

Pharmacy in Portugal (1950-2010) and the Pharmacist Profession

Farmacja w Portugalii (1950-2010) a zawód farmaceuty

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Streszczenie: Artykuł przedstawia rozwój farmacji i zawodu farmaceuty w Portugalii w latach 1950-2010, zwłaszcza po włączeniu Portugalii w Europejską Wspólnotę Gospodarczą w 1986 r. Scharakteryzowano tradycje farmacji portugalskiej oraz system opieki zdrowotnej w Portugalii. Przeanalizowano wpływ zmian prawnych i organizacyjnych dotyczących własności aptek ogólnodostępnych i zaopatrzenia hurtowego w leki na praktykę zawodową farmaceutów. Autorzy opisali rozmieszczenie aptek i dostarczyli szczegółowej wiedzy o różnych aspektach pracy farmaceutów, w tym o organizacjach zawodowych, w Portugalii. Ponadto przedstawiono, jak wprowadzona została opieka farmaceutyczna w Portugalii, a także scharakteryzowano przebieg globalizacji farmacji w tym kraju. Autorzy oparli się na czasopiśmie portugalskich jako źródłach historycznych, a ponadto korzystali z wartościowych opracowań.

Abstract: The article presents the development of pharmacy and pharmacist profession in Portugal in 1950-2010, especially after Portugal's entry into the European Economic Community in 1986. Portuguese pharmaceutical traditions and the health care system in Portugal are characterized. The authors investigated how legal regulations and organizational changes concerning pharmacy ownership and wholesale distribution of medicines and various products influenced on the development of pharmacist profession in Portugal. They described the geographical distribution of community pharmacies and provide detailed knowledge about pharmaceutical practice and pharmaceutical associations in Portugal. Moreover, the history of pharmaceutical care and the course of its implementation were presented. The authors based on the Portuguese journals as historical sources and used some valuable secondary literature.

Słowa kluczowe: historia farmacji, apteki w Portugalii, system prawny aptek w Portugalii, globalizacja farmacji, opieka farmaceutyczna

Key words: history of pharmacy, pharmacies in Portugal, legal system of pharmacy in Portugal, globalization of pharmacy, pharmaceutical care

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Pharmaceutical medicine in Portugal: legal system and regulations (1950-2010)

In 1986, Portugal's entry into the European Economic Community had a profound impact on the pharmaceutical market. Since the Sixties, the European Economic Community has promulgated several directives regarding pharmaceutical drugs.

Portuguese law first adopted a communitarian directive regarding pharmaceutical drugs in 1991. Until then some disperse legislation and "bill n°41448" from 1957 were the official diplomas, some of which were six decades old.

The bill of law from 1957, created for the first time a Technical Committee for New Drugs that worked along with the Direcção Geral de Saúde (General Health Directorate). This Committee had, among other tasks, evaluated the incoming requests for the introduction of new drugs into the Portuguese market. This institution acted under the General Health Directorate. This measure, of the greatest importance led to the reduction of a number of pharmaceutical drugs circulating in Portugal. In 1958 around 30000 "presentations of medicine" were circulating in Portugal, ten years later that number had dropped to 20000. In the 50's various Portuguese pharmaceutical industries tried to consolidate themselves in the market. However, there was strong competition with the foreign pharmaceutical industries. The lack of a strong chemical industry tradition in Portugal, as well as reduced economic resources when compared to foreign countries made the Portuguese pharmaceutical industry less competitive in comparison to other European countries. In 1927 the First National Congress of Pharmacy took place in Lisbon which was also a demonstration of the Portuguese pharmaceutical industry. In 1950 there were 51 pharmaceutical industries and 34 industrial pharmacies in Portugal, which totalled 85 production establishments. In 1966, a total of 8199 commercial brands with 16637 varieties were produced in Portugal.

In 1968 the First National Congress of the Pharmaceutical Industry took place, in Lisbon. In this same year 212 pharmaceutical industries existed in Portugal, of which 64 were drug industries and 2 specifically produced vaccines. The others were pharmacies with the category of industries or pharmacies with their own production of medicine.

Decree-Law n° 72/91, of February 8th profoundly modernised the Portuguese legislation on medicine. With this official text, named *Estatuto do Medicamento* (Status of Medicine), the previous laws, (of which the oldest was dated from 1931), on the matter were revoked and the communitarian directives were introduced into the Portuguese Law. It is a legislation resulting of Portugal's entry into the European Community. Regarding the previous legislation, this diploma introduced profound alterations on the subject related to the entire system of medicine, from their introduction into the market to their commercialisation, emphasising the supervision considered decisive for guaranteeing quality, efficiency and safety of medicine. This diploma introduced profound innovations in matters regarding the introduction of pharmaceutical drugs into the Portuguese market, increasing the technical and scientific requirements, highlighting the innovating process of introducing medi-

cine through out the multi-state process, therefore requesting the possibility of the simultaneous introduction of prescription drugs in the respective markets of various countries of the EEC. The Status of Medicine introduced profound new rules regarding prescription drugs derived from blood and plasma, immunological and radiopharmaceutical drugs. Other innovative aspects of this diploma were subjects related to labelling, patient information leaflet and marketing. This diploma had a profound impact on the measures existing in Portugal regarding marketing. A clear line was drawn between publicity aimed at health professionals and publicity for the public, as well as marketing for medicine not subject to medical prescription and medicine subject to mandatory medical prescription. The Status of Medicine in 1991 was maintained until 2006. During those 15 years the Decree n° 72/91 was subject to various alterations. In Portugal, in 1996 there were 306 authorizations for the introduction of medicine in the Portuguese market and in 2002, 416 authorizations. In 1985 there were 3597 brands of medicine and in 2002, 6424 brands in Portugal, in this case with 28430 presentations.

The adoption of Communitarian Directives in Portugal had a profound impact, in both these practical aspects as well as in institutional aspects. Currently, the pharmaceutical industries established in Portugal are mostly owned by foreign capital, the national capital being extremely reduced. In general they are dedicated to the production and entry of pharmaceutical medicine into the market and are less focused on the investment in research. After Portugal's entry into the European Economic Community, questions related to Good Manufacturing Practices, quality, safety, efficiency, information and publicity of medicine, became questions of the utmost importance, with appropriate legislation and regulations.

