular nature of the drug as good with particular social characteristics.

The aim of this book is to provide information about the Greek pharmaceutical legislation and the duties and responsibilities of pharmacists in Greece as compared to those in Czech Republic. It also focuses on the chambers of pharmacists and the reason they were organized. The book refers not only to community pharmacies, but also to hospital pharmacies and the way they work.



## CHAPTER 1: Health system in Greece

### 1.1 General information about Greece

Greece, officially the Hellenic Republic, is a country in Southern Europe. It is located near the crossroads of Europe and Asia, Greece forms the southern extremity of the Balkan peninsula in south-east Europe. With an area of 131,940 square kilometers (50.942 square miles)<sup>40)</sup>, Greece is a land of mountains and sea. Its territory includes more than 2 000 islands in the Aegean and Ionian seas, of which only around 165 are inhabited.

According to 2010 census, Greece's population is around 10,815,197 (see picture 1 below). Athens is the national capital and largest city (in 2012 it was estimated about 3,75 millions of people).

**Picture 1: PERMANENT POPULATION OF GREECE DURING LAST DECADES<sup>5)</sup>**



The country consists of nine geographic regions: Macedonia, Central Greece, the Peloponnese, Thessaly, Epirus, the Aegean Islands (including Dodecanese and Cyclades), Thrace, Crete, and the Ionian Islands.

Modern Greece has a republican structure based on the constitution of 1975. The 300 members of the single-chamber parliament are elected for a period of four years. The country is divided into 13 administrative regions.

Moreover Greece is member of eurozone since 2001. It is one of the cradles of European civilisation, whose ancient scholars made great advances in philosophy,

medicine, mathematics and astronomy. Their city-states were pioneers in developing democratic forms of government. The historical and cultural heritage of Greece continues to resonate throughout the modern world - in literature, art, philosophy and politics.

Modern Greece has a republican structure based on the constitution of 1975. The 300 members of the single-chamber parliament are elected for a period of four years. The country is divided into 13 administrative regions.

## **1.2 National health system**

Social insurance is compulsory and all citizens are protected. There are three systems: the system of social insurance for the protection of employees, the system of social welfare which provides care for people in need, and the national health system which covers all persons resident in Greek territory.

From the administrative standpoint, the social insurance system is coordinated and supervised mainly by the Ministry of Labour and Social Insurance, and the health and welfare systems are coordinated by the Ministry of Health and Social Solidarity.

The social insurance system seeks to cover the risks faced by employees by granting benefits and services which make up for reduction or loss of income from employment. The system encompasses main and supplementary public insurance and functions through autonomous insurance bodies.

### **Organisations involved**

The general body for the social insurance of employed persons is the **Social Insurance Institute (IKA)**.

Persons with their own business and professionals are insured by the **Self-Employed Professionals' Insurance Organisation**.

The **Agricultural Insurance Organisation** provides insurance cover for the entire farming population.

Civil servants and employees of public bodies are covered by the State and separate insurance bodies.

### **1.3 IKA**

The Greek national health system is operated by the Social Insurance Institute (I.K.A). It is necessary to obtain a health booklet from your local IKA office as soon as you start work. The booklet has to be presented on all visits to a doctor or hospital. At the same time you will be given a social insurance number (AMKA)). The local IKA office will provide a list of doctors who work within the national health system. All medical care is free, but there is a prescription charge equal to 25 percent of the cost of medicines.

Free emergency treatment is provided for EU visitors/employment seekers, who should bring with them the European Health Insurance Card from the country of origin.

Public servants, bank employees, traders and some other professionals have other health insurance.

The Social Insurance Institute (IKA) is the largest insurance body in Greece and covers more than half the population. It provides health care for 5,550,000 insured persons, including family members, and pays pensions to 845,000 pensioners. It provides cover for insured persons and pensioners throughout their life. The Institute's income comes from contributions of employees and employers and from government funding. Persons with IKA insurance are entitled to benefits in kind – medical, pharmaceutical, hospital and dental care, additional health care and preventive medicine, and to cash benefits in the form of the maternity grant, the pregnancy and confinement allowance, sickness and accident benefits, the death grant and pensions.

### **1.4 Sickness insurance**

<sup>35)</sup>Insurance by IKA (Social Insurance Institute) is compulsory and covers employed persons working in Greece or abroad (for employers whose headquarters are in Greece). The insurance also covers persons who are not insured by any other main insurance fund and are working under service lease for a specified period as a primary or secondary employment, and, finally, persons employed on a non-permanent basis. Those persons are insured through their trade union or insurance association.

Apart from the public hospitals, there are private hospitals, and also private doctors.

Non-prescription medicines can be obtained from duty and night chemists in each neighbourhood.

## **1.5 Doctors and pharmacists**

All medical examinations carried out by doctors in IKA surgeries and medical centres by contractual doctors or IKA doctors at home, are free of charge for insured people and their family members. General and specific tests in IKA laboratories are also free of charge, as is dental treatment.

A portion of the fee for a visit to a private doctor, and of the cost of medicines in case of emergency, is reimbursed in accordance with the rates in force.

- Dental care is free of charge, but only when provided by dental surgeries of IKA, by orthodontic and stomatological centres of IKA or by dentists contracted to IKA in their own surgeries
- In an emergency, persons insured with IKA can go to an IKA Immediate Aid Centre
- General and specific tests can be carried out by IKA laboratories or by laboratories contracted to IKA
- The cost of prosthetics and major appliances, such as pacemakers, hearing aids, wheelchairs, contact lenses, is covered by IKA on receipt of a medical report from the attending physician.

On the other hand, there is big percentage of doctors preferring to work in private section because they are working under better conditions with their own schedules and their fees are higher.

## **1.6 Hospitals and Health Care Arrangements**

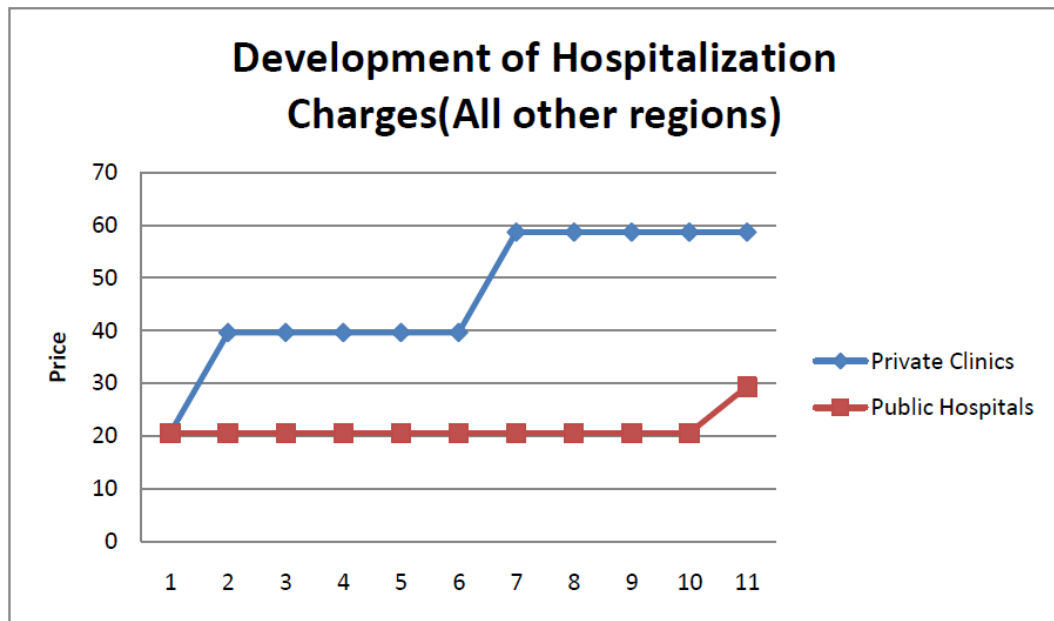
Treatment in IKA hospitals, public hospitals and private clinics contracted to IKA, and in clinics for chronic conditions and handicapped children is provided free of charge. Your IKA doctor, who has to give prior approval, arranges admission to a hospital.

- IKA hospital care covers all hospitalisation expenses of insured persons and pensioners and their family members
- Insurance is compulsory and starts from the first day of employment. Both employers and employees participate in insurance contributions to IKA. Employers are required to pay their own contributions (employer's contribution) and the amounts that they deduct from their employees' wages or salaries (employee's contribution) to the local IKA office at the end of each month.

- Each contribution month relates to the working days of the previous month, i.e. the contributions of January must be paid at the end of February
- The amount paid to IKA is a percentage of the gross wage or salary of the employee. Higher earnings and more working days equate to higher benefits
- If the employee is to work at his or her employer's home (gardeners, domestic servants, chefs, etc.), the employer must notify the fact to the local IKA office when the employment commences, so that the insurance can begin.

City hospitals of the national health system, typically offer outpatient care weekdays with some departments closing early, handling emergencies outside normal hours on a rotating basis. These hospitals will only provide basic services and can be open as little as two hours a day, switching between summer and winter schedules. On the other hand, there are also the private hospitals which provide private medical care more trustworthy and convenient with all day schedules. As a result, an increasing number of residents willingly pay more for better quality of medical treatment.

**Picture 2:**Development of Hospitalization Charges<sup>(36)</sup>



## **Chapter 2: *The role of Pharmacist in Public Health***

### **2.1 Introduction**

It is fact that the role of a pharmacist is very vital in many aspects. Pharmacists have many duties and responsibilities towards the patients and society in general. First of all, they distribute prescription drugs to individuals.

They advise their patients, physicians, and other health practitioners on the selection, dosages, interactions, and side effects of medications. Moreover, they monitor the health and progress of those patients to ensure that they are using their medications safely and effectively.

Pharmacists in community pharmacies dispense medications, counsel patients on the use of prescription and over-the-counter medications, and advise physicians about medication therapy. They also advise patients about general health topics, such as diet, exercise, and stress management, and provide information on products, such as durable medical equipment or home healthcare supplies.

Some community pharmacists provide specialized services to help patients with conditions such as diabetes, asthma, smoking cessation, or high blood pressure. Some others are trained to administer vaccinations. It also needs to be mentioned that some pharmacists are involved in research for pharmaceutical companies, developing new drugs and testing their effects.

Others work in marketing or sales, providing clients with expertise on the use, effectiveness, and possible side effects of drugs. Additionally, some pharmacists work for health insurance companies, developing pharmacy benefit packages and carrying out cost-benefit analyses on certain drugs.

## **2.2 The main duties of pharmacist**

The main duties of the pharmacist include:

- Laboratory processing,
- production of new drugs and medical supplies ,
- quality control and action of drugs ,
- preparation of drugs which are not received in packaged form
- Provision of drugs under prescription drugs or drugs that are available to the public on free
- Information of customers about how to obtain and drug and its substances
- Provides guides to the work of his assistants in the laboratory
- Information for the status of stored drugs and the supplement of the quantities that are necessary for the operation of the pharmacy,
- Advice on making medicines for the use of various medical devices and general medication,
- Keep records of prescriptions that has performed and the toxic preparations that has
- Commercial or advisory activity in pharmaceutical companies
- Participation in selling cosmetic and hygiene products.<sup>33)</sup>

## **2.3 The role of pharmacist in public health and how it can be developed**

The role of the pharmacist has acquired a significant importance in latest years, as the increased requirements have as a result the creation of greater obligations that pharmacist should respond. More specifically, the pharmacist:

- Must inform and highlight in the society that prevention is what we should seek not the treatments as many people believe today. Millions of lives could have been saved if this applied in practice.
- Has an obligation to alert the community and the state against phenomena such as counterfeit drugs and doping and to require tighter controls, a more stringent legislative framework from governments for the movement of such goods, and of course in constant vigilance.

Still, they must inform all stakeholders and especially to push those responsible to obtain a responsible attitude to the problem. (Tsikandilakis, 2009)

- Pharmacist is the health care professional, who knows more than anyone else the size of the problem of drugs and the addiction of drugs, not only due to his scientific training but also due to his experience in pharmacy. He is perhaps the only health care professional, who knows the so-called "hidden population" of addicts in his region, but also the behavior and the action of these.

It is quite common for the addicts to daily visit our pharmacy to ask for insulin syringes and many are those, who try to fake prescriptions to get a sleeping drug. The pharmacist, through his experience, should recognize and behave accordingly. It is fact that until today there has not been a collective effort to assist these people through the pharmaceutical industry.

However, it is quite difficult, even for someone qualified to talk about detox at the moment, a person reaches to the pharmacy to ask syringe, the time that you only have in mind is to ensure the dose.

