EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

Scientific conclusions and grounds for the variation to the terms of the marketing authorisation(s)

Active substance(s): dexmedetomidine

Procedure No. EMEA/H/C/PSUSA/00000998/201903

Period covered by the PSUR: 16 March 2018 To: 15 March 2019

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Scientific conclusions

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

The pharmacodynamic effects of dexmedetomidine include a known potential to induce bradycardia, and first-degree AV block is already mentioned in the product information as an adverse reaction for dexmedetomidine. Concerns have been raised from spontaneous case reports describing higher degree atrioventricular block and cases of cardiac arrest often preceded by bradycardia or atrioventricular block. These concerns are supported by a plausible mechanism from the known pharmacodynamic actions of dexmedetomidine and by a randomised, open-label, multi-center, controlled trial that compared the effects of dexmedetomidine to standard of care in close to 4000 ICU patients requiring sedation (Shehabi et al, NEJM, 2019). The totality of evidence provides sufficient support for a plausible causal link between dexmedetomidine and higher degree atrioventricular block as well as cardiac arrest to warrant a variation to the terms of the marketing authorisation.

The CHMP 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 dexmedetomidine the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing dexmedetomidine is unchanged subject to the proposed changes to the product information.

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