PART VI SUMMARY OF THE RISK MANAGEMENT PLAN

SUMMARY OF RISK MANAGEMENT PLAN FOR VYXEOS

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

The Vyxeos Summary of Product Characteristics (SmPC) and Package Leaflet give essential information to healthcare professionals and patients on how Vyxeos should be used.

This summary of the RMP for Vyxeos 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 the RMP for Vyxeos.

I THE MEDICINE AND WHAT IT IS USED FOR

Vyxeos is authorised for the treatment of newly diagnosed adults with high-risk acute myeloid leukaemia (AML) as defined by therapy-related acute myeloid leukaemia (t-AML) or acute myeloid leukaemia with myelodysplasia-related changes (AML-MRC).

Further information about the evaluation of the benefits of Vyxeos can be found in the Vyxeos EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage link to:
http://www.ema.europa.eu/ema/index.jsp?curl=/pages/medicines/human/medicines/human_med_002273.jsp&mid=WC0b01ac058001d124

II RISKS ASSOCIATED WITH THE MEDICINE AND ACTIVITIES TO MINIMIZE OR FURTHER CHARACTERIZE THE RISKS

Important risks of Vyxeos, 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 patient (e.g., with or without prescription) can help to minimise its risks.

Together, these measures constitute routine risk minimisation measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, including Period Safety Update Report (PSUR) assessment - 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 Vyxeos is not yet available, it is listed under ‘missing information’ below.

II.A List of Important Risks and Missing Information

Not applicable as there are no Important Identified Risks, Important Potential Risks and/or Missing Information for Vyxeos.

II.B Summary of Important Risks

Not applicable as there are no Important Identified Risks and/or Important Potential Risks for Vyxeos.

II.C Post-Authorisation Development Plan

II.C.1 Studies Which Are Conditions of the Marketing Authorization

There are no studies which are conditions of the marketing authorisation or specific obligation of Vyxeos.

II.C.2 Other Studies in Post-Authorisation Development Plan

There are no studies required for Vyxeos.