The Decree-Law n° 176/2006 of August 30th, gathered various legislations in a single document, which were dispersed and promulgated after 1991, adjusting communitarian directives to Portuguese Law. That document established the legal system of market authorization, manufacturing, import, export, commercialisation, labelling, information, publicity, pharmacovigilance and use of prescription drugs for human use, including homeopathic medication, radiopharmaceutical medications and traditional medications based on plants. With this document, the sector of pharmaceutical drugs was modernised with the introduction of some aspects which were an innovation regarding the former provisions. Market authorization for new medicine, and new measures were introduced, allowing companies, for example, to conduct a market authorization request of a given medicine in various Member States at the same time. The conditions of market re-authorization of medicine were also modified, with the general rule of a single renewal. Special attention was given, for the first time, to parallel import of pharmaceutical drugs, also making special use and direct acquisition of prescription drugs easier. This diploma allowed the introduction of a special authorization for the entry of medicine not commercialised in the Portuguese market. Besides some updates regarding labelling and the package leaflet of medicines, it also became important to highlight some alterations in the marketing system for medicines.

Community pharmacies: legal system, characterization and professional practice (1950-2010)

The legal system regarding ownership of pharmacies in the 20th century in Portugal has five distinct periods: before 1924; from 1924 to 1933; from 1933 to 1965; from 1965 to 2007; after 2007.

Between 1924 and 1933, Portuguese legislation determined that pharmacists and non pharmacists could own community pharmacies. This legislation came to contradict the Portuguese tradition where, until then, the ownership of a pharmacy was reserved for pharmacists or a partnership of pharmacists. The legislation which regulated the ownership of a pharmacy was the following: Decree n° 9431, of 1924, Decree n° 13470, of 1927 and Decree n° 17.636 of 1929.

The Decree of 1924 was somehow equivocal regarding the ownership of the pharmacy, although the technical supervisor had to be a pharmacist. It valued the role of the pharmacist in the technical supervision of a pharmacy, which should be performed in exclusivity.

The Decree of 1927 established that the owner of a pharmacy had to be a pharmacist or a partner in the partnership which explored the pharmacy. In that case, it indicated that the pharmacist was the owner of the pharmacy or the co-owner even if the other partner was not a pharmacist. However, as in the previous case, there were exceptions, being one of them, for example, institutions of assistance or mutuality which could only sell medicines or supply them to their associates.

In many newspapers and pharmaceutical journals of that period, the ambiguity of the diplomas of 1924 and 1927 is clear, allowing for a less reliable practice regarding the ownership and the activity of the pharmacies and questioning the prestige of the pharmaceutical profession and public health.

In 1929, although the practice of the pharmaceutical profession was regulated more solidly, the Decree does in no way refer to the ownership of pharmacies, leaving it clear that anyone could be the owner. The Decree of 1929 only refers that the preparation of medicines was one of the competencies exclusively performed by pharmacists, as well as the dispatching of medical prescriptions and their supply to the public. The technical supervision of the pharmacy was a task that had to be carried out by a pharmacist.

Decree n° 23422, of December 29th 1933 established again that the ownership of a pharmacy was mandatorily of a pharmacist or a partnership of pharmacists. The attendance record of the technical supervisor was not being complied with and the only way to overcome this situation was to establish a direct interest of the technical supervisor in the ownership of the pharmacy, similar to what was happening in various foreign countries. The Decree n° 23422, of December 29th 1933 finally resolved all doubts regarding the ownership of pharmacies. This Decree established some exceptions, such as the pharmacies of Misericórdias, of Associações de Socorros Mútuos, pharmacies attached to thermal spas, and pharmacies belonging to widows or sons of deceased pharmacists (both for a period of a certain term).

The legislation of 1933, yet not ideal was the best possible legislation. Many problems which affected the Portuguese pharmacy for many years were not immediately resolved. It suffices to read through Portuguese pharmaceutical newspapers and journals of the 30's and 40's to understand that the functioning of the Portuguese pharmacies was not the best and that certain concerns continued to prevail as, for example, the illegal practice of the profession, the absence of a pharmacist in the pharmacy, the excessive number of pharmacists, etc. The crisis existing in community pharmacies in Portugal was one of the most relevant causes related to the industrialisation of medicine.

Law n° 2125, of March 20th of 1965 along with the Decree-Law n° 48547, of August 27th 1968 consolidated the principle of indivisibility of the ownership of a pharmacy and the technical supervisor. Law n° 2125 refers that a business license for the function of a pharmacy can only be "attributed to pharmacists or partnerships in collective name or by quotations, if all the partners are pharmacists and while they are". The technical supervision of a pharmacy had to be performed by a pharmacist which should also be the owner or one of the pharmacists' in the partnership which owned the pharmacy. The Law of 1965 further established, similar to previous diplomas, some exceptions, namely those occurring from the death of the owner where in a transitory system the property could belong to anyone. The Law of 1965 established that Misericórdias and other institutions of social assistance and welfare could own pharmacies as long as these and the medicines they dispatched were destined for their services. Law n° 2125, indicated that to guarantee the functioning of a pharmacy at risk of closing or to guarantee the sanitary coverage of regions less attractive from a professional perspective authorization could be given to the institutions of social assistance and welfare or institutions related to the pharmaceutical activities to open a pharmacy in these places. This, as an exception and as long as no pharmacists interested in the installation of a new pharmacy or the acquisition of an already functioning pharmacy appeared.

The opening of new pharmacies and their installation suffered a profound alteration in 1987 through the Order n° 806/87, of September 22nd. Through this document the opening of new pharmacies was no longer an individual initiative of each pharmacist. For the opening of new pharmacies the Ministry of Health opened a governmental bid, enabling any pharmacist or partnership of pharmacists to apply. The same Order further established criteria for the classification of the candidates. From 1987 until 2007 this criteria suffered some modifications through the Orders n° 513/92, of June 22nd; 325/97, of May 13th; 936-A/99, of October 22nd; 1379/2002, of October 22nd; 168-B/2004, of February 18th; 865/2004, July 19th. However, in general aspects, from 1987 to 2007 the government system to open new pharmacies was thus done by governmental bid. It should also be mentioned that since the 60's there was a demographic and geographic conditioning for the opening of a new pharmacy, i.e., requiring a minimum number of inhabitants per pharmacy a minimum mandatory distance between pharmacies and a minimum distance from health establishments as, for example, hospitals. These parameters changed over the years.

