<Date>

Kisqali (ribociclib): change to storage conditions and shelf-life

Dear Healthcare professional,

Novartis Europharm Ltd. in agreement with the European Medicines Agency and the <national competent authority> would like to inform you of the following:

Summary

- **Kisqali should now be stored in a refrigerator (between 2°C to 8°C) for up to 10 months until dispensed to patients.**
- **Inform patients that upon dispensing, Kisqali may be stored at up to 25°C for up to 2 months in the original blister packs.**
- **The shelf life of Kisqali is now limited to 12 months in total.**
- **The product information, labelling and package leaflet have been amended to reflect the new storage conditions and shelf life.**

Background

Kisqali is indicated for the treatment of women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer in combination with an aromatase inhibitor or fulvestrant as initial endocrine-based therapy, or in women who have received prior endocrine therapy.

In pre- or perimenopausal women, the endocrine therapy should be combined with a luteinising hormone-releasing hormone (LHRH) agonist.

The following additional indication has recently been authorised in the EU:

Kisqali, in combination with an aromatase inhibitor, is indicated for the adjuvant treatment of patients with HR-positive, HER2-negative early breast cancer at high risk of recurrence (see SmPC section 5.1 for selection criteria).

In pre- or perimenopausal women, or in men, the aromatase inhibitor should be combined with a LHRH agonist.

The storage conditions and shelf-life have been updated to ensure the quality of the product throughout its shelf-life in the new indication, however these are to be applied to the product irrespective of indication. Current stock should be stored as per instructions in the applicable product information. Novartis will implement a detailed plan for managing existing stock and ensuring the transition to the revised product.

The product information (summary of product characteristics and package leaflet) has been updated to reflect the new storage conditions.

Call for reporting

Any suspected adverse events should be reported to {Insert details of the national spontaneous reporting system e.g. name, postal address, fax number, website}

Company contact point

Further information can be obtained by contacting <local Novartis affiliate, contact details to be added by affiliate>

DHPC COMMUNICATION PLAN	
Medicinal product(s)/active substance(s)	Kisqali (ribociclib)
Marketing authorisation holder(s)	Novartis Europharm Limited
Purpose of the communication	Change of storage conditions and shelf-life
DHPC recipients	Pharmacists, Medical Oncologists; the target group should be further defined at national level, in agreement with the respective national competent authority
Member States where the DHPC will be distributed	EU Member States where Kisqali is marketed

Timetable	Date
DHPC and communication plan (in English) agreed by CHMP/CMDh	17 October 2024
Submission of translated DHPCs to the national competent authorities for review	EC Decision for EMEA/H/C/004213/II/0045 22 October 2024
Agreement of translations by national competent authorities	EC Decision for EMEA/H/C/004213/II/0045 1 November 2024
Dissemination of DHPC	To be issued when the change in storage conditions is implemented locally in each Member state.