

Regulatory Processes & Innovation Cycles in Times of Digitalization – a Contradiction?

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Digitalization - without a doubt - is the main driver of innovation nowadays. This phenomenon takes place in almost every business, even within the medical device industry digital development is an important driving force. Digitalization allows a broad range of people to create their own mobile applications, as demonstrated by the enormous number of digital products available for mobile devices. While the simplified creation of digital products accelerates innovation in the medical device industry, regulatory processes remain the same yet seem to be necessary to provide a safe market entry. This work examines the influence of digital innovation on medical devices and compares the regulatory processes in the US and Germany. Therefore, a theoretical background of innovation and regulation theory is given. Subsequently, the regulatory systems of medical devices in the US and Germany are analyzed regarding their fit for mobile applications. After describing problems arising due to long and inappropriate regulation systems, recommendations are given by a fictive regulatory system on how regulatory processes can be adjusted to accommodate mobile medical applications.

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1 Introduction

Innovative developments within healthcare industry are often regarded as both a boon and bane at the same time. On one hand, making progress in medical devices offers huge potential: Processes may be simplified and optimized, providers better connected, and patient care improved. On the other hand, technological progress is blamed as a main driver for the continuous increase in healthcare costs (Sorenson et al., 2013). A substantial role within innovation in healthcare is played by digitalization. The range of benefits of digitalization for the healthcare industry and health systems can still hardly be imagined, though it is evident that digital products have had a huge impact (Malvey and Slovensky, 2014, p. 1). This rapid change to digitalization leads to several challenges: The subordinate problem deals with a still missing coherent terminology for digital, innovative products in healthcare (Albrecht and Jan, 2016, pp. 48–52). Of greater importance is the creation of an appropriate regulatory system, which allows fast access to the market but still considers and eliminates potential threats (Kramer et al., 2012, p. 853). Due to health systems often being strictly regulated, beneficial circumstances for creating innovative products are scarce. Nevertheless, the number of digital products seems to grow without any limits while the political and regulatory frameworks around the globe struggle to keep pace (Bierbaum and Bierbaum, 2017, pp. 255–256; Boulos et al., 2014, p. 1; Roh and Kim, 2017). There is no doubt that regulation of medical devices is a mandatory part within every health system to secure patients' health. Regulatory processes must fit adequately to the fast cycles of innovation and follow the rapid changes initiated by digitalization as well as the confusing number of digital products which claim to be part of the healthcare system.

This work examines the problems within the medical device industry due to rigid and long regulatory processes in addition to the dynamic innovation cycles within the industry. Because the meaning of digitalization for innovation in healthcare is still to be determined this work will just focus on digital products within the medical device industry. A theoretical framework about regulation and innovation forms the basis for this topic. Afterwards, the application of regulatory processes on digital medical devices is investigated. Corresponding to the topic of the book, the focus is on these processes in the US and Germany. An evaluation of the suitability of the current situation and potential suggestions for improvement closes this essay.

2 Innovation and regulation – a theoretical background

2.1 Theory of regulation and the principal-agent phenomenon

The act of regulating market entry and distribution of medical devices within a health system has the intention of protecting people from undesirable effects on their health status (Cheng, 2003, pp. 3–8). This is based on a very fundamental understanding of

regulation: The interaction of normative objects and private interests demands governmental action, which is represented through politics (Baron, 2007, p. 1,349). Regulation is commonly separated into *economic regulation*, *social regulation* and *administrative regulation*. While economic regulation is used for improving the performance of markets (e.g. through restrictions, standards, market entry conditions, etc.), social regulation relates to the protection of public health and well-being. Finally, administrative regulation determines governmental actions in private and public sectors, e.g. taxes and healthcare administration (OECD, n.a.).

Within markets, those regulatory interventions are required because of asymmetric information, a main part within the principal-agent theory. This phenomenon occurs when there are parties contracting with each other which are suffering an unequal level of information and individual action cannot be observed. As a consequence, this leads to moral hazard, which prohibits “first best” solutions (Holmstrom, 1979, p. 74). In the case of asymmetric information, regulation serves as mediator to create equal conditions between the principal and agent and to eliminate economically inefficient behavior (Baron, 2007, p. 1,349). Regarding regulation of medical devices, asymmetric information can be observed in different scenarios: the manufacturer of a medical device (both physical and digital) has a strong advantage in information compared to customers; customers may be patients acquiring the product directly from the manufacturer or distributor and uses it for himself; or the customer is represented by a care provider, who acquires the medical device for commercial use and applies the medical device for patient treatment. The user in the last two cases is unable to assess the benefit of a medical device in advance, as is common in health economics (Zweifel and Manning, 2000, pp. 412–413). Furthermore, the manufacturer has an incentive to maximize his profit. A corresponding minimization of the costs to achieve greater profits in this situation could lead to a reduction of efforts to protect the interests of consumers. This legitimizes governmental regulation to reduce economic costs and guarantee patient safety (Cheng, 2003, pp. 7–8). Regarding medical devices affecting peoples’ health, the role of governmental regulation is mainly to introduce and adopt a minimum standard of quality.

There are several theoretical mechanisms through which asymmetric information can be solved by governmental regulation (Baron, 2007). In a concrete setting with a regulatory framework, the manufacturer of the medical device would have to pass a predefined and comparable standard, which allows the users to trust the product is at least a certain level of quality. Attention should be paid to changing circumstances, though. Regulatory processes may be adequate for a certain range or type of products, but changes and drifts over time may influence the industry and demand an adoption of new regulatory framework.