Due to the legal system of 1965 and 1968 pharmacies were authorised to commercialise other products, besides medicine: pharmacy accessories, hygiene products, mineromedicinal waters, diet products, cosmetic articles, optic, acoustic and prosthetic articles in general. The pharmacies were also authorised to commercialise phytopharmaceutical products and pesticides. The prescription of medicines, information and counselling on medicine were the most relevant tasks of the pharmaceutical professional in community pharmacies. It should be highlighted that the industrialisation of medication, as in other countries of Europe, had consequences in the professional practice of community pharmacies. Pharmacies which were places of production and supply of medicines, gradually transformed mainly into selling points, the intention of the pharmacy being questioned frequently. In Portuguese pharmaceutical journals, between the 30's and 60's we find many articles referring to this subject. Student numbers in the Portuguese Pharmacy Faculties were significantly reduced; there was a significant decrease in the number of pharmacists in community pharmacies or practicing it in a convict manner and exclusively; there were pharmacies going through an economic crisis; etc. In the 70's we gradually see a revaluation of the role of community pharmacies and the pharmacist. External factors of a scientific, technical, professional and economic nature played a role in this revaluation. The concepts related to clinical pharmacy, pharmacovigilance, the development of studies and the emergence of areas as biopharmacy and pharmacokinetics, alter the final purpose of the practice of the pharmaceutical profession. The pharmacist and the pharmacy's medicines were considered the ultimate purpose, focusing on high-quality production and sales. However, gradually, the ultimate focus of pharmacy and medicine became the patient. The last deontological code of Portuguese pharmacists clearly reflects this situation. Thus, pharmacies started to possess services and means which allowed the pharmacist to focus on the patient, adequate advice and information on medicine.

The Decree-Law n° 307/2007, of August 31st established a new legal system for pharmacy ownership in Portugal. Through this system the ownership of a pharmacy was liberalised, enabling both pharmacists and non pharmacists to own a pharmacy, individually as in commercial partnerships. The same legislation further determined that no health professionals (who prescribed medicines), associations which represented pharmacies, companies of retail distribution of medicine or pharmaceutical industries; private companies of health care services; subsystems of health which were involved in the price of medicines could be owners or co-owners of pharmacies. The same Decree further established that no single person or commercial society could own more than four pharmacies. The technical supervision will always have to be performed by a pharmacist which can never be the technical supervisor of more than a single pharmacy. However, although there was the liberalisation of the ownership of the pharmacy, the conditioning for the installation based on geographical and demographical criteria continued to be in place. A new criteria was stipulated that facilitated the transfer of pharmacies, and which have allowed the relocation of pharmacies from places with fewer inhabitants to areas with more population. The attribution of new pharmacies continues to be done through an organism of the Min-

istry of Health called INFARMED, any person or partnership interested are enabled to apply for the attribution of a new business license, the licence is allotted between the applicants ranked in first place, those who already own a pharmacy cannot be awarded first place. The liberalisation of the ownership of a pharmacy was not peaceful. The measure of a socialist Government programme which took place in 2005 was polemic and the focus of discussion, within and without the pharmaceutical community.

With this legislation another legislation and regulation on the practice of the pharmaceutical activity was announced. The Order n° 1429/2007, of November 2nd established which pharmaceutical services were to be offered by community pharmacies. The pharmaceutical services are: "domicile support; first aid; administration of medicine; use of auxiliary means of diagnosis and therapy; administration of vaccines are not included in the National Plan of Vaccination; programmes of pharmaceutical care; information campaigns; collaboration in programmes of education for health".

The Good Practices of Pharmacy constituted the ideal professional basis for community pharmacists. In 1995, the approved version by the Pharmaceutical Group of the European Union started to be divulged in Portugal. This was done by the Order of Pharmacists and the National Association of Pharmacists. The Good Practices of Pharmacy, are a set of recommendations and measures to be implemented over time, aimed at assuring a better quality of services offered by pharmacists, both at the level of medicine supply and in the involvement in activities promoting health and prevention of disease in the population.

In Portugal, pharmacies have a relevant role in the health system, being well known establishments by the population due to the quality of services rendered. The official inquiries that have been done to evaluate the quality of services and the satisfaction of costumers are very positive for Portuguese pharmacies. The same surveys tell us that safety and quality, inseparable factors when talking about medicines, can be guaranteed by pharmacies.

One of the characteristics of community pharmacies in Portugal is their geographical distribution throughout the territory which results in the current legislation. According to the legislation, the geographical distribution of pharmacies (sustained in geographical and demographical criteria) aims to give the population better access to medicines, in a secure manner, with quality and all the adequate pharmaceutical services.

However, the legislation of 2007 facilitated the transfer of community pharmacies within the same district. For this reason there are currently many pharmacies in Portugal asking to be transferred from locations with low population density to locations with more population.

Portugal (Continental Portugal and the Autonomous Regions). Continental Portugal is divided into 18 districts and the Autonomous Regions are composed of the archipelagos of the Azores and Madeira. In 2009 there were 2853 pharmacies in Portugal of which 2733 were located in Continental Portugal, 57 in the Azores and 63 in Madeira. The geographical distribution of pharmacies in Portugal is as follows:

