

press release

Novo Nordisk announces positive scientific opinion from EMA on human insulin with more flexible storage without refrigeration

Bagsværd, Denmark, 22 April 2022 – Novo Nordisk today announced that the European Medicines Agency (EMA) has granted the company a positive scientific opinion for a proposed update to the storage conditions of two human insulins.

EMA's positive scientific opinion will now be used to support obtaining approval of the more flexible storage conditions by national health authorities in a number of relevant low- and middle-income countries. This to allow that Actrapid® (short-acting insulin) and Insulatard® (intermediate-acting insulin) can be stored for four weeks outside of a refrigerator (if kept below 30° C) prior to use if there are six months or more to the expiry date. Once in use, the insulin should be stored without refrigeration.

The new guidance aims to improve flexibility and convenience for many people with diabetes in low- and middle-income countries, who have limited access to reliable refrigeration, and who may live within long distances from a clinic or pharmacy.

"For patients receiving insulin therapy, maintaining insulin within recommended temperatures can be a source of anxiety, challenge and poor compliance and it is not always possible to find a solution. Creating new opportunities for established products to benefit people with diabetes in resource-constrained settings is a recognisable contribution to help address unmet needs of majority of the people with diabetes in low- and middle-income countries," said Dr. Kaushik Ramaiya, honorary general secretary, Tanzania Diabetes Association.

Insulin is temperature-sensitive and loses potency when exposed to too high or low temperatures. The cold storage requirement of insulin can be a challenge, especially in hot climates and in countries or humanitarian settings where people have limited access to refrigeration or reliable electricity.

The company undertook the project of investigating the safety of its human insulin at different temperatures as part of its social responsibility strategy Defeat Diabetes. This demonstrates Novo Nordisk's commitment to drive sustainable solutions and create enduring value for people with diabetes and society.

Novo Nordisk's efforts to address thermostability as a barrier to access to care are well aligned with the asks presented to the company by humanitarian, academic and public health actors. With these efforts, Novo Nordisk also aims to support the World Health Organization's Global Diabetes Compact and the private sector asks to industry, one of which is to collaborate to advance the thermostability agenda for insulin.

"I am proud of our continuous efforts to innovate and adapt to improve access to life-saving medicines for people living with serious chronic diseases. The EMA positive opinion paves the way for us to start updating the label for two human insulin products in low- and middle-income countries, to allow patients to store their insulin outside of the refrigerator for one month before use. Looking ahead, we hope to be able to develop an actual thermostable insulin but until then, we will continue to pursue other means of addressing this barrier," said Martin Holst Lange, executive vice president, Development at Novo Nordisk.

Learn more about Novo Nordisk's [access and affordability initiatives here](#).

Novo Nordisk is a leading global healthcare company, founded in 1923 and headquartered in Denmark. Our purpose is to drive change to defeat diabetes and other serious chronic diseases such as obesity and rare blood and endocrine disorders. We do so by pioneering scientific breakthroughs, expanding access to our medicines, and working to prevent and ultimately cure disease. Novo Nordisk employs about 47,800 people in 80 countries and markets its products in around 170 countries. For more information, visit novonordisk.com, [Facebook](#), [Twitter](#), [LinkedIn](#) and [YouTube](#).

Further information

Media:

Ambre Brown Morley	+45 3079 9289	abmo@novonordisk.com
Natalia Salomao Abrahao (US)	+1 848 304 1027	niaa@novonordisk.com

Investors:

Daniel Muusmann Bohsen	+45 3075 2175	dabo@novonordisk.com
Ann Søndermølle Rendbæk	+45 3075 2253	arnd@novonordisk.com
David Heiberg Landsted	+45 3077 6915	dhel@novonordisk.com
Jacob Martin Wiborg Rode	+45 3075 5956	jrde@novonordisk.com
Mark Joseph Root (US)	+1 848 213 3219	mjhr@novonordisk.com