GENERAL PHARMACEUTICAL COUNCIL OF SPAIN

Good Pharmacy Practice in Spanish Community Pharmacy

08 Recalls, Shortages, Emergencies and Alert Management

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Introduction

The functions of the community pharmacy include actions related to the notification of alerts[1], recalls[2], emergencies[3] and information notes, which are crucial for the fulfilment of the responsibilities of a community pharmacy.

The information on recalls is generally intended for all agents in the supply chain and those involved in dispensing medicines. The pharmacist must participate in the recall procedures communicated by the authorities or pharmaceutical industry, following a procedure that ensures that said recalls are effectively carried out in the shortest amount of time possible.

It is crucial for there to be an information system that enables the process to be carried out effectively. The affected medicines, medical devices and health products must be clearly separated from the rest of the pharmacy stock.

The pharmacist must also participate in the strategies and contingency plans[4] established by the authorities and the rest of the members of the supply chain in the case of shortages or emergency situations.

This document presents the necessary recommendations for good professional practice in the management of alerts, shortages, recalls and emergencies.

Objectives of the procedures for recalls, shortages, emergencies and alert management

a) To establish the system for action (reception, procedure, registration, archiving and information) that ensures the immediate immobilisation[5] and physical removal in the community pharmacy of a medicine for human or veterinary use, medical device, health product, food supplement or cosmetic or other product in the event of receiving a notification that orders its recall in order to prevent its dispensing or supply by said community pharmacy.

b) To establish the procedure to follow in the event of a notification of an emergency, alert, safety note[6] or information note[7] (regarding quality defects, illegal medicines[8], supply problems, temporary suspensions, information on the risks and/or modifications in the conditions of use of the medicines.).

[1] Alert: a written statement from the competent health authorities about an incident involving a medicine for human or veterinary use, a medical device, health product, cosmetic product or food supplement.

[2] Recall: to remove any type of the aforementioned products from the dispensing channel at the pharmacy, as the result of a quality defect or a potential safety risk for the patient. The product must be returned to the manufacturer through the normal channels.

[3] Emergency: notification by the health authorities about a specific incident of an urgent nature that might pose a risk to the population.

[4] Shortages: notification through the normal competent channels regarding the lack of supply of a medicine or medical device.

[5] Immobilisation: to remove a medicine or medical device from the dispensing channel and to keep in the custody of the pharmacy owner as the result of an order from a health authority, until new orders are received.

[6] Safety note: written notification by the competent Health Authorities regarding problems that imply a risk to the health of citizens.

[7] Information note: written notification from the competent Health Authorities in relation to problems with quality or of a general nature that affect medicines for human or veterinary use, medical devices, health products, cosmetics and food products.

[8] Illegal medicine: any medicine not approved by the Health Authorities.

Procedures for recalls, shortages, emergencies and alert management

The procedure applies to community pharmacies that dispense medicines for human or veterinary use, medical devices, health products, food supplements, cosmetics or other products that must manage any incident mentioned in the aims of this procedure.

For the purposes of this procedure, the pharmacy owner is ultimately responsible for:

- Ensuring the distribution of information to all pharmacy staff involved.
- Ensuring that the measures adopted in the notifications by the health authorities are carried out.
- Recording and archiving these notifications, unless another person is specifically assigned to file them.
- Communicating these notifications to patients when applicable

In the event of any incident reported by the health authorities, the pharmacy owner must initiate the proper procedure in each case.

1. Reception of the document: The incidents reported by the health authorities may reach the pharmacy via different routes:

- Spanish Agency of Medicines and Medical Devices (AEMPS)
- Spanish Agency for Consumer Affairs, Food Safety and Nutrition
- EU Consumer Authorities
- General Pharmaceutical Council of Spain
- Provincial Pharmacy Chambers
- Scientific associations
- Distribution wholesalers
- Pharmaceutical industry

2. Verification and internal communication: First of all, the pharmacist must verify the authenticity of the document received and whether or not action should be taken.

On the AEMPS website, the information notes, safety notes, alerts, information on illegal medicines, supply problems or access to medicines in special situations can be consulted (http://www.aemps.gob.es/medicamentosUsoHumano/portada/home.htm).

