GENERAL
PHARMACEUTICAL
COUNCIL OF SPAIN

Good Pharmacy Practice in Spanish Community Pharmacy

01

Dispensing Service for Medicines and Medical Devices

This document has been developed by the Good Pharmacy Practice Working Group from the General Pharmaceutical Council of Spain, constituted by:

General Pharmaceutical Council of Spain
Pharmacy Chamber – Barcelona
Pharmacy Chamber – Cádiz
Pharmacy Chamber – Gipuzkoa
Pharmacy Chamber – Zaragoza
Foundation Pharmaceutical Care
Spanish Society of Community Pharmacy (SEFAC)
University of Granada

The General Pharmaceutical Council of Spain's Plenary approved the circulation of this document at the session held on 23rd July 2014

Published by:
General Pharmaceutical Council of Spain
Villanueva, 11, 7th Floor. 28001 Madrid
E-mail congral@redfarma.org
Web: www.portalfarma.com

Legal Deposit: M-27201-2014

Layout and graphic production: Comuniland S.L.

Good Pharmacy
Practice in Spanish
Community Pharmacy

01 Dispensing Service for Medicines and Medical Devices

CONTENTS

Introduction

The dispensing of medicines and medical devices is an essential service in the everyday professional practice of any community pharmacist.

This service ensures the population's access to medicines and medical devices while at the same time providing information to patients on their proper use process and detecting and correcting potential problems that could appear associated with their use.

According to the definition of the Pharmaceutical Care in Community Pharmacy Forum (FORO AF-FC), it is "*the professional service offered by pharmacists to ensure, through individual assessment, that patients correctly receive and use medicines and medical devices, based in their clinical needs, in proper dosages in accordance with their individual needs, over the appropriate period of time, receiving the necessary information to guarantee correct usage and in compliance with applicable laws*". This definition, while specific to medicines, is generally applicable to medical devices.

An absolute requirement for the dispensing of medicines and medical devices is the presence and professional action of the pharmacist. Pharmacy technicians and pharmacy assistants may, however, under the pharmacist's supervision, take part in the procedure.

This document contains the necessary recommendations so that the practice of the dispensing of prescription only and non-prescription medicines, and of medical devices can be regarded as a good professional practice.

Objectives of the Dispensing Service for Medicines and Medical Devices

a) To ensure access to the medicine/medical device and supply it in optimal conditions, in accordance with the applicable legal regulations.

b) To ensure that the patient is aware of and accepts the process for using the medicine/medical device.

c) To protect the patient against the emergence of possible negative outcomes associated with the use of medicines/medical devices by identifying and resolving any problems related to their use.

d) To identify, in certain cases, negative outcomes and attempt to resolve them.

e) To detect other needs so as to offer additional services, as applicable.

f) To record and document the interventions carried out.

Procedure of the Dispensing Service for Prescription Only Medicines and Medical Devices

When a prescription only medicine or medical device is requested, the pharmacist must consider:

1. Contents and period of validity of the prescription handed: the pharmacist must check that the prescription is legitimate and contains all of the information required by the legislation in force.

a) **Patient information:** name, surname and date of birth.
   i. In the case of prescriptions from the healthcare public system, these must also include the number of the individual health insurance card, if any. For foreign patients who do not have such card, the number of the European health insurance card or temporary replacement certificate, or of the relevant European right to care form, shall be consigned. For non-EU citizens, the passport number or the information required by the relevant healthcare administration shall be included. In any case, the reimbursement scheme corresponding to the patient shall be annotated.
   ii. For private prescriptions, the national identity number (DNI) shall be recorded. In the case of junior patients, the DNI of either parent or of a tutor shall be recorded, and for foreigners, the passport number.

b) **Data on the prescriber:** name, surname, direct contact information (e-mail, phone or fax number with country code), business address (city and country name), professional qualification, professional affiliation number (or identification code provided by the relevant administration for prescriptions from the National Health System (SNS)) and signature (handwritten for paper prescriptions or electronic for e-prescriptions).

