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mHealth apps as medical devices under the new EU regulation: uncertainties and opportunities in the era of the Internet of Medical Things

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ABSTRACT

The thesis analyzes the upcoming EU regulation on medical devices (Regulation 2017/745 dated 5 April 2017) and its impact on the developers of the mHealth apps. Emphasis is placed on the well-being apps, which are one of the most significant segments of the mHealth apps and are not regulated as medical devices under the present EU legal framework. The new EU regulation on medical devices is changing the existing language. It is assumed that a new language will strengthen the regulation of mHealth apps.

The research first explains the development of the mHealth market. Later, the EU and the US regulation of the mHealth apps is reviewed since the EU and the US are the two largest markets for medical applications development. In the final chapter, based on practical examples found during research, the opportunities and problems of the new regulation are analyzed.

The study provides pros and cons to strengthening the regulation of mHealth apps as the fastest-growing economic sector to assist with access to healthcare.

KEYWORDS

EU MDR, Mobile Medical Applications, mHealth, Well-Being Applications, US, EU.

ABBREVIATIONS USED

1989 Computer Regulation	FDA Policy for the Regulation of Computer Products 11/13/89
2019 Policy	The Policy for Device Software Functions and Mobile Medical Applications. Guidance (non-binding) by the FDA, issued on 27 September 2019
21 Century Cures Act	The 21st Century Cures Act is a United States law enacted by the 114th United States Congress in December 2016. Public Law 114–255 [2016]
Apps	Mobile Applications
Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act: Guidance 2019	Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act: Guidance for Industry and Food and Drug Administration Staff. Non-binding recommendation by FDA. 27 September 2019
CJEU	Court of Justice of the European Union
Commission	European Union Commission
EU	European Union
EU MDR	European Medical Device Regulation, Regulation 2017/745 of the European Parliament and of the Council 5 April 2017
FDA	US Food and Drug Administration
FDCA	The United States Federal Food, Drug, and Cosmetic Act
General Wellness: Policy for Low Risk Devices	General Wellness: Policy for Low Risk Devices Guidance for Industry and Food and Drug Administration Staff [2019] 6 June 2020
Guidance Document MEDDEV 2.1/6	Guidance document Medical Devices - Scope, field of application, definition - Qualification and Classification of stand-alone software, MEDDEV 2.1/6 [2016]
Manual on the Borderline Products	Manual on Borderline and classification in the community regulatory framework for medical devices. Document date: 1 February 2019
Medical Device Directive	Council Directive 93/42/EEC of June 1993 Concerning Medical Devices
mHealth	Mobile Health
UN	United Nations
WHO	World Health Organization

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INTRODUCTION

Digitalization is one of the trends which can be noted in all the industries, including healthcare. “Connected healthcare,” “MedTech,” and the “Internet of Medical Things” are just a few terms that can be noted when reading about the trends in the healthcare market.

The mobile health technology is here to stay. Steve Jobs hated the design of the health-monitoring devices used to treat him during his final days.[1] Apple Health Kit, released soon after the death of the Apple founder, changed the way many users interact with their phones.

People are no longer using their mobile devices just for connection or updating social media: personal mobile devices are now also being used to track and monitor symptoms, share data with general practitioners, and even receive the advice on lifestyle improvements based on the data inserted in the mobile phone app.

Analysts from Grand View Research forecast that the global mobile health industry will reach $236 billion by 2026, growing at a whopping CAGR[2] of 44.7 percent.[3] The public healthcare system relies on private medical tools to improve healthcare and meet patients' needs better. Digital tools and websites change how patients engage with medicine.

There are a lot of patients with chronic diseases who need constant monitoring by healthcare professionals. For example, based on the data from the World Health Organization, in 2016, an estimated 1.6 million deaths were directly caused by diabetes.[4] Chronic diseases can be monitored with mHealth apps, and the use of such apps can minimize healthcare costs and improve the quality of treatment. Another popular field for the more extensive use of mHealth Apps is female reproductive health. Female-targeted consumer health technology — often called femtech — is aimed at improving welfare and predicted to be a $50bn industry by 2025, according to market research company Frost & Sullivan.[5] Also, as the population of the planet generally gets older, more medical treatment

[1] S.J. Kilker, ‘Effectiveness of Federal Regulation of Mobile Medical Applications’ (2016) 93 (5) Washington University Law Review < https://openscholarship.wustl.edu/cgi/viewcontent.cgi?article=6220&context=law_lawreview > accessed 5 June 2020.
[2] Compound annual growth rate.
[3] N. Alkhaldi, 'Mobile Healthcare In 2020: The Roadmap For Change' (Itransition Corporate News, 2019) < https://www.itransition.com/blog/mobile-healthcare > accessed 3 June 2020.
[4] World Health Organization, ‘Factsheet on Diabetes’ (World Health Organization Official Website, 30 October 2018) < https://www.who.int/news-room/fact-sheets/detail/diabetes > accessed 6 June 2020.
[5] Editorial Opinion, ‘Femtech: a Fertile Area’ (The Financial Times, 1 January 2020) < https://www.ft.com/content/9a312f63-8e23-4792-811d-65a8ea816b96> accessed 4 June 2020.

will be necessary, and mHealth apps can help with medication intake, or generally teach users on healthy habits.

The use of mHealth apps is expanding. In developed countries, the extended use of mHealth apps is primarily driven by the desire to cut the costs of healthcare.[6] In developing countries, mHealth apps can also assist with solving additional problems, such as access to healthcare.[7] At the same time, mHealth apps are still not widely relied upon by healthcare institutions or healthcare practitioners. One of the reasons is inconsistent regulation. Currently, mHealth apps are only lightly regulated; therefore, the advice provided by the mHealth apps or based on the mHealth apps can not always be relied upon. This issue slows down the development of the connected healthcare world.

Differences in regulatory approaches in the United States, European Union, and separate European countries reflect global uncertainty in the regulatory requirements for mHealth apps.[8] This uncertainty in regulation could limit the growth of the mHealth apps market.[9]

Problem Statement

In 2017, the EU MDR was adopted. It will come into force on 26 May 2021[10], replacing the current Medical Device Directive.

The Medical Device Directive that is currently in place was not drafted with software in mind. Therefore, along with several other additions, new rules regarding the regulation of mHealth apps are implemented in the EU MDR.

mHealth apps are considered to be a medical device only if they have an intended "medical purpose." At the same time, the definition of "medical purpose" is not self-explanatory. The distinction between "wellness" apps and "medical" apps may become somewhat vague, as

[6] European Commission 'Summary Report on the Public Consultation on the Green Paper on Mobile Health' (European Commission, 12 January 2015) < https://ec.europa.eu/digital-single-market/en/news/summary-report-public-consultation-green-paper-mobile-health > accessed 6 June 2020.
[7] Ibid.
[8] R. Istepanian R, B. Woodward, M-Health (John Wiley&Sons, Inc 2019) 87 < https://tinyurl.com/yaccgb4v > accessed 4 June 2020.
[9] Ibid.
[10] As the thesis was drafted, the initial date of entry into force was shifted from May 2020 to May 2021 due to the COVID-19 pandemic. More at the official website of the Commission: 'Medical Devices Regulation: Commission welcomes Council support to prioritise the fight against coronavirus' (European Commission press release, 23 April 2020), < https://ec.europa.eu/commission/presscorner/detail/en/IP_20_718 > accessed 6 June 2020.

"wellness" apps supporting preventive and self-monitoring activities may significantly improve health outcomes.[11]

The profile of the mHealth app manufacturer has also changed as compared to the usual medical device industry: it is more often not a corporation, but a smaller business or even an individual skilled in programming.[12] Therefore, in reality, it is pretty hard for the mHealth developer to find out if the app is considered to be a medical device. Currently, there are additional guidelines provided by the authorities as well as numerous "decision trees," which could help the mHealth app developers to find whether the app is a medical device under the new regulation. At the same time, it is not entirely clear whether existing regulation is sufficient when used by the developers of the mHealth apps.

The thesis aims at reviewing the new EU MDR. Regulation in the US is reviewed to compare the approaches in the two markets. The author plans to review the Health apps, which will fall under the definitions of the updated regulation. The thesis is written with mobile application developers in mind. It is also intended to analyze whether the existing and planned regulation can assist in further growth of the mHealth market.

The thesis does not review the specific matters of consumer protection, privacy, and other applicable regulatory issues in the mHealth market. A detailed review of the regulation under US law, as well as the process of applying for certification as a medical device, is also outside the scope of the thesis.

Research Question

Therefore, the central research question of the present thesis is as follows:

How does EU MDR regulate mHealth apps and how does it impact the innovation in mHealth?

To answer the central question, the author poses the following sub-questions:

- When are mHealth apps subject to regulation under the new EU MDR?

[11] White & Case Technology Newsflash 'Mobile Health Apps: Are They a Regulated Medical Device?' (White & Case, August 2015) < https://www.whitecase.com/publications/article/mobile-health-apps-are-they-regulated-medical-device > accessed 5 June 2020.

[12] P. Quinn, 'The EU commission's risky choice for a non-risk based strategy on assessment of medical devices' (2017) 33(3) Computer Law & Security Review 361, 366 < https://www.sciencedirect.com/science/article/abs/pii/S0267364916301637?via%3Dihub > accessed 7 June 2020.

- What are the differences in regulatory approaches regarding mHealth apps, especially well-being apps, in the US and the EU?
- What are the effects on innovation due to the mHealth regulations?

Objective

The main objective of the thesis is to investigate regulation on medical devices in relation to mHealth apps and review the trends and their impact on the mHealth market. In particular, the author intends to investigate which features of the mHealth apps trigger the application of the new EU MDR.

The thesis aims at delivering an overview of the important elements in the mHealth market, that can be used by mHealth app developers that are subject to regulations. The thesis also provides an analysis of the trends in the mHealth apps market that could be useful for the regulators when planning the next steps in mHealth regulation.

Methodology

In order to investigate the EU MDR in relation to the mHealth apps, the following methods will be used:

1) The content analysis: the meaning of words, phrases, and sentences of the EU MDR, Guidance document on Medical Devices MEDDEV 2.1/6, Manual on the Borderline Products, 21st Century Cures Act, the official website of the FDA and documentation issued by FDA, for example, 2019 Policy and General Wellness: Policy for Low Risk Devices, as well as other documents published by governmental authorities in the field of mHealth. The existing literature on the trends in mHealth will be reviewed. The articles published by the journals will be reviewed (for example, research articles published on the HealthAffairs[13], Journal of International Commerce & Economics, JMIR mHealth and uHealth), as well as the newspapers, for example, Financial Times, Forbes, Business Insider.
2) The comparative method will be used when reviewing existing regulation in the US on medical devices and when such regulations apply to mHealth apps. The similarities and differences with the proposed EU MDR will be analyzed.

[13] Health Affairs is a peer-reviewed healthcare journal. Available at:< https://www.healthaffairs.org >.

3) A doctrinal research technique is used when assessing law, cases, and secondary literature on those resources. Opinions and articles will be reviewed, and an overview of the trends regarding the regulation of mHealth apps will be made. It will also be reviewed whether the existing and upcoming regulation might be an obstacle in the development of the Internet of Medical Things. The literature in the field of medical devices over the past ten years (2009-2019) is primarily used. The systematic search is conducted based on the databases available in Tilburg University (for example, HeinOnline, Westlaw UK), Google Scholar, and SSRN.

The following obstacles can be expected in the research.

There are many different mobile applications with various features. Well-being apps, that are currently covering a substantial part of the mHealth apps, are the primary focus of the thesis. It is intended to review whether such well-being apps will be regulated under the new EU MDR, and what risks can arise in the field of medical device regulation with respect to such apps. During the research, when using the terms "the mHealth app" the author refers to a mobile application that can analyze data of the patients in the sphere of health. Examples of the interactions in the spheres of health are as follows: give recommendations, give smart notifications based on the data transferred to the app, allow communication with the general healthcare practitioner, use of artificial intelligence, transfer to the cloud. Software and applications that cannot be used on its own (for example, applications that are to be used together with the medical device, for example, insulin pump) are excluded from the scope of the research.

Literature review

In order to start the research, trends in mHealth are reviewed. For example, Research2Guidance and similar reports are reviewed to find the trends of the healthcare industry. The search is performed on the digital newspaper "Financial Times" by using the search items "healthcare" AND "trends." When reviewing the trends, literature from 2016 is reviewed as relevant. Sources of the earlier years are used for reference, at the same time, due to the fast-changing pace of the mHealth market, sources from the past five years are viewed as more credible. Various reports of the official institutions also reviewed. For

example, the Green Paper of the European Commission[14] is the public consultation document that has revealed that society is looking for the strengthening of regulation in the field of mHealth.

After the review of the trends in the eHealthcare, the laws are reviewed, in particular, EU MDR, Medical Device Regulation, and the website of FDA. The website of the FDA has multiple documents about various domains in mHealth, as well as detailed explanations. At first glance, it seems that the regulation of medical devices in the US is more detailed than in the EU. A similar opinion is shared in several publications, for example, the one in the European Journal of ePractice, where it is indicated that the FDA is ahead of the EU in the mHealth apps domain.[15]

To have additional clarity, the decision trees are reviewed, in particular guidance documents published by the European Commission.

The Dutch national institute for public health and environment has performed a research titled "Apps under the medical devices legislation[16]" showing how the mHealth apps developers perceive the Medical Device Regulation, which will be useful for the thesis. The research was performed in 2018 by the state authority. Additional research relevant for the thesis was performed by TNO, Dutch Organization for Applied Scientific Research, in cooperation with other parties, in 2019 upon request of the European Commission.[17] The empirical part of the said research is of use when reviewing the risks related to the well-being apps and the distinction between the apps with the medical purpose and the well-being purpose.

In the review performed by the representatives of the US office in 2018[18], it is indicated that due to the adoption of the EU MDR, the market can expect the delay with the release of

[14] European Commission 'Summary Report on the Public Consultation on the Green Paper on Mobile Health' (European Commission, 12 January 2015) < https://ec.europa.eu/digital-single-market/en/news/summary-report-public-consultation-green-paper-mobile-health > accessed 6 June 2020.

[15] See the conclusion in H. Papadopoulos, et all 'Comparison of US and EU Regulatory Approaches to Mobile Health Apps: Use Cases of myVisionTrack and USEFIL' (2013) 21 The European Journal of ePractice 27 < https://joinup.ec.europa.eu/sites/default/files/document/2014-06/ePractice-Journal-Vol.21-December%202013.pdf > accessed 7 June 2020.

[16] A. Drongelen, et all, 'Apps under the medical devices legislation' (2019) National Institute for Public Health an Environment of the Netherlands research < https://www.rivm.nl/bibliotheek/rapporten/2018-0083.pdf > accessed 6 June 2020.

[17] Lieshout M.J., et all 'Final study report regarding safety of health, lifestyle and wellbeing apps' (TNO 2019 R10103, European Commission report 2019) < https://ec.europa.eu/digital-single-market/en/news/safety-non-embedded-software-including-safety-health-lifestyle-and-wellbeing-apps > accessed 5 accessed 5 June 2020

[18] B. Daigle, M. Torsekar, 'Executive Briefings. On Trade.The EU Medical Device Regulation and the U.S. Medical Device Industry' (U.S. International Trade Commission, September 2018) < https://www.usitc.gov/publications/332/executive_briefings/eu-mdr_ebot_final.pdf > accessed 7 June 2020.

the new products that need to comply with EU MDR. It is briefly reviewed to what extend the mHealth apps market can be affected by such delays.

Several reviewed documents indicate that the regulation of mHealth apps is inconsistent, for example, authors in the European Journal of General Practice [19], or the book "Mobile e-Health."[20] Book on Mobile e-Health by Marston, Freeman, and Musselwhite, is a good summary of the issues in mHealth in the EU. Similarly, a publication by Roth contains an overview of the regulation of mHealth apps and challenges in the US.[21]

Chapter Structure

To achieve the objective and answer the research question, the thesis is divided into the following chapters.

Chapter 1: Overview of the changes in the healthcare sector related to emerging technologies. The historical aspect, the trends in the healthcare sector, and existing issues are analyzed. The necessity to introduce EU MDR is reviewed.

Chapter 2: Overview of the EU medical device regulation. In this chapter, the requirements for the mHealth apps to be considered "medical devices" under the new EU MDR are reviewed.

Chapter 3: Overview of the regulation in regard to mHealth apps in the US. Since the US already has extended regulation and guidelines on when mHealth apps are considered to be medical devices, FDA regulations in the field of the mHealth is reviewed. Differences in the regulatory approaches with the EU MDR are noted.

Chapter 4. Analyzing the regulations applicable to the well-being mHealth apps and trends in the mHealth. Challenges in the regulation of the mHealth apps, including examples on the well-being apps, are reviewed. The benefits and disadvantages of hands-off and hands-on approaches to regulation are analyzed as well.

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[19] E. Mantovani, P. Quinn, B. Guihen, A.K. Habbug, P.J.A. de Hert, 'eHealth to mHealth: A journey precariously dependent upon apps?' (2013) 21 European Journal of General Practice 48.

[20] H. Marston, S. Freeman, C. Musselwhite, Mobile E-Health (Springer, Cham 2017) < https://link.springer.com/content/pdf/10.1007%2F978-3-319-60672-9.pdf > accessed 5 June 2020.

[21] Roth V.J., 'The mHealth Conundrum: Smartphones & Mobile Medical Apps—How Much FDA Medical Device Regulation is Required?' (2014), 15 (3) The North Carolina Journal of Law & Technology 359 < http://ncjolt.org/wp-content/uploads/2014/04/Roth-Color-Final.pdf > accessed 5 June 2020.

Chapter 5: Conclusion. Recommendations. Suggestions for further research. Summary of the conclusions of the research is made, including, in particular, a table on the comparison between the US and EU approach to regulation. Recommendations for further research are provided.

"It is not the strongest of the species that survives, nor the most intelligent, but the one most responsive to change."

- **Charles Darwin**

Chapter 1: Overview of the Changes in the Healthcare Sector Related to Emerging Technologies

In this chapter, the author reviews the changes in the healthcare sector related to the new technologies, reviews the definition of the mHealth apps, and the historical aspect of the existing regulation on the mHealth apps in the EU.

1.1. Development of the new definitions within the healthcare sector

Health has always been of fundamental importance to European society. The right to health has been acknowledged in numerous international agreements (for example, the Universal Declaration of Human Rights, International Covenant on Economic, Social and Cultural Rights). The health of the population is also of importance to the economy.[22] These days, during the Covid-19 pandemic, the importance of healthcare workers and education about health became important as never before.[23]

Healthcare has traditionally been a regulated domain.[24] In the traditional healthcare industry, ten years is merely the time span for a product development cycle.[25] Recently, the healthcare sector started to open up. The use of mobile devices helped to make healthcare

[22] E. Mantovani, P. Quinn, B. Guihen, A.K. Habbug,., PJA. de Hert, 'eHealth to mHealth: A journey precariously dependent upon apps?' (2013) 21 European Journal of General Practice 48.
[23] More on the Covid-19 pandemic is available at the World Health Organization website. See more at: World Health Organization, 'Coronavirus disease (COVID -19 pandemic (WHO, 2020) < https://www.who.int/emergencies/diseases/novel-coronavirus-2019 > accessed 7 June 2020.
[24] N. Dickson, 'Regulation In A Changing Healthcare Landscape: The Role Of The General Medical Council' (2014) 1(2) Future Hospital Journal 80 < https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6438239/ > accessed 4 June 2020.
[25] Report 'How digital intruders are taking over the healthcare market' (Research2Guidance, mHealth App Economics 2017) < https://research2guidance.com/product/mhealth-economics-2017-current-status-and-future-trends-in-mobile-health/> accessed 5 May 2020.

more accessible. "*Ensuring healthy lives and promote well-being for all at all ages*" was adopted as one of the UN sustainable development goals.[26] Therefore, the policy-makers are working on making sure that more people are educated about healthy lifestyles; and so that fewer barriers exist between patients and the healthcare provider.

