IDF Europe Response to the European Commission's Request for Feedback on the European Biotech Act – July 2026

For the 34 million people living with diabetes in the EU, biotechnology has the potential to transform prevention, treatment and long-term care. Advances such as next-generation insulins, cell and gene-based therapies and other biotechnology-derived medicines could significantly improve health outcomes and quality of life. Europe already has the scientific excellence to lead this transformation. The challenge is ensuring that scientific advances translate into timely, equitable and affordable access to innovative therapies and technologies.

IDF Europe welcomes the ambition of the European Biotech Act to strengthen Europe's biotechnology and biomanufacturing ecosystem and improve the translation of research into clinical practice. However, **the success of the Act should ultimately be measured not only by its contribution to competitiveness, but also by the extent to which it delivers tangible improvements in health outcomes and quality of life across the Union.**

The current proposal places a strong emphasis on industrial competitiveness but does not sufficiently ensure that public investment in biotechnology translates into improved access, affordability and continuity of supply.

Strategic Project designation and eligibility for the proposed 12-month Supplementary Protection Certificate extension should be contingent on projects addressing unmet medical needs and delivering improved patient-relevant clinical benefit. Where additional exclusivity is granted, it should be accompanied by commitments that facilitate timely patient access, including early pricing and reimbursement submissions. At the same time, the Bolar exemption should continue to apply throughout any extended protection period to enable timely market entry of generic and biosimilar medicines once protection expires.

The governance of the Act should provide for the meaningful involvement of people living with diabetes, patient organisations and healthcare professionals. Their lived experience and clinical expertise are essential to identifying unmet needs, informing research priorities and ensuring that innovation delivers meaningful improvements in prevention, treatment and care. This should extend beyond consultation to formal representation within the Steering Group and Foresight Panel, supported by appropriate conflict-of-interest safeguards and adequate resourcing to enable effective participation.

Greater legal clarity is also needed to support implementation. Concepts including "unmet medical need", "patient-relevant clinical benefit" and "access" should be aligned with existing EU Pharmaceutical legislation and Health Technology Assessment regulation to ensure consistent interpretation across the European regulatory framework.

Finally, **maintaining robust evidentiary standards for biosimilar approval is essential to sustaining confidence among healthcare professionals and people using these medicines**, while supporting long-term sustainability and access. The evaluation of the Act should also assess outcomes such as access across Member States, uptake of innovative therapies, biosimilar availability and the implementation of access commitments, alongside industrial and economic indicators.

The Biotech Act represents an important opportunity to strengthen Europe's leadership in biotechnology. Achieving this ambition will require a framework that balances support for innovation with clear commitments to addressing unmet medical needs, equitable access and affordability, ensuring that scientific advances deliver meaningful improvements in health outcomes and quality of life. IDF Europe remains committed to supporting EU institutions and stakeholders in shaping a Biotech Act that delivers on these ambitions.