

Medicine Shortage Communication

<Date>

Note: Angular brackets (<>) are used to allow flexibility for accurately reflecting the respective national situation

Marketing cessation (discontinuation) of selected presentations of:

- **<short- and rapid-acting (bolus/mealtime) insulins (human insulin, solution for injection; insulin lispro, solution for injection)>**
- **<intermediate-acting insulins (isophane human insulin, suspension for injection)>**
- **<mixed-acting (biphasic) insulins (30% soluble insulin and 70% isophane insulin, suspension for injection; 25% insulin lispro and 75% insulin lispro protamine, suspension for injection; 50% insulin lispro and 50% insulin lispro protamine, suspension for injection)>**
- **<long-acting (basal) insulins (insulin glargine, solution for injection)>**

Dear Healthcare Professional,

After careful consideration and a thorough market assessment, Eli Lilly and Company (Lilly) [**affiliate to include country specific information to reflect global or local company name**], is notifying healthcare professionals about the discontinuation of the following presentations of its insulin formulations in **<Member State>**.

Note: This communication follows notifications that have already been made to regulatory agencies in Member States by Lilly according to national reporting requirements.

Overview of situation

- **Lilly has discontinued or will discontinue the below listed presentations of insulins in **<Member State>**.**
 - **The discontinuations differ between countries, and timelines also vary by country.**
 - **<There are alternative treatment options available for the most insulin presentations that will be discontinued.>**
 - **The discontinuations are not a consequence of any safety, efficacy, or quality related issue.**
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<The below mixed-acting presentation will be discontinued across all EU/EEA countries where it is marketed.>

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Table 1. Insulin presentation that will be discontinued in <Member State> and across all EU/EEA countries where it is marketed

Products	Presentation(s) subject to marketing cessation (discontinuation)	Presentation(s) remaining available	Timeline of discontinuation
Mixed-acting (biphasic) insulins			
Humalog Mix25 (25% insulin lispro and 75% insulin lispro protamine, 100 units/ml suspension for injection)	vial	<cartridge> <KwikPen>	<date>

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Table to be kept only for countries where products/presentations are marketed.

<In addition,> Lilly will also discontinue the below listed insulin presentations in <Member State>. These are not EU/EEA-wide discontinuations and only affect selected Member States, and timelines also vary by Member State.

Table 2. Insulin presentations that will be discontinued in <Member State> and across selected EU/EEA countries where they are marketed

Products	Presentation(s) subject to national marketing cessation (discontinuation)	Presentation(s) remaining available	Timeline of discontinuation
<Short-and rapid-acting (bolus/mealtime) insulins>			
<Lyumjev (Insulin lispro, 100 units/ml solution for injection)>	<cartridge> <vial> <KwikPen> <Junior KwikPen>	<cartridge> <vial> <KwikPen> <Junior KwikPen> <none>	<date>
<Lyumjev (Insulin lispro, 200 units/ml solution for injection)>	<KwikPen>	<none>	<date>
<Humulin S (human insulin, 100 units/ml, solution for injection)>	<cartridge> <vial> <KwikPen>	<cartridge> <vial> <KwikPen> <none>	<date>
<Humalog (Insulin lispro, 100 units/ml solution for injection)>	<cartridge> <vial> <KwikPen> <Junior KwikPen>	<cartridge> <vial> <KwikPen> <Junior KwikPen> <none>	<date>
<Liprolog (Insulin lispro, 100 units/ml solution for injection)>	<cartridge> <vial> <KwikPen> <Junior KwikPen>	<cartridge> <vial> <KwikPen> <Junior KwikPen> <none>	<date>

<Intermediate-acting insulins>			
<Humulin I (isophane human insulin, 100 units/ml, suspension for injection)>	<cartridge> <vial> <KwikPen>	<cartridge> <vial> <KwikPen> <none>	<date>
<Mixed-acting (biphasic) insulins>			
<Humalog Mix25 (25% insulin lispro and 75% insulin lispro protamine, 100 units/ml suspension for injection)>	<cartridge> <KwikPen>	<cartridge> <KwikPen> <none>	<date>
<Humalog Mix50 (50% insulin lispro and 50% insulin lispro protamine, 100 units/ml suspension for injection)>	<cartridge> <KwikPen>	<cartridge> <KwikPen> <none>	<date>
<Humulin M3 (30% soluble insulin and 70% isophane insulin, 100 units/ml, suspension for injection)>	<cartridge> <vial> <KwikPen>	<cartridge> <vial> <KwikPen> <none>	<date>
<Long-acting (basal) insulins>			
<Abasaglar (Insulin glargine, 100 units/mL solution for injection)>	<cartridge> <KwikPen>	<cartridge> <KwikPen> <none>	<date>

