

When Digital Health Encounters Regulation: The Approval Process for Prescription Apps in Germany

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Abstract

In late 2019, Germany took significant steps towards becoming a forerunner in digital health. A new legislation stipulated that medical apps for different indications could now be prescribed to patients by their healthcare providers – the so-called Digital Health Applications (DiGAs). Patients' public health insurance then covers the costs of these apps. The precondition for apps to be eligible for prescription and remuneration is that they undergo a prior approval process with the German Federal Institute for Drugs and Medical Devices. We take this transformation of an ordinary health app into a medico-legal product, a DiGA, as the point of departure for a detailed examination of the regulation of digital health in practice. Analysing the approval process for DiGAs allows us to generate insights into what qualities of apps are assessed and how it addresses the fluid ontology of digital apps. Based on regulatory documents and interviews with developers of Digital Health Technologies, we approach the approval as a multi-faceted process and provide two accounts that unpack the complexities digital health poses for regulation: (1) the re-negotiation of the boundary between health-related lifestyle and medical apps and (2) the tension between the dynamic developments of apps and the static nature of regulation. Drawing on Latour's legal sociology and the notion of reality tests developed by Boltanski and Thévenot, we argue that the approval process performs a two-fold ontological politics that transforms the ontology of both apps and regulation itself.

Keywords: Digital Health, Ontological Politics, Medical Apps, Regulation, Healthcare, DiGA

Introduction: The regulation of health-related digital apps

Similar to other healthcare systems, the German healthcare system faces significant challenges: high expenditures, an aging population with growing numbers of chronic diseases, fragmentation and shortages of healthcare provision, especially in rural areas and for mental health.

Responses to these challenges often focus on digital technologies (Blümel et al., 2020). Thus, Germany is not much different from other countries and regions, especially the European Union (EU) which promotes digital health – envisioned in the so-called European Health Data Space, for



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instance – as a panacea for healthcare (Felt, 2025; Lievevrouw et al., 2024). While situating itself in the context of such developments, Germany takes a somewhat independent approach, seeking to position itself as a forerunner rather than a follower. A novel legislation passed in late 2019 is particularly striking. It stipulates the introduction of digital apps into healthcare provision as part of the larger imaginary of a digitalised German healthcare system in which digital data collected by wearables and other sensors, telemedicine and electronic health records enable enhanced (cost-) efficiency, greater equity and an overall improved quality of more personalised healthcare. The Digital Health Applications (*Digitale Gesundheitsanwendungen, DiGAs*) are an important “building block” (Lauer et al., 2021) in this vision as these apps collect data and introduce digital(ised) therapies.

The new regulatory framework is envisioned to create “transparency, safety and reliability” (Lauer et al., 2021: 1195). It provides that Digital Health Applications can either be prescribed by healthcare providers (including psychological psychotherapists) - which has earned these apps the moniker ‘prescription apps’ (*Apps auf Rezept*) - or requested by insured persons directly from their insurance provider. This provision constitutes a partial departure from the traditional system where medical doctors were gatekeepers for prescription drugs. Similar to other prescriptions, however, the costs for DiGAs are then covered by statutory health insurance. In a healthcare system where insurance is mandatory for permanent residents and provided by public sickness funds, this means around 87% of the population (Blümel et al., 2020) are entitled to DiGAs¹.

To become eligible for remuneration by public sickness funds, apps need to undergo an approval procedure at the German Federal Institute for Drugs and Medical Devices (*Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM*). They then become listed as DiGAs in the Digital Health Applications Directory (*DiGA-Verzeichnis*). At the time of writing in March of 2024, 62 apps are available for diverse conditions. These are sorted into twelve categories that range from mental health over metabolic diseases to physical injuries. Besides providing education, apps incorporate

therapy and treatment plans that often combine the tracking of habits or moods and exercises.

