GENERAL PHARMACEUTICAL COUNCIL OF SPAIN

Good Pharmacy Practice in Spanish Community Pharmacy

07

Procedure for Acquisition, Storage, Custody and Conservation of Medicines and Medical Devices

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Introduction

Law 14/1986, 25th April, on General Health, Law 16/1997, 25th April, on the Regulation of Pharmacy Services and Law 29/2006, 26th July, on Guarantees and Rational Use of Medicines and Medical Devices, all establish that community pharmacies are private healthcare facilities in the public interest, whose functions include the acquisition, custody, conservation and dispensing of medicines and medical devices. These functions are also regulated in specific regional legislation. It is therefore clear that they are essential activities of the pharmacist.

The establishment and adoption of professional patterns of behaviour at the level of the most common and sensitive processes in the community pharmacy is essential for progressing towards uniform, standardised, high quality care.

This, fundamentally, relates to ensuring that medicines, medical devices and other types of healthcare products are available to the population and can be dispensed in optimal conditions. This entails making sure that they are of good quality, comply with applicable legal requirements and are kept under the necessary conditions of storage, custody and conservation required for each product until it is dispensed.

This document contains the necessary recommendations for the acquisition, storage, custody and conservation of medicines and medical devices, which can be considered as good pharmacy practice.

Objectives for the acquisition, storage, custody and conservation of medicines and medical devices

a) Guarantee the acquisition of the medicines and medical devices necessary to ensure the pharmaceutical provision to the population.

b) Ensure the observation of rules for the correct conservation of medicines and medical devices under suitable conditions of temperature, humidity and cleanliness.

c) Guarantee the integrity and quality of the products purchased and stored.

Procedure for the acquisition of medicines and medical devices

The community pharmacist should consider the following in the acquisition of medicines and medical devices:

1. Selection of suppliers: the pharmacist should always verify that the suppliers, manufacturers and distribution wholesalers, with which they are working, comply with all applicable legal requirements for the supply and distribution of medicines. The acquisition of medicines and medical devices must be undertaken from authorised distribution wholesalers and pharmaceutical manufacturers[1].

In addition to verifying that the supplier is authorised, the pharmacist will need to consider other aspects such as the services offered, delivery schedules, special / emergency deliveries, catalogue of available products, etc. A community pharmacy will, typically, count on more than one supplier of medicines and medical devices.

2. Stock management: the quantity of medicines and medical devices purchased by the community pharmacy depends, on the one hand, on its available storage capacity and, on the other hand, on the stock rotation that the pharmacy experiences, taking into account the needs of the population it serves. Equally, in the process of the acquisition of medicines and medical devices, community pharmacies will have the required legal minimum stocks and each community pharmacist must ensure he/she has the stock required by the applicable autonomous community.

3. Placing an order: the processing of the order will be made using the channels established by each of the suppliers that work with the community pharmacy (through pharmacy software, order forms, by telephone, etc.).

The acquisition procedure for narcotic medicines will be made according to their specific legislation, through official request vouchers or other existing applicable procedures.

Community pharmacies cannot purchase:

- Medicinal products not authorised in Spain.
- Medicines in clinical packaging and those for hospital use (H), except for dispensing to clinics or hospitals and other centres registered as authorised medicine depots. Community pharmacies that dispense this type of medicines must notify the corresponding health authority to justify their acquisition.

In the event that one of the suppliers to which an order has been made cannot supply some of the products, other alternative suppliers that can meet the demand should be selected. It is important that the community pharmacy uses and has installed a system that notifies whether a particular medicine is available or not, either due to a shortage or for other reasons. In this case, the pharmacists must assess the value of their participation in systems proposed by the Pharmaceutical Organisation such as CISMED[2], among others, which detect an irregular supply of medicines.

4. Order reception: the pharmacist will establish whether or not the medicines and medical devices ordered from the distribution wholesalers and/or manufacturers are acceptable by checking that:

- The supplied goods match the delivery note from the supplier.
- The packaging is in good physical condition, rejecting those where the primary or secondary packaging is damaged or broken.
- If there is a safety seal, it should be undamaged.