But in the field of information and guidance at family level, the pharmacist can play an important role. The pharmacist must be informed about the problem and provides information to the parents and other interested parties. It is time, as pharmacies are



advisory stations at various healthy issues, pharmacist can contribute as he can to alleviate the problem. (Xanthopoulos, 2005)

- In border islands, villages and other places where there are no other available health services center, the pharmacist plays an important role in the community. The pharmacy in the village or the island of barren line is the only oasis of hope and safety for the residents of these areas. Pharmacies are required by the state to subsidize and to encourage other fellow pharmacists to try their luck in such places. Also the pharmacies keep residents in their area, and provide invaluable national service.
- Involved in voluntary non-governmental organizations (Pharmacists world) or social actions (Social Pharmacy), while it is quite helpful their offer in medicines in case of war or humanitarian crises. It is necessary to be free from the bureaucratic obligations of the state and the pension funds set, as to focus solely on the patient and his medication.
- Required to work with honesty and sincerity reimbursed. On the other side, it is important to become tighter controls on pharmacies, to be strict a punishment of the offending pharmacists but also a strict compliance with the obligations of the insurance funds to pharmacies. Also, it is important a cooperation in keeping drug consumption files, cooperation in drawing up the list of drugs that would not be justified at redemption.
- He should also be subsidized from the insurance funds or from another carrier for the operation of pharmacies in remote and inaccessible places. The pharmacist must support the social security system with all its strength. If he is working as a private individual, he must support the public nature of the health system.
- He should collaborate with the academic institutions. They can also create collaborations on issues of proper medication use, side effects and recording training of pharmacists, or in other words a pharmacist needs lifelong education.
- They need to have a better cooperation with pharmaceutical companies so that finally they found and other points of contact and cooperation, not only in providing discounts or gifts.

- Also, it is important to overcoming the distrust that exists between pharmacists and companies and to promote scientific cooperation, training, retraining and anything else that can help the community.
- He should work closely with other scientists, such as doctors, nurses, chemists, agronomists, estheticians.
- Finally, he can participate more effectively in actions that have to do with the protection of the environment (recycling drugs for example).<sup>32)</sup>
- 9)

## **2.4 General principles of ethics of pharmacists**

This section lists the articles that constitute the general and specific principles of ethics of the pharmaceutical profession.

### **Article 1**

The pharmaceutical exercised solely by a University diploma in pharmacy and legal authorization to practice the profession of pharmacy.

### **Article 2**

The drug is an important factor in the prevention and treatment of disease and the pharmacist is the only material specialist in the field of drug trafficking because of his scientific education.

### **Article 3**

To protect the public health and consumer interests, responsibility and participation of pharmacist should cover all stages of the production process as the administration of the drug to the public

### **Article 4**

Pharmacies should belong exclusively to pharmacists so to avoid interference of foreign interests, unrelated to the pharmaceutical profession - function within the marketing and retail distribution of pharmaceutical products. This article is of particular importance since last year discussed the possibility of ownership of pharmacies by non-pharmacists capitalists.

## **Article 5**

It is an inalienable right of free patient choice of pharmacy owners and pharmacists pharmacy operation must avoid any means or manner or method that would limit the freedom of choice of the patient's pharmacy of preference. This is absolutely true and the various providers of pharmaceutical care to the Greek people.

## **Article 6**

Ethics are the principles that govern and guide pharmacists with proprietary owner or chief operating pharmacy in their dealings with patients, colleagues and other health scientists, the institutions of the state, the collective bodies to which they belong and general attitude them to society (FEK, 312 (16/9/92)).

## **2.5 Liability and dignity of pharmacists**

According to the FEK, 312 (16/9/92), the liability and dignity of pharmacists is described in the eight above articles, as following:

### **Article 14**

The pharmacist must exercise personally the pharmaceutical and prepares and personally delivers medications to patients or their relatives. We personally oversee every pharmaceutical work performed by the staff of the pharmacy.

### **Article 15**

Each pharmacy must have a conspicuous place on the front, the name of a licensed pharmacist, and the signals enforce existing laws.

Inherited pharmacies will indicate below the name of the deceased pharmacist and the name of the responsible pharmacist with the same letters.

## **Article 16**

If ethical breaches his replacement licensed pharmacist, the Disciplinary Board will address these offenses should assess and the possible involvement of a licensed pharmacist to them and the need to attribute responsibilities and fees.

## **Article 17**

The pharmacist must indicate in writing to the pharmacists of the area of any change in address of the pharmacy, any interruption in carrying out his duties or responsibility of any recruitment partner or dissolution of the company or partnership of Co – location.

## **Article 18**

Prohibited pharmacists licensees to establish and operate a pharmacy or pharmacists responsible for hereditary pharmacies and beneficiaries inheritance pharmacy congregation particular individual contracts with insurance funds, as long as the law does not provide such discretion, subject always to the provisions of Article 21 of the A. P. 1384-1398, with terms different from those who have accepted the P.F.S. and the pharmaceutical society of which he is a member of the pharmacist.

## **Article 19**

The pharmacist and pharmacy operation or the pharmacist responsible for hereditary pharmacy must not accept remuneration incompatible with the dignity of the office of the pharmacist.

## **Article 20**

The pharmacist must give clear instructions of administered drugs to customers of the pharmacy and indicate thereon summaries instruction manual and any other label to avoid errors during the download or use of drugs administered.

## **Article 21**

The pharmacist when providing the drugs listed in recipes and other traded products, required to check whether the given species meet the legal requirements. (FEK, 312 (16/9/92))

## **Chapter 3: Existing Pharmaceutical legislation**

### **3.1 Directive 432/85/EEC about the education of pharmacists**

“The Directives apply to activities, the access to and pursuit of which are subject to the conditions of professional qualifications defined in Council Directive 85/432/EEC and which are open to holders of one of the diplomas, certificates or other formal qualifications in pharmacy referred to in the Directive.

Each Member State must recognize the diplomas, certificates and other formal qualifications listed in the Directive and awarded by other Member States. They must give to such qualifications the same effect in their territory with regard to access to and the pursuit of the activities in question as the diplomas, certificates and other formal qualifications which they themselves award.

Examples of qualifications include:

- Belgium: "diplôme légal de pharmacien";
- Ireland: Certificate of Registered Pharmaceutical Chemist;
- Spain: "título de licenciado en farmacia".
- Furthermore, when access to or the pursuit of the activity in a Member State requires additional professional experience, that Member State is obliged to accept as sufficient evidence a certificate issued by the competent authorities of the applicant's Member State attesting that he has pursued the said activities for an equivalent period.

Greece is authorized to give effect to the diplomas, certificates and other formal qualifications awarded by the other Member States only in cases of pursuit of the activities concerned as an employed person.

The other Member States are required to give effect to diplomas, certificates and other formal qualifications awarded in Greece only in cases of pursuit of the activities concerned as an employed person.

Directive 90/658/EEC introduces a special arrangement for the recognition of diplomas, certificates and other evidence of formal qualifications awarded by the former German Democratic Republic: German nationals who are pursuing their professional activities in that territory on the basis of training which began before unification and does not conform to Community rules on training are to be granted recognition under the same conditions as other nationals of Member States at the time of the adoption of this Directive, i.e. if they produce a certificate showing that they had at least three consecutive years' professional practice during the five years prior to the date of issue of the certificate.

Host Member States must ensure that nationals of Member States who fulfill the conditions laid down have the right to use their lawful academic title in the language of the Member State from which they come.

About the procedure for the recognition of pharmacists, according to this directive, a host Member State which requires of its nationals proof of good character or good repute or a certificate of physical or mental health when they take up the activities specified must accept as sufficient evidence, in respect of nationals of other Member States, a certificate issued by a competent authority in the Member State from which the foreign national comes.

In particular, Directive 2001/19/EC aims to:

- Incorporate into Directive [89/48/EEC](#) the concept of "regulated education and training", already enshrined in Directive [92/51/EEC](#). The goal is to require the host Member State to take into account the education received by the applicant, including education received in a Member State in which the profession in question is not regulated. Under this new rule host Member States will not be permitted to require two years' professional experience;
- Ensure that the host Member State, when examining an application for recognition of a diploma, takes into consideration the experience acquired by the applicant after obtaining the diploma. The host Member State may no longer systematically require

the applicant to take compensation steps, such as aptitude tests or an adaptation period, but must simplify and if possible eliminate these measures;

- Ensure legal certainty with regard to the recognition of diplomas obtained by Community nationals in third countries; the envisaged system gives each Member State the right to recognize or reject these diplomas except when a first host Member State has already recognized the applicant's professional experience. In this case a second host Member State may not directly reject the application for recognition but must justify its rejection;
- Extend the automatic recognition procedure, already applicable to general practitioners, to other physicians and to nurses responsible for general care, dental practitioners, veterinary surgeons, midwives and pharmacists. The main simplification lies in the updating of the lists of diplomas recognized at European level, since the Commission will from now on be able to publish lists of diplomas notified by the Member States on a regular basis (annexed to this document)". (Directive [85/433/EEC](#))

### **3.2 Directive 2005/36 EC for the recognition of professional qualifications**

In contrast the previous directive, this directive makes a distinction between “freedom to provide services” and “freedom of establishment” on the basis of criteria identified by the Court of Justice: duration, frequency, regularity and continuity of the provision of services. This directive replaces both directives above, which referred only to pharmacists. In addition to this, the new Directive refers to more regulated professions.

According to this directive, “The general system applies to professions not covered by specific rules of recognition and to certain situations where the professional does not meet the conditions set out in other recognition schemes. This system is based on the principle of mutual recognition, without prejudice to the application of compensatory measures if there are substantial differences between the training that acquired by the person concerned and the training required in the host Member State. The compensatory measure may take the form of an adaptation period or an aptitude test. The choice is left to the person concerned, unless specific derogations exist.



When access to or pursuit of a profession is regulated in the host Member State, i.e. it is subject to possession of specific professional qualifications, the competent authority in said Member State is to allow access to the profession in question and pursuit thereof under the same conditions as for its nationals. However, the applicant must hold a training qualification obtained in another Member State that attests to a level of training at least equivalent to the level immediately below that required in the host Member State.

On the other hand, when access to a profession is not subject to possession of specific professional qualifications in the applicant's Member State, access to that profession in a host Member State where it is regulated requires proof of two years' full-time professional experience over the preceding ten years in addition to the qualification".

In practice, "the directive distinguishes five levels of professional qualifications are the followings:

- attestation of competence issued by a competent authority in the home Member State, attesting either that the holder has acquired general knowledge corresponding to primary or secondary education, or has undergone training not forming part of a certificate or diploma, or has taken a specific examination without previous training or has three years' professional experience;
- certificate corresponding to training at secondary level of a technical or professional nature or general in character, supplemented by a professional course;
- diploma certifying successful completion of training at post-secondary level of a duration of at least one year or professional training that is comparable in terms of responsibilities and functions;
- diploma certifying successful completion of training at higher or university level of a duration of at least three years and not exceeding four years;
- Diploma certifying successful completion of training at higher or university level of a duration of at least four years".

On the other side, "the host Member State can make recognition of qualifications subject to the applicant completing a compensation measure (aptitude test or adaptation period of a maximum of three years) in the following three cases:

- the training was at least one year shorter than that required by the host Member State;
- the training covered substantially different matters from those covered by the evidence of formal training required in the host Member State;
- The profession as defined in the host Member State comprises one or more regulated professional activities that do not exist in the corresponding profession in the applicant's home Member State and requires specific training that covers substantially different matters from those covered by the applicant's training.

The directive allows representative professional associations at both national and European level to propose common platforms to compensate for the substantial differences identified between Member States' training requirements. The platform is a way of ensuring that additional measures are not imposed on those concerned, while guaranteeing an appropriate qualification level. The platform is a kind of predefined compensatory measure". (Directive 2005/36 EC)

### **3.3 Pharmaceutical legislation in Greece**

According to the Greek law, the profession is only practiced by pharmacists and by this we mean those people that possess the degree of the pharmacist and the license to practice their profession. Pharmacies can only belong to pharmacists and it is forbidden to anyone who does not have a degree in pharmacy to own such a store. This aims to the maintenance of the public health.

There are documents that describe the deontology that pharmacists should have towards their clients, their colleagues, the other medical scientists and their behaviour towards society in general.

#### **According to article 2 of the law 1963/1991 (ΦΕΚ 138 Α΄):**

For the protection of public health and the rational distribution of drugs to the territory the following limits have been set for municipalities and municipal or communal apartments, like they are referred to the article 1 of the law 2539/1997 (ΦΕΚ 244 Α΄): in the municipalities and municipal or communal apartments with population up to 1500 (one

thousand five hundred) residents only one pharmaceutical license is allowed to be provided.

However, in the municipalities and municipal or communal apartments with population over 1500 residents, the ratio of pharmaceutical licenses to residents is 1:1500 and this means that only one pharmacy is allowed to be built for every 1500 residents. The population is calculated according to the result of the last inventory.

As far as the distances are concerned among adjacent pharmacies:

- One hundred meters at least in the municipalities and municipal or communal apartments with population up to 5.000 residents.
- One hundred and eighty meters at least in the municipalities and municipal or communal apartments with population from 5.000 to 100.000 residents.
- Two hundred meters at least in the municipalities and municipal or communal apartments with population from 100.000 to 200.000 residents.
- Two hundred and fifty meters at least in the municipalities and municipal or communal apartments with population over 200.000 residents.

