The Regulatory Landscape of Health Apps in the European Union

by **Liga Svempe** *

Abstract: Digital tools, including numerous health apps, have become integral to our daily lives. However, the fact that many of these solutions are unregulated raises concerns related to their quality and safety. The current Medical Device Regulation 2017/745 covers devices explicitly designed for medical purposes and does not extend its regulatory scope to wellness applications beyond its intended purpose. Due to the complexity of the regulation, many manufacturers choose to avoid the certification pathway and market their products as wellness apps. As a result of this regulatory stance, the responsibility for preventing harm to users primarily lies with developers, application marketplaces, and consumers themselves. This situation is coupled with increasing consumer skepticism towards the healthcare system and growing reliance on online information, paving the way for uncontrolled and potentially hazardous market development. Real-world examples demonstrate that these non-regulated apps can be harmful; with the market expanding, this issue is likely to worsen. This article investigates the legal framework governing health apps in the European Union. I identify regulatory gaps and associated risks for public health, and propose measures to mitigate these challenges. Policymakers are advised to introduce updates to the General Product Safety Regulation or adopt national-level regulation as a short-term measure. Additionally, the author proposes revising the role and increasing the responsibilities of app marketplaces to prevent harmful apps from entering or operating in the market. Regulatory incentives, such as government reimbursement schemes, are suggested at the national level unless EU initiatives are introduced.

Keywords: Digital Health; Health Law; Health Technology; Medical Device; Wellness Apps

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A. Introduction

1 Technological advancements during the last decades have significantly changed many industries, and they have the potential to also transform the healthcare industry, bringing new digital solutions that were unimaginable in the 90-s when the Medical Device Directive 93/42/EEC[1] (MDD) was adopted. Digital health has emerged as a separate discipline. According to the European Commission, "digital health and care refers to tools and services that use information and communication technologies (ICTs) to improve prevention, diagnosis, treatment, monitoring, and management of health-related issues and to monitor and manage lifestyle habits that impact health".[2] As stated in IQVIA Institute report,[3] in 2021 there were over 350,000 health-related mobile apps for various goals. However, the rapidly evolving market introduces not only new opportunities but also new risks, especially when it comes to their clinical effectiveness and safety, data safety, and pri-

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1 Council Directive 93/42/EEC of 14 June 1993 concerning medical devices [1993] OJ L 169/1 (Medical Device Directive).

2 'eHealth : Digital Health and Care' (Public Health) <https://health.ec.europa.eu/ehealth-digital-health-and-care_en> accessed August 26, 2024.

3 IQVIA Institute, 'Digital Health Trends 2021' (2021) <https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/digital-health-trends-2021> accessed July 18, 2024, 2.

vacy issues.

2 This study focuses on digital health apps . "Health apps" is an umbrella term defining software programs on mobile devices that process health-related data on or for users to maintain, improve, or manage health.[4] Health apps include both wellness and medical apps, the latter known as software as a medical device (SAMD) and certified as a medical device (see Figure 1).

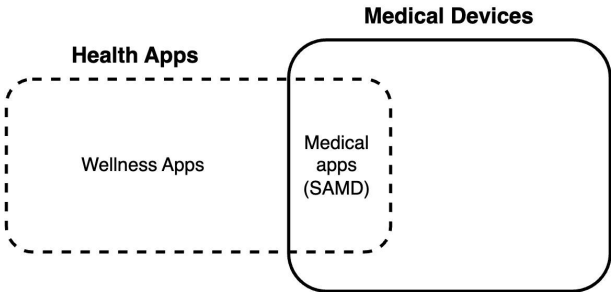

Figure 1: an overview of health app categories

3 International Medical Device Regulators Forum defines SAMD as "software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device".[5] The Medical Device Regulation EU 2017/745 (MDR) similarly defines it as software intended by the manufacturer to be used for human beings for one or more specific medical purposes.[6] Such apps include CardioSignal for heart disease self-monitoring, remote care, and point-of-care diagnostics,[7] Kaia Health as a digital therapy for back pain,[8] and HelloBetter for various mental issues.[9] The key difference between a wellness app and an SAMD lies in its regulatory status - SAMD is certified as a medical device, whereas a wellness app lacks any certification or compliance with any regulations or quality standards related to healthcare. Wellness apps include, for example, BetterSleep to improve sleep quality,[10] Noom for weight management,[11] and Calm as a mental health app to help manage stress, calm anxiety, and improve sleep.[12] Today these wellness apps make up most of the health-related apps market. According to the EUDAMED database,[13] in August 2024, there were slightly over 1,900[14] software applications classified as medical devices, a small fraction of the total number of the 350,000 health apps mentioned above (the EUDAMED database is not yet fully functional therefore the actual number of SAMD would be higher).

4 However, during the last decades, numerous cases in the healthcare industry have highlighted insufficient regulatory oversight and harming the end-users (patients).[15] This along with the rapid technological advancements led to the adoption of Medical Device Regulation (EU) 2017/745,[16] whose main goal is to ensure "a high level of safety and health whilst supporting innovation".[17] However, the MDR does not currently regulate wellness apps that are not designed for medical purposes. As a result, the safety and efficacy can be poorly evaluated, potentially harming the end user.

4 Maaß L and others, 'The Definitions of Health Apps and Medical Apps From the Perspective of Public Health and Law: Qualitative Analysis of an Interdisciplinary Literature Overview' (2022) 10(10) JMIR mHealth and uHealth e37980.

5 International Medical Device Regulators Forum, 'Software as a Medical Device (SaMD): Key Definitions' <https://www.imdrf.org/sites/default/files/docs/imdrf/final/technical/imdrf-tech-131209-samd-key-definitions-140901.pdf> accessed August 9, 2024.

