

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 epinephrine (except for nasal use), the scientific conclusions are as follows:

In view of available data demonstrating an increased risk of QTc prolongation and Torsade de Pointes in predisposed patients (i.e. patients with congenital long QT syndrome or catecholaminergic polymorphic ventricular tachycardia), including published literature cases and spontaneous reports showing plausible temporal relationship in the majority of cases, and considering a plausible mechanism of action, the PRAC considers that a causal relationship between epinephrine and the increased risk of QTc prolongation and Torsade de Pointes in predisposed patients is at least a reasonable possibility.

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 epinephrine (except for nasal use) the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing epinephrine (except for nasal use) 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 4.4

Warnings should be added as follows:

[...]

Cases of QTc prolongation and Torsade de Pointes have been reported following administration of epinephrine in patients with congenital long QT syndrome or catecholaminergic polymorphic ventricular tachycardia.

[...]

Package Leaflet

Section 2

Warnings and precautions

[...]

Tell your doctor if you have a condition called congenital long QT syndrome or problems with heart rhythm.

[...]

Annex III

Timetable for the implementation of this position

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Adoption of CMDh position:	March 2026 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	11 May 2026
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	9 July 2026