Pharmaceutical Care Forum

Consensus document
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Forum Participants

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- National Royal Academy of Pharmacy (Real Academia Nacional de Farmacia)
- General Council of Official Pharmaceutical Associations (Consejo General de Colegios Oficiales de Farmacéuticos)
- Spanish Society of Primary Care Pharmacists (Sociedad Española de Farmacéuticos de Atención Primaria, SEFAP)
- Spanish Society of Community Pharmacy (Sociedad Española de Farmacia Comunitaria, SEFAC)
- Spanish Society of Hospital Pharmacy (Sociedad Española de Farmacia Hospitalaria, SEFH)
- Pharmaceutical Care Foundation, Spain (Fundación Pharmaceutical Care España)
- Pharmaceutical Care Research Group of the University of Granada (Grupo de Investigación en Atención Farmacéutica de la Universidad de Granada)

The Forum wishes to thank the participation and collaboration in the work meetings of those professionals who through their effort and dedication have contributed to the creation of this Document.

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Contents

Introduction

The generalization of Pharmaceutical Care (PC) in Spain constitutes a commonly declared objective of the profession. However, its implementation has suffered delays for a number of reasons, including a lack of unity in the messages generated by the experts and the institutions.

On the other hand, society as a whole is demanding increased implication on the part of the pharmaceutical professional in benefit of the health of citizens. The rise in visits to the emergency units related to the use of medicines (one out of every three patients), or the increase in hospital admissions because of results that are not compatible with the objectives of pharmacological treatment (two out of every 5 admissions), are examples clearly illustrating that a change is needed in professional practice. It has been calculated that a full 75% of all such problems could be avoided through optimization of patient pharmacotherapeutic management.

In February 2004, the Pharmaceutical General Council impulsed the formation of a group for constructive debate composed of representatives from different institutions in all settings of interest to PC, and with the commitment of becoming implicated in the project – which became known as the Pharmaceutical Care Forum (Forum).

This document reflects the recommendations of the Forum in five areas in which it was found to be necessary to work in order to advance in the generalized implementation of PC. The document aims to facilitate work in PC based on scientific evidence and current legislation, and adapting day-to-day practice to each individual patient – the latter being the fundamental reference of health care.

Opening declaration

The Pharmaceutical Care Forum (Forum) is a group for debate on the future of Pharmaceutical Care, conceived with the purpose of establishing the means and strategies needed for its diffusion and development, and conformed by the following entities:

- General Directorate of Pharmacy and Health Care Products of the Spanish Ministry of Health and Consumer Affairs (Dirección General de Farmacia y Productos Sanitarios del Ministerio de Sanidad y Consumo)
- General Council of Official Pharmaceutical Associations (Consejo General de Colegios Oficiales de Farmacéuticos, CGCOF)
- National Royal Academy of Pharmacy (Real Academia Nacional de Farmacia)
- Spanish Society of Primary Care Pharmacists (Sociedad Española de Farmacéuticos de Atención Primaria, SEFAP)
- Spanish Society of Community Pharmacy (Sociedad Española de Farmacia Comunitaria, SEFAC)
- Spanish Society of Hospital Pharmacy (Sociedad Española de Farmacia Hospitalaria (SEFH)
- Pharmaceutical Care Foundation, Spain (Fundación Pharmaceutical Care España)
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Forum began its trajectory in 2004, with the aim of working on a document reflecting the perspectives, previsions and recommended intervention protocols in Pharmaceutical Care. This document attempts to work in-depth in all those aspects that may serve to enhance the practical development of Pharmaceutical Care, stimulate participation on the part of the pharmaceutical professional, provide such professionals with the required means, identify the needs in relation to the upgrading of knowledge, and divulgate all these objectives.

To this effect, five working areas have been defined:

JUSTIFICATION

- It is necessary for the profession to evolve towards the practice of health care, thereby adding value to intervention on the part of the pharmacist.
- There is a social need to draw the maximum benefit from the use of medicines, and to limit their associated risks.

MOTIVATION

- It is necessary to accelerate the change in professional orientation with a view to cover the detected demands.
- The patient of the pharmacist is a key element in the advance of Pharmaceutical Care.

INSTRUMENTS

- The structure, technology and means must adapt to the professional orientation represented by Pharmaceutical Care.

TRAINING

- Pharmaceutical Care implies the need for new knowledge and skills that are essential for putting it into practice.

DIFFUSION

- It is necessary to increase knowledge of Pharmaceutical Care among pharmacists, physicians and other health care professionals, the Health Authorities, and the general population.

Forum will present a **Document** with the results of the global work done by the participating institutions, and related to each of the above defined working areas.

Madrid, December 2004

Preamble

In December 2005, the institutions participating in the Forum decided to publish and diffuse the attached document among all pharmacists, reflecting the global commitment of the profession to the development of Pharmaceutical Care as a professional practice model.

Institutional declaration: our commitment from 1 to 10

1. **Pharmaceutical Care is the active participation of the pharmacist in ensuring improved patient quality of life, through dispensing, OTC prescription and pharmacotherapy follow-up.**
   Such participation implies cooperation with the physician and other health care professionals in order to secure outcomes that improve patient quality of life, as well as pharmacist intervention in activities that offer good health and avoid the development of diseases.

2. **The patient is central to the activity of the pharmacist.**
   Pharmaceutical Care can be implemented in all health care settings: community pharmacy, primary care, and hospital pharmacy.

3. **The systematic and universal application of Pharmaceutical Care is favored with the purpose of ensuring equity in the health care service provided.**
   Pharmaceutical Care makes a significant contribution to reducing the problems related with drug use, helping to improve compliance and effectiveness, and thus promoting rational drug use.

4. **Pharmaceutical Care is to be developed in order to ensure that the patient derives maximum benefit from medicines, while limiting their associated risks.**
   Recent data indicate that over 30% of all visits to the emergency units, and up to 6% of all hospital admissions, are associated with drug-related problems, and over 50% of all chronic patients are poorly controlled.

5. **The pharmacist is the ideal professional for developing this health care activity, through commitment to training and learning on a permanent basis.**
   University education defines pharmacists as drug experts. In addition, as a result of their accessibility and closeness to the general population, pharmacists are key elements in patient health care, within the context of the global health care team.

6. **Optimization of the health care potential of pharmacists is indicated through Pharmaceutical Care.**
   Pharmaceutical Care contributes to health care function, focusing professional activity on health care activities related to optimum drug use and health education. Such activity in turn will contribute to reinforce social and institutional recognition of the pharmacist, and will serve to generate new expectations in the professional career, in accordance with the qualification of these professionals.

7. **The use of standardized Pharmaceutical Care procedures is promoted.**
   Such procedures facilitate the decision taking process in identifying, preventing or resolving problems related with the use of medicines, associated negative outcomes, and moreover promote participation in the global health care team.

8. **Use is indicated of the available scientific evidence as a basis for putting Pharmaceutical Care into practice.**
   Practical experience warrants Pharmaceutical Care, and it has been shown to be useful in preventing and correcting problems related to drug use, the associated negative outcomes, and in improving patient quality of life.

9. **Organization of human and material resources for the practice of Pharmaceutical Care is required.**
   Many pharmacists have found that it is both possible and satisfactory to adapt the available resources to the practice of Pharmaceutical Care. In addition, the latter improves cooperation with other health care professions, and establishes an optimum and continuous relationship with the patients – helping them to resolve daily health problems.

10. **The implication of all in Pharmaceutical Care is required.**
    The development of Pharmaceutical Care requires the implication of all. Only through individual effort and firm support from the Professional Organizations can this professional practice become generalized. The General Council and the Health Administrations, by encompassing all the college-registered pharmacists, represent the best way to consolidate Pharmaceutical Care.

Your effort is necessary.
We are all committed to Pharmaceutical Care. Remember that all the Forum members are at your disposal.
Please do not hesitate to contact them if further information is desired.

Justification

Introduction

Pharmacists, as part of the National Health Care System, share with patients, physicians, other health care professionals, and the Health Authorities the mission of guaranteeing the safe, effective and efficient use of medicines. In this multidisciplinary setting, the pharmacist must contribute specific knowledge and skills to improve patient quality of life in relation to pharmacotherapy and its objectives.

The current challenge for pharmacists is to satisfy the new needs of patients in concordance with the requirements of the Health Care System, which increasingly needs to attend a growing number of patients, and which continuously incorporates new technological developments. In this context it is necessary to take advantage of the potential of pharmacists to improve health care, with a permanent demand for coordination of the interventions on the part of the different agents implicated.

This perspective comes in response to the demands of a society which is increasingly concerned about well being, and with a need for information and education in relation to all aspects associated with the concept of health.
Pharmacists have adapted to the different transformations experienced by the health care setting. Examples of this can be found in the development of clinical pharmacy, collaboration in health education, and the promotion of rational drug use.

However, the concept of health, in its broadest sense, implies the full use of all health care resources – reinforcing the multidisciplinary health care team, and in particular coordination between physicians and pharmacists, with a view to increasing the therapeutic benefits of medicines. Pharmacists, on the basis of their experience and training, must have greater participation in the processes of drug-related health care, since the effectiveness and safety of medicines are not exclusively dependent upon the high quality criteria applied to their manufacture.

The importance of this is reflected by a number of epidemiological data. As an example, in Spain, over half of all patients with chronic illnesses do not comply adequately with the prescribed treatment [1]. In turn, one-third of all visits to the emergency service are attributable to undesired effects of medicines, and 70% of these situations are moreover avoidable [2].

1. Martínez-Mir I, Palop V. El problema del incumplimiento terapéutico en diferentes áreas. In: Cumplimiento Terapéutico. SEMFYC, SEFAP Eds. Madrid, 2001.
2. Baena I. Problemas relacionados con los medicamentos como causa de consulta en el servicio de urgencias del Hospital Universitario Virgen de las Nieves de Granada (Doctoral Thesis). Ed. Ergon. Madrid, 2004.

Pharmacists can contribute to ensure that adequate therapeutic clinical outcomes are obtained, and are largely able to avoid the appearance of drug-related problems (DRPs) and negative medicine outcomes (NMOs) due to the implementation of Pharmaceutical Care (PC), which in accordance to the Consensus Document of the Ministry of Health and Consumer Affairs [3] consists of the following:

- **Dispensing** [4], which implies active intervention on the part of the pharmacist for the provision of medicines.
- **OTC prescription** [5], which implies helping the patient in correctly deciding self-care of health.
- **Pharmacotherapy follow-up** [6], which is based on increased implication of the pharmacist in the monitoring and systematic documentation of the treatment received by the patient.

The proactive attitude in drug dispensing and in OTC prescription is rooted in the professional practice of pharmacists, though increased orientation towards the patient and generalization would be required, as well as adequate documentation and protocolization of the interventions made. In contrast, pharmacotherapy follow-up is a new service that requires a different implication on the part of pharmacists, as a result of continuous commitment to the outcomes of integral patient management.

The aim of the present chapter (*Justification*) is to define the necessary evolution of current pharmaceutical professional practice towards a more patient-centered orientation, and following the consensus-based tendencies in Pharmaceutical Care.

Dispensing

The definition of dispensing implies that it never can be purely mechanical – thus differentiating dispensing from the simple delivery of medicines with or without a medical prescription.

The first objective of dispensing is to guarantee access to the medication. However, the repeated verification of largely avoidable pharmacotherapy failures, with the resulting health problems, points to the need for more committed and active professional intervention, through responsible pharmaceutical practice. Of note is the fact that such practice implies that pharmacists accept responsibility for all dispensed medicines – not only when the patient specifically requests help.

3. Consensus Document on Pharmaceutical Care. Ministry of Health and Consumer Affairs. December 2001.

4. The Consensus Document on Pharmaceutical Care of the Ministry of Health and Consumer Affairs (2001) defines dispensing as the service offered by the pharmacist, based on an active attitude, in response to citizen demand for a concrete drug product – generally involving a medical prescription, or without a prescription, if the patient opts for self-medication. Intervention extends beyond simple delivery of the medicine, and aims to discriminate the existence of potential problems, while also offering instructions on adequate use of the medicine in question.

5. The Consensus Document defines OTC prescription as the service offered by the pharmacist when a patient consults about a possible treatment for some specific health problem, i.e., when the patient asks "What would you recommend for…? In this case intervention always must be referred to those self-limited symptoms or syndromes for which legislation allows drug dispensing without a medical prescription. Referral to a physician, if necessary, is also contemplated.

6. The Consensus Document defines pharmacotherapy follow-up as the professional practice in which the pharmacist assumes responsibility for the drug-related patient needs, through the detection, prevention and solution of drug-related problems on a continuous, systematic and documented basis - in cooperation with both the patient and the rest of health care professionals, with the purpose of securing specific outcomes destined to improve patient quality of life.

When a prescription is needed to provide this service, review of the regulations and the observance of all those implicated in complying with such regulations, will contribute to reach the objectives of dispensing.

Dispensing can help identify and resolve risk situations related to deficient use, a lack of understanding of the therapeutic purpose of medication, inadequacy attributable to the use of other medicines, or the presence of other health problems. Some of these important problems can be avoided or corrected by means of this dispensing service.

Key points

- **Dispensing, as a key part of the professional activity of the pharmacist, guarantees population access to medicines, and is able to avoid and correct some drug-related problems.**
- **Active implication of the pharmacist in drug dispensing causes citizens to view medicines as a health resource – not simply as a consumer product. In addition, such implication serves to reinforce the patient-pharmacist relationship.**
- **Medical prescription, as an essential element in the dispensing process, is a crucial instrument for improving health care in benefit of the patients.**

OTC prescription

The International Pharmaceutical Federation, in a joint declaration with the World Self-Medication Industry (WSMI)[7], states that “pharmacists have the professional obligation to provide objective counseling on self-medication and the medicines available to the effect”, and to “recommend medical help if the patient admits that self-medication is not appropriate”.

Responsible self-medication is recommended by the principal international organizations such as the World Health Organization (WHO)(1998) and the European Council (2001), and is understood to imply that the patient is committed to the self-care of health through healthy habits, and with the use of medicines that do not require a medical prescription for those disorders which do not need a precise diagnosis.

7. Joint declaration of the FIP and WSMI on responsible self-medication. The Hague, June 10, 1999.

In its document "The Role of the Pharmacist in Self-Care and Self-Medication" [8], the WHO assigns an important role to pharmacists in relation to self-medication, stressing their functions as *communicators* (starting dialogue to obtain a detailed history of the medication previously received, and to secure a rapid review of the disease antecedents of the patient); *qualified dispensers of medicines* (ensuring the quality of the drugs dispensed); *educators and supervisors* (to ensure continued upgrading of both their own knowledge and that of their co-workers); *collaborators* (establishing optimum relations for cooperation with all the health care agents); and *health promoters* (with participation in global health-promoting campaigns).

Current Spanish legislation, as stated in Law 29/2006 [9], of July 26, relating to guarantees and the rational use of medicines and health care products, acknowledges the importance of self-care and the role of the pharmacist: "*The idea is to adapt legislation to the social realities of the XXI century, where the use of medicines without a prescription, under the established conditions for use, is becoming increasingly common. However, such practice should adhere to the principles of rational drug use, and in this sense the role of the pharmacist is crucial in reference to all aspects related to responsible self-medication. Drugs not subject to medical prescription are those which are used to treat processes or conditions that do not require a precise diagnosis, and which present toxicological, clinical and utilization and administration route specifications that do not make prescription necessary - thereby allowing their use in the context of self-care through dispensing in a community pharmacy by a pharmacist, who in turn will inform, advise and instruct the patient on correct utilization of the product".*

Help in choosing a medicine that does not require a medical prescription, or other non-pharmacological treatment measures, or patient referral to a physician if necessary, also requires pharmacists to protocolize and document their work through the use of intervention guides. Cooperation between physicians and pharmacists is therefore essential in order to establish consensus-based criteria for the referral of patients to medical consultation.