The "opening up" of the medical sector is sometimes pointed out as a consequence of the advent of **telemedicine,** where the connectivity of devices enabled clinicians to share images and health data in a way that assists diagnoses and treatments.[27] First reference to telemedicine can be found in the 1900s. At first, telemedicine was used to provide medical service in Antarctica with the use of the radio, or by NASA when the first astronauts were to get into space. In the 1990s the telemedicine was reborn as the provision of healthcare at a distance to a larger public, as the communication technologies became were widespread.[28,29]

In 2007 World Health Organization defined **"telemedicine"** as follows:

"The delivery of health care services, where distance is a critical factor, by all health care professionals using information and communication technologies for the exchange of valid information for diagnosis, treatment and prevention of disease and injuries, research and evaluation, and for the continuing education of health care providers, all in the interests of advancing the health of individuals and their communities." [30]

Along with the term "telemedicine," the term "telehealth" can be used. [31] WHO also provides a definition of the "telehealth," as follows:

"*Delivery of health care services, where patients and providers are separated by distance. Telehealth uses ICT for the exchange of information for the diagnosis and treatment of*

[26] Please refer to the website of the UN regarding sustainable development goals. See more at: < https://www.un.org/sustainabledevelopment/health/ > accessed 7 June 2020.
[27] H. Marston, S. Freeman, C. Musselwhite, Mobile E-Health (Springer, Cham 2017) < https://link.springer.com/content/pdf/10.1007%2F978-3-319-60672-9.pdf > accessed 5 June 2020.
[28] M. Maheu,P. Whitten, et al, 'E-Health, Telehealth, and Telemedicine: A Guide to Startup and Success' (John Wiley &Sons , 1 ed., 2002) < https://tinyurl.com/ychvpmwl > accessed 5 June 2020.
[29] A. Darkins, M. Cary, Telemedicine And Telehealth (Springer Publishing Company 2000) < https://tinyurl.com/ycjmqmo3 > accessed 4 June 2020.
[30] World Health Organization, 'Telemedicine. Opportunities and developments in Member States: report on the second global survey on eHealth 2009' (2010) 2 Global Observatory for eHealth series < https://www.who.int/goe/publications/goe_telemedicine_2010.pdf > accessed 6 June 2020.
[31] Additional definitions and discussion on the Telehealth Vs Telemedicine can be found at: A. Darkins, M. Cary, Telemedicine And Telehealth (Springer Publishing Company 2000) < https://tinyurl.com/ycjmqmo3 > accessed 4 June 2020.

diseases and injuries, research and evaluation, and for the continuing education of health professionals…." [32]

Both definitions "telehealth" and "telemedicine" have the distance as the core in the definition. In some of its reports, the WHO agreed to use the definitions as interchangeable due to the debate on the difference on the two definitions.[33]

Slowly, mobile phones became portable and that allowed reviewing websites through cellular networks. The moment that marks the beginning of the use of mobile phones can be indicated in 1997 when the Sony Ericsson is released.[34]

The growing emphasis on mHealth programs is reflected in the WHO's 2016 report of the third global survey on eHealth, noting that more than half of WHO Member States now have an eHealth strategy, and 90% of eHealth strategies reference the objectives of universal health coverage or its key elements.[35] The WHO defines mHealth as follows:

"*Medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices*."[36,37]

The WHO also provides the definition of the eHealth as "*the cost-effective and secure use of information communication technologies (ICT) in support of health and health related fields, including health-care services, health surveillance, health literature, and health education, knowledge and research.*"[38]

When comparing the mHealth and eHealth, similarities are noted. Basically, both refer to the more effective provision of treatment. At the same time, eHealth refers to the use of "*information communication technologies,"* and mHealth talks about practice supported by

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[32] World Health Organization, 'Telehealth' (World Health Organization Website, 2020) < https://www.who.int/gho/goe/telehealth/en/ > accessed 6 June 2020.
[33] World Health Organization, 'Telemedicine. Opportunities and developments in Member States: report on the second global survey on eHealth 2009' (2010) 2 Global Observatory for eHealth series < https://www.who.int/goe/publications/goe_telemedicine_2010.pdf > accessed 6 June 2020.
[34] V.J. Roth, 'The mHealth Conundrum: Smartphones & Mobile Medical Apps—How Much FDA Medical Device Regulation is Required?' (2014), 15 (3) The North Carolina Journal of Law & Technology 359 (2014) < http://ncjolt.org/wp-content/uploads/2014/04/Roth-Color-Final.pdf > accessed 5 June 2020.
[35] World Health Organization, 'Global diffusion of eHealth: Making universal health coverage achievable. Report of the third global survey on eHealth' Global Observatory for eHealth (2016) < https://apps.who.int/iris/bitstream/handle/10665/252529/9789241511780-eng.pdf;jsessionid=A5F9ECC4DD7688CA56B155BA356C908B?sequence=1 > accessed 6 June 2020.
[36] World Health Organization, 'mHealth. New horizons for health through mobile technologies' (2011) (3) Global Observatory for eHealth series < https://www.who.int/goe/publications/goe_mhealth_web.pdf > accessed 6 June 2020.
[37] World Health Organization, 'WHO eHealth Resolution' (World Health Organization, 2020) < https://www.who.int/healthacademy/news/en/ > accessed 6 April 2020.

mobile devices. eHealth is a broader term, where different types of technologies can support healthcare, for example, electronic medical records.

"Connected Health" is another term used in the literature on the development of healthcare, at the same time, no formal definition of connected health exists. To a certain extent, it is similar to the definition of telemedicine. It is the use of technologies that allow instantly delivering better medical care. One of the definitions proposed in the literature is the following:

"*Connected Health encompassess terms such as wireless, digital, electronic, mobile, and telehealth and refers to a conceptual model for health management where devices, services or interventions are designed around the patient's needs, and health related data is shared, in such a way that the patient can receive care in the most proactive and efficient manner possible. All stakeholders in the process are 'connected' by means of timely sharing and presentation of accurate and pertinent information regarding patient status through smarter use of data, devices, communication platforms and people*."[39]

The definition is similar to the definitions of the telemedicine/telehealth. The nature of all three definitions is overlapping and all three definitions can be placed on the same level.[40]

"Connected health" means that distance exists between the healthcare provider and the patient, and the technology is used to provide treatment in the most effective manner. Telemedicine and telehealth have the goal of doing similar activities at a distance. "Connected healthcare" can be a more specific and newer definition that specifically makes references to the new technologies that help to "connect" the participants of the healthcare setting.

Another similar newer definition that can be met in the literature is the "Internet of Medical Things." Most recently, the development of the technologies led to the creation of the Internet of Things.[41] As a logical development of that, an Internet of Medical Things was

[39] B. M. Caulfield and S. C. Donnelly, 'What Is Connected Health And Why Will It Change Your Practice?' (2013) 106 QJM, 703 < https://academic.oup.com/qjmed/article/106/8/703/1576939 > accessed 3 June 2020.

[40] Examples where telehealth and connected health were used together, is, for example in the following article: "*The addition of telehealth technologies …can create a connected health model*". See more at: J. Kvedar, M.J. Coye, W. Everett, 'Strategies To Improve Patient Care With Telemedicine And Telehealth' (2014) 33 (2) Health Affairs journal < https://doi.org/10.1377/hlthaff.2013.0992 > accessed 5 June 2020; J.H. Moeller, 'Connected Health: Telemedicine Patent Landscape' (Moeller Ventures LLC, 9 March 2020) < https://www.moellerventures.com/index.php/blog/25-2020-articles/45-connected-health-telemedicine-patent-landscape > accessed 7 June 2020.

[41] Internet of things means the network of electronic devices that enables the exchange of data between devices for specific domain applications. See more at: G.J. Joyia, R.M. Liaqat, 'Internet of Medical Things (IOMT): Applications, Benefits and Future Challenges in Healthcare Domain' (2017) 12(4) Journal of Communications < http://www.jocm.us/uploadfile/2017/0428/20170428025024260.pdf > accessed 4 June 2020.

created. The Internet of Medical Things allows connected devices to be used in clinical operations, medication management, remote health care, on-patient or in-patient monitoring, and diagnostics.[42]

In 2018, Goldman Sachs estimated that due to the Internet of Medical Things, the major healthcare spending reduction could be anticipated.[43] The first wave of healthcare Internet of Things is described as a "bridge between the digital and physical worlds to change physical and patient behavior." The MarketResearch.com report states that the Internet of Things in Healthcare is expected to reach $117 billion by 2020.[44] The Internet of Medical Things is expected to revolutionize clinical collaboration and care delivery. Thus, for example, in its 2018 brochure, Deloitte estimated the market of the Internet of Medical Things to be valued at more than $150 billion by 2022.[45]

Such new definitions related to the healthcare sector overlap to some degree. When looking at the range of the new definitions that arise in the healthcare sector, certain similarities can be noted. "Overcoming distance," "contributing to the health of the society with lower costs," "use of the new technologies to provide care to patients more effectively" are the words being used in the definitions. It also reflects the direction in which healthcare is moving.

mHealth, out of all the definitions, is the narrowest one. It relates to the actual use of portable devices. Alternatively, eHealth can include other technological advancements, not always related to mobile devices.

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[42] S. Oransi, 'Beyond The Hype: The Internet of Medical Things' Forbes (25 October 2019) < https://www.forbes.com/sites/forbesbusinessdevelopmentcouncil/2019/10/25/beyond-the-hype-the-internet-of-medical-things/ > accessed 5 June 2020.

[43] C. Stern, 'Goldman Sachs says a digital healthcare revolution is coming — and it could save America $300 billion' (Business Insider, 29 June 2015) < https://www.businessinsider.com/goldman-digital-healthcare-is-coming-2015-6?international=true&r=US&IR=T > accessed 6 June 2020.

[44] T.J. McCue, '$117 Billion Market For Internet of Things In Healthcare By 2020' Forbes (22 April 2015) < https://www.forbes.com/sites/tjmccue/2015/04/22/117-billion-market-for-internet-of-things-in-healthcare-by-2020/#32ab298e69d9 > accessed 3 June 2020.

[45] Deloitte Centre For Health Solutions. 'Medtech And The Internet Of Medical Things. How Connected Medical Devices Are Transforming Health Care' (Deloitte, 2018) < https://www2.deloitte.com/content/dam/Deloitte/global/Documents/Life-Sciences-Health-Care/gx-lshc-medtech-iomt-brochure.pdf > accessed 4 June 2020.

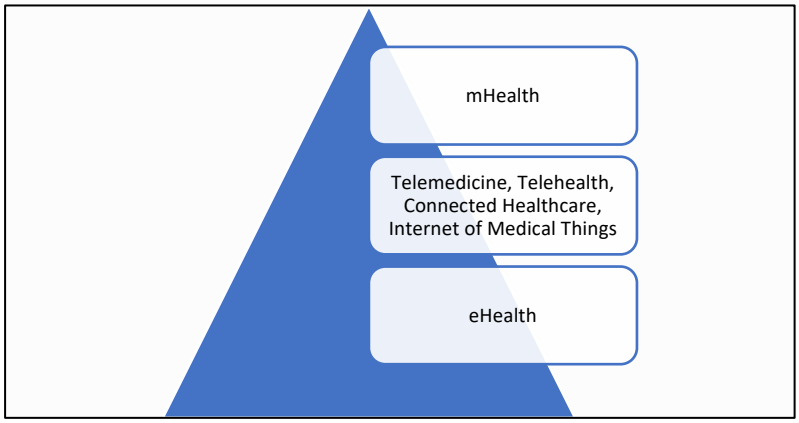

Figure 1. Representation of the connection of the terms on healthcare.

Figure 1 illustrates the diversity of definitions and the direction of development of the mobile healthcare sector. The author suggests using eHealth as an umbrella definition that means the use of the new technologies in all the spheres of healthcare, also in research and education on health. Definition of the eHealth is provided by the WHO and can be used as a starting point of looking at the "electronic" development of the healthcare sector.

1.2. Definition of the mHealth apps

The current mobile application sector is a fast-growing industry. The global mobile applications development market, according to the analysis of Market Research Future, is slated to reach a substantial market valuation and grow at a moderate CAGR[46] of more than 14% over the review period of 2016 to 2022.[47] Mobile applications business started booming since the opening of the app store by Apple and ever since has only been growing.[48] In the 2030 Agenda for Sustainable Development, it is recognized that there is a need to increase access to information and communication technologies significantly.[49] That can be interpreted as meaning that the mHealth apps sector will continue growing as the possibility to contribute the sustainable development goals.

mHealth apps are especially important in developing countries or in countries where it is harder to reach healthcare practitioners. Thus, for example, healthcare apps were used in

[46] Compound annual growth rate.
[47] Press release 'Global Mobile App Development Market Size, Share, Trends, Industry Analysis, Growth Drivers and Opportunities' (MarketWatch, 15 January 2020) < https://www.marketwatch.com/press-release/global-mobile-app-development-market-size-share-trends-industry-analysis-growth-drivers-and-opportunities-2020-01-15 > accessed 5 May 2020.
[48] H. Marston, S. Freeman, C. Musselwhite, Mobile E-Health (Springer, Cham 2017) < https://link.springer.com/content/pdf/10.1007%2F978-3-319-60672-9.pdf > accessed 5 June 2020.
[49] United Nations 'The Sustainable Development Agenda' (United Nations, 2020) < https://www.un.org/sustainabledevelopment/development-agenda/ > accessed 5 June 2020.

Thailand during the treatment of malaria. Compared to paper-based data, the use of the mobile-phone-based data and the use of phones during follow-up doctor visits proved to be highly effective. [50] Healthcare workers in Kenya have also benefitted from mHealth as it has allowed them to collate data and other information that they have obtained during home visitations.[51] Another successful example of the use of mHealth apps in healthcare is speeding up of early infant HIV diagnosis by turning around test results quicker in the SMART project Nigeria.[52]

The definition of mHealth app is not available neither in the laws of the US nor in the laws of the EU. There are, nevertheless, a number of explanatory documents that can be used for the interpretation. Definitions of the guidance documents will be reviewed in closer detail in chapters 2 and 3. At the same time, mobile applications are the primary means by which people interact with both smartphones and tablets. [53]

1.3. Legal problems and the need to regulate the mHealth apps

Traditionally, the regulation of healthcare in the EU started with the regulation of medicines. Technological developments led to the necessity to regulate medical devices, and the regulation of medical devices was developing relatively slow.[54]

The current Medical Device Directive was adopted in 1998 and was not written with software in mind. At the same time, wearables and other medical devices produced by general product manufacturers and mobile application developers have become tremendously popular.[55] The European medical device regulation was drafted with the intent

[50] P. Meankaew, et al, 'Application of mobile-technology for disease and treatment monitoring of malaria in the "Better Border Healthcare Programme"' (2010) 9(237) Malaria Journal < http://www.malariajournal.com/content/9/1/237 > accessed 5 June 2020.

[51] M.W.B. Zhang, R.C.M. Ho, 'M-Health and Smartphone Technologies and Their Impact on Patient Care and Empowerment' In: Menvielle L., Audrain-Pontevia AF., Menvielle W. (eds) The Digitization of Healthcare (2017, Palgrave Macmillan, London) < https://link.springer.com/chapter/10.1057%2F978-1-349-95173-4_16 > accessed 6 June 2020.

[52] R. Istepanian R, B. Woodward, M-Health (John Wiley&Sons, Inc 2019) 87 < https://tinyurl.com/yaccgb4v > accessed 4 June 2020.

[53] E. Mantovani, P. Quinn, B. Guihen, A.K. Habbug, P.J.A. de Hert, 'eHealth to mHealth: A journey precariously dependent upon apps?' (2013) 21 European Journal of General Practice 48.

[54] N. Parvizi, K. Woods, 'Regulation of medicines and medical devices: contrasts and similarities' (2014) 14(1) Clinical medicine 6 <https://doi.org/10.7861/clinmedicine.14-1-6 > accessed 5 June 2020.

[55] M. Contardi'Changes In The Medical Device'S Regulatory Framework And Its Impact On The Medical Device'S Industry: From The Medical Device Directives To The Medical Device Regulations' (2019) 12 (2) Erasmus Law Review 166 < http://www.erasmuslawreview.nl/tijdschrift/ELR/2019/2/ELR-D-19-00012 > accessed 3 June 2020.

to encourage innovation and strengthen the European industry and provide a unified approach, in contrast to the USA, where patient safety concerns motivated device regulation.[56]

The first step in updating of the laws on medical devices was the European Medical Device Directive Amendment 2007/47/EC, which introduced important changes, among others, related to the medical device software development.[57] The amendment provided that software, whether stand alone or incorporated into a medical device, is to be classified as a medical device.

On 10 April 2014, the European Commission launched a public consultation on mobile health, and with respect to the legal framework, a majority of respondents indicated that safety and performance requirements of lifestyle and well-being apps are not adequately covered by the current EU legal framework.[58] Among other points, most of the respondents called for the strengthening of the rules on medical devices. Under the current Medical Device Directive, most "software-based devices" fall under Class I of the Directive, which is the lowest classification class. [59]

As an example, a Research2Guidance Survey data related to China has indicated that 50 percent of respondents think the lack of hardware and software standards is an important factor impeding the development of the mobile medical market. The lack of standards creates uncertainty in the marketplace and makes it more difficult for companies to develop new products and services.[60] Appropriate legislation should give patients, consumers, and healthcare professionals confidence in mobile health apps which they might use every day. Security and privacy issues have to be of core importance in app development.[61]

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[56] R. Galgon, 'Understanding Medical Device Regulation' (2016) 29 (6) Current Opinion in Anaesthesiology 703 < https://oce-ovid-com.tilburguniversity.idm.oclc.org/article/00001503-201612000-00012/HTML > accessed 4 June 2020.

[57] M. McHugh 'How Amendments to the Medical Device Directive Affect the Development of Medical Device Software' (2011) Conference papers of the Technological University of Dublin < https://arrow.tudublin.ie/cgi/viewcontent.cgi?article=1132&context=scschcomcon > accessed 5 June 2020.

[58] European Commission 'Summary Report on the Public Consultation on the Green Paper on Mobile Health' (European Commission, 12 January 2015) < https://ec.europa.eu/digital-single-market/en/news/summary-report-public-consultation-green-paper-mobile-health > accessed 6 June 2020.

[59] R. Istepanian R, B. Woodward, M-Health (John Wiley&Sons, Inc 2019) 87 < https://tinyurl.com/yaccgb4v > accessed 4 June 2020.

[60] Xiaohui Yu, and others. 'mHealth in China and the United States: How Mobile Technology is Transforming Health Care in the World's Two Largest Economies' (Center for Technology Innovation at Brookings, 12 March 2014) < https://www.brookings.edu/wp-content/uploads/2016/06/mHealth_finalx.pdf > accessed 6 June 2020.

[61] H. Papadopoulos, et all 'Comparison of US and EU Regulatory Approaches to Mobile Health Apps: Use Cases of myVisionTrack and USEFIL' (2013) 21 The European Journal of ePractice 27 < https://joinup.ec.europa.eu/sites/default/files/document/2014-06/ePractice-Journal-Vol.21-December%202013.pdf > accessed 7 June 2020.

The need to consolidate and simplify the existing regulatory framework in the EU has emerged. A regulation rather than a directive helps to have a unified regulatory approach at the whole EU level. It will ensure that there are fewer cases when manufacturers would intentionally register their devices in the EU states with weaker regulation, still acquiring access to the whole EU market.[62]

The 2010-2011 the Poly Implant Protheses scandal (on faulty implantable breasts as medical "device") was a key trigger for the review of the Medical Device Directive and current adoption of the EU MDR.[63]

The EU and the US represent the two important medical device markets in the world.[64] The mHealth Regulatory Coalition, an industry group that has been active in engaging FDA on evolving mobile health policies, was extending its efforts to European Union assisting with developing of the new drafts of the Medical Device Regulation. [65] In the following chapters, changes to the current EU regulation will be reviewed in detail, as well as compared to the existing US model.

The new EU MDR was adopted in 2017 and was supposed to come into force in May 2020. On 23 April 2020, the entry into force of the EU MDR was officially extended by one year, until 26 May 2021.[66]

1.4. Conclusion

The healthcare sector is opening up to innovation as the mHealth apps start playing a more important role. New definitions such as "Connected Healthcare" and "Internet of Medical Things" have significant overlap with the other more established definitions such as

[62] Concerns had been raised by both EU regulators and market participants that the current regulatory framework did not ensure consistency across EU member states. See more at: B. Daigle, M. Torsekar, 'The EU Medical Device Regulation and the U.S. Medical Device Industry' (2019) 2019 J Int'l Com & Econ 1.

[63] Additional information on the scandal see at: C. Frumento, 'French breast implants, the Medical Device Regulation, and a theoretical case study' (2017) 26(2) Medical Writing journal < https://pdfs.semanticscholar.org/3d40/97ad10ee00b48acf8f28f4860649499e6af6.pdf > accessed 4 June 2020.

[64] The countries with best market conditions for digital health solutions are the USA, the UK and Germany. The USA (67%) is leading far ahead. The mentioned top 3 countries are followed by Israel (16%), Canada (14%). See more in the Report 'How digital intruders are taking over the healthcare market'. (Research2Guidance, mHealth App Economics 2017) < https://research2guidance.com/product/mhealth-economics-2017-current-status-and-future-trends-in-mobile-health/ > accessed 5 May 2020.