[1] There is a public register of authorised pharmaceutical manufacturers and a catalogue of authorised distribution entities in Spain, which can be found on the AEMPS website:
- Manufacturers: https://labofar.aemps.es/labofar/registro/farmaceutico/consulta.do
- Distribution wholesalers: https://sinaem.agemed.es/AlmacenesMayoristas/Default.aspx

[2] CISMED (Information Centre for Medicines Supply) is the software tool developed by the General Pharmaceutical Council of Spain to detect, in real time, generalised situations of irregular or inappropriate supply of medicines from information relating to medicines that could not be supplied to community pharmacies at the time the order was made. This tool is accessible through Portalfarma (www.portalfarma.com).

- Sufficient time remains before the expiry date. A minimum of six months is recommended, except for medicines with a short shelf life and vaccines. In any case, the community pharmacist must ensure that the medicine dispensed will cover the duration of the prescribed treatment.
- The pharmacy must define criteria for the acceptance of the various products according to their expiry date.
- The medicines and medical devices have been transported properly, following the special instructions for storage and conservation that appear on the packaging (refrigeration, photosensitivity, position, etc.). It must be verified that the cold chain has been maintained when thermolabile medicines are received.
- In the case of narcotics, the corresponding vouchers will be delivered and the supporting counterfoil or equivalent procedure must be retained.
- The reception and acceptance of raw materials for pharmaceutical compounding and officinal preparations will follow the appropriate legislation, in any case, registering and quarantine the materials until final acceptance or rejection.

There should be a distinct area for the reception of orders and another area for non-compliant products, where items that do not correspond with the order delivery note or that are damaged will be placed. This separation ensures that there is no possibility of confusion between compliant and non-compliant products.

5. Claims and returns: for products that do not correspond to the order, that are not in good condition, where the expiry date is close, or that are considered to be non-compliant for any other reason, the supplier will be informed through the procedure which has been established. The distribution wholesalers will accept returns provided the period in which they are made is acceptable, the currently established recommended period is within ten days[3].

It is advisable to keep a receipt of the requested return claim.

6. Entry log and storage: Once the medicines and medical devices have been accepted they can be recorded in the entry log. They can then be stored.

Procedure for the storage, custody and conservation of medicines and medical devices

Once the medicines and medical devices have been received they can be stored. In the storage, custody and conservation of medicines and medical devices, the community pharmacist should consider:

1. General conditions of storage, custody and conservation: all the products available in the community pharmacy should be stored under the established conditions of cleanliness, humidity and temperature, so as to ensure their correct preservation. The products should not be in direct contact with the floor, walls or ceiling.

Community pharmacies that use automated or robotised storage systems should follow the manufacturer's instructions.

Pharmacies are required to maintain temperature conditions between 20°C – 30°C. Room temperature records should be taken daily, either manually or by computer, using calibrated thermometers. These records must be maintained and stored in the community pharmacy. In general, they will be retained for a minimum of two years.

The medicines and medical devices must not be exposed to direct sources of heat or light.

2. Division of storage, custody and conservation areas: the area for the storage, custody and conservation of medicines and medical devices, will be separate from and independent of the area accessible by the public[4] and in any case, never within reach. It must be designed in such a way that different products can be placed in it in an orderly manner, properly separated and classified according to their nature, in order to avoid confusion and errors. In addition, the design of the storage area should allow the quick and easy localisation of the products and provide the maximum use of available space.

[3] Guidelines published on 5th November 2013, on good practice for distribution of medicinal products for human use 2013/C 343/01
[4] Non-prescription medicines as well as healthcare products can be stored in the dispensing area, always following the preservation conditions listed in this procedure.

Occasionally there may be distinct areas for storage according to the available quantity of product, its rotation and whether the community pharmacist wants it to be visible to the public or not.

