

Good Pharmacy Practice in Spanish Community Pharmacy

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Background

Since the end of the eighties, the **World Health Organization (WHO)** and the **International Pharmaceutical Federation (FIP)** have been working on the definition of the role and the functions of pharmacists, as well as developing guidelines for good pharmacy practice.

In 1988, the first meeting on the role of the pharmacist was held in Delhi (India). Since then, meetings have been held in Tokyo (Japan) in 1993, in Vancouver (Canada) in 1997 and in The Hague (The Netherlands) in 1998.

In 1992, FIP developed the document, “Good Pharmacy Practice in Community and Hospital Pharmacy Settings”, collecting regulations about pharmacy services in the community and hospital fields. This document was officially approved in 1993.

A year later (1994), WHO adopted a Resolution¹ on the role of the pharmacist that supported its *Revised Drug Strategy*. During the same year, FIP sent the Good Pharmacy Practice document to the *WHO Expert Committee of Specifications for Pharmaceutical Preparations*, in order to gather opinions and comments. Based on the remarks made by WHO, in 1997, the FIP Council approved the “FIP/WHO Joint Document on Good Pharmacy Practice”, published in 1999 in the 35th Report of the *WHO Expert Committee on Specifications for Pharmaceutical Preparations*².

In 2006, FIP and WHO published the handbook “Developing Pharmacy Practice. A Focus on Patient Care”³, which is focused on the new dimensions in pharmacy practice and establishes, step by step, procedures for Pharmaceutical Care.

In 2007, FIP decided to update the 1997 Guidelines on Good Pharmacy Practice to adapt them to the advancement made in the standards of professional practice. The reviewing process included consultations to FIP Member Organizations, experts on this field and the WHO. It was not until 2011 when the “**Joint FIP/WHO Guidelines on Good Pharmacy Practice: Standards for Quality of Pharmacy Services**”⁴ were adopted. **This document urges national pharmacy professional organizations to adopt these guidelines and to develop some specific regulations for Good Pharmacy Practice.**

At the same time, at the end of 2008, an initiative on Pharmaceutical Services in Primary Health Care (PHC), supported by the Pan American Health Organization (PAHO), started with the intention to emphasise healthcare systems in Latin American countries and the role of pharmacists in developing services. As part of this initiative, PAHO along with a group of experts from different pharmaceutical organisations, prepared the “Guideline for Pharmacy Services in Primary Health Care”⁵.

In Spain, in 1995, the General Pharmaceutical Council of Spain published “Spanish Rules for Good Pharmacy Practice”, based on the Guidelines published by FIP in 1993. These regulations detailed the requirements for a correct professional practice in Spain and the most suitable way to get it.

More recently, in 2008, the General Pharmaceutical Council published the “Quality Standards for Community Pharmacies”, aimed at specifying the minimum requirements that community pharmacy must meet to help community pharmacists to develop and provide quality services for patients.

The Joint FIP/WHO Guidelines on Good Pharmacy Practice urge national pharmacy professional organisations to develop some specific regulations for good practice

¹ World Health Assembly Resolution WHA 47.12

² WHO Technical Report Series No. 885

³ Developing Pharmacy Practice – a focus on patient care. WHO/PSM/PAR/2006.5, 2006

⁴ Joint FIP/WHO Guidelines on GPP: Standards for quality of pharmacy services. Hyderabad, 2011

⁵ Guía Servicios Farmacéuticos en la Atención Primaria de Salud. PAHO. Washington, 2010

Justification

Healthcare services and health systems all over the world are changing. As an integral part of these health systems, pharmacies and pharmacists need to adapt and move forward to meet the needs of both patients and governments.

Now society is better educated and informed on healthcare subjects than ever; and therefore demands quality and efficient services. Optimising resources and obtaining the best possible value from any healthcare intervention is essential due to the current economic situation, along with the generalised ageing of the population. For this reason, **pharmacists, doctors, nurses and other healthcare professionals share the mission of guaranteeing a safe, responsible, effective and efficient use of services, healthcare interventions and medicines, with the ultimate goal of optimising the health outcomes.**

The present and future of the pharmacy profession are linked to the provision of patient-centered services. The mere supply of a medicine is not enough to reach the pharmacotherapy outcomes. Ensuring the responsible use of medicines and trying to maximise pharmacotherapy outcomes can be found amongst the responsibilities of a pharmacist. **The costs associated with inappropriate pharmacotherapy outcomes as a result of problems related to the use of medicines are too high, particularly in a society that is increasingly ageing, using more and more medicines and where a better performance of available resources must be found.**

The nature and functions of pharmacists are becoming increasingly complicated and diverse. It is essential to make a better use of all the pharmacist's competences and to develop his or her potential. Therefore, **there must be guidelines, guides and procedures available** that guarantee that all pharmacists, regardless the field of practice, can offer **quality and efficient healthcare and services that respond to society's needs.**

The present and future of the pharmacy profession are linked to the provision of patient-centered services

FIP and WHO, in their *Joint FIP/WHO Guidelines on Good Pharmacy Practice: Standards for Quality of Pharmacy Services* (2011), recommend national professional organisations to provide support and guidance to professionals, through the production of a series of rules for the services to be provided and the targets that the professional practice must have.

