Summary of risk management plan for INSULIN LISPRO SANOFI (Insulin lispro)

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

INSULIN LISPRO SANOFI's summary of product characteristics (SmPC) and its package leaflet (PL) give essential information to healthcare professionals and patients on how INSULIN LISPRO SANOFI should be used.

This summary of the RMP for INSULIN LISPRO SANOFI 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 INSULIN LISPRO SANOFI's RMP.

I.THE MEDICINE AND WHAT IT IS USED FOR

INSULIN LISPRO SANOFI is authorized for the treatment of adults and children with diabetes mellitus who require insulin for the maintenance of normal glucose homeostasis. INSULIN LISPRO SANOFI is also indicated for the initial stabilization of diabetes mellitus (see SmPC for the full indication). It contains insulin lispro as the active substance and it is given by SC route or continuous SC infusion. If necessary, INSULIN LISPRO SANOFI may also be administered intravenously.

Further information about the evaluation of INSULIN LISPRO SANOFI's benefits can be found in INSULIN LISPRO SANOFI'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/insulin-lispro-sanofi

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

Important risks of INSULIN LISPRO SANOFI, together with measures to minimize such risks and the proposed studies for learning more about INSULIN LISPRO SANOFI's risks, are outlined in the next sections.

Measures to minimize 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 (eg, with or without prescription) can help to minimize its risks.

Together, these measures constitute routine risk minimization measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analyzed, including Periodic Safety Update Report 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 INSULIN LISPRO SANOFI are risks that need special risk management activities to further investigate or minimize 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 INSULIN LISPRO SANOFI. 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 (eg, on the long-term use of the medicine);

Table 1 - List of important risks and missing information

Important identified risk	None
Important potential risk	None
Missing information	None

II.B Summary of important risks

Not applicable

II.C POST-AUTHORIZATION DEVELOPMENT PLAN

II.C.1 Studies which are conditions of the marketing authorization

There are no studies which are conditions of the marketing authorization or specific obligation of INSULIN LISPRO SANOFI.

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

There are no studies required for INSULIN LISPRO SANOFI.