<Note: Angular brackets (<>) are used to allow flexibility for accurately reflecting the respective national situation (taking into account that listed presentations/products are not marketed in all EU/EEA countries). The bracketed text should be removed based on which presentations are currently marketed and will be discontinued in the respective country.>

Please update the above Table, so that HCPs have a clear overview of the national discontinuations in your country.

Mitigation measures

In order to manage the discontinuation, Lilly 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 patients safely transition to alternative options for continuity of care.

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

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

- No new patients should be started on the above listed insulins.
- **Short- and rapid-acting (bolus/mealtime) insulins:** Healthcare professionals should switch any patients who are currently on any of the listed insulins to alternative insulins (such as insulin aspart or its biosimilars, insulin lispro or its biosimilars, or insulin glulisine or its biosimilars) based on existing guidance and clinical judgment.

- **Intermediate-acting (isophane/NPH) insulins:** Healthcare professionals should switch any patients who are currently on any of the listed insulins to alternative insulins based on existing guidance and clinical judgment.
- **Mixed-acting (biphasic) insulins:** Healthcare professionals should switch patients who are currently on any of the above listed insulins to an alternative mixed insulin preparation or basal-bolus therapy or their biosimilars, based on existing guidance and clinical judgment.
- **Long-acting (basal) insulins:** Healthcare professionals should switch any patients who are currently on any of the above listed long-acting insulins to an alternative once-daily or once-weekly basal insulin preparation or their biosimilars.

In addition:

- Healthcare professionals should ensure that all patients are counselled on any changes in the new insulin regimen and/or usage of the new insulin delivery system. This includes a potential need for change in dose and additional glucose monitoring.
- Close glucose monitoring is recommended during the transfer to another type or brand of insulin and in the initial weeks 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.
- Healthcare professionals should follow the relevant product SmPCs for dosing recommendations while switching patients to alternative insulin products.
- Patients may require training when switching to a new presentation/delivery system.

Note:

When switching to an alternative insulin, healthcare professionals may need to adjust the dose due to potential differences in the pharmacokinetics/pharmacodynamics (PK/PD), efficacy and safety profiles between the new insulin and the one being replaced. The dose may need to be adjusted immediately before or after the switch. Additional adjustments may also be required several weeks after the switch and could affect the basal or bolus insulin requirement (if the patient is on basal-bolus regimen) or anti-diabetic medications.

Background information

- **Short- and rapid-acting (bolus/mealtime) insulins** are a type of fast-acting insulin analogue used to manage blood sugar levels, particularly after meals. They start working quickly, typically within 15 minutes, and their effects last for a shorter duration, around 2 to 4 hours. Common examples include insulin lispro, insulin aspart, and insulin glulisine. They are usually taken immediately before or shortly after meals to control mealtime glucose spikes. [\[affiliate to include country specific **indication** information\]](#). [\[affiliate to include country specific **presentation** information\]](#).
- **Intermediate-acting (isophane/NPH) insulins** are a type of insulin that have a longer duration of action compared to short-acting insulins, helping to manage blood sugar levels over a more extended period. These insulins typically start working within 1-2 hours after injection, peak in 4-6 hours, and can last for up to 12-24 hours. They are usually taken once or twice daily, commonly in the morning and/or evening to maintain basal insulin levels throughout the day and night. [\[affiliate to include country specific **indication** information\]](#). [\[affiliate to include country specific **presentation** information\]](#).
- **Mixed-acting (biphasic) insulins** combine rapid- or short-acting insulin with intermediate-acting or long-acting insulin in a single injection. This provides both immediate and longer-lasting coverage for managing blood glucose levels, mimicking the body's natural insulin response to

meals and basal needs. Mixed-acting (biphasic) insulins start to work within 30 minutes and last for up to 24 hours. They are usually taken twice a day, before breakfast and the evening meal. [affiliate to include country specific **indication and presentation** information].

