Esperia Advocacy<sup>+</sup>

## European alliance to overcome diabetes

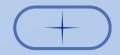
Type 1 Diabetes can be fast, but we can be faster: a call to boost early detection



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# Index

Introduction	1
01. The need for coordinated strategies for EU cooperation	3
02. Standardising European access to technology for the management of T1D	4
03. Formal recognition of early-stage T1D for better care and prosperity	6
04. Psychological support for paediatric patients and their families	7
Conclusions	8
Annex 1	9
Contacts	10

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# Introduction

Type 1 Diabetes is one of the most common autoimmune chronic diseases in children and adolescents, with a significant impact on the quality of life of individuals and their families. T1D can happen to anyone and at any age, regardless of family history, and as with all autoimmune conditions, its appearance is not connected to lifestyle choices. Approximately <u>8.75 million people worldwide</u> are living with the disease, a number that is expected to <u>almost double by 2040</u>.

Europe has the highest paediatric prevalence in the world, with <u>295,000 children</u> and adolescents affected and 31,000 new cases diagnosed each year.

Type 1 Diabetes is an autoimmune condition that occurs when the body attacks insulinproducing cells, whereas Type 2 Diabetes is primarily linked to insulin resistance; **the two are distinct diseases with different causes, treatments, and management approaches, and should not be confused**. T1D, characterised by the autoimmune destruction of pancreatic beta cells, can lead to serious complications such as **diabetic ketoacidosis** if not diagnosed and treated in time.

Early diagnosis plays a crucial role in preventing such medical emergencies, improving clinical outcomes and reducing the burden on families and healthcare systems.

In this context, Italy has taken a world-leading position with the adoption of **Law 130/2023**, the first law to establish a national screening programme for Type 1 Diabetes and coeliac disease in the paediatric population. The law provides for early diagnosis through the detection of diabetes-associated autoantibodies, making it possible to detect the disease in an early, presymptomatic stage. This approach will not only prevent acute complications, but also provide essential data for the development of innovative therapeutic strategies.

The key measures of the law include the creation of a **National Observatory for Type 1 Diabetes**, the funding of awareness campaigns for early diagnosis and a total budget of more than €6.5 millions for the first three years of implementation. Thanks to this initiative, Italy is setting a good example for the whole of Europe, offering a replicable model for tackling the growing incidence of Type 1 Diabetes. Esperia Advocacy

# Introduction

All these topics, were at the centre of the discussion of *The European Alliance to Overcome Diabetes* event, hosted by MEP Salvatore De Meo, organised by Esperia Advocacy, with the support of the European Diabetes Forum (EUDF) and EDENT1FI (European action for the Diagnosis of Early Non-clinical Type 1 Diabetes For disease Interception), that was held on 12 December 2024 at the European Parliament.

The event was an important opportunity to **promote a structured dialogue** between European institutions, scientific societies, patient organisations and key stakeholders in the healthcare sector. The main objective was to involve policy makers in the definition of a common regulatory policy aimed at improving early detection of Type 1 Diabetes through innovative and coordinated approaches.

Within this framework, five key strategic objectives were outlined:

- 01. Promote a collaborative effort at the European level to establish screening programmes for Type 1 Diabetes, enhancing the effectiveness of the Italian model.
- **O2.** Ensure consistent regional and national access to advanced devices and technologies for diabetes management.
- 03. Formal recognition of early-stage T1D for better care and prosperity.
- 04. Facilitate access to appropriate psychological support for paediatric patients and their families.
- **05.** Promote the full implementation of Italian Law 130/2023 and encourage its dissemination as a replicable model in other Member States conclusion.

# 01. The need for coordinated strategies for EU cooperation

Adopting the Italian model at European level will require close cooperation between Member States and the support of key European institutions. Research programmes such as *Horizon Europe* and the involvement of international organisations, including the World Health Organisation (WHO), can act as catalysts to promote the implementation of coordinated policies.

These initiatives aim to create an integrated network of actions capable of:

- improving the quality of life for patients and their families;
- reducing the long-term economic impact of diabetes on European healthcare systems;
- promoting harmonisation of clinical and regulatory interventions through a common approach.

