PROFEEDBACK

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PROFEEDBACK POLICY BRIEF

ADVANCING THE INTEGRATION OF PRESCRIPTION DIGITAL THERAPEUTICS (PDTX) INTO HEALTHCARE SYSTEMS

Prepared by
João Rocha Gomes
Andrea Wandinger

COST Association AISBL
Avenue du Boulevard – Bolwerklaan 21 | 1210 Brussels, Belgium
T +32 (0)2 533 3800 | office@cost.eu | www.cost.eu

1. Introduction

Chronic diseases are a global health crisis, responsible for 71% of all deaths worldwide, equating to 41 million fatalities annually [1]. In Europe, non-communicable diseases (NCDs) like diabetes,hypertension, and depression contribute to 86% of deaths and impose a significant economic burden on healthcare systems [2]. The aging population and lifestyle factors such as poor diet, physical inactivity, and stress exacerbate this issue, leading to increased healthcare costs projected to reach €5 trillion globally by 2025 [3]. In Europe, the economic impact is substantial, with chronic diseases accounting for up to 70% of healthcare budgets [4].

Potential of Prescription Digital Therapeutics

Prescription Digital Therapeutics (PDTx) offer a promising solution to this escalating problem. PDTx are clinically validated, software-based interventions prescribed by healthcare professionals to prevent, manage, or treat medical conditions [5]. They undergo rigorous clinical trials akin to traditional pharmaceuticals, ensuring safety and efficacy. They offer personalized treatment by tailoring interventions based on real-time data and patient feedback, enhancing the effectiveness of care. The remote delivery of PDTx improves accessibility, overcoming geographical barriers - a feature that proved essential during situations like the COVID-19 pandemic. Additionally, their interactive interfaces increase patient engagement and adherence, empowering individuals to manage their conditions more effectively. Research also suggests that prescription digital therapeutics (PDTx) improve outcomes in chronic conditions. For example, PDTx has been shown to enhance glycemic control in diabetes, support blood pressure reduction in hypertension, and alleviate symptoms in mental health treatment.

Current Barriers to Adoption

Despite their advantages, the adoption of PDTx within European healthcare systems remains limited. Regulatory complexities, lack of standardized reimbursement frameworks, and insufficient clinical awareness hinder their integration. While Germany has pioneered pathways for PDTx implementation, many other European countries lack clear guidelines, leading to disparities in access and utilization [6]. This policy brief addresses these challenges by proposing actionable recommendations to facilitate the integration of PDTx across Europe, aiming to improve patient outcomes and reduce the burden on healthcare systems.

2. Supporting Evidence and Case Studies

Germany's DiGA Fast-Track Model

Germany's Digital Healthcare Act (DVG), implemented in 2019, introduced a fast-track process for digital health applications (DiGAs) to be prescribed and reimbursed through statutory health insurance [9]. As of July 2024, there are 56 DiGAs listed by the Federal Institute for Drugs and Medical Devices (BfArM), with 35 permanently listed and 21 preliminarily listed. This model has led to a significant increase in the adoption of PDTx, with over 374,000 prescriptions issued from September 2020 to September 2023 [7]. The DiGA model demonstrates that clear regulatory and reimbursement pathways can accelerate adoption and promote the integration of digital therapeutics into healthcare systems.

Emerging Regions Gaining Traction with PDTx

Countries like France and Belgium are following Germany's lead by developing frameworks for integrating PDTx into their healthcare systems. These countries are planning to use policy briefs similar to this one to guide the development of their own regulatory and reimbursement models. However, many other European countries, such as Italy and Spain, still lack specific guidelines for PDTx, highlighting the need for harmonized policies across the region.

3. Barriers to PDTx Adoption

Regulatory Challenges | Fragmented Regulatory Frameworks Across Europe

The lack of a harmonized regulatory framework creates significant obstacles. Each EU member statehas its own regulations, leading to inconsistent approval processes, duplication of efforts, and increased costs for developers. Uncertainty about whether PDTx should be regulated as medical devices, software, or pharmaceuticals further complicates the approval process.

