Part VI: Summary of the risk management plan

Summary of risk management plan for Adrenaline (epinephrine) 1mg/10ml and 1mg/ml (1:10,000 and 1:1000) injection (Ampoules and pre-filled syringes)

This is a summary of the risk management plan (RMP) for Adrenaline (epinephrine) 1mg/10ml and 1mg/ml (1:10,000 and 1:1000) injection. The RMP details important risks of Adrenaline (epinephrine) 1mg/10ml and 1mg/ml (1:10,000 and 1:1000) injection and how more information will be obtained about Adrenaline (epinephrine) 1mg/10ml and 1mg/ml (1:10,000 and 1:1000) injection.

Adrenaline (epinephrine) 1mg/10ml and 1mg/ml (1:10,000 and 1:1000) injection Summary of Product Characteristics (SmPCs) and its package leaflets give essential information to healthcare professionals and patients on how Adrenaline (epinephrine) Injection 1mg/10ml and 1mg/ml (1:10,000 and 1:1000) injection should be used.

Important new concerns or changes to the current ones will be included in updates of Adrenaline (epinephrine) 1mg/10ml and 1mg/ml (1:10,000 and 1:1000)'s RMP.

I. The medicine and what it is used for

Adrenaline (epinephrine) 1mg/10ml and 1mg/ml (1:10,000 and 1:1000) injection is authorised for cardiopulmonary resuscitation in adults and children over 5kg and acute anaphylaxis in adults (see SmPCs for the full indication). It contains adrenaline (epinephrine) as the active substance and it is given by intravenous injection.

II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of Adrenaline (epinephrine) 1mg/10ml and 1mg/ml (1:10,000 and 1:1000) injection, together with measures to minimise such risks and the proposed studies for learning more about professionals and patients on how Adrenaline (epinephrine) Injection 1mg/10ml and 1mg/ml (1:10,000 and 1:1000) injection in pre-filled syringe's risks, 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 so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

If important information that may affect the safe use of professionals and patients on how Adrenaline (epinephrine) 1mg/10ml and 1mg/ml (1:10,000 and 1:1000) Injection is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of professionals and patients on how Adrenaline (epinephrine) 1mg/10ml and 1mg/ml (1:10,000 and 1:1000) injection 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 Adrenaline (epinephrine) 1mg/10ml and 1mg/ml (1:10,000 and 1:1000) Injection. 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);

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

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 obligations of Adrenaline (epinephrine) 1mg/10ml (1:10,000 and 1:1000) injection.

II.C.2 Other studies in post-authorisation development plan

There are no studies required for Adrenaline (epinephrine) 1mg/10ml and 1mg/ml (1:10,000 and 1:1000) Injection.