Part VI: Summary of the Risk Management Plan

Summary of Risk Management Plan for SUGAMMADEX 100 mg/ml solution for injection

This is a summary of the risk management plan (RMP) for SUGAMMADEX 100 mg/ml solution for injection (hereinafter referred to as Sugammadex). The RMP details important risks, how these risks can be minimised, and how more information will be obtained about product's risks and uncertainties (missing information).

Sugammadex's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Sugammadex should be used.

Important new concerns or changes to the current ones will be included in updates of Sugammadex's RMP.

I. The Medicine and What It is used for

Sugammadex is authorised for reversal of neuromuscular blockade induced by rocuronium or vecuronium in adults and routine reversal of rocuronium induced blockade in children and adolescents aged 2 to 17 years (see SmPC for the full indication). It contains Sugammadex as the active substance and it is given intravenously as a single bolus injection.

II. Risks Associated with the Medicine and Activities to Minimise or Further Characterise the Risks

Important risks of Sugammadex, together with measures to minimise such risks and the proposed studies for learning more about Sugammadex's risks, if any, are outlined below.

Measures to minimise the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;
- The authorised pack size — the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;
- The medicine's legal status — the way a medicine is supplied to the patient (e.g. with or without prescription) can help to minimise its risks.

Together, these measures constitute *routine risk minimisation* measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, including PSUR assessment (according to EURD list) so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

II.A List of Important Risks and Missing Information

Important risks of Sugammadex are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered.

Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of Sugammadex. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g. on the long-term use of the medicine). There were no safety concerns applicable for this EU RMP based on the requirement to present only the important identified or potential risks and missing information linked to further pharmacovigilance activities or additional risk minimization measures in the EU.

Table 4: Summary of Safety Concerns

List of important risks and missing information	
Important identified risks	• None
Important potential risks	• None
Missing information	• None

There are no safety concerns recognised for Sugammadex.

II.B Summary of Important Risks

The safety information in the proposed Product Information is aligned to the reference medicinal product.

II.C Post-Authorisation Development Plan

II.C.1 Studies Which Are Conditions of the Marketing Authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of Sugammadex.

II.C.2 Other Studies in Post-Authorisation Development Plan

There are no studies required for Sugammadex.