

Question for written answer E-004998/2025

to the Commission

Rule 144

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Subject: Ensuring quality and safety of diabetes management devices in the EU

Diabetes is a chronic metabolic disease characterised by high blood glucose levels as a result of insufficient insulin production or an altered response to the hormone. It manifests as type 1 (T1D), which is autoimmune in origin, or type 2 (T2D), which is more common and linked to genetic and lifestyle factors.

T1D requires daily management supported by advanced technological devices such as continuous glucose monitoring (CGM) systems, insulin infusion pumps, and digital platforms for therapeutic follow-up. While T2D can often be managed with diet and non-insulin medications, it can also benefit from the use of CGM systems.

Current EU legislation does not establish minimum quality requirements for these devices, allowing products with variable safety and efficacy standards to enter the market. This results in a dual risk: possible compromise of patients' clinical safety and market distortion in favour of less effective but cheaper products.

In the light of this:

1. Does the Commission intend to define binding minimum standards, based on scientific evidence, for diabetes management medical devices, including the possibility of modelling quality standards such as but not limited to those identified by the US Food and Drug Administration (iCGM)?
2. How does it plan to ensure a coordinated assessment of the quality and clinical effectiveness of such devices within the single market?

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