From a Science and Technology Studies (STS) perspective, health apps are noteworthy because they challenge established regulatory categories and procedures. On the one hand, they straddle the boundary between lifestyle technologies and medical devices (Lucivero and Prainsack, 2015). Regulating such apps then requires re-negotiating this distinction. On the other hand, their fluidity – the possibility of frequently and rapidly updating them – clashes with the relatively static nature of regulation, especially as “[c]urrent regulatory pathways were developed for traditional (hardware) medical devices” (Torous et al., 2022: 1; Bierbaum and Bierbaum, 2017; Diedericks, 2019). Therefore, as one of the first efforts to integrate digital apps into standard healthcare provision, the case of DiGAs can illuminate some of the challenges that digital (health) technologies pose to regulation. It harbors significant contributions to debates on digital health in STS and beyond. Thus far, critical scholars have concentrated on imaginaries or promises of digital health. Only more recently, practices of designing (e.g. Felt et al., 2023) and using (e.g. Jansky, 2023) digital health technologies have come into view. With few notable exceptions (e.g., Lievevrouw et al., 2022a; Marelli et al., 2020), the regulation of digital health has not been investigated in detail, however. This is surprising: Regulation is crucial in and for the development of digital health technologies. It mediates between imaginaries, design and use in ways that reshape our understanding of both digital health and regulation.

In this article, we set out to investigate this transformative encounter of digital health and regulation in the case of the regulation of DiGAs. The research question we pursue is *how specific ordinary health apps can become prescriptible and reimbursable Digital Health Applications*. Answering this question requires identifying (1) what qualities an app needs to possess to become a legal object in the sense of this regulation and teasing out (2) how the approval process addresses the fluidity of digital apps. We approach these questions through a conceptual lens that links Bruno Latour’s (2010) legal sociology with Luc Boltanski and Laurent Thévenot’s (1999)

notion of “reality tests.” While the former draws our attention to the ontological transition at stake in the regulation, the latter illuminates the organisation of the approval procedure and its underlying politics. We consequently argue that this procedure is a multi-faced reality test in which the BfArM assesses whether an app can become a legal object in the German healthcare system. To account for the rapid evolution of digital apps, the BfArM deploys four strategies. It (1) extends the requirements for approval to test the developer company; (2) intervenes in the development of the app from its earliest stages; (3) subsumes DiGAs under the established regulatory practices for pharmaceuticals; (4) and emulates the flexibility of apps in the regulatory framework.

We unfold our argument as follows. We begin by situating our research within the only just emerging scholarship on the regulation of digital health. In particular, we show that the rapid advancement of digital health has created challenges for regulation and scholarship at the same time. Previous STS research into regulation in the biomedical domain provides resources to consider these challenges. We then develop our conceptual framework and show how it helps to frame our case. After briefly presenting our methodology, we present the empirical findings of our research in two steps. We describe the qualities of DiGAs assessed in the approval process and then outline the four strategies sketched above. In conclusion, we discuss how our findings illustrate the co-emergence of digital health and regulation and reflect on the affordances of our conceptual framework.

Digital health, regulation and STS

Critical scholars of digital health have often approached their object of research as “first and foremost, a vision” (Wieser, 2019: 428; Petersen, 2019). More recently, scholarship has begun implementing Deborah Lupton’s (2014) call to move “beyond techno-utopia” and to interrogate lived, socio-material realities of digital health. Attending to regulation intersects both of these approaches. On the one hand, promissory discourses and their politics serve as the background of state-led initiatives to implement digital health technologies into healthcare systems (Geiger and Gross, 2017).

They go hand in hand with new understandings of health (Sharon, 2018), citizenship, and patienthood (Felt, 2025). On the other hand, regulatory requirements shape design practices that have to negotiate the different “layers” of regulation (Williams et al., 2018). For the situated realities of consumers of digital health, it also makes a difference if health apps are labeled as “medical,” a sort of “quality brand” (Lievevrouw et al., 2022a: 562; see also Geiger and Kjellberg, 2021), prescribed by healthcare providers, and remunerated by public health insurance.

