Translation from original French

ANSM - French National Agency for Medicines and Health Products Safety

FRENCH REPUBLIC

MEMO FOR CHIEF PHARMACEUTICAL OFFICERS
TRANSPORTATION OF MEDICINAL PRODUCTS FOR HUMAN USE

The ANSM (French National Agency for Medicines and Health Products Safety) reminds you that, in compliance with Articles R. 5124-36 and R. 5124-48 of the Public Health Code (PHC), it is the responsibility of the Chief Pharmaceutical Officer to ensure that transport conditions guarantee the satisfactory storage, integrity and safety of medicinal products for persons authorised or approved to dispense medicinal products to the public or to use such products. A medicinal product's storage conditions are defined in the Summary of Product Characteristics (SmPC). These conditions are the result of the evaluation of the stability studies included in the Marketing Authorisation application.

The ANSM also reminds you that the provisions of items 9.2., 9.3 and 9.4 of the Good Distribution Practice of medicinal products for human use (GDP) establish that:

- The required storage conditions for medicinal products must be maintained during transportation within the limits defined by the manufacturers or on the outer packaging;
- Certain products, such as narcotics or psychotropics, medicinal products containing highly active and radioactive materials and thermosensitive medicinal products, require special transport conditions (containers, packaging, special labelling or, where applicable, temperature-controlled vehicles).

The ANSM draws the attention of Chief Pharmaceutical Officers to the fact that stability studies under accelerated conditions identified by the ICH Q1A (R20) guidelines *Stability testing of New Drug Substances and Products (CHMP/ICH/2736/99)* and the European Union guidelines *Stability testing of existing active ingredients and related finished products (CPMP/QWP/122/02 Rev. 1 Corr),* referred to in item 2.2.7 *Storage conditions* of these texts, do not aim to encourage the non-observance during transportation of the storage conditions defined and approved in the SmPC and appearing on the outer packaging/labelling (see Note for Guidance CPMP/609/96/Rev 2). They provide for the evaluation of the impact on stability of the finished product during short and unforeseeable temperature excursions outside the limits, referred to on the outer packaging, and which can occur, for example, during the transportation of medicinal products.

Original French text signed

Acting Director
Inspection Directorate
Jacques MORENAS

Inspection Directorate – November 2017