Reimbursement Difficulties | Absence of Standardized Reimbursement Models

Without reimbursement mechanisms, there is limited patient access because high out-of-pocket costs restrict usage to those who can afford it, exacerbating health inequalities. Clinicians may also be reluctant to prescribe PDTx without assurance of coverage for patients, while European healthcare providers consider reimbursement policies a critical factor in prescribing PDTx. Limited Clinical Adoption | Insufficient Training and Guidelines.

Inconsistent Evidence Base | Variability in Clinical Validation and Applicability
While PDTx are grounded in evidence-based research, the supporting data can be inconsistent or narrowly applicable. Many studies focus on specific populations or settings, resulting in variability in perceived effectiveness across diverse patient groups and healthcare environments. This lack of universal validation complicates efforts to establish PDTx as widely trusted and adopted treatment options.

4. Policy Recommendations

A.) Harmonize Regulatory Frameworks Across Europe
The European Commission should establish a centralized regulatory framework for PDTx, similar to the European Medicines Agency's (EMA) process for pharmaceuticals. This involves: - Creating guidelines explicitly tailored to PDTx, recognizing their unique digital nature. - Defining criteria for evaluating software updates, data management, and cybersecurity to ensure safety and effectiveness.

- Establishing a fast-track approval pathway for PDTx, focusing on chronic disease management where they have demonstrated significant potential.
- Facilitate Mutual Recognition of Approvals: Encouraging EU member states to recognize PDTx approvals granted by other countries within the Union can minimize duplication, expedite market entry, and promote consistency in patient care across Europe.

B.) Integrate PDTx into Reimbursement Frameworks
National health authorities should:

- Define PDTx as a reimbursable category, distinct from traditional drugs and devices. - Develop criteria for PDTx reimbursement based on clinical effectiveness, cost-effectiveness,and patient outcomes.
- Conduct Health Technology Assessments (HTAs) for PDTx to ensure that only evidence-based interventions are reimbursed.
- Adopt value-based pricing models, ensuring that healthcare spending is aligned with patient outcomes and promotes continuous improvement in PDTx offerings.

C.) Enhance Clinical Adoption

Incorporate PDTx Training into Medical Education

Medical schools and professional bodies should integrate digital health competencies into curricula and continuing education programs. Developing accredited courses and certification programs on PDTx will equip healthcare professionals with the knowledge to effectively prescribe and manage these therapies.

Develop Clinical Practice Guidelines

Collaborating with European medical societies to create evidence-based guidelines for PDTx use in various conditions provides clinicians with clear protocols, increasing confidence and standardizing care.

5. Steakholder Analysis

Patients: Patients stand to gain significantly from Prescription Digital Therapeutics through improved outcomes via personalized care, leading to better management of chronic conditions. The convenience of accessing therapy anytime reduces the need for frequent clinic visits, enhancing patient satisfaction and adherence to treatment plans. However, the digital divide presents a notable challenge; elderly or low-income populations may lack access to smartphones or reliable internet connectivity, potentially exacerbating health inequalities if not adequately addressed.

Healthcare Providers: Healthcare providers can enhance care delivery by remotely monitoringpatients and intervening proactively, with access to real-time data supporting informed decision making and personalized treatment adjustments. This can lead to better patient outcomes and moreefficient use of clinical resources. Nevertheless, integrating PDTx into existing workflows requires adaptation of current processes, which can be challenging. Providers may need additional training and support to effectively incorporate these digital tools into their practice.

Insurers and Public Finances: Insurers and public health systems could benefit from significant cost reductions through lower long-term healthcare expenditures achieved via preventive care and adecrease in acute health events. Efficiency gains include optimized resource allocation and reduced strain on healthcare infrastructure. However, upfront costs are a concern, as initial investments are required for technology infrastructure, integration systems, and education programs for both providers and patients, impacting short-term budgets and requiring careful financial planning.

Industry and Developers: For the industry and developers, harmonized regulations across Europe open access to a broader market, encouraging innovation and facilitating market expansion. This presents opportunities for growth and increased return on investment in research and development.

On the downside, meeting standardized compliance requirements may necessitate additional resources, including investments in regulatory expertise and adjustments to

product development processes, which could pose challenges, especially for smaller enterprises or startups.