6 Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009, and repealing Council Directives 90/385/EEC and 93/42/EEC [2017] OJ L 117/1 (Medical Device Regulation), art 2.

7 'CardioSignal' (*CardioSignal*) <https://cardiosignal.com/> accessed November 26, 2024.

8 'Pain Relief in the Palm of Your Hand' (*Kaia Health*) <https://kaiahealth.com/> accessed November 26, 2024.

9 'Effective Psychological Online Courses' (*HelloBetter*) <https://hellobetter.de/en/> accessed November 26, 2024.

10 'BetterSleep' (BetterSleep) <https://www.bettersleep.com/> accessed November 26, 2024.

11 'Noom: Lose Weight and Keep It Off' (*Noom*) <https://www.noom.com/> accessed November 26, 2024.

12 'Experience Calm' (*Calm*) <https://www.calm.com/> accessed November 26, 2024.

13 'EUDAMED - European Database on Medical Devices' <https://ec.europa.eu/tools/eudamed/#/screen/search-device> accessed August 9, 2024.

14 The search was conducted on August 9, 2024. Since the MDR transition period is ongoing, devices on the market are currently assessed either under the MDR or the MDD. Therefore, two separate searches were conducted: (1) search string included parameters "Applicable legislation: MDR (REGULATION (EU) 2017/745 on medical devices)" AND "Device types: Software" AND "Status: On the EU market"; this search returned 1392 records, (2) search string included parameters "Applicable legislation: MDD (Directive 93/42/EEC on Medical Devices)" AND "Device types: Software" AND "Status: On the EU market"; this search returned 513 records. Both searches return 1905 records in total.

15 Such as Martindale V and Menache A, 'The PIP Scandal: An Analysis of the Process of Quality Control That Failed to Safeguard Women from the Health Risks' (2013) 106(5) Journal of the Royal Society of Medicine 173 and Cohen D, 'Faulty hip implant shows up failings of EU regulation' (2012) 345 BMJ e7163.

16 Medical Device Regulation (n 6).

17 Ibid, rec 1.

5 On the one hand, the absence of regulatory oversight might bring health risks to users and the latest data show that the quality of the apps is troubling (the risks are discussed and exemplified later in this paper); on the other hand, subjecting numerous digital solutions to the extensive medical device certification process, which entails significant time and financial resources, will slow their development.[18] While the exemption from regulatory scrutiny could be justifiable for applications posing minimal or no risk to human health, it simultaneously creates an open gateway for harmful applications, because the evaluation of the safety and efficacy of such applications are left to developers' discretion (developers' role in relation to marketplaces' role is discussed later in this paper).

6 The current consumer health decision-making process reveals several underlying challenges. First, there is a growing scepticism among consumers about the healthcare system, which was evident during the Covid-19 pandemic.[19] Furthermore, reliance on online information has surged, particularly among younger demographics,[20] though this varies depending on the health condition. For instance, research indicates that 65% of adolescents use online resources as their primary source for sexual advice, compared to just 8% seeking orthodontic treatment guidance. Cultural and national differences also influence the degree of reliance on online information.[21] Another study found that 56.6% of high school students had sought health information online rather than consulting a physician in person.[22] While some consideration is given to the credibility of sources, 51.9% of respondents admitted they rarely or never checked when the website was last updated or reviewed by a medical professional.[23]

7 Research indicates that the source of a message significantly influences how it is perceived, with endorsements from trusted sources enhancing the credibility of claims.[24] However, while such endorsements may change consumer attitudes, they do not necessarily translate into behavioural changes. In some cases, high-credibility labelling may have little to no impact on consumer health behaviour and, occasionally, may even have the opposite effect.[25] The author suggests further research into health decision-making, particularly within the context of digital health.

8 An increasingly important factor in health decision-making is the role of marketing, as individuals today can access information through a wide array of channels beyond traditional physician visits. Research highlights that marketing messages often include scientifically unfeasible health claims,[26] exploiting emotional vulnerabilities, which promote unrealistic consumer expectations and increase susceptibility to these misleading messages.[27] According to Pirsch et al.,[28] consumers can be categorized into three groups: the "smart consumer," who is educated, critical, and at a lower

18 Svempe L, 'Exploring Impediments Imposed by the Medical Device Regulation EU 2017/745 on Software as a Medical Device' (2024) 12 JMIR Medical Informatics e58080.

19 Shmerling MRH, 'What Happened to Trusting Medical Experts?' (Harvard Health, October 19, 2021) <https://www.health.harvard.edu/blog/what-happened-to-trusting-medical-experts-202110192621> accessed August 1, 2024.

20 Gordon D, '33% Of Gen Zers Trust TikTok More Than Doctors, New Survey Shows' (Forbes, December 20, 2022) <https://www.forbes.com/sites/debgordon/2022/12/20/33-of-gen-zers-trust-tiktok-more-than-doctors-new-survey-shows/> accessed August 9, 2024; Evans N, 'Online Medical Advice: How Google and TikTok Are Shaping Patient Behaviors' *The Intake* (February 28, 2024) <https://www.tebra.com/theintake/medical-deep-dives/tips-and-trends/online-medical-advice-deep-dive-how-google-and-tiktok-are-shaping-patient-behaviors> accessed November 27, 2024.

21 Park E and Kwon M, 'Health-Related Internet Use by Children and Adolescents: Systematic Review' (2018) 20 Journal of Medical Internet Research e120.