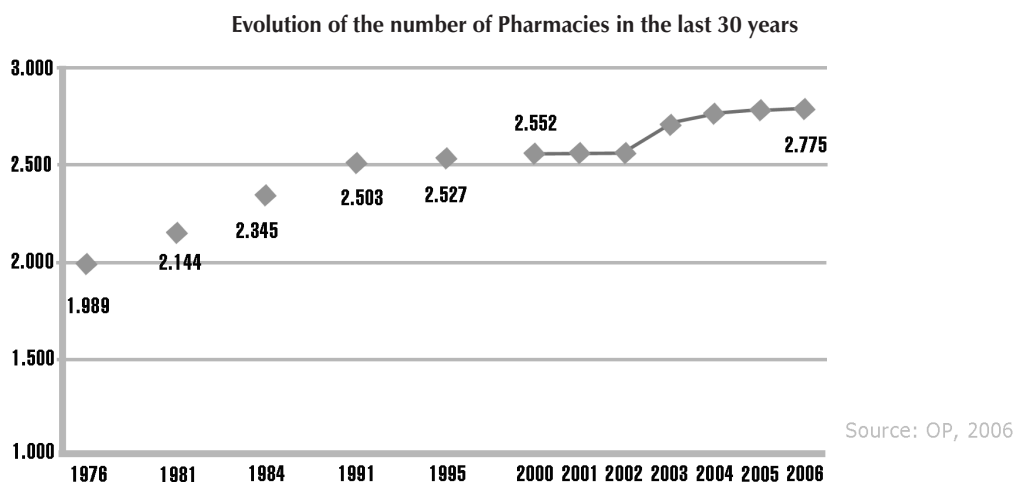
CONTINENTAL PORTUGAL	
DISTRICT	Nº OF PHARMACIES PER DISTRICT
AVEIRO	186
BEJA	53
BRAGA	180
BRAGANÇA	39
CASTELO BRANCO	59
COIMBRA	142
ÉVORA	53
FARO	110
GUARDA	56
LEIRIA	122
LISBON	673
PORTALEGRE	45
PORTO	434
SANTARÉM	144
SETÚBAL	198
VIANA DO CASTELO	64
VILA REAL	70
VISEU	105
TOTAL	2733

Comparing the numbers between 1954 and 2008, we have the following:

COMPARASION OF THE NUMBER OF PHARMACIES PER DISTRICT 1954 - 2008		
DISTRICT	YEAR 1954	YEAR 2008
AVEIRO	111	186
BEJA	60	53
BRAGA	92	180
BRAGANÇA	31	39
CASTELO BRANCO	45	59
COIMBRA	118	142
ÉVORA	50	53
FARO	75	110
GUARDA	52	56
LEIRIA	66	122
LISBON	364	673
PORTALEGRE	42	45
PORTO	242	434
SANTARÉM	112	144
SETÚBAL	69	198
VIANA DO CASTELO	40	64
VILA REAL	49	70
VISEU	88	105
TOTAL	1706	2733

In the Autonomous Regions of the Azores and Madeira the geographical distribution is the following: 57 pharmacies for the archipelago of the Azores and 63 pharmacies for the Archipelago of Madeira.

Comparing the last 30 years, we can deduct from the graphic below that in 1976 Portugal had about 2000 pharmacies. The number of pharmacists per pharmacy, as we will see further, increased significantly.



The Decree-Law n° 307/2007 and Order n° 1427/2007 allowed for pharmacies and selling points of medicines not subject to medical prescription to supply medication to the home, accept orders at a distance as well as through the Internet. Any medication can be commercialized in this manner. The Portuguese law has not established any criteria for the commercialisation of medicine through the Internet or any other method at a distance: telephone, fax and e-mail.

Pharmacies and selling points of medicines not subject to medical prescription which adhered to selling on the Internet have to have an electronic site, individualised, property of the pharmacy or selling point of medicines not subject to medical prescription, with the following information:

- Price of the services rendered regarding the supply of medication and respective home delivery;
- Accepted methods of payment;
- Geographical area in which the pharmacy secures home deliveries;
- Estimated time for the delivery of the solicited medication
- Name of the pharmacy's technical supervisor or the supervisor responsible for the selling point of medicines not subject to medical prescription.

The pharmacies which aim to supply medication through the Internet have to register in INFARMED, this is, the Ministry of Health. At the end of 2009, 5 pharmacies were registered at INFARMED, 1 in the District of Faro (South Portugal), 2 in the District of Lisbon, 1 in the District of Santarém (central south of the country) and 1 in the District of Setúbal (South Portugal).

The hospital pharmacy: legal system, characterization and professional practice (1950-2010)

The legal system of hospital pharmacies in Portugal was instituted by the Decree 44.204 of February 22nd, of 1962. That official text defines a hospital pharmacy as: “the set of pharmaceutical activities that take place in hospital organisms or services connected to them to collaborate in functions of assistance which belong to these organisms and services to promote scientific investigation and teaching which are their responsibility”. The pharmaceutical hospital service is where these functions are executed.

In the Decree of 1962 the technical autonomy of pharmaceutical services was established. This same diploma created a hospital career for pharmacists, as well as a pharmacist internship. In the Decree-Law n° 48.357 of 1968 pharmacist careers were created and the Decree-Law n°275/71 compares the pharmacist career to the medical career reinforcing the importance of hospital pharmacists in the health area. The Decree-Law n°414/91 started to include the hospital pharmacists in the career of superior health technicians. In 1999 (Decree-Law n° 501/99) the area of activity of the hospital pharmacist was extended to the domain of radiopharmacy.

The main functions of the hospital pharmacist in Portugal are: organization and management; distribution and information; pharmotechnics; quality control; pharmacovigilance; clinical testing in an hospital environment; pharmacokinetics; radiopharmacy; pharmaceutical follow-up. These functions were in no way indicated Decree of 1962. Over the years, pharmaceutical services adapted to new social, economic, technical, scientific realities and currently the existent activities are related to current needs.

The dimension of pharmaceutical services corresponds to the dimension of the hospitals where they are installed and the nature of the hospitals. For example, paediatric hospitals present their specificities, as well as hospitals for the treatment of cancer.

In Portugal the main network of hospitals distributed throughout the country belongs to the State. Others, also of large dimension, belong to Santa Casa da Misericórdia. In the last few years there have appeared various private hospitals belonging to private investor groups. Portuguese legislation refers to the existence of pharmacies in private health units, where the technical responsibility is of the pharmacist.

The sale of medicine outside of pharmacies: a novelty in 2005

In Portugal, until 2005, pharmacies were the only places where medication could be commercialised. In 2005, medicines not subject to medical prescription and not subsidised started to be commercialised outside community pharmacies in locations duly authorised. It was the first measure included in the same set of decisions which led to the liberalisation of the property of pharmacies in 2007. These locations have to be authorised by the Ministry of Health through INFARMED and their ownership is free, not existing any installation restrictions regarding geographical and demographic criteria as is the case of community pharmacies.

The technical supervision can be of a pharmacist or pharmacy technician (who can accumulate up to five establishments), not requiring any qualification for the employees. It was the Decree-Law n.º 134/2005, of August 16th that established the system of selling «over the counter» medicines outside of pharmacies and the Ordinance n.º 827/2005, of September 14th established the conditions for selling them. In 2007, «over the counter» medicines not subject to subsidised medical prescription by the State were commercialised in these establishments, losing in this case subsidisation (Decree-Law n.º 238/2007, June 19th).

