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Digital Therapeutics Alliance
Consultation Response: Artificial Intelligence Act

The Digital Therapeutics Alliance (DTA) is a global non-profit trade association of industry leaders and stakeholders that works to enable expanded access to high quality, evidence-based digital therapeutics (DTx) for patients, clinicians, and payors to improve clinical and health economic outcomes. DTA's 50+ member companies – including DTx manufacturers, pharmaceutical, technology, and provider organizations – represent 17 countries across Europe, Asia-Pacific, North America, and South America.

DTA welcomes the opportunity to provide feedback to the European Commission's proposed regulation on the Artificial Intelligence Act. This is an important step towards expanding Europe's vision to become a global hub for safe, effective, and trustworthy Artificial Intelligence (AI) technologies and systems.

In line with DTA's primary focus on providing policymakers, payors, clinicians, and patients with the necessary tools to recognize, evaluate, and utilize digital therapeutics (DTx) – many of which incorporate AI into treatment delivery processes – we are encouraged by the Commission's leadership in this quickly evolving ecosystem.

Therefore, to avoid these regulations from becoming an obstacle to innovation in the development and application of AI technologies and systems in Europe, we encourage the Commission to consider the following:

- AI definition and risk assessment
    - Currently, the definition in the proposed Act of an AI system is too general and broad to appropriately reflect the available spectrum of AI techniques, approaches, and systems.
    - The definition of AI should clearer and more specific to differentiate and reflect the spectrum of possible AI applications on the market, in addition to the differences represented in the development, assessment, and delivery of underlying algorithms and interventions.
    - The proposed Act introduces new oversight for "high-risk" AI systems which would require a case-by-case assessment from AI providers. Among the identified high risks are harm to health and safety that could result from human use, the risk of negative impact on fundamental rights, and the potential for discrimination. While it is very necessary to address these risks, the proposed Act creates additional challenges for developers of AI-driven software, especially if different risk-levels are applied compared to the EU Medical Device Regulations (Regulation (EU) 2017/745 and Regulation (EU) 2017/746).
- Relationship to EU regulations
    - Given the existing regulatory frameworks related to the potential risks of developing, assessing, and implementing AI technologies and systems, it is necessary to clearly distinguish how this proposed Act corresponds to – and potentially overlaps with – regulations such as the Medical Devices Regulation (MDR), the In Vitro Diagnostics Regulation (IVDR), the General Data Protection Regulation (GDPR), the Data Governance Act (DGA), and the European Health Data Space (EHDS).

- Further clarity on post-market surveillance obligations, the types of data and experiences collected by and as a result of AI system use, and how data would need to be stored and protected, is also necessary to ensure that the proposed Act does not create duplication or overregulation with MDR/IVDR post-market requirements.

- Burdens on AI developers
  - It is critical that this proposed Act balance the need to enable small, medium, and large businesses to thrive in Europe, while simultaneously ensuring that end users have access to high-quality, safe, and effective AI technologies and systems.
  - One component of enabling the ongoing sustainability of product developers and manufacturers is to clearly identify AI technologies that are high-risk and the specific requirements they are subject to. It is important to differentiate these products from lower-risk AI systems in order to minimize unnecessary burdens on other organizations.
- Financial implications
  - The proposed Act does not sufficiently address the financial and time requirements that small and medium enterprises would face if this proposal moves forward as currently drafted.
    - According to the European Commission, a quality management system could cost businesses between €193,000 and €330,000 upfront, an additional €71,400 in yearly maintenance costs, and potentially result in a 40 percent decline in profits.[1]
    - Additionally, according to the Center for Data Innovation, this proposed Act will cost the European economy €31 billion over the next five years and reduce AI investments by almost 20 percent. A European small or medium enterprise (SME) that deploys a high-risk AI system will incur compliance costs of up to €400,000, which could cause profits to decline by 40 percent.[2]
    - The proposed Act also excludes other unquantifiable costs that may be imposed, such as "deterring investment into European AI startups, slowing down the digitization of the economy, and encouraging a brain drain of European entrepreneurs to countries where they can build AI companies with fewer bureaucratic hurdles than they face at home."[3]

The short and long-term burdens that this proposed Act will place on AI developers would have serious impacts on small and medium enterprises based in Europe, in addition to other entities looking to enter the European market. The Commission should therefore further evolve this regulation to ensure it is both understandable and feasible for SMEs and start-ups.

Thank you for the opportunity to provide insight on this proposed Act. We appreciate the Commission's efforts to ensure the safety, efficacy, and trustworthiness of AI technologies. We anticipate that the evolution of this proposal will further solidify a strong ecosystem within Europe that supports innovation, plus the safe and effective uptake of AI technologies and systems.

[1] https://digital-strategy.ec.europa.eu/en/library/study-supporting-impact-assessment-ai-regulation
[2] https://www2.datainnovation.org/2021-aia-costs.pdf
[3] Ibid.

Appendix: Background on Digital Therapeutics (DTx)

Digital therapeutics represent a quickly evolving category of medicine that frequently incorporates AI components into the generation and delivery of therapeutic interventions directly to patients. DTx products use scientifically developed, clinically evaluated software to treat, manage, and prevent diseases and disorders. As such, DTx products are subject to rigorous patient-centered core principles (*below*),[4] an industry code of ethics,[5] and product development best practices.[6]

Digital therapeutics address a wide array of health conditions,[7] with products developed for ADHD, anxiety, asthma, cancer side effect management, diabetes, depression, insomnia, migraine, movement disorders, and opioid and substance use disorders — to name a few. DTx products are used independently, alongside medications, or in tandem with clinician-delivered therapy. They differ from pure lifestyle, wellness, adherence, diagnostic, and telehealth products.

DTx products use numerous mechanisms of action to deliver high-quality medical interventions, such as:

- Providing personalized disease treatment, management, and prevention programs
- Offering therapies to address comorbidities, side effects, or affiliated conditions
- Providing treatments that produce direct neurologic changes
- Delivering cognitive behavioral therapy (CBT) and other evidence-based treatments
- Enhancing, supporting, and optimizing current in-person and medication treatments
- Delivering responsive physical exercises and behavioral interventions

Building on the ease of DTx product scalability and access through patient-owned devices, digital therapeutics enable healthcare decision makers to deliver treatments to populations that have otherwise been unable to secure care – either due to geographic limitations, cultural and language boundaries, well-documented disparities, or health condition severity. Patients may now receive personalized therapeutic interventions based on their specific needs and abilities, in an engaging way, independent of their work or education schedule, with familiar languages and cultural references, in the privacy and safety of their own environment, and with access to actionable insights that convey their movement toward clinical improvement.

[4] https://dtxalliance.org/wp-content/uploads/2019/11/DTA_DTx-Definition-and-Core-Principles.pdf
[5] https://dtxalliance.org/wp-content/uploads/2019/11/DTA_DTx-Industry-Code-of-Ethics_11.11.19.pdf
[6] https://dtxalliance.org/wp-content/uploads/2019/11/DTA_DTx-Product-Best-Practices_11.11.19.pdf
[7] https://dtxalliance.org/wp-content/uploads/2020/03/DTx-Disease-State-Targets_03.20.pdf