22 Gazibara T and others, 'Searching for Online Health Information Instead of Seeing a Physician: A Cross-Sectional Study among High School Students in Belgrade, Serbia' (2020) 65 International Journal of Public Health 1269

23 Park E and Kwon M (n 21).

24 Parkinson TL, 'The Role of Seals and Certifications of Approval in Consumer Decision-Making' (1975) 9 Journal of Consumer Affairs 1; Ko Y and Phua J, 'Effects of Eco-Labels and Perceived Influencer Expertise on Perceived Healthfulness, Perceived Product Quality, and Behavioral Intention' (2024) 45 Journal of Current Issues & Research in Advertising 369.

25 Griffiths M and others, 'Evaluating Source Credibility Effects in Health Labelling Using Vending Machines in a Hospital Setting' (2024) 19 PLOS ONE.

26 Federal Trade Commission, 'Deception in Weight-Loss Advertising Workshop: Seizing Opportunities and Building Partnerships to Stop Weight-Loss Fraud' (2003) <https://www.ftc.gov/sites/default/files/documents/reports/deception-weight-loss-advertising-workshop-seizing-opportunities-and-building-partnerships-stop/031209weightlossrpt.pdf> accessed November 27, 2024; Sweney M, 'Olay Anti-Ageing Cream Ad Banned' *The Guardian* (March 4, 2009) <https://www.theguardian.com/media/2009/mar/04/olay-ad-banned> accessed November 27, 2024; Dodgson L and Hosie R, 'TikTok Said It Would Be a Haven for Body Positivity. Then It Took $4.3 Million to Push Weight-Loss Products' *Business Insider* (January 30, 2023) <https://www.businessinsider.com/tiktok-sold-ads-weight-loss-products-break-own-rules-2023-1> accessed December 27, 2024.

27 Berzins LG, 'Protecting the Consumer Through Truth-in-Dieting Laws' (1999) 55 Journal of Social Issues 371.

28 Pirsch JA, Landreth Grau S and Polonsky MJ, 'Lose 30 Lbs in 30 Days' (2013) 3 Journal of Social Marketing 56.

risk of being harmed; the "dumb consumer," who is easily influenced and prone to impulsive decisions; and the vulnerable audience, who cannot recognize or protect themselves from persuasive tactics and face significant risks from deceptive marketing. However, even "smart consumers" are not immune to being misled in health-related decisions. The vividness and proximity of promised health rewards in marketing messages can narrow attention and induce impulsive behavior, overriding skepticism. Thus, many consumers, irrespective of their critical thinking abilities, are willing to trust unproven claims. Another study further shows that decisions often prioritize short-term, easily measurable outcomes, such as achieving thinness, over genuine long-term health benefits.[29] Although regulatory efforts to combat false claims have led to fines for manufacturers, these measures have not effectively eliminated misleading practices.[30]

9 A survey conducted by Blagec et al. provides insights into the perspective of manufacturers.[31] It shows that companies working in a business-to-business (B2B) model, serving hospitals and other large organizations, demonstrate a higher willingness to undergo certification. It is less appealing when the prospective buyer is a medical professional and lacks appeal when the buyer is an individual patient. However, this study relied on a convenience sample of just 21 respondents, limiting the generalizability of the results. The author recommends further, more in-depth research to explore the manufacturers' perspective

10 To sum up, in the B2C market, consumers often prioritize emotional appeal and short-term outcomes over clinical evidence or long-term health benefits. Marketing messages frequently rely on emotionally engaging claims that influence consumer perceptions and behavior, even when such claims are unverified, and high-credibility endorsements may not be effective. At the same time, manufacturers often find the certification pathway unappealing. Therefore, regulatory intervention is suggested to ensure consumer protection.

11 This article examines the legal framework governing health apps within the European Union, with a focus on identifying regulatory gaps that may pose risks to user health and safety. The research scope is limited to industry-specific regulatory frameworks concerning product quality. It excludes data governance matters, as it represents a broad and complex subject that would be more appropriately addressed in a separate, dedicated study. The main target audience is policymakers, who are positioned to address these shortcomings and enhance public protection through regulatory action. Additionally, the findings aim to benefit the general public by raising awareness about the current limitations in their legal protections and encouraging more informed decision-making regarding the quality and reliability of health apps.

12 The article starts with a policy analysis to investigate the legal framework governing medical and wellness apps, highlighting the differences and shortages. The descriptive case study method is used to explore and provide examples of how individual countries can support manufacturers and promote quality assurance. The next section examines the regulatory framework for AI-based healthcare solutions. The following section examines marketplace policies for health apps, which are the final gateways for developers to enter the market. The final section investigates the quality of wellness apps using data from previous scientific studies and real-life examples from the media.

B. The Current Regulatory Status of Health Apps

13 The adoption of the MDR provides a clear definition of the SAMD concept. It defines that a medical device "means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes".[32] Thus, the MDR specifically mentions that a medical device can be software if it is designed for a medical purpose such as diagnosis, prevention, monitoring, prediction, prognosis, treatment of a disease or injury, investigation or modification of a physiological or pathological process or state, or for the control or support of conception. In general, the MDR establishes specific risk-based requirements for the development and marketing of devices, ensuring product quality and clinical evaluation with the overarching aim of safeguarding patient health.

14 Additionally, the MDR extends its oversight to cover several groups of products without an intended medical purpose, including contact lenses, invasive products intended for cosmetic purposes, high-intensity electromagnetic radiation equipment,

29 Calder RK and Mussap AJ, 'Factors Influencing Women's Choice of Weight-Loss Diet' (2015) 20 Journal of health psychology 612.