[65] D. Tahir, 'European Regulation Looms Over Mobile Health' (2013) 39 (11) Elsevier Business Intelligence "The Gray Sheet" < http://static.basenet.nl/cms/106131/website/Publications-2013/The%20Gray%20Sheet.pdf > accessed 6 June 2020.

[66] Regulation 2020/561 amending Regulation (EU) 2017/745 on medical devices, as regards the dates of application of certain of its provisions [2020] L 130/18 < https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32020R0561&from=EN > accessed 7 June 2020.

"Telemedicine." At the same time, all these definitions indicate the direction of development of the mobile healthcare sector. "Overcoming distance," "contributing to the health of the society with lower costs," "use of the new technologies to provide care to patients more effectively" are the words being used in the definitions that are in line with the UN sustainable goal on making healthcare more accessible.

There are already successful examples of the use of mHealth apps in developing countries which allows having better access to healthcare.

At the same time, currently existing or upcoming law of the EU on medical devices does not have a definition on the mHealth apps. Regulation of healthcare started, traditionally, with the adoption of the laws on medicines, and, as technological advancements happened, transferred to the medical devices. Public opinions often show that legislation needs further updates to ensure trust in the emerging mHealth technologies.

The most recent update of the existing regulation on medical devices in the EU was triggered by a number of issues. Changes introduced by the EU MDR that have an effect on the mHealth apps will be reviewed in the next chapters.

Chapter 2: Overview of the upcoming EU Medical Device Regulation

In this chapter, the author reviews the scope of application of upcoming EU MDR, the definition of the medical device under the new EU MDR, and to what extent it covers mHealth apps, consequences of the mHealth app being marked as a medical device under one of the classes. In conclusion, the author reviews the changes in the regulatory regime concerning the mHealth apps.

2.1. Scope of application of the EU MDR

The new EU MDR will replace the existing Medical Devices Directive. The EU MDR will lay down the rules for the use of the medical devices and accessories for such devices in the European Union.[67]

Since EU MDR is a regulation, new requirements of such will directly apply in the territory of EU member states, without the need for separate implementation in the member states of the EU.

The regulation lays down the rules concerning the "*placing on the market, or making available medical devices in the EU.*"[68] Therefore, in case the mHealth app is expected to be used in the EU, and is considered to be a "*medical device for human use and accessory for such device,*" the developer of such mHealth app needs to ensure compliance with the EU MDR. The definitions of "*medical device*" and "*accessory*" are reviewed further in the text.

"Medical devices" intended for use in the EU fall within the scope of application of the EU MDR. An app developed outside of the EU would still need to comply with the EU MDR. The fact that the apps available on the internet can be accessed from anywhere in the world makes it hard to ensure that only adequately certified apps are made available to European consumers.[69]

[67] Art. 1, EU MDR.
[68] Ibid.
[69] A. Drongelen, et all, 'Apps under the medical devices legislation' (2019) National Institute for Public Health an Environment of the Netherlands research < https://www.rivm.nl/bibliotheek/rapporten/2018-0083.pdf > accessed 6 June 2020.

Currently, app stores that make mobile applications available on the market, do not check the compliance of the mHealth apps with necessary regulatory requirements.[70] While online mobile applications stores request some essential requirements to be fulfilled, these do not relate to the requirements on EU MDR or other safety requirements.[71]

2.2. Definition of the "medical device" under the EU MDR

Article 1 of the EU MDR specifically indicates the cases to which the EU MDR does not apply. For example, cosmetic products, or advanced therapy medicinal products covered by Regulation (EC) No 1394/2007 [72] do not fall under the scope of the EU MDR. Mobile phone applications, or mHealth apps, are not on the list.

Article 2 of the EU MDR defines the medical device as follows: "*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 (as defined in the regulation) and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means."*

Therefore, for a mHealth app to be considered a medical device, it has to be (1) a "software," and it has to be (2) "intended" by the manufacturer to be used for specific medical purposes, as provided in the regulation.

Recital 19 of the EU MDR provides an additional explanation to what types of software are not considered to be medical devices, in particular, "*software for general purposes even when used in a healthcare setting, or software indented for lifestyle and well-being purposes.*"[73]

Both articles 2 and recital 19 have definitions of "software," which raises the question of whether a mobile phone app can be considered a "software."

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[70] Ibid.
[71] M.J. Lieshout., et all 'Final study report regarding safety of health, lifestyle and wellbeing apps' (TNO 2019 R10103, European Commission report 2019) < https://ec.europa.eu/digital-single-market/en/news/safety-non-embedded-software-including-safety-health-lifestyle-and-wellbeing-apps > accessed 5 accessed 5 June 2020.
[72] Art. 1, p. 6 EU MDR.
[73] Recital 19, EU MDR.

2.2.1. Definition of software

The definitions section (article 2) of the EU MDR does not define "software." Chapter II of the EU MDR already provides the rules about software classification; for example, "*if the software is independent of any other device, it shall be classified in its own right*."

The Medical Device Directive was drafted without software in mind and was updated to cover the regulation of software as the market was expanding.[74] A guidance document provides additional guidance on "software" under the Medical Device Directive: Guidance Document MEDDEV 2.1/6. This document was adopted to clarify the provisions of the currently existing MDD and defines stand-alone software. In the Guidance Document MEDDEV 2.1/6, "software" is defined as a "*set of instructions that processes input data and creates output data."* Stand-alone software means "*software which is not incorporated in a medical device at the time of its placing on the market or its making available.*" The definition does not refer to apps that are used on mobile phones. At the same time, mHealth apps are considered to be stand-alone software under the guidance document, since it explicitly indicates that "*the criteria specified in this document apply also to mobile applications.*"[75] Similar sentence "the criteria specified in this document shall also apply to applications, commonly referred to as apps" is also indicated in the 2019 document adopted by the Medical Device Coordination Group to provide clarifications on EU MDR.[76] Therefore, it is well-accepted that certain mobile apps might qualify as regulated medical devices if they meet the necessary conditions.[77]

In addition, to illustrate the definition that mHealth apps are a stand-alone software, the interpretation of certain European countries is reviewed.

Thus, in the UK, the "Guidance on Medical device stand-alone software including apps" is published on the national agency's web page.[78] In Germany, the Federal Institute for Drugs and Medical Devices in the Guidance on Medical apps indicates that "stand-alone software

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[74] A. Drongelen, et all, 'Apps under the medical devices legislation' (2019) National Institute for Public Health an Environment of the Netherlands research < https://www.rivm.nl/bibliotheek/rapporten/2018-0083.pdf > accessed 6 June 2020.

[75] Page 3, Guidance Document MEDDEV 2.1/6.

[76] Medical Device Coordination Group, MDCG 2019-11, Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745- MDR and Regulation (EU) 2017/746 [2019] < https://ec.europa.eu/docsroom/documents/37581 > accessed 10 June 2020.

[77] B. Kelly, et all 'EU Updates MEDDEV 2.1/6 Guidance on Standalone Software' (Covington & Burling LLP, 5 August 2016) < ttps://www.covingtondigitalhealth.com/2016/08/new-eu-medical-device-guidance-on-standalone-software/ > accessed 5 June 2020.

[78] Guidance, 'Medical devices: software applications (apps)' (GOV.UK, 8 August 2014) < https://www.gov.uk/government/publications/medical-devices-software-applications-apps > accessed 6 June 2020.

like smartphone apps can indeed be classified as a medical device."[79] In the Netherlands, the National Institute for Public Health and the Environment, in its recent research, analyzed the compliance of mobile apps with the new EU MDR.[80]

EU MDR does not have any additions regarding the software or qualification of the mHealth apps. Existing guidelines might need to get updated with new classification advice. At the same time, since the definition of apps being "software" is not amended under EU MDR, not much change can be expected.

Therefore, mHealth apps are stand-alone software that can be considered a medical device under a new EU MDR.

2.2.2. Intended purpose

The second element that needs to be analyzed to find whether a mHealth app is a medical device is the "intended purpose."

When reviewing the language of Article 2 with the definition of the medical device, it is noted that the definition uses the word "intended": "*any software…**intended** by the manufacturer to be used*…[emphasis added]". The same word is used in recital 19, which states that "*software… **intended by** the manufacturer to be used for one or more of the medical purposes set out in the definition of a medical device, qualifies as a medical device, while software for general purposes, even when used in a healthcare setting … is not a medical device*…[emphasis added]."

Therefore, the intended use of the software and not its actual use is essential in determining whether the software is a medical device. Therefore, not all software that is used in a healthcare setting or which interacts with medical devices will be considered a medical device.[81]

Based on the analysis of the EU MDR and available guidance documents, these are the following intended uses that the developers of MHealth apps could consider:

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[79] Federal Institute for Drugs and Medical Devices (Germany) 'Guidance on "Medical Apps"' (Federal Institute for Drugs and Medical Devices, 11 November 2015) < https://www.bfarm.de/EN/MedicalDevices/Differentiation/MedicalApps/_artikel.html > accessed 6 June 2020.

[80] A. Drongelen, et all, 'Apps under the medical devices legislation' (2019) National Institute for Public Health an Environment of the Netherlands research < https://www.rivm.nl/bibliotheek/rapporten/2018-0083.pdf > accessed 6 June 2020.

[81] S. Hanson, et all 'Digital Health - The new regulation of medical software and apps' (CMS Cameron McKenna Nabarro Olswang LLP, 13 December 2018) < https://www.cms-lawnow.com/ealerts/2018/12/digital-health?cc_lang=en > accessed 24 May 2020.

1. Apps for general use.
2. Apps for medical purposes.
3. Wellness and well-being apps.
4. App as an accessory to a medical device.

2.2.2.1. Apps with the general purpose

Some apps have no medical purpose. As stated previously, under recital 19 of EU MDR, such mHealth apps will not be medical devices under EU MDR. Therefore, under the Guidance Document MEDDEV 2.1/6. drafted in the interpretation of the MDD, *" if the software does not perform an action on data, or performs an action limited to storage, archival communication, 'simple search' or lossless compression (i.e., using a compression procedure that allows the exact reconstruction of the original data) it is not a medical devic*e." [82]

On 7 December 2017, the Court of Justice of the European Union (CJEU) rendered its judgment in case C-329/16, where it was confirmed that the essential criteria for the software to be classified as a medical device are the intended use of such software.[83] The software in the case was not found to be a medical device, since "*while intended for use in a medical context, has the sole purpose of archiving, collecting and transmitting data."*

Only mHealth apps that perform any action on data (i.e., more than only storing data and/or communicating data) are considered to be medical devices. Therefore, an app that provides "simple search," which refers to the retrieval of records by matching record metadata against record search criteria or to the retrieval of information, does not qualify as medical device software (e.g., library functions). [84]

Therefore, even when performing an action on the data and used in the medical environment, apps with general purpose might not fall under the scope of EU MDR as a medical device. The Manual on the Borderline Products provides several examples of such apps.[85] One of them is the app with the intended use to improve the quality of communication between the patient and caregivers. Therefore, even though such an app is

[82] Page 11, Guidance Document MEDDEV 2.1/6.
[83] Case C.329/16 Snitem - Syndicat national de l'industrie des technologies médicales [2017] Judgment of the Court (Fourth Chamber) < http://curia.europa.eu/juris/liste.jsf?language=en&num=C-329/16 > accessed 6 June 2020.
[84] Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745-MDR and Regulation (EU) 2017/746-IVDR. [2019] < https://ec.europa.eu/docsroom/documents/37581 > accessed 6 June 2020.
[85] Example 9.2., Manual on Borderline and Classification in the Community Regulatory Framework for Medical Devices. Version 1.22 [2019] < https://ec.europa.eu/docsroom/documents/35582 > accessed 6 June 2020.

used in the medical environment, it performs an action on data limited to storage and simple search, and (under the recommendation is not qualified as a medical device.

2.2.2.2. Apps with medical purposes.

"*Medical purposes*" of MHealth apps are identified in Article 2 of the EU MDR. They are as follows:

> *" diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,*
>
> *diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,*
>
> *investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,*
>
> *providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations*".[86]

It is important to note that the definition of "medical purposes" in the EU MDR is almost identical to the definition of "medical purposes" under the Medical Device Directive.

Comparison between the old and the new definitions of medical purposes (new language in ***bold italic***) shows the following changes:

- diagnosis, prevention, monitoring, ***prediction, prognosis***, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, ***alleviation*** of, or compensation for, an injury or ***disability,***
- investigation, replacement or ***modification*** of the anatomy or of a physiological ***or pathological*** process ***or state,***
- ***providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,***

Further adding of the language on "prediction" and "prognosis" in the first line will be reviewed in greater detail. Adding the language on "prediction" and "prognosis" can be a crucial addition since it expands the scope of the definition. For example, that could mean

[86] Art. 2, EU MDR.

that an app designed to predict a patient's likelihood of developing a particular disease will now fall squarely within the definition of a medical device because such a mobile application will be performing "prediction."[87]

In order to assist with determining whether the apps are medical devices under the EU MDR, several new decision trees have already been developed.[88]

Correct assessment requires enough consideration. For example, an app to prevent sunburn is not considered to be a medical device, as prevention of an injury is not within the definition of a medical device from the MDD and MDR, contrary to the prevention of disease.[89]

2.2.2.3. Apps with the well-being purposes

EU MDR does not define apps with "lifestyle and well-being purposes." At the same time, the distinction between "medical purpose" and software "for lifestyle and well-being purposes" is essential. As stated in recital 19 of the EU MDR, apps with the lifestyle and well-being purposes are not medical devices. There is no additional clarification on the distinct difference between lifestyle purpose or medical purpose. Interpretation is up to the app developers based on the functionality they intend for their mHealth app.

The Manual on Borderline Product provides several examples of the apps and the ways to qualify them. It currently provides no examples on the apps that could be considered "well-being" apps, even though it provides some apps that are qualified as the "general purpose" apps instead.[90]

The study published on the website of the European Commission indicates that well-being and lifestyle apps are one of the most widely used in the mHealth apps sector.[91] Further,

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[87] S. Hanson, et all 'Digital Health - The new regulation of medical software and apps' (CMS Cameron McKenna Nabarro Olswang LLP, 13 December 2018) < https://www.cms-lawnow.com/ealerts/2018/12/digital-health?cc_lang=en > accessed 24 May 2020.

[88] For example, the following decision trees: (1) A. Drongelen, et all, 'Apps under the medical devices legislation' (2019) National Institute for Public Health an Environment of the Netherlands research < https://www.rivm.nl/bibliotheek/rapporten/2018-0083.pdf > accessed 6 June 2020; (2) page 9, Guidance Document MEDDEV 2.1/6.

[89] A. Drongelen, et all, 'Apps under the medical devices legislation' (2019) National Institute for Public Health an Environment of the Netherlands research < https://www.rivm.nl/bibliotheek/rapporten/2018-0083.pdf > accessed 6 June 2020.

[90] Manual on Borderline and Classification in the Community Regulatory Framework for Medical Devices. Version 1.22 [2019] < https://ec.europa.eu/docsroom/documents/35582 > accessed 6 June 2020.

[91] M.J Lieshout, et all 'Final study report regarding safety of health, lifestyle and wellbeing apps' (TNO 2019 R10103, European Commission report 2019) < https://ec.europa.eu/digital-single-market/en/news/safety-non-embedded-software-including-safety-health-lifestyle-and-wellbeing-apps > accessed 5 accessed 5 June 2020.

the author will review in greater detail if the addition of the new language to the EU MDR can affect how mHealth apps are regulated.[92]

2.2.2.4. Accessory to a medical device

Another important definition is "accessory to a medical device." The definition is also provided in Article 2 of the EU MDR.

It is crucial to identify whether a mHealth app is an accessory to a medical device, since in such cases, even if the mHealth app is not a medical device, provisions of the EU MDR might apply to such mobile application.

2.3. What are the consequences of being marked as class I, II, or III

Therefore, in case the mHeath app has one or more of the medical purposes as defined above, such app will be considered a medical device and will need to be classified under one of the existing classes.

A new rule 11 is added to EU MDR. Under this rule, all the software with medical purposes will fall under class I, IIa, IIb, or III. The classification is based on the risk-based approach: the class that the mHealth app is assigned depends on the impact the mHealth app might have on the health of the individual. Besides a few exceptions, most medical apps are classified as class I so far. There is a discussion that with the upcoming MDR is that this will change, and every class I medical app will shift up to either class IIa or IIb.[93]

Under the existing medical device directive, the mHealth apps are classified based on the purpose. The significant impact of the EU MDR is that now mHealth apps will be classified both based on **purpose** *and* **risk assessment** and not based on purpose alone, which can have implications for medical apps. For example, an app that collects and transmits blood pressure and heart rate data with the intended use of assisting in the management of heart disease could be categorized as a class I device based on the current regulations but could be considered a class IIb when risk assessment is taken into account.[94]

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[92] See Chapter 4 for additional practical research on the qualification of the mHealth apps as medical apps and wellbeing apps.

93 P. Werner, 'Classification of medical apps under MDR — it's not the end of the world' (Medium, 12 February 2009). < https://medium.com/@pascalwerner/classification-of-medical-apps-under-mdr-its-not-the-end-of-the-world-d7a1ce4b577b > accessed 6 June 2020.

[94] H. Akker van den, 'Medical Apps Under The New European MDR' (CRO for Medical Devices and IVDs | Factory CRO, 2017) < https://www.factory-cro.com/news/medical-apps-under-the-new-european-medical-device-regulation/ > accessed 2 June 2020.

A research performed by the National Institute for Public Health and the Environment of the Netherlands in 2018[95] has shown that at least one app was classified as Class I under the MDD, but will be a Class III medical device under the MDR: an app predicting the three-month mortality risk in patients with chronic liver disease. This score is used for prioritization of donor organ allocation to patients awaiting liver transplantation. The research has shown that the change in the definition will lead to up-classification for a considerable number of apps, especially apps that are currently classified as Class I and, to a lesser extend, Class IIa.[96]

The new Rule 11 provides the following classification:

- *Class IIa software:*
    - *Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes;*
    - *Software intended to monitor physiological processes.*
- *Class II b software:*
    - *Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes and if such decisions have an impact that may cause a serious deterioration of a person's state of health or a surgical intervention;*
    - *Software intended to monitor physiological processes and is intended for monitoring of vital physiological parameters, where the nature of variations of those parameters is such that it could result in immediate danger to the patient.*
- *Class III software:*
    - *Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes; and if such decisions have an impact that may cause death or an irreversible deterioration of a person's state of health.*
- *Class I software: any other software.*

Once it is determined that a mobile app is a medical device under the EU MDD, necessary certification can be obtained. After reviewing the EU MDR requirements, the technical documentation needs to be compiled by the mHealth app manufacturer. The Notified

[95] A. Drongelen, et all, 'Apps under the medical devices legislation' (2019) National Institute for Public Health an Environment of the Netherlands research < https://www.rivm.nl/bibliotheek/rapporten/2018-0083.pdf > accessed 6 June 2020.
[96] Ibid.

Bodies review the documentation and audit the manufacturer to ensure compliance before the product can be distributed on the market. Class I devices are self-certified and do not require an audit by the Notified Body. New EU MDR has strengthened the requirements to the technical dossier that needs to be collected and extended the requirements for the post-market surveillance.[97] Obtaining the CE mark for higher-class devices has a more significant regulatory load for the mHealth app developer. [98]

The EU has consistently ranked favorably as having a relatively short time to market-three to nine months-for high-risk devices. Therefore, in the future, it can be monitored if the new procedure will affect these deadlines.[99]

2.4. Conclusion. Comparison of the new EU MDR with the existing MDD

After reviewing the provisions of the upcoming EU MDR, as well as existing guidelines and explanations for the MDD, the author has identified the key elements which are of importance for software developers when determining whether the mHealth app is a medical device under the new EU MDR.

The changes relevant for mHealth developers between EU MDR and MDD are summarized in the following table.

Issue	**Medical Device Regulation (upcoming)**	**Medical Device Directive (currently in effect)**
Definition of software	No definition of software. Additional EU guidance is to be looked into for clarification. It is acknowledged that mobile applications are software.	

[97] General overview on the changes related to the EU MDR can be found in the summary article: B. Daigle, M. Torsekar, 'The EU Medical Device Regulation and the U.S. Medical Device Industry' (2019) 2019 J Int'l Com & Econ 1.

[98] For example, Notified Body needs to be involved, stricter Quality Management System requirements, stricter requirements for design documentation. See more at: H. Akker van den, 'Medical Apps Under The New European MDR' (CRO for Medical Devices and IVDs | Factory CRO, 2017) < https://www.factory-cro.com/news/medical-apps-under-the-new-european-medical-device-regulation/ > accessed 2 June 2020.

