

(English version)

**Question for written answer E-001223/25
to the Commission
Loucas Fourlas (PPE)
(24 March 2025)**

Subject: Access to critical technologies for type 1 diabetes mellitus

Type 1 diabetes mellitus is a chronic autoimmune disease affecting thousands of children across the European Union, requiring continuous and specialised support with medical technology to effectively manage the condition. However, access to state-of-the-art medical tech solutions, such as continuous glucose monitoring systems, insulin pumps and automated insulin delivery systems, is not uniform across Member States, with smaller states, such as Cyprus, facing significant challenges. Unequal access to these critical technologies has a direct impact on the quality of life of patients, especially children, as well as on public health costs. Urgent action is needed because access to state-of-the-art technology is a fundamental right for all European citizens.

In view of the above:

1. How does the Commission intend to ensure that all European citizens, including those living in smaller Member States, have access to the most advanced medical tech solutions for managing type 1 diabetes?
2. Does the Commission intend to propose a European framework for the adoption of national diabetes strategies, including minimum standards for accessing new technologies for managing type 1 diabetes mellitus?

Submitted: 24.3.2025

**Answer given by Mr Várhelyi on behalf of the European Commission
(17 June 2025)**

In line with Article 168(7) of the Treaty on the Functioning of the EU ⁽¹⁾, the organisation and delivery of health services and medical care is a national competence.

Regulation (EU) 2017/745 on medical devices ⁽²⁾, including on type 1 diabetes, provides the regulatory framework for a high level of safety and supports innovation.

In line with the Mission letter for Commissioner for Health and Animal Welfare ⁽³⁾, the Commission will also step up the implementation of the current framework and evaluating the need for potential legislative changes.

A targeted evaluation of this regulation is currently looking at the scope for simplification, burden-reduction, more harmonisation, support for small and medium enterprises, digitalisation, increase of competitiveness and support to innovation, which contributes to access to these devices.

Regulation (EU) 2021/2282 on health technology assessment ⁽⁴⁾ provides a framework to assess the clinical aspects of innovative health technologies.

On that basis, national authorities can make more timely and informed decisions on the pricing and reimbursement of health technologies.

The scope of the regulation is limited to some high-risk medical devices. It could include a technology for type 1 diabetes mellitus if that technology receives an opinion from the expert panels ⁽⁵⁾ under the regulation (EU) 2017/745.

The ‘Healthier Together’ initiative ⁽⁶⁾ supports Member States in disease prevention and collaborative action between Member States on cardiovascular diseases and diabetes ⁽⁷⁾ is supported.

The Commission will step up work on preventative health by building on existing actions. A European Cardiovascular Health Plan is being developed to address also diabetes and obesity.

⁽¹⁾ http://data.europa.eu/eli/treaty/tfeu_2008/art_168/oj.

⁽²⁾ <http://data.europa.eu/eli/reg/2017/745/oj>.

⁽³⁾ https://commission.europa.eu/document/download/b1817a1b-e62e-4949-bbb8-ebf29b54c8bd_en?filename=Missionletter-VARHELYI.pdf.

⁽⁴⁾ <http://data.europa.eu/eli/reg/2021/2282/oj>.

⁽⁵⁾ https://health.ec.europa.eu/medical-devices-expert-panels/overview_en.

⁽⁶⁾ https://health.ec.europa.eu/non-communicable-diseases/healthier-together-eu-non-communicable-diseases-initiative_en.

⁽⁷⁾ <https://jacardi.eu/>.