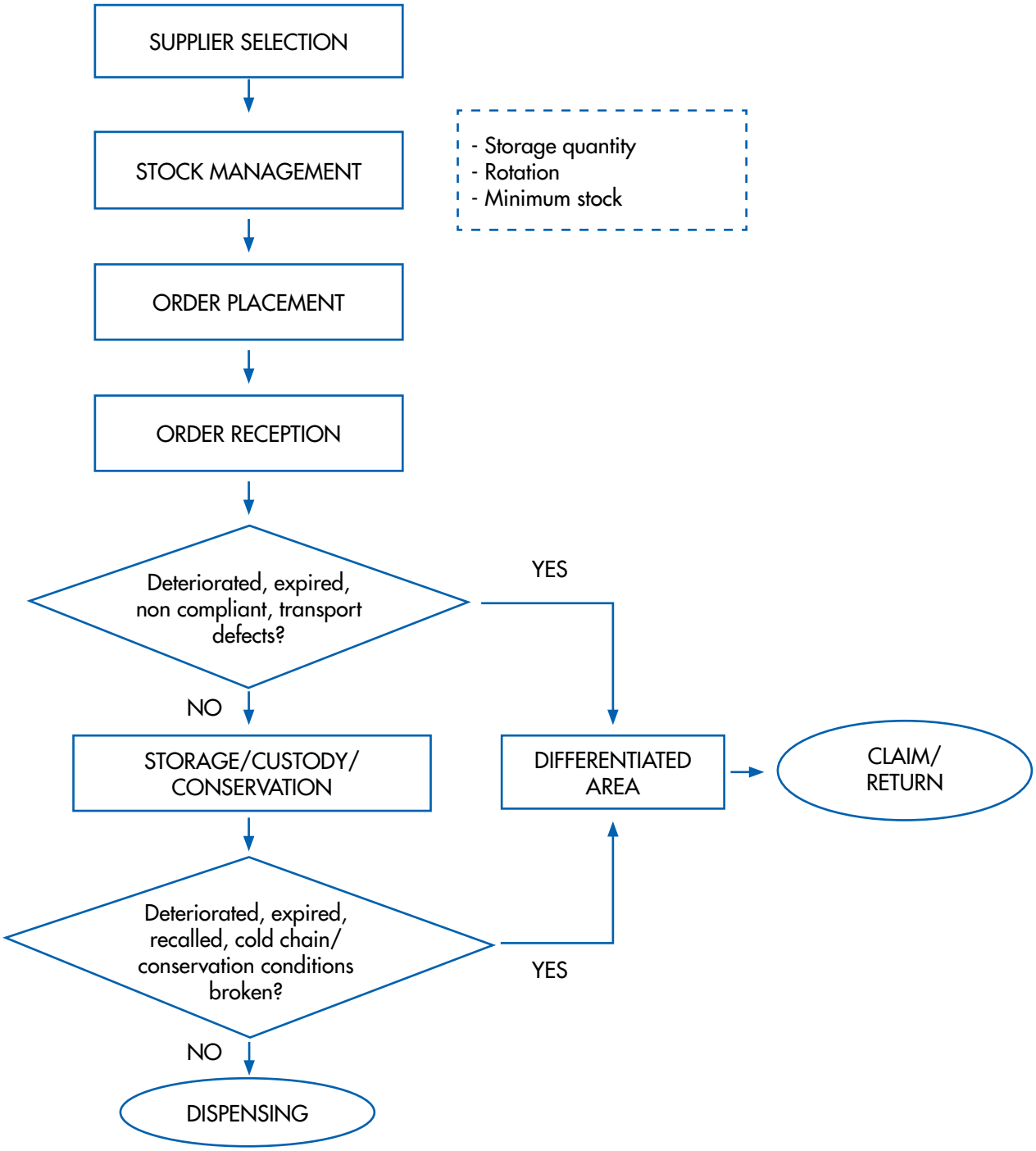
There must be different areas for the storage of narcotic medicines, products that require special conditions of preservation, non-compliant products, expired products or other types of medicines, for example, veterinary medicinal products.

