

Health Guidance: The Temperature Requirements for Medicines Storage

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Introduction and purpose of guidance

If medicines are not stored properly they may not work in the way they were intended, and so pose a potential risk to the health and wellbeing of the person receiving the medicine.

Medicines should be stored under conditions which ensure that their quality is maintained. The temperature of storage is one of the most important factors that can affect the stability of a medicine.

The purpose of this guidance is to clarify the temperature storage arrangements that a residential care service should have in place when it manages medicines on behalf of people in the service.

Background

Tests on the chemical and physical characteristics of a medicine are required before a marketing authorisation is granted for its use.

The integrity of a medicine will depend on the individual medicine and the conditions under which it has been stored.

The storage requirements for a medicine can be found either on the product itself and/or the patient information leaflet that accompanies each dispensed medicine. The care service should comply with these storage instructions.

Storage conditions for *most* medicines can be satisfied by either cold storage (between 2-8°C) OR storage that is not above 25°C (although some medicines now suggest storage not above 30°C).

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Many medicines require storage between 2°C and 8°C. Some products can be irreversibly degraded even by brief periods at sub-zero temperatures, and so monitoring of storage temperature is vital.

The temperature of the medicine refrigerator should be monitored daily when it is in use – a maximum/minimum thermometer is recommended for this purpose. The thermometer should be read and reset daily, and the maximum and minimum temperatures recorded.

Where the temperature is out with recommended limits measures should be introduced by the service to rectify this situation e.g. defrosting the fridge. Any action taken should be recorded.

There should be a procedure in place to ensure regular cleaning and defrosting of the fridge.

A separate, secure and dedicated refrigerator should be available for medicines in services where there is a regular need for medicines to be stored between 2°C – 8°C.

In smaller services where the need for cold storage may only be, for example, for the occasional bottle of oral antibiotic or eye drops, medicines could be stored in a domestic fridge. Here medicines should be kept on a separate shelf in a lidded plastic container which will help in isolating the medicines from any other fridge items. The medicines container in the domestic fridge should not be accessible to service users.

Some medicines require storage at less than 15°C. Since most services do not have a cool room a refrigerator would probably provide appropriate storage for such products, provided that storage below 8°C does not affect the medicine.

The requirement to store medicines at 25°C or below can usually be satisfied by room temperature storage. The requirement to monitor room temperatures is only an issue if the room appears to be “warm”. This might be the case, for example, if the room was next to the kitchen, contained a cupboard with a hot water tank, was consistently warmed by sunshine through a window etc.

If the main medicines room falls into this sort of situation, or if there is any doubt about the temperature of the room, it would be recommended that daily temperature readings are recorded for a sustained period (e.g. 2-3 months) to ascertain if the temperature is consistently above 25 degrees.

If the main storage area is found to be consistently above 25°C measures such as the introduction of an air conditioner should be implemented by the service in an attempt to control the problem.

While some medicines will be unaffected at temperatures consistently above 25°C, others, however, will not. If the service is in any doubt about which medicines may be affected they should contact their supplying pharmacist for advice.

Summary

- Storage conditions can influence the stability of medicines.
- Maximum and minimum temperatures over the previous 24 hours should be recorded daily in fridges used to store medicines between 2°C and 8°C.
- Temperatures should be recorded daily for any central medicines storage areas if there is any concern that the temperature is above 25°C.

Useful Links/Further Reading

The Handling of Medicines in Social Care

<http://www.rpharms.com/support-pdfs/handlingmedsocialcare.pdf>

Recommendations on the control and monitoring of storage and transportation temperatures of medicinal products

www.mhra.gov.uk/home/groups/comms-ic/documents/publication/con007569.pdf

Vaccine Cold Storage

<http://www.nrls.npsa.nhs.uk/alerts/?entryid45=66111>

Safe and Secure Handling of Medicines: A Team Approach

<http://www.rpharms.com/support-pdfs/safsechandmeds.pdf>