Key points

- **OTC prescription is commonly demanded in the community pharmacy, where the pharmacist – as health care agent – play a key role, optimizing the use of medicines in self-limiting disorders.**
- **The development of a standardized methodological process, of consensus-based criteria for physician referral, and pharmacotherapeutic guides, are all very useful tools for correctly dealing with these situations so often seen in community pharmaceutical practice.**

8. The Role of the Pharmacist in Self-Care and Self Medication. World Health Organization 1998. Report of the 4th WHO Consultive Group on the Role of the Pharmacist. The Hague, The Netherlands 26-28 August 1998.

9. Law 29/2006, of July 26, relating to guarantees and the rational use of medicines and health care products (BOE 178, of 27/07/2006).

Pharmacotherapy follow-up

Different international organisms such as the WHO (1993) [10], the European Council (2001) [11], or the International Pharmaceutical Federation (1993) [12] recommend the implementation of the service of Pharmacotherapy follow-up as "*a patient health care need*", reflected as an obligation by Spanish law since 1997 [13], and confirmed in the recent law on guarantees and the rational use of medicines and health care products [9] – article 84.1 of which establishes that "*In community pharmacies, the pharmacists – as professionals in charge of drug dispensing to citizens – will ensure compliance of the regimen established by the prescribing physician, cooperating with the latter in the follow-up of patient treatment through Pharmaceutical Care, and contributing to ensure the efficacy and safety of the treatment provided. Likewise, the pharmacist will participate in the activities destined to secure rational drug use, particularly as refers to informed dispensing to patients*".

Article 81.2 in turn specifies that primary care, among other functions, must "*Establish a system for the follow-up of the treatments of the patients, contributing to guarantee adherence to therapy, as well as programs destined to promote safe drug use*".

In reference to hospital and specialized care, article 82.2 states that "*In order to contribute to rational drug use, the hospital pharmacy units or services will carry out the following functions: guarantee and accept technical responsibility for the acquisition, quality, correct storage, the covering of needs, custody, the preparation of galenic or office formulations, and dispensing of the medicines required for the in-hospital activities and those other activities which – in the context of out-hospital care – demand special vigilance, supervision and control*".

Among other factors, the result of pharmacological treatment depends on the follow-up carried out by different professionals, including the pharmacist. The latter possesses the training needed to this effect, and is able to relate health problems to the effects of the medicines used by the patient; detect associated problems; and prevent and resolve those negative results associated with the need, effectiveness and safety of drug substances. The pharmacist is also able to contribute a complementary approach to follow-up conducted by other health care professionals, and can thus contribute to equip health care with the required multidisciplinary character.

10. The role of the pharmacist in the health care system. Report on the Meeting of the WHO. Tokyo, Japan. August 31 to September 3, 1993.
11. Council of Europe, Committee of Ministers. Resolution ResAP (2001) concerning the pharmacist's role in the framework
of health security. Adopted by the Committee of Ministers on 21 March 2001 at the 76th meeting of the Ministers´
Deputies. http://cm.coe.int/ta/resAP/2001/2001xp2.htm (6 February 2004).
12. The Tokyo Declaration. Good Pharmaceutical Practice: Quality Norms for Pharmaceutical Services. International Pharmaceutical Federation (FIP). Tokyo, Japan. 1993
13. Law 16/1997, of April 25, Regulating the Services of Community pharmacies (BOE 100, of 26/04/1997).

On the other hand, as a result of their accessibility and closeness to the general population, and their knowledge of the full patient pharmacotherapy, pharmacists are the ideal professionals for conducting pharmacotherapy follow-up.

Morbidity-mortality related to drug use constitutes an important public health problem, in view of its great prevalence and consequent economical cost. Over 35% of all emergency units consultations and up to 6% of all hospital admissions are attributable to drug-related problems. On the other hand, over 70% of these problems could be avoided if adequate pharmacotherapy follow-up were implemented [2].

Increased implication of the pharmacist is needed in evaluating the outcomes of patient treatment, based on pharmacotherapy follow-up, with the purpose of identifying, preventing and resolving possible drug-related problems – and thus contributing to avoid or minimize the negative results associated with pharmacotherapy.

Key points

- **Morbidity-mortality related to drug use constitutes an important public health problem that can be reduced by pharmacotherapy follow-up conducted by the pharmacist.**
- **The implementation of pharmacotherapy follow-up represents an opportunity for cooperation among different health care professionals, with a view to improving patient health.**

Motivation

The legal setting and Pharmaceutical Care

Current Spanish legislation defines the activity of the pharmaceutical professional and establishes regimens, functions and norms of obligate application related to the practice of Pharmaceutical Care.

On one hand, Law 16/1997 [13], relating to regulation of the services of community pharmacies, defines the latter as "*private health care establishments of public interest*", in which medicines are dispensed to patients, with the provision of advice and information on their use; compounding is performed; and collaboration is ensured with patients and the Public Administration regarding rational drug use and different health care services of general interest.

This law addresses a broad range of functions which, from the community pharmacies, are developed in the context of the evolution of professional activity:

- *The acquisition, custody, storage and dispensing of medicines and health care products.*
- *The vigilance, control and custody of the dispensed medical prescriptions.*
- *The guarantee of Pharmaceutical Care in the corresponding pharmaceutical recruitment zone, to those population nuclei that have no community pharmacies.*
- *Compounding, in the established cases and according to the specified procedures and controls.*
- *Information and follow-up of patient pharmacological treatment.*
- *Collaboration in the control of individualized drug use, in order to detect possible adverse reactions and report them to the corresponding pharmacovigilance authorities.*
- *Collaboration in the programs promoted by the Health Administration relating to the quality assurance of Pharmaceutical Care and health care in general, the promotion and protection of health, the prevention of diseases, and health education.*
- *Collaboration with the Health Administration in training and information destined to the rest of health care professionals and users in relation to the rational use of medicines and health care products.*
- *Intervention coordinated with the health care structures of the Health Services of the different Spanish Autonomous Communities.*
- *Collaboration in training and education for the title of Degree in Pharmacy, based on the specifications of the corresponding Community Directives and the State and University regulations establishing the corresponding study plans applicable in each case.*

Many of the described activities are included within the setting of Pharmaceutical Care [3], defined in the Consensus Document of the Ministry of Health as "*Active participation of the pharmacist in patient care, in the dispensing and follow-up of pharmacotherapy – thereby cooperating with the physician and other health care professionals with the purpose of securing results that improve patient quality of life. Pharmaceutical Care also implies pharmacist implication in the activities that offer good health and contribute to prevent disease*".

Law 16/2003, relating to the cohesion and quality of the National Health Care System [14], establishes that "*Community pharmacies will cooperate with the National Health Care System in affording pharmaceutical services, to guarantee the correct use of medicines. To this effect pharmacists are required to act in coordination with the physicians and other health care professionals.* In turn, article 16 establishes that "*Pharmaceutical service comprises medicines and health care products, and the global interventions for ensuring that patients receive them adequately in relation to their clinical needs, at the precise doses defined by their individual requirements, for the appropriate period of time, and at the least cost possible for them and for the community as a whole*".

Law 29/2006, relating to guarantees and rational use, the new regulation of June 29, 2006 [9], the norm replacing the Drug Law of 1990 and harmonizing Spanish legislation with respect to the European Community procedures for drug authorization and control, establishes that in order to ensure rational drug use, "*The pharmacist will demand a prescription to dispense those medicines that require a prescription, and cannot personally prescribe a medicine that requires a medical prescription. However, the pharmacist may cooperate in the pharmacotherapy follow-up of the prescribed treatments, though the procedures relating to Pharmaceutical Care*".

This Law, in its article 84, considers community pharmacies to represent private establishments of public interest, and states that "*Pharmacists, as the professionals in charge of drug dispensing to the public, will ensure compliance with the regimen established by the prescribing physician, and will cooperate with the latter in the follow-up of therapy through the procedures contemplated by Pharmaceutical Care – contributing to ensure its efficacy and safety. Likewise, pharmacists will participate in the global activities destined to secure rational drug use, particularly as refers to informed dispensing to patients*".

On the other hand, the legislations applicable in some Spanish Autonomous Communities in relation to pharmaceutical practice explicitly cite the need for development of the professional model in its broadest sense, oriented towards the patient, as advocated by the professional practice of Pharmaceutical Care.

14. Law 16/2003, of May 28, relating to the cohesion and quality of the National Health Care System (BOE 128, of 28/05/2003).

Situation of the implementation of Pharmaceutical Care in Spain

In recent years there have been important advances in the development of standardized procedures in the practice of Pharmaceutical Care in this country, as a response to legislation pointing to the need for responsible implication on the part of the pharmacist in the optimized use of medicines and their outcomes.

There is no doubt that pharmacists in the different professional settings (hospitals, primary care, and community pharmacy practice) carry out certain aspects relating to responsible dispensing, informing patients on the treatments dispensed, adopting an active role in the control of drug use, and following-up on the treatments with the purpose of detecting, preventing and resolving drug-related problems / negative medicine outcomes (DRPs / NMOs). However, it seems clear that much remains to be done in order to achieve universal coverage for some of these services.

Forum is aware that the efforts made to date are helping the evolution of the pharmaceutical professional, though it seems advisable to examine the true degree of the development of Pharmaceutical Care in Spain today.

In effect, Forum estimates that only 10% [15] of the professionals participate in point activities related to Pharmaceutical Care (from dispensing to pharmacotherapy follow-up) on a homogeneous and systematic basis, and including consequent registry. **Pharmacist motivation must play a key role in the development of Pharmaceutical Care.**

In this chapter (*Motivation*), Forum intends to reflect the possible benefits which Pharmaceutical Care can offer both patients and the professionals and society as a whole. This principle may be the starting point for achieving global implication on the part of the professional sector, from the basis of motivation.

Benefits of Pharmaceutical Care, the basis for motivation

The evolution and even change of any aspect related to the practice of the pharmaceutical profession requires an important personal effort, with satisfaction for the pharmacist from the personal, social or professional perspective, in order to secure individual and collective motivation.

In order to generalize evolution of the professional model, it is necessary to identify the reasons leading to a change in attitude among pharmacists, with a view to accelerating the change in orientation. Knowing what needs and achievement are required by the pharmacist to modify his or her professional activity in favor of a more health care-oriented model would mean having achieved the necessary motivation to allow Pharmaceutical Care to advance.

15. Pharmacists. Number 308. Consejo General de Colegios Oficiales de Farmacéuticos. March 2006. Madrid.

Benefits for the patient as an individual

Improvement of the service received

- The patient can perceive and receive an improved level of care as regards his or her individual needs with respect to medication.
- The development of Pharmaceutical Care and its generalized application ensures homogeneous and standardized pharmaceutical service in all pharmaceutical professional settings.
- Service quality is guaranteed in both public and private pharmacy services.
- The great accessibility of the community pharmacies network makes it possible to offer this service when the patient needs it, thereby contributing to generate new habits and flows in the demand for services.

Benefits for society

Optimum drug use

- Pharmaceutical Care significantly reduces the problems and negative outcomes associated with medicines use in the population.
- Pharmaceutical Care helps rationalize health care expenditure associated with medicines, improving compliance, reducing the number of hospital admissions, increasing drug effectiveness, and minimizing the possible deleterious effects of medication.
- Pharmaceutical Care guarantees equity in the health care service provided.
- Pharmaceutical Care is able to contribute to improve the quality of life of the population.

Benefits for the pharmaceutical profession

Social and institutional recognition

- Due to the opportunity for change represented by Pharmaceutical Care in the profession.
- Due to social perception of the pharmacist as a health care professional.
- Due to active participation in improving the results of pharmacological treatment, represented by responsible implication of the pharmacist in health care processes.

Global redefinition of professional activity

- Pharmaceutical Care unifies the concept of professional practice, regardless of the professional setting or level in which the pharmacists may happen to work.
- The needs of society, related to safe drug use and the achievement of results in line with the therapeutic objectives, demands a professional definition that includes Pharmaceutical Care.

- The necessary evolution of the profession inevitably requires the implementation of Pharmaceutical Care.

The opening of new routes for professional development

- The implementation of Pharmaceutical Care will generate professional career expectations better suited to the training and qualification of the pharmacist.
- The progressive development of Pharmaceutical Care will imply the incorporation of a larger number of professionals to the work setting.

Benefits for the pharmacist

Professional satisfaction

- The practice of Pharmaceutical Care represents a more active implication on the part of the pharmacist in the health care process of each patient.
- Individual recognition by the attended patients.
- Participation in multidisciplinary teams, as another health care member.
- The acceptance of new and important responsibilities that allow for professional evolution.
- Increased professional recognition.
- Pharmaceutical Care, in any of its services or activities, generates an optimum relational setting that facilitates close and lasting ties among the professional, the patient, and the rest of health care professionals.

In sum, the Forum stresses that the national and autonomous legal setting contemplates the practice of Pharmaceutical Care as part of the professional activity of the pharmacist. Motivation among this profession is largely related to the undeniable benefits of such activity for patients, society and pharmacists alike. It is the aim of the Forum, and of the institutions that participate in it, to transmit a message that is both unified and coherent with the current situations, in order to ensure that motivation proves effective and is able to ensure the generalized practice of Pharmaceutical Care.

Forum proposal. Actions to improve motivation

With the purpose of favoring motivation among the professionals in the practice of Pharmaceutical Care, the Forum suggests a series of specific actions that could be implemented both individually by the associations and entities participating in the Forum, and on a collective-consensual basis.

- The development of **communication campaigns** designed to sensitize pharmacists, other health care professionals and society in general.
- The promotion of **legal measures** to facilitate introduction of the health care activities, in collaboration with other health care agents.
- A request for the **development of consensus-based norms** allowing uniform definition of the pharmaceutical functions.

- The elaboration of interventional guides coordinated with other health care agents, along with **good practice codes** and the **establishment of standard operating procedures (SOPs)**, in the context of ongoing and continuous improvement in service quality.
- The establishment of **cooperative references** through the different professional organizations and entities, to facilitate active participation of the pharmacist in the multidiscipline health care team.
- The sharing of **experiences** with other health care professionals, promoting working sessions, joint training courses, and clinical sessions, in collaboration with the respective Colleges (to be related to Training and Communication…).
- The accreditation of Pharmaceutical Care: recognition of health care implication on the part of the pharmacist through specific stimuli that favor the development of a **professional career**.
- The offering of adequate capacitation and training for the development of health care activity in Pharmaceutical Care.
- The generation of **opinion flows** through professional leaders, with the aim of conveying to the pharmaceutical profession the need and opportuneness of offering Pharmaceutical Care services to the population.
- The establishment of optimum feedback mechanisms for improved follow-up of **drug-related problems / negative medicine outcomes (DRPs / NMOs)**, complying where required with current legislation regarding the Spanish National Pharmacovigilance System.

Diffusion

Definition and antecedents

The aim of this chapter is to address communication of the concept of Pharmaceutical Care (PC), analyzing the role it may play in the successful implementation of such professional practice, and defining objectives which to date have not been reached but which are essential.

It is clear that an adequate diffusion strategy, targeted both to society in general and to the different stakeholders implicated in health care, is essential to ensure that the concept of Pharmaceutical Care becomes universalized and its practice generalized.

To date, the concept and practical meaning of Pharmaceutical Care have not been clearly transmitted to all pharmacists, and this may be one of the key reasons why its implementation has been less than expected. Pharmaceutical Care may have been viewed more as a bureaucratization process than as a health care support process; as a result, pharmacists may believe its application to be “just one burden more”.

In recent years, the initially implicated work groups have generated different tendencies within the global concept of Pharmaceutical Care. Although much of the work philosophy of these experts is shared by all of them, and aims to secure adequate development of the pharmaceutical profession through specific programs, the fact is that different and even contradictory messages have been generated, leading to confusion.

It is also possible that the concept and purpose of this professional practice has not been correctly transmitted to the medical profession. This has generated some barriers, due to a lack of any clear perception of what benefits can be expected from this professional activity. There is no doubt that to date, the medical profession is unaware of the scope of Pharmaceutical Care (functions, objectives, setting, etc.). In particular, physicians are unaware that Pharmaceutical Care implies a pharmacist wish to cooperate and participate in the health care teams, addressing aspects which at present are difficult to cover by other professionals. In some cases this situation has generated mistrust among the medical professionals.

