Summary of risk management plan for Azacitidine AqVida (azacitidine)

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

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

I. The medicine and what it is used for

Azacitidine AqVida is authorised for certain forms for myelodysplastic syndromes (MDS), chronic myelomonocytic leukaemia (CMML) and certain types of acute myeloid leukaemia (AML) (see SmPC for the full indication). It contains azacitidine as the active substance and it is given by subcutaneous route of administration.

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

Important risks of Azacitidine AqVida, together with measures to minimise such risks and the proposed studies for learning more about Azacitidine AqVida´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 public (e.g. with or without prescription) can help to minimises its risks.

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

In the case of Azacitidine AqVida, these measures are supplemented with **additional risk minimisation measures** mentioned under relevant important risks, below.

In addition to these measures, information about adverse events 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 Azacitidine AqVida is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Azacitidine AqVida 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 Azacitidine AqVida. 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	Haemorrhagic events Infections
Important potential risks	Medication error
Missing information	None

II.B Summary of important risks

Medication error	
Risk minimisation measures	Additional risk minimisation measures: **Dear Healthcare Professional Communication**

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 Azacitidine AqVida.

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

There are no studies required for Azacitidine AqVida.