2.2 Theory of innovation and the innovation process

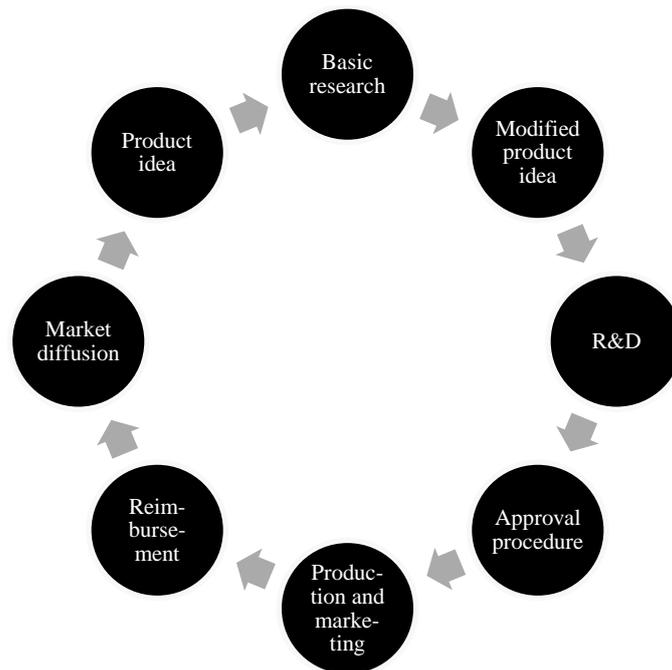
The term “innovation” is widespread and used in several contexts with different meanings (Baregheh et al., 2009). For a better understanding, there should be a common definition of innovation: following the Sociologist Everett M. Rogers and his pioneering book “Diffusion of Innovations” innovation should be understood as something that distinguishes itself through a certain novel characteristic (Rogers, 2003, p. 12). This can be expressed through new processes, products, or changes in organization. The aim innovation strives for - from a company’s point of view - is either to reduce unit costs and/or enlarge demand within the market (Sengupta, 2014, p. 1). Therefore, innovation is also seen as a possible way to create competitive advantage (Porter, 1990, p. 74).

Innovation is often separated into different subtypes. We will just focus on few which are relevant to the medical device industry and digitalization:

- One subtype is technology-based innovation. This term sums up all product innovation, process innovation, investments of the industry in research and development, and the transmission of technology (Sengupta, 2014, p. 1).
- Another separation into subtypes involves endogenous and exogenous innovation. Endogenous innovation develops from the incentives of the market. Innovation in this case is most often created by being the first company with a new technology and earning a monopolistic standing within the industry, e.g. through patent protection. Exogenous innovation describes a form of innovation which develops through a background outside the industry, e.g. academic research (Sengupta, 2014, pp. 1–5).
- Finally, there should be separation between incremental and radical/disruptive innovation. While the first means to make small changes piece by piece on an already existing product, the latter describes a complete substitution of an existing product (Stewart, 2011, p. 2).

These “types” of innovation take place in an innovation process. One of the most common interpretations is from Andrew van de Ven (1999), who distinguishes between a linear and a cyclical model. The main difference between these models is that there are straightforward, defined tasks within the linear model and a more blurry, interdependent, and repeating process within the latter. Additionally, the cyclical model makes it difficult to comprehend which aspects are influencing which development. In comparison to the linear model, a cycle of the innovation process is defined by the obligatory fact that it must repeat itself (Figure 10.1).

Figure 1: Innovation cycle in the medical device industry



Source: Own representation based on Van de Ven, 1999 and Mostardt, Ochs, et al., n.a.

If we consider the previous information about the different subtypes and characteristics, innovation within the medical device industry by digital products can be categorized as follows: The first aspect of innovation arises through digitalization, which represents a divergent technology. Therefore, we see technology-based types of innovation. Second, mainly endogenous innovation can be observed. This is a result of the incentives of the healthcare market and its demand for innovative solutions. Third, digital products represent disruptive innovation. Those products do not only improve but also substitute existing products on the market. All this technology-based, endogenous, and disruptive innovation in the medical device industry happens within a cycle of innovation that creates incremental progress. This means that this new area in the medical device industry is improving through its changes. All these special factors lead to a special demand for regulation of the products created.

This leads us to how innovation is adopted by the users: innovation - digitalization in particular - can hardly be described without diffusion. Diffusion is the process of communicating an innovation through a social system (Rogers, 2003, p. 10). Rogers distinguishes between different types of adopters, according to their innovativeness. This factor determines the rate of adoption of an innovation, i.e. how fast does an innovation establish itself within a system (Rogers, 2003, pp. 22–23). Additionally, innovation must be separated from invention: while innovation means a change in the producing systems of manufacturers, invention describes a shift within the technical opportunities themselves (Brozen, 1951, p. 239). Innovation itself always creates uncertainty, which

depends on the user's possibility to evaluate the risks. Because the risks of medical products can hardly be assessed by the users - according to the principal-agent theory - it is the duty of regulatory procedures to reduce those risks for the patients. The specific aspects of health systems, e.g. the reimbursement system and the number of different actors, influence the diffusion of innovation. In consequence, the economic success of a medical app depends on the rate of diffusion, which in turn benefits from low uncertainty and short regulatory processes. Regulation therefore can have huge impact on diffusion of medical device innovation.

2.3 The mutual impact of regulation and innovation

The governmental approach of implementing regulatory processes in markets represents an interference with the liberal market environment. These actions are mandatory as a result of market failure provoked by asymmetric information as mentioned above (Akerlof, 1970; Samuelson, 1984). Consequently, those diverse conditions have several positive and negative effects on innovation cycles.

