



# Implementing a New Model for Admission and Qualification of Portuguese Pharmacists

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The new statute of the Portuguese Pharmaceutical Society (PPS) has established a mandatory registration examination to become a licensed pharmacist. It also establishes a professional accreditation process of university degrees in Pharmaceutical Sciences, performed by the PPS according to criteria specified in its Admission Internal Rules. Students graduating from an accredited degree will be exempt from the registration examination. Moreover, it defines as mandatory the renewal of pharmacists' professional license. Since the PPS intended to initiate the accreditation process in the academic year 2003/04, a discussion within the PPS and between the PPS and Portuguese Schools of Pharmacy took place in order to reach mutual agreements on the rules and regulations governing such a process. Simultaneously, the PPS discussed a model for professional license renewal, on a five year basis, subject to a pre-defined number of credit units obtainable through continuous professional development activities. This paper describes the approved model for admission and qualification, with special focus on the main phases of its implementation.

Keywords: Accreditation; Continuing professional development; Registering examination; Professional license revalidation

### **INTRODUCTION**

The pharmacy profession plays a major role in the discovery, development, production and distribution of drugs and in the creation and dissemination of related knowledge. In addition to these traditional roles, pharmacists are becoming increasingly involved in direct patient care and taking responsibility for the resolution of drug related problems of patients. Pharmacists are unique as they possess a comprehensive understanding of the physical,

chemical, and biological outcomes of drug therapy. Pharmacists in all settings require an understanding of the chemistry of drugs, the delivery characteristics of dosage formulations, the disposition of drugs within the body, the physiological and pharmacological outcomes of drugs' interactions and aspects of modern drug development and production. Therefore, student education requires a dynamic, challenging, and comprehensive curriculum, which includes a foundation in the chemical, biological, biomedical, clinical, pharmaceutical and physical sciences, a clear focus on application and use of knowledge in practical settings, and a general education in healthcare systems, management, professional issues, communication and practice skills. Pharmacists must possess this broad range of specific knowledge, attitudes, skills and behaviours in support of their roles. It is essential to create a dynamic, continuous and interactive trilogy between education, research and the profession. Such mutual influence is underpinned by the interaction between professionals, professors and students. It shall entail the continuous observation, in real time, of the needed adjustments in the paths to follow concerning education and training of pharmacists and pharmacist to be. It is in this context that professional organisations must be considered as stakeholders in the assurance of the scientific, professional and ethical quality of professionals, taking an active role in influencing the future direction of the profession as well as in its continuity (Silveira, 2000).

It is in the public interest to regulate pharmacists. The Portuguese Pharmaceutical Society (PPS) is the representative body recognised by the state as the organisation with the ability to self-regulate as well

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as the deontological and scientific competence for representing and defending the public interests on behalf of the State (Constituição, 1976).

The PPS, within the fulfilment of its legal duties and responsibilities, decided to implement a new admission and qualification system during its General Assembly of March 1998 reflecting the following issues:

- the Portuguese Higher Education system and the current teaching conditions;
- modern practice demands of the pharmaceutical activity;
- professional mobility within the EU;
- need for quality assessment and accreditation of courses in Pharmaceutical Sciences;
- continuing professional development.

These changes were integrated into the PPS's new statute (Decree-Law 288/2001).

Hence, faced by an explosion of new pharmacy degrees and consequently a potential for a range of heterogeneous curricula, the PPS decided to implement a new admissions process in order to: (i) Establish a comparable baseline for all its future members; (ii) Promote collaboration among academics, students and professionals in developing a dynamic, challenging and comprehensive curriculum for the future.

The approved model includes a mandatory registration examination to become a licensed pharmacist (to be implemented in October 2004). It also establishes a professional accreditation process of university degrees in Pharmaceutical Sciences, performed by the PPS according to criteria specified in its Admission Internal Rules. Students graduating from an accredited degree will be exempt from the registration examination.

In parallel, the new statute of the PPS defines as mandatory the renewal of pharmacists' professional license. Accordingly, the PPS has discussed a model for professional license renewal, on a five year basis, subject to a pre-defined number of credit units obtainable through undertaking continuing professional development activities. The discussion of the model involved over 3,000 pharmacists (out of 9,000). In general, pharmacists, a number of professional associations and academic institutions were largely in favour of the proposed process as the benefits to the profession, patients and society were clear.