30 Pirsch JA, Landreth Grau S and Polonsky MJ (n 28).

31 Blagec K and others, 'Effects of Medical Device Regulations on the Development of Stand-Alone Medical Software: A Pilot Study' (2018) 248 Studies in health technology and informatics.

32 Medical Device Regulation (n 6), art 2(1).

and other products.[33] For the SAMD products, this extension of regulatory scope is irrelevant due to its tangible nature, however, this represents the intention to cover a more expansive array of products, considering their widespread usage and potential impact on human health, even when their purpose is non-medical. This intention suggests that the list of included products could potentially be expanded in the future if deemed necessary, considering that the previous regulation (MDD) did not include such a clause.

15 Compared to the MDD, the MDR requirements are more stringent, posing several challenges that threaten businesses for manufacturers. These include increased expenses, lack of regulatory expertise, constraints on product updates, and other issues. Consequently, this can lead to delays in market entry, withdrawal from the European market in favour of other regions, or even the discontinuation of devices.[34] Therefore, considering the complexity, some manufacturers decide to pursue the business strategy of positioning their products as wellness applications, not for medical purposes. This approach allows them to avoid the lengthy and expensive certification process, even though the actual functionality and use of the app could be regarded as medical. The possibility of this strategy is supported by the European Union Court of Justice ruling on Brain Products.[35] The decision clarified that if a manufacturer hasn't designed a product for medical purposes, the necessity for CE certification does not apply. This approach, however, can pose risks to consumers, as the products have not undergone a review process and can lack clinical evidence.

16 When a manufacturer opts for the wellness pathway, there are no mandatory quality standards or specific requirements to adhere to. The General Product Safety Regulation 2023/988,[36] which aims to ensure consumers' health and safety,[37] stipulates that only safe products may be marketed.[38] A "safe product" is defined as one that "does not present any risk, or only minimal risks compatible with the product's use, considered acceptable and consistent with a high level of protection of consumer health and safety". The term "health" here is interpreted according to the World Health Organization's definition: "a state of complete physical, mental, and social well-being, and not merely the absence of disease or infirmity".[39] Product safety can be demonstrated by assessing the product's characteristics,[40] its compliance with relevant European standards or national requirements,[41] or through other documents addressing product safety.[42] However, since no specific mandatory quality standards or safety metrics exist for digital health apps, determining whether a product meets the definition of a "safe product" is left to the manufacturer's discretion, allowing room for interpretation. This means there are no preventive legal measures to protect consumer health, potentially exposing them to low-quality or harmful products. A study by Singh et al. indicates that only a minority of health-related apps are likely to be useful.[43] This means that the consumers may waste money on a product with no health benefits; in the worst case, the product could harm their health. In such instances, consumer protection mechanisms were established by Product Liability Directive 85/374/EEC[44] and transposed into national legislation, which held manufacturers liable for damage caused by defects in their products. It established that the burden of proof lies with the injured party, who must demonstrate the defect and the causal relationship between the defect and the injury.[45] However, this can be challenging for regular consumers without specific knowledge, leaving many injury cases unaddressed. As per data from the Impact assessment report by the European Commission,[46] 77% of the public indicated moderate to significant difficulties in proving defects in technically complex or AI-based products. While only a limited number of software incorporates AI,

33 Ibid, art 1(2).

34 Svempe L (n 18).

35 Case C-219/11 *Brain Products GmbH v BioSemi VOF and Others* [2012] ECR.

36 Regulation (EU) 2023/988 of the European Parliament and of the Council of 10 May 2023 on general product safety, amending Regulation (EU) No 1025/2012 of the European Parliament and of the Council and Directive (EU) 2020/1828 of the European Parliament and the Council, and repealing Directive 2001/95/EC of the European Parliament and of the Council and Council Directive 87/357/EEC [2023] OJ L 135/1 (General Product Safety Regulation).

37 Ibid, rec 4.

38 Ibid, art 5.

39 Ibid, rec 19.

40 Ibid, art 6.

41 Ibid, art 7.

42 Ibid, art 8.

43 Singh K and others, 'Developing a Framework for Evaluating the Patient Engagement, Quality, and Safety of Mobile Health Applications' (2016) 5 Issue brief (Commonwealth Fund) 1.

44 Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products. [1985] OJ L 210/29 (Product Liability Directive).

45 Ibid, art 4.

46 European Commission, 'Impact Assessment Report Accompanying the Document Proposal for a Directive of the European Parliament and of the Council on Liability for Defective Products' (2022) <https://eur-lex.europa.eu/legal-content/HR/TXT/?uri=CELEX:52022SC0316> accessed August 22, 2024.

any digital health app can be considered a technically complex product requiring technical savviness. Therefore, in October 2024, the EU adopted a new directive on liability for defective products which replaces the directive 85/374/EEC.[47] It suggests a less stringent burden of the proof rule if "the claimant faces excessive difficulties, due to technical or scientific complexity".[48] This suggests that it will be easier for consumers to claim compensation in case a defective product has caused harm to their health.

17 While consumers have the option to seek compensation for damages, the author suggests that it should not be the primary approach. The foremost objective should be to protect individuals' health before any harm occurs. Given the absence of specific quality measures for wellness apps, several voluntary codes of conduct have been discussed and established to promote best practices. Yet these codes are often siloed and country-specific, requiring greater policy coordination to ensure that standards are clear, comprehensive, and consistent on an international scale.[49] Furthermore, due to their voluntary nature, developers may disregard these codes.

18 Therefore, policymakers should establish a reasonable regulatory framework for wellness apps to ensure their quality and safety or find ways to support manufacturers in pursuing regulatory compliance. These two options are not mutually exclusive and can be pursued simultaneously to enhance consumer safety and benefit society.