c) **Data on the medicine (or medical device):** name of the active ingredient(s) of the medicine or name of the medicine in the case of biological medicines or when deemed necessary by the prescriber and according to the applicable legislation; dosage, pharmaceutical form, route of administration (if necessary), number of units per package or contents by weight or volume, number of packages to dispense, posology and treatment duration.

d) **Inspection endorsement, if applicable.**

e) **Prescription refill number** (in the case of repeat prescriptions for chronic diseases or renewable prescriptions).

f) **Official prescription for narcotics, if applicable.**

g) **Date of prescription.**

h) **Expected dispensing date, if applicable.**

In general, the period of validity for an SNS prescription will be 10 days from the date of issue or from the expected dispensing date in the case of repeat prescriptions for chronic diseases or renewable prescriptions. In the case of medicines/medical devices requiring an inspection endorsement, the period of validity will generally start on the date of the endorsement. In the case of prescriptions for isotretinoin for women of childbearing age, the validity of the prescription will be 7 days from the date of the prescription, as specified on the summary of product characteristics.

When there are reasonable doubts as to the authenticity or validity of the prescription, the pharmacist shall not dispense the medicine/medical device requested unless the legitimacy of the prescription can be verified. If this is not possible, it shall be brought to the attention of the relevant healthcare authority.

In the case of **electronic prescriptions**, the pharmacist will access the computer systems through the individual health card presented by the patient. Electronic prescription systems will feature the necessary security measures to limit access to prescribers and pharmacists. To proceed with the dispensing, the owner, regent, associate or substitute pharmacist, must have the relevant electronic certificate issued by the competent entity.

2. Who it is for: the identification shall take into account the gender, approximate age and relationship to the person requesting the medicine or medical device; whether it is the patient himself/herself, a caregiver or a third party.

When collecting information of a personal nature, this shall be done so as to ensure its confidentiality in keeping with the purposes, limitations and rights set out in the relevant legislation.

For medicines containing narcotic substances in Schedules I and II of the Single Convention on narcotic drugs or psychotropic substances listed in the national legislation, the identity of the person, who access to the pharmacy to collect the medication will be recorded by writing down his/her DNI or equivalent number on the prescription.

3. Verify non-dispensing criteria: The pharmacist will verify if the patient is using other medicines, present concomitant diseases, is pregnant/breastfeeding, and has any known allergies, contraindications, interactions or duplications, which may affect the aim of the treatment and the health status of the patient based on the information available.

For medicines subject to a special prescription (psychotropic medicines, narcotics) and/or medicines with restricted medical prescription (hospital diagnosis and special medical control), the pharmacist will take into account the additional precautions specific to each case.

In general, in case of reasonable doubt involving the possible misuse or abuse of a prescription only medicine, the pharmacist will decide whether to dispense or not based on the specific situation.

In the case of electronic prescriptions, the pharmacist may, as a precaution, block the dispensing of a medicine/medical device if any of the above criteria is detected. The pharmacist shall inform the patient of this circumstance and report it to the prescriber who shall review the prescription before reactivating it or cancelling it, as appropriate.

If there are no administrative problems or criteria preventing the dispensing, the next step shall depend on whether it is the first time the patient is using that medicine/medical device (initial treatment) or not (continued treatment).

4. Initial treatment: if it is the first time a patient is using a prescription only medicine or medical device, the pharmacist shall, by means of a brief interview, obtain the information needed to ensure that the patient or caregiver knows how to use that medicine or medical device.

Typical questions to ask will preferably be aimed at obtaining the maximum assessable information on the patient. The pharmacist must ensure the patient knows:

- What it will be used for.
- How much (dosage and dosage regimen).
- How long.
- How to use it (if there are special usage/handling and/or storage conditions).
- Effectiveness and safety precautions.