#### **DEVELOPING THE NEW SYSTEM**

The statute of the PPS, mandates the National Board of Directors (NBD) to establish a new official body within the PPS's structure, namely – the Council for Qualification and Admission (CQA). The CQA

#### TABLE I The Constitution of the CQA

- 1 CQA is nominated by the NBD, being composed by a minimum of 5 and a maximum of 11 members, who elect, from amongst themselves, the chairman.
- 2 CQA is composed by university professors and professionals of acknowledged merit from the different fields in pharmaceutical activity.
- 3 CQA may be advised by individualities of acknowledged scientific or professional merit, on a permanent or casual basis, and request judgements to specialized commissions of the PPS or to third entities, every time it is deemed to be convenient.

constitution and terms of reference are described in Tables I and II, respectively.

When setting up the CQA, the NBD decided to nominate a taskforce (TF) in November 2001 to prepare an action plan and timetable for actions to be taken during 2002, namely the review of national and international experiences, the drafting of proposed models to be followed and the promotion and moderation of discussion sessions. The CQA was formally recognised in March 2003.

The TF undertook an intensive period of work which included meeting with schools of pharmacy, student associations and other national professional societies, visiting the USA and the UK, and organising debate forums and sessions to improving the awareness of individuals. Two PPS General Assemblies (GA) also took place in this period. The most relevant are briefly enumerated in Table III.

#### TABLE II CQA competences

The CQA, in accordance with the NBD, is to:

- (a) Collaborate in drawing up the professional and scientific training plan for pharmacists;
- (b) Express its view on pre-graduation, post-graduation and continuous training courses, as well as on the entities ministering them;
- (c) Recommend the NBD with conditions for regular entrance exams in the PPS;
- (d) Recommend the NBD with objective criteria for the exemption from entrance examinations, to be regularly reviewed, based on the courses' curricula, on teaching resources and on evaluation methods;
- (e) Express its view on the apprenticeship program, its nature and purposes, as well as on the fitness of services and institutions;
- (f) Express its view on accreditation/creditation of courses/ activities for continuous training;
- (g) Express its view on the examinations for the PPS, as well as to evaluate the adequate courses for such exams;
- (h) Recommend the national board with professional qualification levels and specialist titles;
- (i) Express its view on the creation of new specialties;
- (j) Co-operate, within the applicable legal regime, with the bodies, responsible, for guidance and planning of models for pharmaceutical teaching;
- (k) Propose the organization of update and upgrade courses, with the possible collaboration of pharmaceutical schools and other university schools from other fields, specialty committees, professional groups and other public or private, national or foreign institutions;
- Issue judgements on scholarships and scientific awards to be granted.