Yet, the regulation of digital health has rarely been an object of detailed exploration. We can arguably attribute this gap to the slow emergence of regulation due to what we could call the dialectics of regulation and digital health. As Elisa Lievevrouw and colleagues (2022a) have shown, regulation in different sectors has created the conditions for the growth of digital health in the USA. It aims to settle the intricate ontology of digital health apps otherwise straddling the boundaries of consumption and medicine through its categories and institutional purviews (Geiger and Kjellberg, 2021; Lievevrouw et al., 2022b; Lucivero and Prainsack, 2015). In turn, however, digital technologies tend to quickly outgrow regulatory frameworks, leading to a situation where we could describe regulation as “lag[ging] behind a rapidly evolving digital health sector” and requiring adjustments both of regulation and of the identities of regulatory institutions (Diedericks, 2019: 66; Lievevrouw et al., 2022b; Marelli et al., 2020). The approval process for DiGAs allows us to explore this co-emergence of regulation and its object, as well as the provisions it makes to keep up with the development of digital technologies.

To investigate the regulation of digital health, we can draw inspiration from earlier STS scholarship on regulation in the biomedical domain. For instance, studies of the regulation of pharmaceuticals have debated the question of who shapes changes in regulatory frameworks: patient activism or the pharmaceutical industry (Davis and Abraham, 2011). The introduction of DiGAs is mainly embedded in a broader top-down strategy of the German Minister of Health at the time (Bandelow et al., 2020), as patients tradition-

ally had little clout in drug regulation in Germany (Daemmrich and Krücken, 2000). The other perspective – highlighting that the pharmaceutical industry uses different mechanisms to skew regulation in the direction of its (profit-)interests (Abraham and Davis, 2009; Davis and Abraham, 2011) – seems to have a better fit, given that the German regulatory model is based on a close collaboration between regulators, the medical profession and industry (Daemmrich and Krücken, 2000). However, if we explain regulation solely through its political economy, this may obscure regulators' potential influence on the companies. Understanding the politics of regulatory processes may thus require a different conceptual framework.

Studies on regulating medical devices direct our attention to the performativity of regulatory frameworks and their ontological import (Faulkner, 2009, 2012a, 2012b). Hybrid technologies such as tissue engineering that straddle the boundaries of pharmaceuticals and medical devices are particularly instructive examples. Here, policymakers and regulators have to decide whether to “break” or “stretch” existing frameworks that then reshape the ontologies of novel technologies (Faulkner and Poort, 2017). In this case, tissue engineering has been subsumed under categories and institutions of the regulations of pharmaceuticals in the EU (Faulkner, 2012b).

Conceptual framework

From the preceding literature review, we can draw two conclusions. First, attending to the ontological dimension of regulation is particularly important for technologies such as digital health that blur established boundaries. Regulation resolves this uncertainty in one way or another by establishing a clear distinction. Second, a more fine-grained perspective is necessary to understand how the approval procedure addresses the fluidity of DiGAs. Our conceptual framework incorporates these sensitivities by combining Latour's legal sociology and Boltanski and Thévenot's notion of reality tests.

Latour's legal sociology is suitable for addressing the ontology of regulation because it conceives the law as a practice that enables a particular way of being, a “mode of existence”

(Latour, 2013) that shapes how an entity relates to other entities. In his ethnography of the Conseil d'État, Latour (2010) describes, for instance, how a meteorological map produced by scientists becomes a piece of evidence in legal proceedings. In this view, at the center of the law is the work of “grounding” (van Dijk, 2015: 178), bringing an entity – in our case, a DiGA – into a stable legal position. Legal practitioners who engage in grounding seek to create durable relations between an extra-legal entity and legal texts through which this entity obtains legal relevance. This does not mean they simply subsume the entity under the legal provisions (Latour, 2010; Lezaun, 2012). Instead, a resonance has to be created between them. This is important because it means that we cannot simply identify the regulatory requirements for DiGAs but have to investigate what enables the resonance between an ordinary health-and-wellness app and these requirements.