On the one hand, different regulatory actions enhance the circumstances for innovation in markets. Regulation can ensure an appropriate level of competitiveness and openness among businesses. This is a main condition to promote innovation in an industry because a certain level of competitiveness sets incentives to achieve a competitive advantage (OECD, n.a., p. 12). Therefore, companies have to reach several requirements which can only be fulfilled by creating product or process innovations (Blind, 2016, p. 3). In contrast to this indirect way of promoting innovation, the straight approach would be realized by handing out intellectual property rights. This form of regulation is explicitly dedicated to enhancing innovation by giving patents to create a monopolistic situation as a reward (Blind, 2016, p. 3).

On the other hand, regulation can lead to massive impediments for innovation. The regulatory burden on the companies requires financial resources and time which could otherwise be invested in innovative approaches. This hits small companies trying to focus on their innovative initiatives especially hard (Stewart, 2011, p. 2). Regulation might also restrict research efforts, the possibility of using different technologies, and the technology diffusion (OECD, n.a., p. 12). Furthermore, competition can be hindered and market entry can be complicated. This leads to a delay in supply or even a cessation of production (Blind, 2016, pp. 8–10). Especially within the medical device industry, the interaction between regulation of and innovation in market entry plays a huge role: how is it possible to ensure patients have access to the newest innovations in a fast way but also make sure that safety is not jeopardized (WHO, 2010, p. 14)?

The relationship between regulation and innovation seems to be one-sided because regulation has huge impact on innovation. Despite this, it can also be mutual and digitali-

zation is a very suitable example. The development of digital products created new sections within many businesses, if not a business itself. Following Rogers (2003), innovation leads to uncertainties about how to treat new products. Consequently, this innovative development encourages the creation of new regulatory mechanisms (Bierbaum and Bierbaum, 2017, p. 249).

3 Regulatory processes as a hurdle for innovation? Data from the U.S. and Germany

3.1 The ‘mobile medical device’ – an example of innovation

When renowned Harvard professor Clayton M. Christensen stated back in 2000 that healthcare could be “saved” by disruptive innovation, he would not have known that digitalization will maybe make this happen (Christensen et al., 2000). The introduction of digital opportunities created several new but blurry business fields in healthcare, e.g. mobileHealth (mHealth), telehealth and eHealth (Malvey and Slovensky, 2014). Accordingly, the range of digital medical devices is very inconsistent and does not improve with growing technical opportunities (Hudes, 2017, p. 1). For consistency in this work, a common understanding of what is meant with the term “medical device” in the digital spheres should be determined. First, the focus is exclusively on digital products. There is no doubt that innovation in the medical device industry happens in many ways, but digitalization has an outstanding position in the present time. Also, the innovation cycles of digital products differ heavily from physical products, creating several challenges for regulation.

Second, a standard definition of “medical device” should be adopted by the *US Food and Drug Administration* (FDA) and the *Bundesinstitut für Arzneimittel und Medizinprodukte* (BfArM). These institutions are responsible for approval procedures for medical devices in the US and Germany. Accordingly, this essay will focus on the regulatory processes of mobile medical applications and will exclude health applications (programs with only preventive purpose), telemedicine, and any kind of health information systems (BfArM, 2015; FDA, 2017b). The investigated programs are used by patients or professional users. mobile medical apps are software programs running on mobile devices, which fall into the category of medical devices in the US and Germany (BfArM, 2015; FDA, 2017c). This will be further be specified in the following sections.

3.2 Regulatory processes and innovation cycles in the US

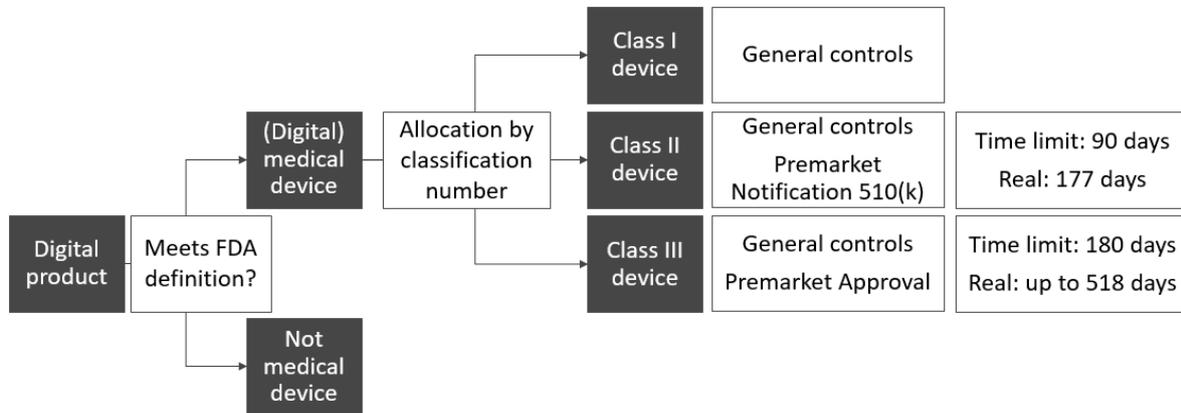
The FDA first published a guideline for mobile medical applications in 2013 and updated this due to dynamic development in 2015. This guideline states that a mobile medical app must fall under section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (FDA, 2015, p. 7). This states the app has to be an accessory to a regulated