These establishments can be integrated in shopping centres or in spaces created specifically for this effect, in any location. There is no criteria in geographical or demographical requirements for their installation as there is for pharmacies. These establishments, besides medicines, can sell other products as some medical equipment, cosmetic products, body hygiene, childcare, etc.

In 2007, the Decree-Law n.º 238/2007, of June 19th established that «over the counter» medicines subsidised by the State can be sold in these places, in the same conditions as other medicines but without subsidisation from the State.

According to INFARMED, the sales in these establishments, during the period from January until February of 2009 represented 11% of the total volume of «over the counter» medicine market.

In 2009, there were 569 selling points of OTC medicines which are distributed throughout the districts as the following:

POINTS OF SALE OF OTC MEDICINES	
DISTRICT	Nº OF LOCATIONS
AVEIRO	40
BEJA	6
BRAGA	44
BRAGANÇA	2
CASTELO BRANCO	11
COIMBRA	29
ÉVORA	7
FARO	46
GUARDA	6
LEIRIA	26
LISBON	137
PORTALEGRE	7
PORTO	87
SANTARÉM	26
SETÚBAL	49
VIANA DO CASTELO	19
VILAREAL	9
VISEU	18
TOTAL	569

The pain killer and antipyretics medicine group was the one that registered a higher number of sales with 27.7% of the total of sales. Paracetamol was the drug most sold in terms of quantities and ibuprofen was the most sold in value.

Warehouses of medicines

In Portugal the wholesale distribution of medicines and various products is carried out by wholesale warehouses of pharmaceutical products also designated warehouses for the distribution of medicines.

In Portugal, these establishments are of three kinds: multinationals of distribution; cooperatives of community pharmacies; warehouses of smaller dimensions owned by an individual or a society.

These warehouses are not allowed, by law, to sell directly to the public. They can just sell medicines among themselves and to pharmacies and other healthcare establishments. The law further establishes that these locations should have their own installations for distribution, specific equipment and a technical pharmacist supervisor.

The opening of these establishments, as well as their functioning is governed by a set of specific norms, ruled by the Ministry of Health through INFARMED.

In Portugal there is a strong tradition of cooperative systems of distribution. The first cooperative of distribution of medicines, the "Union of Pharmacists of Portugal", based in Lisbon appeared in 1935. It is interesting to point out that in 1927, on the occasion of the First National Congress of Pharmacy, in Lisbon, the distribution by wholesale of medicines was a versed subject in some communications. In some it was defended that it was important to fund a cooperative of wholesale distribution of medicines in Portugal which would be the only viable way out for Portuguese pharmacies regarding the industrialisation of medicines. After founding the Union of Pharmacists in Portugal, other cooperatives appeared reaching a total of 7. It is interesting to highlight that over a period of eighteen years, between 1967 and 1985, the remaining six cooperatives were founded. In our view the modifications which operated in the pharmaceutical industrial environment, as well as the economic sector of pharmacy, were reasons for the foundation of these establishments.

DATES OF THE FOUNDATION OF PORTUGUESE COOPERATIVES		
COOPERATIVE	LOCATION	YEAR
UNION OF PHARMACISTS OF PORTUGAL	LISBON	1935
COFANOR - COOPERATIVA FARMACÊUTICOS DO NORTE	PORTO	1967
CODIFAR - COOPERATIVA DE DISTRIBUIÇÃO FARMACÊUTICA	LISBON	1973
FARBEIRA - COOPERATIVA DE FARMACÊUTICOS DO CENTRO	COIMBRA	1973
COPROFAR - COOPERATIVA DOS PROPRIETÁRIOS DE FARMÁCIA	PORTO	1975
FARCENTRO - COOPERATIVA FARMACÊUTICA DO CENTRO DE PORTUGAL	COVILHÃ	1977
COFARBEL - COOPERATIVA DE COMERCIALIZAÇÃO DA BEIRA LITORAL	COIMBRA	1985

In 2006, three cooperatives located in central Portugal merged and Farbeira, Co-farbel and Farcentro gave origin to Plural – Cooperativa Farmacêutica, CRL based in Coimbra.

This tendency to merge also occurred in small warehouses which either closed their doors or were integrated in warehouses of bigger dimensions.

The frequency of delivery of medicines to the pharmacies is, in most locations, three times a day, which allows pharmacies to minimise their stock and at the same time satisfy their customers in the same day. In general, pharmacies place the orders through the computer to the warehouses where these are processed and distributed in vehicles duly equipped for the purpose.

Besides the distribution of medicines there are many other services offered by warehouses to the pharmacies. Among these services are: diverse information on medicine and products; collection and treatment of expired medication and medication waste for incineration (Valormed); organisation of post graduate continuing education and professional valorisation for the teams of the pharmacies; etc.

The following table shows the main warehouses and cooperatives of pharmaceutical distribution in Portugal. Some warehouses are national and others foreign but with participation of Portuguese companies, as is the case of Alliance Healthcare which was in part acquired by ANF (National Association of Pharmacies).

DISTRIBUTION WAREHOUSE	LOCALISATION	AREA
Alliance Healthcare	Lisbon	Centre
OCP Portugal	Lisbon	Centre
Udifar	Coimbra	Centre
Cooprofar	Guarda	Centre
Plural	Coimbra	Centre
Botelho & Rodrigues	Lisbon Linda-a-Velha	Centre
Disfaport	Lisbon- Rio de Mouro	Centre
Alliance Healthcare	Aveiro	North
OCP Portugal	Porto	North
Cooprofar	Porto - Gondomar	North
Cofanor	Porto	North
Plural	Feira	North
Botelho & Rodrigues	Braga	North
Medicanorte	Barcelos-Braga	North
Alliance Healthcare	Almancil - Faro	South
OCP Portugal	Setubal	South
Udifar (Codifar)	Lisbon	South
Udifar (União)	Lisbon	South
Cooprofar	Alcochete	South
Cofanor	Coimbra	South
Plural	Faro	South
Neodifar	Lisbon- Benfica	South

As can be observed, the warehouses are distributed uniformly throughout different regions of the country.

