

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 bleomycin, the scientific conclusions are as follows:

In view of available data on Acute Myeloid Leukaemia (AML)/ Myelodysplastic syndrome (MDS) from the literature, spontaneous reports and in view of a plausible mechanism of action, the PRAC considers that a relationship between bleomycin and acute myeloid leukaemia/myelodysplastic syndrome when used in combination with other antineoplastic agents cannot be ruled out. The PRAC concluded that the product information of products containing bleomycin should be amended accordingly.

The CMDh agrees with the scientific conclusions made by the PRAC.

Grounds for the variation to the terms of the Marketing Authorisation(s)

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

The CMDh reaches the position that the marketing authorisation(s) of products in the scope of this single PSUR assessment should be varied. To the extent that additional medicinal products containing bleomycin are currently authorised in the EU or are subject to future authorisation procedures in the EU, the CMDh recommends that the concerned Member States and applicant/marketing authorisation holders take due consideration of this CMDh position.

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 4.4

A warning should be added as follows:

Blood and lymphatic system disorders

Acute myeloid leukaemia and myelodysplastic syndrome have been reported in patients who have received concomitant treatment with bleomycin and other antineoplastic agents.

Package Leaflet

2. What you need to know before you take <product name>

Cases of cancer in the blood (acute myeloid leukaemia) and a syndrome where the bone marrow does not make enough healthy blood cells or platelets (myelodysplastic syndrome) have been reported in patients treated concomitantly with bleomycin and other cytostatics (substances which inhibit cell growth/cell division).

Annex III

Timetable for the implementation of this position

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Adoption of CMDh position:	December 2022 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	30 January 2023
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	30 March 2023