On the other hand, society as a whole also knows little about Pharmaceutical Care, since there has been no genuine implementation of the service, and no efforts have been made to date to inform about this activity of the pharmaceutical profession in any health care setting – except in rare instances, and on an individualized basis.

One of the initial objectives of the Forum is to unify the messages on Pharmaceutical Care that are transmitted to the profession and to the different implicated agents, developing homogeneous communication. The aim is for Pharmaceutical Care to be perceived as a guarantee of professional service

quality, and to be interpreted in a standardized manner by all those who receive the information.

The **innovative character** of Pharmaceutical Care also may have been one of the reasons for the defects in communication observed to date. It is obvious that many of the activities included in dispensing, OTC prescription or pharmacotherapy follow-up form part of the daily professional activity of the pharmacist. In the hospital setting, the protocolization of follow-up is a consolidated fact; over-the-counter (OTC) drug prescription is common practice in all community pharmacies; and the provision of supportive information on the prescriptions made in primary care is routine practice. For this reason, sometimes, Pharmaceutical Care has been conveyed as a process representing continuity rather than change.

Hence the importance of transmitting to the entire pharmaceutical collectivity the need for evolution in professional activity, resorting to the arguments of *ethical and legal responsibility*. In effect, the pharmacist is responsible for the good use of medicines, and cooperates with the rest of professionals forming part of the health care team, to ensure that the outcome of drug use is optimum.

Another need is to start communication targeted to the general population, in order to expand knowledge of Pharmaceutical Care and generate a demand for the service. Such demand in turn could be a powerful motivating element for pharmaceutical professionals.

It seems clear that an adequate diffusion plan can improve the knowledge of Pharmaceutical Care, not only among patients and their supportive organizations, but also among the rest of the health care professionals, the pharmacists working in different areas of the profession, and the health administrations.

In this chapter, the Forum wishes to reflect the will to establish new diffusion strategies, proposing unified communication objectives, and establishing the measures of action that have been reflected in the following Plan.

Diffusion plan

General objectives

- To present Pharmaceutical Care in a generalized manner to society, other health care agents, pharmacists and the health administrations, as a new concept resulting from evolution of the pharmaceutical profession.
- To attach content to this new concept and transmit a clear, standardized and single definition of Pharmaceutical Care.
- To directly diffuse the benefits of Pharmaceutical Care for society: Pharmaceutical Care is a valid and essential tool for helping to resolve serious health and health care organizational problems.

- To present the pharmacist in any setting or health care level as the undisputable protagonist of Pharmaceutical Care, with clear communication of the capacity of the pharmacist – as drug expert – to practice Pharmaceutical Care, and of the idoneity of the community pharmacies network for the generalized implementation of Pharmaceutical Care.
- To intensify perception of the pharmacist as a health care agent implicated in the multidiscipline teams that work in favor of the individual and global health of the population.
- To inform that Pharmaceutical Care is an essential evolution of the profession with a view to the future (responsibility or obligation).

Objectives of diffusion among the general population

- To inform of the services of Pharmaceutical Care with a view to generating social demand in all the settings.
- To convey Pharmaceutical Care as a right contemplated by law, and which offers undeniable benefits for both individual and global health.
- To inform on the active role of the pharmacist as part of the health care team, explaining that the pharmacist is the professional with expertise in medicines who cooperates with other health care professionals to ensure the correct use of drugs.
- To present Pharmaceutical Care as an innovative process that forms part of the evolution of the pharmaceutical profession towards increased commitment to the health of the population.

Specific objectives for physicians and other health care professionals

- To address the existence and magnitude of the social and health care problem posed by drug-related problems / negative medicine outcomes (DRPs / NMOs), transmitting the need for drug experts in the health care teams, in all health care settings, to become involved in resolving this problem.
- To clearly transmit the benefits of Pharmaceutical Care for patients.
- To inform of the benefits of Pharmaceutical Care for physicians and other health care agents, clarifying doubts as to the role of each agent, from a professional perspective and free of interferences.
- To inform of the new pharmacy-physician communication channels to be established with the implementation of Pharmaceutical Care, based on the need to improve drug use and prevent or identify DRPs / NMOs.

Specific objectives for pharmacists

- To transmit the benefits of Pharmaceutical Care for the profession, in terms of both personal satisfaction and as regards professional future.
- To inform the pharmacist on the assigned role and functions as contemplated by the legislation.
- To enhance pharmacist awareness of ethical and legal responsibility, as an expert in medicines, with a view to ensuring their correct use.

- To present the implementation of Pharmaceutical Care as an assumable and gratifying personal and professional challenge, providing starting guidance and appropriate references for those pharmacists who decide to adopt Pharmaceutical Care in their professional setting.
- To inform that Pharmaceutical Care guarantees adaptation to new management models.
- To explain that Pharmaceutical Care opens up possibilities for new professional outlets and opportunities.
- To implicate pharmacists as active agents, and specifically as bearers of the message of Pharmaceutical Care in their respective environments, targeted to both other professionals and to the general population.
- To generate and conduct Pharmaceutical Care as a "quality guarantee", facilitating a proactive attitude on the part of professionals and society as a whole.
- To transmit the necessary cooperation between pharmacists in the different health care settings – hospital, community pharmacy and primary care pharmacy – based on specific actions.

Forum proposal. Diffusion actions

With the purpose of reaching the contemplated objectives, the Forum suggests certain specific actions that could be carried out both on an individual basis by the associations and entities belonging to the Forum, and on a collective-consensual basis.

- The elaboration of a "**Decalogue or Manifesto**" to explain and diffuse the meaning, practice and benefits of Pharmaceutical Care (included as a preamble to this document).
- The sequential preparation of a series of **short and popular articles** offering a summarized account of the agreements reached regarding methodology and terminology (disclosed in the publication "Farmacéuticos", available on the website **www.portalfarma.com** since October 2006, and on **www.pharmaceutical-care.org**).
- Implication of the General Council in the diffusion and implementation of Pharmaceutical Care:
  - Through the General Assembly of Associations
  - Through the website of the Organization
  - Through the communication channels of the Organization
- Implication of all the institutions forming part of the Forum, as well as of other associations of a health care-professional nature. Use could be made of the communication channels of these different organizations to ensure increased diffusion of the consensus-based messages relating to Pharmaceutical Care.
- Generation of a practical and basic didactic manual destined to train the pharmacist in the initial and real application of Pharmaceutical Care in professional practice.
- Training of communications professionals (in both the health care setting and in the general context) in Pharmaceutical Care, in order to enhance its dissemination.

Training

This chapter is merely of an orientative nature, and documents the analysis made by the Forum of the present and future training needs of pharmacists with a view to offering Pharmaceutical Care to the population, with the maximum quality guarantees. In this sense, and as guidelines, the chapter compiles those interventions which in the opinion of the Forum should be addressed by the competent Health Authorities, to ensure that in both the university pre- and postgraduate setting, and in Ongoing Training in Health Care, pharmacists can receive and permanently stay abreast of scientific knowledge and practices in the field.

Antecedents and current situation

At present, the pharmaceutical profession is developing new functions and responsibilities in response to the needs derived from the activity, benefit, risk and cost of drug therapy. The scope of professional activities includes participation of the pharmacist in the decisions regarding therapy, based on the rational use of medicines, and aimed at securing adequate results in the patient. These activities are framed within a philosophy of pharmaceutical practice that centers attention on the patient as the beneficiary of pharmaceutical intervention. The specific philosophy upon which this practice is fundamented is Pharmaceutical Care [16].

Until only very recently, the practice of Pharmaceutical Care was a consequence of the initiative of some pharmacists and organizations that took the individual decision to investigate and gain training in a new area of knowledge.

In recent years, different professional organizations, universities, administrations, associations and institutions committed to Pharmaceutical Care have launched training programs of different kinds. In a gradual manner, all these programs have reached a growing number of professionals, motivated by the advance of the profession towards health care practices. However, despite the high quality levels of the programs implanted to date, **the Forum members consider that training in Pharmaceutical Care is a point where further advancement is clearly needed**, to ensure that the efforts to implement it in professional practice yield the desired results.

As a starting point, it is noteworthy that Pharmaceutical Care, as a truncal subject, does not form part of the University Degree studies.

16. Hepler CD, Strand LM. Opportunities and responsibilities in pharmaceutical care. Am J Pharm Educ 1989; 53: 7S-15S.

Some specialists in Pharmaceutical Care consider that the obligate practical classes in pharmacy undergraduate training are an important opportunity for coming into contact with the reality of health care, and thus with Pharmaceutical Care. However, it has been shown that while such classes are a source of practical knowledge following the necessary theoretical training, they do not ensure the precise standardized and optimum training required - since the educational objectives and methodology have not been defined in a homogeneous manner. In addition, practical care (Pharmaceutical Care) has not been uniformly introduced in those community pharmacies that offer practical tutoring for future pharmacists.

Regarding postgraduate training, specific preparation in Pharmaceutical Care has been contemplated, and the offer has been amplified in some universities – though not on a generalized basis.

At present, continuous or ongoing training is the most common route to gain access to theoretical and practical knowledge in Pharmaceutical Care. However, despite the fact that continuous training is central to professional upgrading, it is of a voluntary nature.

The present document presents the analysis of the Forum in relation to the training needs in Pharmaceutical Care at pregraduate, postgraduate and continuous training level, and aims to underscore the importance of regulating and systematizing such education.

Graduate training

According to Spanish Royal Decree 1393/2007 [17], "*Graduate education constitutes the first cycle of university education, and comprises basic and general teachings, together with other docent activities destined to prepare students for professional practice*". The title of Degree in Pharmacy is offered by 15 Spanish universities: Alcalá de Henares, Alfonso X el Sabio, Barcelona, Cardenal Herrera CEU, Complutense (Madrid), Granada, La Laguna, Miguel Hernández, Navarra, The Basque Country, Salamanca, San Pablo CEU, Santiago de Compostela, Seville and Valencia.

Most of the new graduates practice the profession in the health care setting (community pharmacy, hospital pharmacy, primary care pharmacy). As a result, it would be reasonable for graduate training – currently imparted on the basis of Royal Decree (RD) 1990 [18], contemplating Directives 85/432/CEE [19] and 85/433/CEE [20] – to adapt to the new needs entailed by the practice of Pharmaceutical Care.

17. Royal Decree 1393/2007 of October 29, establishing the references for official university education (BOE 260, of 30 /10/2007).
18. Royal Decree 1667/1989 of December 22 (BOE 4, of 4/01/1990).
19. Directive 85/432/CEE of the Council, of September 16, 1985 (DOCE, special edition in Spanish, tome 6, vol. 3, page 34), relating to coordination of the legal, regulatory and administrative dispositions for certain pharmaceutical activities.
20. Directive 85/432/CEE of the Council, of September 16, 1985 (DOCE, special edition in Spanish, tome 6, vol. 3, page 28), relating to the mutual recognition of diplomas, certificates and other pharmacy titles, and which includes measures tending to facilitate effective exercise of the right to establish certain pharmaceutical activities.

As has been reflected in the sections corresponding to Justification and Motivation, current legislation attributes a clear role to pharmacists, linking them to activities firmly associated with Pharmaceutical Care. However, the graduate education plans do not include all the theoretical knowledge essential for meeting such requirements.

At present, and within a certain limit of time, the Pharmacy education plans must adapt (among others) to Directive 2005/36/CEE of the European Parliament and of the Council of September 7, 2005 [21], which includes concepts related to the practice of Pharmaceutical Care.

In 2001, the European Council [11], by means of its Resolution relating to the role of the pharmacist in the setting of health care safety (March 21, 2001), recommends reinforcement of the functions of pharmacists as a way to reduce the risks associated with deficient drug use. The Resolution in question proposes actions to ensure pharmaceutical training, and underscores that Pharmaceutical Care is fundamentally destined to offer benefits for patients. Its postulates textually include the following:

- *Pharmaceutical care is an essential element in the prevention and reduction of iatrogenic risks and should be implemented systematically. It includes:*
  - *the keeping of pharmaceutical records that contain details of the patient´s case-history, medicines supplied, clinical information, available therapeutic and biological results, and recommendations made to the patient;*
  - *the monitoring of prescriptions, particularly in the light of the patient´s pharmaceutical record in order to check for consistency and for possible interactions with other medicines;*
  - *the evaluation of patient´s overall medication;*
  - *the rationalisation of the advice given to patients: procedures must be developed whereby, in particular, patients will in certain circumstances receive information in writing;*
  - *the systematic exchange of information with other health professionals (via networks).*

  In order to achieve these tasks, full use should be made of the various information technologies and relevant databases, and it should be possible to access patient profile and incorporate them to the pharmaceutical records.

In 2005, and as a result of the work of all the Faculties of Pharmacy in Spain in relation to designing of the corresponding Degree titles, adapted to the European Space for Higher Education, the ANECA (National Agency for the Evaluation of Quality and Accreditation) [22] was presented with a study relating to “The Title of Degree in Pharmacy”. Among other subjects, the study addressed certain aspects in the field of Pharmaceutical Care, such as:

21. Directive 2005/36/CEE of September 7, 2005. DOUE Section 7 Pharmacist. Article 44 Pharmacist training, page 25.
22. White Book. Title of Degree in Pharmacy. Ed. Aneca. Madrid. October 2005.

- *"Pharmaceutical Care has an important practical purpose, and it is therefore considered necessary for teaching to involve the participation of professionals of established repute and competence in pharmaceutical care, coordinated by the professor or professors designated to the effect by the corresponding Department or Faculty or Center Board."* [23]
- *The Study Plan must ensure that Pharmaceutical Care focusing on the patient, as defined in the declaration of the International Pharmaceutical Federation (FIP)* [24] *in The Hague (1998), becomes an obligatory part of the Plan, as a truncal subject. As refers to the subject matter of Pharmaceutical Care, the descriptors (educational contents) considered are: dispensing, OTC prescription, pharmacotherapy follow-up, pharmacovigilance, and communication with the patient and with other health care professionals."* [23]
- *The introduction of the subject Pharmaceutical Care in graduate studies, in conformity with the recommendations on this matter of the International Pharmaceutical Federation (FIP), the Pharmaceutical Group of the European Union (PGEU), and the European Association of Faculties of Pharmacy (EAFP), is the subject of the fourth section, where special reference is made to the inclusion of Pharmaceutical Care in Pharmacy studies* [23]*. The Coimbra Agreement of the Faculties of Pharmacy of Spain and Portugal (2004)* [24]*, in conformity with the recommendations on the matter of the FIP, PGEU and EAFP, requested the incorporation of the subject Pharmaceutical Care in the graduate studies plan, as an evolution of the university training needed for daily practice of the profession".*
- *Malta Agreement* [25]*: As a recommendation of the EAFP, studies in Pharmacy should "maintain thorough knowledge of basic science, recent concepts in pharmaceutical care, professional ethics, behaviors and attitudes, clinical pharmacy and clinical analyses, prescription and non-prescription drug regulatory mechanisms, and medical services".*
- *The inclusion of Pharmaceutical Care in Area V of Medicine and Pharmacology implies the development of competence in a series of skills and knowledge. In this context, skills are taken to include clinical and social pharmacy activities, following the Pharmaceutical Care cycle; the promotion of rational use of medicines and health care products; and therapeutic counseling and participation in the pharmacotherapeutic and dietary-therapeutic decision taking processes in the community, hospital and home care settings, etc. In turn, as regards knowledge, clinical analyses and their application to pharmacy practice are considered, along with drug properties and characteristics, health and disease, etc."*[23]

23. International Pharmaceutical Federation. Declaration of Principles. Good Pharmaceutical Teaching Practice. FIP. The Hague, The Netherlands.
24. Position of the Faculties of Pharmacy of Spain and Portugal regarding University Education in Pharmacy. Coimbra. February 28, 2004.
25. European Association of Faculties of Pharmacy. Malta Agreement in accordance with the positioning of La Laguna. Malta, 2005.

