SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for Abevmy® (bevacizumab)

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

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

This summary of the RMP for Abevmy® should be read in the context of all the 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 Abevmy® 's RMP.

I. The medicine and what it is used for

Abevmy® is authorized for Metastatic Colorectal Cancer, Metastatic Breast Cancer, Advanced, metastatic or recurrent Non-small Cell Lung Cancer, Advanced and/or metastatic RCC, Epithelial Ovarian, Fallopian Tube and Primary Peritoneal Cancer, and Cervical Cancer (see SmPC for the full indications). It contains bevacizumab as the active substance, and it is given by intravenous route.

Further information about the evaluation of Abevmy®'s benefits can be found in Abevmy®'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/abevmy.

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

Important risks of Abevmy®, together with measures to minimise such 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 addition to these measures, information about adverse events is collected continuously and regularly analysed, including PSUR assessment, 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 Abevmy® are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered to patients. 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 Abevmy®. 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/use in special patient populations etc.).

Table 1 Part VI: Summary of safety concerns

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

II.B Summary of important risks

Since there are no important identified or potential risks and no missing information identified in the summary of the safety concerns, no summary of routine risk minimization measures is applicable.

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 Abevmy®.

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

Not applicable.