In accordance with this recommendation, the General Pharmaceutical Council of Spain has produced the present document on Good Pharmacy Practice in Community Pharmacy, which takes into consideration the needs of Spanish population, the conditions of the profession and the particularities of our healthcare system.

Objetives

This document develops and establishes certain standards of practice for Community Pharmacy in Spain, based on relevant processes and professional requirements. It is aimed at all those pharmacists working in community pharmacies in Spain.

The objectives of this document are:

- To define the roles community pharmacists can perform accordingly to Good Pharmacy Practice.
- To define the functions that comprise each role.
- To establish procedures for Good Pharmacy Practice.

Definition of Good Pharmacy Practice

Good Practices are comprised of a series of guidelines or recommendations for professional practice, generally covering minimum requirements that should be met for a certain professional activity or practice in order to be considered as suitable.

Regarding Good Pharmacy Practice, and according to the definition given by FIP/WHO⁴, is “*the practice of pharmacy that responds to the needs of the people who use the pharmacists’ services to provide optimal, evidence-based care*”.

The implementation of Good Practices could range from a simple recommendation to being associated to systems for professional accreditation or even be compulsory by law and subject to penalties.

Functions and obligations of pharmacy are defined in the legislation, although the recommendations or regulations included in Good Practices obviously go beyond the scope of such legislation.

Guidelines or recommendations for professional practice, generally covering minimum requirements, that should be met for a certain professional activity or practice in order to be considered as suitable

Legal Framework: Functions and Obligations of Community Pharmacy

The functions reserved to pharmacists, as set by regulations, are described in National and Regional provisions and are as transcribed below.

- a) Law 16/1997, 25th April, on the Regulation of Community Pharmacy Services⁶, considers community pharmacies as private healthcare facilities with a public interest. In addition to this, it establishes the need for pharmacy planning and the requirement of being a pharmacist for pharmacy ownership:
- “Under the terms of the Law 14/1986, General Healthcare Law, 25th April, and the Law 25/1990, 20th December, on Medicines, community pharmacies are private healthcare facilities with a public interest, subject to healthcare planning established by the Autonomous Regions, in which the pharmacist titleholder-owner aided, if applicable, by assistants must provide the following basic services to population:*
- 1. To acquire, guard, maintenance and dispensing of medicines and medical devices.*
 - 2. To monitor, control and safe-keeping of the medical prescriptions dispensed.*
 - 3. To guarantee pharmaceutical provision, in the pharmacy area of influence, and for villages where there are no community pharmacies.*
 - 4. To prepare compounded medicines and other preparations, in the cases and according to established procedures and controls.*
 - 5. To inform and monitor the pharmacological treatments of patients.*
 - 6. To cooperate in the control of the individualised use of medicines, in order to detect adverse reactions that may arise and report to pharmacovigilance responsible bodies.*
 - 7. To cooperate in programmes promoted by the Health Authorities on the quality assurance of the pharmaceutical provision and healthcare in general, health promotion and protection, prevention of disease and healthcare education.*
 - 8. To cooperate with the Healthcare Authorities in the training and information addressed to other healthcare professionals and users about the rational use of medicines and medical devices.*
 - 9. To act in coordination with the structures of the Health Services from the Autonomous Regions.*

⁴ Joint FIP/WHO Guidelines on Good Pharmacy Practice: Standards for the Quality of Pharmacy Services. Hyderabad, 2011.

⁶ Law 16/1997, 25th April, on the Regulation of Community Pharmacy Services. BOE-A-1997-9022. Pages 13450 – 13452.

