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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): sugammadex

Procedure No. EMEA/H/C/PSUSA/00002799/202401

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## Scientific conclusions

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

In view of available data on hypersensitivity risk including anaphylactic reactions from the literature, and spontaneous reports and in view of a plausible mechanism of action, the PRAC considers that in patients treated with sugammadex for reversal of rocuronium induced neuromuscular blockade, hypersensitivity reactions for sugammadex-rocuronium complex is at least a reasonable possibility. The PRAC concluded that the product information of products containing sugammadex should be amended accordingly.

Having reviewed the PRAC recommendation, the CHMP 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 sugammadex the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing sugammadex 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.