In the opinion of the Forum, Pharmaceutical Care is to be regarded as a truncal subject in the university graduate studies, with the purpose of clearly integrating the professional activities of pharmacists oriented towards the patient, within the basic training received. To this effect, the Forum recommends that the next revision of the Community Directive should contemplate a catalogue of minimum materials that includes Pharmaceutical Care.

Among the reasons supporting this opinion, mention can be made of the fact that although Pharmaceutical Care is a multicompetent discipline (using knowledge from other areas), it constitutes novel and specific study material that requires teaching to be viewed from a specific methodology not found in other subjects. Pharmaceutical Care moreover includes, as an essential element, student training in skills not presently contemplated in the degree study plan, and requires due response to the new needs generated by implementation of this discipline – such as the management of information systems, registries, sources, protocolization, the evaluation of pharmacotherapy, or communication techniques (both among health care professionals and with the patient). Specific investigation in Pharmaceutical Care, as a curricular subject under development, would be another of the arguments supporting its inclusion as a truncal subject in the study plans. In its development as a truncal subject, it must be taken into account that Pharmaceutical Care is eminently a practical subject, requiring the use of specific technology.

In the opinion of the Forum, this new truncal subject entails the application of knowledge gained in Pharmacology, Physiopathology, etc., with the patient as reference. In this sense, knowledge is required in specific methodologies relating to dispensing, OTC prescription, pharmacotherapy follow-up, etc., along with the development of skills in communication, the management of information systems, registries, sources, protocolization and the evaluation of pharmacotherapy.

Thus, the Forum understands that teaching responsibility should correspond to professionals of established repute and with extensive working experience in the health care setting. Such professionals could be recruited as associated professors, collaborators or visiting lecturers, with the support of university professors from different areas – with the purpose of facilitating scientific investigation in this field. Therefore, and in view of the multidiscipline nature of the subject, and the current university situation, it would be advisable to create a new area of knowledge, which we propose as corresponding to " Pharmaceutical Care", for the organization and teaching of this subject, and allowing the incorporation of academic professors and professionals from different areas and health care settings – thereby reinforcing the multidiscipline character of this subject. Lastly, and once such knowledge and skills have been gained, it would be extremely useful to conduct a period of systematic and accredited professional practices.

Postgraduate training

According to Royal Decree 1393/2007 [26], postgraduate training comprises the second and third cycles of university education. *The second cycle is dedicated to advanced training, of a specialized or multidiscipline nature, and is destined to offer academic or professional specialization, or to promote initiation in research activities. Students who complete the second cycle will be entitled to receive a Master title. The mentioned Royal Decree indicates that the official Master studies can incorporate specialties in their teaching programs corresponding to their scientific, humanistic, technological or professional context.*

The same Royal Decree (1393/2007), which regulates the official university postgraduate studies [26], indicates that *the purpose of the third university cycle is to ensure advanced preparation of the student in research techniques, and can include courses, seminars or other activities dedicated to research training. The third cycle will include the elaboration and presentation of the corresponding Doctoral Thesis (original research work). Students who complete the third cycle will be entitled to receive the title of Doctor (PhD), which in turn authorizes teaching and research practices. The universities are in charge of organizing these programs, and determine both the composition and operating norms of the postgraduate study commissions, and the university centers in charge of imparting them.*

To date, some Faculties of Pharmacy have offered their students different Masters or Doctorate programs related to Pharmaceutical Care. The Universities of Granada, Valencia, Navarra, Seville, Barcelona, Madrid, or the CEU, are only some examples.

The programs corresponding to these courses have been developed on an independent basis by expert groups, with no unification of criteria, objectives or terminology. This has led to heterogeneity in the training offers and their results. Nevertheless, there has been some recent effort to define minimum common contents (e.g., the Conference of Deans of Faculties of Pharmacy, held in March 2007 in Zaragoza), including areas related to Pharmaceutical Care, among others.

In any case, in the present situation, postgraduate and continued or ongoing training are the only options allowing graduates to receive training in Pharmaceutical Care.

The Forum considers that the optimum development of Pharmaceutical Care requires its regulated inclusion in the graduate and postgraduate training programs, to thus ensure the necessary level of formation to be able to attend patients under the criteria of Pharmaceutical Care.

26. Royal Decree 1393/2007, of October 29, regulating official university education (BOE 260, of 30/10/2007).

On the basis that postgraduate studies are centered on academic or professional specialization, and since the majority of Spanish pharmacists carry out their professional activities in areas related to Pharmaceutical Care, the Forum considers that it is necessary to implement postgraduate programs in this field (Pharmaceutical Care). These programs must be accessible to all universities where the Degree in Pharmacy is offered, and may constitute the reference point for future specializations.

Likewise, an important homogenization effort is required among the different Faculties of Pharmacy, to ensure that postgraduate training in Pharmaceutical Care adjusts to the effective needs of the profession.

Once Pharmaceutical Care has become an integral part of the curriculum of all graduates, postgraduate training could be oriented towards more specific contents based on therapeutic areas, pathologies or health care services.

Continuous training

Continuous / continued or ongoing training comprises all education received by a professional after completing university or specialized training, and which is destined to upgrade, maintain and improve professional competence – with no awarded further academic title [27].

According to Law 44/2003 [28], *continuous training comprises active and permanent teaching and learning to which health care professionals are entitled and obliged. It begins on completing the pregraduate or specialization studies, and is dedicated to upgrade and improve knowledge, skills and attitudes among health care professionals in the face of the new scientific and technological developments, and the needs and demands of both society and the health care system itself.*

According to the WHO [29], "*Among the health care professionals, continuous upgrading of the knowledge and skills required for the benefit of the patient is essential*". The rapid progression of scientific knowledge, the increased demands of the users of the health care system, and the ethical obligations of the professionals, define continuous training as a key tool for guaranteeing health care quality.

Mention must be made of the growing interest in Pharmaceutical Care seen in all developed countries, as a core reference in continuous training for health care pharmacists. The Tokyo document of the WHO [12] proposes Pharmaceutical Care as the fundamental basis of the permanent education programs for pharmacists, and recommends the preparation of professionals for related practices and research activities.

27. Laín Entralgo Agency - accreditation. Organization, procedure and criteria for the evaluation of continuous training activities: "Guide to the evaluation of continuous training activities".
28. Law 44/2003, of November 21, regulating the health care professions (BOE 280, of 22/11/2003).
29. World Health Organization. Guide to Good Pharmacy Practice. Geneva 2002.

The European Commission, through its Consulting Committee on Pharmacist Training, adopted a “Report and recommendations for the continued training of pharmacists” in 1997, with equivalent considerations [30].

The concept of continuous or ongoing training receives its maximum expression in some of the most developed countries, where society demands permanent upgrading of health care professionals in order to be able to continue practicing the profession. The Forum proposes gradual progression towards a model in which continuous training is both a right and a duty.

The Professional Organization, together with the universities, scientific societies and other institutions or entities, is responsible for the continuous or ongoing training of pharmacists, with the purpose of offering practical and homogeneous training. In this process, an essential requirement is solid collaboration on the part of the Public Administrations, in accordance with Law 44/2003, of November 21, relating to regulation of the health care professions [28].

The teaching methodology must be adapted to the needs in each case and moment - a fundamental requirement being the accreditation of such activities by the Commission for Continuous Health Care Professional Training [28].

Continuous training in Pharmaceutical Care must offer pharmacists upgraded knowledge and skills for improved professional competence, and which can be put into practice on an immediate basis in the context of daily professional work.

The Forum considers that continuous training in Pharmaceutical Care is an essential upgrading mechanism for all pharmacists, and at present constitutes a basic tool for generalized implementation of the discipline. The Professional Organization must lead this level of training, together with other institutions and the support of the Administrations. In order to ensure the quality of the training programs and their practical usefulness, accreditation from the Commission for Continuous Health Care Professional Training is required.

30. European Commission. Consulting Committee on Pharmacist Training. Report and recommendations for the continuous training of pharmacists. Adopted by the Committee on occasion of the meeting held on April 22 and 23, 1997. Brussels. 28/10/98.

Instruments

General considerations

The great amount of information needed for the practice of Pharmaceutical Care makes it advisable to establish computer-based tools to facilitate the access to information, the generation of interventional protocols, and the registry and evaluation of data.

The tools designed for Pharmaceutical Care must address in an integrated form all the professional services encompassed by the discipline (OTC prescription, dispensing and pharmacotherapy follow-up). On the other hand, such programs must make use of a common language and a single encoding system, to facilitate the inter-relation of data (health problems, medicines, drug substances, etc.) handled in relation to patient care in different situations and settings.

This document presents the opinion of the Forum on the characteristics that should be offered by the computer-based applications for the implementation of Pharmaceutical Care in the different pharmacy settings, as well as the working methodology associated with such tools. These considerations have already been reflected in an exhaustive technical analysis serving as the basis for reporting them to the different software companies, for the development of integrated management and Pharmaceutical Care systems.

Characteristics of the software instruments in Pharmaceutical Care

- Such computer-based tools must be integrated in the management software applications massively used in pharmaceutical practice today – regardless of the setting involved (community, hospital, primary, nursing homes). This would entail automatic integration of the activity in the daily work of the pharmacist, in relation to each patient attended. In fact, this situation would represent a change in the concept of computer resource utilization from “sales-point terminals” to “pharmaceutical care terminals”.
- These software instruments must provide updated and reliable information to facilitate the decision taking process, through the inclusion of practical guides in Pharmaceutical Care, and the facilitation of literature consultations where necessary.
- Access to the clinical information must be possible, in any of the health care settings.
- These applications must be practical, simple, intuitive, and with a predominantly automated registry system.
- Such instruments must guarantee a system of alerts / warnings related to contraindications, precautions, quantified adverse reactions, incompatibilities, etc., in order to facilitate the activity of the pharmacist. These alerts or warnings must be generated as “rapid alerts”, or as complementary (exhaustive) information, to allow consultation.
- Analysis of the health care activity must be allowed.

- These instruments must allow permanent updating and be able to adapt to new technical and clinical needs of Pharmaceutical Care.
- Parameter definition must be possible, i.e., the instruments must allow configuration of the system to work at different service levels, according to the desires of the pharmacist.
- A common coding system must be established, in order to ensure that the information collected is homogeneous. This feature must allow the exchange of information among different professionals, with a view to improving the results of intervention, and statistical exploitation of the data.
- The design must contain the working systematics developed in the pharmaceutical intervention procedures established on a consensus basis by the Forum.
- The instruments must facilitate the generation of the documents and reports, etc., needed for conducting these activities.
- Communication systems must be included, allowing the transmission of information, in order to add the data collected individually.
- The confidentiality and safety of the data of a personal / health nature must be guaranteed, as established by law [31].
- The instruments must be compatible with the systems included in the new technologies, including electronic prescriptions, etc.

The following sections summarize the agreements on definitions and working methodology in Pharmaceutical Care, established by consensus. The Forum recommends the methodology reflected in the present document for developing the computer-based instruments applicable in the context of Pharmaceutical Care.

31. Organic law 15/1999, of December 13, relating to the Protection of Data of a Personal Nature (BOE 298, of 14/12/1999).

Pharmaceutical Care methodology. Characteristics by practice settings and services

Pharmaceutical Care in Community Pharmacy

1. Dispensing

> Dispensing is the professional service of the pharmacist destined to guarantee – following individual evaluation – that patients receive and use their medicines in a way suited to their clinical needs, at the precise doses according to the individual requirements, for an appropriate duration of time, with due information on correct drug use, and in abidance with current legislation.
>
> Forum 2007

For professional dispensing, the pharmacist must take into account a series of data related to the patient and his or her medication (Figure 1). In this way the pharmacist, when requested to supply a given medicine, and after systematically checking that the patient or care giver possesses sufficient information for safe and effective medication, uses the existing information to evaluate whether the medication is adequate for the patient in question – proceeding to deliver the product, with guarantees of accessibility and rational use, in abidance with applicable legislation.

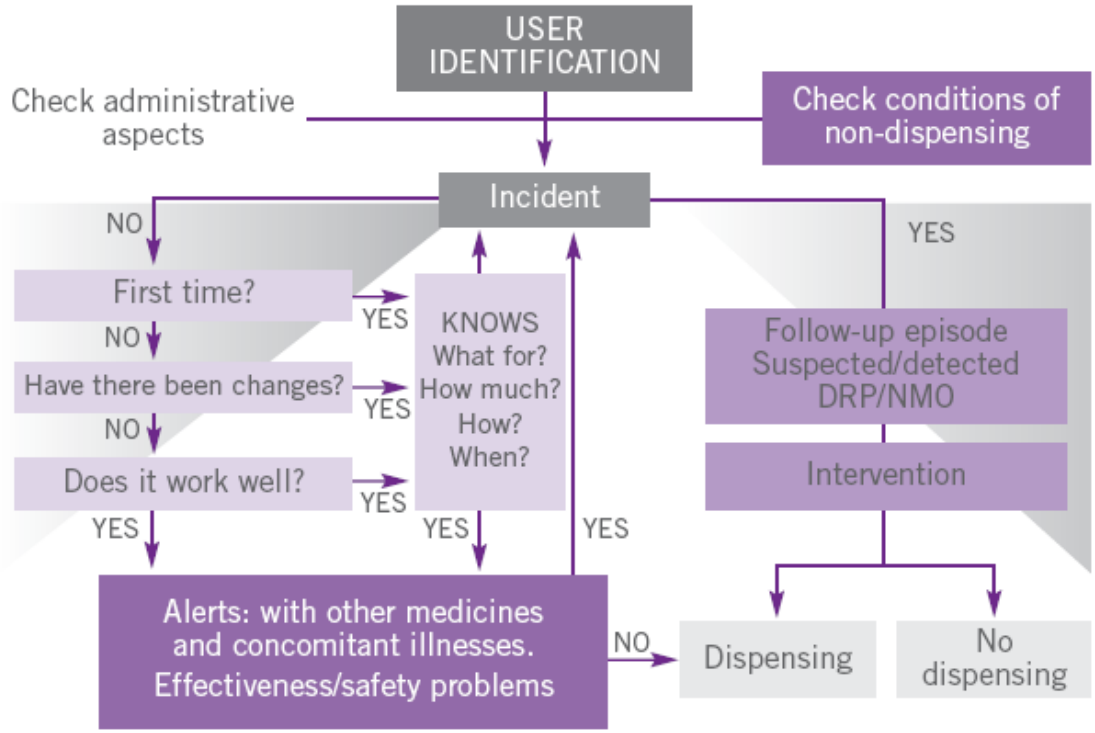

Figure 1. Procedure for dispensing.

In sum, **the objectives** of dispensing are the following:

a) To guarantee access to the medication, supplying it to the patient under optimum conditions, in accordance with current legislation.
b) To ensure that the patient knows the process for correct drug use and will abide with it.
c) To protect the patient against negative medicine outcomes (NMOs), through the identification and resolution of drug related problems (DRPs).
d) To identify (in certain cases) NMOs and attempt to resolve them.
e) To detect other needs, with a view to offering other Pharmaceutical Care services, where applicable.
f) To register and document the pharmaceutical interventions made.

Procedure

In the event of a request for some drug with or without a medical prescription, the pharmacist must consider the following:

- **Who the medication is intended for**: Personal use, care giver, third person. In the case of personal or care giver use, identification is required of the person using the medication: sex, actual / approximate age, and relationship to the individual requesting the medication.
- **Check administrative considerations**.

The pharmacist can determine whether the patient uses other medicines, or presents concomitant illnesses or allergies that could affect the objective of treatment and the health of the patient.

- **Check criteria for non-dispensing:**
  - Pregnancy
  - Lactation
  - Allergy
  - Contraindications due to diseases of health problems
  - Interactions with other drugs
  - Duplicities

If there are no administrative problems or criteria for non-dispensing, the dispensing process begins, with variation according to whether this is the first time the patient uses the medicine or not.

- **If used for the first time: "start of treatment"**

The pharmacist, by means of a brief interview, will obtain key INFORMATION to evaluate whether the patient or care giver knows the process for correct drug use, based on the following questions:

- Knows what it will be used for?
- Knows how much must be used?
- Knows for how long it must be used?
- Knows how to use it? (analyze whether there are special conditions for use / handling)
- Knows the warnings relating to ineffectiveness and safety?