[99] For example, under the MDR, more advanced products that fall into classes II or III will be required to undergo at least yearly assessments of their products' operation in the EU market, as well as any developments that may impact the effectiveness or health outcomes of their devices (including developments that occurred outside the EU market). These new requirements for more advanced devices will also necessitate the collection of greater levels of data and increased transparency relative to U.S. regulations and previous EU regulations. See more at: B. Daigle B., M. Torsekar, 'The EU Medical Device Regulation and the U.S. Medical Device Industry' (2019) 2019 J Int'l Com & Econ 1, 1.

	A new rule 11 on the classification of software is added, which provides additional clarity on certification of mHealth apps.[100]	
Definition of the medical purpose	Now EU MDR applies to software for prediction and prognosis, which might extend the scope of application of the regulation.	
	Comparison of the language (new language added in bold) diagnosis, prevention, monitoring, ***prediction, prognosis***, treatment or alleviation of disease, • diagnosis, monitoring, treatment, ***alleviation*** of, or compensation for, an injury or ***disability***, • investigation, replacement or ***modification*** of the anatomy or of a ***physiological*** or pathological process ***or state***, • ***providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,***	
Well-being and Lifestyle apps	No definition.	

The new EU MDR has no provision that allows currently certified medical device manufacturers to retain their certification. All currently certified medical devices will need to be recertified in accordance with the new requirements. It can be reviewed in the future

[100] Roughly 20% of the apps found in the study conducted in 2019 were judged to be medical devices. For more than 50% of these apps, it was not clear whether the apps were CE-marked. A considerable part of the apps that are medical devices will be up classified as a consequence of the transition from MDD to MDR. See more at: A. Drongelen, et all, 'Apps under the medical devices legislation' (2019) National Institute for Public Health an Environment of the Netherlands research < https://www.rivm.nl/bibliotheek/rapporten/2018-0083.pdf > accessed 6 June 2020.

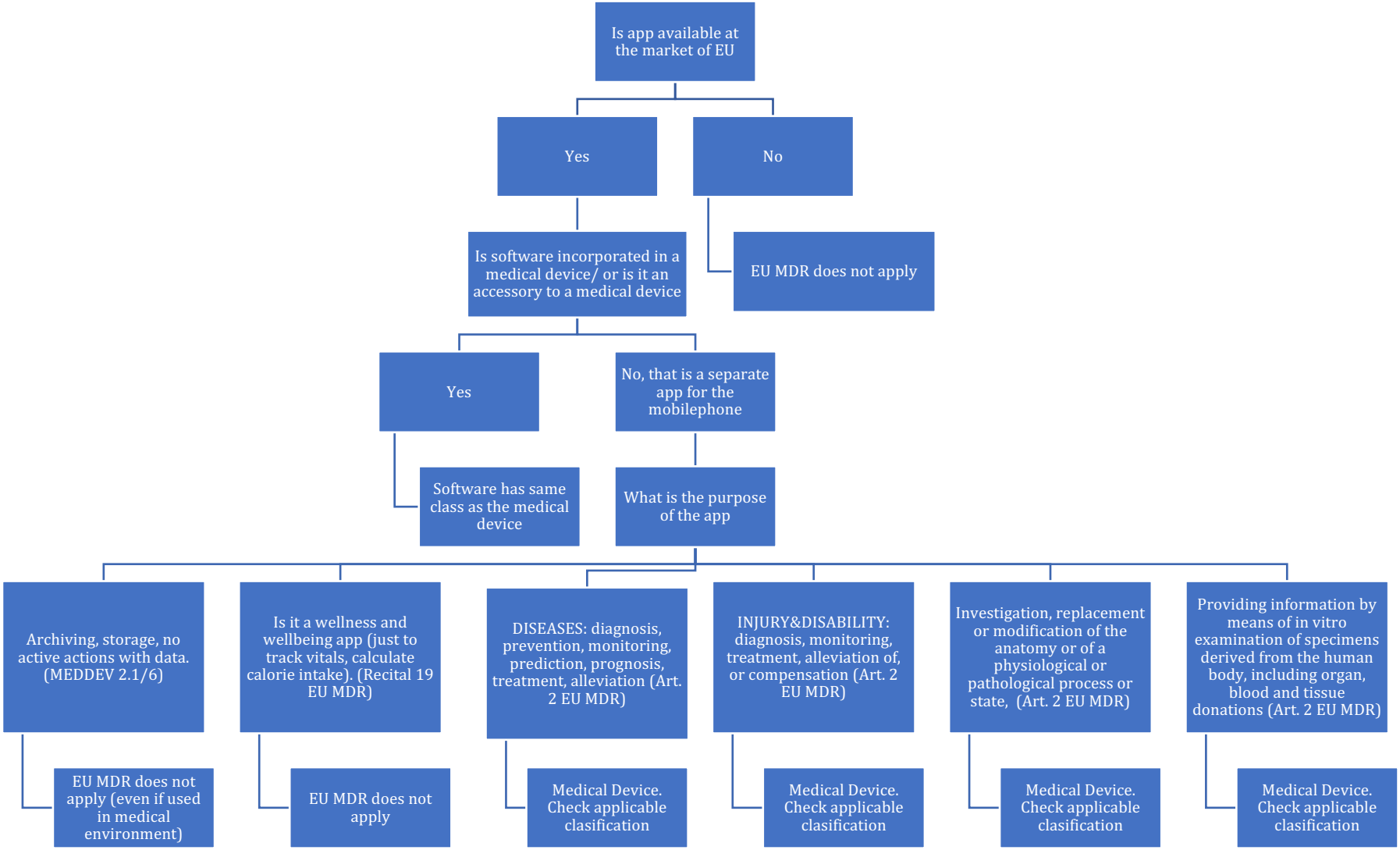
whether the stricter certification rules affect the length of the procedure and whether the EU became less attractive for obtaining the medical device certification.

Upon review, not many significant changes for mHealth apps were identified.

1) Adding the language on the "prediction and prognosis" may extend the scope of application of the EU MDR.
2) Adding Rule 11 to the text of the EU MDR, on the one hand, adds additional clarity, at the same time, it may lead to the higher risk classification of the mHealth app.
3) Additional guidance is needed about a distinction between well-being and lifestyle app, since that may affect the application of EU MDR.
4) The certification process has changed, making it harder for all medical devices (not only mHealth apps) to get a certification.

The decision tree that can be used by software developers to determine whether their software falls under the provisions of EU MDR is as follows:[101]

[101] Decision tree is based on the analysis of Chapter 2, in particular: EU MDR, Guidance Document MEDDEV 2.1/6.


Is app available at the market of EU
Yes
No
EU MDR does not apply
Is software incorporated in a medical device/ or is it an accessory to a medical device
Yes
No, that is a separate app for the mobilephone
Software has same class as the medical device
What is the purpose of the app
Archiving, storage, no active actions with data. (MEDDEV 2.1/6)
EU MDR does not apply (even if used in medical environment)
Is it a wellness and wellbeing app (just to track vitals, calculate calorie intake). (Recital 19 EU MDR)
EU MDR does not apply
DISEASES: diagnosis, prevention, monitoring, prediction, prognosis, treatment, alleviation (Art. 2 EU MDR)
Medical Device. Check applicable clasification
INJURY&DISABILITY: diagnosis, monitoring, treatment, alleviation of, or compensation (Art. 2 EU MDR)
Medical Device. Check applicable clasification
Investigation, replacement or modification of the anatomy or of a physiological or pathological process or state, (Art. 2 EU MDR)
Medical Device. Check applicable clasification
Providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations (Art. 2 EU MDR)
Medical Device. Check applicable clasification

Chapter 3.
Overview of the regulation in regard to mHealth apps in the US

In this chapter, the author is reviewing the historical context of the regulation currently existing in the US, the definition of the mHealth app that may fall under the regulation in the US, and the consequences of mHealth apps being classified as the medical device in the US. The comparison is made with the EU.

3.1. Historical context and regulation of the mHealth apps in the US

In the United States, the regulation on medical devices is provided by the FDA. The FDA carries out its mission through three means: laws, regulations, and guidance documents. Laws are congressionally mandated, whereas regulations are rules published directly by the FDA. Guidance documents outline the policy of the FDA on a variety of topics, and they serve an educational purpose.[102]

The FDA takes an active approach in regulation and pays interest to the development of the use of the mHealth, as well as encourages the development of the new mHealth apps.[103]

Currently, federal and state laws of the US do not provide binding rules regarding mHealth apps in particular, despite the historical involvement of the FDA into mHealth and understanding the importance that mHealth apps have on the market.

The FDA first discussed its approach to regulating software in a 1989 draft policy document entitled "*FDA Policy for the Regulation of Computer Products 11/13/89" (**1989 Computer Regulation**)*. The FDA never codified or formalized the 1989 Computer Regulation. In 2005, the FDA formally withdrew the 1989 draft policy without comment. [104] Between 1989 and 2005, when the 1989 Computer Regulation was adopted, and the moment it was withdrawn, technology has changed drastically. For example, the use of smartphones

[102] B. Borel, 'Health Policy Brief: Mhealth And FDA Regulations' (2013) HealthAffairs Online Journal < https://www.healthaffairs.org/do/10.1377/hpb20131205.399529/full/> accessed 3 June 2020.
[103] FDA, 'Device Software Functions Including Mobile Medical Applications' (FDA, 11 May 2019) < https://www.fda.gov/medical-devices/digital-health/device-software-functions-including-mobile-medical-applications#a > accessed 6 June 2020.
[104] S. Danzis, C. Pruitt, 'Rethinking The FDA 'S Regulation Of Mobile Medical Apps' (2013) 9(3) SCITECH LAW < https://www.cov.com/~/media/files/corporate/publications/2013/02/rethinking_the_fdas_regulation_of_mobile_medical_apps.pdf> accessed 4 June 2020.

became more widespread in the late 2000s. In 2008, the Apple App Store was launched, which revolutionized the way the users interact with their phones.[105] In 2011, the FDA stated it could not adopt a single software or computer policy to address every kind of software or computer-driven medical device.[106]

In July 2011, the FDA released its first draft guidance explicitly addressing mobile medical applications, titled "*Draft Guidance for Industry and Food and Drug Administration Staff Mobile Medical Applications.*" The Guidance was adopted in its final form in September 2013 and was updated in 2015 and 2019, now known as "*The Policy for Device Software Functions and Mobile Medical Applications Guidance" **(2019 Policy)***. [107]

The 2019 Policy is not binding on the FDA or the public and provides only the additional clarifications of FDA on the existing regulations. *[108]* Even so, it is a valuable communication to inform the public of the approach of the FDA to mobile application regulation. [109]

For example, the 2019 Policy provides three primary definitions relevant for this thesis: Mobile Platform, Mobile Application (Mobile App), Mobile Medical Application (Mobile Medical App).

The primary document regulating medical devices is Section 201(h) of the Food, Drug, and Cosmetic Act, with the 2019 Policy providing additional clarifications. In further research, it can be suggested to review to what extent the market can rely on the 2019 Policy released by the FDA since that is not a binding document.

The Cures Act signed into law on December 13, 2016[110] made some changes to the binding Food, Drug, and Cosmetic Act, therefore is also important for regulatory requirements. FDA already confirmed that they plan to take a more relaxed approach towards lower-risk

[105] S. Silver, 'Apple details history of App Store on its 10th Anniversary' (Apple Insider Journal, 5 July 5, 2018) < https://appleinsider.com/articles/18/07/05/apple-details-history-of-app-store-on-its-10th-anniversary > accessed 6 June 2020.
[106] V.J. Roth, 'The mHealth Conundrum: Smartphones & Mobile Medical Apps—How Much FDA Medical Device Regulation is Required?' (2014), 15 (3) The North Carolina Journal of Law & Technology 359 (2014) < http://ncjolt.org/wp-content/uploads/2014/04/Roth-Color-Final.pdf > accessed 5 June 2020.
[107] Policy for Device Software Functions and Mobile Medical Applications. Guidance for Industry and Food and Drug Administration Staff [2019] < https://www.fda.gov/media/80958/download > accessed 6 June 2020.
[108] Ibid.
[109] R. Sekaran, M. Chuang, 'FDA Policy for Mobile Medical Applications', (Nossaman LLP, 14 February 2020) < https://www.thehealthlawticker.com/fda-policy-for-mobile-medical-applications > accessed 6 June 2020.
[110] FDA '21st Century Cures Act' (U.S. Food&Drug Administration, 31 January 2020), < https://www.fda.gov/regulatory-information/selected-amendments-fdc-act/21st-century-cures-act > accessed 6 June 2020.

technologies, the update provided in line with the 21st Century Cures Act helped was important in making the provision a law.[111]

Currently, with the 2019 Policy, the FDA claims to have developed the Agency's mobile medical apps policy to protect public health and promote innovation and does not plan on becoming more involved.[112]

The territorial scope of Section 201 (h) is not expressly defined in Section 201 (h). The FDA adopted the FDCA, the purpose of which is ensuring public health, and the FDA is a US state agency. Therefore, it can be concluded that every mHealth app manufacturer that intends to offer its app to the US market might need to consider whether FDA approval is necessary.

3.2. mHealth app as a medical device under the definition from FDA

In order to understand which mHealth apps fall under the definition of the medical devices in the US, the definition of the "mobile medical app" under the 2019 Policy needs to be reviewed, along with the review of the existing exceptions to the rule.

3.2.1. Intended use

In the US, similar to the EU, "intended use" is important in defining whether the mHealth app falls under the regulations. The FDA generally determines the intended use of a product according to the promotional claims made by the manufacturer or other party legally responsible for the labeling of the product. [113] Intended use may be shown by labeling claims, advertising materials, or oral or written statements by manufacturers or their representatives.[114]

The current regulatory landscape for medical devices, with its focus on intended use rather than actual use, seems to provide a loophole for mobile devices because there is no gatekeeping through prescriptions or pharmacies for mobile medical applications.[115] Since

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[111] FDA 'Digital Health Innovation Action plan' (U.S. Food&Drug Administration, 26 March 2020) < https://www.fda.gov/medical-devices/digital-health > accessed 6 June 2020.

[112] S.J. Kilker, 'Effectiveness of Federal Regulation of Mobile Medical Applications' (2016) 93 (5) Washington University Law Review< https://openscholarship.wustl.edu/cgi/viewcontent.cgi?article=6220&context=law_lawreview > accessed 5 June 2020.

[113] S. Danzis, C. Pruitt, 'Rethinking The FDA 'S Regulation Of Mobile Medical Apps' (2013) 9(3) SCITECH LAW < https://www.cov.com/~/media/files/corporate/publications/2013/02/rethinking_the_fdas_regulation_of_mobile_medical_apps.pdf > accessed 4 June 2020.

[114] As stated in 21 Code of Federal Regulations (CFR) 801.4. See more at: B.A. MacFarlane, FDA Regulation Of Mobile Medical Apps. Whitepaper #3 (2014) < https://www.namsa.com/wp-content/uploads/2015/10/WP-FDA-Regulation-of-Mobile-Medical-Apps-7-7-2014.pdf > accessed 3 June 2020.

[115] V.J. Roth, 'The mHealth Conundrum: Smartphones & Mobile Medical Apps—How Much FDA Medical Device Regulation is Required?' (2014), 15 (3) The North Carolina Journal of Law & Technology 359 (2014) < http://ncjolt.org/wp-content/uploads/2014/04/Roth-Color-Final.pdf > accessed 5 June 2020.

mHealth app developers are responsible for defining the "intended use" of the mHealth app, mHealth developers may be trying to avoid the liability by adding disclaimers, for example, "not intended for use as a medical device." [116] In the US, similar to the EU, it is unclear which consequences can wait for developers if the FDA determines the app is marketed as a to avoid legal and regulatory liability. Liability for the wrongful marking of the intended use of the mHealth apps can be further researched by scholars.

3.2.2. Definition of the mHealth app that can be classified as a medical device

Under the 2019 Policy, a "mobile medical app" is a mobile app that "meets the definition of device in Section 201 (h) of the FDCA" and is intended either:

a) to be used as an accessory to a regulated medical device;

b) or to transform a mobile platform into a regulated medical device. [117]

Section 201 (h) of the FDCA provides a definition of the device. To be a device, the mHealth apps has to be *"recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them*," and have the intended use either as the "*diagnosis of disease or other conditions, or the cure, mitigation, treatment, or prevention of disease"* or *"affect the structure or any function of the body of man.*"

The clarification introduced by the 2019 Policy can be used for support with further classification. With the 2019 Policy, FDA has clarified the focus of the FDA on the control of mobile medical apps that supplement a regulated medical device or apps that transform a mobile platform into a regulated medical device.

An example of the first category identified above could be an application that allows a medical professional to make a diagnosis by viewing a medical image, such as ultrasound from a picture taken and transmitted from the smartphone.[118] Another example can be a mobile app that controls the inflation or deflation of a blood pressure cuff or control the

[116] S.J. Kilker, 'Effectiveness of Federal Regulation of Mobile Medical Applications' (2016) 93 (5) Washington University Law Review< https://openscholarship.wustl.edu/cgi/viewcontent.cgi?article=6220&context=law_lawreview > accessed 5 June 2020.
[117] Policy for Device Software Functions and Mobile Medical Applications. Guidance for Industry and Food and Drug Administration Staff [2019] < https://www.fda.gov/media/80958/download > accessed 6 June 2020.
[118] S.J. Kilker, 'Effectiveness of Federal Regulation of Mobile Medical Applications' (2016) 93 (5) Washington University Law Review< https://openscholarship.wustl.edu/cgi/viewcontent.cgi?article=6220&context=law_lawreview > accessed 5 June 2020.

delivery of insulin on an insulin pump. [119] Basically, that can be any app that is used to treat a medical problem, turning the phone into the controller or screen for the device.[120]

An example of the app that transforms the smartphone into a regulated medical device is a mobile application that uses the functionality of the phone for its features.[121] That can be an application that is using the phone's speaker to produce tones for audiometry, and apps that allow remote monitoring by phone of heart tracings. These mobile medical apps will be regulated under the same rules that the FDA applies to other devices. [122]

Therefore, clarification contained in the 2019 Policy makes most health-related apps defined as non-devices that will not be subject to regulation.[123] 2019 Policy can be viewed as a clarification from the FDA on what types of apps are to fall under the regulatory scope of the FDA.

3.2.3. Exceptions to the definition on the mHealth apps that can be classified as medical device

At the same time, even if the app meets the definition of the mobile medical app and seems to be a medical device under Section 201 (h) of the FDCA, certain exceptions need to be taken into account.

3.2.3.1. Exceptions under the 21 Century Cures act

The definition of the medical device under Section 201 (h) of the FDCA contains certain exceptions.[124]

Some examples of the exceptions of devices added by the 21 Century Cures Act are as follows:[125]

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[119] B. Zegarelli, 'Building a Health App? Part 3: What you Need to Know About FDA's Regulation of Mobile Apps' (Mintz Consulting blog, 3 October 2017) <. https://www.mintz.com/insights-center/viewpoints/2146/2017-10-building-health-app-part-3-what-you-need-know-about-fdas > accessed 6 June 2020.

[120] D. Kamerow, 'Regulating medical apps: which ones and how much' (2013) 347 BMJ < https://www.bmj.com/bmj/section-pdf/749048?path=/bmj/347/7929/Observations.full.pdf > accessed 5 June 2020.

[121] B. Zegarelli, 'Building a Health App? Part 3: What you Need to Know About FDA's Regulation of Mobile Apps' (Mintz Consulting blog, 3 October 2017) < https://www.mintz.com/insights-center/viewpoints/2146/2017-10-building-health-app-part-3-what-you-need-know-about-fdas > accessed 6 June 2020.

[122] D. Kamerow, 'Regulating medical apps: which ones and how much' (2013) 347 BMJ < https://www.bmj.com/bmj/section-pdf/749048?path=/bmj/347/7929/Observations.full.pdf > accessed 5 June 2020.

[123] Ibid.

[124] Following the language of Section 201 (h) of the FDCA, "the term "device" does not include software functions excluded pursuant to section 520(o)".

[125] Section 3060(a) of the 21st Century Cures Act (Cures Act) amended section 520 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) on December 13, 2016, removing certain software functions from the definition of device in section 201(h) of the FD&C Act. See more at: Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act: Guidance 2019.

1) Apps intended for the administrative support of a Health Care Facility. FDA has not historically considered most of these software functions to be devices; however, additional clarification was added.

2) Apps intended for maintaining or encouraging a healthy lifestyle. In addition, for wellness apps, a separate non-binding FDA guidance on general wellness exists.[126] The policy is also can be used for guidance and is not binding.