5. Continued treatment when it is not the first time a patient uses a prescription only medicine or medical device, the pharmacist shall obtain, by means of a brief interview, the information needed to assess the patient's perception of its effectiveness and safety.

Typical questions to ask shall cover the following topics:

- Changes (dosage, dosage regimen, etc.), if any.
  If the answer is affirmative, the same questions used for an initial treatment shall be asked.
- How the treatment is progressing: the patient may answer good or bad in connection to the effectiveness of the treatment (whether it is working or not) and to the safety (whether there are adverse events or not).

6. Intervention:

- **No incidence[1] detectet** the pharmacist will dispense the medicine or medical device along with accurate, personalized, non-commercial information that the patient can understand and adapt to his/her needs.

- **Incidence detected:** if an incidence is detected, a Follow-up Episode[2] shall be opened which could require the pharmacist to take further action. This intervention could involve the provision of personalized information, healthcare education, reporting to the Spanish Pharmacovigilance System, refer patient to a doctor or other healthcare professional or to another professional pharmacy service, or not dispensing the medicine or medical device.

Regardless of whether there are incidences or not, the pharmacist can consider offering other professional pharmacy services, in particular to chronic patients that may be of benefit for caring and controlling their health problems.

7. Supply of the prescription only medicine or medical device: before delivering the medicine or medical device, the pharmacist shall check its expiry date and ensure that it has been properly stored (if cold chain is required to be kept).

In general, the pharmacist will dispense the medicine or medical device prescribed according to the applicable legal regulations. Exceptionally, as required by a shortage or in an urgent necessity, the pharmacist may substitute a medicine or medical device with another, pursuant to applicable criteria in force. Any substitution shall be annotated on the prescription, indicating the name of the medicine or medical device dispensed, along with the signature, date and reason for the substitution. The patient is to be informed of this substitution. For e-prescriptions, the pharmacist shall enter into the system the name of the medicine or medical device dispensed and the reason for the substitution, which shall be visible to the prescriber.

For prescriptions from the National Health System, either in paper or electronic format, the information sheet will be given to the patient when the medicine or medical device is supplied.

The patient will pay the amount stipulated, if any, pursuant to the regulation governing the public system, including mutual societies, and private prescriptions and those governing private insurance and workplace mutual societies.

The pharmacist shall likewise give the patient a receipt including the identification of the community pharmacy, the date the prescription was filled, the name(s) and units of the medicine(s) dispensed the retail price and the amount paid by the patient.

8. Record: to the possible extent, the pharmacist shall electronically record the procedure followed and all the medicines or medical devices dispensed.

9. Consignment of the prescription data: this shall include data on the community pharmacy, the dispensing date and the pharmacist's signature or its equivalent in the case of an electronic prescription.

10. Review of prescriptions filled: every day prescriptions filled shall be reviewed in order to detect potential incidences, administrative errors, etc. The appropriate steps shall be taken to correct any problems detected.

11. Record in the prescription book/narcotics accountability logbook or equivalent record: as required by applicable regulations

12. Custody of filled prescriptions: paper prescriptions shall remain in the pharmacist's custody as long as required by law.

[1] INCIDENCE: any circumstance relating to the pharmacotherapy that during the established dispensing procedure is not consistent with the accepted or expected situation and that interrupts the procedure, requiring its follow-up evaluation. (Practical Guide for Pharmaceutical Care Services in Community Pharmacy. FORO AF-FC).

[2] FOLLOW-UP EPISODE: the isolated study of an incidence occurring during the dispensing service using medication review with follow-up methodologies. It aims to identify the cause of the problem and therefore the risk of a negative outcome (NOM). (Practical Guide for Pharmaceutical Care Services in Community Pharmacy. FORO AF-FC).