19 Germany was the first country to introduce state support for digital health solutions thus promoting product quality and supporting manufacturers. At the end of 2019, the German parliament (Bundestag) adopted the Digital Healthcare Act (Digitale Versorgung Gesetz, DVG),[50] being a pioneer in introducing a government reimbursement scheme for lower-risk digital healthcare solutions (Class I and IIa). DVG allows an eased pathway for the manufacturers, who cannot yet provide clinical evidence of the positive healthcare effect of their digital health application (Digitale Gesundheitsanwendungen, DiGA), to apply for the provisional listing, allowing them to collect the necessary data in one year (or two years in exceptional cases).[51] The DiGAs have to be certified as medical devices, however, this way DVG promotes the certified pathway as more attractive for the manufacturers, as it opens a market of more than 70 million individuals (88% of the population[52]) using public health insurance.

20 In September 2024, there were 20 applications in the provisional listing and 35 applications in the permanent directory listing,[53] indicating that slightly over one-third of the applications have used the eased option in Germany. It can be considered as an incentive from the government, however, it is in favour of society as it nudges the manufacturers to stay on the regulatory track, focusing on quality and consequently ensuring users' safety, contrary to choosing the non-regulatory pathway of wellness apps. Worth mentioning that there were only 9 applications that have been removed since introducing the DVG (5 apps in 2022, 1 app in 2023, and 3 apps in 2024), suggesting that manufacturers can demonstrate the positive effects of their products. However, the manufacturers have already criticized the reimbursement scheme for its pricing model, low awareness and adoption, and insurers-related roadblocks.[54] This indicates that the processes still need improvement.

21 Germany was later followed by other European countries, introducing reimbursement schemes for digital medical devices. France, Italy, the Netherlands, Poland, Sweden, and the United Kingdom are now also reimbursing the digital solutions, while Belgium is reimbursing the entire clinical pathway which includes a digital health solution.[55]

47 Directive (EU) 2024/2853 of the European Parliament and of the Council of 23 October 2024 on liability for defective products and repealing Council Directive 85/374/EEC [2024] OJ L, 2024/2853 (New Product Liability Directive).

48 Ibid, art 10(4).

49 Ferretti A, Ronchi E and Vayena E, 'From principles to practice: benchmarking government guidance on health apps' (2019) 1(2) Lancet Digit Health e55-e57.

50 'Bundestag stimmt Digitale-Versorgung-Gesetz zu' (Deutscher Bundesstag, 2019) <https://www.bundestag.de/dokumente/textarchiv/2019/kw45-de-digitale-versorgung-gesetz-664900> accessed July 29, 2024.

51 'The Fast-Track Process for Digital Health Applications (DiGA) According to Section 139e SGB V. A Guide for Manufacturers, Service Providers and Users' (Federal Institute for Drugs and Medical Devices) <https://www.bfarm.de/SharedDocs/Downloads/EN/MedicalDevices/DiGA_Guide.html>.

52 Blümel M and others, 'Germany: Health System Summary' (The European Observatory on Health Systems and Policies 2022) <https://eurohealthobservatory.who.int/publications/i/germany-health-system-summary-2022>.

53 Federal Institute for Drugs and Medical Devices, 'DiGA-Verzeichnis' <https://diga.bfarm.de/de> accessed September 18, 2024.

54 Nicol-Schwarz K, 'DiGA promised German digital health startups access to 73m patients — but slow insurers and poor adoption hold it back' <https://sifted.eu/articles/diga-promised-german-healthtechs-access-to-73m-patients-but-insurer-roadblocks-and-slow-adoption-are-limiting-its-potential> accessed September 16, 2024.

55 van Kessel R and others, 'Digital Health Reimbursement Strategies of 8 European Countries and Israel: Scoping Review and Policy Mapping' (2023) 11 JMIR mHealth and

22 Another example is the Food and Drug Administration (FDA) in the USA easing compliance rules for mental health apps during the Covid-19 pandemic to address the increased psychological distress in society.[56] It allowed the manufacturers to market their apps without submission of premarket notification, waiving the requirement to submit clinical evidence and compliance with a few other requirements. The incentive allowed various companies to enter the market earlier. For instance, one of them – a Swedish manufacturer Orexo – in 2020 was able to launch three apps in the US market contrary to one planned app without the policy change.[57] Additionally, Mattioli[58] indicates that the relaxed ruling changed product marketing, and wellness apps started claiming more medical benefits. This would not be allowed under previous stricter regulations. While the FDA policy changes were temporary,[59] it provides real-world data for the policymakers. The experienced benefits would potentially allow to improve the existing regulations and incorporate the changes in the standard FDA procedures, while still ensuring safety and effectiveness.[60] Regrettably, so far, the procedures remain unchanged.

C. The Emergence of AI in Healthcare

23 2024 was a landmark year for the Artificial intelligence (AI) regulatory framework. In 2020, 7.2% of mobile health apps incorporated AI,[61] and it would be safe to say that the number of such solutions would only grow, especially with the arrival of generative AI. The use of AI in healthcare presents several challenges, including data-related issues such as privacy, collection, storage, quality, accuracy, and security. Ensuring fairness, preventing various biases and discrimination, and addressing health equity are critical concerns. Additionally, there is a need to ensure transparency, accountability, explainability, and interoperability, and manage potential errors and misdiagnoses.[62] While medical apps are regulated under the MDR to ensure safety, wellness apps currently face much fewer restrictions and their developers may overlook potential risks. According to De Freitas and Cohen,[63] preliminary findings indicate that generative AI can allow consumers to use wellness apps for health-related purposes which may pose health risks, suggesting the need to regulate the technology itself, even if it is not intended for medical purposes.