TABLE III Meetings, visits and discussions

Meeting	Relevant Issues	Relevant documents
Forum PPS/Schools of Pharmacy/ Students' Associations	The five Schools of Pharmacy already graduating pharmacists and the National Pharmaceutical Students' Federation (APEF), representing all pharmaceutical students' associations in the country, were invited to join this forum.  Three meetings were organized between December 2001 and October 2002.  In March 2003 individual meetings with each School of Pharmacy (on site) and with APEF were held to collect final remarks to the approved accreditation system.	In June 2002 written contributions from Schools of Pharmacy and APEF were collected and integrated into the draft document proposing the accreditation system framework.
Meetings with other national Professional Societies	As part of the research work on admission systems already implemented by other Professional Societies, meetings with the Engineers and the Architects' professional societies, held by the end of 2001, were extremely important to gather information and gain experience from their on- going accreditation systems. Continuous information exchange as well as advice and orientation on how to overcome certain implementation	Internal Regulation for Admission and Qualification of the Portuguese Engineers Society, approved on March 29th 1993 Internal Regulation for Admission of the Portuguese Architects Society, approved on February 12th 2000
Visit to the USA and the UK	challenges were extraordinarily helpful.  In February 2002, the PPS met with the American Council on Pharmaceutical Education (ACPE) and with the National Association of Boards of Pharmacy (NABP), in Chicago. In addition, PPS representatives had the unique opportunity to participate as observers of the ACPE's evaluation team in an on site visit to the School of Pharmacy, University of Washington, in Seattle.  Another meeting was held in London, at the Royal Pharmaceutical Society of Great Britain (RPSGB), in June 2002.	ACPE Accreditation Manual, 9th Edition, September 2000 NABP Constitution and Bylaws, revised May 2000 RPSGB Criteria for Accreditation of Degrees in Pharmacy, 16 May 2002.
Meeting within PPS structure	In April 2002 a meeting was held with all national and regional bodies of the PPS structure, gathering over 50 leaders of the profession. The main goal of this meeting was to present and discuss the different options that could be adopted as the PPS admission and qualification system.	
Meeting with Sectorial Professional Organisations	A meeting with the national professional organisations representing pharmacists from different fields of activity was held in May 2002 with the purpose of discussing the proposed model for admission and qualification and collect further suggestions	In June 2002, written contributions were received.
Approval of the FIP Statement of Professional Standards on CPD	The PPS participated in the FIP Council meeting held in Nice, in September 2002, having an active role in the discussions leading to the final text of this statement. The approval of this document represented an important move for advocating CPD at a national level.	FIP Statement of Professional Standards on Continuing Professional Development, approved at the 62nd FIP Annual Congress, Nice, September 2002.
Local discussion sessions on license revalidation	From October 2002 until February 2003, 18 sessions were held in 17 different cities, covering the whole national territory (including the islands of Azores and Madeira). Approximately 2300 pharmacists attended these discussion sessions.	
Regional and National General Assemblies (GA)	Since 1998, the admission and qualification system has been included as a discussion point of the GA agendas. In March 2003 the PPS GA approved the accreditation system and a position paper on the license revalidation process, commending the NBD with several fundamental principles that should be followed within the implementation of this process.	

#### ADMISSION PROCESS

After analysing national and international information relating to admission procedures, five possible options were discussed:

- To sit, the registration examination students must have completed an accredited pharmacy degree programme;
- 2. All graduates must sit the registration examination. There are no exemptions;
- 3. Students who graduate from an accredited degree programme will be exempt from sitting the registration examination;
- All graduates will complete a period of preregistration training and sit the registration examination;
- 5. Graduates who fail the registration examination must complete a period of pre-registration training to sit again the registration examination.

Discussion within the PPS and with schools of pharmacy, sectorial professional associations and student associations lead to the conclusion that options (3) and (5) would be the most appropriate for accomplishing the PPS objectives.

The development of the model to be adopted for programme degree's accreditation involved close collaboration with schools of pharmacy and student associations. As a strong professional focus was advocated by the PPS (supported by sectorial professional associations representing different fields of practice), long discussions took place in order to clearly define the goals, procedures and outcomes which would protect the autonomy of schools of pharmacy and meet the PPS objectives.

Despite some constraints throughout the discussions, a consensus was reached, with schools of pharmacy being not only compliant with the professional accreditation process that is to be carried out by the PPS, but also committed to initiate it in May 2003. In accordance with this, five faculties (out of seven) have already applied for accreditation of their study programmes. The two remaining Schools have not yet completed the first cycle of graduation and therefore are not eligible for application. Accreditation guidelines have been distributed by the end of May, self-evaluation studies should be submitted by October, on site visits will be carried out in March 2004 and accreditation results will become public in May/June 2004.

According to the PPS Internal Regulation for Admission, accreditation will be periodical, once every six years, on a voluntary basis, and based on a self-evaluation report, where pre-requested items are to be completed and documented, and then followed by the visit of an accreditation team. It is important to

note that PPS provides accreditation to the study programmes, not to institutions.

The study programmes' self-evaluation report, in order to be compliant with the guidelines set forward by the PPS, should contain detailed information about the organisation of the study programme, duration, enrolments, core and optional courses (with the number of teaching hours and credits for each course, as well as its study contents), curriculum vitae of all professors, pedagogical methods, details of the recommended bibliography, data on employment of graduates, etc. It also should give sound evidence that the study programme is organised in order to prepare students to be able to perform the pharmaceutical act as defined in Decree-Law 288/2001, of 10th November 2001 (Table IV). This Decree-Law is the legal instrument in which competence for performing the enumerated activities is formally recognized by the State. In order to ensure graduates are fairly prepared to perform such competencies the pharmaceutical act has been considered as fundamental in shaping the accreditation system. To this end, the PPS recommends that early contact with patients and with real practice is promoted during the course of the study programme.