13. Invoicing: for the purposes of billing, the endorsement-coupons, vouchers or approved system established by insurance companies or healthcare services shall be attached. For e-prescriptions, the endorsement-coupons, vouchers or approved system shall be attached to the proof of dispensing document. Paper prescriptions subject to reimbursement shall be classified based on the different entities where agreements are in place and in accordance with the classification and delivery procedures laid out by the correspondent Provincial Pharmacy Chamber.

In the case of e-prescriptions, the system will send the data identifying the product, the number of units dispensed, the payment made by the user, identifying data on the pharmacy and the date the prescription was filled to the relevant Provincial Pharmacy Chamber/healthcare administration.

Procedure of the Dispensing Service for Non-Prescription Medicines and Medical Devices

When a non-prescription medicine or medical device is requested, the pharmacist must consider:

1. Who it is for: as with prescription only medicines, the pharmacist shall determine the gender and approximate age of the patient and whether the person who is requesting the non-prescription medicine or medical device is the patient, a caregiver or a third party.

When collecting information of a personal nature, this shall be done so as to ensure its confidentiality in keeping with the purposes, limitations and rights set out in the relevant legislation.

2. Verify non-dispensing criteria: the pharmacist will verify if the patient is using other medicines, presents concomitant diseases, is pregnant/breastfeeding, and has any known allergies, contraindications, interactions or duplicate prescriptions.

In general, in case of reasonable doubt involving the possible misuse or abuse of a non-prescription medicine, the pharmacist will decide whether to dispense or not based on the specific situation. Special attention will be given in the case of a request for a non-prescription medicine made by a junior.

If there are no problems preventing the dispensing, the next step shall depend on whether it is the first time the patient is using the non-prescription medicine/medical device (initial treatment) or not (continued treatment).

In the case of non-prescription medicines, the pharmacist shall always confirm the indication, that is, what the medicine requested is to be used for.

3. Initial treatment: If it is the first time that a patient is going to use a non-prescription medicine, the pharmacist must obtain the necessary information to ensure that the patient knows what the medicine is going to be used for, how much to use, for how long, how to use it and other safety, effectiveness, and storage information.

4. Continued treatment: If it is not the first time, the pharmacist will need to assess if the product requested is proving effective and safe.

5. Intervention

• **No incidence detected:** the pharmacist will dispense the non-prescription medicine or medical device along with accurate, personalized, non-commercial information that the patient can understand and adapt to his/her needs.

• **Incidence detected:** the pharmacist shall open a Follow-up Episode that will include an intervention that could involve providing personalized information, refer the patient to a doctor or healthcare professional or to another professional pharmacy service, or not dispensing the medicine or medical device.

The pharmacist can consider taking other professional interventions for the benefit of the patient.

