SUMMARY OF RISK MANAGEMENT PLAN FOR GLYXAMBI (EMPAGLIFLOZIN + LINAGLIPTIN)

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

Glyxambi's Summary of Product Characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Glyxambi should be used.

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

I. THE MEDICINE AND WHAT IT IS USED FOR

Glyxambi is authorised for the treatment of adults with insufficiently controlled type 2 diabetes mellitus (see SmPC for the full indication). It contains empagliflozin and linagliptin as the active substances and it is given by oral administration.

Further information about the evaluation of Glyxambi's benefits can be found in Glyxambi'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 Glyxambi, together with measures to minimise such risks and the proposed studies for learning more about Glyxambi'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 (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 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 Glyxambi is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Glyxambi are risks that need special risk management activities to further investigate or minimise 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 Glyxambi. 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	Complicated urinary tract infection[1]
	Genital infection[1]
	Diabetic ketoacidosis with atypical presentation[1]
	Pancreatitis[3]
Important potential risks	Urinary tract carcinogenicity[1]
	Liver injury[1]
	Bone fracture[1]
	Amputation risk[1]
	Pancreatic cancer[2]
Missing information	Pregnancy/breast-feeding

[1] Safety concern derived from mono compound empagliflozin
[2] Safety concern derived from mono compound linagliptin
[3] Important identified risk for the mono compound linagliptin, important potential risk for the mono compound empagliflozin

II.B Summary of important risks

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

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 Glyxambi.

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

PASS 1245.146
Purpose of the study: To evaluate the risk of diabetic ketoacidosis in patients treated with empagliflozin

ABBREVIATIONS

EMA	European Medicine Agency
EPAR	European Public Assessment Report
PASS	Post-authorisation safety study
PSUR	Periodic Safety Update Report
RMP	Risk Management Plan
SmPC	Summary of Product Characteristics