- **If not used for the first time: “continuing treatment”**

The pharmacist, by means of a brief interview, will obtain key INFORMATION to evaluate patient perception of the effectiveness and safety of the medicine, based on the following questions:

- Have there been any changes (treatment regimen, dosage, etc.)? If affirmative, the same questions as at the “start of treatment” are to be asked.
- If negative, how is the treatment going? Are there any problems with the treatment?
- Likewise, necessary biomedical information should be compiled (laboratory tests, blood pressure, etc.), if available.

If no incidents are detected, then the pharmacist will dispense the medication along with health education information, etc.

Definition

> **INCIDENT** is any circumstance related with pharmacotherapy, which in the course of the defined dispensing procedure does not coincide with the expected or accepted situation, and interrupts the procedure – requiring due evaluation in a follow-up episode.
>
> Forum 2007

If an incident is detected, a follow-up episode must be opened. The *follow-up episode* is a process for the evaluation of possible drug related problems (DRPs) and/or associated negative medicine outcomes (NMOs). The follow-up episode may lead the pharmacist to intervene to clarify the patient information (personalized medication information (PMI) or health care education), refer the patient to the physician, or propose referral to some other Pharmaceutical Care service.

Definition

> **FOLLOW-UP EPISODE** is a point evaluation process for the assessment of possible drug related problems (DRPs) and/or associated negative medicine outcomes (NMOs), when an incident in drug dispensing occurs, using proprietary instruments of the pharmacotherapy follow-up Service.
>
> Forum 2007

Definition

> **DRUG RELATED PROBLEMS (DRPs)** are those situations that cause or may cause the appearance of negative medicine outcomes (NMOs). DRPs are elements of the process that entail an increased user risk of suffering an NMO.
>
> Forum 2007

Definition

NEGATIVE MEDICINE OUTCOMES (NMOs) are those patient health results not suited to the objectives of pharmacotherapy, and associated or potentially associated with drug use.

Forum 2007

Definition

PERSONALIZED MEDICATION INFORMATION (PMI) is the information supplied to the patient by the pharmacist regarding the treatment, in the course of the dispensing process, with the purpose of ensuring effective and safe drug use.

Forum 2007

Definition

INTERVENTION is the activity destined to modify some characteristic of the treatment, of the patient receiving it, or the conditions of use, and with the purpose of resolving a DRP / NMO.

Forum 2007

In any case the **intervention** of the pharmacist may be to either **dispense** or **not dispense** the medication in question.
As part of the dispensing process, and whenever possible, the pharmacist will **register the outcome** of his or her intervention in relation to the health of the patient **(improvement, worsening, no change)**.

The Forum proposes the following **list of DRPs** that may give rise to an NMO:

- Wrong administration of the medication
- Personal characteristics
- Inadequate storage
- Contraindication
- Inadequate dose, regimen and/or duration
- Duplicity
- Dispensing error
- Prescription error
- Non-compliance
- Interactions
- Other health problems affecting the treatment
- Probability of adverse effects
- Insufficiently treated health problem
- Others

Forum 2007

The designation of categories in the above list is not established on an excluding basis; as a result, one or more DRPs can be assigned to one same incident. The list likewise is not exhaustive, i.e., more categories can be added according to the different situations found by the pharmacist in the course of his or her daily professional activity.

The Forum divides **NMOs** into three categories:

- Necessity
- Effectiveness
- Safety

Each of these categories in turn is subdivided into two:

- A medication need (non-treated health problem)
- A non-need for medication (effect of an unnecessary medicine)
- A non-quantitative ineffectiveness
- A quantitative ineffectiveness
- A non-quantitative lack of safety
- A quantitative lack of safety

Forum 2007

Likewise, the Forum proposes the following **list of possible interventions:**

- Facilitate information (PMI)
- Offer health care education
- Refer to pharmacotherapy follow-up
- Refer to the physician, reporting the DRP/NMO
- Refer to the physician proposing changes in treatment
- Propose other changes
- Report to pharmacovigilance in accordance with current legislation

Forum 2007

2. OTC prescription

OTC prescription is the professional service offered upon demand from a patient or user who visits the community pharmacy without knowing which medicine to acquire, and wishes the pharmacist to provide the best remedy for his or her specific health problem. If the service requires drug dispensing, the latter is to be carried out according to the definition provided above (Dispensing).

Forum 2007

In order to offer a professional response to an OTC prescription consultation by a user, the pharmacist must take into account a series of data relating to the patient, his or her health condition, and the medications used (Figure 2).

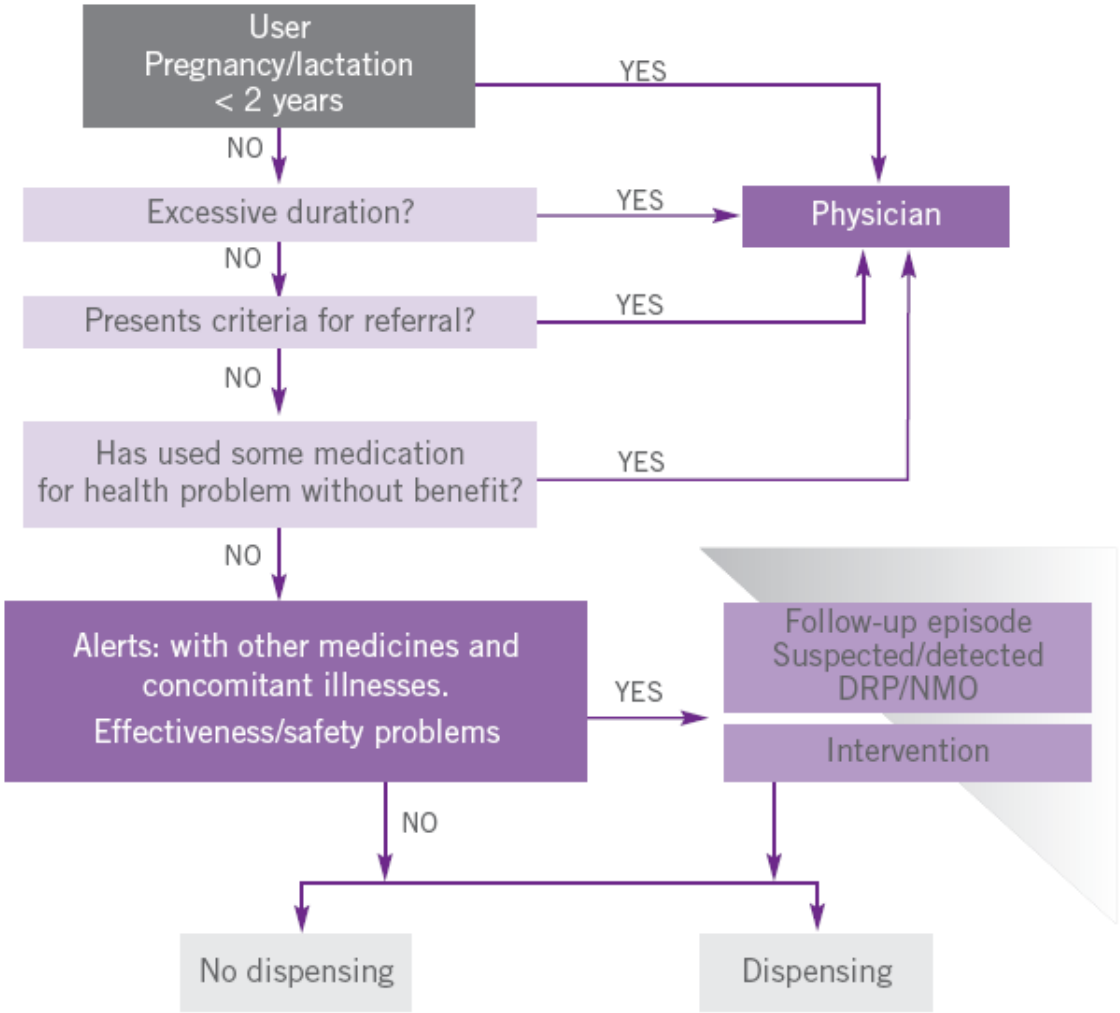

Figure 2. This general diagram is to be adapted to the specific circumstances of each patient and health problem, according to the procedure detailed below.

In sum, **the objectives** of OTC prescription are the following:

a) To inform the patient of the best approach to solving his or her health problem, and where applicable to select a medicine, ensuring that the patient knows the process for correct drug use and will abide with it.
b) To resolve the doubts raised by the user and/or the information deficiencies detected by the pharmacist.
c) To determine whether the health problem reported by the patient is an NMO.
d) To protect the patient against negative medicine outcomes (NMOs), through the identification and resolution of drug related problems (DRPs).
e) To identify (in certain cases) NMOs and attempt to resolve them.
f) To detect other needs, with a view to offering other Pharmaceutical Care services, where applicable.
g) To register and document the pharmaceutical interventions made.

Procedure

In the event of a request for the solution of some health problem, the pharmacist must consider the following:

- **Who makes the consultation:** Patient in person, care giver, third person. Identification of the person who will receive any medication decided: sex, actual / approximate age, and relationship to the individual making the consultation.
- **Reason for consultation:** Health problem reported by the patient. It must be remembered that the health problem must be of a self-limiting nature; if not, referral to a physician is indicated in all cases.
- **Check the following**:
  - Whether the health problem is the adverse effect of some medicine (report to pharmacovigilance).
  - Duration of the health problem (HP): less than 7 days.
  - Of the medicines used for the HP, *has the patient used any already?*
  - Other medicines used for other HPs.
  - Special physiological situations: pregnancy / lactation.
  - Other concomitant illnesses.
  - Known allergies and intolerances.
  - Life style (habits).
  - Biomedical data, if available.
- **Evaluate the following**:
  - Criteria for physician referral
  - Contraindications
  - Interactions
- **Intervention** of the pharmacist, according to the information collected:
  - Counseling without drug dispensing.

- Dispensing of a pharmacological treatment requiring no medical prescription (methodology equivalent to that already described in the section on dispensing).
- Recommendation of non-pharmacological treatment.
- Referral to the physician.
- Referral to pharmacotherapy follow-up.

In those cases in which the intervention comprises the dispensing of a treatment requiring no medical prescription, and whenever possible, the pharmacist will **register the result of his or her intervention** *in relation to the health of the patient* (improvement, worsening, no change).

If the pharmacist detects an incident, he or she will open a *follow-up episode* as described in the section referring to dispensing, taking into account the following concepts:

Definition

FOLLOW-UP EPISODE is a point evaluation process for the assessment of possible drug related problems (DRPs) and/or associated negative medicine outcomes (NMOs), when an incident in drug dispensing occurs, using proprietary instruments of the Follow-up Service.

Forum 2007

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Forum 2007

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Forum 2007

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Forum 2007

3. Pharmacotherapy follow-up

Pharmacotherapy follow-up aims to detect drug related problems (DRPs), for the prevention and resolution of negative medicine outcomes (NMOs). This service entails commitment, and must be provided on a continuous, systematic and documented basis, in cooperation with the patient personally, and with the rest of the health care professionals, in order to secure concrete results that serve to improve patient quality of life.

Forum 2007

In order to be able to offer pharmacotherapy follow-up, the pharmacist must implement a working system allowing him or her to obtain full knowledge of a series of personal [32] and health care data related to the patient.

To this effect, the pharmacist must establish a **sequence of personal interviews**, in order to generate a professional relationship centered on pharmacotherapy and the health problems reported by the patient, with a view to achieving optimum outcomes. If such outcomes prove elusive, then intervention may be decided to correct DRPs or NMOs (detected or at risk).

In sum, the **objectives** of pharmacotherapy follow-up are the following:

a) To detect drug related problems (DRPs), for the prevention and resolution of negative medicine outcomes (NMOs).
b) To maximize treatment effectiveness and safety, with minimization of the risks associated with drug use.
c) To contribute to rational drug use, improving the process of medication.
d) To improve patient quality of life.
e) To register and document professional intervention.

32. Informed consent (models contained in annex) in accordance with current legislation, and complying with the Personal Data Protection Law.

Procedure

The basic scheme (Figure 3) for conducting pharmacotherapy follow-up always must consider the following aspects:

- Offering of the service.
- Interview for the collection of basic information.
- Assessment form (drugs and health problems / biological parameters).
- Study phase.
- Evaluation phase to identify possible DRPs/NMOs.
- Pharmaceutical intervention.
- Evaluation of the outcomes of the intervention (acceptance and health results).

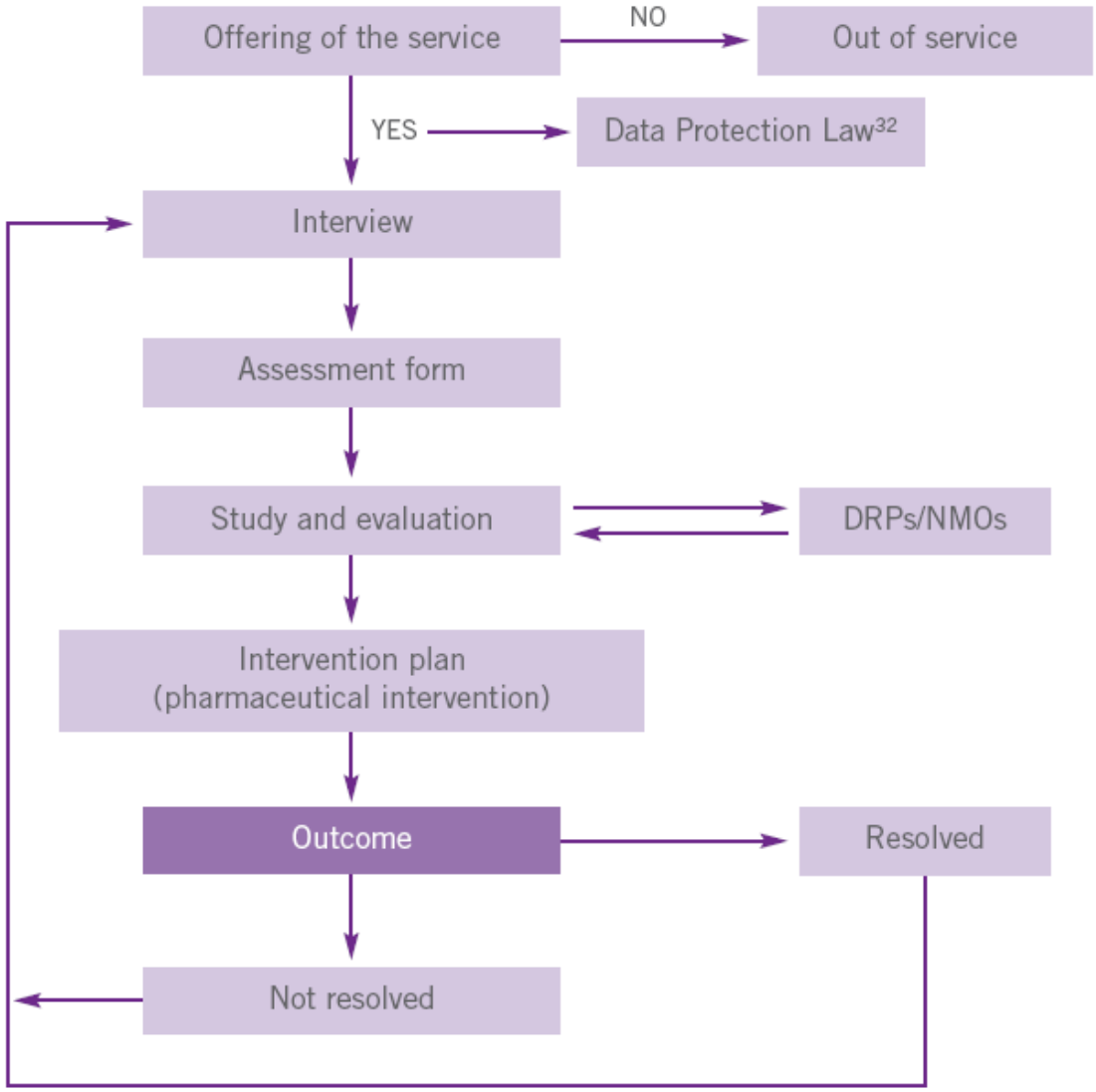

Figure 3. Procedure for pharmacotherapy follow-up.

