Part VI: Summary of the risk management plan

Summary of risk management plan for Decitabine 50 mg powder for concentrate for solution for infusion (decitabine)

This is a summary of the risk management plan (RMP) for decitabine 50 mg powder for concentrate for solution for infusion. The RMP details important risks of decitabine 50 mg powder for concentrate for solution for infusion, how these risks can be minimized, and how more information will be obtained about decitabine 50 mg powder for concentrate for solution for infusion' risks and uncertainties (missing information).

Decitabine 50 mg powder for concentrate for solution for infusion' summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals (HCPs) and patients on how decitabine 50 mg powder for concentrate for solution for infusion should be used.

Important new concerns or changes to the current ones will be included in updates of the decitabine 50 mg powder for concentrate for solution for infusion RMP.

I. The medicine and what it is used for

Decitabine 50 mg powder for concentrate for solution for infusion is indicated for the treatment of adult patients with newly diagnosed de novo or secondary acute myeloid leukaemia (AML), according to the World Health Organisation (WHO) classification, who are not candidates for standard induction chemotherapy.

It contains decitabine as an active substance and it is given by intravenous infusion (I.V) as Powder for concentrate for solution for infusion.

II. Risks associated with the medicine and activities to minimize or further characterize the risks

Important risks of decitabine 50 mg powder for concentrate for solution for infusion, together with measures to minimize such risks and the proposed studies for learning more about decitabine 50 mg powder for concentrate for solution for infusion risks, are outlined below.

Measures to minimize 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 authorized 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 minimize its risks.

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

In addition to these measures, information about adverse reactions is collected continuously and regularly analyzed, 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 decitabine 50 mg powder for concentrate for solution for infusion are risks that need special risk management activities to further investigate or minimize the risk, so that the medicinal product can be safely taken. 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 decitabine 50 mg powder for concentrate for solution for infusion. 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-authorization development plan

II.C.1 Studies which are conditions of the marketing authorization

There are no studies which are conditions of the marketing authorization or specific obligation of decitabine 50 mg powder for concentrate for solution for infusion.

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

There are no studies required for decitabine 50 mg powder for concentrate for solution for infusion.