PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for Arsenic trioxide medac (arsenic trioxide)

This is a summary of the risk management plan (RMP) for Arsenic trioxide medac. The RMP details important risks of Arsenic trioxide medac, how these risks can be minimised, and how more information will be obtained about Arsenic trioxide medac's risks and uncertainties (missing information).

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

This summary of the RMP for Arsenic trioxide medac should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

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

I. The medicine and what it is used for

Arsenic trioxide medac is authorised for treatment of acute promyelocytic leukaemia (APL) in adult patients (see SmPC for the full indication). It contains arsenic trioxide as the active substance and it is given intravenously.

Further information about the evaluation of Arsenic trioxide medac's benefits can be found in Arsenic trioxide medac's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage https://www.ema.europa.eu/en/medicines/human/EPAR/arsenic-trioxide-medac.

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

Important risks of Arsenic trioxide medac, together with measures to minimise such risks and the proposed studies for learning more about Arsenic trioxide medac'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.

If important information that may affect the safe use of Arsenic trioxide medac is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Arsenic trioxide medac 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 Arsenic trioxide medac. 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	- Carcinogenicity
Missing information	- Long-term safety

II.B Summary of important risks

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

Carcinogenicity	
Risk minimisation measures	<u>Routine risk minimisation measures</u> SmPC sections 4.4 and 5.3 PL section 2 SmPC section 4.4: Monitoring for the development of second primary malignancies is recommended. Prescription only Arsenic trioxide must be administered under the supervision of a physician who is experienced in the management of acute leukaemias. <u>Additional risk minimisation measures</u> None

Long-term safety	
Risk minimisation measures	<u>Routine risk minimisation measures</u> Prescription only Arsenic trioxide must be administered under the supervision of a physician who is experienced in the management of acute leukaemias. <u>Additional risk minimisation measures</u> None

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 Arsenic trioxide medac.

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

There are no studies required for Arsenic trioxide medac.