The market is divided in the following manner: Cooperatives – 40%; International Companies – 29%; National Companies (more significant) – 9.5%; Others – 21.5%

Global characterisation of the pharmaceutical profession in Portugal

In the last thirty years the pharmaceutical profession has undergone profound changes. These alterations were observed in the scientific, technical, professional and economic field. In 2009 there were no unemployed pharmacists in Portugal. All newly graduates are absorbed by the work market in different areas. It is the profession that, according to current data, gives the best salaries to newly graduates.

The situation was not always this way. The industrialisation of medicines in the first half of the 20th century led to a strong crisis in Portuguese pharmacies and the practise of the pharmaceutical profession, mainly between the 30's and 60's of the 20th Century. The Schools of Pharmacy had very few students, there were few pharmacists in Portugal, and economically the profession became less attractive. In various pharmaceutical periodicals there was talk of a crisis, the illegal practice of the profession, and the lack of economic and social prestige of the profession. All we have to do is look at pharmaceutical periodicals as *Notícias Farmacêuticas*, *Acção Farmacêutica*, *Eco Farmacêutico*, among others, to understand the state of things.

In the 70's we started to witness profound alterations in the practice of the profession. The foundation of the National Health Service, the system of subsidisation of medicines, the valuing of the profession incentivised by institutions as the National Association of Pharmacies, and later, the entrance of Portugal into the European Economic Community and all the alterations occurring from that in the midst of the 80's are some of the most important marks for revaluing the role and prestige of the pharmacist and pharmacies. We should further mention the alterations done in the pharmaceutical industry where foreign influence is determinant.

In Portugal, access to the pharmaceutical profession is done by the Order of Pharmacists. This is: after concluding their studies in Pharmaceutical Sciences existent in the various Portuguese Universities, the young pharmacists have to be admitted by the Order of Pharmacists. In Portugal it is this institution which regulates, the access to the profession. No pharmacist can practice the profession without being enrolled in the Order of Pharmacists.

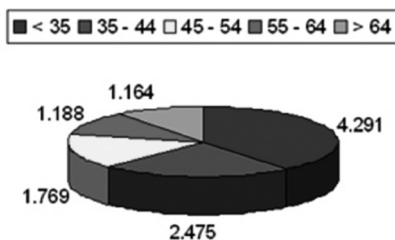
In Portugal, the pharmacists can practice their activity in various professional areas: Retail Pharmacy (commonly designated as a community pharmacy); Hospital Pharmacy; Biological Testing; Pharmacy Industry; Pharmaceutical Distribution; Teaching; Research; various other areas.

The Order of Pharmacists also attributes the title of specialist in some professional areas. The Schools of Speciality of the Order of Pharmacists are organisms of this institution which regulate the attribution of specialist titles. All those interested, after appropriate evaluation, can receive the specialist title which is presented by the Order

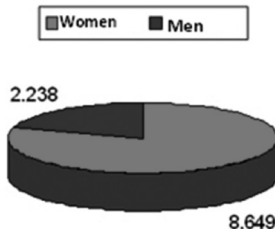
of Pharmacists. Currently, there are 5 Schools of Speciality: Clinical Analysis (founded in 1981); Pharmaceutical Industry (founded in 1981); Hospital Pharmacy (founded in 1995); Regulatory Issues of Medication (founded in 1999); Community Pharmacy (founded in 2009).

There are 11624 pharmacists enrolled in the Order of Pharmacists (data referring to 2008). From this number, 812 do not practice the profession. The pharmacists are divided into various age groups, gender, professional areas and regional sections according to the following graphics:

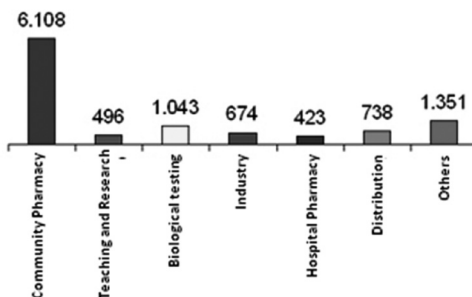
Distribution according to age group



Distribution according to gender

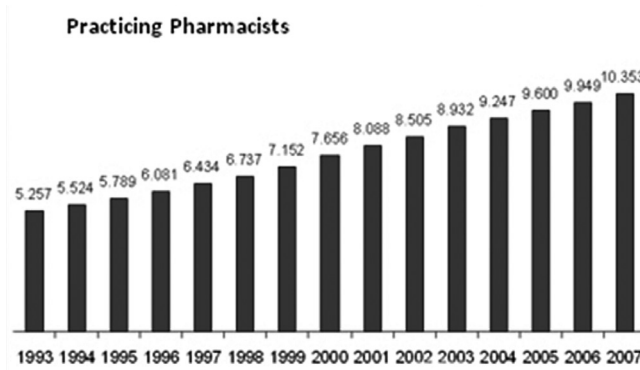


Distribution according to professional area



Data from the Order of Pharmacists referring to 2008.

The number of pharmacists doubled since 1993 according to what can be observed.



Data of the Order of Pharmacists referring to 2008.

The number of pharmacists has increased significantly since the 60's until today. However, their distribution in professional groups has been more or less similar over the last three decades.

Most pharmacists practice their activity in community pharmacies.

EVOLUTION OF THE N° OF PHARMACISTS IN EACH PROFESSIONAL AREA					
	1970	1980	1990	2000	2004
BIOLOGICAL TESTING	170	533	952	1162	1157
PHARMACEUTICAL DISTRIBUTION	8	31	146	318	434
TEACHING	51	164	346	450	412
HOSPITAL PHARMACY	53	107	294	640	777
COMMUNITY PHARMACY	1178	1905	2898	4816	6089
PHARMACEUTICAL INDUSTRY	137	217	399	630	717
RESEARCH	13	41	95	149	157
DOES NOT PRACTISE	58	69	95	117	130
NOT INDICATED	95	241	246	635	860
OTHERS	34	70	146	264	301
TOTAL	1797	3378	5617	9181	11034

In the distribution of genders the pharmaceutical profession is still in its majority a female profession.

EVOLUTION OF THE N° OF MALE AND FEMALE PHARMACISTS					
	1970	1980	1990	2000	2004
MEN	497	780	1281	1829	2284
WOMEN	1300	2598	4336	7352	8750
TOTAL	1797	3378	5617	9181	11034

Source: Order of Pharmacists

This significant increase of the number of pharmacists contributed to an increase in the number of pharmacists per pharmacy. This increase of the number of pharmacists per pharmacy, on the other hand, allowed for greater diversification of their functions.