The data obtained by the pharmacist during the **interview** with the patient should include the following:

- **Who** the patient is: personal and health care data, antecedents, special physiological conditions.
- What **medicines** are used or have been used, checking the following items:
  - Dispensing date
  - Starting date
  - Drug name
  - Prescribed and actually used regimen
  - Prescribing professional
  - Number of times and time measurement unit
  - Type of treatment: sporadic or not, active or not
  - Knowledge of treatment
  - Duration of treatment
- What **illnesses** or health problems are reported by the patient, along with the degree of concern, knowledge, and their control.
- **Biological parameters** (laboratory tests, anthropometric parameters, etc.)

With these data the pharmacist **elaborates an assessment form** [33] relating medication to the referred illness or health problem, and taking into account other information such as the biological parameters.

The **study phase** is started, with the purpose of gaining further insight to the health problems and medications. This in turn facilitates the evaluation and identification of DRPs and NMOs, or of the risk of their appearance.

The pharmacist **registers the result of the intervention**, which may be accepted or not accepted by the patient or the physician. In addition, on occasion of interviews posterior to the intervention, the pharmacist is to register its outcomes: resolution of the DRP/NMO, and intervention for the prevention of NMOs.

The service of pharmacotherapy follow-up is conceived as a **continuous relationship**, of an interdisciplinary nature, and that affects all the heath care levels. On occasion of each patient interview, the described phases are initiated and repeated, with the aim of ensuring optimum pharmacotherapeutic results through the identification and resolution of NMOs.

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>
> Forum 2007

33. Pharmaceutical Care Research Group. University of Granada. Dáder method. Guide to Pharmacotherapy follow-up. 3rd edition, 2007. Available at: www.atencionfarmaceutica-ugr.es

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Forum 2007

Pharmaceutical Care in Primary Care Pharmacy *

The primary care pharmacist faces the dual challenge of affording "population-based pharmaceutical care" and also "pharmacotherapeutic care or follow-up for patients on an individualized basis" [34].
The concept of "population-based pharmaceutical care" promotes the use and analysis of demographic and epidemiological data for the selection of medicines, the definition of forms or guides for the treatment of certain pathologies, the analysis and preparation of reports on drug use in a concrete setting, the areas for improvement detected in a given population, drug-related cost analyses, etc.

1. Pharmacotherapy follow-up (PTF)

Procedure
The system proposed by Canaday and Yarborough, known as **FARM** (*findings, assessment, resolution, monitoring*) is adopted. This methodology takes into account whether the desired objectives are reached, and whether the objectives relating to communication of the pharmaceutical intervention to the rest of the health care professionals has been met. Four steps are contemplated:

- **F** (*Findings*): Identification and collection of data to help clarify DRPs/NMOs. To obtain these data, the professional asks the patient a series of questions according to the type of DRP/NMO involved, completing the information with the data contained from the clinical history.
- **A** (*Assessment*): Interpretation and evaluation of these data to determine whether they reflect actual or potential DRPs/NMOs, along with their severity, magnitude and clinical significance, and the nature of the problem and its underlying cause. In this section it is advisable to classify the DRP/NMO. An analysis is also required of the causes of the NMO, in order to allow for correct posterior intervention.
- **R** (*Resolution*): Interventions carried out. These are fundamentally of three types:
  - Patient information and/or counseling
  - Physician information and/or recommendations
  - Referral to the physician

The interventions should be aimed at reaching the objectives of therapy, established jointly with the patient and the rest of health care professionals, and providing the patient with the information needed to reach these objectives. These interventions are to be adequately documented and classified.

- **M** (*Monitoring and follow-up*): The follow-up plan comprises the following:
  a) The agreements between the pharmacist and the patient and rest of health care professionals to secure the established **pharmacotherapeutic objectives** (improvement in compliance, reduction of side effects, simplification of the dosing regimen, health care education, etc.).

34. Developing pharmacy practice. Handbook 2006 edition. Who/Psin/Porr/2006.5 Karin Wiedenmayer.

** Document prepared by the Sociedad Española de Farmacéuticos de Atención Primaria (SEFAP).*

b) The programming of implementation, determining the periodicity of the visits, with the purpose of:

- Reviewing (in cooperation with the rest of health care professionals) the evolution of certain parameters that provide information on the effectiveness and safety of treatment, with the aim of evaluating response and avoiding complications.
- Checking compliance in the course of treatment.
- Providing the patient with new information on the treatment received.

In the follow-up plan, information is exchanged with the patient, and if alerts or suspicions of new problems are generated, repeat evaluation is carried out.

1. Patient selection

The primary care pharmacist (PCP) centers on the PTF of risk groups (model of C. Hepler: *Therapeutics Outcomes Monitoring*), i.e., patients with chronic diseases, prolonged treatments, or associated with specific activities for health education in relation to the use of drugs (anticoagulants, diabetics, asthmatics, etc.), as well as on those subjects demanding PTF on their own initiative or in response to medical and nursing criterion – such as for example patients that fail to make adequate use of medicines; present suspected adverse drug reactions (ADRs) or a risk of pharmacological interactions; patients receiving drugs with a narrow therapeutic margin, etc.
PTF is carried out through visits upon demand or of a programmed nature, according to the needs of the patient and the objectives defined by the health care team.

2. The process

The process begins with the **initial patient interview**, and can be conducted in the following way:

1. Compilation of the pharmacotherapeutic history.
2. Identification of DRPs/NMOs: IES scheme.
3. Analysis, resolution and follow-up of DRPs/NMOs: FARM note.

Compilation of the pharmacotherapeutic history (PTH)

- Initial interview: After interviewing the patient, the PTH is compiled, including the following sections:
  - Habits: Diet, smoking, alcohol.
  - Known allergies and antecedents of ADRs.
  - Description of the health problems reported by the patient.
  - Pharmacological treatment:
    * Drugs which the patient reports using, date of start of treatment, and origin of prescription.
    * Posology and form of administration.
    * Medicines used in the past.

The PTH is completed with a review of the patient clinical history, including the medical and nursing antecedents, to register the patient illnesses, medical prescriptions and clinical situation.

- Successive interviews: The aim is to update the PTH, placing special attention on the following points:
  - Appearance of new health problems.
  - Changes in pharmacological treatment (including changes in the prescribed drugs, dosage, duration of treatment, etc.).

Identification of DRPs/NMOs: IES scheme

With all the data collected in the PTH, useful information can be obtained for the identification of actual or potential DRPs/NMOs. The patient requires his or her pharmacological treatment to be adequately indicated; it must be as effective and safe as possible; and it must be sufficiently convenient to ensure due compliance. These patient needs must be translated in an organized and structured manner by the pharmacist to DRPs, grouped in the three categories of NMOs. To this effect, a classification system can be used, referred to as the **IES (Indication, Effectiveness, Safety) scheme**, in the form of a "screening" procedure to identify possible NMOs (Figure 4).

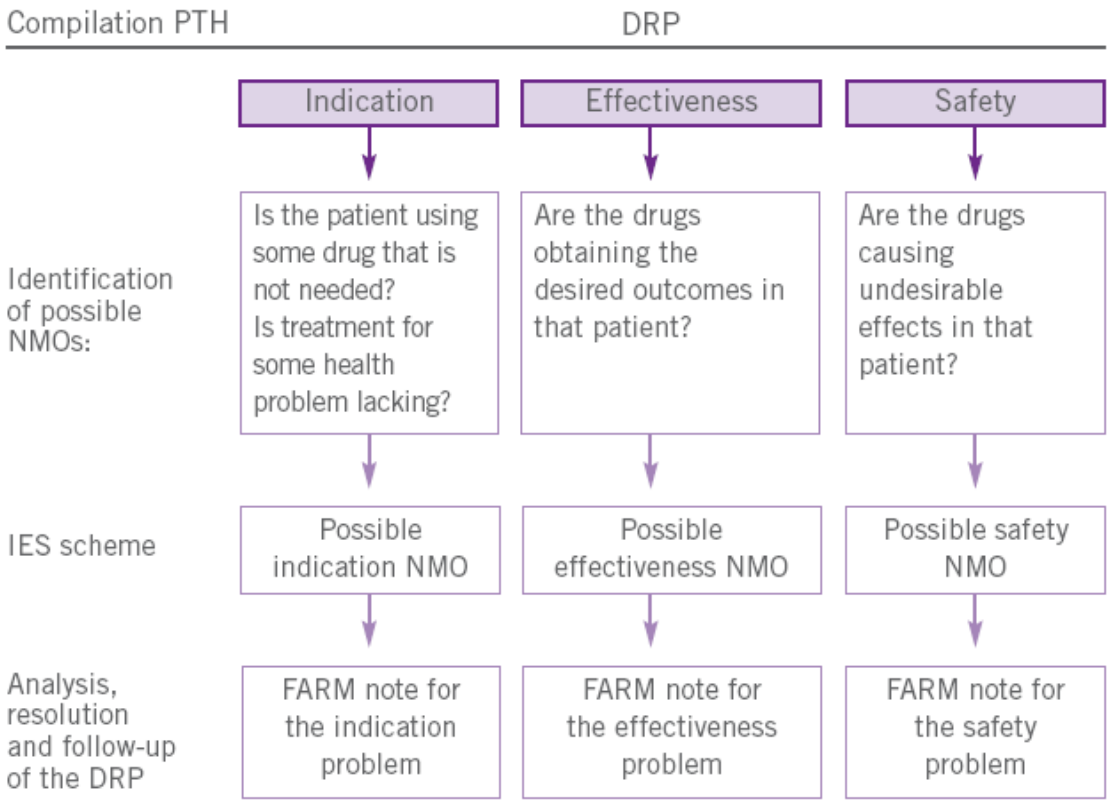

Figure 4. Pharmaceutical care process: Identification of possible NMOs according to the IES scheme.

Analysis, resolution and follow-up of DRPs/NMOs: FARM note

Once the possible DRPs/NMOs have been classified, a FARM note is generated for each of them (Figure 5).

	Problem related to Indication / Need	Problem related to Effectiveness	Problem related to Safety
F	• Patient (P) knowledge of treatment. • Concordance indication to treatment. • Concordance treatment according to P with data in clinical history (CH). • Self-medication. • Medical explorations.	• P perceptions. • Physician and/or nurse perceptions. • Medical and laboratory test explorations.	• P perceptions. • Physician and/or nurse perceptions. • Medical and laboratory test explorations.
A	• Is there need NMO? • Is some medication lacking or superfluous? • Is it clinically significant? • Is it actual or potential? • Why does it happen? (identify cause)	• Is there effectiveness NMO? • Is it a quantitative problem? • Is it clinically significant? • Is it actual or potential? • Why does it happen? (identify cause)	• Is there safety NMO? • Is it a quantitative problem? • Is it clinically significant? • Is it actual or potential? • Why does it happen? (identify cause)
R	Intervention: • Patient recommendations / information • Physician recommendations / information • Referral to physician Classification of the intervention		
M	Programming to conduct follow-up through successive visits (in cooperation with the rest of professionals), in order to assess: • Evolution of response evaluation parameters • Evolution of parameters for prevention of complications • Treatment compliance		

Figure 5. Generation of a “FARM” note according to the type of problem involved.

3. Continuation or end of the procedure

If the pre-established objectives are not reached, repeat evaluation will be required in order to examine the possible presence of DRPs/NMOs, or of some circumstance precluding achievement of the mentioned objectives.
In many cases the follow-up process is not indefinite. There are circumstances that can lead to termination of the Pharmaceutical Care process, such as for example resolution of the health problem giving rise to the need for medical prescription.

Pharmaceutical Care in Hospital Pharmacy *

The functions of the hospital pharmacist are to assume – within the global health care team – personal responsibility for the designing, follow-up and evaluation of pharmacotherapy and its outcomes in the patient [35]. The acceptance of responsibilities on the part of the hospital pharmacist does not imply exclusive authority, and does not lessen the importance of the intervention of the rest of health care professionals involved in the multidisciplinary process of drug utilization. The practice of Pharmaceutical Care adds value to the intervention of the health care team in that it contributes to improve the effectiveness, safety and adequate use of medicines. This contribution also extends to the clinical research setting, process management, and teaching activities related with medicines. Accordingly, **the specific health care objectives of Pharmaceutical Care in the hospital pharmacy setting are the following**:

- To design a follow-up plan capable of evaluating the therapeutic objectives, in cooperation with the health care team and the patient.
- To collect and organize all the necessary specific information on the disease, the patient and the medication, as well as on ethical and pharmacoeconomical aspects, in order to detect DRPs/NMOs.
- To determine the presence of DRPs/NMOs, particularly in the patient groups at highest risk of suffering such problems.
- To establish the necessary recommendations for solving and preventing DRPs/NMOs, based on the existing scientific evidence.
- To typify the categories and causes underlying DRPs/NMOs.
- To evaluate in each patient the intermediate and definite results of Pharmaceutical Care in relation to health and quality of life.
-

The health care activity of the pharmacist is carried out at different times and in different phases of the patient care process: upon admission, in the different phases of the pharmacotherapeutic procedure, at discharge, and in the context of the patient follow-up programs, conducted from a population-based perspective.

In any case, in order to guarantee the quality of the process, it is essential to incorporate interventional methodology, such as for example the **IASER** method[36] for Pharmaceutical Care, which includes the identification of patients with needs for improvement in the quality of pharmacotherapy, pharmaceutical intervention, pharmacotherapy follow-up, the evaluation of outcomes in the patient, and proposals for improvement of the Pharmaceutical Care programs based on the analysis and diffusion of their results.

35. Calvo MV, Alós M, Giráldez J, Inar-Calvo MV, Alós M, Giráldez J, Inaraja MT, Navarro A, Nicolás J. Grupo de Trabajo Atención Farmacéutica. Sociedad Española de Farmacia Hospitalaria. Bases de la atención farmacéutica en Farmacia Hospitalaria. Farm Hosp 2006; 30: 120-123.
36. Climente M and Jiménez NV. Manual para la atención farmacéutica. Ed IVADIS CEE. Valencia 2005.
** Document elaborated by Manuel Alós and Juan Peris, of the Sociedad Española de Farmacia Hospitalaria (SEFH).*

On analyzing the practice of Pharmaceutical Care in hospital pharmacy, another of the aspects to be considered is the fact that in hospital centers and nursing homes the drug utilization process begins and is dependent upon due evaluation and selection (Figure 6).

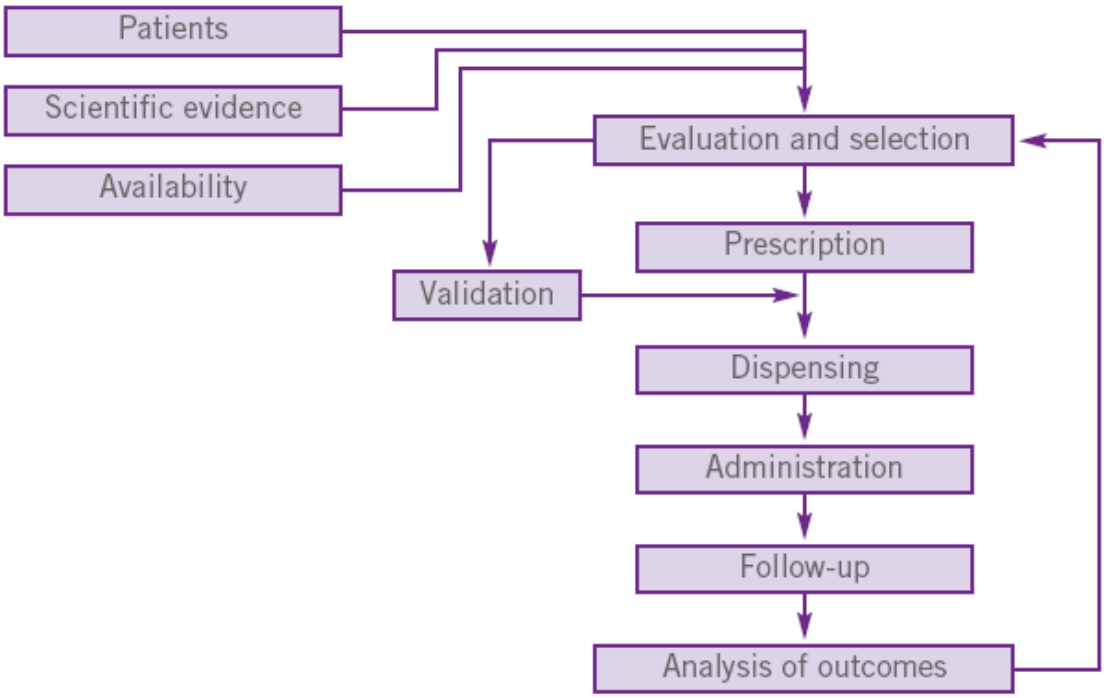

Figure 6. The process of drug utilization in hospitals and nursing homes.