In some cases, the pharmacies can be transferred to a different location but inside the geographical boundaries of the municipalities and municipal or communal apartments. This can only happen under the following circumstances:

After eight years of function, the pharmacy can be transferred at least forty meters far from the adjacent pharmacies. After ten years of function, the pharmacy can be transferred at least twenty meters far from the adjacent pharmacies.

The license for the erection of a new pharmacy is given, after the meeting and the consultation of the local chamber, by decision of the responsible prefect within the municipality and municipal or communal apartment.

It is worth noting that under the memorandum there are a number of amendments to existing legislation, which are voted from Greek parliament in March 2014. These include:

- A pharmacist may have more than one license pharmacy.
- It can also hold any share capital wishes, an operator of a pharmacy.
- Pharmacies can be housed in any store.
- The land use criteria for new pharmacy are abolished
- Everyone may create pharmacy 100 meters from the hospital gate
- Repealed earlier arrangement by which the wholesalers were required to have a specific buffer.
- The profit rates for pharmacists are abolished for non- mandatory prescription drugs (MYSYFA).
- By the end of 2016, there are increasing rates of circulating MYSYFA.
- The MYSYFA that placed on, will be sold at the same or a lower price as the corresponding already available.
- There is a free possibility for free discounts on MYSYFA.
- The stringent provisions are abolished in relation to the period of patent protection of medicines.
- Pharmacists can be freely extended hours. (FEK 138 1963/1991)

## **Chapter 4: *Professional license***

### **4.1 Conditions for professional license**

The first condition under which any student with a degree in pharmacy can obtain his professional license is to sit exams in order to prove his knowledge concerning pharmaceutical matters.

There are two examination centers in the country, one in Athens and one in Thessaloniki. The lessons that students should be aware of are pharmacology, toxicology, pharmaceutical technology, legislation concerning their profession and they also should know everything about prescriptions. The dates that students can participate in the exams

are always announced by the Ministry for Health and Social Solidarity and exams are usually carried out five times within a year.

Another condition in order to obtain their license is to fulfill a whole year practice in a private drugstore which is open to the public and in a hospital's drugstore.

After passing successfully the exams and having completed their year-practice, what remains to be done is to provide some supporting documents to the Public Health Directorate.

These documents contain an application form, proof of their degree or equivalent degree for those who have studied outside, proof of their work in drugstores during their practice, proof of passing the exams successfully, certified copy of their identity card, proof of clean criminal record, photocopies and an amount of money. Moreover, for foreigners is required permanent resident status as well as license of reciprocity from the Ministry of Foreign Affairs. (FEK 138 1963/1991)

Greek students also have the chance to sit similar exams in Cyprus in order to obtain their professional license. However, in that case the students are examined on the Cypriot legislation concerning pharmacies. After passing those exams successfully, they also have to provide some documents in order to get the license. (FEK 138 1963/1991)

## **4.2 Documents for Greek Universities graduates**

These documents contain an application form, proof of having passed the exams successfully, a health certificate from a pathologist of the public sector, a mental health certificate from a public mental health center, certified copy of their identity card, proof of clean criminal record, photocopies and an amount of money.

Summarizing, according to the Greek law 3457/2006 the main conditions that someone should have in an attempt to gain a professional license are the followings:

- 1) Bachelor.
- 2) Internship twelve months (six months in a pharmacy open to the public three months in hospital pharmacy , three months in a pharmacy open to the public or hospital pharmacy) .

- 3) Successful exam

### **Required documents:**

- 1) Application (available from the department)
- 2) Duplicate Greek university degree in Pharmacy or equivalent degree from DOATAP for graduates from school foreign country .
- 3) Certificates internships
- 4) Certification exam success
- 5) Affidavit of N.1599/86 ( GG 1637/V/7-11-2006 ) that: " I have not been convicted of any offense or an act relating to the exercise of my professional status " otherwise "I have ordered for the following offenses ..... " instead of criminal record)
- 6) Photocopy of a validated identify
- 7) Payment of a prevailing government fund
- 8) Two photos
- 9) For foreign people, it is required the residence and reciprocity certificate by the Ministry of Foreign Affairs. (Law 3457/2006)

### **4.3 Documents for graduates of Universities Abroad - non EU Member States**

The main documents for the non EU member States, who have a certificate from a University abroad, are:

- Application (Application for a license to practice )
- A copy of the foreign diploma and official translations thereof (Certificate of DOATAP on the rate and correlation with the degrees of pharmaceutical faculties of Greek universities ) .
- Certificate of biennial exercise in Pharmacy resident (during the summer holidays or after completion of studies) or foreign certificate showing analytically the exercise time, will bring his signature stamp and signature Pharmacist , certified by the president of the relevant Pharmaceutical Association , the local prefecture and the Greek Consul in official translation.
- A certificate of Greek nationality.

- Fee stamp of 30 € and a government fee of 8 €.
- A copy of criminal record (mandatory automatic search for criminal records or court of general use , DIADP/A/22863/06 FEK/V/1551/23-10-06 )
- Photocopy of ID card that should be validated.
- Two recent photos
- A prosecution certificate or statutory declaration (not prosecuted as either a fugitive from justice).
- For expatriates, work permit (from the Ministry of Labour) and subsistence (of the Foreign Division of the Ministry of Public Order) For foreigners also reciprocity certificate by the Ministry of Foreign Affairs, except those from Member States of the EU. (Law 3457/2006)

#### **4.4 Documents for graduates of Universities Abroad - EU Member States**

The main documents for the EU member States, who have a certificate from a University abroad, are:

- Application (Application for a license to practice)
- A copy of the diploma with an official translation.
- Diploma, certificate or other evidence of drug than those referred to in paragraph 2 of Article 5 of Presidential Decree 213 / 03 for the exercise of the pharmaceutical profession in the country of origin or provenance (with official translation).
- Certificate attesting that the applicant meet the minimum training requirements or other conditions for the award of a diploma, certificate or other evidence of drug for the exercise of the pharmaceutical profession (Articles 3, 4 and 5 of Presidential Decree No. 213 sgd "Adaptation of Greek legislation to the provisions of Directives 85/432/EEC , 85/433/EEC , 85/584/EEC, 90/658/EEC and Directive 2001/19/EC , relating to the profession of pharmacy."
- Citizenship certificate.
- Certificate of good character and repute of the competent authority of the Member State of origin or to enter the pharmaceutical profession and start the exercise thereof or an extract or failing that, an equivalent document issued by the

competent authority of the Member State of origin or provenance (Not applicable if submitted within three months of their issue .

- Copy of criminal record (mandatory automatic search for criminal records or court of general use , DIADP/A/22863/06 FEK/V/1551/23-10-06 ) Prosecution Certificate or Statutory Declaration ( not prosecuted as either a fugitive from justice ) .
- Photocopy of an ID card that is validated
- A permission about residence
- Two recent photos
- A certificate military status (males).
- Fee stamp of 30 € and a government fee of 8 €. (Law 3457/2006)

## **CHAPTER 5:***Permit the establishment of pharmacies and authorization of pharmacies*

### **5.1 Permission of pharmacies**

In Greece the accurately number of pharmacies is 11.482(calculated on 2013).The procedure to get the license or the authorization to establish a pharmacy differs from the one mentioned above. In this case, the applicant should meet the criteria below which are certified by documents submitted by relevant authorities.

- The applicant must be Greek citizen or must have citizenship among the nations of the European Union.
- He also must have a degree in pharmacy and a professional license obtained in Greece or in another country of the European Union which have been proved to be equivalent.
- He must have carried out his military duties or must legally be exempted from them.
- He must not have been condemned to an offense or a crime or any violation and must have clean criminal record.

A license to establish a pharmacy is not granted to pharmacists that:

- receive a pension for health reasons from social security institutions



- have been punished for offences concerning their profession
- have completed the seventieth year of their age

The order of preference concerning the obtaining of the license to establish a pharmacy is conducted as followings:

The license is given firstly to the pharmacist that has submitted an application to the relevant authorities earlier than others. That means that the date that the pharmacist declares the need to establish a pharmacy plays an essential role. (Law 3457/2006)

Among those who have submitted an application to the relevant authorities during the same day, the one who is preferred is the pharmacist

- who does not have license to establish a pharmacy in any other municipality or communal apartment
- who has obtained his professional license earlier and has never before obtained license to establish a pharmacy
- who has obtained his diploma earlier and in the case there are pharmacists that have obtained their degree at the same time, the one who has achieved higher grades is preferred
- Who has many children (at least three) or is coming from a family that has many members. (Law 3457/2006)

It is also worth noting that there are population criteria for the choice to permit the establishment of a pharmacy in Greece. More specifically, there is a ratio of one pharmacy per 1,000 inhabitants. Establishing a second pharmacy must complete the second thousand, establishing third pharmacy must complete the third thousand etc.

Also, in local or municipal communities, with a population of 1000 inhabitants may be granted a license to establish a pharmacy.

## 5.2 Documents for the authorization of establishment a pharmacy

The main documents that someone should provide in an attempt to take a grant for an establishment of a pharmacy are:

- Application (served by the bailiff)
- Copy of diploma in pharmacy school
- A copy of the license to practice as a pharmacist in Greece
- Certificate municipality or community that has Greek nationality
- An affidavit with the following: " I have not been irrevocably sentenced for theft , embezzlement , fraud , extortion , forgery , crimes against morality , slander for acts connected with the exercise of the profession , counterfeiting, forgery , breach of Article 5 the N1729/1987 , FEK144 / D and recurrent Article 11 of the same law or have not been irrevocably sentenced for a felony or recurrent misdemeanor for which imposed deprivation of political rights or may not have been referred to the irrevocable decree for any of the above offenses . Also I have not punished for violations of drug laws to permanent revocation of license establishing the pharmacy or drugstore "or otherwise "... I have been convicted of the following offenses ... "
- Certificate of Public Prosecutions (not prosecuted as either a fugitive from justice)
- Certificate military status type A
- An affidavit of Article 8 of N 1599/86 that it revoked the license pharmacy , drugstore or laboratory for violations of drug laws , does not get a full state pension , the TSAI or any other institution or social security does not receive pension for health reasons and has not reached full retirement conditions , does not hold a public or private place and not another direct - pharmaceutical wholesaler pharmacy or laboratory medicine and cosmetics
- An affidavit of Article 8 of N 1599/86 that I have filed another application for Regional Unity license Foundation Pharmacy.
- A promissory stock 6, 00 € fund depository and loan (secured for authorization to establish a pharmacy).
- Photocopy of ID card validated
- A paper folder with elastic. (Law 3457/2006)

### **5.3 Documents for the authorization for a dispensation of established a Pharmacy**

The main documents that someone should provide in an attempt to take a grant for an establishment of a pharmacy in a dispensation are:

- Application (served by the bailiff)
- Certified copy of diploma in pharmacy school
- A certified copy of a license to practice as a pharmacist in Greece
- Certificate municipality or community that has Greek nationality certificate of Public Prosecutions
- An affidavit with the following: "I have not been irrevocably sentenced for theft , embezzlement, fraud, extortion, forgery, crimes against morality, slander for acts connected with the exercise of the profession, counterfeiting, forgery , breach of Article 5 the N1729/1987 , FEK144 / D and recurrent Article 11 of the same law or have not been irrevocably sentenced for a felony or recurrent misdemeanor for which imposed deprivation of political rights or may not have been referred to the irrevocable decree for any of the above offenses . Also I have not punished for violations of drug laws to permanent revocation of license establishing the pharmacy or drugstore "or otherwise ... I have been convicted of the following offenses ... ".
- A certificate of military status A (mandatory automatic search from our Service)
- Affidavit of Article 8 of N 1599/86 that it revoked the license pharmacy , drugstore or laboratory for violations of drug laws , does not get a full state pension, then, social security does not receive pension for health reasons and has not reached full retirement conditions , does not hold a public or private place and not another direct - pharmaceutical wholesaler pharmacy or laboratory medicine and cosmetics (if it holds another position will withdraw it with the approval of the operation of the pharmacy)
- An affidavit of Article 8 of N 1599/86 that I have not filed in another county request for permission Pharmacy Foundation.
- A Bill deposit from the Deposits and Loans Fund.  
A photocopy of the identities cards both of two pharmacists.

## **5.4 Co – licensed pharmacies**

Moreover, the state gives the possibility for a co-location of pharmacies, which means that with prefect's decision after consulting with the pharmaceutical association, it may allow the co-location of the same store more than one establishment in pharmacies, as long as you do not obstruct the spatial serve the public and not declared function in a specific store or pharmacy nascent transfer pharmacy already working in another position, less than the planned.

Similarly, it may allow the co-location of pharmacies in establishing a functioning pharmacies and pharmacies that operated together.