medical device or has to convert from a mobile platform into a regulated medical device (FDA, 2017c). The section 201(h) also gives a description of which criteria have to be met to be declared as medical device: a medical device has to affect body functions or be involved in “the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease”(FDA, 2015, p. 7). The application of this definition represents the first level of regulation. If the product does not meet this description, there will not be any regulatory process. As soon as the intended use of the digital product meets the definition, the same regulatory processes used for physical medical devices are applied (FDA, 2017c). The process starts with the classification of the mobile medical device into three classes of risk. With a higher risk class, the severity of regulatory requirements increases. The medical device is allocated to one of the risk classes by a classification number, which belongs to the area of application on a human body (FDA, 2014a). No matter which class a medical device is part of, there are general controls like being manufactured under a quality assurance program, fit for the intended use, labeled adequately, and registered as well as listed by the FDA (FDA, 2014b). Class I is the most common for mobile apps and represents devices with low risk for the user which must only fulfill general controls in most cases. Medical devices with moderate risk ranked as Class II must pass a Premarket Notification 510(k) in addition (FDA, 2014a). This process should demonstrate to the FDA that the medical device is safe and effective by comparing it with an already established device on the market. After the 510(k) is found successful by the FDA, the product can be introduced immediately on the condition that there might be inspections at any time by the FDA (FDA, 2016). For high risk devices (Class III), a Premarket Approval is mandatory. This includes scientific, regulatory documentation that demonstrates safety and effectiveness and is often supported by clinical studies (FDA, 2017d). After passing those regulatory processes the mobile medical device can be introduced to the US market (Kramer et al., 2012).

The time-consuming parts within the regulatory process of the FDA are the Premarket Notification 510(k) and the Premarket Approval for risk classes II and III. For the 510(k), the FDA sets itself a time frame of 90 days from the receipt of the 510(k) to come to a decision. If 100 days are exceeded, clarifying communication will take place (FDA, 2017e). In the case of the more strictly handled Premarket Approval for Class III devices, the time frame is extended to 180 days. The FDA confesses that the process may be lengthen if necessary (FDA, 2017d). In practice, the length of both regulatory processes take much longer: an investigation of all 510(k)-processes between 2012 and 2016 shows an average of 177 days in 2016 instead of the proclaimed 90 days (Emergo Group, 2017, p. 5). Not even 20% of all devices are cleared within the proposed timeline (Emergo Group, 2017, p. 7). The same situation can be examined for the Premarket Approval process for class III medical devices. Data varies between 290 and up to 518 days

as average instead of 180 days (AOK-Bundesverband, 2013; Makower et al., 2010; Walter et al., 2016). *Figure 10.2* summarizes the path of a digital product through the regulatory processes of the US.

Figure 2: Regulatory process of a Mobile Medical Device in the US



Meanwhile, innovation in the medical device industry is accelerating and the number of digital products is growing at an annual rate of 25 percent (Cortez et al., 2014, p. 372; FDA, 2017a). A survey under manufacturers carried out, that the most important drivers to gain competitive advantage are product innovation and reduction of time-to-market (PA Consulting, 2016, p. 12). Yet the time-to-market for medical devices takes three to seven years from conception to completing the regulatory processes (Fargen et al., 2013). From the start of communication with the FDA to approval, it takes an average of one to two and a half years (Makower et al., 2010, p. 6; Rising and Moscovitch, 2015). This development provokes reaction from the regulatory institutions. To keep the number of mobile medical applications under control, the FDA sets very strict definitions of what is regulated and which products are not. *Table 10.1* shows a selection of different regulations concerning mobile medical devices. Class III devices were not represented in the given examples of the FDA. A large portion of mobile apps which are per definition a medical device is excluded from regulatory processes because they pose low risk to consumer safety. For these low risk products there is no list with concrete details, only different examples (FDA, 2015, pp. 15–18). The broad exclusion of regulated mobile medical apps suggests an overload of the regulatory capacity. Furthermore, the FDA presents a list of apps which *may* be a medical device (FDA, 2015, pp. 23–26). The FDA also does not make clear how to deal with updates. It is simply stated that “minor, iterative product changes” do not require a re-evaluation of the product (FDA, 2017c). This underlines the uncertainty the institution when handling innovative products.

Table 1: Examples of FDA regulations for Mobile Medical Devices

Device Name	Applicant	Clearance Date	Regulation Description	Risk Class
JiveX	VISUS TECHNOLOGY TRANSFER GMBH	9/16/2016	Picture archiving and communications system	Class II
Lumify Ultrasound System	Philips Healthcare	10/3/2016	Ultrasonic pulsed doppler imaging system	Class II
(If a manufacturer's device falls into a generic category of exempted class I devices as defined, there is no explicit regulation)			(e.g.) Calculator/data processing module for clinical use	Class I

