Summary of Risk Management Plan for Humalog/Liprolog and Liumjev (Insulin Lispro)

This is a summary of the risk management plan (RMP) for Humalog/Liprolog and Liumjev. The RMP details important risks of Humalog/Liprolog and Liumjev, how these risks can be minimised, and how more information will be obtained about Humalog/Liprolog's and Liumjev's risks.

Humalog/Liprolog's and Liumjev's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Humalog/Liprolog and Liumjev should be used.

This summary of the RMP for Humalog/Liprolog and Liumjev should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all of 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 Humalog/Liprolog's and Liumjev's RMP.

I - The medicine and what it is used for

Humalog/Liprolog and Liumjev are indicated for treatment of diabetes mellitus (see SmPC for the full indication). They contain insulin lispro as the active substance, and are given by subcutaneous injection, continuous subcutaneous insulin infusion (CSII), and intravenous use under medical supervision, depending on the pharmaceutical form and strength.

Further information about the evaluation of Humalog/Liprolog's and Liumjev's benefits can be found in Humalog/Liprolog's and Liumjev'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/liumjev

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

Measures to minimise the risks identified for Humalog/Liprolog and Liumjev include:

- 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.

Together, these measures constitute *routine risk minimisation* measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed including periodic safety update report (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 Humalog/Liprolog and Liumjev are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered. 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 Humalog/Liprolog and Liumjev. 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	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 that are conditions of the marketing authorisation or specific obligation of Humalog/Liprolog or Liumjev.

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

There are no studies required for Humalog/Liprolog or Liumjev.