Also, the co-location is allowed in the same store pharmaceutical warehouses under establishment, operation and in establishing a functioning of wholesalers.

In practice, licensed co - located pharmacists and pharmaceutical warehouses are jointly responsible for any breach of the law, the personal direction and the normal operation of pharmacies and pharmaceutical warehouses and are required to indicate their names on display and these inscriptions

In addition, the co-location between pharmacies those operate between and operated with pharmacies to be established, not authorized, and permitted regardless of the distance they are from another pharmacy or co-location

Regarding the operation of co-located pharmacies, those are considered as operating separately and are required to be a living room and a special night.

So, in the event of retirement, resignation for health reasons or death of a pharmacist in the store was approved or approved co-location, in accordance with the preceding paragraphs do not apply, the winding of co – located for the remaining there in pharmacists on area and distance provisions.

Co-location pharmacies work required to form of a general partnership, which recommended under an authenticated paper, which designated to joint directors of all participants in the co-location of pharmacists, in which all pharmacists participate with the same percentages. (University of Patras, 2007)

## **5.5 Division of pharmacies in Greece**

Greek hospitals wishing to have in-house pharmacies must receive authorization from the local health department and submit to an examination from a regional inspector. Once established, the pharmacy is granted an annual budget that pays for drugs, medical devices, and other pharmaceutical products, but not for salaries. The number of pharmacists per bed in Greek hospitals is quite low, typically only one or two in a medium hospital of 200 – 400 beds. This serious shortage of personnel (and software too) means that, even though prescriptions should ideally be analyzed by the hospital pharmacist and dispensed in unit doses, drugs are still distributed in bulk in many hospitals, based on lists of orders from the wards. Greek hospital pharmacies purchase drugs for hospitalized patients, outpatients under special pharmacotherapy such as cancer treatment, and indigent patients covered by Social Security. Indigent patients can only receive their drugs free of charge directly from hospital pharmacies. Drug pricing in hospital pharmacies is different from that in community pharmacies, resulting from consultations made by the Ministries of Health and Commerce with the pharmaceutical industries

## **Chapter 6: *Operation pharmacy***

### **6.1 Procedure after the authorization for the establishment of a pharmacy**

Upon notification by the District of decisions regarding the authorization for the establishment of a pharmacy in a certain Municipality in the claimant pharmacist, he should within six months to draw up the pharmacy in a specific store.

If this period of six months for establishing pharmacy passed without the settlement of a pharmacy, then the license becomes null and void and the forfeit paid to the public.

### **6.2 Documents for the operation pharmacy**

The main documents for the operation pharmacy are the followings:

- Applicant's application (Application for a license to operate a pharmacy )
- Royalty foundation (decision notified) .
- Copy of lease agreement by the applicant pharmacist on the premises where you operate a pharmacy or a recent certificate of ownership of the land register (stamped by the tax office)

- Excerpt of a street plan of the area at a scale of 1:200, which will occur pharmacies that are near the pharmacy concerned up to a distance of one hundred (100) meters for district with a population of 5,000 inhabitants located up to one hundred eighty (180) measures district with a population of 5,000 to 100,000 inhabitants.
- Top view of pharmacy in 1:50 scale which will show the net dimensions
- A Certificate of the Urban Service that ensures the store is not arbitrary and does not include arbitrary structures or additions.
- Certificate of a fire brigade.
- Affidavit of engineering testimony in Snippet Street plan pharmacies and drew the floor plan of pharmacy stating that: "the data in a street map and a plan view of pharmacy is accurate."

It is also noting that it is possible to ensure pharmacy location (before issuing authorization and authority of the requirements for the position and building) of its filing accompanied by concession or lease or purchase agreement for building.

### **6.3 Organization and formation of a pharmacy**

The presidential decree 312 (16-9-92) defines regarding the organization and formation of a pharmacy the followings:

#### **Article 1, paragraph 1:**

- In pharmacy are performed all kinds of recipes that quoted by doctors, dentists, midwives and also the veterinarians recipes and
- Retailled medicines pharmaceutical products and pharmaceutical substances, except those with decision EOF excluded the jurisdiction of pharmacies and species as authorized by other provisions of law or decisions.
- Also sold in pharmacies free articles general medicine, cosmetics , dietary products, milk and infant foods, toiletries infants, pregnant and postpartum, cosmetic, orthopedic equipment and machinery, medical instrument , machines and devices.

#### **Article 1, paragraph 2:**

Pharmacies can sell and veterinary drugs, but in this case must have for storage and sale of these special addition, which must be prominently displayed in capital letters, the words "VETERINARY DRUGS".

**Article 1, paragraph 3:**

The sale in pharmacies foreign objects that not covered by the above paragraphs 1 and 2 shall be prohibited.

**Article 2, paragraph 1:**

The frontage of the store pharmacies placed mandatory within illuminated panels, cross green color, the center of which there may be the display of complex medicinal pot and snake.

**Article 2, paragraph 2:**

Pharmacists at the time of labor required to wear a white blouse and the upper left side of this bear badge (badge) with their names and functions.

Also, the white coats are required to carry and licensed pharmacy technicians, with their names and functions. (FEK, 312 (16/9/92))

Moreover, each pharmacy, according to the law, shall be equipped with drugs that:  
a) specified by the National Organization for Medicines drugs, chemicals, and draggers of Greek Pharmacy industry.

b) Sufficient quantities of proprietary formulations and antibiotics , hormonal , hemostatic , cardiotoxic , analgesic , therapeutic sera and other current medications to cover the needs of the public in relation to the population density of the area , the frequency of a day and nights and this general motion operation prescriptions.

c) Net oxygen canisters, ready for use, along with the necessary parts for use by the patient.

Except drugs, each pharmacy should have a quantity of equipment and utensils and more specifically:

At least two scales, with the necessary weights in the decimal system. A susceptible for the weighing of small quantities, with vulnerability 0,005 (5 mm) of a gram and a lower for the

weighing of large amounts up to 20 grams. Also, a scale for weighing the liquids and solids, in quantities of kilos.

b) A porcelain mortar, tongs, spatula, pans, funnels, volumetric tubes, test tubes, filters and generally anything, that it can fulfill its intended purpose seamlessly.

c) Electric refrigerator.

d) Safe, permanent and sufficient weight or built an iron box, which will be insured in both cases, with security keys or combination of letters or numbers, for storage of drugs, which is solely responsible for a licensed pharmacist.

Also, it should be noting that is prohibited the existence and operation of pharmacies within the chemical or microbiological laboratories, the optical parts, unless specifically authorized to do so. (FEK, 312 (16/9/92))

## **6.4 Pharmacy in operation**

In practice, the address of the pharmacy in person belongs to the owner of a licensed pharmacist. Also, as it obvious, violators shall be punished with fine or with immediate closure of the pharmacy

Regarding the absence of the pharmacist may from the pharmacy, the Greek law defines that:

A Pharmacist can absence two months every year continuously or intermittently. The permission for these absences is granted from the concerned Medical Officer at the request of the pharmacist without any specific reasons.

If there is no other scientist pharmacist in pharmacy to replace him, then pharmacy technicians with supervision of another pharmacist, who has a pharmacy in the same municipality or village or a doctor if the Municipality or Community pharmacies are less than three, replace him.

The scientist pharmacist or pharmacy technicians and supervising pharmacist or doctor is partly responsible for the normal operation of the pharmacy.

Also, a pharmacist can absence more than two months, only if he is replaced by another pharmacist, who does not manage another pharmacy or pharmaceutical wholesaler and not incompatible under Law 1932.



The reasons for the authorization of two months is health reasons, trip wider education or exceptional reasons that will judge the Administration are adequate.

## **6.5 Royalty temporary closure**

A pharmacist can temporary close its pharmacy, according to the above situations:

- a) Three days (the time) without the permission of the competent authority, however requires notification to the competent authority (Department of Health, or address of the local prefecture)
- b) One month time without specific reasons after obtaining the assent of the medicinal club.
- c) six months for the following reasons:
  - transportation or renovation,
  - for health reasons
  - for economic reasons
  - For other serious reasons at the discretion of the Competent Authority, if he cannot find a replacement.

In practice, the time of year is considered as temporary closure operation and taken into account; regard the distances and the retirement of pharmacist

Finally, the closure of the pharmacy arbitrarily considered infringement harming public health, punishable by a fine or revocation of the license if the pharmacy is closed over three months (six months in the case of inheritance pharmacy) without permission of the Competent Authority.

## **CHAPTER 7: *Historical Development of the pharmacist' association***

### **7.1 Aim and Priorities**

The Panhellenic Pharmaceutical association is a body corporate under public law N.3601/1928. It was founded in 1928 under the title of Greek Pharmaceutical Association.

Members of SFEE are 60 Pharmaceutical enterprises operating in Greece which cover all innovative medicinal products as well as 90% of the pharmaceutical market.

The Association was created in order to protect and promote the interests of its members and to secure the implement of the law. It represents an organism which informs its members and furthermore safeguards its significant role to the public health.

More specifically, the mission of the Hellenic Association of Pharmaceutical Companies (SFEE) is to create favorable policy conditions, which will enable the research-based pharmaceutical industry to participate and to benefit from the international scientific progress, consolidate its competitiveness and contribute to the greater possible development of innovative medicinal products to the benefit of the patients' healthcare.

In addition, a basic aim of SFEE is the creation of policy conditions, adapted to the European pharmaceutical policy that consolidates competitiveness and allows for a greater possible development of medicinal products in an attempt to the benefit of patients' healthcare.

One of the significant roles of SFEE is to develop a climate of co-operation with all the parties that involved, such as Health Authorities, Public service, Physicians and pharmacists' to enable the research-based pharmaceutical industry to meet the present and future expectations of Greek citizens.

Moreover, SFEE is “committed to promote legislative, provisions, economic and political conditions and implement existing legislation, which favor the development of innovative research. This kind of research leads to new therapies which improve the quality of life and save the lives of millions of patients”.

It is worth noting that the necessary investment for this innovative research will assist the Pharmaceutical Industry to contribute to a greater extent to the economic growth, employment and industrial competitiveness.

However, pharmaceutical companies are confronted with a plethora of strict measures which are:

a) “The determination of prices based on the average of the three lowest prices in Europe,

- b) The establishment of a reimbursement list which will probably result in further reduction of the prices of medicinal products in order to include them in this list,
- c) The parallel requirement of compulsory discounts on already low prices,
- d) The additional requirement of a rebate to be paid to social security funds,
- e) The compulsory payment of all costs for the distribution of medicinal products throughout the country by pharmaceutical companies,
- f) The compulsory payment of all costs for the return of medicinal products by pharmaceutical companies”.<sup>15)</sup>

About the priorities of SFEE, according to its statute, the main priorities are:

- “Establishment of SFEE as trustworthy interlocutor and consultant of the political leadership so that political decisions are taken after dialogue with representatives of the interested parties (physicians, pharmacists, industry, patients) to the benefit of patients' care.
- Creation of favorable climate for research and development of new medicinal products by utilizing the scientific potential of the country.
- Establishment of a legislative framework which will ensure the quality, efficacy and safety of new medicinal products.
- Establishment of conditions for healthy competition so that the policy pursued and legislative provisions enhance investments in the research and development of innovative medicinal products.
- Support of investments through legislative provisions which will favor expansion in the international market and effective protection of intellectual property.”<sup>16)</sup>

Supreme body of the association is the General Assembly and its members are gathered occasionally in March and November of every year. Members of the association become all the pharmacists that possess a pharmacy legally and they have to conform to the internal regulations.

The association has organized the function of a Solidarity Fund in order to deal with its members' urgent needs, like severe injury that leads to permanent or contemporary disability or destruction of the pharmacy from natural reasons that is out of the pharmacist's control.

It also provides information to the pharmacists regularly for many scientific topics and other news concerning their work. Moreover, it participates in the controls done by the officials who are authorized by the Prefecture. It is also considered to be the "voice" of all the pharmacists and this makes the association powerful.

Regarding the source of funding of SFEE, these are allocated to regular and extraordinary.

In practice, the regular financial resources are stem from the ordinary members' registration fees, their yearly membership fees and the income from the Association's assets.

On the other side, extraordinary financial resources are mainly donations, inheritances, and all other income legally obtained, as well as extraordinary fees decided by the General Assembly and the penalties imposed to the members by the First Degree Committee.

Finally, we can refer that the Association's registration fee and the yearly membership fee paid by ordinary members every calendar year are determined by decision of the General Assembly.

## **7.2 Structure**

The administration bodies of SFEE are the General Assembly of the Members, the Board of Directors, the Director General, and the Disciplinary Board.

As we said above, Supreme body of the association is the General Assembly and its members are gathered occasionally in meetings together with Board of Directors in March and November of every year.

Members of the association become all the pharmacists that possess a pharmacy legally and they have to conform to the internal regulations.