10. *To cooperate in the education to obtain the qualification of Graduate in Pharmacy, in accordance with that set forth in the EU Directives, and in State and University regulations that establish the corresponding study plans in each of them”.*

The different laws pertaining to the Autonomous Regions on pharmacy planning have taken the abovementioned drafts into account, describing professional actions to be developed by pharmacies in their respective territorial areas.

b) Law 16/2003, 28th May, on Cohesion and Quality of the National Health System⁷ specifically mentions, in Art. 33, the necessary cooperation of pharmacies with the National Health System in the provision of pharmacy services, pointing out a coordinated action with other healthcare professionals:

1. *“Community pharmacies will cooperate with the National Health System in the provision of pharmacy services in order to guarantee the rational use of medicines. In order to do this, pharmacists will act in coordination with doctors and other healthcare professionals.*
2. *Within the framework of the Law 25/1990, 20th December, on Medicines, the Ministry of Healthcare and Consumerism, after agreement by the Inter-territorial Council of the National Health System, will establish the general and common criteria for developing the cooperation of community pharmacies, by way of arrangements that guarantee citizens the dispensing of medicines under conditions of effective equality throughout the nation, regardless of their Autonomous Region of residence. Individualised dispensing of medicines and the implementation of electronic prescriptions will be attempted, with the participation of medical and pharmaceutical professional associations.*
3. *Amongst the criteria included in the above section, the basic pharmacy data necessary for management purposes, and using computing means of information, to perform the abovementioned activities as well as for the cooperation with healthcare structures of the National Health System will be defined. They will be adapted to that set forth in the General Law 15/1999, 13th December, on Personal Data Protection and to the specifications established by the health services in the Autonomous Regions”.*

c) The Law 44/2003, 21st November, on Planning of Healthcare Professions⁸, in Article 6.2 indicates that “[...] *the activities aimed at the production, conservation and dispensing of medicines correspond to Pharmacy Graduates, along with the cooperation in the analytical, pharmacotherapy and public health monitoring processes. [...]”.*

d) The Law 29/2006, 26th July, on Guarantees and Rational Use of Medicines and Medical Devices⁹ in its article 84 defines the professional activity of pharmacists, with a view to guaranteeing the rational use of medicines and medical devices:

1. *“In community pharmacies, the pharmacists, as those responsible of the dispensing of medicines to citizens, will take care to fulfil the rules on the prescription established by the doctor in charge of the patient, and they will cooperate with him/her in the monitoring of the treatment using Pharmaceutical Care procedures, contributing to ensure treatment’s efficiency and safety. Likewise, they will take part in the performance of all the activities aimed at the rational use of medicines, particularly through the informed dispensing to patients. Once the medicine has been dispensed, they may provide personalised dosing systems for patients who ask for them, in order to improve the therapy adherence, in the treatments and with the conditions and requirements that are established by the competent healthcare administrations”.*

Functions reserved for pharmacists are described in State and Autonomous Regions provisions

⁷ Law 16/2003, 28th May, on Cohesion and Quality of the National Health System. BOE-A-2003-10715. Pages 20567-20588.

⁸ Law 44/2003, 21st November, on Planning of Healthcare Professions. BOE-A-2003-21340. Pages 41442-41458.

⁹ Law 29/2006, 26th July, on Guarantees and Rational Use of Medicines and Medical Devices. BOE-A-2006-13554. Pages 28122-28165.

Community Pharmacist's Mission

The pharmacist's mission consists of caring for patients' needs regarding the medicines they use, cooperating with the healthcare authorities to guarantee the pharmaceutical provision and developing all those questions related to health and that are within their professional scope. The pharmacist must guarantee the population access to medicines and medical devices, helping patients in the correct process of safe, effective, efficient and responsible use of medicines and getting involved in the achievement of health outcomes.

To achieve this mission, certain characteristics of the community pharmacy network are necessary, such as accessibility and the execution of a series of professional actions by the pharmacist:

- **Accessibility:** pharmacies are healthcare facilities and, frequently, are the entry point for patients to the healthcare system. Pharmacists are the most accessible healthcare professionals, available without appointment, 24 hours a day and 365 days. In Spain, 99% of the population has a pharmacy where they live, both in rural, urban and isolated areas and in socially deprived districts.

The community pharmacy network guarantees fairness, quality and cohesion in the access to medicines. Access is highly efficient and safe, armouring against the entry of counterfeited medicines. In turn, the system provides the universalisation of new services using arrangements with the Autonomous Regions. The community pharmacy network in Spain, with a model of ownership/pharmacist titleholder, gives priority to healthcare over economic interests.

- **Promoting the safety of medicines and medical devices:** pharmacists must not limit their work to supply medicines or medical devices; first they must check that there are no problems that can impede the dispensing, such as contraindications, allergies, special situations, etc. In addition, the pharmacist provide information about the correct use process (dosage, instructions, possible side effects, interactions, etc.). All of this with the goal of preventing and avoiding the appearance of any possible harm and/or unexpected results, as a consequence of medicine related problems.