“Value objects” (Latour 2010: 127f.) mediate between the statements of the law and the entities involved in a legal case. The notion of ‘value objects’ is borrowed from semiotics, where this concept refers to what animates the relations among actors of a plot by transporting values between them. In a similar way, value objects animate, shape, and mediate the communication between an entity and legal texts. Legal practitioners seek to extract and align value objects from the encounter between the entities in question in a legal process and the relevant legal text. They propose a (fragile) sequence of value objects that can underpin a legal claim and ground an entity in the legal text. This entity then re-emerges as a “jurimorph” (McGee, 2015: 64), which is an “attention-orienting device[.]” (Latour, 2015: 335): It reminds us that this entity may not itself be legal (like the meteorological map in the example above) but has now become a legal object through its successful grounding in the law.

Accordingly, Latour provides a vocabulary to unpack the ontological dimension of the approval procedure for DiGAs. To identify what qualities an app needs to possess to potentially become a DiGA, we need to identify the value objects that mediate between the materiality of the app under consideration and the requirements laid down

in the regulatory framework. Thus, value objects cannot be reduced to these requirements as if DiGAs are only subsumed under these. Instead, they point us to the deeper-seated layer of negotiations and exchanges between developer companies and the BfArM about what a DiGA should be and deliver. This will allow us a glimpse at the broader values underpinning the digitalised German healthcare system. The value objects we extract point us to the different visions of the healthcare system, the role of the BfArM, the developer companies and the users of DiGAs.

However, Latour's framework does not help us specify how the transition to a stable legal object has to be organised to account for the fluidity of digital technologies. Addressing this shortcoming requires that we elaborate on the implicit role that *tests* play in his sociology of the law as a mode of existence. Considered through this lens, this approach describes a process of testing wherein the ontology of an entity is at stake – whether or not it can exist as a legal entity. Boltanski and Thévenot (1999: 359) describe similar situations as “critical moments”. These are moments where divergent definitions of a situation collide and suspend its self-evidence. In such circumstances, actors stage ‘reality tests’ that assess the ontological status of actors, human and non-human, in order to ‘repair’ the situation. Reality tests are socio-material practices organised in particular ways that can become contested themselves (Boltanski and Thévenot, 1999). Actors may question whether the assumptions of the test and the way it is carried out are appropriate for the situation at hand. This draws our attention to the “infrapolitics” (Potthast, 2012: 562) of reality tests: the way tests posit the actors who test, the actors who are tested, the relation between them, and the test's temporal and spatial arrangement. This framework now enables us to specify the implicit test carried out in the approval process to assess whether an app can become a DiGA. It also makes visible the (infrapolitical) strategies this test deploys to address the fluidity of digital apps.

Methodology

Our research targets a particular point in the trajectory of DiGAs: their approval. It marks the

moment when a DiGA becomes a legal object in the German healthcare system. This moment precedes negotiations about pricing (with insurance companies) or the actual prescription of the app (by healthcare providers). Hence, we zoom in on the perspectives of the two key actors of this part of the process, the BfArM, and developers of potential DiGAs.

We approached the viewpoint of the BfArM through publicly available documents pertinent to the regulatory procedure. Regulatory documents are crucial actors in the regulation process. They are often not only the first point of contact with regulation, but they also co-construct the objects and domains to be regulated (Asdal, 2015). Therefore, “legislative texts and documents could be accorded a more prominent place in theorising the emergence of new biomedical and other sociotechnological fields” (Faulkner, 2012a: 772). This is especially crucial for fields currently reshaped by regulation, such as digital health. The documents we collected encompass Germany's 2019 Digital Healthcare Act and the 2020 Digital Health Application Ordinance as the documents in which the legislation for Digital Health Applications is outlined; the so-called DiGA Guide (Federal Institute for Drugs and Medical Devices, 2020) meant to assist developers (and other interested parties) regarding the approval process; another set of documents authored by officials at the BfArM and developers published in a special issue of the German Federal Health Bulletin dedicated to Digital Health Applications (Broich et al., 2021; Brönneke et al., 2021; Lauer et al., 2021; Löbker et al., 2021; Ludewig et al., 2021); and two blogposts published by officials at the BfArM (Grünwald, 2022; Löbker, 2021). Recruiting interlocutors at the BfArM proved difficult with contact persons citing the general workload they face. We interpret this as a sign of ongoing reorganisations to accommodate the regulation of DiGAs at the BfArM. This hypothesis was corroborated by some of the developers we spoke to.

