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 rocuronium, the scientific conclusions are as follows:

In view of the available data on hypersensitivity reactions, including anaphylactic reactions reported in the literature, and consistent with the previous PRAC recommendation concerning sugammadex, the PRAC considers that hypersensitivity reactions to the rocuronium-sugammadex complex are at least a reasonable possibility in patients receiving sugammadex for reversal of rocuronium-induced neuromuscular blockade.

Also in view of the available data on hypertensive crisis temporally associated with rocuronium administration in patients with known or latent pheochromocytoma reported in literature, including cases with positive rechallenge —the PRAC concludes that this risk should be reflected in the product information. Accordingly, the PRAC recommends that the product information for medicinal products containing rocuronium be amended to include these safety concerns. The PRAC concluded that the product information of products containing rocuronium should be amended accordingly.

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 rocuronium the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing rocuronium 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

A warning should be added as follows:

Hypertensive crisis in patients with phaeochromocytoma

Postmarketing data have identified cases of hypertensive crisis temporally related to administration of rocuronium in patients with diagnosed or latent phaeochromocytoma. Rocuronium should therefore be used with caution in such patients.

- Section 4.8

New information regarding hypersensitivity reactions should be added into the existing description under the ADR table as follows:

Description of selected adverse reactions

Anaphylaxis

Although very rare, severe anaphylactic reactions to neuromuscular blocking agents, including Esmeron, have been reported. Anaphylactic/anaphylactoid reactions are: bronchospasm, cardiovascular changes (e.g. hypotension, tachycardia, circulatory collapse – shock), and cutaneous changes (e.g. angioedema, urticaria). These reactions have, in some cases, been fatal. Due to the possible severity of these reactions, one should always assume they may occur and take the necessary precautions.

Since neuromuscular blocking agents are known to be capable of inducing histamine release both locally at the site of injection and systemically, the possible occurrence of itching and erythematous reactions at the site of injection and/or generalized histaminoid (anaphylactoid) reactions (see also under anaphylactic reactions above) should always be taken into consideration when administering these drugs.

In clinical studies only a slight increase in mean plasma histamine levels has been observed following rapid bolus administration of 0.3-0.9 mg.kg-1 rocuronium bromide.

In postmarketing reports, hypersensitivity has been observed for rocuronium as well as for rocuronium-sugammadex complex.

Package Leaflet

Section 2. What you need to know before rocuronium is given

Warnings and precautions

(…) Tell your doctor if you have or have had the following:

a rare tumour of the adrenal glands (pheochromocytoma); this may increase the risk of severe high blood pressure

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	November 2025 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	05 January 2026
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	26 February 2026