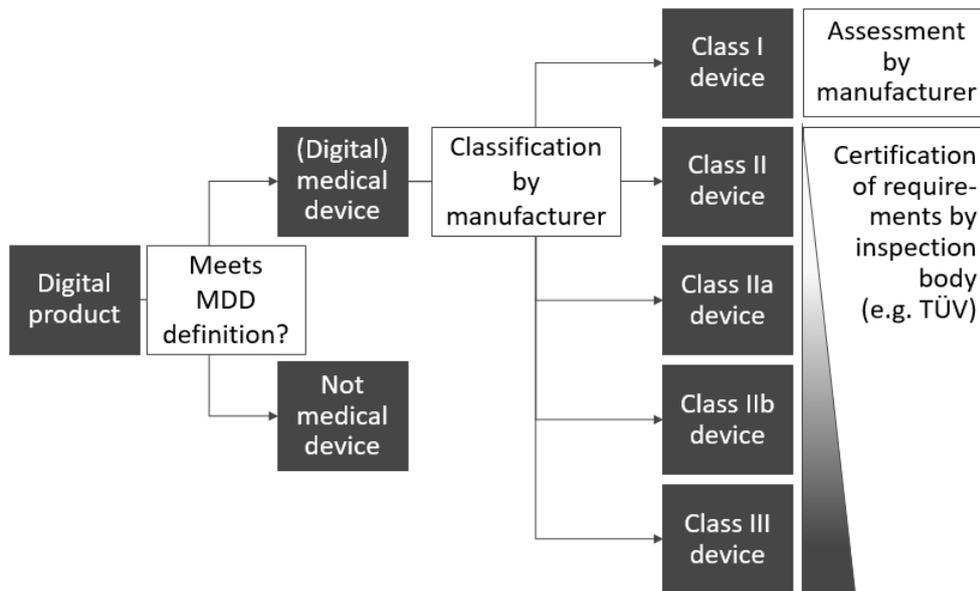
Source: FDA 2015.

3.3 Regulatory processes and innovation cycles in Germany

In Germany, most of the responsibility for defining products as medical devices and regulating market entry is transferred to the European Union. These European laws must be implemented into national law. Therefore, all European regulations are compulsory for the German system.

As in the US, the first aspect for commercial distribution is the definition of the product. The German definition set in the *Medizinproduktegesetz* (MPG) follows the guideline 93/42/EWG of the European Union (also called Medical Device Directive; MDD). The decisive factor for a mobile app being declared as medical device is – similar to the FDA – the intended use. If the device should be used for diagnosis, prevention, supervision, or cure of sickness or injury, to change a physiological process, or for contraception the MDD is applied. Comparable to the FDA, a risk classification for these medical devices is used. Applications are separated into Class I with low risk (with Is for sterile and Im for measuring), Classes IIa and IIb are for middle and increased risk products, respectively, and Class III is for high risk devices. *Figure 10.3* represents the process in Germany. The classification is regulated under the MDD, which defines 18 rules regarding health risks (BfArM, 2015). According to these rules, most mobile medical devices are ranked Class I and sometimes IIa or IIb (BfArM, 2015; Bierbaum and Bierbaum, 2017, p. 255). The MDD further classifies mobile medical devices as *active medical devices* which are dependent on an external power source and often ranked within higher risk classes (BfArM, 2015). If medical apps are changed or expanded by updates, there is no clear way to deal with the change. In cases of a tremendous impact on users health, the responsible authority has to be informed (*Richtlinie 93/42/EWG des Rates*. Europäisches Parlament und Rat, 1993).

Figure 3: Regulatory process of a Mobile Medical Device in Germany



The aim of the regulatory process is the CE-sign, which shows the safety and effectiveness and also allows medical devices to be distributed within the European Single Market. Depending on the risk classification, the product must pass different assessments. Class I devices can be assessed by the manufacturer themselves and no inspection body is needed (e.g. TÜV; *Technischer Überwachungsverein*). For all other classes, an inspection body must be involved and a declaration of conformity must be provided (BfArM, 2015). The declaration of conformity depends on the risk classification and is determined by the regulations of the European Union. The requirements of approval procedures rise to correspond with higher risk classes. These can include risk management, technical documentation up to clinical studies, and cost-benefit-analysis within the MDD (BMG, 2010). In contrast to the US, where the state-owned FDA does the assessment by 510(k) or Premarket Approval, the risk classification and the declaration of conformity is done by the manufacturer itself. Just the certification is performed by a chosen inspection body according to appendix I of the MDD (BMG, 2010). Germany is in a decentralized and less arranged setting compared to the more centralized and transparent one in the US (Kramer et al., 2012, pp. 850–851).

As in the US, the regulatory processes play the leading role on the way to the market. In contrast, the time-to-market is reduced due to decentralized regulation: empirical data shows that the CE-certificate is assigned 36 months earlier in Germany than in the US for devices with Premarket Approval (Hwang et al., 2016, p. 4). Yet, the whole process is still estimated to be between four to six years (Neumann et al., 2016, p. 50). In both countries, the approval for low- and moderate-risk devices seems quite similar, where most mobile medical apps are concerned (Kramer et al., 2012, p. 852). Nevertheless, with a maximum release cycle of less than one year (in comparison to more than three

years for normal medical devices), time-to-market increases and represents a loss of potential due to regulatory processes for innovative digital products (Knöpple et al., 2016, p. 13).