Our analysis of the perspective of DiGA developers is based on interviews and an article co-authored by developers for the German Federal Health Bulletin (Laumann et al., 2021). Interviews allow to explore views of “those who have knowledge of or experience with the

problem of interest" (Rubin and Rubin, 2012: 3) – in our case, the developers whose DiGA has passed the approval process and the representative of a digital health lobbying organisation. The interviews were semi-structured to cover the topics our research sought to explore but also to give respondents the space needed to set their own priorities. This enabled us to exploit the full benefits of interviews as an interactive practice (Silverman, 2006). Developers were recruited using the contact data provided in the article authored by DiGA developers (Heimann et al., 2021) and by contacting other companies listed in the DiGA registry. The digital health lobbyist was recruited through personal networks. Of the 25 companies contacted, only three agreed to an interview. We view this low response rate as a significant result in itself. In their rejections, developers mentioned that they had few additional capacities for interviews because they were currently finishing their clinical research as a requirement to have their DiGA permanently listed. Moreover, some interlocutors intimated that they feared repercussions for critical remarks on the approval process, which could also explain why others were reluctant. Hence, we decided to anonymise the interview excerpts we draw on in this article. All information that could identify or trace statements back to respondents has been erased. We introduce quotes from interviews by linking them to the respective group (developers, digital health lobbyist). Our sample is limited to developers who have passed the approval process. This gives it a 'success bias' and excludes those developers whose applications have been rejected or retracted. These constituted the largest group at the time of research (Lauer et al., 2021). Their views would have allowed for an even more nuanced perspective, but information on ongoing assessments or negative outcomes of the approval processes is not in the public domain. For obvious reasons, companies do not publish this information, either. This made it impossible for us to follow this option further.

The research was carried out in the spring/summer of 2022 –which situates our findings as a snapshot of a process that is developing fast. Due to the restrictions of COVID-19 at the time, all interviews were conducted online (Lobe et al.,

2020) using a videoconferencing tool provided by the University of Vienna. Informed consent was obtained (in written form) during the first contact with developers and (orally) before the start of the interview. Interviews lasted between 30 and 90 minutes. They were transcribed verbatim. We analysed interview transcripts and documents drawing on the thematic coding approach (Rivas, 2018). Through iterative coding and constant comparison across data sources, this approach seeks to identify underlying themes and concepts in the material. For presenting our findings, quotations were translated from German after the analysis.

The ontological transition of digital health applications

We begin by tracing what qualities an app has to have to become a prescriptible and remunerable DiGA following the novel German regulatory framework. We first extract the value objects that mediate between the apps and the regulation and then identify the emerging jurimorphs.

Value-objects of the approval process

To be eligible for the approval process, digital apps must first obtain the CE mark. According to the EU's Medical Device Regulation (MDR), it certifies them as medical devices.² From the perspective of the BfArM, this requirement distributes the regulation of the risks of DiGAs. As certified medical devices, a Notified Body has already tested them and subsumed them under a risk class. "[T]he CE conformity marking of the medical device is considered to be proof of safety and functional capability" (Digitale Gesundheitsanwendungen-Verordnung - DiGAV, 2020, §3(1)). For the developers, the requirement introduces a temporal order to the application process. The certification is "a step that precedes, a very important step" (developer) wherein "no exceptions are possible" (Federal Institute for Drugs and Medical Devices, 2020: 37). Accordingly, the two value objects we can identify are (1) *the distributed process of risk regulation across several regulatory bodies* and (2) *the temporal sequence of the application process*.

The following three requirements concern the technical features of the app: interoperability,

privacy and information security, and usability. In the early stage of the regulation all three were assessed through checklists (with 'yes', 'no', and a justification if 'no' was selected as the only potential responses) that developers needed to fill in themselves. This was changed with a recent reiteration of the regulation, stipulating that developers must provide certificates issued by the German Federal Office for Information Security.

