EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 September 2025
EMA/322020/2025
Stakeholders and Communication Division

Highlights – European Medicine Agency (EMA) and European Association for the Study of Diabetes (EASD) bilateral meeting

26 September 2025, 10h30-12h00 CET

1. Introduction and tour de table

The Head of Public and Stakeholders Engagement welcomed the European Association for the Study of Diabetes (EASD) delegates to this first formal bilateral meeting with the European Medicines Agency (EMA).

2. EASD update on recent developments and future goals in Type 1 & Type 2 Diabetes and beyond

EASD outlined current challenges in the field of Diabetes and opportunities for action where collaboration with EMA could be further explored.

Diabetes is a **growing problem globally**, with a marked increase in the Asian continent. In Europe, 72.4 million people are expected to be living with diabetes by 2050. Type 2 diabetes is increasing in the younger age and many older people are living with diabetes. Nevertheless, these **populations are not included or sufficiently represented in clinical trials** for medicines under development. In parallel, more patients living with type 1 diabetes are developing obesity. The heterogeneity of diabetes requires **rethinking the condition in the wider context of obesity and cardiovascular fields** and looking into implications for pathogenesis, prevention and treatment.

New developments with **agents targeting obesity** require the definition of what the **new endpoints** are and what are robust enough outcomes to consider in benefit-risk assessment. For example, the definition of remission of type 2 diabetes was highlighted as a potential topic for qualification discussions.

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In addition, the **explosion of continuous glucose sensors and automated insulin delivery systems** for type 1 diabetes demands further focus on medical devices and robust evaluation requirements as such applied for new therapies.

The arrival of new biomarkers will allow precision medicine with **clinical and biochemical biomarkers** with a focus on predicting futility of treatment and targeting those who would best respond to treatment.

EASD is working on many different fronts. Examples of interest include:

- INNODIA – the EU network of excellence to accelerate the development of curative therapies for people living with type 1 diabetes.
- EASD Academy – e-learning programme where most of the topics are clinical related; more science related topics include clinical design; EMA could be invited to showcase how next generations can be involved in what EMA does.
- Metabologia – international, peer-reviewed, open-access journal that aims to publish experimental, pre-clinical, clinical, translational and interdisciplinary research on all forms of diabetes and its complications, obesity, and metabolic aspects of other conditions, including cardiovascular, renal and hepatic disease. This includes comorbidity, nutrition and exercise, psychosocial aspects, and health economics and technology.
- Global EASD Council – initiative to connecting diabetes research and collaboration worldwide
- Guideline development – guidelines take a long time to produce (around 2 years) and EASD Guidelines Oversight Committee plans to create one guideline per year; in September 2025, the finalised draft of its first evidence-based clinical practice guideline, focusing on the assessment and management of diabetes distress among adults with type 1 and type 2 diabetes, was presented at the EASD Annual Meeting and is now open for public consultation.

  The EASD Committee on Clinical Affairs (CCA) is responsible for structuring and overseeing EASD's activities in the development of formal statements, consensus reports, and other clinical resources that complement the clinical practice guidelines and may be endorsed by EASD alone or together with other organisations.

3. EMA update on recent topics and opportunities for engagement

EMA provided an update on **measures taken to mitigate shortages of Glucagon-Like Peptide-1 receptor agonists (GLP-1 RA)**, including increased production capacity by companies and controlled distribution in some member states. EMA and the regulatory network, through the Medicines Shortages Steering Group (MSSG), have issued recommendations in June 2024 and organised a multistakeholder workshop for which EASD also contributed; public health communications have been published and drug utilisation studies have been conducted. Recent feedback seems to confirm the situation has improved; however it is difficult to identify which mitigation measures had the greatest impact. It was noted the increasing problem with counterfeiting, which extends also to insulins,.

In relation to **real world data (RWD) and real world evidence (RWE) activities**, EMA explained its approach to support the use of patient registries for regulatory purposes and pointed out the DARWIN EU® studies conducted with a focus on diabetology and the foreseen study to determine the extent of how well data on obesity, weight and obesity-related variables are captured across DARWIN EU® data partners to inform the feasibility of conducting further real world data (RWD) studies on obesity and related comorbidities. EASD underlined that diabetes and obesity, as chronic diseases, have been at the forefront of generating RWE however the instruments required to collect data require

more granularity and more research is needed to validate questionnaires. In addition, data quality is crucial and EASD is collaborating with other organisations as part of the European Diabetes Forum (EDF) in that respect. EMA highlighted the ongoing revising of its data quality framework and the fact that 6000 checks are conducted related with data quality as a requirement to onboard DARWIN EU® data partners.

EMA gave an update on its initiative addressing **Patient Experience Data (PED)** and invited EASD input on:

- Survey on PED and therapeutic areas for healthcare professionals; deadline for input by 19 October 2025
- Draft reflection paper for public consultation; deadline for comments by 31 January 2026

EMA concluded its updates with an overview of the support provided to developers for the **Qualification of Novel Methodologies (QoNM).** EMA would appreciate more involvement from the diabetes community and EASD could stimulate awareness amongst the clinical community to exploit how to come to QoNM (e.g. C-Peptide as a surrogate endpoint, patient reported outcomes (PROs), registries), also making use of existing incentives for academia/non-commercial organisations.

The meeting also provided an opportunity to inform EASD about the **CVSWP work plan** and the **key changes introduced in the latest revision of EMA's guideline** on the clinical investigation of medicines for the treatment and prevention of diabetes.

In addition to the areas already identified, the role of EASD in helping to **identify experts** for involvement in product-specific activities as well as topic-specific involvement of EASD researchers in the **European Platform for Regulatory Science Research** were emphasised.

4. Summary of discussion/next steps

The meeting concluded with a shared sense of having had a constructive discussion, focusing on current and future opportunities for collaboration.

It was agreed to **hold an annual bilateral** to continue the oversight of key strategic topics. This could be complemented with more specific and targeted discussions on specific topics.