Summary of risk management plan for EMPLICITI (elotuzumab)

The RMP details important risks of EMPLICITI, how these risks can be minimised, and how more information will be obtained about EMPLICITI's risks and uncertainties (missing information).

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

This summary of the RMP for EMPLICITI 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 EMPLICITI's RMP.

I. The medicine and what it is used for

EMPLICITI is authorised for treating multiple myeloma. Empliciti is approved in several countries in combination with Ld and dexamethasone in adults who have received at least one prior therapy and in combination with pomalidomide and dexamethasone for the treatment of adult patients with relapsed and refractory MM who have received at least two prior therapies including lenalidomide and a proteasome inhibitor and have demonstrated disease progression on the last therapy (see SmPC for full indications). Empliciti contains elotuzumab as the active substance and it is given by intravenous infusion.

Further information about the evaluation of EMPLICITI's benefits can be found in EMPLICITI's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage.

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

Important risks of EMPLICITI, together with measures to minimise such risks and the proposed studies for learning more about EMPLICITI'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 (eg, 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 EMPLICITI is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of EMPLICITI 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 EMPLICITI. 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 (eg, on the long-term use of the medicine).

List of important risks and missing information

Important identified risks	Infusion reaction Infections Second Primary Malignancies
Important potential risks	Hypersensitivity and Anaphylactic reaction
Missing information	Safety in patients with moderate and severe hepatic impairment

II.B Summary of important risks

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

Important identified risk

Infusion Reaction

Evidence for linking the risk to the medicine	In clinical trials with elotuzumab, infusion reactions were mild to moderate using the premedication mandated by the study protocols.
Risk factors and risk groups	No risk groups can be identified.
Risk minimisation measures	Routine risk minimisation measures: SmPC sections 4.2, 4.4, and 4.8. In addition, the package leaflet also includes specific warning and description of the infusion reaction in a language suitable for the patient.

Important identified risk

Infections

Evidence for linking the risk to the medicine	Multiple myeloma is associated with immune dysfunction and the natural course of the disease includes increased infection risk. As such, infection can be a marker of clinical deterioration and disease progression
Risk factors and risk groups	No risk groups can be identified.
Risk minimisation measures	Routine risk minimisation measures: SmPC sections 4.4 and 4.8.

Important identified risk

Second Primary Malignancies

Evidence for linking the risk to the medicine	Prognosis of second primary malignancies, depending from the nature of the malignancy and the primary organ, may vary between good to potentially very poor prognosis.
Risk factors and risk groups	No risk groups can be identified.
Risk minimisation measures	Routine risk minimisation measures: SmPC sections 4.4 and 4.8

Important potential risk

Hypersensitivity and Anaphylactic reaction

Evidence for linking the risk to the medicine	Anaphylaxis is a severe, potentially life-threatening allergic reaction. Hypersensitivity reactions may vary in severity from unpleasant to potentially life threatening.
Risk factors and risk groups	No risk groups can be identified.
Risk minimisation measures	Routine risk minimisation measures: SmPC sections 4.2 and 4.4

Missing Information

Safety in patients with moderate and severe hepatic impairment

Risk minimisation measures	Routine risk minimisation measures: SmPC section 4.2

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 EMPLICITI®.

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

There are no studies required for EMPLICITI®.