The evaluation and selection of medicines is an interdisciplinary decision process conducted in the setting of the Pharmacy and Therapeutics Commission, and aims to determine the incorporation of new medicines to the Pharmacotherapeutic Guide (PTG), define therapeutic positioning, and guarantee their use under adequate clinical indications and conditions of use.

Lastly, mention should be made of the growing importance gained by the Pharmaceutical Care of external patients in the setting of hospital pharmacy. Although the global definitions and processes relating to Pharmaceutical Care for external patients are basically similar to the situation found in hospitalized patients, or in patients treated on an ambulatory basis (e.g., in day hospitals or hemodialysis units), this modality of external or outpatient care reinforces its messages in certain aspects, e.g., in the importance of the clinical interview or patient health education.

1. Dispensing

In the pharmacy services of hospitals and nursing homes, and particularly through the introduction of new technologies, **individualized drug dispensing in unit doses** is tending to become generalized. This process is defined as the provision of medicines from the pharmacy service to the individual patient, following due review and validation of the medical prescription, and after adequate conditioning of the medication for use without the need for ulterior manipulation, or with only the minimum necessary manipulation [37].

Pharmaceutical validation of the prescription, which makes it possible to address different aspects directly related to patient pharmacotherapy (Table 1), is defined as a key process in the therapeutic chain – with the principal objective of optimizing the pharmacotherapeutic outcomes through improvement in drug handling (quality) and of reducing the risk of adverse events (safety), particularly in high risk patients [35].

This process must be carried out at the start, modification or updating of treatment, following periodic and integral evaluation of the patient, in the event of a significant change in the clinical situation of the patient (e.g., renal impairment), or when some selection criterion is identified – such as for example belonging to a given risk group, patients specifically proposed by the health care team, etc.

Pharmaceutical validation, whenever possible, should be carried out prospectively, in order to avoid any possible drug related problem (DRP) that may affect the patient.

Administrative
- Relating to the patient, center, clinical unit and prescribing physician.

Pharmacotherapeutic
- Adaptation to the Pharmacotherapeutic guide (PTG).
- Suitability of treatment.

Technical
- Drug availability and adequacy.
- Management of the dispensing process (e.g., emergency or programmed).

Table 1. Aspects to be validated in relation to medical prescription.

37. Alós M, Andrés C, Casterá E, Jiménez NV, Ordovás JP, Poveda JL, Ruiz MC, Sirvent M. Criterios de calidad para la acreditación de los servicios de farmacia hospitalaria. Ed. Generalitat Valenciana. Valencia, 2005.

From the perspective of Pharmaceutical Care (Figure 7), two fundamental activities can be underscored in the pharmaceutical validation of prescription: the adaptation of the treatment to the PTG and the identification of medication errors, DRP and NMO.

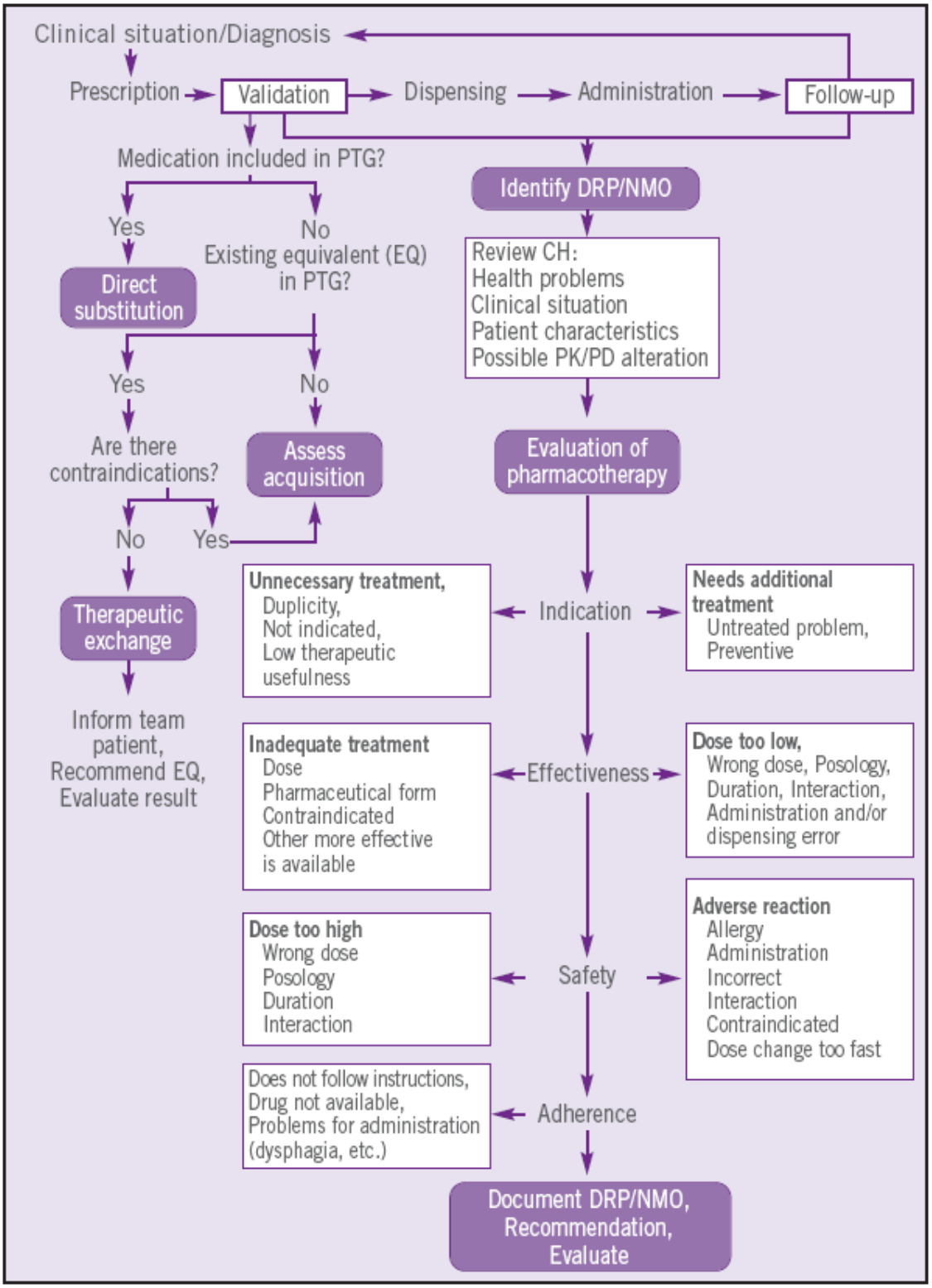

Figure 7. Pharmacist health care activity in the validation and pharmacotherapy follow-up phases.

The adaptation of treatment to the PTG is a working method that attempts to adapt drug use to the therapeutic policy of the center, established by the Pharmacy and Therapeutics Commission, and by the legal specifications. This adaptation comprises three processes that require definition:

- Direct replacement of the prescribed medication with the generic drug or brand name selected in the center.
- Suspension of the treatment when the latter is considered inconvenient or unnecessary, regardless of the underlying reason.
- Therapeutic exchange: Replacement involving a drug chemically different from the prescribed drug, but considered to be therapeutically equivalent or superior, on the basis of a protocol previously established and approved by the Pharmacy and Therapeutics Commission. In order to ensure the quality of the therapeutic exchange, these protocols will contain sufficient information to facilitate selection of the equivalent therapeutic scheme and posterior clinical monitoring of the patient.

The validation of medical prescription, prior to drug dispensing, makes it possible to identify prescription errors, DRPs and NMOs. To this effect it is essential to have access to a series of information sources, together with close communication with the health care team (Table 2).

- Pharmacotherapeutic history
- Laboratory data (test parameters, microbiological, pharmacokinetic and other data)
- Functional and cognitive evaluation scales
- Clinical data (new clinical reports, clinical course, vital signs, etc.)
- Nursing data (administration method and registry, consumption registries, etc.)
- Communication with the health care team
- Interview with the patient or care giver (adherence to therapy, etc.)

Table 2. Information sources required for the validation process.

These information needs condition the requirements (Table 3) for the computer-based registry of Pharmaceutical Care and of the interventions of the hospital pharmacist in relation to patient follow-up [38].

38. Bermejo T, Álvarez A, Codina C, Herranz A, Hidalgo FJ, Queralt M, Martín I, Martínez J, Poveda JL, Prado JR, Rubia A, Sanjurjo M. Grupo TECNO. Sociedad Española de Farmacia Hospitalaria. http://www.sefh.es/ficherosweb/peaaf.pdf.

	System technical requirements	R	S
USER	Definition of system users with different levels of access		
	Date relating to user name, post and service		
	Personal keyword access to the system		
PATIENT	Entry of admission data		
	• Birth date		
	• Sex		
	Patient identification and search		
	• Bed		
	• Name		
	• Clinical history		
	• Episode number		
	Type of episode: Discharge, Hospitalization, Emergency, etc.		
PHARMACEUTICAL INTERVENTION	Starting date on interventional activity Ending date of interventional activity		
	Clinical service		
	Supervising physician		
	Pharmacist		
	Reason for intervention		
	Type of intervention:		
	• Pharmaceutical intervention in: - Indication - Effectiveness - Safety		
	• Other interventions: patient education, pharmacotherapeutic consultations, discharge reports, coordination with primary care, etc.		
	Severity of the problem leading to pharmaceutical intervention		
	Degree of acceptance of the pharmaceutical intervention		
	Impact of the intervention upon patient clinical course		
	Data on the implicated drug: name, dose, frequency, route, duration, price, etc.		
	Time taken by intervention		
	Calculation of costs		
ACTIVITY REGISTRY	Patients by type of episode		
	Patients by service		
	Patients by type of reason for intervention		
	Patients by type of intervention		
SERVICES	Availability of mobile registry systems (PDAs)		
	Availability of the program on hospital network		
REPORTS	Possibility of exporting to databases		
	Parameter-defined reports:		
	Relating to activity		
	Clinical		
	Economical		
	Quality		

R: Requires access to databases; S: Requires connection to other systems

Table 3. Requirements to be met by the computer-based registry of Pharmaceutical Care in hospital pharmacy practice.

2. Pharmacotherapy follow-up

The possibilities for selecting patients with a high risk of DRPs/NMOs, amenable to inclusion in a Pharmaceutical Care program, will depend on the available human resources, the population attended, the technical resources, and the existing information sources. In those hospitals and nursing homes [39] in which Pharmaceutical Care activities exist or are planned, a **professional practice model** must be implanted, with the following orientation:

- To integrate the hospital pharmacist in the health care teams.
- To implicate the pharmacist in patient care.
- To define the responsibilities of the hospital pharmacist with respect to the patient.
- To establish the range of services offered by Pharmaceutical Care.
- To design a growing program for clinical implication of the pharmacist, according to the availability of resources.

The model presents **three levels of responsibility**, according to the type of intervention and implication involved (Table 4) – ranging from the most basic level (Level III) where clinical activities that can be carried out on a population basis are contemplated, to the optimum level (Level I), which requires direct commitment to the patient.

Hospital Pharmaceutical Care	**Level III Clinical specialization**	**Level II Integration in clinical team**	**Level I Patient Pharmaceutical Care**
% time in ward	20% (daily)	60% (daily)	100%
Daily work with access to	Pharmacotherapeutic history	Clinical history	Patient
Location of medication	Pharmacy	Clinical unit	Clinical unit and patient
A	There is specialization by clinical areas. Initially the following areas are suggested: clinical and surgical services, infections, critical care, pediatrics, oncology-hematology.	Participation in clinical sessions. Resolution of consultations (personal or via official interconsultation form) and active information. Visiting rounds with the medical team, in the case of selected patients.	Admission. Review of clinical history. Interview with patient and compilation of pharmacotherapeutic history. Evaluation of ambulatory and hospital treatments.

39. Bermejo T, Álvarez A, Anoz L, Codina C, Herranz A, Hidalgo FJ, Delgado O, Martínez I, Aquerreta I, Climente M , Martínez J, Poveda JL, Sanjurjo M. Grupo TECNO. Sociedad Española de Farmacia Hospitalaria. http://www.sefh.es/ficherosweb/protocoloaf.pdf.

… Continued

Hospital Pharmaceutical Care	Level III Clinical specialization	Level II Integration in clinical team	Level I Patient Pharmaceutical Care
B	Follow-up of prescription of medicines. Prospective treatment evaluation as regards dose, regimen, interactions, allergies, duration of therapy, duplicities.	Evaluation of treatments as regards need, clinical indication, follow-up of side effects, with documentation of the clinical history and information on the visiting rounds. Review of untreated pathologies or symptoms. Use of the clinical history for intervention and as a means of communication with the rest of the health care professionals.	Follow-up. Detection and prevention of DRPs/NMOs. Evaluation of the effectiveness and safety of the treatments applied. Evaluation of complementary tests and follow-up. Evaluation of patient symptoms and course.
C	Structured population-based intervention programs (interactions, drugs with narrow therapeutic margin, duplicities, sequential therapies). Passive consultation activities. Active information on drugs to physicians and nurses. Selection of medicines for the clinical areas.	Hospital prescription follow-up. Prescription-based follow-up of prescribed drug. Reporting of medication errors. Reporting of adverse effects. Cooperation and elaboration of therapeutic protocols.	Patient information at discharge. Delivery of graphic documentation. Evaluation of prescriptions at discharge. Adaptation to the prescription criteria of the health area. Outpatient consultation: establishment of patient follow-up in outpatient clinics.
Registry of activity. Evaluation of outcomes of the pharmaceutical intervention (clinical, economical and humanistic assessment) Research. Publication of the activity in scientific journals.			

Table 4. Levels of development and responsibility in Pharmaceutical Care.

The activities corresponding to Level III center on specialization by clinical areas, instead of on the traditional functional areas of the service of pharmacy. The areas of responsibility are defined by access to the pharmacotherapeutic history of the patient and the laboratory databases.

The activities corresponding to Level II in turn correspond to integration in the clinical team, with 60% time dedication to the clinical units, and the responsibility of the hospital pharmacist derives from his or her access to the full clinical history of the patient, and to the patient in person, where considered opportune.

At Level I, the pharmacist establishes contact with the patient, has access to the patient course throughout the entire process, and takes part in the treatment decisions – accepting responsibility along with the rest of the health care team for the clinical outcomes obtained. In this case the pharmacist is required to have 100% dedication to clinical activity.