   The example provided by FDA indicates that mHealth apps will not be considered regulated devices in case they are intended to be used for general wellness purposes and are not related to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition.[127]

   Under the existing exception, software with healthy lifestyle claims, such as weight management, physical fitness, relaxation or stress management, mental acuity, self-esteem, sleep management, or sexual function, are not devices when not related to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition.[128]

3) Apps intended to serve as electronic patient records.

4) Apps intended for transferring, storing, displaying data, and results. [129]

In addition, even if the exceptions exist, if FDA makes a finding that "*software function would be reasonably likely to have serious adverse health* consequences," the exception will not apply.[130] That is not entirely clear when "serious adverse health consequences" can arise, triggering the fact that the exception does not apply. When talking, for example, a person using a weight scale for wellness purposes may not experience harm if the scale displays an incorrect weight. Nevertheless, that same person may experience a moderate or high risk if the person is required to notify his/her doctor when s/he exceeds a certain weight

[126] General Wellness: Policy for Low Risk Devices.
[127] Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act: Guidance 2019.
[128] Ibid.
[129] 520(o)(1)(D) of the FDCA.
[130] The Cures Act also provides that a software function described in section 520(o)(1)(A) – (D) of the FD&C Act will not be excluded from the device definition under section 201(h) of the FD&C Act if FDA makes a finding that the software function would be reasonably likely to have serious adverse health consequences and certain substantive and procedural criteria are met. (Section 520(o)(3) of the FD&C Act). Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act: Guidance 2019.

and fails to do so because the scale displayed an incorrectly low weight."[131] A similar example can apply to the well-being app.

Other than this exception, the new 21 Cures Act turns the "least burdensome" standard already existing as a principle of the FDA into a law.[132]

3.2.3.2. Apps regulated under the "discretion" of the FDA

In addition, the 2019 Policy leaves a considerable amount of possible medical devices to the "discretion of the FDA."[133] "Enforcement discretion means" (according to the language of the 2019 Policy) that FDA does not intend to enforce regulatory requirements under the FDCA for such devices.[134] Mostly devices that pose a low risk to patients fall under this category. The 2019 Policy has a lot of detailed examples for mHealth apps that are left for "enforcement discretion."

For example, the 2019 Policy indicates that the FDA intends to exercise enforcement discretion for a number of software functions, for example, the ones that "help patients (i.e., users) self-manage their disease or conditions without providing specific treatment or treatment suggestions" or "automate simple tasks for health care providers."[135]

Dale Cooke, Vice President and Group Director of Digitas Health provided the following comment: "*When FDA asserts that it will exercise regulatory discretion [over software], it is stating that (it) has the legal authority to enforce regulations, but that it is choosing not to do so*." Therefore, even if FDA chooses not to regulate certain software under its "discretion," it means that such an app could still be a medical device under other criteria, but due to its lower risk is not regulated by FDA.[136]

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[131] V.J. Roth, 'The mHealth Conundrum: Smartphones & Mobile Medical Apps—How Much FDA Medical Device Regulation is Required?' (2014), 15 (3) The North Carolina Journal of Law & Technology 359 < http://ncjolt.org/wp-content/uploads/2014/04/Roth-Color-Final.pdf > accessed 5 June 2020.
[132] N.G. Cortez, et all, 'Questions About the FDA's New Framework For Digital Health ' (2017) HealthAffairs Online Journal < https://www.healthaffairs.org/do/10.1377/hblog20170816.061554/full/ > accessed 3 June 2020.
[133] Page 12, the 2019 Policy.
[134] Policy for Device Software Functions and Mobile Medical Applications. Guidance for Industry and Food and Drug Administration Staff [2019] < https://www.fda.gov/media/80958/download > accessed 6 June 2020.
[135] Page 12 and further, the 2019 Policy.
[136] S. McInerney, 'Can You Diagnose Me Now? A Proposal to Modify the FDA's Regulation of Smartphone Mobile Health Applications with a Pre- Market Notifification and Application Database Program' (2015) 48 University of Michigan Journal of Law Reform < https://repository.law.umich.edu/cgi/viewcontent.cgi?article=1143&context=mjlr > accessed 5 June 2020.

3.3. Consequences of the mHealth apps being classified as the medical device

In case the mHealth app is subject to FDA oversight, the manufacturer must classify the mHealth app, to determine the appropriate regulatory route. Mobile medical apps use the same classification scheme as other medical devices. They may be classified as Class I (lowest risk), Class II (moderate risk), or Class III (highest risk - often requires premarket approval). [137]

The FDA has a dedicated page that provides guidance to the app developers and explains applicable laws, allowing the developers to classify their apps.[138] Moreover, if there are grounds to believe that the mHealth app is a medical device, but cannot satisfactorily determine its device classification and regulatory status, there is a possibility to request classification assistance from the FDA using the 513(g) process. In response to a 513(g) request, the FDA will issue a confidential letter indicating if a mobile app is considered a medical device and the appropriate classification.[139]

If the app developer determines that the mHealth app is a medical device, then one must evaluate several layers of regulation to determine whether certain regulations apply and whether the developer or manufacturer meets those regulations in offering the product to the public.[140]

In 2005, the FDA posted guidelines for the software contained in medical devices, entitled "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," FDA indicates the guidance pertains "to software devices regardless of the means by which the software is delivered to the end-user." Therefore, this also applies to mobile medical applications [141]. This guidance has never become a legally binding final policy. The Software Device Guidance is still only in the "proposed" form." Despite the fact the guidance

[137] A. Swearingen, 'Mobile Medical Applications and US FDA Regulations' (Emergo, a UL Company, 2017) < https://www.emergobyul.com/resources/articles/white-paper-us-fda-mobile-medical-applications > accessed 6 June 2020.

[138] FDA, 'Classify your device' (U.S. Food&Drug Administration), 2 July 2020 < https://www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device > accessed 7 June 2020.

[139] A. Swearingen, 'Mobile Medical Applications and US FDA Regulations' (Emergo, a UL Company, 2017) < https://www.emergobyul.com/resources/articles/white-paper-us-fda-mobile-medical-applications > accessed 6 June 2020.

[140] V.J. Roth, 'The mHealth Conundrum: Smartphones & Mobile Medical Apps—How Much FDA Medical Device Regulation is Required?' (2014), 15 (3) The North Carolina Journal of Law & Technology 359 < http://ncjolt.org/wp-content/uploads/2014/04/Roth-Color-Final.pdf > accessed 5 June 2020.

[141] Ibid.

regulation is still a draft, the industry follows this as is if it were a formal regulation, and the FDA treats it as such. [142]

FDA process is known for complicated premarket notification, and the FDA review cycles are not consistent with the short product life cycles. [143]

3.4. Conclusion. Differences in the regulatory approach of the mHealth apps between US and EU

The approach to regulation of mHealth apps in the US is different. FDA on a legislative level identified a very narrow number of apps that are the focus of the FDA regulation, and for most of the apps, a "hands-off" approach is used.

The following differences can be identified:

1) A number of non-binding regulations provide additional requirements for mHealth apps regulation.

   In the US, there is a number of non-binding regulations that provide detailed lists with examples on mHealth apps. At first glance, such a detailed approach can provide additional clarity than that of the EU. Thus, an app developer may open a General Wellness: Policy for Low Risk Devices and find the example that fits the app the most. At the same time, having a number of non-binding regulations and clarifications, in the opinion of the author, can lead to greater confusion.

   The existing number of guidelines and policies makes it very hard for the user to navigate the documents. Creating a decision-tree for US regulation is out of the scope of the present research. In the future, it can be recommended to review to what extent the market can rely on the 2019 Policy released by the FDA and other non-binding documents in this domain.

   2) There are many Notified Bodies in the EU that handle the requests for certifying. In the US, the FDA is the only authority that handles certification requests.

[142] V.J. Roth, 'The mHealth Conundrum: Smartphones & Mobile Medical Apps—How Much FDA Medical Device Regulation is Required?' (2014), 15 (3) The North Carolina Journal of Law & Technology 359 < http://ncjolt.org/wp-content/uploads/2014/04/Roth-Color-Final.pdf > accessed 5 June 2020.
[143] N.G. Cortez et all, 'Questions About the FDA's New Framework For Digital Health ' (2017) HealthAffairs Online Journal < https://www.healthaffairs.org/do/10.1377/hblog20170816.061554/full/ > accessed 3 June 2020.

Such approach can be understood, since the FDA, in line with the 21 Century Cures Act, intended to regulate a smaller amount of the mHealth apps. At the same time, approval times for the mHealth apps in the US are longer than those in the EU.

Both in the EU and the US there is a lot of burden on the developer of the mHealth app to find correct intended use. Liability for the wrong marking of the intended use of the mHealth app is not clear. There can be a suggestion for further research on this topic, to find whether the disclaimers "not intended for medical use" are effective, and what liability can happen in case the wrong marking is placed.

In general, the current absence of regulation leaves the mobile health industry uncertain. Dan Haley, Vice President of Government and Regulatory Affairs at Athena, has expressed dissatisfaction with the fact: "*That the FDA gave the industry little more than a set of non-binding recommendations that may be changed at the FDA's whim*."[144]

A more "hands-off" in the US, and a more "hands-on" in the EU makes it interesting to review whether a stronger regulation can prevent a mHealth market from further growth. This question is reviewed in the next chapter, based on the previous research.

[144] S.J. Kilker, 'Effectiveness of Federal Regulation of Mobile Medical Applications' (2016) 93 (5) Washington University Law Review < https://openscholarship.wustl.edu/cgi/viewcontent.cgi?article=6220&context=law_lawreview > accessed 5 June 2020.

Chapter 4: Analyzing the Regulations Applicable to the Well-being mHealth Apps and Trends in the mHealth

In this chapter, the author reviews in greater detail the elements that are of importance to the developer of the well-being app, and elements that can trigger the app being categorized as the medical device under the new EU MDR. The author analyzes whether the changes to the existing regulation could be suggested to spread the use of mHealth apps.

4.1. Identified challenges in the regulation of mHealth apps

In the world, there are over 150 countries that have to develop any kind of regulatory framework for mHealth apps.[145] Some of the following considerations are to be taken into account when developing a mHealth app and well-being apps in particular.

4.1.1. Importance of the intended use in the classifications of the apps

Article 2 and definition of the "intended purpose" of the EU MDR are crucial in classifying an app under the EU MDR. It is sometimes hard to distinguish between the medical purpose and well-being purpose of such applications. [146,147] When giving a broad definition, lifestyle and well-being apps, rather than medical apps, primarily include apps intended to directly or indirectly maintain or improve healthy behaviours, quality of life, and well-being of individuals.[148] The mHealth developers can refer to the terms allowed to be used in advertising in order to qualify the intended use of their app.[149]

The difference between well-being and medical purpose can get blurry. For example, an app that uses an accelerometer as a fall detector in epileptic patients is likely to be

[145] A. Ugon A., B. Seroussi, C. Lovis C., Transforming Healthcare with the Internet of Things: Proceedings of the EFMI Special Topic Conference 2016 (online via IOS Press BV, 2016) < https://tinyurl.com/y83wmow7 > accessed 6 June 2020.
[146] I.C. Aguilar, 'TEN/551 EU Framework on "mHealth" and "health and well-being applications' (2014) 458 Official Journal of the European Union, European Economic and Social Commitee < https://www.eesc.europa.eu/en/our-work/opinions-information-reports/opinions/eu-framework-mhealth-and-health-and-wellbeing-applications > accessed 6 June 2020.
[147] European Commission, Green Paper on mobile health (2014) < https://ec.europa.eu/digital-single-market/en/news/green-paper-mobile-health-mhealth > accessed 6 June 2020.
[148] Ibid.
[149] A. Drongelen, et all, 'Apps under the medical devices legislation' (2019) National Institute for Public Health an Environment of the Netherlands research < https://www.rivm.nl/bibliotheek/rapporten/2018-0083.pdf > accessed 6 June 2020.

regulated as a medical device.[150] The same app, but being used in a social care context, for example, if an older adult stands up from a chair, will not meet the definition of a medical device and the medical device regulation would not apply.[151]

TNO, Dutch independent organization for applied scientific research, in its 2019 year research performed upon the request of the European Commission has indicated, that over 60% of the apps downloaded on the Member States market relate to health and fitness. [152] The investigation has revealed that cases or incidents that involve well-being apps are rare.[153] At the same time, it was indicated that the problem might be "the loose connection between the safety incident and the use of the app."[154]

The same investigation brought up a fertility app[155] that used the data inserted into the app by the users, in order to calculate "safe" days, and promised to be a natural birth control.[156,157] The app, among others, is used in the research as an example of when the "Health/Lifestyle/Wellbeing App" that was subject to the security failure (not many examples of such type were found in the research). The app mentioned in the research was CE certified.[158] At the same time, the app was under investigation since, at some point, 37 out of 600 women undergoing abortion had used this app.

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[150] Accelerometer is a sensor, the purpose of which is to determine a device orientation in case. Accelerometers measure the acceleration across two or three dimensions. See more at: E. Stankevich, et all 'Mobile Phone Sensors in Health Applications' (2012) 12th conference on Fruct association < https://www.cs.odu.edu/~cs441/Papers/app-006.pdf > accessed 6 June 2020.

[151] S. Shorthose, 'M-Health Applications; Legal Framework and Advertising' (Bird&Bird, July 2016) < https://www.twobirds.com/en/news/articles/2016/uk/m-health-applications-legal-framework-and-advertising > accessed 6 June 2020.

[152] Page 18, M.J. Lieshout, et all 'Final study report regarding safety of health, lifestyle and wellbeing apps' (TNO 2019 R10103, European Commission report 2019) < https://ec.europa.eu/digital-single-market/en/news/safety-non-embedded-software-including-safety-health-lifestyle-and-wellbeing-apps > accessed 5 accessed 5 June 2020.

[153] M.J. Lieshout, et all 'Final study report regarding safety of health, lifestyle and wellbeing apps' (TNO 2019 R10103, European Commission report 2019) < https://ec.europa.eu/digital-single-market/en/news/safety-non-embedded-software-including-safety-health-lifestyle-and-wellbeing-apps > accessed 5 accessed 5 June 2020.

[154] Investigation of court cases performed in 2019, for four EU countries (France, Italy, Netherlands, Spain) has revealed that there were no safety issues with health, lifestyle and well-being apps, which can explain the exclusion provided by the regulator. The court cases investigation was performed using the keywords "software", "security" in order to find court cases that involved health, lifestyle, and well-being apps. More at: M.J. Lieshout, et all 'Final study report regarding safety of health, lifestyle and wellbeing apps' (TNO 2019 R10103, European Commission report 2019) < https://ec.europa.eu/digital-single-market/en/news/safety-non-embedded-software-including-safety-health-lifestyle-and-wellbeing-apps > accessed 5 accessed 5 June 2020.

[155] The app is not named, but it is assumed that it is an app in Figure 2.

[156] E. Lundin, 'Could an algorithm replace the pill' the Guardian (7 November 2020) < https://www.theguardian.com/lifeandstyle/2016/nov/07/natural-cycles-fertility-app-algorithm-replace-pill-contraception > accessed 5 June 2020.

[157] O. Sudjic, 'I felt colossally naive': the backlash against the birth control app' (The Guardian, 21 July 2018) < https://www.theguardian.com/society/2018/jul/21/colossally-naive-backlash-birth-control-app > accessed 6 June 2020.

[158] Natural Cycles app is also certified in US. See more at: E. Ferron 'Cycle-tracking app officially approved as contraceptive in Europe' (New Atlas news, 9 February 2017) < https://newatlas.com/natural-cycles-app-approved-contraceptive/47834/ > accessed 7 June 2020.

The app indicated in the research is placed in the App Store under the category "Hormone-Free Contraception."[159] Therefore, most likely, the developers of the said app determined that the intended use is more than the well-being. The app is also advertised as the first non-hormonal birth control. Any safety issues aside, the app is intended to be more than a well-being app and is advertised as the first efficient birth-control app.[160] When searching for another app that deals with tracking of fertility, another similar app was located in the "Cycle, Ovulation, and Fertility" subsection of the app store. The worlds "wellness and wellbeing" are used both in the website of such app and inside of the app, meaning that the developers of this app had a different intended use in mind.[161]

Therefore, the intended use is of the key importance when defining whether the app will be regulated. At the same time, even if the app developer defines such intended use, while reviewing the description of the two apps, the similarity in descriptions of both was noted.

Moreover, one of the apps has a disclaimer (see Figure 4 below) that the app shall be used as a level of contraception only in the USA and Europe, which are two regions where the app is currently certified. When speaking not only of liability of app manufacturers, but also the safety of the users, it could be reviewed in detail to what extent users of the mHealth apps pay attention to such disclaimers when accessing the apps from various locations in the world.

[159] See Figure 2 below.
[160] Natural Cycles, official website < https://www.naturalcycles.com > accessed 7 June 2020.
[161] See Figure 3, as well as the website of the app Flo < https://flo.health/our-mission > accessed 17 May 2020.

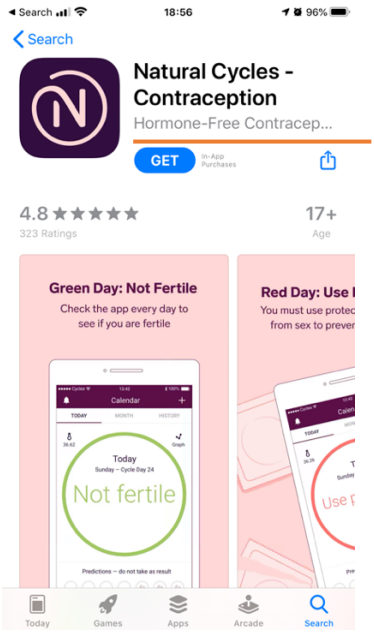

Figure 2. View of the app in the app store on iPhone, as of 10 May 2020.

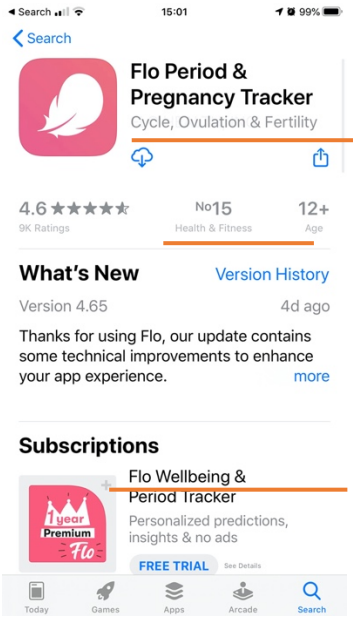

Figure 3. View of the app in the app store on iPhone, as of 17 May 2020.

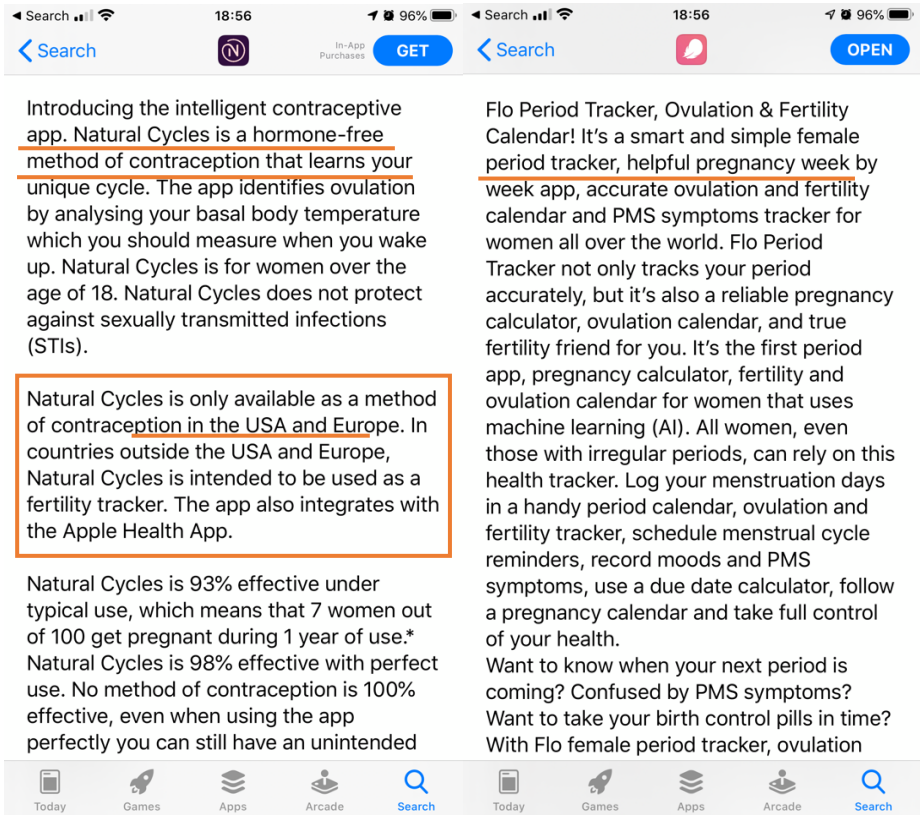

Figure 4. Description of the two apps with similar functionality on the app store on iPhone, as of 10 May 2020. Flo on the right, Natural Cycles on the left.

