ANALYSIS OF LEGAL AND REGULATORY FRAMEWORKS IN DIGITAL HEALTH

A Comparison Of Guidelines And Approaches In The European Union And United States

The Need for Efficient Regulation in Digital Health

- Growth in digital health solutions
- Improve the quality of healthcare
- Contain costs

Problems in Regulating Digital Health Technologies

- Regulation needs to keep pace with technology
- 'Regulatory Barriers' do not appear to support innovation

Why European Union & United States?

- Pioneers in the field of digital health
- Lead in regulatory guidance
- Different systems and approaches to achieve same goal

Goal

To assess the amenability and furtherance of regulatory frameworks in digital health by evaluating and comparing existing legal requirements currently in use in the EU and US

Objectives

Review existing guidelines on the use of digital health in the EU and US and compare them in terms of **comprehensiveness** and **potential deficiencies**;

Evaluate **processes** and **adoption** of current regulatory guidelines, through purposeful sampling with interviews of key informants;

Recommend **strategies conducive to improvement** and **acceptability** of the current legislative framework.

Study Design

FRAMEWORKS

- Privacy & Protection of Data
- Regulatory Pathways
- Clinical Decision Support Systems
- Regulation of mHealth
- Classification of Software as a Medical Device
- Regulation of Emerging Digital Technologies
- Telemedicine
- Liability
- Reimbursement

Search for Documents

Government and Organisational Websites
Relevant grey literature

Analysis of Documents

Strengths & Weaknesses

Interview with Key Informants

Purposeful sampling with key informants related to field of digital health
Questionnaire with open-ended questions

Analysis of Interviews

Thematic Analysis & Construction of Mind Maps

Results

EUROPEAN UNION		UNITED STATES
No separate dedicated body, EC guides all processes	Regulatory Authority	FDA with other departments is the main authority
Single pathway through notified bodies	Regulatory Pathways	Pathways deviate from norm, focusing on speed of approval
Pan European data protection law	Data Protection	No centralized data protection law
MDR regulation places SaMD in a higher classification	Classification of SaMD	Enforcement discretion applied to many SaMD categories
Classification solely risk based	Risk-based Determinants	Classification based on risk, efforts to include effectiveness
No separate CDSS category, software is called active device	Regulation of CDSS	Detailed classification of CDSS
Guidelines for use of AI, few directed to healthcare	Regulation of AI-based SaMD	Proposed guidelines for AI-based SaMD
Part of cross-border healthcare; Licensure covered	Telemedicine	Remote services recognition; Licensure covered
Efforts directed at new models	Reimbursement	Efforts to extend coverage, coding
General product liability laws	Liability	General product liability laws

SWOT Analysis

Strengths
- Recent initiatives
- Data protection of high concern
- Certification endeavors
- Reimbursement strategies, coding, coverage
- Facilitation of licensure

Weaknesses
- GDPR exemption for research
- Classification excludes effectiveness
- Inadequate mHealth regulation
- New challenges of AI
- Nonspecific liability rules

Opportunities
- Allow introduction of new laws / frameworks / models
- Meaningful Regulation
- Consumer organisations for liability
- Score quality of life
- Enriched data by consent within GDPR

Threats
- Higher classification of software
- Inadequacy of risk-based classification
- Vulnerabilities of initiatives
- Uncertain liability rules
- Need to show financial advantage

Efficient + Effective + Flexible + Trustworthy = 'Meaningful Regulation'
Frameworks to promote use & foster innovation and not to impede

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