PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for Kixelle® (insulin aspart)

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

Kixelle®'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 Kixelle® 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 Kixelle®'s RMP.

I. The medicine and what it is used for

Kixelle® is authorised for treatment of diabetes mellitus in adults, adolescents and children aged 1 year and above. It contains insulin aspart as the active substance and it is given by subcutaneous route of administration.

Further information about the evaluation of Kixelle®'s benefits can be found in Kixelle®'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

There are no important risks or missing information considered as relevant for Kixelle®'s RMP.

II.A List of important risks and missing information

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

Not 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 Kixelle®.

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

There are no studies required for Kixelle®.