- **Ensuring the effectiveness of medicines:** aimed at maximising the benefits of the treatment and, at the same time, minimising the appearance of any possible inappropriate results inherent to problems related to the use process.

- **Detecting, identifying and managing health problems:** particularly those that are related to the incorrect/unsafe use of medicines or medical devices.

- **Public Health, health promotion and disease prevention:** pharmacists take part in Public Health activities and programmes developed by the public administrations, to protect, promote and recover population's health, as well as to aware of any possible undiagnosed pathology. Likewise, pharmacists develop activities aimed at improving the state of health and the quality of life, as well as preventing diseases.

- **Contributing to the responsible use of healthcare resources:** pharmacists directly cooperate in the control and rationalisation of public expenditure on medicines, avoiding inappropriate use of resources and allowing the National Health System to achieve its target of budgetary balance.

- **Teaching, research and development:** community pharmacists cooperate in the acquisition of the competences to obtain the qualification in Pharmacy. They must also become involved in research and development activities in different areas, as well as in innovation and transfer.

Based on the abovementioned points, roles, functions and activities that comprise Good Pharmacy Practices in Community Pharmacy are defined.

Pharmacist's mission consists of caring for patients' needs regarding the medicines they use



Roles, Functions and Activities of Good Pharmacy Practice in Community Pharmacy

FIP and WHO recommend that to determine roles, functions and activities that comprise the Good Pharmacy Practice, the needs and expectations of society regarding pharmacy and pharmacists must be taken into consideration. It is also necessary to respond to the needs and expectations of healthcare systems.

The roles, functions and activities identified are a direct responsibility of pharmacists. Over these, application levels are determined, establishing minimums for which each pharmacist have to prove competent.

The roles, functions and activities of the **Good Pharmacy Practices in Spanish Community Pharmacy** are determined based on the recommendations by the international organisations – FIP and WHO, and the national legislation in force.

Society's needs and expectations regarding pharmacy and pharmacists must be taken into consideration. It is also necessary to respond to the needs and expectations of healthcare systems

ROLE 1: ACQUISITION, CUSTODY, CONSERVATION, PREPARATION, DISPENSING AND DISPOSAL OF MEDICINES AND MEDICAL DEVICES	A: Acquisition, custody and conservation of medicines and medical devices
	B: Preparation of compounded medicines and other preparations
	C: Dispensing of medicines and medical devices
	D: Management of expiry dates and disposal of medicines and medical devices
ROLE 2: OFFER AN EFFECTIVE MANAGEMENT OF THE PHARMACOLOGICAL TREATMENTS	A: Evaluate the patient's health condition and needs
	B: Follow-up patients' pharmacological treatment
	C: Control patient's progress and outcomes
	D: Offer information about medicines and health-related issues
ROLE 3: HELP TO IMPROVE THE EFFICIENCY OF THE HEALTHCARE SYSTEM AND PUBLIC HEALTH	A: Disseminate evidence-based information about medicines and different aspects of self-care and public health
	B: Participate in preventive care services and activities
	C: Comply with professional obligations, guidelines and legislation
	D: Recommend and support national policies that encourage better health outcomes
	E: Contribute to the efficiency of the health system
ROLE 4: MAINTAIN AND IMPROVE PROFESSIONAL PERFORMANCE, COLLABORATE WITH TEACHING AND PARTICIPATE IN RESEARCH ACTIVITIES	A: Arrange and implement continuous professional development strategies to improve performance today and in the future
	B: Participate in competence-acquiring activities for future pharmacists
	C: Participate in research and development activities

Role 1: Acquisition, Custody, Conservation, Preparation, Dispensing and Disposal of Medicines and Medical Devices

Function A: Acquisition, Custody and Conservation of Medicines and Medical Devices

- The Pharmacy will have some **suitable facilities and conditions** for the storage, custody and conservation of medicines and medical devices.
- The pharmacist must acquire and ensure the **maintenance of a stock** of medicines and medical devices in order to guarantee the correct pharmaceutical provision in the pharmacy's area of influence. The pharmacist must keep a minimum stock of certain medicines and medical devices according to the applicable regulations in each case.
- At all times the pharmacist will ensure the **integrity and quality of the acquired and stored products**. The medicines will be obtained from authorised distributors, in order to minimise the risk of acquiring any counterfeited medicines and when necessary maintaining special storage conditions for medicines that might need it (cold chain, controlled medicines, etc.) as well as performing periodical checks to remove products that are about to reach their expiry date.
- The pharmacist will take part in the **recall procedures** communicated by the authorities or manufacturing laboratories, following a procedure that guarantees the fact that this recall is performed effectively and in the shortest time possible. The existence of an information system that allows this process to be performed effectively is essential. The expired medicines and products, as well as those recalled by the authorities or by laboratories, will be clearly separated from the stock in the pharmacy in order to proceed with their return.
- The pharmacist will take part in the **strategies and contingency plans in the case of shortages or emergency situations** established by the authorities and by other parties of the medicines supply chain.

