Medicine Shortage Communication

<Date>

Insulin Lispro Sanofi (insulin lispro 100 U/mL) solution for injection - cartridges and pre-filled pen (3 mL): Supply shortage

Dear Healthcare Professional,

Sanofi <affiliate to include country specific information to reflect global or local company name> is notifying healthcare professionals about a shortage of:

- Insulin Lispro Sanofi (insulin lispro 100 U/mL) solution for injection in cartridges, and;
- Insulin Lispro Sanofi 100 units/ml solution for injection in pre-filled pen.

Insulin Lispro Sanofi (100 units/ml) solution for injection in vial is **not impacted**

Overview of situation:

- **A supply shortage of the above listed presentations of Insulin Lispro Sanofi is expected to start in <the first quarter of 2026>.**
- **Currently, it is not clear when the shortage will end.**
- **The shortage is not due to any safety, efficacy or quality concerns and it stems from an unprecedented surge in demand for Sanofi insulin products.**

Mitigation measures

In order to manage the supply shortage, Sanofi is engaging with the European Medicines Agency and the [National Competent Authority] on mitigation measures.

Regulatory authorities, physicians, healthcare providers and patient organisations are being informed to help ensure patients transition safely to alternative options for continuity of care.

Patients need to be switched to an alternative treatment in time to avoid the risk of missing doses, which may lead to serious clinical consequences.

Healthcare professionals (HCPs) should consider the following mitigation measures:

- During the shortage, no new patients should be started on the affected presentations of Insulin lispro Sanofi.
- Patients who are currently receiving treatment with the affected presentations of Insulin Lispro Sanofi should be switched to alternative insulin lispro-containing products or to products containing other rapid-acting insulin analogues (e.g., insulin aspart or insulin glulisine).

- <Insulin lispro Sanofi is a 'biosimilar medicine'; the following insulin lispro containing medicines are available in <country> and can be considered interchangeable with Insulin lispro Sanofi: > <To be modified by affiliate at national level>
- If you switch patients to another rapid-acting insulin, take the following into consideration:
    - Alternative rapid-acting insulins provide comparable glycemic control but may require individualised dose adjustments due to differences in insulin pharmacokinetics, specifically onset, peak, and duration of action.
    - Provide clear instructions on the use of any new insulin delivery system. This includes a potential need for change in dose and additional glucose monitoring.
    - Close glucose monitoring is recommended during the switch to alternative fast-acting insulin analogues and in the first week or at the discretion of the healthcare provider thereafter, especially in pregnant women and children who may need closer monitoring than the general population. The risk of hypoglycaemia may be higher in these populations.
    - Follow dosing recommendations in the relevant summary of product characteristics while switching patients to alternative fast-acting insulin analogs.

Background on the shortage and the medicinal product

There has been an unprecedented increase in demand on all Sanofi Insulins. Sanofi will be unable to immediately adapt and increase its supply for Insulin lispro Sanofi 100 units/ml solution for injection in cartridge and Insulin lispro Sanofi 100 units/ml solution for injection in pre-filled pen.

Insulin lispro Sanofi is indicated 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 stabilisation of diabetes mellitus. It contains the active substance insulin lispro. Insulin lispro Sanofi is a 'biosimilar medicine' which means that it is highly similar to a biological medicine (also known as the 'reference medicine') that is already authorised in the European Union (EU). The reference medicine for Insulin lispro Sanofi is Humalog 100 U/ml solution.

Insulin lispro Sanofi is a fast-acting insulin analog; it is usually given shortly before a meal and, when necessary, soon after a meal. The dose of Insulin lispro Sanofi is worked out for each patient and depends on the patient's blood glucose level. Healthcare professionals should instruct the patient on how to use the medicine properly.

For up-to-date information on the availability of Insulin Lispro Sanofi and the alternatives in a particular EU/EEA country, consult the National Competent Authority.

Company contact point

Further information can be obtained by contacting <local Sanofi affiliate contact details to be added by affiliate>

Yours sincerely,
Medical Director

Annex

References:

Insulin lispro Sanofi | European Medicines Agency (EMA)

Communication Plan for Medicine Shortage Communication

MSC COMMUNICATION PLAN	
Medicinal product(s)/active substance(s)	Insulin Lispro Sanofi (insulin lispro 100 U/mL)
Marketing authorisation holder(s)	Sanofi Winthrop Industrie
Purpose of the communication	Inform healthcare professionals about anticipated shortages on Insulin Lispro Sanofi for both Insulin Lispro Sanofi (insulin lispro 100 U/mL) solution for injection in cartridges and Insulin Lispro Sanofi 100 units/ml solution for injection in pre-filled pen.
MSC recipients	Endocrinologists, diabetologists, internal medicine specialists, general practitioners, family physicians, pharmacists, and diabetes nurses. The target group should be further defined at national level, in agreement with the respective national competent authority.
Member States where the MSC will be distributed	In agreement with NCAs

Timetable	Date
MSC and communication plan (in English) agreed by SPOC WP	10/11/2025
MSC and communication plan (in English) agreed by MSSG	21/11/2025
Submission of translated MSCs to the national competent authorities for review	Within 10 days after receipt of the approved MSC (or according to the timelines set by NCAs)
Agreement of translations by national competent authorities	According to the timelines set by NCAs
Dissemination of MSC	Within 2 weeks after respective NCA approval