The medicines information centres of the Provincial Pharmacy Chambers also provide this information.

The pharmacist must communicate internally the content of the information received to all pharmacy staff.

If an incident with a medicine is detected, a pharmacist must notify the Spanish Agency of Medicines and Medical Devices, the Pharmacovigilance System of the Autonomous Community or the Provincial Pharmacy Chamber.

3. Actions and interventions:

a) Recall: medicine recalls due to quality or safety defects constitute preventive measures.

The alerts received usually refer to a specific batch[9] or batches of manufactured products. It is important to stress that many times the quality defect detected affects a single pack, although the preventive recall of the entire manufacturing batch to which it belongs is ordered, in order to prevent any possible health risk in the case that additional units are affected.

[9] A manufacturing batch consists of those units of a medicine manufactured from the same group of starting materials, in a single process or a series of manufacturing processes; it is assumed to be homogeneous. Different manufacturing batches of marketed medicines are commonly found on the market.

The defects are classified according to the possible health risk they pose for patients and according to international consensuses established between health authorities.

Quality defects are classified into one of three classes (1, 2 or 3), with Class 1 representing the highest possible risk and Class 3 the lowest risk[10].

On other occasions, re-evaluation studies of the risk/benefit balance of a medicine already on the market may lead to its permanent recall.

The pharmacist must immediately verify whether the pharmacy has the product and/or batch subject to the recall and inform the entire pharmacy staff accordingly. Likewise, the pharmacist must record the product, batch, date and units affected.

The pharmacist must remove the product to a separate place away from the rest of the stock and return it to the supplier who provided it. If the pharmacy has no units, this must also be recorded.

Similarly, adequate mechanisms must be available to prevent a product subject to recall from being added to the pharmacy stock.

b) Immobilisation: In the case of immobilisation, the medicine, medical device or health product must be blocked immediately, so that it is not available for dispensing until further notice. Immobilised products must be separated from the rest of the products and correctly labelled.

c) Shortages: In the event of the lack of supply of a medicine, medical device or health product, the pharmacist must inform the patient of the situation and offer appropriate therapeutic alternatives, according to current regulations, suggesting an alternative to the prescribed medicine to the prescriber, the possibility of making a compounded medicine (with a prescription), or requesting it from an area hospital, in the case that its supply has been authorised as a foreign medicine when there are no therapeutic alternatives in the national market.

It is important for the community pharmacy to participate and to have a system that makes it possible to detect that a certain medicine cannot be accessed, either because of a shortage or for other reasons. In this case, the community pharmacist must consider participating in the systems proposed by the Pharmaceutical Organisation, such as CISMED[11], that detect the irregular supply of medicines.

d) Emergencies: Pharmacists must comply with the requirements of health authorities, collaborating in all actions they deem necessary, and must have a contingency plan in order to make special purchases in cases of emergency.

e) Information notes: These are related to risks and/or changes in the conditions or indications for use of the medicines. In this case, the community pharmacist must provide pertinent information to affected patients.