During the first meeting, the General Assembly meets in quorum, if at least  $\frac{1}{2}$  of the ordinary members are present. Otherwise, the meeting is re-scheduled for the same day of the following week, during which  $\frac{1}{4}$  of the members must be present.

On the other side, the Board of Directors consists of 15 members, elected by the General Assembly, the Chairman, six Vice-Chairmen, a Secretary, a Treasurer and six Consultants.

The Board of Directors is elected for a 3-year term and meets on a regular basis once a month and it may hold extraordinary meetings whenever 2 ordinary members submit such a written request to the Chairman.

Also, the decisions of Board of Directors are taken by absolute majority of the members present, while in case of parity the vote of Chairman prevails.

More specifically, the Chairman, (or his legal substitute appointed by the Chairman during the first meeting of the Board of Directors) presides over the Board meetings, represents the Association before all natural persons or legal entities and before any Legal, Administrative, Municipal Authority and any other authority whatsoever.

The General Director supervises the Association services, all communications between the Association and the Administrative Authorities, the Ministries, the Political Parties, the Mass Media, the Association Members. The Director General supervises the Association's participation to the collective bodies.

The Disciplinary Board consists of three members, which elected by the General Assembly, and its decisions are taken by simple majority. The Disciplinary Board proposes to the General Assembly the deletion of an ordinary member from the Association records, if case the ordinary member refuses to conform to the sanctions that may have been imposed by SFEE's Code of Practice Second Degree Committee.

The Disciplinary Board also reviews all issues that may lead to an ex officio deletion of a member from the Association's records or following an application by an ordinary member.

Finally, two auditors, representing ordinary members, elected by the General Assembly, supervise and audit the management of the Association's financial resources.

In practice, the auditors submit to the Regular General Assembly an annual written report, on the management of the Association's financial resources.<sup>15)</sup>

### **7.3 Other Pharmaceutical Associations**

The Pharmaceutical Association of Athens (FSA) and Pharmaceutical Association of Thessaloniki (FSTH) were established in accordance with the provisions of Law No. 3601/1928 on the establishment of Pharmaceutical Associations.<sup>13)</sup>

Both of them work with public entities form and their operation is governed by the applicable provisions for drug associations. They are governed by a nine Board elected every three years by the General Assembly.

Members of FSA must be all pharmacists who operate legally their own pharmacy in Attica region. Respectively members of FSTH must be also pharmacists who operate their own pharmacy in Thessaloniki region.

From its foundation the FSA:

- Has signed collective agreements with 42 Social Security Funds. The association receives the prescriptions of every pharmacy member and pays them off, covering that way the interests of its members.
- Has a dynamic intervene in cases of problems with members of the Funds , which enter into individual contracts with them.
- Has organized the function of a Solidarity Fund in order to deal with its members' urgent needs, like severe injury that leads to permanent or contemporary disability or destruction of the pharmacy from natural reasons that is out of the pharmacist's control.
- Provides to its members the fullest information about scientific and sector issues on a monthly basis.
- Participates by representatives on the controls that carried out by the authorized bodies in the prefecture during the inspection of pharmacies that are established or are going to be authorized.
- In general is the voice of 40 % of Greek pharmacies, which gives special power and prestige as a association.

Finally, an ambition and priority of the Board of Directors of the F.S.A. is to modernize the profession and providing unwavering support to the pharmacist of Attica, in any professional problems that they are face. (<http://www.fsa.gr>)

On the other side, FSTH' aim is the concentration and distribution of prescription insurance funds and organizations performing in pharmacies belonging to the power of the Pharmaceutical Association in Thessaloniki

Also, FSTH has established the non-profit organization called "Distributing Account membership Pharmaceutical Association Thessaloniki" (DI.LO.F.). The DILOF aims primarily to "the concentration and distribution of prescription from insurance funds and organizations, which are performing in pharmacies belonging to the power of the Pharmaceutical Association of Thessaloniki, the collection of payments through the FSTH on behalf of pharmacists and distribution to those of the corresponding amounts", as described in its statutes.<sup>14)</sup>

## **CHAPTER 8: *National organization for medicines***

### **8.1 National Drug Organization (EOF)**

The National Drug Organization (EOF) is the main regulatory authority functioning under the auspices of the Ministry of Health and Social Solidarity. In 2004, total pharmaceutical expenditure in Greece reached the level of 2.9 billion euro, of which 77.9% were public expenditure and the remaining 22.1% private.

According to Organization for Economic Cooperation and Development (OECD) data, the total per-capita expenditure on pharmaceutical care in Greece was among the lowest in Europe. In 1998, Greece introduced a reimbursement list, and the lowest reference pricing system among the 15 European Union member states with the purpose of controlling the growth of pharmaceutical expenditure.

The measures proved to be ineffective since pharmaceutical expenditure continued to increase at similar rates to those before the introduction of price control mechanisms. New pharmaceutical legislation, no. 3457, was enacted on May 8th 2006, aiming at greater access to medicines, improvements to citizens' quality of life, effective

and efficient utilization of health resources, transparency in public management, protecting public health, and maintaining long-term financial viability of the insurance system.

The innovative aspect of the new legislation is the abolition of the positive list and the establishment of a rebate system granting the National Insurance Funds a rebate rate paid by the pharmaceutical companies.<sup>17)</sup>

## **8.2 Historical data**

The National Organization for Medicines (EOF) was established in 1983, with Act 1316, and is a public entity of the Ministry of Health.

EOF mission is to ensure public health and safety with regard to the following products, marketed in Greece:

- medicinal products for human and veterinary use
- medicated animal foods and food additives
- foodstuffs intended for particular nutritional uses and food supplements
- biocides
- medical devices
- cosmetics

Within the framework of its mission, EOF, in co-operation with the European Union, performs the following tasks:

- Evaluates and authorizes new, safe and efficient health related products.
- Monitors the post-marketing product quality, safety and efficiency.
- Monitors product manufacturing procedures, clinical studies and the marketing of products, in order to ensure compliance with good manufacturing, laboratory and clinical practice, as well as with the existing legislation regarding the marketing, distribution, commercialization and advertising of the products.
- Develops and promotes medical and pharmaceutical research.
- Provides health scientists, competent authorities, and the general public with objective and useful information regarding medicines (for human or veterinary use) and other



products, in order to ensure their rational use and provide an assessment of their cost-effectiveness.<sup>17)</sup>

### 8.3 Structure

“EOF is administered by a Management Board. Today's EOF structure was set in place by Presidential Decree (P.D.) 142/89. It has 9 divisions (see organization scheme attached).

EOF achieves its objectives with the co-operation of 238 employees, which include 80 pharmacists, chemists, physicians, biologists, and veterinarians as well as 26 economists, mathematicians, lawyers and information scientists. It also co-operates with approximately 400 external health related scientists of various specialties. EOF has 45 representatives that participate in committees and working groups of the European Union and Council of Europe and with the help of expert scientists, it has formed 24 scientific committees and boards among which the most important are:

- **The Scientific Board of Approvals.** States its opinion on the issue of authorizations, amendments, revocations, and suspensions of marketing authorizations for products under the authority of EOF. This board is composed of several divisions which encompass conventional medicinal products, biological medicinal products, blood products, radioactive medicinal products, special foods, veterinary medicinal products and veterinary vaccines.
- **Pharmacovigilance Committee.** Evaluates the adverse drug reactions and makes suggestions on correcting or amending the Summaries of Products Characteristics (SPC's) and Patient Information Leaflets (PILs).
- **Scientific and Ethics Committee of Clinical Studies Authorization.** Ensures the protection of the rights, safety and health of people who participate in clinical studies.
- **Pharmacopoeia Committee.** Drafts the Hellenic Pharmacopoeia. National Formulary Committee. Is responsible for the elaboration of issues regarding the marketing of cosmetics.

The Medical Devices Committee. Makes suggestions on the characterization of products as medical devices, their classification, the appointment and control of Notified

Bodies, and the specific regulations for the implementation of related legislation. Second Degree Scientific Board. Revis appeals against initial EOF decisions”.17)

## **CHAPTER 9: Pricing of drugs**

### **9.1 Definitions for pricing**

1. “Maximum Wholesale Price of Medicines” is the price at which medicinal products are sold to pharmacies. This price shall include the wholesale gross profit margin, calculated as a percentage on the net price of producer or importer.

2. Maximum Retail Price of Medicines” is the price at which medicinal products are sold by pharmacies to consumers, and it is defined by the wholesale price, adding the lawful profit margin of the pharmacy the applicable and VAT. Maximum retail prices shall be uniform across the country.

3. “Maximum Hospital Price of Medicines” is the price at which medicinal products are sold by importers, manufacturers or packers to the State, public hospitals, social Care Units, EOPYY pharmacies. The maximum hospital price shall be determined on the basis of the wholesale price reduced by 13%.

### **9.2 Pricing**

The Price [Bulletin](#) of Medicines for Human Use (including re-pricing, new generics and new original medicines) has been uploaded on the site of the Ministry of Health on Tuesday 06 August 2013. According to this, medicines for human use will be priced as following:

- The wholesale price and the hospital price will be tax free.
- The retail price includes tax and this tax is 6,5 %.

Regarding the profit margins of pharmacies, these are:

#### **1. For wholesalers, gross profit margins shall be determined as follows:**

- for non-prescribed medicines (OTC), at 7.8% on the ex-factory price;
- for prescribed medicinal products not reimbursed by social security agencies, at 5.4% on the ex-factory price;

- for medicinal products reimbursed by social security agencies, at 4.9% on the exfactory price; and
- for the medicinal products of par. 2 of Article 12 of Law 3816/2010, at 2% on the hospital price. The resulting price shall hereinafter be referred to as “special wholesale price”.

**2. for pharmacies, gross profit margins shall be determined as follows:**

- for non-prescribed medicines (OTC), at 35% on the wholesale price;
- for prescription medicinal products not reimbursed by social security agencies, at 35% on the wholesale price;
- for medicinal products reimbursed by social security agencies and having a wholesale price of up to €200, at 32,4% on the wholesale price;
- for reimbursed medicinal products having a wholesale price or a special wholesale price over €200, the profit margin of private pharmacies shall be equal to a fixed amount of €30.00.
- for reimbursed medicinal products included in the list of par. 2 of Article 12 of Law 3816/2010 and having a Special Wholesale Price of up to €200, the profit margin of private pharmacies shall be determined at 16% on the Special Wholesale Price.

**9.3 Unfair competition**

They are three article in the (FEK, 312 (16/9/92)) about the unfair competition in pharmacies. More specifically these are:

**Article 22**

Pharmacists must avoid attracting clients through actions and contrary to the dignity of man and the scientist in pharmacy and public health function (providing gifts or other compensation).

**Article 23**

Prohibited the pharmacist to replace with other drugs listed in a prescription , even if administered to replace the listed considered at the discretion of the larger and better

therapeutic value without the approval of the doctor who issued the prescription.

## **Article 24**

Generally prohibited pharmacists pharmacy operation, beneficiaries inherited pharmacies and pharmacists responsible inherited pharmacies follows:

a) Each drug sale at a price less than the prescribed retail price with vouchers Department of Commerce .

b) Any contract, transaction or arrangement aimed at profiting at the expense of patients' health and any other person.

c) Any distribution or sharing with others the rate of profit pharmacist.

d) Each of gifts or other benefits to doctors, dentists, midwives, nurses or other brokers to attract customers.

e) Any violation of the opening hours of the pharmacy.

f) Any exchange of money or other items of indicated prescription drug insurance fund.

g) Any action that may procure an undue benefit to the customer.

h) Each facility to anyone who employs illegal pharmaceutical science.

i) Any agreement with any possibly employing , any health profession in order to reap benefits of the pharmacist and this agreed upon at the expense of the health of the patient and any other person .

j) Any use honorific office held by the pharmacist to attract customers.

k) Any contract with an insurance fund or legal persons providing pharmaceutical care with terms different from those who have accepted the P.F.S. and the pharmaceutical society of which he is a member of the pharmacist. (FEK, 312 (16/9/92))

## **CHAPTER 10: *Pharmaceutical pricing and reimbursement reforms in Greece***

## **10.1 Pharmaceutical policy 2009-2012**

It is a fact that in recent years and due to Memorandum, there have been done a number of changes which have changed significantly pharmaceutical policy , which followed hitherto in Greece

A significant feature is the fact that only for the period under examination, ie 1/1/2012 to 31/12/2013 has been three ministerial decisions which related to pharmaceutical policy.

First of all, we will refer to the beginning of the reform on the pharmaceutical sector, which started in 2010, within the general framework of the Memorandum, which commanded the modernization and improvement of this sector.

More specifically, the Law 3816/2010 introduced new drug lists (positive, negative , OTC and serious illness), to the separation of pharmaceuticals on the market with various technical criteria, so as to establish a different rate for state compensation in each drug according to the list belongs to.

Moreover, in 2010 it started the attempt to set up a system of electronic prescription in an attempt to monitor and control better and more effectively the prescribing behavior of physicians and the pharmaceutical expenditure of social security institutions.