On a complementary basis, the **levels of demand** or need for Pharmaceutical Care can be established according to the following characteristics of the patient and of the provided pharmacotherapy:

a. Related to the patients and their clinical situation:

a.1. Usual readmissions
a.2. Allergies
a.3. Three or more concurrent diseases
a.4. Presence of renal failure (RF), hospital infection (HI) or congestive heart failure (CHF)
a.5. Obesity or low body weight
a.6. Perioperative period
a.7. Extrarenal filtration procedures

b. Related to pharmacotherapy:

b.1. Administration of 5 or more drugs
b.2. More than 12 daily doses
b.3. Parenteral treatment
b.4. Drugs with a narrow therapeutic window
b.5. Drugs requiring the individualization of posology
b.6. Drugs posing a risk of serious adverse effects
b.7. Drugs involving clinically significant interactions
b.8. Drugs with predefined utilization criteria (protocols, clinical routes, etc.)

Based on these characteristics of the patients and their treatments, criteria can be established to define **priority** in the selection of clinical services. Thus, each service of pharmacy will evaluate the clinical services amenable to Pharmaceutical Care, with due assessment of the following aspects:

- Type of patient and benefits of Pharmaceutical Care
- Number of patients attended

- Impact in the health care area
- Cohesion of the clinical team
- Predisposal and previous relationship with the clinical team
- Professional prestige
- Physical space and availability for accommodating the pharmacist
- Cost of the treatments
- Historical registry of patients with medication errors, drug related problems (DRPs), etc.

In this professional practice model for Pharmaceutical Care, the intervention of the pharmacist should abide with the following general concepts:

- A change in mentality is needed, implying structural and organizational changes applicable to the hospital pharmacist and to the rest of the personnel ascribed to the service of pharmacy. The primary objective is shifted from “medication” to “patient”.
- A given patient does not form part of a point intervention, but rather of a continuous process over time, and for the full duration of the care provided in the center - including discharge and follow-up in the context of posterior interventions, in the case of chronic patients.
- The pharmacist must become integrated in a health care model that is already operating in the institution or center; as a result, knowledge is required of the current health care circuits in order to adapt to the working activities.
- The physicians and nurses of the health care team in which the hospital pharmacist is integrated must have explicit knowledge of the program and of the objectives of the contemplated activity.
- From the start, the hospital pharmacist must work integrated within the clinical team (physicians, nurses) – not on an isolated basis. It is important for the patient to identify the hospital pharmacist as a member of the clinical team, and the message received by the patient should be uniform and coordinated.
- Work should be carried out on the basis of written protocols known to all the members of the health care team, and with due prior establishment of consensus.
- The activity of the pharmacist should center on the optimization of treatment, not exclusively on the detection of problems. The seeking of solutions is the reference objective.
- It is necessary to know the clinical and pharmacotherapeutic history before any intervention is made, particularly before any interview with the patient.
- Careful evaluation is required of the degree of patient knowledge of the disease and treatment, as well as of those aspects of life style allowing for adequate planning of the administration of the medication.
- The route for documentation of the patient process is the clinical history.

The specific activities of the hospital pharmacist at each of the levels of responsibility defined in this model of professional practice in the context of Pharmaceutical Care are specified below:

a) Activities corresponding to Level III (basic)

- Specialization by clinical areas must be planned: for example, medical and surgical services, infectious diseases unit, critical care, pediatric and oncology-hematology.
- Follow-up of drug prescription. A prospective evaluation of the treatments is to be made, relating to dose, regimen, interactions, allergies, duration of therapy and duplicities.
- Structured population-based intervention programs are to be implemented relating to interactions, drugs with a narrow therapeutic margin, and sequential therapies.
- A system is to be implemented for addressing consultations of services and clinical units of the specialty.
- Active drug information programs are to be implemented for the health care personnel of the institution or center.

b) Activities corresponding to Level II (intermediate)

- Active participation in the clinical sessions of the service or clinical unit to which the hospital pharmacist is assigned.
- Evaluation in cooperation with the medical and nursing team of the patients selected for the Pharmaceutical Care program, and evaluation of their treatments based on the clinical history and clinical interview of patients.
- Follow-up of hospital prescription and of clinical services prescription.
- Detection and reporting of adverse effects.
- Detection and reporting of medication errors.
- Collaboration and elaboration of therapeutic protocols.
- Collaboration with the rest of the health care team (physicians, nurses, biologists, etc.) and the patients for the prevention, identification and resolution of any problem or negative outcome related with the medication provided.

c) Activities corresponding to Level I (advanced)

c.1) Upon admission

- Review of the new admissions. A review is required of the clinical histories of the newly admitted patients, particularly as refers to the reason for admission and the diagnostic orientation. From the perspective of the hospital pharmacist, special emphasis is to be placed on documenting the pharmacotherapeutic history regarding the drugs commonly used by the patient, adherence to therapy, and availability in the hospital. Documentation is required of drug allergies and intolerances, as well as of the initial liver and kidney function parameters, dietary requirements, and other relevant aspects associated with the patient life style. All this information is to be registered in order to explain the possible changes in medication that have taken place with respect to admission, and their causes.

- An evaluation of the patient is to be made along with the medical team, collaborating particularly in the area of treatment strategy.
- The patient is to be informed about the changes in his or her usual treatment, stressing the suspension or continuation of habitual therapy during the period of hospital admission.
- In any case, the activities carried out must be reported to the personnel involved (physicians, nurses, etc.), and to the patient, and are to be reflected both in the clinical history and on the treatment form.

c.2) During hospital stay

- The professional activity of the hospital pharmacist is preferentially to take place in the clinical unit, throughout the duration of the health care process.
- Clinical response to treatment is to be evaluated, both as regards effectiveness and in relation to the appearance of side effects.
- The **pharmacotherapy follow-up** of each patient will comprise the following aspects:
  - Adequate indication of treatment, based on the criteria defined in the Pharmacotherapeutic Guide.
  - Adaptation of treatment dose and regimen to the indications and clinical situation of the patient.
  - Correct drug dosing in special clinical situations such as renal failure, obesity, etc.
  - Avoidance of therapeutic duplicity.
  - Identification of needs for additional treatment, such as untreated indications, the continuation of home (domiciliary) treatments, and premedication in those health care or treatment circumstances where required.
  - Promotion of sequential therapy.
  - Avoidance of interactions with food or drugs.
  - Adjustment of treatment duration.
  - Reporting of special treatment administration to the nursing personnel, with evaluation of whether administration is carried out correctly.
  - Introduction of necessary additional drugs in the presence of an untreated indication.
  - Suspension of unnecessary drugs.
  - Specific evaluation of treatments in the institution or center protocolized from the Pharmacy and Therapeutics Commission, e.g., antibiotics and analgesics, drugs for the prevention of infections, deep venous thrombosis and ulcer, and those which imply correction of the nutritional status of the hospitalized patient.
  - Drugs with a narrow therapeutic margin or window will be subject to special follow-up, and where possible through pharmacokinetic and pharmacogenetic monitoring techniques.

- Identification and collaboration with the clinical team in the treatment and prevention of adverse effects resulting from drug administration.

c.3) At hospital discharge

- Collaboration with the clinical team in designing patient treatment at hospital discharge.
- Evaluation of treatment at discharge, and its adequacy in relation to the prescription parameters of the Pharmacotherapeutic Guide.
- Patient interview to provide information on the treatment at discharge, particularly as refers to the following aspects:
  - Changes introduced in terms of treatment, dietary measures and life style with respect to the situation at the time of admission.
  - Active encouragement of treatment compliance, explaining to the patient the importance of compliance and securing personal commitment to adhere to therapy.
  - Information regarding the administration of the more complex drug formulations (inhaled, injected, etc.).
  - Information on interactions with food and/or other medicines.
  - Express information on finite treatments and on the ascending and descending dosing regimens of the medications.
  - Preparation of a timetable relating to integral treatment, including previous home medication and the medication established in hospital.

Actions for the diffusion of Pharmaceutical Care procedures and the development of software tools

The Forum suggests certain specific actions that could be carried out both on an individual basis by the associations and entities belonging to the Forum, and on a collective-consensual basis:

- Preparation of a technical instructions manual, available for companies and institutions that wish to develop integrated software applications for the practical implementation of Pharmaceutical Care.
- Planning and publication of a series of divulgating and scientific articles in the professional press media relating to the new definitions and methodological concepts on Pharmaceutical Care established by consensus in the Forum.
- Diffusion of the agreements reached in the scientific (congresses, scientific meetings) and professional settings.

Annex

Informed consent models
WARNING TEXT

A model is provided below of a document corresponding to the mechanism by which users are informed of the collection of data for Pharmaceutical Care by the community pharmacies. This document is to be signed by the user before including his or her data in the Pharmaceutical Care Registry, with due filing by the pharmacist.

PRIOR WARNING

Destined to the functions of Pharmaceutical Care, based on the computer-based processing of data.
It is necessary to abide with the Spanish Law on the Protection of Personal Data 15/99, of December 13, and the rest of applicable regulations.

To this effect, the following must be taken into account:

- **Prior to the collection and processing of information of a personal or confidential nature, the community pharmacy authorization holder (pharmacist) must abide with the following as specified by current legislation**:
- Adoption of the technical, organizational and software measures corresponding to a HIGH security level, to ensure the security of the personal data collected from the users (Security document).
- **Declare the Pharmaceutical Care form to the Data Protection Agency (DPA).**
- An option is to download from the DPA website (www.agenciaprotecciondatos.org) and complete the form according to Annex III. The completed form is to be submitted to the DPA, which in turn will notify the applicant of the corresponding file inscription code.
- **Express and informed consent is to be obtained, prior to any collection or processing of data of a personal nature. An orientative model (A) is enclosed at the end of this document.**

Warning – Represented consent

The non-authorized disclosure of personal or confidential information is forbidden by law. Thus, exceptionally, if Pharmaceutical Care is provided to a person through a relative or other authorized person other than through accredited legal representation, consent from the person implicated is required, before collecting or processing any personal or confidential information from the pharmacy to any person – relative or otherwise.

In this circumstance, voluntary authorization in writing is to be obtained from the person implicated, referred to the collection and processing of his or her personal data, and authorization to cede such information to the relatives stated in the mentioned authorization.
An orientative model (B) to this specific effect is enclosed at the end of this document.

- Each user is to be guaranteed the right to access, rectification and cancellation and opposition of his or her own data, in the terms established by legislation.
- Compliance is required with all other obligations relating to especially protected health information established by law.
- Legislation also establishes that data of a personal nature are to be canceled once they are no longer necessary or pertinent to the effects for which they were collected in the first place, and will not be stored for periods of time longer than required for their initially intended purpose.
- Lastly, any modification posterior to notification and inscription of the file by the DPA must be reported to the latter, to the effects of due inscription, within one month following the mentioned modification. Within the same time limit, the decision to suppress the file to the effect of cancellation of the inscription will be notified.

The Law on the Protection of Personal Data allows the DPA to sanction failure to comply with its specifications as follows, as stipulated in the subsequent 43 articles of the Law:

600 to 60,000 euros (minor infraction)
60,000 to 300,000 euros (serious infraction)
300,000 to 600,000 euros (very serious infraction)

(A)
ORIENTATIVE MODEL INFORMING USERS OF THE COLLECTION OF DATA FOR PHARMACEUTICAL CARE BY THE COMMUNITY PHARMACIES

Mr./Ms.
with ID no. , birth date , sex
Social Security number , and address

The undersigned is precisely and unequivocally informed, and expressly authorizes the Pharmacy (name of holder/s)

to collect and process in a file for which it is responsible the data requested in the present form. The data will be used only for the stated purpose of offering personalized Pharmaceutical Care, comprising the following functions:

- Deliver the medication and/or health care product under optimum conditions and according to current legislation.
- Protect the patient against possible drug related problems.
- Inform the patient of the best way to resolve his or her health problem, and to select a medication where applicable.
- Resolve user doubts or any lack of information detected by the pharmacist.
- Evaluation of whether the health problem is precisely a consequence of some drug related problem.
- The seeking of maximum effectiveness of pharmacological treatment.
- Minimization of the risks associated with drug use, thereby contributing to improve the safety of pharmacotherapy.
- Contribution to the rational use of medicines as the principal therapeutic tool available to society.
- Improvement of patient quality of life.
- Data to be collected from the patient:
- Personal antecedents:
    - Special dietary considerations
    - Smoking
    - Alcohol consumption
    - Caffeine consumption
    - History of hypersensitivity reactions
    - History of intolerances
- Diseases diagnosed and vaccines administered
- History of pregnancy and lactation (nursing)
- Pharmacological history
- History of adverse events
- Other health care particulars of interest

The information requested is of a medical nature, though if it is not supplied, the mentioned service cannot be offered. You are informed that the aforementioned consent is revocable, and that you have the right to access, rectification and cancellation and opposition, in the terms established by legislation, upon written request addressed to:

(pharmacy address)

Signed:

(B)
ORIENTATIVE MODEL FOR AUTHORIZATION TO COLLECT, PROCESS AND CONVEY DATA TO A THIRD PERSON

Mr./Ms.
(full name), legally adult and with ID no.
with address
by means of the present document, expressly authorizes Mr./Ms. (*)

and Mr./Ms. (*)
to disclose the personal data of the undersigned, including health information, to Mr./Ms.
pharmacist of the community pharmacy with address

with the purpose of receiving Pharmaceutical Care from the mentioned community pharmacy, prior to processing of the mentioned personal data.
Likewise, the undersigned authorizes the pharmacist to disclose and report the mentioned data to Mr./Ms. (*)
and Mr./Ms. (**)
as well as to the latter to exercise (where required) the right to access, rectification, cancellation and opposition of their own data.

Signed: Mr./Ms.
(the undersigned)

Glossary

Definitions

Pharmaceutical Care

Pharmaceutical Care is the active participation of the pharmacist in ensuring improved patient quality of life, through dispensing, OTC prescription and pharmacotherapy follow-up. Such participation implies cooperation with the physician and other health care professionals in order to secure outcomes that improve patient quality of life, as well as pharmacist intervention in activities that offer good health and avoid the development of diseases.

Pharmaceutical Care comprises professional activity in which the pharmacist assumes responsibility for the drug-related needs of the patient.

Dispensing

Dispensing is the professional service of the pharmacist destined to ensure – following individual evaluation – that the patients receive and use their medicines adequately in relation to their clinical needs, at the precise doses indicated for their individual necessities, during the adequate period of time, with information for correct use, and in abidance with current legislation.

OTC prescription

OTC prescription is the professional service offered upon demand from a patient or user who visits the community pharmacy without knowing which medicine to acquire, and wishes the pharmacist to provide the best remedy for his or her specific health problem. If the service requires drug dispensing, the latter is to be carried out according to the definition provided above.

Pharmacotherapy follow-up

Pharmacotherapy follow-up aims to detect drug related problems (DRPs), for the prevention and resolution of negative medicine outcomes (NMOs). This service entails commitment, and must be provided on a continuous, systematic and documented basis, in cooperation with the patient personally, and with the rest of the health care professionals, in order to secure specific outcomes that serve to improve patient quality of life.

Incident

An incident is any circumstance related with pharmacotherapy, which in the course of the defined dispensing procedure does not coincide with the expected or accepted situation, and interrupts the procedure – requiring due evaluation in a follow-up episode.

Follow-up episode

A follow-up episode is the point evaluation of an incident in the context of dispensing, using the proprietary instruments of the Follow-up Service to identify the drug related problem (DRP)(the cause, and thus the risk of appearance of an NMO), or the negative medicine outcome (NMO).

Drug related problems (DRPs)
Drug related problems (DRPs) are those situations that cause or may cause the appearance of negative medicine outcomes (NMOs). DRPs are elements of the process that entail an increased user risk of suffering an NMO.

Negative medicine outcomes (NMOs)
Negative medicine outcomes (NMOs) are those patient health outcomes not suited to the objectives of pharmacotherapy, and associated or potentially associated with drug use.

Personalized medication information (PMI)
Personalized medication information (PMI) is the information supplied to the patient by the pharmacist regarding the treatment, in the course of the dispensing process, with the purpose of ensuring effective and safe drug use.

Intervention

Intervention is the activity destined to modify some characteristic of the treatment, of the patient receiving it, or the conditions of use, and with the purpose of resolving a DRP / NMO.

We are all commited to Pharmaceutical Care.
Remember that all the members of the Forum are at your disponsal.
If you desire information, please feel free to contact them.