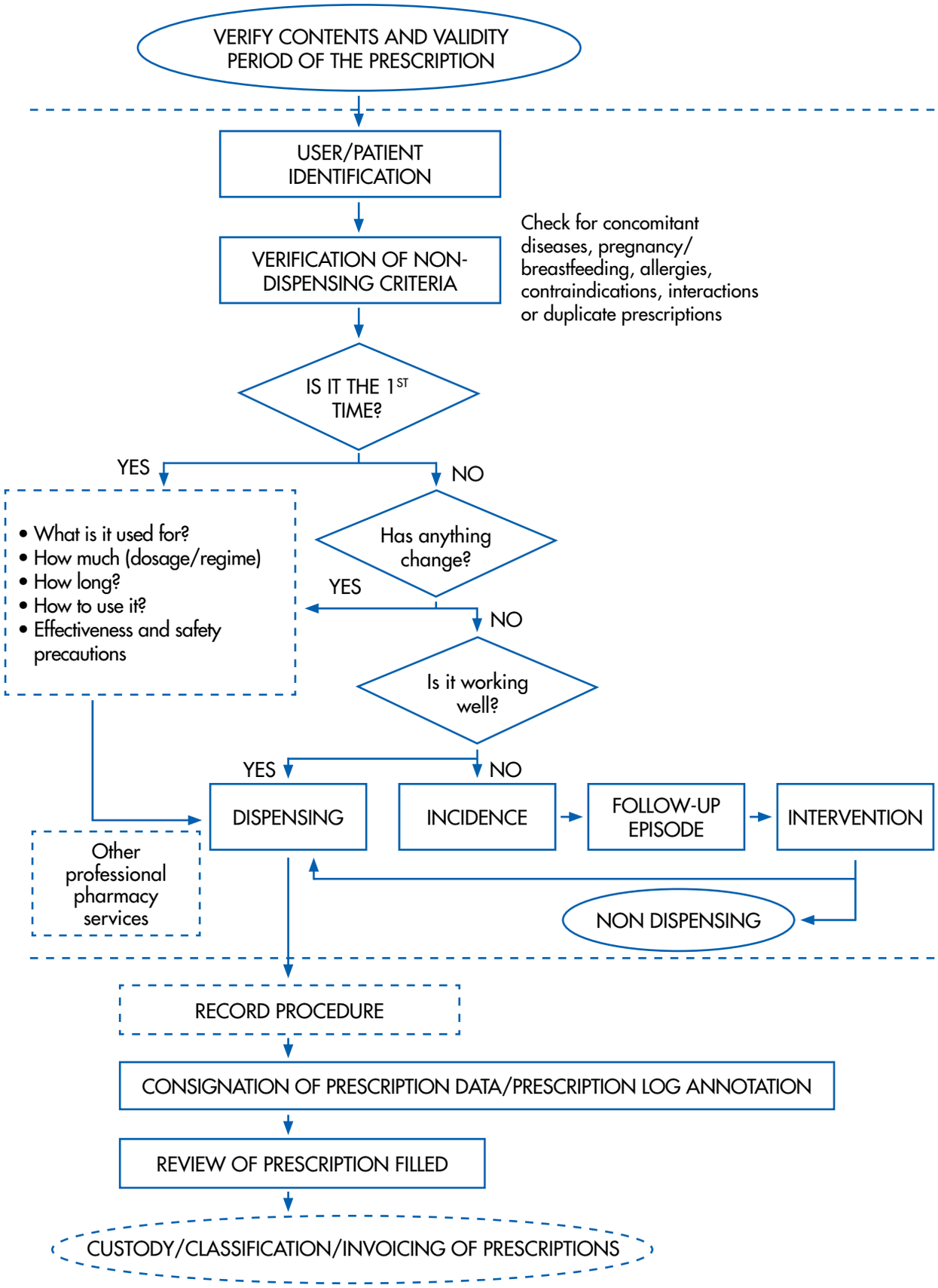
6. Supply of the non-prescription medicine or medical device: before delivering the product, the pharmacist shall check its expiry date. The patient shall pay the corresponding amount.

7. Record: to the possible extent, the pharmacist shall electronically record the procedure followed and all the medicines or medical devices dispensed.