24 To address these AI challenges, it is essential to establish reasonable regulation and governance that supports innovation, promotes transparency and accountability, and protects society. It is also important to prioritize ethical considerations, as emphasized in the European Commission's Ethics Guidelines for Trustworthy AI.[64] Therefore in March 2024, the pioneering Artificial Intelligence Act[65] (AI Act) in the EU was passed. It employs a risk-based approach, setting requirements for development and transparency, mitigating risks, and prohibiting solutions with unacceptable risk levels.[66] It also applies to all health apps, regardless of their regulatory status as medical devices or wellness apps. Seemingly, as AI-based SAMD are considered at least class IIa under the MDR,[67] they correspond to being classified as high-risk AI systems under the AI Act.[68] Wellness apps at this point would rarely classify as

uHealth e49003.

56 Office of the Commissioner, 'Coronavirus (COVID-19) Update: Daily Roundup April 15, 2020' (U.S. Food and Drug Administration, 2020) <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-daily-roundup-april-15-2020> accessed July 20, 2024.

57 Simonite T, 'The Therapist Is In—and It's a Chatbot App' (Wired, June 17, 2020) <https://www.wired.com/story/therapist-in-chatbot-app/> accessed September 16, 2024.

58 Mattioli M, 'Second Thoughts on FDA's Covid-Era Mental Health App Policy' (2021) 21 Houston Journal of Health Law and Policy 9.

59 FDA Center for Devices and Radiological Health, 'Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency' <https://www.fda.gov/media/155038/download>.

60 'Remarks by Commissioner Stephen Hahn, M.D. — The COVID-19 Pandemic — Finding Solutions, Applying Lessons Learned - 06/01/2020' (U.S. Food and Drug Administration) <https://www.fda.gov/news-events/speeches-fda-officials/remarks-commissioner-stephen-hahn-md-covid-19-pandemic-finding-solutions-applying-lessons-learned> accessed August 16, 2024.

61 Stewart C, "mHealth Apps Share with Advanced and Standard AI Worldwide 2020" (Statista, October 20, 2020) <https://www.statista.com/statistics/1180814/mhealth-apps-share-incorporating-ai/> accessed August 16, 2024.

62 Bouderhem R, 'Shaping the future of AI in healthcare through ethics and governance' (2024) 11(1) Humanities and Social Sciences Communications.

63 De Freitas J and Cohen IG, 'The Health Risks of Generative AI-Based Wellness Apps" (2024) 30(5) Nature Medicine 1269.

64 European Commission, 'Ethics Guidelines for Trustworthy AI. Shaping Europe's Digital Future.' <https://digital-strategy.ec.europa.eu/en/library/ethics-guidelines-trustworthy-ai> accessed September 5, 2024.

65 Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 [2024] OJ L, 2024/1689 (Artificial Intelligence Act).

66 Ibid, art 1(2).

67 Medical Device Regulation (n 6), annex VIII, ch III, 6.3.

68 Artificial Intelligence Act (n 65), art 6(1).

high-risk AI systems: in case they use biometrics for emotion recognition[69] and if they "pose a significant risk of harm to the health, safety or fundamental rights of natural persons".[70] However, some wellness apps might be classified as low-risk AI systems,[71] for instance, chatbots.

25 Nevertheless, the AI Act is still new, therefore the full impact on the development of digital health solutions yet remains uncertain. Potential issues may arise where the AI Act intersects with the MDR in practical applications.

D. Marketplaces

26 A crucial component in any business is the marketplace, where manufacturers (supply side) meet consumers (demand side). It serves as the final checkpoint where regulatory requirements can be enforced before the product reaches the consumer. This section will explore how marketplaces function as the final gatekeepers to screen out potentially harmful apps.

27 Currently, the predominant platforms for accessing all health mobile applications are the Apple Store (for iOS) and Google Play (for Android). According to the MDR definition, these platforms act as distributors - "any natural or legal person in the supply chain, other than the manufacturer or the importer, that makes a device available on the market, up until the point of putting into service".[72] The regulation establishes the general obligations for distributors, mainly being responsible for verifying that the device conforms with the requirements of the regulations and prohibiting market access to non-conforming devices.[73] These rules apply only to medical devices, not wellness apps.

28 While both platforms implement guidelines to mitigate the risks associated with potentially harmful applications, it is important to note that these platforms do not serve as a screening checkpoint.

29 The Apple Store's review guidelines for developers[74] state that applications behaving in a way that poses physical harm risks to users may face rejection. It is recommended that these applications provide supporting data and methodology to substantiate the beneficial health claims made. Although there is no separate review process for health claims' legitimacy or mandatory data submission, developers can accomplish this by providing references to data sources within the application. Furthermore, the guidelines stipulate that medical applications having received regulatory clearance should submit a link to the corresponding documentation. However, the Apple Store does not assess the necessity of regulatory clearance during the review process.

30 Google Play policy[75] also states that harmful health applications are not allowed in the store. It explicitly declares that the developer is fully responsible for being compliant with the applicable regulations. The guidelines define SAMD and set policies that the developers must comply with. Additionally, their policy states that the manufacturer is obliged to acquire the regulatory clearance, and while it shall not be submitted to Google Play, it should be provided upon request.

31 Both app stores highlight that applications with medical functionality that use only the built-in device features or sensors are not permitted. These would include, for example, apps to measure blood pressure, glucose level, oxygen level, and such. This provision directly constrains the range of functionalities permissible. While the Apple store requires a validated methodology for the products, Google Play requires supporting external products that ensure the provided functionality.

