Part VI: Summary of the risk management plan

Summary of risk management plan for Dofliga and Dapagliflozin ELPEN (Dapagliflozin)

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

Dofliga, Dapagliflozin ELPEN's summary of product characteristics (SmPC) and their package leaflet give essential information to healthcare professionals and patients on how Dofliga, Dapagliflozin ELPEN should be used.

Important new concerns or changes to the current ones will be included in updates of Dofliga, Dapagliflozin ELPEN's RMP.

I. The medicine and what it is used for

Dofliga, Dapagliflozin ELPEN are authorised:

- In adults and children aged 10 years and above for the treatment of insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise:
  - as monotherapy when metformin is considered inappropriate due to intolerance;
  - in addition to other medicinal products for the treatment of type 2 diabetes.
- In adults for the treatment of symptomatic chronic heart failure.
- In adults for the treatment of chronic kidney disease

(see SmPC for the full indication).

They contain dapagliflozin as the active substance and they are given orally.

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

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

II.A List of important risks and missing information

Important risks of Dofliga, Dapagliflozin ELPEN are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal products 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 Dofliga, Dapagliflozin ELPEN. Potential risks are concerns for which an association with the use of these medicines 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 products that is currently missing and needs to be collected (e.g. on the long-term use of the medicines).

List of important risks and missing information	
Important identified risks	• Diabetic Ketoacidosis including events with atypical presentation
Important potential risks	• Bladder cancer • Breast cancer • Prostate cancer
Missing information	• Use in patients with NYHA class IV • Long-term safety in the paediatric population (aged 10 years and above)

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 Dofliga, Dapagliflozin ELPEN.

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

There are no studies required for Dofliga, Dapagliflozin ELPEN.