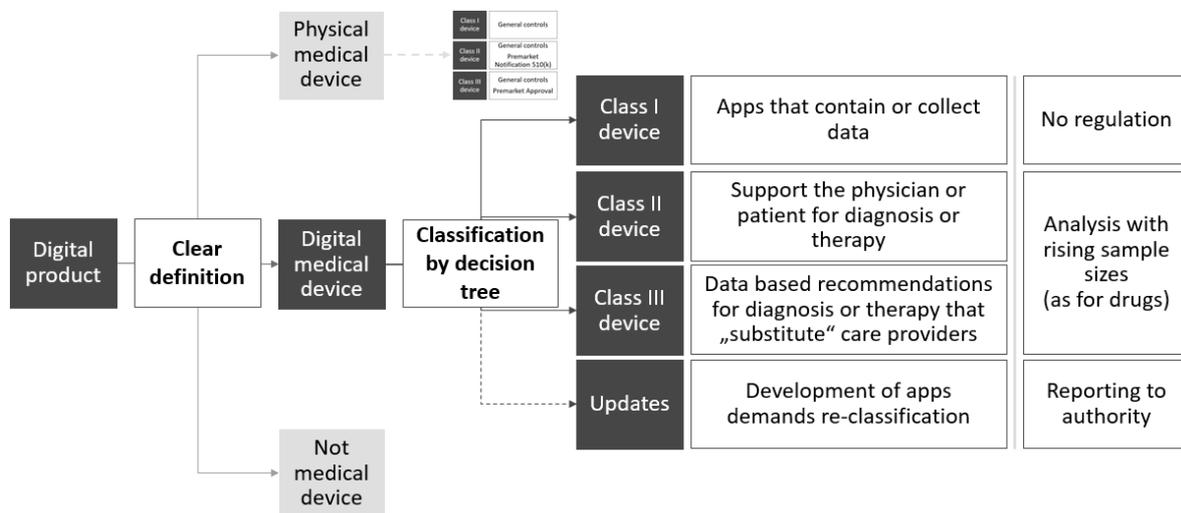
4 Possibilities for a harmonious interaction between regulation and innovation in healthcare

After looking at American and German medical device regulation, both have commonalities and differences. The risk classification systems are obligatory and seem to be quite similar, while the degree of centralization as well as the length of regulatory processes differs (Kramer et al., 2012, p. 850). Theory also provides a necessary component of economic and social regulation to maintain fair market conditions and secure population health. Yet this has partly negative effects on innovation and diffusion of innovation due to long regulatory processes. Since innovation cycles are much shorter for mobile medical apps, the application of the same regulatory processes as for physical devices seems questionable. Regarding the huge number of medical apps, a separate regulatory process would be more appropriate. For a better alignment, such a process is fictively proposed hereinafter:

For manufacturers of mobile medical apps, it is important to get a fast and comprehensive overview of the regulatory requirements. Therefore, a clear definition of a digital medical product must be found. The confusing mixture of terms like eHealth, mHealth, etc. prohibits a clear understanding and impedes the dialogue. The definition should be determined by concrete criteria and not the intended use or blurry examples. After an adequate definition and separation from apps with just preventive character, a classification must take place. The used risk classifications seem to be proven, but the results are biased due to the mixture with normal medical devices. A system tailored for digital products is necessary because the risks of digital products can hardly be compared to risks of physical devices. Lewis & Wyatt (2014) e.g. separate between inherent (those within an app) and contextual risks (which occur through use). A three-stage classification may maintain: Class I includes apps that contain or collect data. Within class II are apps that give support to the doctor or patient for diagnosis or therapy based on data. Class III would contain apps with data based recommendations for diagnosis or therapy that “substitute” care providers (Knöpple et al., 2016, pp. 22–25; Neumann et al., 2016, p. 25). This classification may be executed by a decision tree or similar tool. Of decisive importance is the consideration of updates. The development of digital products often happens through an iterative process and in cooperation with the final user. Furthermore, algorithms may be used, which evolve with increasing application (Neumann et al., 2016, pp. 32–35). This must be considered within the regulatory process and demands a reporting system. This hypothetical regulatory process is depicted in *figure 10.4*.

No approval procedure should be prescribed for class I devices because these would not intervene in treatment. For classes II and III, a procedure similar to that used for drugs can be conceivable: due to the iterative development process of apps, it may be tested step-by-step by raising sample sizes until a market maturity can be attested to (Neumann et al., 2016, pp. 32–35). This process may also lead to an upgrade in risk classes for medical apps. Accordingly, updates must be reported to the competent authority within a post-market surveillance system. If this authority should be centralized or decentralized is hard to answer. Since a decentralized system can accomplish regulatory processes obviously faster, it seems to be more suitable for medical apps to enable an appropriate chance for diffusion (for further inspiration how regulatory processes might be adopted to medical apps see Boulos et al., 2014; Lewis and Wyatt, 2014; Neumann et al., 2016).

Figure 4: Hypothetical regulatory process for Mobile Medical Devices



It remains unclear how such a risk classification system is appropriate for learning algorithms and how to evaluate the storing of personal data. As such, this example of an autonomous regulation for medical apps might go too far for now, but it may give ideas for future improvements to regulatory processes.

5 Conclusion

Innovation in healthcare calls for changes in the rigid systems of the US, Germany, and many other countries. The barriers to creating medical devices decline due to the opportunities presented by digitalization. Strongly altered structures are the consequence and governments must adapt their regulatory processes. Internationally changes are occurring: The European Parliament approved a new Medical Device Regulation in April 2017 with a transitional period of three years. Therein, medical apps earn greater importance, but the regulatory processes will not be simplified, quite the contrary. The old classification system remains but new wording ranks software risks often higher than

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before, which leads to longer regulatory processes. This means much more burden on most, often young, innovative companies, which might fail due to this regulation. Instead, a regulatory system that encourages innovative products by enabling an adequate speed of the process would be a better way to promote and enable innovation in the medical device industry.