Correct identification of the "intended use" is essential when classifying an app. It allows having a more democratic approach to the qualification of the mHealth app. At the same time, that can also lead to the fact that even though some mHealth apps are not classified as a medical device under the concept of "intended use," such apps are capable of offering functions that are suitable for medical devices.[162]

During the research of the apps in 2019 by the National Institute for Public Health and the Environment of the Netherlands, it was indicated that for some mHealth apps, the marking "the app is not a replacement for a physician's advice" was used.[163] Such designation has the purpose of clarifying the "intended use." During the said research, such an indication was not taken into consideration when deciding whether an app was a medical device or not. Indeed, such designations shall not be 100% relied upon, since such designation may be wrong.

The EU Commission has opted to maintain its current approach in the newly proposed EU MDR, choosing not to employ other approaches as the FDA has, for example, done in opting to use a 'risk-based case-by-case approach.' [164] In the US, there is always an option of the case-by-case analysis.[165] Thus, if the FDA makes a finding that "*software function would be reasonably likely to have serious adverse health consequences*,"; the exception for well-being will not apply.[166]

At the same time, the CJEU in 2012 had a ruling[167] that confirmed the desire of the legislator to require the express intention of the manufacturer.[168] The case is important since it is stated that the concept of the medical device covers only those objects that are intended for a medical purpose. A more recent case was by the CJEU in 2016.[169] The question was

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[162] P. Quinn, 'The EU commission's risky choice for a non-risk based strategy on assessment of medical devices' (2017) 33(3) Computer Law & Security Review 361 < https://www.sciencedirect.com/science/article/abs/pii/S0267364916301637?via%3Dihub > accessed 7 June 2020.

[163] A. Drongelen, et all, 'Apps under the medical devices legislation' (2019) National Institute for Public Health an Environment of the Netherlands research < https://www.rivm.nl/bibliotheek/rapporten/2018-0083.pdf > accessed 6 June 2020.

[164] P. Quinn, 'The EU commission's risky choice for a non-risk based strategy on assessment of medical devices' (2017) 33(3) Computer Law & Security Review 361 < https://www.sciencedirect.com/science/article/abs/pii/S0267364916301637?via%3Dihub > accessed 7 June 2020.

[165] See Section 3.2.2.1 of the thesis, when exceptions under the 21 Century Cures Act are reviewed.

[166] Public Law 114–255 [2016] (21st Century Cures Act) < https://www.congress.gov/114/plaws/publ255/PLAW-114publ255.pdf > accessed 6 June 2020.

[167] Case C-219/11 Brain Products GmbH v Bio Semi VOF [2012] JUDGMENT OF THE COURT (Third Chamber) < http://curia.europa.eu/juris/document/document.jsf?docid=130247&doclang=en > accessed 6 June 2020.

[168] P. Quinn, 'The EU commission's risky choice for a non-risk based strategy on assessment of medical devices' (2017) 33(3) Computer Law & Security Review 361 < https://www.sciencedirect.com/science/article/abs/pii/S0267364916301637?via%3Dihub > accessed 7 June 2020.

[169] Case C.329/16 Snitem - Syndicat national de l'industrie des technologies médicales [2017] Judgment of the Court (Fourth Chamber) < http://curia.europa.eu/juris/liste.jsf?language=en&num=C-329/16 > accessed 6 June 2020.

whether it is of importance that the software was used on "humans."[170] The Court has identified that most important is the intended purpose (which is medical), and not whether the software acts directly on the human body. [171]

Therefore, in the EU, there are no binding rules as to distinction between the lifestyle and well-being apps and a medical device. [172] Intended purpose, identified by the mHealth app developers, is the primary source of information. Any app developer that provides apps relating to fitness, well-being, health, needs to be aware of the impact of the new upcoming EU MDR on their mHealth app. At the same time, since the changes to the definition are minor, the definition of the "intended purpose" remains the key definition to define whether the app is a medical device.

A new risk-based approach is added under Rule 11, which is used when clarifying the class once the app is confirmed to be a medical device. Therefore, mainly app developers that already have their apps classified as a medical device might need to consider that the app will go up in the certification class.

4.1.1.1. Case 1. mHealth app that sends reminders to take medication on time

That is a common type of mHealth app. The addition of the new language in the EU MDR on "prognosis" and "prediction" may raise a question whether the reminder has a medical purpose of "prediction how likely a disease is to happen in case the user forgets to take medicine."

Based on the analysis of the "intended purpose," which is the critical definition in EU MDR, it is crucial to see if the app influences the decision on the treatment of the patient. If not, then an app is a well-being app. When influencing the decision of treatment of individual patients, the apps are more likely to be qualified as a medical device. [173]

The use of software that is intended to be used by healthcare professionals and general users to optimise the patient's medicinal product intake is increasing. In addition to

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[170] S. Stefanelli, 'The Court of Justice takes a broad interpretation of when softwares fall within the notion of medical devices' (Stefanelli&Stefanelli legal website, 12 December 2017) < https://s3.amazonaws.com/documents.lexology.com/597c36f0-1863-4583-9e61-ba4b6c9842a1.pdf?AWSAccessKeyId=AKIAVYILUYJ754JTDY6T&Expires=1591453284&Signature=qSqgnbV042OBinhAsXpjr8pG4Jo%3D > accessed 6 June 2020.

[171] Paragraph 39, Case C.329/16 Snitem - Syndicat national de l'industrie des technologies médicales [2017] Judgment of the Court (Fourth Chamber) < http://curia.europa.eu/juris/liste.jsf?language=en&num=C-329/16 > accessed 6 June 2020.

[172] A. Ugon A., B. Seroussi, C. Lovis C., Transforming Healthcare with the Internet of Things: Proceedings of the EFMI Special Topic Conference 2016 (online via IOS Press BV, 2016) < https://tinyurl.com/y83wmow7 > accessed 6 June 2020.

[173] See suggested criteria for the apps that allow the automatic decision making on the basis of input data, p. 26 at: M.J. Lieshout, et all 'Final study report regarding safety of health, lifestyle and wellbeing apps' (TNO 2019 R10103, European Commission report 2019) < https://ec.europa.eu/digital-single-market/en/news/safety-non-embedded-software-including-safety-health-lifestyle-and-wellbeing-apps > accessed 5 accessed 5 June 2020.

reminders, the apps could provide warnings concerning possible interactions between the medication or conditions with the previous treatment. The Manual on the Borderline Products provides that the software that will help with such decisions will fall within the definition of a medical device. Such classification depends on the fact that the medication decision support software is used for prevention, monitoring, treatment, or alleviation of disease. Therefore, if the mHealth app has as its purpose not only with the formation of the habit but also advises on how to include the medication in the daily routine, the answer on whether an app should be regulated as a medical device is not entirely clear.[174]

Thus, based on the definition in the borderline manual issued in 2019, the following is indicated:

1) If the mHealth app merely sends reminders, it will not be considered a medical device.
2) The mHealth app will be considered to be a medical device in case such alarms are part of the treatment. For example, if the mHealth app is part of patient monitoring, for example, the doctor intends to adjust the treatment based on the behavior of the patient based on the "live" data received from the bedside device. Therefore, action taken from alarm (i.e., an alarm is delayed) contributes to the monitoring and follow-up of the patient connected to the bedside device. [175]

A similar approach exists in the US. Under the example lists drafted by the FDA, mobile apps that automate general office operations in a health care setting and are not intended for use in the diagnosis of a disease or other conditions or the cure, mitigation, treatment, or prevention of disease are not considered a medical device. An example of this is an app that generates reminders for scheduled medical appointments or blood donation appointments.[176]

Returning to the previous example of the app that assists with the pill-taking and finding a better moment during the day when the pill is to be taken, the author notes the following. Firstly, the app helps with the routines, which, in the end, can make sure that the use of medicine is more effective. Secondly, if the app is labeled as a tool for

[174] One example of the app from the article, listed on the day of the article as an "(currently unreleased) example would be a software app to support oral contraception adherence." V.J. Roth, G. Niezen,A.A. O'Kane, K. Stawarz 'Can Standards and Regulations Keep Up With Health Technology?' (2015) 3 (2) JMIR Mhealth Uhealth < https://mhealth.jmir.org/2015/2/e64 > accessed 5 May 2020.

[175] Manual on Borderline and Classification in the Community Regulatory Framework for Medical Devices. Version 1.22 [2019] < https://ec.europa.eu/docsroom/documents/35582 > accessed 6 June 2020.

[176] M. Herron, 'When is a Health and Fitness App Not Just an App?' (Mason Hayes &Curran, 19 September 2019) < https://www.mhc.ie/latest/blog/health-and-fitness-apps-v-medical-devices > accessed 4 June 2020.

supporting medication-taking habits, then the app is likely to be classified as a medical device. However, if the wording refers to the change of habits, then even though the functionality stays the same, the answer on the qualification of the mHealth app may change.[177]

That is a simple drafting approach and use of words, but correct labeling of the "intended use" of the app can help avoid the app being marked as a mHealth app.

4.1.1.2. Case 2. Apps especially with the use of the neural networks/AI, that can give additional recommendations based on the entries of the users [178]

EU MDR added "prognosis" and "prediction" to the "medical purpose." Apps that use neural networks[179] can make better predictions, avoid mistakes, and a create personalized experience for the user, based on the behavior of such user.

Lack of further clarification in the EU MDR may suggest that self-learning neural networks can be class 1 medical devices since they "predict" and give "prognosis."[180]

Until now, since no additional guidance exists on the predictions done by the neural networks, the "intended use" will continue to be a key defining element in examining the classification of the mHealth app.

Therefore, the app developer has to be sure that the app is indeed a well-being app if there is an intention to lower the certification burden of the app developer. A thin line separates health and well-being apps that are considered to be medical devices from apps that are not considered to be so.[181] For the EU app developer, it is a good first step to refer to Manual on borderline classification.[182] Even though the provisions of the document are not binding, and only the European Court of Justice can interpret the EU laws, the document provides

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[177] V.J. Roth, G. Niezen,A.A. O'Kane, K. Stawarz 'Can Standards and Regulations Keep Up With Health Technology?' (2015) 3 (2) JMIR Mhealth Uhealth < https://mhealth.jmir.org/2015/2/e64 > accessed 5 May 2020.

[178] One of the known apps as an example is Flo. See more at: A. Kukwa 'First Period Tracking App Using AI Is From Belarus' (150 sec, 23 February 2017) < https://150sec.com/first-period-tracking-app-using-ai-is-from-belarus/6199/ > accessed 6 June 2020.

[179] The concept of the "neural network" means that the app will be able to gather knowledge by detecting how the user interact and "learn" through experience. Therefore, a more custom notifications can be sent to the users, or predictions on the effects of the treatment can be calculated. More at: N. Shahid, T. Rappon,W . Berta, 'Applications of artificial neural networks in health care organizational decision-making: A scoping review' (2019) 14 (2) PLoS ONE < https://journals.plos.org/plosone/article/file?id=10.1371/journal.pone.0212356&type=printable > accessed 6 June 2020.

[180] S. Buttron, 'CE Marking Of Digital Health Technologies: Stricter Rules For Medical Device Software Under The EU MDR' (NAMSA, a Medical Research Organization, 2018) < https://www.namsa.com/european-market/mdr-stricter-rules-medical-device-software/ > accessed 3 June 2020.

[181] M. Christen, B. Gordijn B., M. Loi "Introduction". In: Christen M., Gordijn B., Loi M. (eds) The Ethics of Cybersecurity. The International Library of Ethics, Law and Technology, vol 21. Springer, Cham (2020) < https://doi.org/10.1007/978-3-030-29053-5_1 > accessed 3 June 2020

[182] Manual on Borderline and Classification in the Community Regulatory Framework for Medical Devices. Version 1.22 [2019] < https://ec.europa.eu/docsroom/documents/35582 > accessed 6 June 2020.

useful guidance.[183] In many cases, an app might fall into one of the categories listed in the document, which can be easier for the mHealth app developer.

4.1.2. Extraterritorial use of the mHealth apps as a challenge in regulation

It is important to note that mHealth apps are available in online stores. Therefore, it is easier to reach users from various countries. Therefore, it is crucial for mHealth app developers that even though the app is available to the users through similar tools (for example, app store), the regulatory regime for the same app in different countries may be different. What is exempt in the United States will not necessarily be so in the EU.[184]

The problem for the regulator, on the other side, is that the global nature of the market for apps makes it difficult to ensure that only appropriately CE-marked apps[185] are made available to European consumers.[186] The app store is the most popular place to find mHealth apps. [187]

International cooperation in developing mHealth standards is of importance when developing new standards applicable to mHealth. It is beneficial not only for mHealth app developers since it will be easier to ensure compliance of the mHealth app with necessary standards with lower costs, but also for a regulator. Little or no difference in regulation in the most significant markets can help with ensuring that compliant mHealth apps are available to the users.

There are already initiatives working in the field of harmonization. International Medical Device Regulators Forum (IMRDF), set up in 2011[188], is a crucial voluntary group that works in the field of medical device regulations. [189] IMDRF is established to address the common public health regulatory challenges to convergence due to the globalization of

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[183] Ibid.

[184] Joris Wiersinga, Regulation of Medical Digital Technologies. In: Marston H., Freeman S., Musselwhite C. (eds) Mobile e-Health. Human–Computer Interaction Series. (2017, Springer, Cham) < https://link-springer-com.tilburguniversity.idm.oclc.org/content/pdf/10.1007/978-3-319-60672-9_13.pdf > accessed 6 June 2020.

[185] Refer to 2.3. on the consequences of the mHealth app being found a mHealth app. Self-certification or a necessary dossier may be necessary to be collected and presented to the Notified Bodies of the EU.

[186] A. Drongelen, et all, 'Apps under the medical devices legislation' (2019) National Institute for Public Health an Environment of the Netherlands research < https://www.rivm.nl/bibliotheek/rapporten/2018-0083.pdf > accessed 6 June 2020.

[187] L. Kerkhof, et all. 'Characterization of Apps and Other e-Tools for Medication Use: Insights Into Possible Benefits and Risks' (2016) 4(2) JMIR MHealth and UHealth < https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4838755/ > accessed 5 June 2020.

[188] IMDRF terms of reference, IMDRF Management Committee [2018] < http://www.imdrf.org/docs/imdrf/final/procedural/imdrf-proc-180727-terms-of-reference.pdf > accessed 6 June 2020.

[189] Official website of IMDRF, International Medical device Regulation forum < http://www.imdrf.org/about/about.asp > accessed 6 June 2020.

medical device production and the emergence of new technologies. Currently, the membership comprises representatives from the medical device regulatory authorities of Australia, Brazil, Canada, China, the European Union, Japan, the Russian Federation, Singapore, South Korea, and the United States.

As an outcome of the European Commission's Green Paper on mHealth,[190] subsequent consultation and eHealth week, the European Commission presented an initiative to draw up a code of conduct for mHealth application developers, to increase the public trust in mHealth apps and to promote guidelines and compliance with the data protection among app developers. [191]

The popularization of such platforms, conducting of public research where mHealth app developers are involved, are practices that can help with the safety of the mHealth apps and harmonization of the regulation.[192]

4.2. Review on the hands-off and hands-on approaches on regulation of the mHealth apps

In this section, based on the research of the changes related to the new EU MDR, as well as the regulation that exists in the US, the author reviews the pros and cons of the more regulated approach towards mHealth apps.

4.2.1. Benefits of having more regulation for well-being apps

On the one hand, additional stricter regulation can be beneficial since it increases the trust of the users and assists the mHealth apps developers with getting extra funding.

4.2.1.1. Stricter regulation helps to ensure the trust of the users

The users may be reluctant to use mHealth apps since most of them are not medical devices and are not checked before becoming available in the phone stores for download.

[190] On 10 April 2014 the European Commission published a Green Paper on mobile health. European Commission, Green Paper on mobile health (2014) < https://ec.europa.eu/digital-single-market/en/news/green-paper-mobile-health-mhealth > accessed 6 June 2020.

[191] World Health Organization, From Innovation to Implementation: eHealth in the WHO European Region (Regional Office for Europe, 2016) < http://www.euro.who.int/__data/assets/pdf_file/0012/302331/From-Innovation-to-Implementation-eHealth-Report-EU.pdf?ua=1 > accessed 6 June 2020.

[192] Thus, On 10 April 2014 the European Commission published a Green Paper on mobile health (hereafter "mHealth") which launched a public consultation, open until 10 July 2014, in which it invited stakeholders to provide their views on 11 identified barriers to the uptake of mHealth in the EU, see more at: European Commission, Green Paper on mobile health (2014) < https://ec.europa.eu/digital-single-market/en/news/green-paper-mobile-health-mhealth > accessed 6 June 2020.

In the research performed in 2016, the user experiences about mHealth apps were analyzed.[193] Most people indicated that they used built-in mobile stores for finding mHealth apps. Some respondents indicated using other sources for finding apps, especially health care professionals and users building their apps. Moreover, when asked if respondents knew the apps that they used were reliable, most frequently, respondents indicated that they did not know if the apps were reliable.[194]

Uncertainty in regulation may scare away not only the users. Developers of mHealth apps may also become discouraged from designing mHealth apps due to the uncertainty in regulation and unclear enforcement policies. If the FDA finds that the new mHealth app requires to be certified, they will alert the company with the letter titled "it has come to our attention." [195] One mHealth Economics survey has shown that 18% of mHealth apps developers are held back from developing apps due to uncertain regulatory conditions. [196]

Therefore, a more consistent regulation can increase the trust of the users, developers, and boost innovation. Both more mHealth apps will be developed, and more users will opt for mHealth apps since they will know that mHealth apps can be reliable.

4.2.1.2. Financing and monetization of more regulated mHealth apps can become easier

When it comes to monetizing the mHealth app, additional regulation may be of use.
For example, in order to make additional profit, the mHealth apps have in-app purchases,[197] but it is unclear whether the users will be willing to pay for unregulated apps. [198]

[193] L. Kerkhof, et all. 'Characterization of Apps and Other e-Tools for Medication Use: Insights Into Possible Benefits and Risks' (2016) 4(2) JMIR MHealth and UHealth < https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4838755/ > accessed 5 June 2020.
[194] Ibid.
[195] S.J. Kilker, 'Effectiveness of Federal Regulation of Mobile Medical Applications' (2016) 93 (5) Washington University Law Review < https://openscholarship.wustl.edu/cgi/viewcontent.cgi?article=6220&context=law_lawreview > accessed 5 June 2020.
[196] Report 'How digital intruders are taking over the healthcare market' (Research2Guidance, mHealth App Economics 2017) < https://research2guidance.com/product/mhealth-economics-2017-current-status-and-future-trends-in-mobile-health/ > accessed 5 May 2020.
[197] Additional purchases by the user inside of the mHealth app, after downloading of the free mHealth app. Usually for additional features.
[198] Lindsey Dayer and others, 'Smartphone Medication Adherence Apps: Potential Benefits To Patients And Providers' (2013) 53 (2) Journal of the American Pharmacists Association 172 <https://secure.medactionplan.com/mymedschedule_var/assets/downloads/Smartphone_Medication_Adherence_Apps.pdf > accessed 4 June 2020.

Clear guidance on mHealth apps can facilitate reimbursement models. Moreover, the mHealth apps that are approved are more likely to be prescribed by professionals or be reimbursed as part of medical insurance. [199]

Therefore, on the one hand, mHealth apps, especially in the field of well-being, are contributing to making the population healthier, and are granting access to health care. At the same time, limited regulation may keep sophisticated investors away.

4.2.2. Benefits of having less regulation for well-being apps

On the other hand, even though many can consider that additional regulation can be a positive move towards mHealth apps, others, however, may see this additional regulation as limiting in the world of the fast-changing technology. [200] Therefore, less regulation is needed since an increase of awareness (for apps developers and among mHealth app users) can help in achieving of the similar goals. Additionally, regulatory compliance requires finances, which is not always available in emerging mHealth companies; additional regulation may slow down innovation while the negative impact of the well-being apps has not been proven.