- The narcotic medicines must be stored separately from the rest of the medicines, in a place that is not accessible to unauthorised people. They must be stored in a security cabinet or safety deposit box and will be the pharmacist's responsibility. Their delivery will be recorded in the narcotics' log or equivalent registration system.
- Thermolabile medicines should be stored in a refrigerator, placed without touching its walls, between 2 °C - 8 °C and with great diligence to avoid breaking the cold chain. There must be corresponding temperature recording systems. A daily record of the refrigerator's maximum and minimum temperature will take place. The thermometer must be placed in the central area of the refrigerator, never in the door.

  It would be useful to have a list of thermolabile medicines [5] which contains their term of validity at room temperature in order to know which medicines should be discarded in case of failure of the refrigerator or electrical power failure and to be able to respond to queries on the subject by users before they go on a trip, for example.
- Veterinary medicinal products must be placed in a specific area, clearly separated from medicines for human use.
- Substances that present a special risk of fire or explosion will be stored in isolated areas equipped with the necessary safety measures.
- Non-compliant or expired products will be stored in a clearly defined area. The community pharmacy must not include for dispensing any medicine or medical device that has expired, been immobilised, or withdrawn by the health authorities.
- For community pharmacies preparing officinal preparations or undertaking pharmaceutical compounding, there must be a separate space for the quarantine of raw materials and for the storage of wastage derived from this formulating activity.

[5] The lists of medicines that require special storage conditions can be found on www.portalfarma.com

Flowchart for the acquisition, storage, custody and conservation of medicines and medical devices



References

- Various Authors. Guidelines on Good Pharmacy Practice in Spanish Community Pharmacy. General Pharmaceutical Council of Spain. 2013. [Internet – last retrieved 9th April 2015]. Available at: http://www.portalfarma.com/Profesionales/Buenas-practicas-profesionales/Paginas/Buenas-practicas-Farmacia-Comunitaria.aspx

- Law 14/1986, 25th April, on General Health. [Internet – last retrieved 9th April 2015]. Available at: http://www.portalfarma.com/Profesionales/legislacion/recopilacion/Paginas/leysanidad.aspx

- Law 16/1997, 25th April 25, on Regulation of pharmacy services. [Internet – last retrieved 9th April 2015]. Available at: http://www.portalfarma.com/Profesionales/legislacion/recopilacion/Paginas/leyregu.aspx

- Law 29/2006, 26th July, on Guarantees and rational use of medicines and medical devices. [Internet – last retrieved 9th April 2015]. Available at: http://www.portalfarma.com/Profesionales/legislacion/recopilacion/Paginas/leygarantiasyusoraciona.aspx

- Royal Decree 1345 / 2007, 11th October, which regulates the procedure for authorisation, registration and conditions for dispensing industrially manufactured medicinal products for human use. [Internet – last retrieved 9th April 2015]. Available at: http://www.boe.es/buscar/pdf/2007/BOE-A-2007-19249-consolidado.pdf

- Regional legislation on minimum stocks. [Internet – last retrieved 9th April 2015]. Available at: http://www.portalfarma.com/Profesionales/legislacion/recopilacion/Paginas/existenciasminimas.aspx

- Guidelines of 5th November 2013, on good practice in the distribution of medicinal products for human use 2013/C 343/01. [Internet – last retrieved 9th April 2015]. Available at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2013:343:0001:0014:ES:PDF

- Manual of Good Professional Practice in Pharmacy. COF Asturias. 2012

- Professional Pharmacy. Vol.23, No. 1, January-February 2009

- Course on how to resolve the main conflict types in the pharmacist-patient relationship. Classroom of the Pharmacy. [Internet – last retrieved 9th April 2015]. Available at: http://2011.auladelafarmacia.org/sefac/DOCUMENTOS/curso_conflictos_unidad_2.pdf

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