References

- Akerlof, G. A. (1970), 'The Market for "Lemons": Quality Uncertainty and the Market Mechanism', *The Quarterly Journal of Economics*, vol. 84, no. 3, p. 488.
- Albrecht, U.-V. and Jan, U. (2016), 'Kapitel 1. Einführung und Begriffsbestimmungen', in Albrecht, U.-V. (ed.) *Chancen und Risiken von Gesundheits-Apps (CHARISMHA)*, pp. 48–61.
- AOK-Bundesverband (2013), *Medizinprodukte - Mythen und Wahrheit*, AOK-Bundesverband [Online]. Available at: http://aok-bv.de/imperia/md/aokbv/politik/versicherte/thesenpapier_gross_0713_dt.pdf (Accessed May 02, 2017).
- Baregheh, A., Rowley, J. and Sambrook, S. (2009), 'Towards a Multidisciplinary Definition of Innovation', *Management Decision*, vol. 47, no. 8, pp. 1323–1339.
- Baron, D. P. (1989), 'Chapter 24 Design of Regulatory Mechanisms and Institutions', in Schmalensee, R. and Willing, R. (eds.) *Handbook of Industrial Organization*, 2nd edn, Amsterdam, Elsevier, pp. 1347–1447.
- BfArM (2015), *Orientierungshilfe Medical Apps*, BfArM [Online]. Available at: http://www.bfarm.de/DE/Medizinprodukte/Abgrenzung/medical_apps/_node.html (Accessed April 23, 2017).
- Bierbaum, M. and Bierbaum, M. E. (2017), 'Medical Apps im Kontext von Zulassung und Erstattung', in Pfannstiel, M. A., Da-Cruz, P. and Mehlich, H. (eds.) *Digitale Transformation von Dienstleistungen im Gesundheitswesen I*, Wiesbaden, Springer Fachmedien Wiesbaden, pp. 249–263.
- Blind, K. (2016), 'The Impact of Regulation on Innovation', in Edler, J., Cunningham, P., Gök, A. and Shapira, P. (eds.) *Handbook of Innovation Policy Impact*, Cheltenham, UK, Northampton, MA, USA, Edward Elgar Publishing, pp. 450–482.
- BMG (2010), *Medizinprodukterecht im Überblick*, Bundesministerium für Gesundheit [Online]. Available at: https://www.bundesgesundheitsministerium.de/fileadmin/redaktion/pdf_allgemein/Medizin_Produkte_Marktzugangsvoraussetzungen_fuer_Medizinprodukte.pdf (Accessed May 01, 2017).
- Boulos, M. N. K., Brewer, A. C., Karimkhani, C., Buller, D. B. and Dellavalle, R. P. (2014), 'Mobile Medical and Health Apps: State of the Art, Concerns, Regulatory Control and Certification', *Online Journal of Public Health Informatics*, vol. 5, no. 3, p. 229.
- Brozen, Y. (1951), 'Invention, Innovation, and Imitation', *The American Economic Review*, vol. 41, no. 2, pp. 239–257.
- Cheng, M. (2003), *Medical Device Regulations: Global Overview and Guiding Principles*, Geneva, World Health Organization.

Christensen, C. M., Bohmer, R. and Kenagy, J. (2000), 'Will Disruptive Innovations Cure Health Care?', *Harvard Business Review*, vol. 78, no. 5, pp. 102-112.

Cortez, N. G., Cohen, I. G. and Kesselheim, A. S. (2014), 'FDA Regulation of Mobile Health Technologies', *The New England Journal of Medicine*, vol. 371, no. 4, pp. 372–379.

Emergo Group (2017), *How Long it Takes the US FDA to Clear Medical Devices via the 510(k) Process: An Examination of 15,000 Medical Device Applications Cleared by the US Food and Drug Administration between 2012 and 2016*, Emergo Group [Online]. Available at: <https://www.emergogroup.com/sites/default/files/emergo-fda-510k-data-analysis-2017.pdf> (Accessed April 29, 2017).

Europäisches Parlament und Rat (1993), *Richtlinie 93/42/EWG des Rates*.

Fargen, K., Frei, D., Fiorella, D., McDougall, C., Myers, P. and Hirsch, J. (2013), 'The FDA Approval Process for Medical Devices: An Inherently Flawed System or a Valuable Pathway for Innovation?', *Journal of Neurointerventional Surgery*, vol. 5, no. 4, pp. 269–275.

FDA (2014), *Classify Your Medical Device* [Online], U.S. Food and Drug Administration. Available at: <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/default.htm> (Accessed April 24, 2017).

FDA (2014), *Classify Your Medical Device - Class I/II Exemptions* [Online], U.S. Food and Drug Administration. Available at: <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051549.htm> (Accessed April 29, 2017).

FDA (2015), *Mobile Medical Applications: Guidance for Industry and Food and Drug Administration Staff*, U.S. Food and Drug Administration [Online]. Available at: <https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf> (Accessed April 23, 2017).

FDA (2016), *Premarket Notification 510(k)* [Online], U.S. Food and Drug Administration. Available at: <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm> (Accessed April 29, 2017).

FDA (2017), *Consumer Updates: Keeping Up with Progress in Mobile Medical Apps* [Online], U.S. Food and Drug Administration. Available at: <https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm368634.htm> (Accessed April 30, 2017).

FDA (2017), *Digital Health* [Online], U.S. Food and Drug Administration. Available at: <https://www.fda.gov/MedicalDevices/DigitalHealth/default.htm> (Accessed April 23, 2017).

FDA (2017), *Mobile Medical Applications* [Online], U.S. Food and Drug Administration. Available at: <https://www.fda.gov/MedicalDevices/DigitalHealth/MobileMedicalApplications/ucm255978.htm> (Accessed April 23, 2017).

FDA (2017), *Premarket Approval (PMA)* [Online], U.S. Food and Drug Administration. Available at: <https://www.fda.gov/medicaldevices/deviceregulationandguidance/howtomarketyourdevice/premarket submissions/premarketapprovalpma/default.htm> (Accessed April 29, 2017).