Regarding the satisfaction with the implementation of electronic prescribing, we can say that this is satisfactory, since the end of 2012, 90 % of prescriptions were recorded in most electronics. (Foundation for Economic and Industrial Research, 2013)

In addition, in 2011 are issued the Laws 3918 and 4025, which stipulated changes in profit rates wholesalers and extend the list of serious diseases medicines, industry discounts on hospital sales, a rebate for each prescription drug , each company had to trade EUR 4% of sales of this formulation and the so-called entry fee set equal to 4% of the producer price (ex-factory) and which will fall exclusively licensees medicinal preparations.

Then after a brief reference to major changes in pharmaceutical policy, which occurred prior to the study period of this study , we come to 2012, where a variety of measures and

reforms in the health and drug introduced and implemented in the framework of the second program economic Adjustment.

In particular, the adopted automatic return (claw back) to pharmaceutical companies. This measure provides that if the monthly public pharmaceutical expenditure of the social security exceeds the estimated cost of the excess amount will be recovered from marketing authorization holders of preparations, namely pharmaceutical companies.

Moreover, it was given the opportunity to offset various requirements of FKA and hospitals with claims against pharmaceutical companies. In an effort that had began to hold public pharmaceutical expenditure from 2010 had highlighted the usefulness of increasing generic penetration.

By N.4052/2012 became mandatory prescription under active substance, initially for ten active substances with the highest circulation and by June 2012, mandatory for all active substances. (Foundation for Economic and Industrial Research, 2013)

Simultaneously with this measure promoted changes in pricing of generic drugs by establishing a new dynamic pricing system. (Foundation for Economic and Industrial Research, 2012)

Also, this system provides that the first generic to be introduced to the market immediately after patent expiration of the original will have a default value which will not exceed 40 % of the original price just before the expiry of the patent , and for each following triad generic maximum allowable value will be 10 % lower than the first generic, or from the previous generic triad that had received approval for marketing .

It should be noted that the same law included changes in margins both the wholesalers and pharmacists, which is now different for positive and negative drug list for wholesalers and different depending on the wholesale price of the drug to pharmacists.

Accordingly, in October 2012, as per above, issued three ministerial decisions with new changes in the lists of drugs, the compensation scheme and margins of pharmacists. More specifically , for medicinal wholesale or special wholesale price of over € 200 profit pharmacists set at € 30, regardless of the compensation scheme, which governs each formulation .

Also, for drugs reimbursed by the state and under the list of drugs serious diseases N.3816/2010 profit pharmacists set at 16% of the special wholesale price. Moreover, under the interministerial decision of 104747, its sets up a list of medicines you with reduced participation of the patients and the completion of a list of drugs by the National Medicines Agency under the classification system anatomical therapeutic classification with ATC the estimated participation rate for each formulation. (Foundation for Economic and Industrial Research, 2013)

More specifically, in October 2012 issued a ministerial decision of 104744, which sets up a positive list of medicines under ATC4, in which are introduced for the first time reference values .

For the definition of the reference value of each medication on the list will take into account data on the efficacy, safety, quality, cost - effectiveness and wider socio-economic implications.

The Reference Price of each therapeutic class is defined as the lowest cost Daily Therapy between the set of all reference drugs (with or without protection regime) and the average of the entire generic category. (Foundation for Economic and Industrial Research, 2013).

Based N.4093/2012, the automatic return will be calculated at 6-month basis and can no longer be offset against debts EOPYY or NHS hospitals to pharmaceutical companies . Also , the same law introduced payment by patients for each prescription performed by a pharmacist in the amount of one (1 ) euro and the payment of € 25 for each admission for treatment in NHS hospital , from 1.1 -2014 .

Further, a restriction was that the percentage of the total annual value of prescription drug under the trade name of each physician not to exceed 15 %.

In addition, the law 229A/19.11.2012 also provides for temporary fee equal to 15 % of sales of each formulation was in the positive list in 2011, with the possibility of clearing the automatic refund for the year 2012 .

The validity of this measure starts from 1-1-2013 and non-compliance of the marketing authorization holders of preparation will lead to automatic transfer of the preparation in the negative list of drugs.

Moreover, the law 3035/15.11.2012 entered new limit public pharmaceutical expenditure for 2013 to € 2,44 bn Thus , an excess of the limit will trigger the automatic return mechanism. (Foundation for Economic and Industrial Research , 2013)

## **10.2 Pharmaceutical interventions for the period 2013 – 2016**

In accordance with the provisions in the Memorandum between Greek government and the European Commission, ECB and IMF (December 2012) , will continue efforts to reduce public pharmaceutical expenditure , so that to reach 1% of GDP in 2014 .

To achieve this goal it will make automatic return to pharmaceutical expenditure is kept within the budgeted limits , will further reduce the price of off-patent and generic pharmaceuticals , will reduce the average profit margin of pharmacies in 15 % , will reduce operating costs of hospitals , will raise contributions of farmers and revised service package that offers EOPYY .

In particular, we have:

### **A) Health System Governance**

- Direct purchase hospital services from EOPYY on a budget, based on costed procedures.
- A 10% reduction in medical staff EOPYY until December 2012 and a further 10 % in 2013. (Foundation for Economic and Industrial Research , 2013)

### **B) Control of pharmaceutical expenditure**

Revision of the structure of contribution to the costs of buying medicines which will be excluded from participating small number of formulations related to specific treatments. (Foundation for Economic and Industrial Research, 2013)



## **C) Pricing**

- Downward revision of prices of drugs and medicines repricing with price less than € 10, which includes reducing the price by 10 % .
- Implementation of automatic return (clawback) every six months in an attempt to ensure that there are no deviations from the target.
- Development Implementation Report on the impact of new margins of pharmacies, which shows that if not achieved the goal of the average pharmacy margin of 15%, resulting in a revision of the margin .
- Ensure that EOPYY will negotiate a 5% discount through price - volume agreements on 200 drugs.
- Extend the 5% discount from pharmaceutical companies on all products sold in pharmacies EOPYY. (Foundation for Economic and Industrial Research, 2013)

## **D) Prescription**

- Extension of electronic prescribing in all doctors, medical centers and hospitals .
- Implementation system of electronic submission of prescriptions pharmacists those not registered by doctors.
- Version mandatory prescribing standards / protocols to doctors with priority for the most expensive and most widely used drugs .
- Further development of a monitoring and control of electronic prescribing
- Provide prior year's monthly reports on the use of electronic prescribing in the national health system and affiliated with EOPYY
- Provide regular assessments of the information obtained from electronic prescriptions.
- Prepare detailed quarterly reports on prescribing and pharmaceutical expenditure , which will include information on the volume and value of medications, use of generics and off-patent drugs and discounts received by pharmacies and pharmaceutical companies .
- Production of detailed information and prepare reports for each physician prescribing behavior compared with the whole class (depending on the specialty and the number of patients) , which give signals violating prescriptions.

- A penalty when finding a breach of prescribing standards.
- Select expensive drugs sold in pharmacies in order to be sold to hospitals or pharmacies EOPYY. (Foundation for Economic and Industrial Research , 2013)

### **E) Increased use of generic**

- Increased use of generics to 35 % of the volume of drugs sold in pharmacies by the end of 2012 and 60 % by the end of 2013.
- Additional measures will ensure that at least 50 % of the volume of medicines used in public hospitals is generic price lower than or similar branded off-patent products.
- Determining liability in all public hospitals procure at least two thirds of pharmaceutical formulations based on the active substance , using centralized procedures requiring the submission of tenders and compliance with treatment protocols and prescribing guidelines .
- Adoption in cooperation with pharmaceutical companies and physicians practices. (Foundation for Economic and Industrial Research, 2013)

## **Chapter 11: Comparison of Pharmacies and Pharmacy Practice in Greece with Czech Republic**

It is fact that in Czech Republic have been many attempts in the direction of harmony with the European Transparency Directives. For this reason, competencies were transferred from Ministry of Health to the State authority for Drug Regulation. This change was set as a part of the Act about stabilization of public budgets, with effectiveness from 1st January 2008.

“More specifically, in 2007 government of Czech Republic issued an amendment about the Act on Public Health Insurance was prepared with the introduction of regulatory fees, limits on these fees per year and the introduction of generic substitution, with effectiveness from the beginning of 2008”.

“The new statutory text of the Act about Medicine was discussed in autumn 2007, during the approval process parliamentary amendments appeared which could negatively affect the development of pharmacy in the Czech Republic. Thanks to intensive work by the Chamber of Pharmacists and its cooperation with the state authorities it was managed to defend inevitable task of pharmaceutical care and possibility of further development”.<sup>3)</sup>

“It is also worth noting that the amount of these changes and regulations were exposed to daily pharmaceutical practice, so the Chamber organized series of seminars during 2007, where the members were informed about all current and forthcoming changes. The start of new reforms 2008 were supported by the chamber too. The printed materials were published for patients with detailed and clear explanations of all new changes connected with regulation fees from the beginning of 2008”.<sup>3)</sup>

As we see above, a similar situation exists in Greece, where in the field of Memorandum, the Greek government issued amendments in an attempt to be harmonized with the European directive about pharmacies and pharmacy policy.

With the exception of non-prescription pharmaceutical products which are not subject to reimbursement, all pharmaceutical products in the Czech Republic are subject to price control.

Regarding the prices and the profit margins, it is fact that manufacturers and importers submit their price proposals to the Ministry of Finance, which issues a List of Maximum Prices (based on a therapeutic reference pricing system).

More specifically, “the prices of domestic products in Czech Republic are set on a basis of a maximum 30% pre-tax profit margin; regarding imported products, importers have to present their price lists and advise the Ministry of Finance on turnover and pre-tax profits.

Different prices apply throughout the various trade channels. The margins applied to pharmaceutical products in the Czech Republic can be expressed in the following:

- Wholesaler: eight digressive margin groups (which are cumulatively built up), starting with a 36% maximum common margin for products cheaper than CZK 150 (€ 109)

and ending with 5% for those above CZK 10,000 (€ 7280). A zero margin is also possible.

- Pharmacist: the margin is calculated according to the following formula, plus a dispensing fee of CZK 30 (€ 22) per item: Regulatory fee  $(=CZK\ 30) * \{0.25 * [ARCTG\ (manufacturer\ selling\ price / 50 - 2.5) + 1.6]\}$
- State (Value Added Tax - VAT): a discounted VAT of 10% on the wholesale price (the standard VAT rate is 20%)” (CBI market survey, 2010)

If we compare this data with the data that we refer above regarding the profit margins in Greece, we can observe that in Greece the profit margins of wholesalers are significantly lower than Czech Republic.

Also, we can point out that “the Czech Republic has a strong production of generic medicines, which was enhanced in 2003 by the merger of the country’s leading manufacturer, Leciva, with one of Slovakia’s leading pharmaceutical companies, Slovakofarma, to form Zentiva. In 2007, the company acquired Turkey’s Eczacibasi Generic Pharmaceuticals and boosted its sales growth.

In spite of important mergers involving Czech companies, the Czech Republic’s pharmaceuticals industry is characterized by a high degree of foreign ownership, according to PriceWaterHouseCoopers.

Pharmaceutical companies operating in the Czech Republic are subject to an extremely strict and complex regulatory environment. The Czech State Institute for Drug Control regulates every aspect of business, from pricing to packaging, from clinical trials to advertising.

Production of branded pharmaceutical products in the Czech Republic is minimal, since they are easily obtainable from neighbouring countries such as Germany and Austria.

In addition, the Czech Republic is forbidden by the EU’s accession treaty to parallel low-priced patented pharmaceutical products to high-price EU markets (e.g. Germany and the UK), in the case this product has a patent in the target market.

On the other side, the situation is quite better in Greece, as the pharmaceutical production is quite average, while there are high margins of further development in the next years, in contrast to the existing situation in Czech Republic.

Finally, the pharmaceutical policy under the Act No. 372/2011 Coll., refers that on health services for pharmaceutical care as care, whose purpose is the provision , preparation, treatment, storage, control and distribution of drugs, with the exception of blood products and raw materials for the production of blood derivatives according to the law on drugs, laboratory chemicals, reagents, disinfectants.

Furthermore, the provision, storage, distribution and sale of medical is associated with the Medical Devices Act, together with the provision, storage, distribution and sale of food for special medical purposes and other services in the area of prevention and early detection of disease, health promotion.

Likewise, the assessment and control of efficiency, the safe and economical use of medicines and procedures associated with it.

About pharmacies, the law refers that are the most easily accessible medical facilities for the general public and often are the first point of contact of the patient in the health care delivery system.

In addition, pharmacists specialize in a wide range of options, particularly with regard to the specific diagnosis or specific group of patients. Modern pharmaceutical care is an evolving set of activities, based on the professional level pharmacy staff, its unique identity and technology available. A prerequisite is coherent cooperation with physicians and other health care workers. (Act No. 372/2011 Coll)

As we can observe the legislation about pharmacists and pharmacies in Greece and Czech Republic have many similarities, but the laws are modified to the field and the conditions of each country.

