

Annex I

**Scientific conclusions and grounds for the variation to the terms of the Marketing
Authorisation(s)**

Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for cytarabine, the scientific conclusions are as follows:

In view of available data on neutrophilic eccrine hidradenitis and auricular erythema (“Ara-C ears”) from individual case safety reports and case series from the literature including cases with a close temporal relationship, a positive de-challenge and/or re-challenge and in view of a plausible mechanism of action, the PRAC considers a causal relationship between cytarabine and neutrophilic eccrine hidradenitis and auricular erythema (“Ara-C ears”) is at least a reasonable possibility. The PRAC concluded that the product information of products containing cytarabine should be amended accordingly.

Having reviewed the PRAC recommendation, the CMDh agrees with the PRAC overall conclusions and grounds for recommendation.

Grounds for the variation to the terms of the marketing authorisation(s)

On the basis of the scientific conclusions for cytarabine the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing cytarabine is unchanged subject to the proposed changes to the product information

The CMDh recommends that the terms of the marketing authorisation(s) should be varied.

Annex II

Amendments to the product information of the nationally authorised medicinal product(s)

Amendments to be included in the relevant sections of the Product Information (new text **underlined and in bold**, deleted text ~~strike through~~)

Summary of Product Characteristics

- Section 4.8

The following adverse reaction(s) should be added under the SOC *Skin and subcutaneous tissue disorders* with a frequency *unknown*:

Neutrophilic eccrine hidradenitis

Auricular erythema (“Ara-C ears”)

Package Leaflet

4. *Possible side effects*

Other side effects

Not known: frequency cannot be estimated from the available data

- **Redness, pain or swelling of the ears that may occur during or shortly after cytarabine treatment (known as “Ara-C ears” or auricular erythema).**
- **Inflammation of sweat glands, sometimes causing tender red patches on the skin (called neutrophilic eccrine hidradenitis).**

Annex III

Timetable for the implementation of this position

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Adoption of CMDh position:	December 2025 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	25 January 2026
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	26 March 2026