Function B: Preparation of Compounded Medicines and other Preparations

- The preparation of compounded medicines and other preparations continues to be essential to cover therapeutic gaps and special requirements for dosage and formulation. In order to prepare them, **the regulations in force for the correct preparation and quality assurance will be followed** along with the guidelines set down by the National Formulary (for standard compounded medicines and other formulas).
- The compounded medicines and formulae will be made of **substances with actions and indications legally recognised in Spain**. In the case of active ingredients or medicines that are not authorised, an explicit authorisation by the competent healthcare will be required. The pharmacist will certify that the raw materials meet all the necessary quality requirements.
- The **pharmacist will be responsible for the preparation and control** of compounded medicines and formulas produced in the pharmacy. This preparation and control will be carried out by a pharmacist or under the pharmacist's supervision by a person with the necessary qualifications and experience.
- The **pharmacy will have suitable facilities** for the proper preparation, storage and conservation of compounded medicines and formulas. The facilities and tools used will be adapted to the dosage form, type of preparation and the volume of production.
- These products will be produced in a **clearly differentiated area** that allows an efficient supervision by the pharmacist.
- The **pharmacist will record all the information related to the preparation** of compounded medicines and formulas. This includes general information (operating procedures, cleaning process, personal hygiene, functions assigned to pharmacy staff, etc.), information on raw materials (registration, specifications and quality assurance), information for packaging and record of the preparation of the formula (standard operating procedure –preparation method, checks to be performed, materials, etc. and preparation and control guidelines – information about how the compounded medicine has been prepared).
- In the case of compounded medicines, their preparation will respond to a detailed medical prescription of the active ingredients involved and **it will be dispensed with sufficient oral and written information for its correct identification, conservation and responsible use**.

Function C: Dispensing of Medicines and Medical Devices

- The **presence** and professional **performance** of the pharmacist is an essential condition and **requirement for the dispensing** of medicines.
- For prescription only medicines, **the pharmacist will check such prescription, ensuring that contains all the necessary information** (patient, medicine and prescriber details, date and prescriber's signature) and its period of validity. For electronic prescriptions, the patient will be identified using his/her healthcare card and the prescriber will be identified electronically using the validation of his/her electronic signature.
- The pharmacist will dispense the prescribed medicine, although in **exceptional circumstances**, due to shortages or urgent need for treatment, pharmacist **will substitute it for another medicine** according to the conditions established in the legislation (same composition, pharmaceutical form, administration route, dose, etc.).
- Prescriptions forms dispensed will remain under the **surveillance, control and custody of the pharmacist** according to the specific requirements in terms of the type of prescription (NHS, mutual insurance companies – MUFACE, ISFAS and MUGEJU –, private prescription, etc.). In the case of electronic prescriptions, these will be kept on secure servers.
- The dispensing of both prescription only and non-prescription medicines will be performed following the **Dispensing Service Procedure**¹⁰.
- The **information** provided by pharmacists during the dispensing of medicines and medical devices will be **based on the scientific evidence available. It will be comprehensible, accurate, adapted to the patient's needs and will not have any commercial nature.**
- The dispensing will always be performed in such a way that the patient's **confidentiality is guaranteed. The personal details** that a patient might provide **will be used for the purposes, in the way and with the restrictions and rights included in the legislation** on the protection of personal data.
- In the case of **compounded medicines** and formulas, the dispensing will be performed using suitable containers for the nature and use of such medicine, in order to guarantee the protection of the content and the quality during its shelf-life. The **dispensing will be accompanied by the sufficient oral and written information to guarantee its correct identification** (including the name of the pharmacist who prepared it), **conservation and safe use**. The dispensing of a compounded medicine or formulae that requires a prescription will be recorded in a prescription book or stipulated registration document.
- The prescriptions dispensed will be systematically **checked on a daily basis in order to detect any possible incidences, administrative mistakes, etc.**

Function D: Management of Expiry Dates and Disposal of Medicines and Medical Devices

- **The pharmacist** will fulfil his/her part of the shared responsibility, according to which all the parties involved in the preparation, distribution and dispensing of medicines and medical devices, must **contribute to the management of the waste** derived from the use of these products.
- The pharmacist **will facilitate citizens' access** to the disposal of medicines and medical devices (unused and/or expired medicines, containers, etc.) and he/she will control and keep these products safe.
- The disposal of a medicine returned by patients will be done using **specific containers installed in the pharmacies**, in which patients will deposit medicines that are no longer required or that are out of date, as well as their containers.
- **Where the waste returned** is considered to be dangerous by the legislation or **come from the preparation of a compounded medicine/formulae**, the pharmacist **must identify, classify and correctly store it** in terms of the type of waste generated. This waste will be disposed by an authorised manager responsible of its treatment and final disposal.