Finally, we can refer that the main aim of Czech Chamber of Pharmacists has many similarities with the EOF of Greece. More specifically, the main aims of Czech Chamber of Pharmacists are:

- To pay for pharmaceutical care was provided by a multicomponent pharmacist was evaluated for contribution to ensuring the safety and effectiveness of drug therapy, and also to minimize the costs of payers and patients.
- In order to clarify the conditions regulating the operation of public pharmacies, as well as demographic and geographic criteria for their establishment.
- That responsibility for the management and operation of public pharmacies was the domain of pharmacists.
- That the conditions have been established specialized education effectively and flexibly.
- In order to pharmacists in relation to occupational motivated to engage in postgraduate education, lifelong learning and scientific research activities.
- In order to identify the types and range of specialized pharmacists meet the demands of modern pharmaceutical care.
- To have achieved specialization linked to competencies to specific professional activities, including links to the reimbursement system to deliver them.
- To other sources of funding pharmaceutical care helped to further develop the pharmacy.
- In order to provide support to all activities aimed at popularizing the pharmacy.

Also, the laboratory activities are:

- Ensuring the availability and safety of medicinal
- Improving treatment outcomes of individual patients
- Activities to promote public health
- Increasing the efficiency of the health system

Finally, the mission of pharmacists in Czech Republic is to promote public health goes far beyond the simple use of pharmaceuticals. It is part of a wider strategy to strengthen and improve public health. Attention is shifting from treatment to prevention.

Due to the number and distribution of pharmacies is easily accessible for the vast majority of the population. Hits pharmacies are two times more frequent than visits to doctors' offices. The pharmacist has become a doctor with the largest number of contacts with the patient.

This puts pharmacies and their potential in a unique position to influence patients to improve public health, which has been repeatedly verified in both the Czech Republic and abroad.

- **Pharmacovigilance:** Since pharmacists are expected to collect and report information about unexpected adverse reactions to the national authorities. This will help protect the health of patients and improve the quality of care.

- **Detection of emergency management for public health and crisis.**

Pharmacists are in a unique position to detect a risk to public health and played a vital role in national strategies for dealing with crisis situations. Pharmacy may be in crisis situations are readily adapted to provide information to citizens.

- **Dissemination of information for public health**

Availability pharmacies increases the effectiveness and reach of health campaigns and public health authorities allows targeted focus on specific issues such as the use of antibiotics and prevention of bacterial resistance, screening for cancer - melanoma, for example , stopping smoking , lifestyle changes, or nutritional advice.

- **Participation in the control and management of treatment in the early diagnosis and prevention of disease**

Pharmacies are equipped with instruments and devices that can measure and evaluate indicators still hidden disease. Early detection is especially in people who have not yet come into contact with other health care providers.

When finding a revelation, outside the normal range or abnormalities that cannot be adjusted or normalized freely available drugs, the pharmacist is a health professional with the best scholarship to direct the patient to the doctor or specialist. Pharmacies are also an integral part of the programs of vaccination campaigns warning to the administration of the same vaccine. For the development of these services through special training of pharmacy employees.

- **Support for Self- Medication**

Pharmacists advice on medicines obtained without a prescription. It is essential for safe and effective self - treatment. Offer patients a wide range of services to address the health problems associated with obesity , smoking cessation and other addictions, sexual health and family planning , which is directly related to issuing emerging contraception.

- **Safety and Environment**

Proper and safe disposal of unused or unusable drugs and medical devices is important for the environment and safety.

Part of pharmacists, such as consultancy and implementation of these activities. The success of these activities depends on the proactive approach of state government. To the above directions the Czech Chamber of pharmacists attempts to:

- To strengthen the involvement of pharmacists in support of public health is necessary
- Encourage pharmacists to report adverse drug reactions.
- Embed pharmaceutical information and communications technology solutions to the national e-Health system that can record pharmacists actively collect data related to public health through patient records medication.
- Better use of pharmacies in a unique position to disseminate information in the field of public health. Moreover, public health authorities should make better use of the expertise of pharmacists, their communication skills and the availability of network pharmacies when preparing scenarios for crisis management in the field of public health.
- To encourage and motivate pharmacists to develop screening programs, vaccination strategies and work with at-risk groups of patients. These activities are also incorporated in the return system.<sup>2)</sup>

In practice, there are not significant differences in the mission of pharmacists and the aims of EOF and Czech Chamber of pharmacists, as both countries make efforts to harmonize with the European directives regarding the pharmacies, pharmacists and the pharmaceutical policy in general.



## DISCUSSION

During the last decades in Greece, the pharmacist's job shows an upward trend. According to statistics, the establishment of pharmacies has been rising sharply. As a result, nowadays, Greece has the largest number of pharmacies, per inhabitant, in all Europe.

**Picture 3: PHARMACIES IN EUROPE PER RESIDENTS<sup>(37)</sup>**

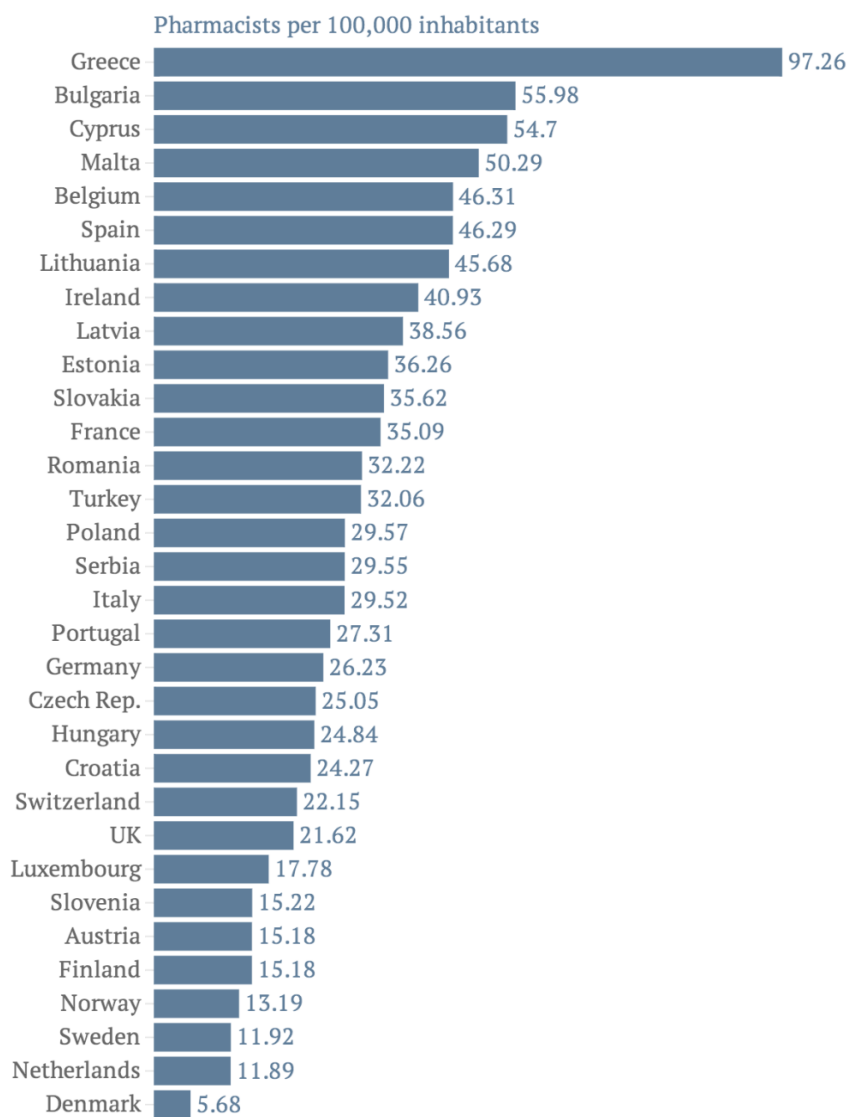
COUNTRY	PHARMACY	POPULATION	PHARMACY/POPULATION
<b>Greece</b>	<b>9.500</b>	<b>11.260.402</b>	<b>1.185</b>
Cyprus	434	796.875	1.836
Malta	210	413.609	1.970
Belgium	5.149	10.750.000	2.088
Spain	21.057	45.828.172	2.176
Lithuania	1.520	3.349.872	2.204
Latvia	882	2.261.294	2.564
Ireland	1.608	4.450.014	2.767
Slovakia	1.931	5.412.254	2.803
Estonia	474	1.340.415	2.828
France	22.590	64.350.759	2.849
<b>Europe</b>	<b>141.582</b>	<b>470.517.730</b>	<b>3.323</b>
Italy	17.796	60.045.068	3.374
Poland	10.628	38.115.641	3.586
Germany	21.602	82.002.356	3.796
Portugal	2.777	10.627.250	3.827
Hungary	2.410	10.030.975	4.162
<b>Czech Republic</b>	<b>2.346</b>	<b>10.467.542</b>	<b>4.462</b>
United Kingdom	13.071	61.634.599	4.715
Luxembourg	86	493.500	5.738
Filandia	807	5.326.314	6.600
Austria	1.233	8.355.260	6.776
Slovenia	294	2.032.362	6.913
Netherlands	1.976	16.405.399	8.302
Sweden	883	9.256.347	10.483
Denmark	318	5.511.451	17.332

The approximately number of pharmacies in Greece, in 2012 was estimated at 11,500. According to the law the ration between pharmacies and population is 1 pharmacy per 1000 residents.

For example in Belgium (which has same population with Greece) the ratio is 1 pharmacy per 6,000 residents. According to statistics in Belgium the average number of pharmacies is estimated at 6,000 while in Greece there are 12,000 nowadays. On the other hand, according to different source and specifically the table above (see picture 3), numbers don't verify this fact.

Moreover it is calculated that city of Athens (calculated population:3,75 in 2012) has average number of pharmacies same, in comparison with whole Austria (calculated population:8,462 in 2012). Furthermore the percentage of pharmacists in Greece, has increased during the last decays(as you can see on picture 4 below). On a per capita basis, there are more than twice as many Greek pharmacists as French or Spanish ones, 74% more than in Bulgaria—Greece’s nearest competitor in druggist density—and an astonishing 17 times as many as in Denmark.

**Picture 4: Pharmacists per 100,000 inhabitants<sup>(38)</sup>**



## CONCLUSIONS

As we said above, pharmaceutical industry is one of the significant sectors of the economy with many strategic benefits, which are identified either in the sense of mature capabilities either in the sense of good times and potential growth prospects.

In this thesis has been described the Greek pharmaceutical legislation and the duties and responsibilities of pharmacists in Greece as compared to those in Czech Republic. It also focuses on the chambers of pharmacists and the reason they were organized.

It is also worth noting that this thesis refers not only to community pharmacies, but also to hospital pharmacies and the way they work.

The basic conclusion, which we can exact from our thesis, is the fact that both Greece and Czech Republic made significant efforts in latest years to harmonize their legislation to the European standards and directives. For this reason, both Czech government and Greek government issued many amendments in latest year, which aimed to this direction.

However, a significant difference between Greece and Czech Republic is profit margins of wholesalers, which are higher in Czech Republic in comparison to Greece, while the production of drugs in Greece is significant higher than Czech Republic, which based more in its neighboring countries for the supply of drugs.

Also, pharmaceutical companies, which are operating in the Czech Republic, are subject to an extremely strict and complex regulatory environment. The Czech State Institute for Drug Control regulates every aspect of business, from pricing to packaging, from clinical trials to advertising.

Finally, there are not significant differences in the mission of pharmacists and the aims of EOF and Czech Chamber of pharmacists, as both countries make efforts to harmonize with the European directives regarding the pharmacies, pharmacists and the pharmaceutical policy in general.

The general conclusion from this thesis is that the legislation about pharmacists and pharmacies in Greece and Czech Republic has many similarities, but the laws are modified to the field and the conditions of each country.

