

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 adenosine, the scientific conclusions are as follows:

In view of available data on arteriospasm coronary which may lead to myocardial infarction from the literature, spontaneous reports, the PRAC considers a causal relationship between adenosine and arteriospasm coronary which may lead to myocardial infarction is at least a reasonable possibility. The PRAC concluded that the product information of products containing adenosine 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 adenosine the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing adenosine 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 adenosine are currently authorised in the EU or are subject to future authorisation procedures in the EU, the CMDh recommends that 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 Products Characteristics:

- Section 4.8

The following adverse reaction(s) should be added under the SOC cardiac disorders with a frequency not known:

Arteriospasm coronary which may lead to myocardial infarction.

Package Leaflet:

- Section 4 Possible side effects, under frequency not known:

Spasm of the artery in the heart which may lead to a heart attack.

Annex III

Timetable for the implementation of this position

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Adoption of CMDh position:	26 April 2023 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	9 June 2023
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	9 August 2023