Since interoperability is considered an "essential success factor for the entire digitalisation strategy" (Broich et al., 2021: 1295), DiGAs need to comply with this expectation.³ For example, in the broader vision of a digital healthcare system, data produced by DiGAs will eventually become shareable with care providers. Consequently, the value object is that (3) *the submitted DiGA-to-be supports the vision of the German digitalised healthcare system imagined by policymakers and the BfArM as the responsible regulatory agency.*

The requirements for data protection and information security build on existing regulatory frameworks. This further underscores the distributedness of regulation. In many cases, the DiGA regulatory framework draws on legal frameworks, such as the General Data Protection Regulation (GDPR) or standards established by other national and international regulatory agencies with which the BfArM collaborates. Similar to the case of medical apps in the US (Lievevrouw et al., 2022a), the regulation of DiGA then also co-produces the organisational identity of the BfArM which presents itself as well-networked with other regulatory bodies and authorities. But the regulation also makes provisions beyond established legal frameworks. "Data processing is geographically restricted, there may be no advertising, and only certain purposes of data processing relevant to the provision of care are permitted" (Ludewig et al., 2021: 1199). These stipulations mark a crucial difference between DiGAs and ordinary health-and-wellness apps. The latter can, and frequently do, include advertisements, and data is processed for commercial purposes.

Existing frameworks also inform the requirements for information security. These consider security not as a "conglomerate of technical measures, but rather as a process to be anchored in the company" (Federal Institute for Drugs and

Medical Devices, 2020: 45). This broad understanding of security speaks to the presumed characteristics of digital technologies, particularly to the speed of their developments. A "secure DiGA is always only a snapshot: The DiGA evolves in short release cycles, and new threats and risks affect it from outside. Security measures that are state-of-the-art today can therefore be ineffective in just a few months" (Federal Institute for Drugs and Medical Devices, 2020). Having analysed these requirements, we can identify two further value objects: (4) *the difference from commercial health apps based on enhanced user privacy and (5) an organisational structure conducive to information security against the backdrop of rapid developments.*

The requirements for usability provide a glimpse of how the future user of DiGAs is imagined within the regulatory framework. Generally, usability is informed by an idea of fairness that imagines the potential DiGA user's state of mind. "[U]sers of DiGA find themselves in a special life and/or illness situation simply because of their motivation to use a particular DiGA, which must not be exploited by the manufacturer to take advantage of the users or lead them to make irrational decisions" (Federal Institute for Drugs and Medical Devices, 2020: 66). Beyond this, there is a tension in the digital literacy assumed of future users. On the one hand, users are considered to have a basic understanding of digital technologies. Consequently, DiGAs should align with the "usual look & feel of digital applications for persons used to dealing with applications" (Federal Institute for Drugs and Medical Devices, 2020: 71). On the other hand, users are envisioned as fallible and not overly tech-savvy so that DiGAs need to be robust against 'false' uses. Therefore, these regulations point to the value objects of (6) *a particular attention to the vulnerability of the envisioned user and (7) an appreciation of the heterogeneity and diversity of users with diverging levels of digital literacy.*

Finally, developers need to provide evidence of the clinical efficacy of their app. The regulatory framework introduces a conceptual novelty for this. The notion of the "positive healthcare effect" (Ludewig et al., 2021) encompasses improvements in the user's *health* (similar to pharma-

ceuticals) but also improvements in *healthcare provision*, including the ability to better navigate the healthcare system. Moreover, the way in which this requirement can be proven introduces a temporal distinction between DiGAs listed in the registry. While developers must provide clinical evidence to have their DiGA listed permanently from the outset, DiGAs can also be listed provisionally for one year. In this case, although developers need to respond to the other requirements and provide a scientific evaluation concept, submission of their clinical evidence is postponed until the end of the provisional listing period. During this listing period, the DiGA can already be prescribed (and remunerated) and data from its use can serve to produce the evidence. In principle, the requirements allow for several ways and methodologies to prove the positive healthcare effect. However, in practice, this range was reduced to randomised clinical trials (Lauer et al., 2021). Proving the positive effect on health marks a further distinction from other health apps. As one developer summarised, the effect “can’t just be sold somehow on the marketing side, but [...] actually has to be demonstrated.” The value object here is, thus, (8) *the scientifically proven positive impact on health and healthcare provision*.