#### 1.1 – COST-EFFECTIVENESS AS A CORNERSTONE OF SCREENING ACTIVITIES

An essential aspect of ensuring the sustainability of screening activities is their costeffectiveness. The Italian experience shows that it is possible to implement widely accessible and functional programmes:

- Low cost: ensures large-scale deployment in heterogeneous healthcare environments.
- Ease of use: to facilitate adoption in paediatric settings and primary care.
- **Transportability**: making the tests easily accessible even in the most remote areas or areas with limited infrastructure.

These elements, in addition to promoting the rational use of healthcare resources, enable the implementation of a greater number of screening initiatives, significantly reducing the economic impact of complications related to Type 1 Diabetes while improving the quality of life of patients and their families.

## 02. Standardising European access to technology for the management of Type 1 Diabetes

Ensuring equitable access to advanced technologies for the management of Type 1 Diabetes is essential to significantly improve patients' quality of life and reduce territorial inequalities. The event underlined the importance of an integrated approach in promoting uniform access across Europe, including state-of-the-art devices such as continuous insulin infusion systems (CSII) and continuous glucose monitoring (CGM) sensors.

In Italy, the model set out in Law 130/2023 has laid the foundations for a comprehensive strategy, supported by a network of around 350 diabetes centres. These centres, staffed by multidisciplinary teams, not only support the optimal use of devices. The integration of the paediatric screening programme with such innovations makes it possible to plan personalised therapies that significantly reduce the risk of complications and improve the stability of glycaemic control.

At the same time, telemedicine and the use of electronic health records are transforming healthcare, enabling constant communication between patients and healthcare professionals and continuous remote monitoring of blood glucose data. These advanced tools provide real-time support, reduce the logistical burden of in-patient visits and optimize therapeutic management.

At the European level, it is essential to overcome the existing disparities between Member States:

- Encourage public-private partnerships to develop affordable nextgeneration technologies;
- Stimulate scientific research, focusing on cell therapies and approaches to modulate the immune response to slow disease progression;
- Standardise health policies and create shared funding mechanisms to expand the availability of technologies on a continental scale.

This vision, backed by investment in research and development, aims to create a robust and innovative healthcare ecosystem. The introduction of next-generation devices and therapies will not only improve patients' life prospects, but also strengthen Europe's leadership in life sciences.

## 2.1 – STIMULATING RESEARCH INTO INNOVATIVE THERAPEUTIC AND TECHNOLOGICAL SOLUTIONS

The event highlighted the absolute importance of a structural and concerted effort to promote scientific and technological research as a strategic foundation to address the complex challenges posed by Type 1 Diabetes. Research is not only a pillar for the advancement of therapeutic options, but also an indispensable lever for strengthening Europe's leadership in life sciences.

In recent years, significant advances in understanding the immunological and metabolic mechanisms of the disease have opened up new therapeutic frontiers, including:

- **Cellular research**, focusing on the development of stem cell-based treatments to restore impaired insulin function.
- Advanced technologies, such as increasingly accurate, intuitive and accessible continuous glucose monitoring (CGM) devices, which are significantly improving day-to-day management of the disease.

At European level, stimulating research requires coordinated and targeted action along three main lines:

- 01. **Promote transnational funding programmes** involving public and private institutions to support projects with high scientific and societal impact.
- **O2.** Create networks of excellence between research centres, universities and the pharmaceutical industry, fostering synergies that can accelerate the development of cutting-edge therapies.
- **O3.** Facilitate access to clinical and genetic data, while respecting the highest standards of privacy, to optimise the effectiveness of personalised treatments.

The strategic goal is to create a stable regulatory and financial framework that fosters continuous innovation and ensures that scientific discoveries can be translated into tangible benefits for patients on a European scale. This model aims to strengthen Europe's competitiveness in the life sciences and contribute to improving the lives of people with type 1 diabetes.