32 In general, although neither platform assesses the necessity for regulatory clearance, their policies are oriented toward user protection, as evidenced by the requirement to provide data substantiating the manufacturer's claims. A facet that is noticeably absent in the MDR. However, the real-life effectiveness of these requirements is questionable, as the app stores rely on the information submitted by the manufacturer without reviewing its quality and completeness. The reliability of such self-declaration by developers is questioned in a study conducted by Huckvale et al.[76] The research examined apps certified by the UK NHS Health Apps Library as clinically safe and trustworthy but found that a significant portion of these apps failed to comply with data protection principles. This finding highlights the shortcomings of accreditation processes that heavily rely on developers' self-declarations, ultimately failing to achieve one of

69 Ibid, annex III, cl 1.

70 Ibid, art 6(3).

71 Ibid, art 51.

72 Medical Device Regulation (n 6), art 2(34).

73 Ibid, art 14.

74 'App Review Guidelines' (Apple Developer) <https://developer.apple.com/app-store/review/guidelines/#physical-harm> accessed July 3, 2024.

75 'Health Content and Services' (Play Console Help) <https://support.google.com/googleplay/android-developer/answer/12261419?hl=en&sjid=13806500483766338070-EU> accessed July 3, 2024.

76 Huckvale K and others, 'Unaddressed privacy risks in accredited health and wellness apps: a cross-sectional systematic assessment' (2015) 13(214) BMC Medicine.

their primary goals – helping people to find trusted, safe, and secure health apps and serving as a mark of quality. Another example is a study by Tangari et al.[77] which examined the privacy practices of health apps on Google Play and discovered discrepancies between the declared and actual data protection measures, suggesting that Google Play may not be sufficiently safeguarding its users' privacy. These examples illustrate the challenges of enforcing regulations in practice, where stakeholders may intentionally or unintentionally overlook process gaps and minimize their efforts, therefore it underscores the need for increased attention and governance.

E. Apps Causing Harm

33 The overall growing concern is that with the emergence of new technology, bringing new digital health apps, individuals are increasingly placing trust in these apps for their health-related decisions.[78] This section will explore the available evidence to support the theoretical examination of the legal framework in the previous sections to demonstrate that the lack of clinical evaluation, misuse, or product underdevelopment can cause harm to the consumer.

34 According to the IQVIA Institute report,[79] a trend of specialization is noticeable – general health wellness apps lose the majority, while more and more health condition management apps are entering the market, and now mental health, diabetes, and cardiovascular disease-related apps account for almost half of disease-specific apps. In the following section, the mental health and diabetes apps will be explored.

35 Nowadays, when there is rapid technological advancement and development of generative AI, it has become very tempting to quickly develop a product, and various mental health apps arise. Also, the Covid-19 pandemic with limitations in social and professional life contributed to the rise of mental health app downloads.[80]

36 However, the quality of these apps is alarming. As per Sucala et al., the majority of the anxiety relief apps have been developed without involving psychology professionals and there is a lack of data on their efficacy and effectiveness.[81] The lack of evidence is also highlighted in Koh et al. umbrella research,[82] additionally pointing out that some applications do not even provide a therapeutic rationale or evidence behind their interventions. Wang et al.[83] point out that clinical efficacy does not correlate with the popularity (number of downloads) and apps' ratings, which underscores the effect of marketing and search engine optimization processes. The shortcomings of large language models (LLMs) have been explored by Heston,[84] suggesting that LLMs cannot properly detect and address hazardous mental states, consequently not being able to manage the condition safely. De Freitas and Cohen[85] pointed out that wellness apps featuring generative AI, while not intended for mental health purposes, can be used for that purpose thus creating health risks.

37 The lack of regulation and control over the conversations can be even lethal. In 2023 an eco-anxious Belgian man after a six-week-long conversation with an AI chatbot committed suicide to save the planet.[86] Recently, a 14-year-old boy committed suicide after forming a deep emotional attachment to a fictional character during conversations with an AI-powered chatbot.[87] Another case of a harmful application is chatbot Tessa, which The National Eating Disorders Association removed for giving dangerous advice about eating disorders.[88] While initially the service was provided by professionals, soon after replacing them with AI, the problems arose. These are examples where a

77 Tangari G and others, 'Mobile health and privacy: cross sectional study' (2021) 373 BMJ n1248.

78 Hogan NM, Kerin MJ, 'Smart phone apps: Smart patients, steer clear' (2012) 89(2) Patient Education and Counseling 360.

79 IQVIA Institute, 'Digital Health Trends 2021' (n 3), 2.

80 Wang X, Markert C, Sasangohar F, 'Investigating Popular Mental Health Mobile Application Downloads and Activity During the COVID-19 Pandemic' (2021) 65(1) Human Factors 50.

81 Sucala M and others, 'Anxiety: There is an app for that. A systematic review of anxiety apps' (2017) 34(6) Depression and anxiety 518.

82 Koh J, Tng GYQ, Hartanto A, 'Potential and Pitfalls of Mobile Mental Health Apps in Traditional Treatment: An Umbrella Review' (2022) 12(9) Journal of Personalized Medicine 1376.

83 Wang X, Markert C, Sasangohar F (n 80).

84 Heston TF, 'Safety of Large Language Models in Addressing Depression' (2023) 15(12) Cureus.

85 De Freitas J and Cohen IG, 'The Health Risks of Generative AI-Based Wellness Apps" (2024) 30(5) Nature Medicine 1269.

86 Laura W, 'Belgian man dies by suicide following exchanges with chatbot' *The Brussels Times* (March 28, 2023) <https://www.brusselstimes.com/430098/belgian-man-commits-suicide-following-exchanges-with-chatgpt> accessed August 12, 2024.