¹⁰ Practical Guide for Pharmaceutical Care Services in Community Pharmacies – Forum for Pharmaceutical Care in Community Pharmacy. Madrid, General Pharmaceutical Council of Spain, 2010. ISBN-13: 978-84-693-17174.

- As an expert in medicines, the pharmacist is the **more convenient healthcare professional to advise users about the correct disposal of out of date or unwanted medicines**.
- The pharmacist will perform a **periodic control of expiry dates** of medicines and medical devices. The management and disposal of these will be done using the normal channels (pharmaceutical distribution).

Role 2: Offer and Effective Management of the Pharmacological Treatments¹¹

Function A: Evaluate the Patient's Health Conditions and Needs

- **When providing any care service**, the pharmacist's main concern will be the wellbeing of the patients, evaluating their health condition, individual requirements and helping them to use their medicines responsibly and correctly.
- The **application of the procedures established by the Forum for Pharmaceutical Care in Community Pharmacy (PhC-CP Forum)¹⁰**, for Dispensing, OTC-Counselling & Dispensing and Medication Review with Follow Up Services, **guarantee that the evaluation of a patient's condition and his/her individual requirements are performed**.
- The pharmacist in order to be able to make an effective evaluation of the patient, as well as applying the specific procedures, will need certain **competences and communication skills** to adapt his/her speech to the level of education, cultural/religious beliefs, physical/mental capacity, etc. of patients and to guarantee that they receive and understand the information provided.
- The requirements for the evaluation of patients' health condition and needs will **also be applicable in the field of disease prevention and health promotion activities**.

Function B: Follow-up of Patient's Pharmacological Treatment

- The pharmacist will be able to perform the management of the patients' pharmacological treatments **in order to maximise the benefits and minimise the risks** inherent to the use of medicines.
- Within the activities to **contribute to improving medicine safety**, pharmacists may:
 - o Notify any suspected adverse event to the Pharmacovigilance Surveillance System for Medicines for Human Use using available channels.
 - o Inform users about the identification of any suspected adverse reaction and the possibility of directly report it.
 - o Disseminate information to users and other healthcare professionals about safety warnings affecting medicines.
- When necessary, and **in order to improve adherence** to the prescribed pharmacological treatment, the pharmacist may use different tools, amongst others the **Personalised Dosing Systems¹²**.
- The pharmacist will count on a **working system^o and access to a minimum amount of information** about the patient and available treatments.
- The **information** to which the pharmacist must have access must be **updated and based on the best impartial, integral and objective evidence available**. The pharmacist will have access to the Spanish Pharmacopeia and the National Formulary. He/she will also have access to medicines

¹¹ The management of pharmacological treatments refers to those services used to optimise pharmacotherapy in individual patients, specifically, the Medicines Review & Pharmacotherapy Follow up Service.

¹² Article 84 of Law 29/2006, in its modification by the Royal Decree-Law 9/2011, of 19th August, on actions to improve quality and cohesion of the National Health System, on the contribution to the fiscal consolidation and on raising of the maximum amount of the State guarantees for 2011, includes the fact that, "once a medicine has been dispensed [the pharmacists] may provide personalised dosage systems for patients who request them, in order to improve adherence and in the treatments and with the conditions and requirements that are established by the competent healthcare administrations".

databases, listings provided by authorities, reference books about interactions, side effects, dosage forms, compounded medicines and formulas, toxicology, pharmacology, treatment guidelines, scientific magazines, applicable legislation, etc.

- In order to get an efficient management, the pharmacist must have **access to the patient's pharmacotherapy details**. This access will include all the medication, both publicly and privately financed, prescribed in primary care and secondary care, self-medication that do not require a prescription and medical devices.
- The tendency will be towards the **interoperability of databases and registration systems** that contain information about patient's pharmacotherapy details. These should be shared databases between pharmacists and all healthcare professionals who intervene in the patient's care process. To optimise outcomes, **collaborative practice** is essential, along with having **communication protocols** amongst the different healthcare professionals.
- The pharmacist may **agree, with other healthcare professionals, on patient referral protocols** from community pharmacy to primary healthcare services or other healthcare services.
- The existence of **interoperable electronic prescriptions may contribute to the rationalisation** of the pharmaceutical provision and therefore, of the public expenditure on medicines. In turn, it may encourage the responsible use, improve adherence to treatments and conduct the Medication Review with Follow Up Service as well as the agreed referral guidelines or patient's medicines management.