## REFERENCES

- 1) Centre for the Promotion of Imports from developing countries (CBI) market survey, (2010), “The pharmaceutical products market in the Czech Republic”, Publication date, February 2010.
- 2) Czech Chamber of Pharmacists, Available at: <http://www.lekarnici.cz/O-CLnK/Kdo-je-CLK/Koncepcje-verejneho-lekarenstvi.aspx>, Accessed 10.5.2014.
- 3) Czech Chamber of Pharmacists, (2007), “Annual report 2007”, Available at: [http://www.lekarnici.cz/getattachment/O-CLnK/Vyrocnj-zpravy/Vyrocnj-zprava-za-rok-2007/Vyrocnj\\_zprava\\_2007\\_anglicky.pdf.aspx](http://www.lekarnici.cz/getattachment/O-CLnK/Vyrocnj-zpravy/Vyrocnj-zprava-za-rok-2007/Vyrocnj_zprava_2007_anglicky.pdf.aspx), Accessed 10.5.2014
- 4) Czech Republic Constitutional Court Judgment, (2012), Act No. 372/2011 Coll, Available at: [http://www.usoud.cz/en/decisions/?tx\\_ttnews\[tt\\_news\]=1814&cHash=da4ccfa835ec017dd7db8a124460297f](http://www.usoud.cz/en/decisions/?tx_ttnews[tt_news]=1814&cHash=da4ccfa835ec017dd7db8a124460297f), Accessed 10.5.2014
- 5) Directive [85/432/EEC](#) of the European Council, concerning the mutual recognition of diplomas, certificates and other evidence of formal qualifications in pharmacy, including measures to facilitate the effective exercise of the right of establishment relating to certain activities in the field of pharmacy, (1985), “Pharmacy: mutual recognition of diplomas in pharmacy”, Official Journal L 253 of 24.9.1985. Available at: [http://europa.eu/legislation\\_summaries/other/123020b\\_en.htm](http://europa.eu/legislation_summaries/other/123020b_en.htm) , Accessed 5.5.2014
- 6) Directive 2001/39/EC of the European Parliament and of the Council, (2001), “amending Council Directives 89/48/EEC and 92/51/EEC on the general system for the recognition of professional qualifications and Council Directives 77/452/EEC, 77/453/EEC, 78/686/EEC, 78/687/EEC, 78/1026/EEC, 78/1027/EEC, 80/154/EEC, 80/155/EEC, 85/384/EEC, 85/432/EEC, 85/433/EEC and 93/16/EEC concerning the professions of nurse responsible for general care, dental practitioner, veterinary surgeon, midwife, architect, pharmacist and doctor”, Official Journal of the European Union. Available at: [http://www.aic.lv/bolona/Recognition/dir\\_prof/GENERAL/2001\\_19\\_SLIM.pdf](http://www.aic.lv/bolona/Recognition/dir_prof/GENERAL/2001_19_SLIM.pdf), Accessed 5.5.2014

- 7) Directive 2005/36/EC of the European Parliament and of the Council, (2005), “On the recognition of professional qualifications (Text with EEA relevance)”, Official Journal of the European Union, L 255/22, Available at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2005:255:0022:0142:en:PDF> , Accessed at: 5.5.2014
- 8) Economou M, Madianos, Peppou L, Patelakis A, Stefanis C. (2012), “Major depression in the Era of economic crisis: A replication of a cross-sectional study across Greece”, Journal of Affective Disorders, August.
- 9) Foundation for Economic and Industrial Research, (2013), "Development prospects of Greek Pharmaceutical Industry", February 2013.
- 10) Godman B, Bucsics A, Burkhardt T, Haycox A, Seyfried H, Wieninger P, (2008) “Insight into recent reforms and initiatives in Austria; implications for key stakeholders.” Expert Rev. Pharmacoecon. Outcomes Res., 8, pp.357-371
- 11) Kaponis, P., (2005), “Compendium Pharmaceutical Legislation”, Volume I and II, 2nd Edition. Athens, Publications: Pharmaceutical World, pp.68-74,89-97,102 of Volume I and pp.35-48, 54-67 of Volume II
- 12) Kaponis, P. (2008), “Pharmaceutical Law”, Volume I, University of Athens. Athens, Sakkoulas Publications, pp.227-245, 291-302
- 13) Pharmaceutical Association of Athens (FSA), Available at: <http://www.fsa.gr>, Accessed 1.5.2014
- 14) Pharmaceutical Association of Thessaloniki (FSTH), Available at: <http://www.fsth.gr>, Accessed 1.5.2014
- 15) Hellenic Association of Pharmaceutical Companies, (SFEE), Available at: <http://www.sfec.gr/en/node/6009> , Accessed 1.5.2014
- 16) Hellenic Association of Pharmaceutical Companies, (SFEE), [http://www.csrhellas.org/csr\\_last2/portal/gr/misc/551oz\\_20071113551.php3](http://www.csrhellas.org/csr_last2/portal/gr/misc/551oz_20071113551.php3), Accessed 1.5.2014
- 17) National Drug Organization (EOF), Available at: <http://www.eof.gr/web/guest/activities>, Accessed 8.5.2014
- 18) Republic of Greece. Article 11 of Law 1316/1983, paragraph 1b, (1983), “Assessment and reassessment per form and content of the medicinal product in order for it to be

- classified in therapeutic group according to the applicable procedure”, In: Government Gazette of Republic of Greece, Volume 1316/1983. Athens, Available at: <http://www.ypakp.gr/>, Accessed 8.5.2014
- 19) Republic of Greece. Article 22 of Law 1483/1984, (1984), “Timeouts operating of pharmacies”, etc. In: Government Gazette of Republic of Greece, Volume 153A’. Athens, Available at: <http://www.ypakp.gr/>, Accessed 8.5.2014
- 20) Republic of Greece. Article 58 of Law 1339/1985, (1985), “Licenses to establish and operate pharmacies and pharmaceutical warehouses”, In: Government Gazette of Republic of Greece. Athens, Available at: <http://www.ypakp.gr/>, Accessed 8.5.2014
- 21) Republic of Greece. Article 7 of Law 1985, (1985), “Co-location of Pharmacies”, In Government Gazette, of Republic of Greece, Volume 64A’. Athens, Available at: <http://www.ypakp.gr/>, Accessed 8.5.2014
- 22) Republic of Greece, Articles 8 and 14 of Law 1988, (1988), “Co-location of Pharmacies.” Government Gazette of Republic of Greece Volume 271A’ Athens, Available at: <http://www.ypakp.gr/>, Accessed 8.5.2014
- 23) Republic of Greece, (1989), “Presidential Decree No. 142/89”, In: Government Gazette of Republic of Greece, Volume 106. Athens, Available at: <http://www.ypakp.gr/>, Accessed 8.5.2014
- 24) Republic of Greece. Presidential Decree Article 41 of Law No. 1892/90, (1990), “Working time. In Government Gazette of Republic of Greece”, Volume 205A’. Athens. Available at: <http://www.ypakp.gr/>, Accessed 4.5.2014
- 25) Republic of Greece, (1991), “Circular Clarification”, In: Government Gazette of Republic of Greece, Volume 138A’, Athens. Available at: <http://www.ypakp.gr/>, Accessed 4.5.2014
- 26) Republic of Greece. Law No 1963/91, (1991), “Establishment and operation of pharmacy, amending and supplementing the Government Gazette of Pharmaceutical Regulatory and other Provisions”, In: Government Gazette of Republic of Greece, Volume 138A’. Athens. Available at: <http://www.ypakp.gr/>, Accessed 4.5.2014
- 27) Republic of Greece, Presidential Decree of Law No. 312, Article 44, (1992), “Organization and formation of pharmacy”. In: Government Gazette of Republic of

- Greece, Volume 300A'. Athens, Available at: <http://www.ypakp.gr/>, Accessed 4.5.2014
- 28) Republic of Greece. Presidential Decree of Law No 327, (1993), “Code of ethics of pharmacy”, In: Government Gazette of Republic of Greece, Volume 157, Available at: <http://www.ypakp.gr/>, Accessed 4.5.2014.
- 29) University of Patras, (2007), Available at: [http://webcache.googleusercontent.com/search?q=cache:SK2BW5TRPQ8J:www.pharmacy.upatras.gr/index.php/el/studies/undergraduate/-mainmenu-63/doc\\_download/1567--&cd=2&hl=el&ct=clnk&gl=gr](http://webcache.googleusercontent.com/search?q=cache:SK2BW5TRPQ8J:www.pharmacy.upatras.gr/index.php/el/studies/undergraduate/-mainmenu-63/doc_download/1567--&cd=2&hl=el&ct=clnk&gl=gr), Accessed 7.5.2014.
- 30) Sermet C., Andrieu V., Godman B., Van Ganse E., Haycox A., Reynier J.P., (2010), “Ongoing pharmaceutical reforms in France; considerations for other countries and implications for key stakeholder groups in France”, Appl. Health Econ. Health Policy, 8, pp.7-24
- 31) Wettermark B, Godman B, Andersson K, et al. (2008), “Recent national and regional drug reforms in Sweden implications for pharmaceutical companies in Europe”, Pharmacoconomics. 26, pp.537-50
- 32) Tsikandilakis, J. (2009), “The social role of the pharmacist”
- 33) Xanthopoulos, C. (2005), “The problem of drugs and the role of pharmacists as health officer”, Pharmaceutical Bulletin, February 2005
- 34) [http://pharmakeutika.blogspot.gr/2012/12/blog-post\\_29.html](http://pharmakeutika.blogspot.gr/2012/12/blog-post_29.html)
- 35) Available source: <http://www.inegsee.gr/wp-content/uploads/2014/04/files/report7.pdf>
- 36) Available source: <http://kastoria.teikoz.gr/icoae2/wordpress/wp-content/uploads/articles/2011/10/006-2009.pdf>
- 37) Available source: <http://www.fsa.gr/Circulars/SEPTE.pdf>
- 38) Available source: <http://qz.com/183989/greece-has-a-truly-absurd-number-of-pharmacists/>
- 39) <http://clinicalpharmacist.gr/2014/05/17/%CF%84%CE%BF-%CE%BC%CE%AD%CE%BB%CE%BB%CE%BF%CE%BD-%CF%84%CE%B7%CF%82-%CE%BD%CE%BF%CF%83%CE%BF%CE%BA%CE%BF%CE%BC>

[%CE%B5%CE%B9%CE%B1%CE%BA%CE%AE%CF%82-%CF%86%CE%B1%CF%81%CE%BC%CE%B1%CE%BA%CE%B5%CF%85/  
40\) http://www.nationsencyclopedia.com/economies/Europe/Greece.html](http://www.nationsencyclopedia.com/economies/Europe/Greece.html)



## ABSTRACT

### PHARMACIES IN GREECE

**Author:** Georgios Zacharakis

**Tutor:** RNDr. Jana Kotlářová, Ph.D.

Department of Social and Clinical Pharmacy, Faculty of Pharmacy in Hradec Kralove, Charles University in Prague, Czech Republic

**Aim of diploma thesis:** The aim is to get current facts and knowledge about the situation of pharmacies in Greece, including their basic problems, and to compare it with the Czech Republic.

**Methods:** Data collection through appreciation of information and studying of literature, esp. Greek legislation.

**Results:** It was given necessary information on the National Health System in Greece and about place and role of pharmacies in this. The main part of thesis deals with pharmacies in Greece (legislation, statistics, pharmacists, activities in pharmacy). There are many private community pharmacies and low amount of hospital pharmacies which are only for inpatients.

Both Greece and Czech Republic made considerable efforts in latest years to harmonize their legislation to the European standards. However, a significant difference between Greece and Czech Republic is profit margins of wholesalers, which are higher in the Czech Republic in comparison to Greece, while the production of drugs in Greece is significant higher than Czech Republic, which based more in its neighboring countries for the supply of drugs.

**Conclusion:** It has been described Greek pharmacies and the Greek pharmaceutical legislation for pharmacies, the duties and responsibilities of pharmacists in Greece as compared to those in the Czech Republic. It also focuses on the chambers of pharmacists and the reason they were organized. The basic EU legislation in field of pharmacy practice is the same for both countries.

# ABSTRACT

## LÉKÁRNY V ŘECKU

**Autor:** Georgios Zacharakis

**Vedoucí diplomové práce:** RNDr. Jana Kotlářová, Ph.D.

**Katedra sociální a klinické farmacie, Farmaceutická fakulta v Hradci Králové,  
Univerzita Karlova v Praze, Česká republika**

**Cíl práce:** Cílem práce je získat aktuální fakta a znalosti o řeckých lékárnách, včetně základních problémů s nimi souvisejících, a porovnat se situací v této oblasti s Českou republikou.

**Metodika práce:** Data byla získána studiem a porozuměním potřebné literatury a zvláště současné řecké legislativy.

**Výsledky:** Byly poskytnuty základní informace o zdravotním systému v Řecku a o postavení a roli lékáren v něm. Hlavní část práce se zabývá lékárnami v Řecku (legislativa, statistika, lékárníci, činnosti v lékárně). V Řecku je velké množství soukromých veřejných lékáren a menší počet vládních nemocničních lékáren, které slouží pouze hospitalizovaným pacientům.

V Řecku i v České republice je v posledních letech věnováno velké úsilí harmonizaci s legislativou Evropské unie. Rozdíl mezi Řeckem a Českou republikou je v zisku distributorů, který je v ČR vyšší.

**Závěr:** Byly popsány řecké lékárny, řecká legislativa pro lékárny, povinnosti a odpovědnost lékárníků v Řecku a porovnána celková situace lékáren s Českou republikou. Pozornost byla věnována i komoře lékárníků a důvodům její existence. Základní legislativa Evropské unie je závazná pro obě země.