FDA (2017), *Premarket Notification (510k) - 510(k) Submission Process* [Online], U.S. Food and Drug Administration. Available at: <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm> (Accessed April 29, 2017).

Holmstrom, B. (1979), 'Moral Hazard and Observability', *Bell Journal of Economics*, vol. 10, no. 1, pp. 74–91 [Online]. Available at: <http://econpapers.repec.org/RePEc:rje:bellje:v:10:y:1979:i:spring:p:74-91> (Accessed October 03, 2017).

Hudes, M. K. (2017), 'Fostering Innovation in Digital Health a New Ecosystem', in *Microelectronics Symposium (Pan Pacific)*, pp. 1–6.

Hwang, T. J., Sokolov, E., Franklin, J. M. and Kesselheim, A. S. (2016), 'Comparison of Rates of Safety Issues and Reporting of Trial Outcomes for Medical Devices Approved in the European Union and United States: Cohort study', *BMJ (Clinical Research Ed.)*, vol. 353, no. 3323.

Knöpple, K., Oschmann, L., Neumann, J. and Neisecke, T. (2016), *Transfer von Digital-Health-Anwendungen in den Versorgungsalltag: Teil 1: Transfermodell, Varianten und Hürden*, Bertelsmann Stiftung.

Kramer, D. B., Xu, S. and Kesselheim, A. S. (2012), 'Regulation of Medical Devices in the United States and European Union', *The New England Journal of Medicine*, vol. 366, no. 9, pp. 848–855.

Lewis, T. L. and Wyatt, J. C. (2014), 'mHealth and Mobile Medical Apps: A Framework to Assess Risk and Promote Safer Use', *Journal of Medical Internet Research*, vol. 16, no. 9.

Makower, J., Meer, A. and Denend, L. (2010), *FDA Impact on U.S. Medical Technology Innovation: A Survey of Over 200 Medical Technology Companies*, MedTech Europe [Online]. Available at: http://www.medtecheurope.org/sites/default/files/resource_items/files/01112010_FDA%20impact%20on%20US%20medical%20technology%20innovation_Backgrounder.pdf (Accessed May 02, 2017).

Malvey, D. and Slovensky, D. J. (2014), *mHealth: Transforming Healthcare* [Online], Boston, MA, s.l., Springer US. Available at: <http://dx.doi.org/10.1007/978-1-4899-7457-0> (Accessed October 03, 2017).

Neumann, K., Larisch, K., Dietzel, J., Kurepkat, M., Weißer, M. and Wenzlau, V. (2016), *Digitale Versorgungsprodukte: Chancen nutzen, sichere Wege in den Markt schaffen*, IGES Institut.

OECD (n.d.), *Regulatory Reform and Innovation*, OECD [Online]. Available at: <https://www.oecd.org/sti/inno/2102514.pdf> (Accessed April 17, 2017).

PA Consulting (2016), *Gaining Competitive Advantage in Medical Devices: How to Optimise Time- and Cost-to-Market in Product Development*, PA Consulting [Online]. Available at: <http://www2.paconsulting.com/rs/526-HZE-833/images/Gaining%20competitive%20advantage%20in%20medical%20devices.pdf> (Accessed April 30, 2017).

Porter, M. E. (1990), *The Competitive Advantage of Nations: With a New Introduction*, New York, N.Y., Free Press.

Rising, J. P. and Moscovitch, B. (2015), ‘Characteristics of Pivotal Trials and FDA Review of Innovative Devices’, *PloS One*, vol. 10, no. 2.

Rogers, E. M. (2003), *Diffusion of Innovations*, 5th edn, New York, u.a., Free Press.

Roh, C.-Y. and Kim, S. (2017), ‘Medical Innovation and Social Externality’, *Journal of Open Innovation: Technology, Market, and Complexity*, vol. 3, no. 1, p. 386.

Samuelson, W. F. (1984), ‘Bargaining under Asymmetric Information’, *Econometrica*, vol. 52, no. 4, p. 995.

Sengupta, J. (2014), *Theory of Innovation*, Cham, Springer International Publishing.

Sorenson, C., Drummond, M. and Bhuiyan Khan, B. (2013), ‘Medical Technology as a Key Driver of Rising Health: Disentangling the Relationship’, *ClinicoEconomics and Outcomes Research : CEOR*, vol. 5, pp. 223–234.

Stewart, L. A. (2011), *The Impact of Regulation on Innovation in the United States: A Cross-Industry Literature Review*, Information Technology & Innovation Foundation.

van de Ven, A. H. (1999), *The Innovation Journey* [Online], New York, N.Y., Oxford Univ. Press. Available at: <http://www.loc.gov/catdir/enhancements/fy0604/99012927-d.html> (Accessed October 03, 2017).

Walter, J. R., Hayman, E., Tsai, S., Ghobadi, C. W. and Xu, S. (2016), ‘Medical Device Approvals through the Premarket Approval Pathway in Obstetrics and Gynecology: Process and Problems from 2000 to 2015’, *Obstetrics and Gynecology*, vol. 127, no. 6, pp. 1110–1117.

WHO (2010), *Barriers to Innovation in the Field of Medical Devices: Background Paper 6*, WHO [Online]. Available at: http://apps.who.int/iris/bitstream/10665/70457/1/WHO_HSS_EHT_DIM_10.6_eng.pdf (Accessed April 30, 2017).

Zweifel, P. and Manning, W. G. (2000), ‘Chapter 8 Moral Hazard and Consumer Incentives in Health Care’, in Culyer, A. J. and Newhouse, J. P. (eds.) *Handbook of Health Economics*, Elsevier, pp. 409–459.