Function C: Control Patient's Progress and Outcomes

- To carry out a correct follow up/monitoring and reach the expected health outcomes, the pharmacist needs to **record and document all the necessary data**, both about patient details and about his/her treatment, including information linked to the interventions performed and the results observed.
- The pharmacist will have available **support tools for the registration of the information** mentioned in the previous point (personal and healthcare details of the patient, background information, special physiological situations, medicines used, diseases or health problems referred, analytical tests results, anthropometric measurements, etc.).
- The pharmacist will have to **collaborate with other healthcare professionals** in order to guarantee patients' safety and to improve health outcomes. This cooperation must implicitly involve mutual trust.

Function D: Offer Information about Medicines and Health-Related Issues

- The pharmacist must use **active listening** techniques for the problems and queries that the patient can have and offer him/her **enough information** on health, diseases and medicines, in order to make him/her take part in a **shared decision-making process**.
- The pharmacist, if possible, will have to know the receptor's **level of understanding** as an essential element for the **best utilization of the information**.
- The provision of information will be performed **guaranteeing the patient's confidentiality**, and if possible, a differentiated and separate area will be available for this purpose within the pharmacy premises. Whenever possible, the pharmacy will have a personalised care area (PCA) available.
- Among informational activities, the importance of adherence to treatments, the appropriate use of antibiotics and the problem of resistances, the responsible use of medicines, etc., will be promoted. The pharmacists **will cooperate on training and information programmes both for citizens and for other healthcare professionals**.

Role 3: Help to Improve the Efficiency of the Healthcare System and Public Health

Function A: Disseminate Evidence-based Information about Medicines and Different Aspects of Self-Care and Public Health

- The pharmacist will play a **central role in the field of self-care and self-medication**. The pharmacist will be the main source of information about non-prescription medicines and will provide healthcare advice on different health problems and symptoms referred by the patient.
- The pharmacist will adopt **protocols for action** to treat health problems that may be susceptible to **self-care**.
- Likewise, the pharmacist **will collaborate in actions** to improve the knowledge and capabilities of population on **health promotion and disease prevention**. These actions may be developed either by the administration or by private bodies, professional organisations, patients' organizations, etc.
- The **information** about public health provided by pharmacists will be **based on the best scientific evidence available; will be understandable, accurate, adapted to patient's needs and will not have a commercial nature**. Ideally, the materials to be used for health maintenance and promotion and disease prevention should be adapted to a wide range of population, age groups and level of knowledge about health/disease.
- The pharmacist will also perform **health education tasks** for the population regarding the **search for healthcare information**, particularly about medicines, using reliable sources with acknowledged quality, especially on the Internet. The pharmacist will always recommend consulting the most appropriate healthcare professional in the case of any queries.

Function B: Participate in Preventive Care Services and Activities

- The pharmacist **will take part in healthcare campaigns**, cooperating in the dissemination of information about public health. These campaigns will be developed by the pharmacists themselves or cooperating with the authorities and other healthcare professionals.
- The pharmacist **will also offer services aimed at dealing with recognised public health problems**, such as obesity and smoking cessation, amongst others, as well, he/she will cooperate in vaccination strategies for the population.
- The pharmacist may take part in **early disease detection and screening programmes** promoted by the healthcare authorities.
- The pharmacist will also take part in the **detection of any possible public health problem** and in the **management of crisis and emergency situations that could arise**. The community pharmacy network may be used not only as a healthcare information point, but it may also provide any services deemed as appropriate in the event of these situations.

Function C: Comply with Professional Obligations, Guidelines and Legislation

- Pharmacists must observe **the obligations, provisions and recommendations established** in the legislation in force and the ethic codes laid down by the Professional Pharmacy Organisation and by scientific societies, ensuring that they are kept constantly up to date on these points.

Function D: Recommend and Support National Policies that Encourage Better Health Outcomes

- The pharmacist must **help** the citizens and groups of professionals **to encourage, evaluate and improve community's health**.

- The pharmacist will take part in the development of policies that encourage the **improvement of adherence to treatments, the responsible use** of medicines and facilitate medication **conciliation** throughout the different levels of healthcare.
- The pharmacist may collaborate in **management programmes for chronic or polymedicated patients**.

