Hospital Pharmacy
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DOI: 10.1177/00185787221134696
journals.sagepub.com/home/hpx
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Review of Drug Storage Conditions, A Case Report

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Abstract

High temperatures during the summer season are a very important factor to be considered due to their possible influence on drug stability and effectiveness. This is especially important in those patients included in clinical trials, polymedicated or with long-term pharmacological therapies.

Keywords
stability, storage, clinical trial

Introduction

In the last 30 years, Spain has registered about 90 heat waves.[1] Currently, it is considered normal for the thermometer to reach or exceed 40°C during the summer months. Various scientific societies insist on the importance of taking extreme precautions during the summer period, due to the high incidence of heat waves (temperatures above 40°C for several days). These climatic conditions not only affect people, but also the good condition of medicines.[2]

The Spanish Agency for Medicines and Health Products (AEMPS) recommends storing medicines in a clean, cool, and dry place. In addition, the conditions indicated on the package should always be respected: refrigerator between +2°C and +8°C and room temperature for storage medicines at a temperature lower than 25°C to 30°C. On the other hand, it is recommended to keep syrups and suspensions, creams, suppositories and ovules in the refrigerator since they are pharmaceutical forms more sensitive to high temperatures. In the pharmaceutical presentations of suppositories and ovules, it is advisable to temper them for a few minutes before application.[3]

The reason for this concern about the storage conditions of drugs is due to their capacity to favor the decomposition of the active ingredient, and therefore to reduce their efficacy, or even to produce adverse effects.[4] It is known from household surveys that the main storage places in the home are the kitchen and the bathroom. These locations are not appropriate for good storage, as they are subject to sudden changes in humidity and temperature. Another frequent place for medication storage is the glove compartment of vehicles, in case of travel, which is also not suitable for storing drugs because they are places where heat accumulates.[5,6]

In addition to the location, drugs should be protected from light and kept in the original container. In situations where the person uses pill dispensers, it is recommended to cut the blister packs to keep the pills well protected and identified, inside the original package.[7]

Below, we describe a clinical case about inadequate storage of medicines.

Case Report

A 72-year-old Caucasian male patient with Ukrainian nationality diagnosed with prostate adenocarcinoma for 12 years. In May 2022, after a metastatic relapse, the patient decides to participate in a phase III clinical trial, which evaluates the efficacy of the combination enzalutamide together with an investigational drug in metastatic castration-sensitive prostate cancer.

From the time the patient is enrolled in the trial to the time of the incident, no incident is recounted. He had received 3 cycles of medication when the patient went to the Pharmacy Service to report that one of the medications that was dispensed to him, was in poor condition.

The pharmacist in charge of the study reviewed the medication to confirm that it was in poor condition and observed that the affected drug was enzalutamide in soft capsule form. This pharmaceutical form includes in its composition several

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Table 1. Excipients of enzalutamide soft capsules.

Tablet nucleus	Tablet coating
Hypromellose acetate	Hipromelosa
Microcystalline cellulose	Talco
Colloidal anhydrous silica	Macrogol
Croscarmellose sodium	Dioxido de titanio
Magnesium stearate	Oxido de hierro amarillo

excipients (hypromellose, microcrystalline cellulose, magnesium stearate, etc.) (Table 1) that are thermolabile at temperatures easily reached in the region. After checking the drug, it was observed that the soft gelatin capsules had a pasty and dense appearance, indicating that they had been exposed to higher temperatures than recommended for good preservation (graphical abstract Figure 1(A)). Their original appearance under conditions of good preservation is shown in graphical abstract Figure 1.

Subsequently, the physician interviewed the patient, accompanied by his daughter, about the situation in which the drug had been stored. The relative stated that the drug was stored in the kitchen and pointed out the high temperature of the medication in the patient's home (>32°C–34°C), due to the absence of a refrigeration system. The Pharmacy Service reminded us of the importance of storing the medication in cool, humidity-free places.