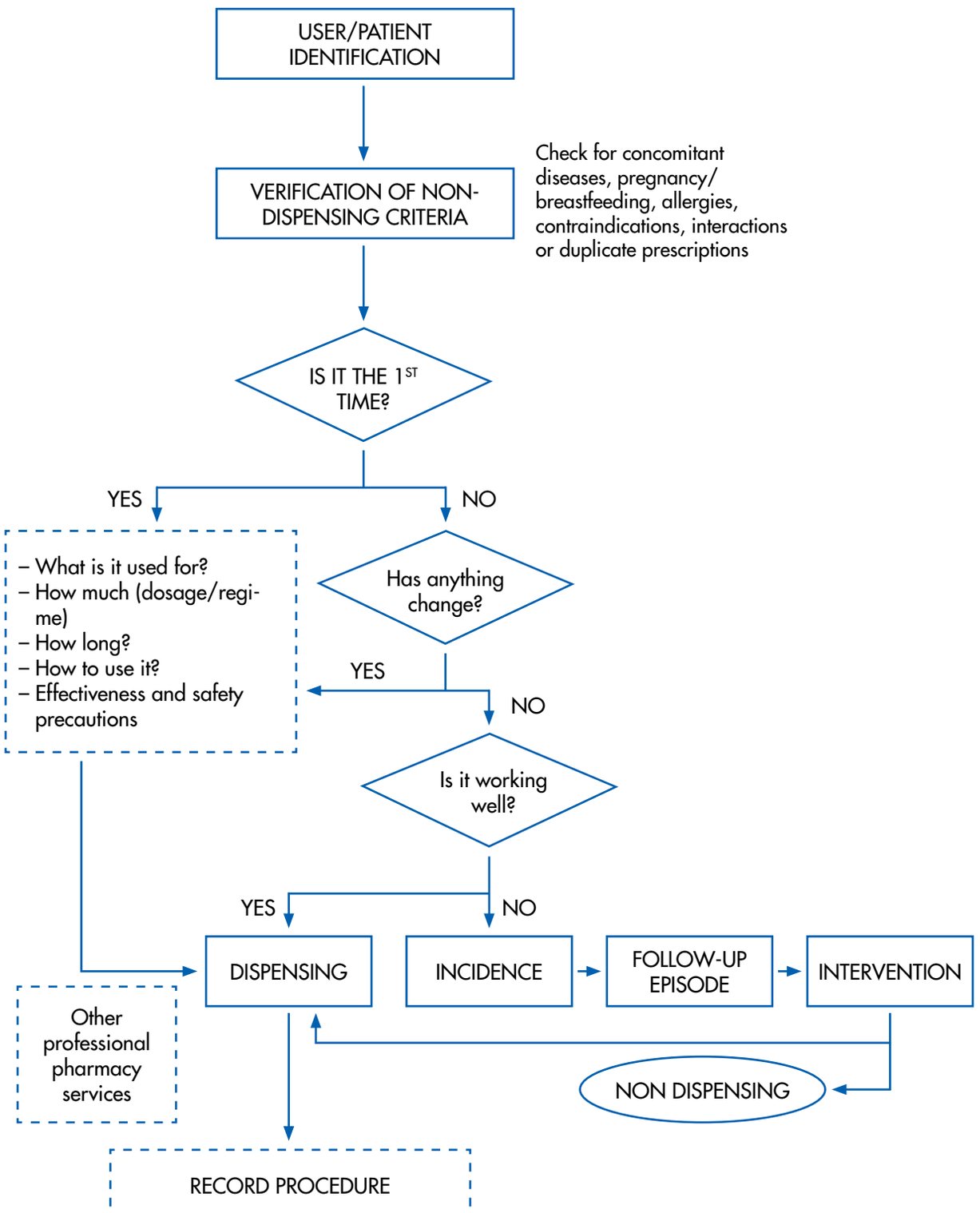
The **dispensing of non-prescription medicines through websites** shall be done by a legally authorized community pharmacy that is open to the public, with the intervention of the pharmacist and after advising the patient. These community pharmacies must first have notified the relevant authority in the autonomous community where they are located that they are engaged in online commerce. The websites of these community pharmacies must include a link to the website of the competent regional authority and of the Spanish Medicines and Medical Devices Agency (AEMPS). They shall also display the identifying common logo for the European Union.

The pharmacist intervention shall be bound by the same legal and ethical standards as when dispensing products on-site. Therefore, the pharmacy must make available questionnaires for users to fill out to identify the medicine requested, as well as to provide any other information needed to ensure the responsible use of the medicine.