Function E: Contribute to the Efficiency of the Health System

- The pharmacist **will contribute to an efficient, high quality and satisfactory, in terms of meeting the needs of population, healthcare system**. In such a way that:
 - o Will prioritize solely and exclusively the **public interest and health** in his/her professional performance.
 - o **Healthcare criteria will always prevail over** economic interests.
 - o Will take part in the **control and rationalisation of public expenditure in** medicines through the Dispensing Service.
 - o Will improve the **availability and accessibility to** a range of **services**, such as preventive activities, services to improve adherence to treatments, Medication Review with Follow Up (particularly for chronic and/or polymedicated patients), etc.
 - o Will take part in the **reporting of any suspected medicines adverse reactions** to the Spanish Pharmacovigilance System for Medicines for Human Use.
- Through **arrangements** between the Professional Pharmacy Organisation and the Administration, pharmacists **will guarantee that population has a fair and effective access to the pharmaceutical provision and services**.
- The pharmacist's involvement in the **detection of medicines related problems** and his/her intervention to avoid associated negative outcomes, as well as medication mistakes, will reduce unnecessary expenses to the system. This action by the pharmacist will allow the detection of unnecessary treatments and complications due to the incorrect use of the medicines, which will imply a cost saving in expenses to the system, in visits to the GP or other healthcare professionals, hospital admissions, absenteeism from workplace, etc.
- The pharmacist **will contribute to the reduction of work and bureaucratic burden** to the healthcare system, with his/her potential on self-care and self-medication, and through the electronic prescription system, avoiding medical consultations for repeat prescriptions in long-term treatments, as well as those other new technological tools (ICT) that could arise and be suitable for this purpose.

Role 4: Maintain and Improve Professional Performance, Collaborate with Teaching and Participate in Research Activities

Function A: Arrange and Implement Continuous Professional Development Strategies to Improve Performance Today and in the Future

- The pharmacist must understand that **continuous education and continuous professional development** are activities that must be developed throughout the pharmacist's professional life in order to **adapt and up-date his/her knowledge, skills and aptitudes** to the advancement of the pharmaceutical sciences and practice. Continuous Education will include the participation in **courses, seminars, scientific congresses**, professional meetings, publications, scientific magazines, participation in healthcare campaigns, etc.
- Likewise, the pharmacist may take part in **training** courses and activities related to **new technologies** and their implementation (electronic prescription, on-line education, mobile devices, etc.).

- The **professional organisations and other bodies must provide continuous education courses adapted** to the changing needs of the pharmaceutical profession, as well as tools to allow self-evaluation of competences.

Function B: Participate in Competence-Acquiring Activities for Future Pharmacists

- Within the functions of the Spanish community pharmacies is that of **collaborating in the acquisition of competences** to obtain the Pharmacy qualification.
- The pharmacist, during the tutored compulsory training period of the student, will be **responsible for the acquisition of the foreseen competences and will take part in the evaluation of the aforementioned period.**
- The pharmacist may cooperate in the university education, as established in the curricula, to **provide training both in theory and in practice for future pharmacists.**
- The pharmacist must **try to ensure that pharmacy staff holds the suitable and up to date training** for the tasks to be performed. Likewise, **the pharmacist will take part and encourage the continuous education of pharmacy technicians and pharmacy assistants.**

Function C: Participate in Research and Development Activities

- The pharmacist must become involved in research and development, innovation and transfer activities, both in the field of the **development of new medicines** and in that of **research in pharmacy practice.** The pharmacist will be able to **develop and implement new cost effective pharmaceutical services** that respond to the needs of the population and of the healthcare system, research about the **responsible use of medicines**, perform **pharmacoepidemiology and pharmaco-economy** studies, etc.
- The pharmacist who takes part in research, development, innovation and transfer activities must follow the **specific protocols** for each of the studies in which he/she is involved.
- The performance of research activities in pharmacy practice will be promoted in **collaboration** with other **healthcare professionals, universities and private and public bodies.**

Implementation of Good Pharmacy Practice in Community Pharmacy

The implementation of Good Pharmacy Practice in Community Pharmacy involves the participation of pharmacists in the four roles previously described in this document:

- **Role 1: Acquisition, custody, conservation, preparation, dispensing and disposal of medicines and medical devices.**
- **Role 2: Offer an effective management of the pharmacological treatments.**
- **Role 3: Help to improve the efficiency of the healthcare system and public health.**
- **Role 4: Maintain and improve professional performance, collaborate with teaching and participate in research activities.**

The functions and activities that are grouped together in each of the roles, and that must be kept present for a suitable pharmacy practice, are included in this document.

For the correct development of these activities, procedures of minimum requirements will be developed as annexes to this document.



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