

Insulin Storage in Europe

A comment to Grajower et al., Eli Lilly, and Novo Nordisk

MARCO GALLO, MD^{1,2}
MARCO COMOGLIO, MD^{1,3}
ALBERTO DE MICHELI, MD^{1,4}

LUCA MONGE, MD^{1,5}
GIACOMO VESPASIANI, MD^{1,6}

The commentary by Grajower et al. (1) raised important questions concerning the storage of an opened insulin vial, prefilled syringe, or cartridge. This is a very important topic because, as the author states, due to contradictory

information on this subject, most physicians are not aware of the real effectiveness of insulin once it is opened.

Individual responses from the three pharmaceutical companies that supply insulin revealed different storage indications for every type of insulin they produce, depending on the particular formulation of insulin, its method of manufacture, its container, and ambient storage conditions.

Companies agree on recommending the storage of unopened vials, cartridges, or prefilled insulin delivery systems at recommended temperatures (between 36 and 46°F [2 and 8°C]), so that they can be used until the expiration date printed on the packaging. In our opinion, it is important to note that company recommendations for in-use products differ not only between one another, but also between the U.S. and Europe. Aventis, which markets insulin glargine, univocally states that an in-use open vial can be kept non-refrigerated for up to 28 days in a place away from direct heat and light, at controlled room temperature (<86°F [$<30^{\circ}\text{C}$]). On the other hand, relevant differences exist for Eli Lilly and Novo Nordisk insulins when comparing official responses, both in the aforementioned commentary (1) and on the Internet (2), and information leaflets for European commercialized products, which are regulated by the EMEA (European Agency for the Evaluation of Medicinal Products) (3), the regulatory authority for drug licensing in the European Union. Substantial discrepancies specifically concern cartridges and prefilled devices containing insulin NPH and fast-acting and long-acting mixtures. While European insulin information leaflets recommend discarding every type of insulin after 28–42 days from the first use, American warnings recommend not to use cartridges and prefilled devices containing NPH and mixture insulins beyond 14, 10, or even 7 days after opening (Table 1). If it is true that, as Eli Lilly and Novo Nordisk say, in-use dating recommendations for pens and cartridges are shorter than those for

Table 1—Days of duration for in-use insulin in the U.S. and Europe

Product	U.S.	EU/Italy
Aventis		
Vials, prefilled syringes, and cartridges		
Lantus	28	28
Eli Lilly		
Vials		
Humulin R, Humulin N (Humulin I), Humulin 70/30 (Humulin 30/70), Humalog, and Humalog Mix 75/25 (Humalog Mix 25)	28	28
Prefilled syringes		
Humalog	28	21
Humulin N	14	28
Humulin 30/70 and Humalog Mix 75/25	10	28
Cartridges		
Humulin R	28	28*
Humalog	28	21
Humalog Mix 75/25, Humulin N, and Humulin 30/70	7–10	28
Novo Nordisk		
Vials		
Novolin R (Actrapid), Novolin 70/30 (Actraphane 30), Novolin I (Protaphane), NovoLog (Novorapid), Monotard, and Ultratard	28	42
Prefilled syringes and cartridges		
NovoLog and Novolin R	28	28
Novolin I	14	42
Novolin 70/30	10	42

Names in parentheses indicate the corresponding brand name in Europe. *For 3-ml and 1.5-ml cartridges of Humulin R and Humulin 50/50. For 1.5-ml cartridges of Humulin N, Humulin 10/90, 20/80, 30/70, and 40/60: 21 days.

From the ¹AMD (Associazione Medici Diabetologi) scientific information website board (www.infodiabetes.it) Turin, Italy; the ²Diabetes Unit, Chivasso Civic Hospital, Turin, Italy; the ³Diabetes Service, Moncalieri, Turin, Italy; the ⁴Diabetes Unit, San Martino Hospital, Genoa, Italy; the ⁵Diabetes Unit, CTO Hospital, Turin, Italy; and the ⁶Diabetology and Metabolic Disorders Center, Madonna del Soccorso Hospital, San Benedetto del Tronto, Ascoli Piceno, Italy.

Address correspondence and reprint requests to Marco Gallo, MD, Diabetes Unit, Chivasso Civic Hospital—ASL7, Corso Galileo Ferraris, 3, 10034 Chivasso, Turin, Italy. E-mail: diabetologia@asl7.to.it.

Received for publication 4 February 2004 and accepted in revised form 6 February 2004.

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See accompanying letters, p. 1240 and p. 1241.

vials, reflecting the reduced volumes and the environment to which these products might be exposed, it is difficult for us to understand why the same companies allow longer utilization periods for the same products in Europe. We believe it is important for manufacturers to provide the medical community scientific and precise data on this issue. This would really enable both pa-

tients and physicians to minimize waste of unused insulin.

References

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