Flowchart of the Procedure of the Dispensing Service for Prescription Only Medicines and Medical Devices



Flowchart of the Procedure of the Dispensing Service for Non-Prescription Medicines and Medical Devices



References

- Foro AF-FC. Practical Guide for Pharmaceutical Care Services in Community Pharmacy. General Pharmaceutical Council of Spain; 2010 [Internet – last retrieved 24th June 2014]. Available at: http://www.portalfarma.com/Inicio/atencionfarmaceutica/forofarmaciacomunitaria/Documents/ATFC_Guia%20FORO.pdf

- Head of State. Law 29/2006, 26th July, on guarantees and rational use of medicines and medical devices. BOE-A-2006-13554. [Internet – las retrieved 24th June 2014]. Available at: http://www.portalfarma.com/Profesionales/legislacion/recopilacion/Paginas/leygarantiasyusoraciona.aspx

- Head of State. Law 41/2002, 14th November, basic regulating patient autonomy and rights and obligations in clinical documentation and information. BOE-A-2002-22188 [Internet – last retrieved 24th June 2014]. Available at: http://www.portalfarma.com/profesionales/legislacion/recopilacion/Paginas/indicegeneral.aspx

- Ministry of Presidency. Royal Decree 1675/2012, 14th December, which regulates official prescriptions and special requirements for prescription and dispensing of narcotics for human and veterinary use. BOE-A-2012-15711. [Internet – las retrieved 24th June 2014]. Available at: http://www.portalfarma.com/Profesionales/legislacion/recopilacion/Paginas/recetas.aspx

- Ministry of Health and Consumerism. Royal Decree 1345/2007, 11th October, which regulates the procedures for the authorization, register and dispensing conditions of medicines for human use industrially manufactured. BOE-A-A2007-19249. [Internet – last retrieved 24th June 2014].Available at: http://www.portalfarma.com/Profesionales/legislacion/recopilacion/Paginas/especialidadesfarmaceuticas.aspx

- Ministry of Health, Social Policy and Equality. Royal Decree 1718/2010, 17th December, on medical prescription and dispensing orders. BOE-A-2011-1013. [Internet – last retrieved 24th June 2014].Available at: http://www.portalfarma.com/Profesionales/legislacion/recopilacion/Paginas/recetas.aspx

- Ministry of Health, Social Services and Equality. Royal Decree 81/2014, 7th February, which establishes rules guaranteeing the cross border healthcare and modifying Royal Decree 1718/2010, 17th December, on medical prescription and dispensing orders. BOE-A-2014-1331 [Internet – last retrieved 24th June 2014]. Available at: http://www.portalfarma.com/profesionales/legislacion/recopilacion/Paginas/indicegeneral.aspx

- Ministry of Health, Social Services and Equality- Royal Decree 577/2013, 26th July, regulating pharmacovigilance of medicines for human use. BOE-A-2013-8191. [Internet – last retrieved 24th June 2014].Available at: http://www.portalfarma.com/Profesionales/medicamentos/farmacovigilancia/Paginas/farmacovigilancia.aspx

- Ministry of Health, Social Services and Equality. Royal Decree 870/2013, 8th November, regulating distant sales to public, through websites, of non-prescription medicines. BOE-A-2013-11728. [Internet – last retrieved 24th June 2014].Available at: http://www.portalfarma.com/Profesionales/medicamentos/medicamentos-internet/dispensacion-medicamentos-online/Paginas/Dispensacion-medicamentos-online.aspx

- Multiple authors. Guidelines on Good Pharmacy Practice in Spanish Community Pharmacy. General Pharmaceutical Council of Spain. 2013. [Internet – last retrieved 24th June 2014].Available at: http://www.portalfarma.com/Profesionales/Buenas-practicas-profesionales/Paginas/Buenas-practicas-Farmacia-Comunitaria.aspx

- Multiple authors. Guidelines for the online dispensing of over the counter medicinal products for human use. General Pharmaceutical Council of Spain, 2013 [Internet – last retrieved 24th June 2014].Available at: http://www.portalfarma.com/profesionales/medicamentos/medicamentos-internet/Paginas/Medicamentos-Internet.aspx

GENERAL
PHARMACEUTICAL
COUNCIL OF SPAIN