Emerging jurimorphs

If the existence of these eight value objects can be argued to be present in the encounter of an app and the regulatory framework, this app can become a DiGA. At this point, we may say the app is legally grounded and has become a ‘jurimorph’: It is a legal object primarily defined through its relation to the regulation. It is important to note that this is a purely legal qualification. There is not necessarily a real *technical* difference between a DiGA and other health-related lifestyle apps, e.g., in terms of capabilities or features. The digital health lobbyist put it bluntly: “Any fitness tracker can do more” than a DiGA on a technical level. The legal status acquired in the approval process appears to make all the (ontological) difference as it integrates the app into the healthcare system and makes it eligible for prescription and remuneration. In other words, the regulation establishes the otherwise slippery boundary between health-related lifestyle apps and medical apps

through a legal specification through which apps come to exist as DiGAs in a legal mode. The same app, existing outside the German healthcare system, would be just another health-related lifestyle app.

But it is not only the app that is jurimorphed. Previously, the medical profession was dominant in the German healthcare system (Daemmerich and Krücken, 2000) and only medically-trained healthcare providers could prescribe treatments. With the introduction of the new legislation, the right (and obligation) to prescribe DiGAs extends to psychological psychotherapists who were previously excluded. This signifies a shift in the power relations within the German healthcare system. Even more far-reaching is the shift introduced by the stipulation that an insured person may request a DiGA for their condition directly from their health insurance. It allows them to almost completely sidestep the previous gatekeeping role of healthcare providers and their expertise on suitable therapies. While this novel mode of obtaining treatment in the German healthcare system comes close to the consumerist logic of health-related lifestyle apps, it does not render medical knowledge entirely inconsequential. Even if they request a DiGA from their insurance directly, insured persons need a diagnosis from their healthcare provider to justify their request.

Finally, the developers obtain new rights and obligations once their app has become a DiGA. They now have the *right* for their app to be prescribed. One developer reported they frequently received feedback from potential users that physicians refused to prescribe their app. Its new socio-legal status, following its approval, now gives them a lever to demand its prescription. “I think this year I’m going to sue a doctor”, the interviewee said. With the approval of their app as a DiGA, in their view, “this has become malpractice” from a medico-legal perspective. Furthermore, developers are obliged to report any ‘significant changes’ to their DiGA to the BfArM which will assess whether it still meets the regulatory requirements. Such changes encompass both technical and textual changes. For instance, if a developer conducts further clinical trials to add clinical indications for which their app may be prescribed, this would constitute a significant

textual change to the description of their app in the official registry and would consequently entail an assessment of the trial data.

The approval process as a reality test: Responding to the complexities of digital health

The obligation to report ‘significant changes’ of the DiGA indicates the previously mentioned tension between the dynamic development of digital technologies and regulation. Digital media are “constantly asking/needing to be refreshed” (Chun, 2017: 2) and there is a cultural expectation of frequent updates (Simon, 2018). Apps, in particular, are fluid and open-ended objects where more or less stable versions only exist until the next update. This fluidity has the potential to undermine regulation designed as a one-off assessment. In this section, we explore how the approval process for DiGAs responds to this fluidity and what kinds of politics we can observe.

Testing the developer company

The first strategy the BfArM deploys is to extend the test to the developer company. In other words, the approval procedure does not only assess the qualities of the potential DiGA. Through the way it is organised, it *also* tests the qualities of the developer company. First and foremost, the financial resources of the applicants are put to the test. Some costs directly arise from the approval process (the DiGA Guide estimates costs of at least 3,000€) and the clinical trial to prove the positive health/healthcare effect. Indirect costs stem from possible waiting times. For one developer, the approval process took longer than initially calculated, posing a potentially existential threat: “You have to be able to do it, I mean, it didn’t get us into trouble, but...”. Given that according to privacy and information security requirements, the company cannot earn money through in-app advertisement, the process favors particular business models: start-up companies with sufficient venture capital or corporations. As one interviewee observed, somewhat frustratedly, “it’s actually almost only spin-offs of corporations that ultimately bring new DiGAs to the market” (developer).