The accreditation team visits the institution for two days and interviews members of the Executive Board, professors, students and staff. After the visit the team writes a preliminary report, including main findings, the opinion about the clarity, objectivity

TABLE IV The Pharmaceutical Act (Decree-Law 288/2001, article 77)

- (a) Development and preparation of the form of presentation of medicines;
- (b) Registration, manufacture and control of human and veterinary medicines as well as medical devices;
- (c) Quality control of medicines and medical devices in quality control laboratory for medicines and medical devices;
- (d) Storage, preservation and wholesale distribution of human and veterinary medicines as well as medical devices;
- (e) Preparation, control, selection, purchase, storage and dispensation of human and veterinary medicines as well as medical devices, in pharmacies that are open to the public, hospital pharmaceutical services and private pharmaceutical services from any other public and private entities;
- (f) Preparation of antiseptic solutions, disinfectants and intravenous mixtures;
- (g) Interpretation and evaluation of medical prescriptions;
- (h) Information and reference to bibliography on human and veterinary medicines as well as on medical devices subject and not subject to medical prescription, destined to health professionals and patients, so as to promote their correct use;
- (i) Follow-up, surveillance and control of distribution, dispensation and use of human and veterinary medicines as well as medical devices;
- (j) Drugs monitoring, including calculation of pharmacokinetical parameters and definition of individualized posologies;
- (k) Collection of biological products, execution and interpretation of clinical analyses and quantification of serum levels;
- Execution and interpretation of toxicological, hydrological and bromatological analyses;
- (m) All practice or functions directly connected to activities described in the previous items.

and completeness of the elements of the self-evaluation report and an appreciation of strong and weak points. This report is forwarded to the institution that will check that there are no factual mistakes. The CQA, supported on the accreditation team's report, elaborates a position paper including recommendations for improvement of the study programme, and a recommendation for a positive or negative decision on the accreditation process. The position paper also contains detailed explanations of the rationale that justifies the recommendations. This position paper is then submitted to the NBD for appreciation and final decision.

The School of Pharmacy is then given notice of the final decision in writing. Final decision can take one of three possible forms:

- 1. Full accreditation for a period of six years, when renewal of the accreditation will be necessary;
- Conditional accreditation for a maximum period of three years, with recommendations of improvements that need to be implemented over that period and that needs to be confirmed by an accreditation team once the approbatory period is over;
- 3. Refusal of accreditation with a list of the reasons that support this decision.

The whole procedure is confidential and can only be made public with permission from the institution being accredited. The PPS publishes a list of the accredited study programmes (but not of those programmes that were denied accreditation).

#### **QUALIFICATION PROCESS**

Since publication of its new Statute, the PPS has promoted an extended debate on how to implement the mandatory professional license revalidation. The debate has gathered over 3000 pharmacists from all over the country. Discussion sessions and general assemblies have been promoted with pharmacists and individual meetings were made with different professional bodies within the PPS, sectorial professional associations, schools of pharmacy and student associations in order to collect as many opinions, reactions and suggestions as possible.

This course of action has lead to the definition of basic principles as laid out in Table V. It has also identified several activities that may be considered as CPD activities (Table VI).

Professional license revalidation will be made every five years. However, first revalidation after the inscription in the PPS will be made in a seven years period.

During the sessions an evaluation questionnaire was distributed in order to investigate pharmacists'

TABLE V  $\;$  Basic principles of the mandatory professional license revalidation

- To promote the continuous professional development in any way considered to have interest to the profession;
- (ii) To allow the participation of all the pharmacists without restrictions concerning the professional activity nor the localization of his/hers working place;
- (iii) To have a minimum cost for all the pharmacists;
- (iv) To be suitable and compatible with the PPS structure;
- (v) To be an evolving model, that follows-up the developments in pharmacy practice and the pharmacists concerns;
- (vi) Age shouldn't be an exception factor;
- (vii) Continuing professional development should be mostly in the professional activity area;
- (viii) Supported by the acquisition of a previous established number of credit units;
- (ix) The credit unit should be objective enough to evaluate the different CPD activities

reaction to the proposed model for license revalidation. A total of 1147 questionnaires were collected, representing a response rate of 50.6%. As a first reaction to the proposed model, 49.5% said they were open to the process, 26.6% worried and expectant about the process, 13.9% willing to embrace the process, 3.9% confident and positively in favour of the process and 4.0% frightened by the process.