A more detailed follow-up of patients through pharmaceutical care, the implementation of quality certification and specialisation of pharmacists in certain areas (child-care, orthopaedics, and dermocosmetics, among others) were only made possible with the existence of more than one pharmacist per pharmacy.

It should be mentioned that the legislation of the pharmacy ownership and the pharmacist professional practice promulgated in 2007 determined that each pharmacy in Portugal has to have at least two pharmacists and that the team of each pharmacy half of its members should be pharmacists.

It can be said that today the pharmaceutical profession in Portugal is mainly carried out by women and that it is a young profession.

History of the implementation of pharmaceutical care in Portugal

Pharmaceutical care constitutes a recent pharmaceutical professional practice which is done with the purpose of improving the use of medicines and reducing the negative results which are associated to these medicines. In this manner it is relevant to supply medicines in a personalised manner, as well as a follow-up of the medication supplied to the patient. This set of activities is usually designated as follow-up or pharmacotherapeutic monitoring.

This practice is associated, as well, to some other services, as pharmaceutical indication, pharmacovigilance, and education for health, etc. Thus, all the activities can give a significant contribution to the rational use of medication and are also articulated, necessarily, with this type of practice as they benefit from a better use of medicines.

Pharmaceutical care was established around 2000 in Portugal, through a group of pharmacists which had a strong scientific connection to the Group of Research in Pharmaceutical Care of the University of Granada, in Spain. The Spanish influence was felt more intensely in Portugal than the influence of the United States of America, pioneer country of the genesis of Pharmaceutical Care. Portugal has certainly been influenced by some measures applied in Spain. Remember that in 1998, a group of pharmacists reunited in the city of Granada to establish a uniform set of criteria and concepts. From that meeting the so called Consensus of Granada on Problems Related to Medication (PRM) was founded, which resulted in a publication in 1999. Three years later, in 2002, the Second Consensus of Granada on Problems Related with Medication was established; this process determined some criteria which helped clarify some existent doubts. The Third Consensus of Granada appeared in 2007, having resulted in a new concept, RNM: Negative Results associated to Medication. PRMs started, in this manner, to be considered elements of the process while RNMs started to be considered as their causes.

Pioneer Portuguese pharmacists in Pharmaceutical Care, seeing the advantage that pharmaceutical care could bring to their customers through the work done by

pharmacists, made an effort to offer various training workshops in Portugal. The goal was to try to introduce this new area in Portugal.

They started their work with a reduced number of pharmacists interested in the area. Then they affiliated with the Universidade Lusófona, in Lisbon, a private University, creating the first *Curso de Especialização Pós-Graduada em Cuidados farmacêuticos-seguimento fármaco terapêutico* (Post-Graduate Specialisation Course on Follow-up pharmaceutical care of therapeutic medicines). This course allowed the access of a wider number of pharmacists and had a significant adherence.

This group from the Universidade Lusófona has organised activities in divulging Pharmaceutical Care. The organization of *Encontros de Casos Práticos de Seguimento Farmacoterapêutico* should be highlighted, the support of projects along with the pharmaceutical industry and, more recently, the role performed by the Portuguese Society of Pharmaceutical Care.

The National Association of Pharmacies, realising the importance of pharmaceutical care, also created, various qualification trainings in this area, although in this case the programmes of Pharmaceutical Care were focused on certain specific pathologies as diabetes, hypertension and asthma.

Currently there are various institutions dedicated to the teaching of pharmaceutical care in Portugal, namely through Post-Graduations and Masters. However, the Universidade Lusófona, the National Association of Pharmacies and more recently, the Portuguese Society of Pharmaceutical Care are some of the most directly interacting with pharmacies. More recently the Order of Pharmacists has been advising Portuguese pharmacists on training courses in Pharmaceutical Care for Portuguese pharmacists. At the level of pre-graduate university training, the Faculties of Pharmacy in Portugal started to invest in this area, meeting the needs of the professional community.

In Portugal, various pharmaceutical journals frequently publish articles on the subject. Pharmaceutical care has widely been the focus in professional journals as *Mundo Farmacêutico*, *Boletim Informativo da Associação Portuguesa de Farmácia Hospitalar* and *Farmácia Observatório*. Also in periodicals of a more scientific nature as *Revista Lusófona de Ciências e Tecnologias* we find some studies related to pharmaceutical care.

Associations of the pharmaceutical class in Portugal

In Portugal there are various associations which develop their activity in the pharmaceutical sector. There are institutions some which have been in place for many decades and others whose history is more recent. Their creation and organisation articulates with various political and social moments of the country.

There is an institution which confers the labour evidence booklet and regulates the practice of the profession – the Order of Pharmacists.

There is an institution of the State dependent on the Ministry of Health, IN-FARMED, which administers in Portugal all that regards pharmacy and medicines.

There are other sectorial institutions of pharmacy constituted by pharmacists or employers which are aimed at defending the interests of those pharmaceutical sectors.

The origin of INFARMED remounts to 1940 with the creation for the first time in Portugal of an institution aimed to regulate a large sector of pharmacy and medicine – the Regulatory Committee of Chemical Products and Pharmaceuticals – CRPQF, this institution appears in full force during the Estado Novo, and in the sequence of a set of normalising measures established by the State. Its competences were administrating different areas related to medical products, chemicals and fertilisers. Among the various competences the orientation and discipline of import and commerce of these products in the country and, the guarantee of the supply of these products in the country should be mentioned. Tutelage institution of prices, guaranteeing the quality of products and inspecting the sector were the functions of this institution. The creation of CRPQF was based on the awareness of a certain disorganisation in the industrial and commercial activities, mainly in medicines and medical products.

Many of these normalising measures were related to the institutions and commerce of products, of the medicines rather than the quality. It should be highlighted that the implementation of the Decree n° 41448, of December 18th of 1957 was relevant in accentuating the tutelage measures on medicines. In effect, this Decree created the Technical Commission of New Medicines and functioned along with the General-Directorate of Health, with the purpose of studying and giving an opinion on the authorizations of launching medicines on the market. This way, the role of the State in supervising the control of new medicines became clear. When this Committee came into force, the number of medicines in Portugal was drastically reduced within the space of about a decade. Through the Decree n.° 35/72, of January 31st, the Regulation of the National Institute of Health Dr. Ricardo Jorge was approved, affiliating the mentioned Committee to that Institute. It was dependent on the Department of Approval of Medicines, Vaccines, Serums and Other Biological Products.