Finally, it was decided to withdraw the bottle of enzalutamide in poor condition and a new dispensation of this product was generated, so that the patient could continue with his therapeutic plan.

As an improvement action, the Pharmacy Service recommended to the patient a change in the storage of the medication to a place that complied with the requirements and advice previously mentioned (ie, medication cabinet).

Discussion

In the clinical trials area of a pharmacy service, the state and temperature of the medication under investigation is closely monitored. Any deviation from the limits indicated by the sponsor, regardless of the number reached and duration, should be reported and quarantined until a response is received from the manufacturer/promoter. Sometimes, after temperature deviations, the medication is considered unfit and the destruction of all affected products is ordered.

This exhaustive control carried out in the pharmacy services is understood as necessary, but do we have any control and information on how medications are stored and preserved outside our hospital facilities?

Conclusion

As a consequence of this case, the Clinical Trials Area of the Pharmacy Service stresses the importance of the place and conditions of medication storage, both clinical trial and care.

It is very important that, as pharmacists, we reinforce this message to patients, at the time of dispensing, which helps to improve adherence to treatments and, therefore, to their benefits.

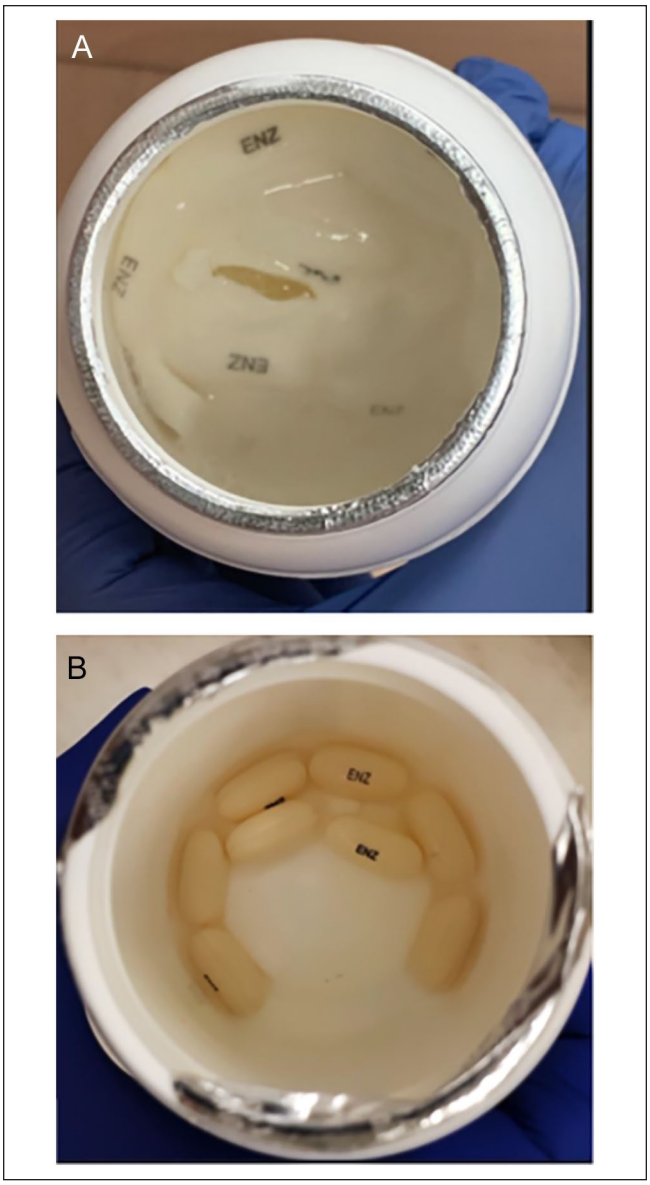

Figure 1. (A) Medication returned by the patient in a decomposed state and (B) medication in good state.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The author(s) received no financial support for the research, authorship, and/or publication of this article.

Ethical Considerations

The data presented are completely truthful. No informed consent was required.

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