#### **FUTURE DEVELOPMENTS**

Of concern is a recent parliament bill (Law 1/2003) determining a mandatory accreditation process of higher education institutions and study programmes which may put into practice two parallel accreditation systems. The extension in which those processes are complementary is under discussion between the

#### TABLE VI CPD activities

- Continuing Education courses
- Continuing Education/ Evaluation in the scope of a career development
- Continuing Education provided by the employer
- Distance learning (e-learning, monographs, etc.)
- Implementation of Quality Management Systems
- Participation in congresses, symposiums and other scientific reunions
- Plenary lectures in congresses, symposiums and other scientific reunions
- Teaching activities only considered if in the scope of continuing education; it includes the development of teaching materials (CD-rom; handouts; handbooks; etc.)
- Training supervision of undergraduate and post graduated students from courses with PPS accreditation
- Expert activities (in pharmaceutical legislation or other areas also mentioned in the pharmaceutical act)
- PPS Specialist title
- Publication of articles in journals
- Publication of books or chapters of books within the Health Sciences area
- Presentations or publications of professional interest
- Presentations of abstracts in congresses with a scientific committee
- Post Graduation courses
- MsD, PhD or other academic graduation

PPS and the Ministry for Science and Higher Education. The Parliament passed, in January 2003, a law that determines an academic accreditation of higher education institutions and of study programmes. The State agency, responsible, for quality evaluation, National Quality Evaluation Agency (NQEA), will be also, responsible, for the accreditation. It is not at all clear what the academic accreditation mechanisms will be. A possible development could be to use directly the quality evaluation procedures to produce accreditation decisions, despite the obvious difficulties of such a course of action. On the other hand, it is not at all obvious what will be the relationship of this new system to the parallel activities of professional societies. A strong possibility could be a joint effort of the NQEA and the professional societies to reach an agreement that will allow for a harmonisation of both systems. The third possibility is to run the two systems in parallel, running the risk of producing incompatible decisions on the same study programme and creating an excessive burden for the institutions.

Although it is too early to imply what will the future developments be, the PPS has already expressed its willingness to collaborate with the national authorities in order to harmonise both systems and use the already available resources and expertise.

Another relevant issue for the PPS is related to the content of the Prague Declaration (Prague Document, 2001) in which ministers stressed the need to welcome and involve universities and other higher education institutions as competent, active and constructive partners in the establishment and shaping of a European Higher Education Area. Ministers also pointed out that quality is the basic underlying condition for trust, relevance, mobility, compatibility and attractiveness in the European Higher Education Area. Ministers expressed their appreciation of the contributions toward developing study programmes combining academic quality with relevance to lasting employability and called for a continued proactive role of higher education institutions. Furthermore, Ministers have emphasised that lifelong learning is an essential element of the European Higher Education Area. In the future Europe, built upon a knowledgebased society and economy, lifelong learning strategies are necessary to face the challenges of competitiveness and the use of new technologies and to improve social cohesion, equal opportunities and the quality of life (Berlin Document, 2003).

In light of these recommendations, and having in mind the above CPD project that the PPS is preparing, the PPS has expressed how beneficial it would be if these two projects could evolve simultaneously, welcoming the involvement of schools of pharmacy at this level. It is important that the definition and implementation of improvements to the study programmes is done in an integrated framework of post graduation and specialization courses, which will be taken by pharmacists as parts of their CPD activities. Moreover, having a vast and qualified expertise, schools of pharmacy can play an important role as continuing education providers. This role should be enhanced and further developed as a key factor for widening the existing continuing education courses.

A nationwide survey on continuing professional development activities will be undertaken in order to establish a starting point for future CPD developments. The main goal is to identify existing continuous education habits and investigate specific education and training needs per field of activity, country region and age. Time and financial resources to be allocated for CPD activities will also be investigated.

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