In 1984, the General Direction of Pharmaceutical Issues – DGAF was created. This institutions purpose was the supervision of all aspects regarding pharmacy and medicines in Portugal. The referred committee for evaluating new medicines continued its work now dependent on DGAF, as a specialised technical commission of consulting nature, in articulation with the Direction of Services of Pharmacy and Medicines, its competence was to conduct activities leading to the market authorization of new medicines.

With the adherence of Portugal to the European Community it became necessary to adapt the internal laws to communitarian directives. The modernisation of the institutions of tutelage related to medicine and the promulgation of laws according to communitarian directives was not observed. In 1993 was a new Organic Law of the Ministry of Health was promulgated, creating the National Institute of Pharmacy and Medicine – INFARMED in 1993. This institution was aimed at supervising all aspects regarding pharmacy and medicine, from research to its commercialisation.

Recently, in 2006, INFARMED became the National Authority of Medicine and Health Products, IP. It maintained the initials INFARMED. It is a public institute under the tutelage of the Ministry of Health and follows the policy of health established by this Ministry. INFARMED's purpose is regulating and administrating all the sectors regarding medicine, medical equipment, cosmetics and body hygiene

products. INFARMED contributes to the existence of an adequate policy for medicines in Portugal, authorising the entrance of new medicines in Portugal, suspending medication, opening a competition for the attribution of new pharmacies, closing pharmacies and pharmaceutical industries, regulating, evaluating, authorising, supervising, controlling distribution, commercialisation, use of medicines and medical and cosmetic equipment, etc.

The Order of Pharmacists was founded in 1972, by the Decree-Law n.º 334/72, of August 23rd. It is a public association which defends the interests of all Portuguese pharmacists who practice their activity in Portugal. The genesis of the Order of Pharmacists goes back to 1835, year in which the Sociedade Farmacêutica Lusitana was founded, forerunner institution of the Order of Pharmacists. In 1935 the *Sindicato Nacional dos Farmacêuticos* (National Union of Pharmacists) was founded, it was the institution which succeeded the Sociedade Farmacêutica Lusitana. Its foundation was due to a decision made by the Government which profoundly altered the creation of associations in Portugal and led to the merge of various associations by governmental imposition. This associative policy articulates with the established policy of Estado Novo and has to be analyzed, correctly, in a political and social-economic context. One of the consequences of the new political order of the country operated after the revolution of 1926 was the cooperative organisation of the pharmacy. The launch of the labour evidence booklet and its regulation in 1939 were equally relevant. Since the thirties, Portuguese pharmacists aspired to have an Order of Pharmacists. However, it only came to be in 1972. The Order of Pharmacists came to succeed in the rights and patrimonial obligations of the National Union of Pharmacists which was extinct, precisely in 1972. The Order of Pharmacists has a National Direction; it has its headquarters in Lisbon and is constituted by the Regional Sections of Lisbon, Coimbra and Porto, and the Regional Delegations of the Azores and Madeira. The Order of Pharmacists has the purpose of regulating the practice of the pharmaceutical profession and the dignity of the profession, defending the interests of the pharmaceutical profession and collaborating with the government in the definition of health policies. In this manner, the Order of Pharmacists practices its functions in the social, scientific, cultural, deontological, professional and economic domain of the pharmaceutical activity. The CIM – This organism was created in 1984 with the purpose of giving pharmacists updated information on medication allowing them to improve its use, making it more objective and secure.

There are also various sectorial associations which defend the interests of pharmacy in Portugal. It is the case of the National Association of Pharmacies – ANF. It was founded in 1975. In its origin is the fact that after the revolution of the 25th of April of 1974 there was the need to give a public voice and defend the interests of the pharmaceutical sector of community pharmacies in a period in which the relations between the State and the pharmacies were not harmonious, mainly in the economic sector. ANF has currently, approx. 97% of the Portuguese pharmacies. Its objectives are the defence of interests of Portuguese pharmacies and their owners. Before that association existed in Portugal the Grémio Nacional das Farmácias was founded in 1938, the institution which in some way preceded ANF in its functions. ANF constitutes today

an institution of great economic and negotiable power among Portuguese pharmacies the State and other sectors of public and associative life.

Another association with significant negotiable and economic power is APIFARMA – Portuguese Association of the Pharmaceutical Industry. It is an institution of defence of the interests of the companies which in Portugal produce, import and export medicines for human use, veterinarian medicines, serums, vaccines, medical products and diagnostics auxiliary products. It was founded in 1975, precisely one year after the Revolution of April 25th, in a period in which Portugal was living an accentuated political and social agitation. Before APIFARMA the *Grémio das Indústrias e Especialidades Farmacêuticas* was in place in Portugal, created in 1939, precisely in an accentuated period of normalisation of pharmacy and medicines, which marks some of the first years of the *Estado Novo*. APIFARMA and ANF occupied partially the space left open with the extinction of *Grémio Nacional dos Industriais de Especialidades Farmacêuticas* and *Grémio dos Armazenistas de Drogas e Produtos Químicos e Farmacêuticos do Norte* and *Grémio dos Armazenistas de Drogas e Produtos Químicos e Farmacêuticos do Sul*. These were sectorial institutions of pharmaceutical activity, founded in the end of the thirties and their foundation can only be understood in the context of the political regime of the time.

Besides these two institutions, which present greater public notoriety at the level of the pharmaceutical sector – ANF and APIFARMA – mainly economic and pharmaceutical, there are other associations of the pharmaceutical sector related to community pharmacy, the pharmaceutical industry and hospital pharmacy. Among the most relevant is, for example, the Association of Pharmacies of Portugal – AFP (founded in 1990). The *Associação de Grossistas de Produtos Químicos e Farmacêuticos*, whose origin goes back to 1931 with the foundation of the *Associação Comercial de Droguitas do Sul de Portugal*. The *Associação dos Profissionais de Registos e Regulamentação Farmacêutica* – APREFAR, was founded in 1992. The Portuguese Association of Hospital Pharmacies. The Portuguese Association of Generic Medicines – APOGEN.

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