- **Long-acting (basal) insulins** start to work after 30 minutes to 4 hours, depending on the type. Their action usually lasts for 16 to 24 hours, depending on the type and dose. They are usually taken once or twice a day. [affiliate to include country specific **indication and presentation** information].

Healthcare professionals should refer to the relevant SmPC for more information.

Safety instructions and general information

A delay in switching to an alternative insulin treatment could result in patients missing their required doses, which may lead to serious clinical consequences.

When changing patients' insulin therapy, the following should be taken into account:

- Switching a patient to a different type and/or brand of insulin must be carried out under medical supervision.
- A change in insulin therapy can lead to an unstable metabolic situation. In turn, this can lead to impairments in the patient's daily life (e.g., driving a motor vehicle) and must be discussed with the patient.

Company contact point

<Contact point details for access to further information, including relevant website address(es), telephone numbers and a postal address>

Communication Plan for Medicine Shortage Communication

MSC COMMUNICATION PLAN	
Medicinal product(s)/active substance(s)	<p><u>Presentations to be discontinued across all EU/EEA countries:</u></p> <p><Humalog Mix25 (25% insulin lispro and 75% insulin lispro protamine, 100 units/ml suspension for injection) [Vial]></p> <p><u>Presentations currently subject to only national discontinuation in one or more EU/EEA countries:</u></p> <p><Lyumjev (Insulin lispro, 100 units/ml solution for injection) [<cartridge,> <vial,> <KwikPen,> <Junior KwikPen>]></p> <p><Lyumjev (Insulin lispro, 200 units/ml solution for injection) [KwikPen]></p> <p><Humulin S (human insulin, 100 units/ml, solution for injection) [<cartridge,> <vial,> <KwikPen>]></p> <p><Humalog (Insulin lispro, 100 units/ml solution for injection) [<cartridge,> <vial,> <KwikPen,> <Junior KwikPen>]></p> <p><Liprolog (Insulin lispro, 100 units/ml solution for injection) [<cartridge,> <vial,> <KwikPen,> <Junior KwikPen>]></p> <p><Humulin I (isophane human insulin, 100 units/m, suspension for injection) [<cartridge,> <vial,> <KwikPen>]></p> <p><Humalog Mix25 (25% insulin lispro and 75% insulin lispro protamine, 100 units/ml suspension for injection) [<cartridge,> <KwikPen>]></p> <p><Humalog Mix50 (50% insulin lispro and 50% insulin lispro protamine, 100 units/ml suspension for injection) [<cartridge,> <KwikPen>]></p> <p><Humulin M3 (30% soluble insulin and 70% isophane insulin, 100 units/ml, suspension for injection) [<cartridge,> <vial,> <KwikPen>]></p> <p><Abasaglar (Insulin glargine, 100 units/mL solution for injection) [<cartridge,> <KwikPen>]></p>
Marketing authorisation holder(s)	<p>Eli Lilly Nederland B.V.</p> <p>Papendorpseweg 83 3528 BJ Utrecht The Netherlands</p>
Purpose of the communication	<p>Inform healthcare professionals of discontinuations of selected insulins and measures to take.</p>
MSC recipients	<p>Target group for this letter is specialists that treat patients with diabetes (e.g. endocrinologists, diabetologists, specialists in internal medicine, general practitioners /family physicians, pharmacists, diabetes nurses) in all EU/EEA countries in which the medicinal products are marketed. The target group can be further defined at national level, in agreement with the respective national competent authorities.</p>

MSC COMMUNICATION PLAN

Member States where the MSC will be distributed	In agreement with the national competent authorities.
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Timetable *[Delete steps which are not applicable]*

Date

MSC and communication plan (in English) agreed by SPOC WP	9/03/2026
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MSC and communication plan (in English) agreed by MSSG	16/03/2026
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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)
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Agreement of translations by national competent authorities	According to the timelines set by NCA
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Dissemination of MSC	According to the timelines set by NCA
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