87 Roose K, 'Can a Chatbot Named Daenerys Targaryen Be Blamed for a Teen's Suicide?' *The New York Times* (October 23, 2024) <https://www.nytimes.com/2024/10/23/technology/characterai-lawsuit-teen-suicide.html> accessed December 7, 2024.

88 'NEDA Suspends AI Chatbot for Giving Harmful Eating Disorder Advice' (Psychiatrist.com, June 5, 2023) <https://www.psychiatrist.com/news/neda-suspends-ai-chatbot-for-giving-harmful-eating-disorder-advice/> accessed August 12, 2024.

lack of oversight and control over technology and generative AI poses imminent risks to consumers' health.

38 A similar situation is evident with the other large segment – diabetes apps. Research shows that the overall quality of apps is moderate, and most of the self-management apps lack rationale – only 8% of apps had any evidence behind their program.[89] There is a low number of randomized controlled trials on diabetes apps, a small number of proven long-term benefits, and even limited high-quality short-term data.[90]

39 All these factors affect the trust and credibility of the technology and jeopardize the health app market development in the long term. Losing consumers' trust will decrease the adoption of the new technology in general, also of the apps that are clinically validated and actually do provide positive healthcare effects. And having low-quality apps in the market poses additional risks to the well-being of the individuals who already seek help.

40 From the legal perspective, the wellness applications do have a disclaimer in their terms of service and the app that it does not provide medical advice, and in case of any health concerns, the consumers shall consult with healthcare professionals. However, research[91] has demonstrated the common tendency of the average consumer to overlook the details in the fine print.

F. Conclusion

41 The current regulatory approach, which focuses only on the official intended use of the application, poses evident risks, as the oversight is not extended to wellness apps even though their functionality may resemble medical purposes. This is especially evident in the case of generative AI-based solutions. Hence, to ensure consumer safety, it is important that these apps have also undergone safety, quality, and efficacy evaluation, and are continuously monitored during their operation time as required by the MDR in the post-market surveillance process for medical apps. One potential solution is to expand Annex XVII of the MDR, which lists products without an intended medical purpose to which the regulation applies, to include wellness apps. However, the author believes that this extension of scope would be unreasonable because wellness apps typically pose minimal, if any, health risks and the current complex regulatory framework could potentially have a detrimental impact on the digital wellness market.

42 Thus, a specific regulation for wellness apps is suggested. Considering the arguments mentioned in this article, it is important to find a balance and introduce a fair regulatory framework. Policymakers need to make sure that they do not overregulate the sector, making it difficult for manufacturers to meet the requirements and unappealing to work in the market at all. However, reasonable and feasible requirements should be implemented to ensure the software is science-backed and safe. The author proposes adding a new clause to Article 6 of the General Product Safety Regulation, specifically addressing products intended for health-related use. The clause would reference an annex detailing the requirements necessary to ensure the quality of such products. For instance, it would mandate the involvement of relevant experts in product development: a mental health app should include input from professionals such as psychologists or psychiatrists, while a diet app should involve a qualified nutritionist. For generative AI solutions, regulatory requirements could consist of built-in limitations on the scope of advice provided. Additionally, recognizing that disclaimers and fine print are rarely read, it should be mandatory for users to be referred to health professionals during their interaction with the app, particularly when it resembles medical use or when the user is in a potentially harmful situation.

43 Until a proper European approach is established, the EU member states may implement such safety and quality requirements at the national level. However, this could lead to a fragmented internal market and is therefore recommended only as a temporary measure until unified European requirements are adopted.

44 Given the high health risks associated with AI in unregulated wellness apps, the author further proposes expanding the list of high-risk systems in Annex III of the AI Act to include products that would fall under the proposed new clause in Article 6 of the General Product Safety Regulation.

45 There is also unused potential in the collaboration between app marketplaces and regulatory bodies. While marketplaces currently provide guidelines for health apps to be accepted in the stores, the

89 Geirhos A and others, 'Standardized evaluation of the quality and persuasiveness of mobile health applications for diabetes management' (2022) 12(1) Scientific Reports.

90 Fleming GA and others, 'Diabetes Digital App Technology: Benefits, Challenges, and Recommendations. A Consensus Report by the European Association for the Study of Diabetes (EASD) and the American Diabetes Association (ADA) Diabetes Technology Working Group' (2019) 43(1) Diabetes Care 250.

91 Bakos Y, Marotta-Wurgler F, Trossen DR, 'Does Anyone Read the Fine Print? Consumer Attention to Standard-Form Contracts' (2014) 43(1) The Journal of Legal Studies 1.

responsibility of quality, compliance, and evidence behind claims is assigned primarily to the developers. Moreover, the app stores are minimally engaged in quality monitoring during apps' operation time. However, enhancing their role as gateways and assigning greater responsibility to them would be advantageous for society, mitigating health risks. For instance, if the additional clause to the General Product Safety Regulation mentioned above is adopted, gatekeepers should be required to actively verify whether the technical requirements have been implemented in the app, rather than relying solely on developers' self-declarations.

46 Additionally, attention should also be directed towards encouraging manufacturers to opt for the certification pathway, as it ensures the validation of apps for safety and quality. The current complex regulatory framework is unattractive to developers of lower-risk products. Hence, it is recommended to introduce incentives aimed at supporting the manufacturers. While the implementation of such programs at the EU level may require considerable time and effort, it is advised for individual countries to introduce incentives at the national level to support their med-tech companies. For example, national governments could establish reimbursement schemes for digital healthcare solutions. This is particularly crucial for small and medium-sized enterprises with limited financial resources.