## 03. Formal recognition of early-stage T1D for better care and prosperity

The event highlighted the urgency of a coordinated European effort to establish screening programmes for the early detection of Type 1 Diabetes. A cornerstone of this initiative is **the official recognition of presymptomatic**, a phase preceding the clinical onset of Type 1 Diabetes characterised by the presence of specific autoantibodies indicating a high risk of progression to the clinical stage of T1D. Although there are no overt symptoms, this is a crucial time for clinical management and prevention.

The introduction of specific diagnostic codes, such as ICD-10-CM 2024 (E10.A0, E10.A1, E10.A2), is essential to ensure formal recognition of Type 1 Diabetes, to standardise clinical monitoring and facilitate its inclusion in screening programmes. In Italy, the use of ICD-9-CM 790.29 has been proposed as an interim solution until the full adoption of the new ICD codes. The lack of uniform coding currently hinders early diagnosis, with significant implications for patients' quality of life and social and health care costs.

Official recognition of presymptomatic Type 1 Diabetes would also allow **access to new immunomodulatory therapies** that may slow or even prevent progression to overt diabetes. This approach represents a breakthrough in the European healthcare landscape, promoting an integrated model combining scientific research, regulatory policy and advanced clinical practice.

Finally, the integration of these diagnostic codes is closely linked to the success of the national screening programme provided for by Law 130/2023, which serves as a reference model at European level. This law not only establishes a unified system for early detection, but also shows how the recognition of presymptomatic Type 1 Diabetes can become a pillar of common prevention strategies, helping to improve diagnostic accuracy and harmonise interventions across Europe.

# 04. Psychological support for paediatric patients and their families

The event highlighted the need to integrate psychological support as an essential component in the management of Type 1 Diabetes, particularly for paediatric patients and their families. Type 1 Diabetes is not only a medical challenge, but also **a significant psychological and social burden**: the emotional stress associated with the diagnosis and daily management of the disease has a profound impact on quality of life.

During the event it became clear how psychological support should be articulated:

- **Personalised interventions** to help children and families develop emotional management strategies.
- Health education aimed at providing practical tools to make living with the disease easier and to reduce anxiety and uncertainty.
- Training of health professionals to integrate psychological skills into daily clinical practice.

The creation of **a national register of patients positive for specific autoantibodies**, already provided for by Law No. 130/2023, also offers a unique opportunity to monitor not only the clinical but also the psychological aspects of the disease. This registry could be a strategic reference point for the early identification of psychological support needs, allowing for targeted and timely interventions.

# Conclusions

Italian Law No. 130/2023 and the paediatric national screening programme mark a turning point in the prevention and management of these autoimmune diseases in Italy, prioritizing our young population. However, addressing the growing challenges of Type 1 Diabetes at the European level requires a comprehensive and coordinated strategy among Member States.

A key priority is to replicate the Italian model, which emphasises early diagnosis, integrated care and systematic collection of patient data. To achieve this, **Europe must invest in the development of common registries, harmonisation of monitoring protocols and cross-border collaborations** that facilitate the exchange of best practices. In addition, progress in innovation, supported by **strategic investment in advanced technologies and research**, can catalyse the development of therapies that address both clinical and psychosocial needs.

Equitable access to care remains a central pillar of these efforts. This not only means ensuring the availability of state-of-the-art diagnostic tools and technologies for diabetes management, but also addressing regional inequalities between Member States. Integrating psychological support into standard care pathways will further improve clinical outcomes by recognising the emotional and social dimensions of living with Type 1 Diabetes.

The active involvement of the European institutions will be crucial in translating these ambitions into concrete policies. The pooling of resources, expertise and political will can lead to the creation of a single regulatory framework to combat Type 1 Diabetes. Such collaboration will not only reduce the incidence of complications and improve the quality of life of patients, but will also help to reduce the long-term economic and social burden on European healthcare systems.

The 12 December event highlighted **the urgency of collective and concerted action**. By harnessing the momentum generated, stakeholders have a unique opportunity to lead Europe into **a new era of prevention and care**: one that prioritises innovation, inclusivity and sustainability, for the benefit of the millions of individuals and families affected by Type 1 Diabetes.

# Annex 1

#### **POSTER OF THE EVENT**



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# Contacts

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