4.2.2.1. Increase of awareness can be easier than additional regulation

Rather than trying to regulate the mHealth apps, different, more flexible approaches are needed by shifting focus toward educating users about the implications of using technology (e.g., raising awareness about human factors), and this way, better progress can be achieved. [201]

There are initiatives (mainly websites) where healthcare professionals and patients review health apps. The online health apps library by the National Health Service, UK, is one such source.[202] Royal Dutch Medical Association[203], the professional organization of the Dutch doctors, also provides tools for checking the quality of apps. However, it will be impossible to review and/or regulate all possible apps available at the market. Educating consumers

[199] World Health Organization, From Innovation to Implementation: eHealth in the WHO European Region (Regional Office for Europe, 2016) < http://www.euro.who.int/__data/assets/pdf_file/0012/302331/From-Innovation-to-Implementation-eHealth-Report-EU.pdf?ua=1 > accessed 6 June 2020.

[200] Esmita Charani and others, 'Do Smartphone Applications In Healthcare Require A Governance And Legal Framework? It Depends On The Application!' (2014) 12 BMC Medicine < https://www.researchgate.net/publication/260193478_Do_smartphone_applications_in_healthcare_require_a_governance_and_legal_framework_It_depends_on_the_application > accessed 3 June 2020.

[201] V.J. Roth, G. Niezen,A.A. O'Kane, K. Stawarz 'Can Standards and Regulations Keep Up With Health Technology?' (2015) 3 (2) JMIR Mhealth Uhealth < https://mhealth.jmir.org/2015/2/e64 > accessed 5 May 2020.

[202] United Kingdom National Health Service website < https://www.nhs.uk > accessed 6 June 2020.

[203] The Royal Dutch Medical Association 'Medische App Checker: handreiking bij het beoordelen van medische apps' (In Dutch, KNMG, 15 February 2016) < https://www.knmg.nl/actualiteit-opinie/nieuws/nieuwsbericht/medische-app-checker-handreiking-bij-het-beoordelen-van-medische-apps.htm > accessed 6 June 2020.

and healthcare professionals about the risks and the proper caution required when using apps is one of the most realistic ways forward. [204]

Creating extensive regulation will not usually mean the compliance of the mHealth apps developers. Since mHealth apps developers can be located outside of the EU but still develop mHealth apps for the EU market, it is the awareness that will be especially important to ensure that developers offer compliant apps, and users do necessary checks when downloading a new app.

4.2.2.2. Monetary constraints associated with the necessity to obtain certifications may be a burden for mHealth market development.

Compliance with medical device regulations requires time and has fees involved. Therefore, having less regulation helps to save time and to decrease app release costs. [205]

Policy and regulation have yet to catch up with this evolving technology, and every time the regulation comes up, it might already be outdated.

At the same time, if there are additional requirements with which mHealth app developers have to comply, the fees will apply. These fees add up. Therefore, it might make it harder for new mHealth apps to enter the market.

Moreover, many safety and privacy standards already exist that can confirm the compliance of the mHealth app with safety and regulatory standards. For example, in case it is important for app users or investors, mHealth app developers can get the certification of the International Standardization Organization for the necessary aspects.[206] Compliance with these standards will already incur costs; therefore, additional regulation in the medical device domain may not be desirable.

The hands-off approach that exists in the US, where having well-being apps as less regulated, is preferred. At the same time, the FDA can always review an app that can be considered high risk. Such an approach does not offer much predictability either and can lead to adding up the costs in the future.

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[204] L. Kerkhof, et all. 'Characterization of Apps and Other e-Tools for Medication Use: Insights Into Possible Benefits and Risks' (2016) 4(2) JMIR MHealth and UHealth < https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4838755/ > accessed 5 June 2020.

[205] S.J. Kilker, 'Effectiveness of Federal Regulation of Mobile Medical Applications' (2016) 93 (5) Washington University Law Review < https://openscholarship.wustl.edu/cgi/viewcontent.cgi?article=6220&context=law_lawreview > accessed 5 June 2020.

[206] For example, ISO standard 27001 Information Security Management can be used as a proof that information assets are safely secure. See more at: ISO, ISO/IEC 27001 Information Security Management (ISO official website, 2020) < https://www.iso.org/isoiec-27001-information-security.html > accessed 7 June 2020.

4.2.2.3. Additional regulation may slow down the release of new features and delay the progress

As apps are regularly updated, this allows for easily changing and enhancing features. Additional regulation and necessity to get new market authorization can delay the release of the new updates. [207] In addition, there was research performed upon the request of the European Commission in 2018, where as part of the research, the cases in France, Italy, and the Netherlands were reviewed that involved health, lifestyle, and wellbeing apps. [208] Based on this research, it was revealed that lifestyle and well-being apps do not pose a risk to citizens' health.[209] Therefore, a more relaxed approach in regulation towards producers of the well-being mHealth apps (i.e., where the intention is that they do not have a medical use) can boost innovation and lead to greater economic growth, without causing unnecessary risks.[210]

4.3. Conclusion

The line between lifestyle and well-being app and the medical app is not entirely easy to draw, especially to the app developer. As a rule, app developers are less informed about the existing rules and regulations than lawmakers or lawyers that work with the applicable laws. Currently, it is a burden of the app developer to identify if the mHealth app can be considered to be a medical device. The following key findings have been identified:

1) The case study has shown that the new EU MDR does not introduce significant changes for the well-being mHealth apps. Mostly apps that are already classified as the medical app might face re-classification to a higher class, based on the newly introduced risk-based approach. The main criteria for the qualification of the mHealth app remains the "intended purpose." It is in the responsibility of the mHealth app developer to identify the "intended purpose" correctly.

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[207] A. Drongelen, et all, 'Apps under the medical devices legislation' (2019) National Institute for Public Health an Environment of the Netherlands research < https://www.rivm.nl/bibliotheek/rapporten/2018-0083.pdf > accessed 6 June 2020.

[208] M.J. Lieshout, et all 'Final study report regarding safety of health, lifestyle and wellbeing apps' (TNO 2019 R10103, European Commission report 2019) 26 < https://ec.europa.eu/digital-single-market/en/news/safety-non-embedded-software-including-safety-health-lifestyle-and-wellbeing-apps > accessed 5 accessed 5 June 2020.

[209] Similar finding is also noted in the following book, see in general: S. A Fricker, C Thümmler and A Gavras, Requirements Engineering Digital Health (Springer 2014) Springer 2014) < https://tinyurl.com/ya874h5d > accessed 4 June 2020.

[210] P. Quinn, 'The EU commission's risky choice for a non-risk based strategy on assessment of medical devices' (2017) 33(3) Computer Law & Security Review 361 < https://www.sciencedirect.com/science/article/abs/pii/S0267364916301637?via%3Dihub > accessed 7 June 2020.

Correct labeling of the "intended purpose" is of importance when releasing the mHealth app, since the wording can determine marking the app as the medical device.

At the same time, users may not always check all the disclaimers and markings when downloading an app. In future research, it could be advised to review to what extent users pay attention to the wording of the "intended use," and whether the mHealth apps developers have to inform of intended use in more explicit form than it is currently done.

2) New technologies, for example, more extensive use of the self-learning neural networks in the mHealth app may create certain confusion, since such mHealth apps may be considered as assisting in "prognosis" of the medical conditions. It can be suggested to the EU regulator to expressly exclude mHealth apps using the self-learning neural networks unless such apps are used in the medical environment. Since currently nothing to the contrary is indicated, it is assumed that such apps indeed, can fall under the definition of the well-being apps.

3) The author does not consider a more detailed regulation is advisable. The current approach of the EU, where only apps that have the medical purpose are regulated, is a preferred approach in the view of the author. It could also be of use to expressly exclude more mHealth apps from the regulation unless they are used for treatment. A similar approach already exists in the US. In the view of the author, such approach allows to reach similar or even more goals without exposure to more significant risks.

4) Currently, well-being apps, for example, those that are used in addition to the primary treatment or which are suitable for improving health habits are not regulated much. On the one hand, more regulation can increase the trust of the users, and make it easier to monetize such apps. On the other hand, the overregulation of well-being mHealth apps can be a limiting factor in their further development. Which approach is more advisable can be reviewed in additional research, also from the privacy, security, and other perspectives. At the same time, similar to the conclusion above, the author considers that the more hands-off approach allows reaching goals both of the regulator and the users without exposure to greater risks.

Chapter 5: Conclusions and Recommendations

5.1. Conclusions

The world of mHealth apps is a world of "two opposites." [211] On the one hand, the healthcare industry is known for extensive regulation. Clinical trials, extensive documentation, as well as other formalities related to the approval of new medical devices may lead to the fact that it will take years before a new medical tool or medicine is available on the market. On the other hand, mobile applications and their lifecycle are substantially different. Mobile applications can be released when they are viable at a minimum, and it is way easier to issue an update of the fix if needed. Data within the apps is also easy to be shared with the third parties since most of the population uses phones these days. [212]

The thesis has shown that society is, to a certain extent, looking forward to getting additional regulation and increasing the control on the mHealth apps. Additional regulation can help with the predictability of regulation and will increase the trust of healthcare providers and users. As a consequence, more mHealth apps will be developed, and such apps will be more likely to be advised to the public even by healthcare professionals. Currently, in the EU, most mHealth apps can be self-certified, and the new EU MDR is expected to increase the threshold, based on the additional risk-based approach added to the regulation.

An increase in regulation can also lead to the fact that financing of medical startups will get easier. For example, healthcare insurance companies will be more likely to cover certain apps if they are more confident in the reliability of mHealth apps. In addition, support of healthcare institutions and insurance companies will lead to the increase of the user base and, as a consequence, will ensure that it will be easier to justify the financing of mHealth apps.

The thesis has shown that reclassification of the mHealth apps is more likely to occur for the mHealth apps that are already certified. A new risk-based element is added specifically

[211] Joris Wiersinga, Regulation of Medical Digital Technologies. In: Marston H., Freeman S., Musselwhite C. (eds) Mobile e-Health. Human–Computer Interaction Series. (2017, Springer, Cham) < https://link-springer-com.tilburguniversity.idm.oclc.org/content/pdf/10.1007/978-3-319-60672-9_13.pdf > accessed 6 June 2020.
[212] Ibid.

for the “software”, which may lead to the mHealth apps be reclassified. As to the mHealth apps that currently fall under the exceptions, for example, well-being apps, not much change can be expected.

In the thesis, it was identified that “indented use” stays one of the essential elements in the classification of the apps. Case studies have shown that the primary source for classification is the mHealth app developer. Therefore, it stays the burden of the mHealth app developer to identify the use of the mHealth app correctly. Such approach can lead to uncertainties since, for many apps, their functionality can be on the border between the “treatment and prognosis” and mere “improvement of lifestyle.” For example, the new EU MDR adds the definitions of “prognosis” and “prediction” to the “medical purpose.” At the same time, mHealth apps that learn from the input of the users can be of help when predicting certain medical conditions. Since no additional guidance is provided on the apps for prediction of the disease, it stays the burden on the mHealth app developer to indicate that the app is not a replacement of the medical advice and is merely here for the improvement of habits, rather than for actual prognosis of the disease. This approach can be seen as somewhat “formalistic.” Correct drafting of the language of the “intended use” of the mHealth app may be of the same importance as the functionality of the mobile application.

The research had identified two apps, fertility trackers, with similar functionality. Currently, it is the obligation of the mHealth app developer to label the medical application correctly before placing it in the online stores. At the same time, most users do not know how to check if the app is reliable. Most users use build-in stores and are unlikely to check official websites. It is also unclear to what extent the description of the mHealth apps, along with the disclaimers, is analyzed by mHealth apps users when downloading a new app.

Currently (pre-EU MDR), the EU is known for having relatively a short time for approval of the medical devices that are subject to regulation. In the future, additional research can be suggested on how the new way of approving medical devices, as well as the post-approval market monitoring, could affect the timelines and attractiveness of the EU vs the US as the jurisdiction to obtain a certification.

The US is known for a more hands-off approach towards regulation of the mHealth apps. Only medical applications that are very likely to cause serious damage to the health of the user fall under the regulation of the FDA. There is a number of additional guidelines that provide clarifications as to how to classify the mobile application based on its functionality.

At the same time, most documents from the FDA are also not binding. Therefore, it is not entirely correct to say that mHealth apps are regulated in the US in greater detail.

Some differences between the US and EU regulatory approaches that can be of importance for the mHealth apps developers are summarized in the following table.

	EU	US
Definition on what is the mHealth app.	Not provided in the EU MDR, additional non-binding documents to be reviewed for definition of the medical application.[213]	Not provided. Additional non-binding documents indicate what medical mobile application is.
	In both countries, mobile applications can be medical devices if conditions are met.	
Responsible entity for medical device regulation	National authorities (notified bodies).	Governmental organization: FDA.
Post-Market review	Post-market surveillance is introduced in the EU MDR.	Post-market surveillance requirement is already in place.
Exceptions to the "rule"	If software does not satisfy the definition of a medical device then it is not certified as the medical device.	Most apps do not fall under the regulation of the FDA. Some apps are exempt, for example, "well-being apps." If such apps have a greater risk to the health of the population; such apps will still need to be certified. On the other hand, some apps may meet the definition of the medical device, but still be released from the necessity to certify under the "regulatory discretion" of the FDA.

The thesis has shown that even though a new EU MDR is adopted, the problems in the mHealth environment, such as trust of the users, and regulation complexity for the use of the mHealth app developer, are here to stay.

5.2. Recommendations

There are several recommendations that governments and society can take into account to contribute to the spread of mHealth apps.

[213] For example, Guidance Document MEDDEV 2.1/6.

It would not be advisable to have more additional regulation. Existing regulation in the EU and the new rules provide a good baseline for the regulation of mHealth apps. Unlike in the US, many apps may fall under the regulation, at the same time, that is still not a guarantee that only medical applications safe for use will end up in the hands of the user. Extensive regulation can lead to an increase in costs when developing a mHealth app. A typical mHealth developer is a startup; therefore, additional costs can jeopardize the development of the mHealth market. In addition to EU MDR, additional internationally acceptable security standards exist, such as the ones by ISO or rules on privacy.

One of the important sectors of improvement is the education of users, as well as mHealth apps developers and medical professionals on the existing standards of safety. Very often, additional regulation or stricter rules do not solve the problem with the safety of the users. In case the general public is more aware of risks related to the use of the mHealth apps, as well as the elements and resources that can be checked to ensure that the app is safe to use, trust in the mHealth apps will increase, and strict regulation will not be necessary. The use of codes of conduct, public consultations, and harmonization of regulation is the way forward in the mHealth app development field.

Another important sector is international cooperation. Online mobile applications stores keep being the primary source of distribution of the mHealth apps. Such online stores can be easily accessed from any point in the world, at the same time, the stores do not check compliance with regulations. Also, mHealth app developers that submit the apps to the stores can be located in any place of the earth. A unified legal regulation that can be achieved through working groups, public consultations, can ensure a more unified approach universally. Little or no difference in regulation in the most significant markets can help to ensure that compliant mHealth apps are available to the users.

There is no doubt that mHealth apps are disrupting the healthcare sector, and they are here to stay. They are of importance when creating a healthier world and make healthcare more accessible in remote places. Many apps that are considered to be “well-being apps” can be a valuable addition to the treatment of the patients. Therefore, a flexible but consistent approach in the regulation of the mHealth apps is of importance.

Bibliography

BOOKS, NEWSFLASHES, NEWSPAPER ARTICLES

Aguilar I.C. 'TEN/551 EU Framework on "mHealth" and "health and well-being applications' (2014) 458 Official Journal of the European Union, European Economic and Social Commitee < https://www.eesc.europa.eu/en/our-work/opinions-information-reports/opinions/eu-framework-mhealth-and-health-and-wellbeing-applications > accessed 6 June 2020

Akker van den H, 'Medical Apps Under The New European MDR' (CRO for Medical Devices and IVDs | Factory CRO, 2017) < https://www.factory-cro.com/news/medical-apps-under-the-new-european-medical-device-regulation/ > accessed 2 June 2020

Alkhaldi N, 'Mobile Healthcare In 2020: The Roadmap For Change' (Itransition Corporate News, 2019) < https://www.itransition.com/blog/mobile-healthcare > accessed 3 June 2020

Borel B, 'Health Policy Brief: Mhealth And FDA Regulations' (2013) HealthAffairs Online Journal < https://www.healthaffairs.org/do/10.1377/hpb20131205.399529/full/ > accessed 3 June 2020

Buttron S, 'CE Marking Of Digital Health Technologies: Stricter Rules For Medical Device Software Under The EU MDR' (NAMSA, a Medical Research Organization, 2018) < https://www.namsa.com/european-market/mdr-stricter-rules-medical-device-software/ > accessed 3 June 2020

Caulfield B, and Donnelly S, 'What Is Connected Health And Why Will It Change Your Practice?' (2013) 106 (8) QJM 703 < https://academic.oup.com/qjmed/article/106/8/703/1576939 > accessed 3 June 2020

Charani E and others, 'Do Smartphone Applications In Healthcare Require A Governance And Legal Framework? It Depends On The Application!' (2014) 12 BMC Medicine < https://www.researchgate.net/publication/260193478_Do_smartphone_applications_in_healthcare_require_a_governance_and_legal_framework_It_depends_on_the_application > accessed 3 June 2020

Christen M., Gordijn B., Loi M. "Introduction". In: Christen M., Gordijn B., Loi M. (eds) The Ethics of Cybersecurity. The International Library of Ethics, Law and Technology, vol 21. Springer, Cham (2020) < https://doi.org/10.1007/978-3-030-29053-5_1 > accessed 3 June 2020

Contardi M, 'Changes In The Medical Device'S Regulatory Framework And Its Impact On The Medical Device'S Industry: From The Medical Device Directives To The Medical Device Regulations' (2019) 12 (2) Erasmus Law Review 166 < http://www.erasmuslawreview.nl/tijdschrift/ELR/2019/2/ELR-D-19-00012 > accessed 3 June 2020

Cortez N.G, et all, ‘Questions About the FDA’s New Framework For Digital Health ' (2017) HealthAffairs Online Journal < https://www.healthaffairs.org/do/10.1377/hblog20170816.061554/full > accessed 3 June 2020

Daigle B., Torsekar M., 'Executive Briefings. On Trade.The EU Medical Device Regulation and the U.S. Medical Device Industry' (U.S. International Trade Commission, September 2018) < https://www.usitc.gov/publications/332/executive_briefings/eu-mdr_ebot_final.pdf > accessed 7 June 2020

Daigle B., Torsekar M., 'The EU Medical Device Regulation and the U.S. Medical Device Industry' (2019) 2019 J Int'l Com & Econ 1 < https://www.usitc.gov/publications/332/journals/eu_medical_device_regulation_us_medical_device_industry.pdf > accessed 7 June 2020

Danzis S, and Pruitt C, 'Rethinking The FDA’s Regulation Of Mobile Medical Apps' (2013) 9(3) SCITECH LAW < https://www.cov.com/~/media/files/corporate/publications/2013/02/rethinking_the_fdas_regulation_of_mobile_medical_apps.pdf > accessed 4 June 2020

Darkins A, and Cary M, Telemedicine And Telehealth (Springer Publishing Company 2000) < https://tinyurl.com/ycjmqmo3 > accessed 4 June 2020

Dayer L and others, 'Smartphone Medication Adherence Apps: Potential Benefits To Patients And Providers' (2013) 53 (2) Journal of the American Pharmacists Association 172 < https://secure.medactionplan.com/mymedschedule_var/assets/downloads/Smartphone_Medication_Adherence_Apps.pdf > accessed 4 June 2020

Deloitte Centre For Health Solutions. Medtech And The Internet Of Medical Things. How Connected Medical Devices Are Transforming Health Care' (Deloitte, 2018) < https://www2.deloitte.com/content/dam/Deloitte/global/Documents/Life-Sciences-Health-Care/gx-lshc-medtech-iomt-brochure.pdf > accessed 4 June 2020

Dickson N, 'Regulation In A Changing Healthcare Landscape: The Role Of The General Medical Council' (2014) 1(2) Future Hospital Journal 80 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6438239/> accessed 4 June 2020

Drongelen A., et all, ‘Apps under the medical devices legislation’ (2019) National Institute for Public Health an Environment of the Netherlands research < https://www.rivm.nl/bibliotheek/rapporten/2018-0083.pdf > accessed 6 June 2020

Editorial Opinion, ‘Femtech: a Fertile Area’ (The Financial Times, 1 January 2020) < https://www.ft.com/content/9a312f63-8e23-4792-811d-65a8ea816b96 > accessed 4 June 2020

European Commission ‘Summary Report on the Public Consultation on the Green Paper on Mobile Health’ (European Commission, 12 January 2015)

< https://ec.europa.eu/digital-single-market/en/news/summary-report-public-consultation-green-paper-mobile-health > accessed 6 June 2020

European Commission, Green Paper on mobile health (2014) < https://ec.europa.eu/digital-single-market/en/news/green-paper-mobile-health-mhealth > accessed 6 June 2020

FDA, 'Device Software Functions Including Mobile Medical Applications' (FDA, 11 May 2019) < https://www.fda.gov/medical-devices/digital-health/device-software-functions-including-mobile-medical-applications#a > accessed 6 June 2020

Federal Institute for Drugs and Medical Devices (Germany) 'Guidance on "Medical Apps"' (Federal Institute for Drugs and Medical Devices, 11 November 2015) < https://www.bfarm.de/EN/MedicalDevices/Differentiation/MedicalApps/_artikel.html > accessed 6 June 2020

Ferron E., 'Cycle-tracking app officially approved as contraceptive in Europe' (New Atlas news, 9 February 2017) < https://newatlas.com/natural-cycles-app-approved-contraceptive/47834/ > accessed 7 June 2020.

