Section Guidance for Part 3 Patient Information Leaflet (PIL) of a WHO Public Assessment Report (WHOPAR)

SECTION 5 (STORING X)

The Patient Information Leaflet (PIL) is submitted by the applicant when submitting a finished pharmaceutical product to WHO for prequalification. After evaluation by the WHO Prequalification Team: medicines (PQTm) it will be included as Part 3 of the WHO Public Assessment Report that will be posted on PQTm's website, should the product attain prequalification.

The PIL should include a description of any special storage conditions. The applicable storage statement(s) are determined during the quality assessment of the stability data and may include one or more of the following statements. <text> signifies text to be selected or deleted as appropriate.

<Do not store above <30 °C> <25 °C>> <or> <Store below <30 °C> <25 °C>>

<Avoid excursions above <30 °C> <25 °C>>[1]

<Store in a refrigerator (2 °C – 8 °C)

<Store and transport refrigerated (2 °C – 8 °C)>

<Store in a freezer {temperature range}>

<Store and transport frozen {temperature range}>

<Do not <refrigerate> <or> <freeze>>

<Store in the original <package>>

<Keep the {container}** in the outer carton>

<Keep the {container}[2]** tightly closed>

<in order to protect from <light> <moisture>>

[1] The stability data generated at 30 °C/75%RH and 40 °C/75%RH is taken into account when deciding whether excursions above <30 °C> <25 °C> may not be appropriate for the safe use of the medicine in climatic zones III, IVa and IVb.
[2] The type of the container should be stated (e.g. bottle, blister).