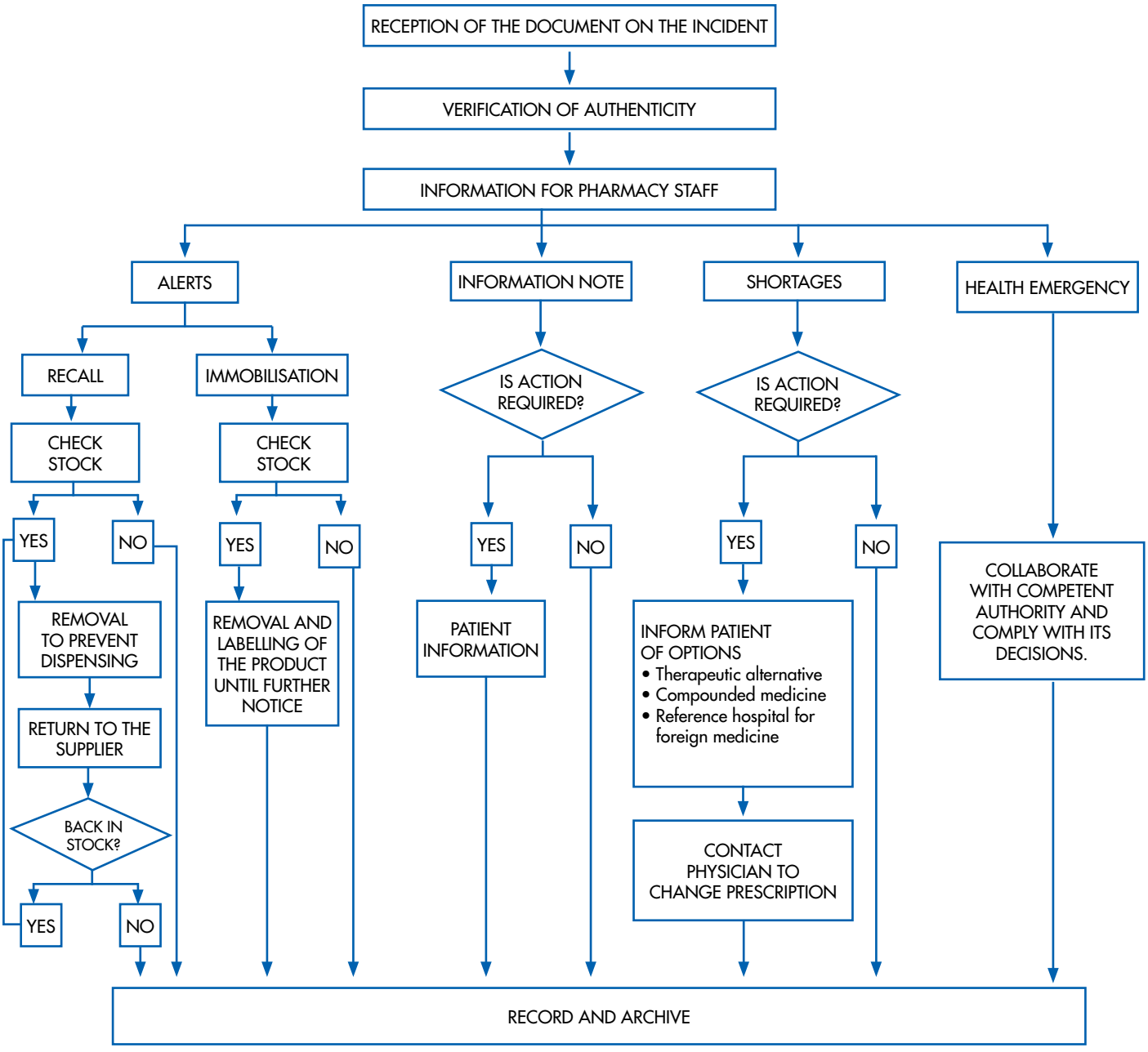
4. Recording and archiving: Each pharmacy must establish the recording and archiving system, either electronic or paper-based, that it deems necessary.

In general, it is desirable for all the notifications indicated in this procedure to be encoded sequentially, recording the result applied in each case. They must be kept in a place that is accessible to all pharmacy staff. In the case of recalls, it is especially important to record the name of the product, the number of units affected, the manufacturing batch, expiry date, supplier and any other relevant data that permit adequate traceability.

[10] The different classes of defects are based on the possible risk to public health as follows:
Class I: defects that could potentially be life-threatening or pose a serious health risk.
Class II: defects that could cause illness or injury, but which are not Class I defects.
Class III: defects that may not pose a significant health risk, but there may be other reasons for a recall, and they are neither Class I nor Class II defects.

[11] CISMED (Centre for Information on the Supply of Medicines) is the computer-based tool developed by the General Pharmaceutical Council of Spain to detect, in real time, widespread situations of irregular or inadequate supply of medicines based on information related to medicines that could not be supplied to community pharmacies by suppliers when orders have been placed. This tool is accessed through the member area of Portalfarma.

Flowchart of the procedures for recalls, shortages, emergencies and alert management



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