Fricker S, Thümmler C, and Gavras A, Requirements Engineering Digital Health (Springer 2014) < https://tinyurl.com/ya874h5d > accessed 4 June 2020

Frumento C., 'French breast implants, the Medical Device Regulation, and a theoretical case study' (2017) 26(2) Medical Writing journal < https://pdfs.semanticscholar.org/3d40/97ad10ee00b48acf8f28f4860649499e6af6.pdf > accessed 4 June 2020

Galgon R, 'Understanding Medical Device Regulation' (2016) 29 (6) Current Opinion in Anaesthesiology 703 < https://oce-ovid-com.tilburguniversity.idm.oclc.org/article/00001503-201612000-00012/HTML > accessed 4 June 2020

Guidance, 'Medical devices: software applications (apps)' (GOV.UK, 8 August 2014) < https://www.gov.uk/government/publications/medical-devices-software-applications-apps > accessed 6 June 2020

Hanson S., et all 'Digital Health - The new regulation of medical software and apps' (CMS Cameron McKenna Nabarro Olswang LLP, 13 December 2018) < https://www.cms-lawnow.com/ealerts/2018/12/digital-health?cc_lang=en > accessed 24 May 2020

Herron M., 'When is a Health and Fitness App Not Just an App?' (Mason Hayes &Curran, 19 September 2019) < https://www.mhc.ie/latest/blog/health-and-fitness-apps-v-medical-devices > accessed 4 June 2020

Istepanian R, and Woodward B, M-Health (John Wiley&Sons, Inc 2019) < https://tinyurl.com/yaccgb4v > accessed 4 June 2020

Joyia G.J., Liaqat R.M, 'Internet of Medical Things (IOMT): Applications, Benefits and Future Challenges in Healthcare Domain' (2017) 12(4) Journal of Communications

< http://www.jocm.us/uploadfile/2017/0428/20170428025024260.pdf > accessed 4 June 2020

Kamerow, D., 'Regulating medical apps: which ones and how much' (2013) 347 BMJ < https://www.bmj.com/bmj/section-pdf/749048?path=/bmj/347/7929/Observations.full.pdf > accessed 5 June 2020

Kelly B., et all 'EU Updates MEDDEV 2.1/6 Guidance on Standalone Software' (Covington & Burling LLP, 5 August 2016) < https://www.covingtondigitalhealth.com/2016/08/new-eu-medical-device-guidance-on-standalone-software/ > accessed 5 June 2020

Kerkhof L. et all. 'Characterization of Apps and Other e-Tools for Medication Use: Insights Into Possible Benefits and Risks' (2016) 4(2) JMIR MHealth and UHealth < https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4838755/ > accessed 5 June 2020

Kilker S.J., 'Effectiveness of Federal Regulation of Mobile Medical Applications' (2016) 93 (5) Washington University Law Review < https://openscholarship.wustl.edu/cgi/viewcontent.cgi?article=6220&context=law_lawreview > accessed 5 June 2020

Kukwa A., 'First Period Tracking App Using AI Is From Belarus' (150 sec, 23 February 2017) < https://150sec.com/first-period-tracking-app-using-ai-is-from-belarus/6199/ > accessed 6 June 2020

Kvedar J., Coye MJ., Everett W., 'Strategies To Improve Patient Care With Telemedicine And Telehealth' (2014) 33 (2) Health Affairs journal < https://doi.org/10.1377/hlthaff.2013.0992 > accessed 5 June 2020

Lieshout M.J., et all 'Final study report regarding safety of health, lifestyle and wellbeing apps' (TNO 2019 R10103, European Commission report 2019) < https://ec.europa.eu/digital-single-market/en/news/safety-non-embedded-software-including-safety-health-lifestyle-and-wellbeing-apps > accessed 5 June 2020

Lundin E., 'Could an algorithm replace the pill' the Guardian (7 November 2020) < https://www.theguardian.com/lifeandstyle/2016/nov/07/natural-cycles-fertility-app-algorithm-replace-pill-contraception > accessed 5 June 2020

MacFarlane B, FDA Regulation Of Mobile Medical Apps. Whitepaper #3 (2014) < https://www.namsa.com/wp-content/uploads/2015/10/WP-FDA-Regulation-of-Mobile-Medical-Apps-7-7-2014.pdf > accessed 3 June 2020

Maheu M., Whitten P. et al, 'E-Health, Telehealth, and Telemedicine: A Guide to Startup and Success' (John Wiley &Sons , 1 ed., 2002) < https://tinyurl.com/ychvpmwl > accessed 5 June 2020

Mantovani, E., Quinn, P., Guihen, B., Habbug, A. K., & de Hert, P. J. A. 'eHealth to mHealth: A journey precariously dependent upon apps?' (2013) 21 European Journal of General Practice 48

Marston H, Freeman S, and Musselwhite C, Mobile E-Health (Springer, Cham 2017) < https://link.springer.com/content/pdf/10.1007%2F978-3-319-60672-9.pdf > accessed 5 June 2020

McCue, TJ., '$117 Billion Market For Internet of Things In Healthcare By 2020' Forbes (22 April 2015) < https://www.forbes.com/sites/tjmccue/2015/04/22/117-billion-market-for-internet-of-things-in-healthcare-by-2020/#32ab298e69d9 > accessed 3 June 2020

McHugh M. 'How Amendments to the Medical Device Directive Affect the Development of Medical Device Software' (2011) Conference papers of the Technological University of Dublin < https://arrow.tudublin.ie/cgi/viewcontent.cgi?article=1132&context=cschcomcon > accessed 5 June 2020

McInerney S., 'Can You Diagnose Me Now? A Proposal to Modify the FDA's Regulation of Smartphone Mobile Health Applications with a Pre- Market Notifification and Application Database Program' (2015) 48 University of Michigan Journal of Law Reform < https://repository.law.umich.edu/cgi/viewcontent.cgi?article=1143&context=mjlr> accessed 5 June 2020

Meankaew et al. 'Application of mobile-technology for disease and treatment monitoring of malaria in the "Better Border Healthcare Programme' (2010) 9:237Malaria Journal < https://malariajournal.biomedcentral.com/track/pdf/10.1186/1475-2875-9-237 > accessed 5 June 2020

Meankaew P., et al, 'Application of mobile-technology for disease and treatment monitoring of malaria in the "Better Border Healthcare Programme"' (2010) 9(237) Malaria Journal < http://www.malariajournal.com/content/9/1/237 > accessed 5 June 2020.

Medical Device Coordination Group, MDCG 2019-11, Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745- MDR and Regulation (EU) 2017/746 [2019] < https://ec.europa.eu/docsroom/documents/37581 > accessed 10 June 2020

Medical Devices Regulation: Commission welcomes Council support to prioritise the fight against coronavirus (European Commission press release, 23 April 2020), < https://ec.europa.eu/commission/presscorner/detail/en/IP_20_718 > accessed 6 June 2020.

Moeller J.H., 'Connected Health: Telemedicine Patent Landscape' (Moeller Ventures LLC, 9 March 2020) < https://www.moellerventures.com/index.php/blog/25-2020-articles/45-connected-health-telemedicine-patent-landscape ≥ accessed 7 June 2020

Oransi, S., 'Beyond The Hype: The Internet of Medical Things' Forbes (25 October 2019) < https://www.forbes.com/sites/forbesbusinessdevelopmentcouncil/2019/10/25/beyond-the-hype-the-internet-of-medical-things/ > accessed 5 June 2020

Papadopoulos H., et all 'Comparison of US and EU Regulatory Approaches to Mobile Health Apps: Use Cases of myVisionTrack and USEFIL' (2013) 21 The European Journal of ePractice 27 < https://joinup.ec.europa.eu/sites/default/files/document/2014-06/ePractice-Journal-Vol.21-December%202013.pdf > accessed 7 June 2020

Parvizi, N., Woods, K. 'Regulation of medicines and medical devices: contrasts and similarities' (2014) 14(1) Clinical medicine 6 < https://doi.org/10.7861/clinmedicine.14-1-6 > accessed 5 June 2020

Press release 'Global Mobile App Development Market Size, Share, Trends, Industry Analysis, Growth Drivers and Opportunities' (MarketWatch, 15 January 2020) < https://www.marketwatch.com/press-release/global-mobile-app-development-market-size-share-trends-industry-analysis-growth-drivers-and-opportunities-2020-01-15 > accessed 5 May 2020

Quinn P, 'The EU commission's risky choice for a non-risk based strategy on assessment of medical devices' (2017) 33(3) Computer Law & Security Review 361 < https://www.sciencedirect.com/science/article/abs/pii/S0267364916301637?via%3Dihub > accessed 7 June 2020

Report 'How digital intruders are taking over the healthcare market' (Research2Guidance, mHealth App Economics 2017) < https://research2guidance.com/product/mhealth-economics-2017-current-status-and-future-trends-in-mobile-health/> accessed 5 May 2020

Roth V.J., 'The mHealth Conundrum: Smartphones & Mobile Medical Apps—How Much FDA Medical Device Regulation is Required?' (2014), 15 (3) The North Carolina Journal of Law & Technology 359 < http://ncjolt.org/wp-content/uploads/2014/04/Roth-Color-Final.pdf > accessed 5 June 2020

Roth V.J., Niezen G, O'Kane A.A., Stawarz K. 'Can Standards and Regulations Keep Up With Health Technology?' (2015) 3 (2) JMIR Mhealth Uhealth < https://mhealth.jmir.org/2015/2/e64 > accessed 5 May 2020

Sekaran R., Chuang M., 'FDA Policy for Mobile Medical Applications', (Nossaman LLP, 14 February 2020) < https://www.thehealthlawticker.com/fda-policy-for-mobile-medical-applications > accessed 6 June 2020

Shahid N., Rappon T., Berta W., 'Applications of artificial neural networks in health care organizational decision-making: A scoping review' (2019) 14 (2) PLoS ONE < https://journals.plos.org/plosone/article/file?id=10.1371/journal.pone.0212356&type=printable > accessed 6 June 2020

Shorthose S., 'M-Health Applications; Legal Framework and Advertising' (Bird&Bird, July 2016) < https://www.twobirds.com/en/news/articles/2016/uk/m-health-applications-legal-framework-and-advertising > accessed 6 June 2020

Silver S., 'Apple details history of App Store on its 10th Anniversary' (Apple Insider Journal , 5 July 5, 2018) < https://appleinsider.com/articles/18/07/05/apple-details-history-of-app-store-on-its-10th-anniversary > accessed 6 June 2020

Stankevich E., et all 'Mobile Phone Sensors in Health Applications' (2012) 12th conference on Fruct association < https://www.cs.odu.edu/~cs441/Papers/app-006.pdf > accessed 6 June 2020

Stefanelli S., 'The Court of Justice takes a broad interpretation of when softwares fall within the notion of medical devices' (Stefanelli&Stefanelli legal website, 12 December 2017) < https://s3.amazonaws.com/documents.lexology.com/597c36f0-1863-4583-9e61-ba4b6c9842a1.pdf?AWSAccessKeyId=AKIAVYILUYJ754JTDY6T&Expires=1591453284&Signature=qSqgnbV042OBinhAsXpjr8pG4Jo%3D > accessed 6 June 2020

Stern C., 'Goldman Sachs says a digital healthcare revolution is coming — and it could save America $300 billion' (Business Insider, 29 June 29 2015) < https://www.businessinsider.com/goldman-digital-healthcare-is-coming-2015-6?international=true&r=US&IR=T > accessed 6 June 2020

Sudjic O., 'I felt colossally naive': the backlash against the birth control app' (The Guardian, 21 July 2018) < https://www.theguardian.com/society/2018/jul/21/colossally-naive-backlash-birth-control-app > accessed 6 June 2020

Swearingen A., 'Mobile Medical Applications and US FDA Regulations' (Emergo, a UL Company, 2017) < https://www.emergobyul.com/resources/articles/white-paper-us-fda-mobile-medical-applications > accessed 6 June 2020

Tahir. D., 'European Regulation Looms Over Mobile Health' (2013) 39 (11) Elsevier Business Intelligence "The Gray Sheet" < http://static.basenet.nl/cms/106131/website/Publications-2013/The%20Gray%20Sheet.pdf > accessed 6 June 2020

The Royal Dutch Medical Association 'Medische App Checker: handreiking bij het beoordelen van medische apps' (In Dutch, KNMG, 15 February 2016) < https://www.knmg.nl/actualiteit-opinie/nieuws/nieuwsbericht/medische-app-checker-handreiking-bij-het-beoordelen-van-medische-apps.htm > accessed 6 June 2020

Ugon A., Seroussi B., Lovis C, Transforming Healthcare with the Internet of Things: Proceedings of the EFMI Special Topic Conference 2016 (online via IOS Press BV, 2016) < https://tinyurl.com/y83wmow7 > accessed 6 June 2020

Werner P., 'Classification of medical apps under MDR — it's not the end of the world' (Medium, 12 February 2009). < https://medium.com/@pascalwerner/classification-of-medical-apps-under-mdr-its-not-the-end-of-the-world-d7a1ce4b577b > accessed 6 June 2020

White & Case Technology Newsflash 'Mobile Health Apps: Are They a Regulated Medical Device?' (White & Case, 12 August 2015) < https://www.whitecase.com/publications/article/mobile-health-apps-are-they-regulated-medical-device > accessed 5 June 2020

Wiersinga J. 'Regulation of Medical Digital Technologies' In: Marston H., Freeman S., Musselwhite C. (eds) Mobile e-Health. Human–Computer Interaction Series.

(2017,Springer, Cham)< https://link-springer-com.tilburguniversity.idm.oclc.org/content/pdf/10.1007/978-3-319-60672-9_13.pdf > accessed 6 June 2020

World Health Organization, 'Factsheet on Diabetes' (World Health Organization Official Website, 30 October 2018) < https://www.who.int/news-room/fact-sheets/detail/diabetes > accessed 6 June 2020

World Health Organization, 'Global diffusion of eHealth: Making universal health coverage achievable. Report of the third global survey on eHealth' Global Observatory for eHealth (2016) < https://apps.who.int/iris/bitstream/handle/10665/252529/9789241511780-eng.pdf;jsessionid=A5F9ECC4DD7688CA56B155BA356C908B?sequence=1 > accessed 6 June 2020

World Health Organization, 'mHealth. New horizons for health through mobile technologies' (2011) (3) Global Observatory for eHealth series < https://www.who.int/goe/publications/goe_mhealth_web.pdf > accessed 6 June 2020

World Health Organization, 'Telehealth' (World Health Organization Website, 2020) < https://www.who.int/gho/goe/telehealth/en/ > accessed 6 June 2020

World Health Organization, 'Telemedicine. Opportunities and developments in Member States: report on the second global survey on eHealth 2009' (2010) Global Observatory for eHealth series < https://www.who.int/goe/publications/goe_telemedicine_2010.pdf > accessed 6 June 2020

World Health Organization, 'WHO eHealth Resolution' (World Health Organization, 2020) < https://www.who.int/healthacademy/news/en/ > accessed 6 April 2020

World Health Organization, From Innovation to Implementation: eHealth in the WHO European Region (Regional Office for Europe, 2016) < http://www.euro.who.int/__data/assets/pdf_file/0012/302331/From-Innovation-to-Implementation-eHealth-Report-EU.pdf?ua=1 > accessed 6 June 2020

Xiaohui Yu, and others. 'mHealth in China and the United States: How Mobile Technology is Transforming Health Care in the World's Two Largest Economies' (Center for Technology Innovation at Brookings, 12 March 2014)< https://www.brookings.edu/wp-content/uploads/2016/06/mHealth_finalx.pdf > accessed 6 June 2020

Zegarelli, B., 'Building a Health App? Part 3: What you Need to Know About FDA's Regulation of Mobile Apps' (Mintz Consulting blog, 3 October 2017) < https://www.mintz.com/insights-center/viewpoints/2146/2017-10-building-health-app-part-3-what-you-need-know-about-fdas > accessed 6 June 2020

Zhang M.W.B., Ho R.C.M. 'M-Health and Smartphone Technologies and Their Impact on Patient Care and Empowerment' In: Menvielle L., Audrain-Pontevia AF.,

Menvielle W. (eds) The Digitization of Healthcare (2017, Palgrave Macmillan, London) < https://link.springer.com/chapter/10.1057%2F978-1-349-95173-4_16 > accessed 6 June 2020

LAWS AND GUIDANCES

EU legislation acts and clarification documents

Council Directive 93/42/EEC concerning medical devices (EC Medical Device Directive) [1993] OJ L 169

Guidance document Medical Devices - Scope, field of application, definition - Qualification and Classification of stand alone software, MEDDEV 2.1/6 [2016] < https://ec.europa.eu/docsroom/documents/17921/attachments/1/translations > accessed 6 June 2020

Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745-MDR and Regulation (EU) 2017/746-IVDR. [2019] < https://ec.europa.eu/docsroom/documents/37581 > accessed 6 June 2020

IMDRF terms of reference, IMDRF Management Committee [2018] < http://www.imdrf.org/docs/imdrf/final/procedural/imdrf-proc-180727-terms-of-reference.pdf > accessed 6 June 2020

Manual on Borderline and Classification in the Community Regulatory Framework for Medical Devices. Version 1.22 [2019] < https://ec.europa.eu/docsroom/documents/35582 > accessed 6 June 2020

Regulation 2017/745 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 (Medical Device Regulation) [2017]

Regulation 2020/561 amending Regulation (EU) 2017/745 on medical devices, as regards the dates of application of certain of its provisions [2020] L 130/18

US legislation acts and non-binding recommendations

Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act: Guidance for Industry and Food and Drug Administration Staff. Non-binding recommendation by FDA. 27 September 2019 < https://www.fda.gov/media/109622/download > accessed 6 June 2020

FDA '21st Century Cures Act' (U.S. Food&Drug Administration, 31 January 2020) < https://www.fda.gov/regulatory-information/selected-amendments-fdc-act/21st-century-cures-act > accessed 6 June 2020

FDA 'Digital Health Innovation Action plan' (U.S. Food&Drug Administration, 26 March 2020) < https://www.fda.gov/medical-devices/digital-health > accessed 6 June 2020

General Wellness: Policy for Low Risk Devices Guidance for Industry and Food and Drug Administration Staff [2019] < https://www.fda.gov/media/90652/download > accessed 6 June 2020

Policy for Device Software Functions and Mobile Medical Applications. Guidance for Industry and Food and Drug Administration Staff [2019] < https://www.fda.gov/media/80958/download > accessed 6 June 2020.

Public Law 114–255 [2016] (21st Century Cures Act) < https://www.congress.gov/114/plaws/publ255/PLAW-114publ255.pdf > accessed 6 June 2020

OFFICIAL WEBSITES

Flo, official website < https://flo.health > accessed on 17 May 2020.

ISO, official website of the International Organization for Standardization < https://www.iso.org> accessed 7 June 2020.

Natural Cycles, official website < https://www.naturalcycles.com > accessed 7 June 2020.

Official website of IMDRF, International Medical device Regulation forum < http://www.imdrf.org/about/about.asp > accessed 6 June 2020

United Kingdom National Health Service website < https://www.nhs.uk > accessed 6 June 2020

United Nations, official website, < https://www.un.org/en/ > accessed 6 June 2020

United States Food&Drug administration website < https://www.fda.gov > accessed 7 June 2020

World Health Organization, official website, < https://www.who.int > accessed 6 June 2020

COURT CASES:

Case C-219/11 Brain Products GmbH v Bio Semi VOF [2012] Judgment of the Court (Third Chamber) < http://curia.europa.eu/juris/document/document.jsf?docid=130247&doclang=en > accessed 6 June 2020

Case C.329/16 Snitem - Syndicat national de l'industrie des technologies médicales [2017] Judgment of the Court (Fourth Chamber) < http://curia.europa.eu/juris/liste.jsf?language=en&num=C-329/16 > accessed 6 June 2020