6. Conclusion and Call to Action

Integrating Prescription Digital Therapeutics into European healthcare systems is imperative to address the escalating burden of chronic diseases. By harmonizing regulatory frameworks, establishingreimbursement models, and promoting clinical adoption through education and guidelines, the full potential of PDTx can be realized.

Policymakers and Stakeholders Should Take Decisive Action:

- The European Commission should lead the development of an EU-wide regulatory framework for PDTx.
- National governments should incorporate PDTx into health insurance schemes and invest in infrastructure to support digital health.
- Healthcare institutions should prioritize training for healthcare professionals and update clinical protocols to include PDTx.
- The industry should engage with regulators and providers to align PDTx development with clinical needs and standards.

The Time to Act is Now

With the projected rise in chronic diseases and the associated economic impact, delaying the integration of PDTx is not an option. Embracing digital innovation allows Europe to improve health outcomes for millions, reduce healthcare costs by billions of euros, and set a global standard for modern, patient-centered care.

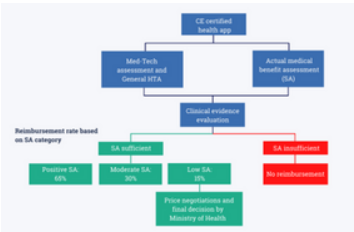
7. Graphical Elements

Table 1. Potential Economic and Health Impact of PDTx Integration Across Major Chronic Diseases in Europe [8]

Chronic Disease	Estimated Number of Affected Individuals in Europe	Annual Healthcare Costs (estimated)	Potential Annual Cost Savings with PDTx	Expected Health Outcomes Improvement
Diabetes	38 M	€167.5 MM	Up to €10 MM	- Reduction in HbA1c levels- Reduced complications and hospitalizations
Hypertension	200 M	€155 MM	Up to €20 MM	- Increase in medication adherence - Significant reduction in blood pressure levels
Depression	40 M	€118 MM	Up to €35 MM	- Improvement in symptoms- Improved quality of life and productivity
Chronic Pain	100 M	€300 MM	Up to €20 MM	- Enhanced pain management effectiveness - Reduced reliance on opioids

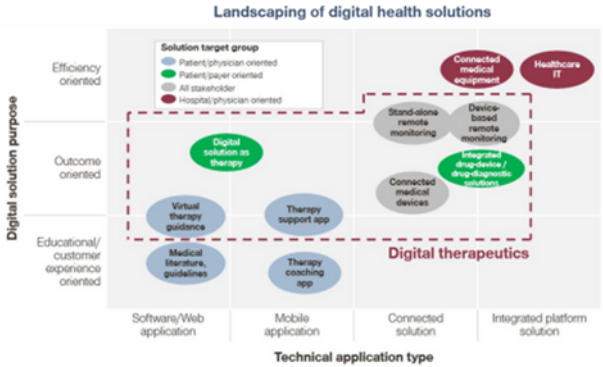
This table presents the potential economic and health impacts of integrating Prescription Digital Therapeutics (PDTx) into European healthcare systems for major chronic diseases. It highlights the estimated number of affected individuals, current annual healthcare costs, potential cost savings with PDTx implementation, and expected improvements in health outcomes for each condition. M=Million; MM=Billion.

Figure 1. Reimbursement Decision Process for Health Applications Based on Clinical Benefit Assessment



This flowchart illustrates the stages of assessment for health applications to qualify for reimbursement. Starting with CE certification, the app undergoes Med Tech assessment, Health Technology Assessment (HTA), and clinical evidence evaluation. If deemed to have sufficient clinical benefit (SA), it proceeds to reimbursement rate assignment and price negotiations. Apps with insufficient benefit do not qualify for reimbursement.

Figure 3. Landscape of Digital Health Solutions by Purpose, Target Group, and Application Type [9]



This figure categorizes digital health solutions based on their purpose (Y-axis), application type (X-axis), and target user groups (color-coded). Purposes range from Educational/Customer Experience-Oriented to Outcome-Oriented and Efficiency-Oriented solutions. Application types vary from Software/Web and Mobile Apps to Connected and Integrated Platform Solutions. Digital Therapeutics (DTx) are highlighted in the Outcome-Oriented section, focusing on therapeutic interventions to improve patient health. Solutions are color-coded to indicate their primary target groups: patients, physicians, payers, and hospitals.

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