The work ethics of employees of the developer companies are also implicitly put to the test. The approval process consists of a back-and-forth between the BfArM and the developers, as the former follows up with additional queries throughout the three-month process. The deadlines for these additional queries are “very, very tight and very, very strict” (developer). We learned of cases where the query would arrive on Friday, and responses would be expected by Monday, requiring the developers to be flexible and work over the weekend. Furthermore, developing a DiGA “hasn’t paid off yet” (digital health lobbyist). Once an app has been listed permanently, prices are negotiated between developers and the umbrella organisation of German health insurance firms (during the preliminary listing, developers can set a price). Because DiGAs are pitted against (cheaper) pharmaceuticals for the same condition in these negotiations, the calculated sum likely remains below developers’ expectations. One developer reflected on another developer company, presuming that for them, the price negotiations would be “considerably difficult [...] because the drugs that are called there [for the same condition], they cost somewhere around [low two-digit price].” This makes it close to impossible to bargain for a medium three-digit price for the app. More than financial considerations, developers need to be motivated by a sense of idealism. “There is a lot of enthusiasm to actually improve the world a little bit and to improve treatment” on the part of the developers “who [often] are more or less directly or indirectly affected” (digital health lobbyist) by the condition their app responds to.

Finally, the approval process implicitly tests how well developers can bridge the cultural gaps between regulation and the digital industries. As the digital health lobbyist concisely put it: “When I’m in administration, I talk in an administration language. A start-up talks in a start-up language. And then there are always problems with understanding”. This language barrier is a hurdle that the developer companies must overcome mostly by themselves because the one-off encounters offered by the consulting services at the BfArM do not suffice. Overall, we can conclude that the dimensions thus tested point to an interest in the *longevity* of the DiGA within the digitalised

German healthcare system. Through the organisation of the approval procedure, developer companies must prove that they are financially viable, interested in more than short-term profits and able to maintain good relations with the BfArM.

Reverse regulatory capture: The BfArM as an obligatory passage point

The BfArM figures as an ambivalent actor in the empirical material we collected. On the one hand, manufacturers describe it as “friendly, competent, professional and solution-oriented” (Heimann et al., 2021: 1249). The BfArM itself states that it “want[s] manufacturers to go through the process successfully” (Löbker, 2021). The range of consultation offers exemplifies this attitude. The so-called kick-off meeting, for example, is one way “to give [manufacturers] orientation in early development phases on the way to market access for their (digital) innovative approaches” (Broich et al., 2021: 1296). One document describes the BfArM’s overall approach as “consulting and accompanying” (Löbker et al., 2021: 1247) developers throughout the development of their app and their application.

On the other hand, the interviews with developers offer a different perception of the relational dynamics. One developer confessed that they “never had the feeling that they were trying together to bring a DiGA to the market, but it was always, we try to bring the DiGA to the market and they try to prevent it.” Regarding the consultations offered by the BfArM, some developers felt pressured into purchasing this service to have a chance at being successful. The BfArM also ascribes responsibility for failed applications to the developers. Failed applications “had not been the subject of consultations before the application [...] or the recommendations of the BfArM had not been followed” (Löbker et al., 2021: 1246). While the consultation results are not legally binding for the BfArM and its decision-making, developers must justify their approach if they deviate from them.

The regulatory framework posits the BfArM as an “obligatory passage point” (OPP) (Callon, 1984) that developers must pass through if they want their app to become a DiGA. Developers then need to find out “to what the BfArM attaches a

great deal of importance” (developer) and adjust their app accordingly, even if they disagree with its priorities. Because their ultimate goal is to get their app approved as a DiGA, “then you just do it at that moment” (developer) and acquiesce to the BfArM’s demands. Through simultaneously “consulting and accompanying” and gatekeeping access to the German healthcare market as an OPP, the BfArM can steer the development of apps through their lifecycle and along the imaginations that underpin the German approach to digital health. This guidance possibly contains the fluidity of the app within the boundaries defined by the BfArM. We can refer to this second strategy as a ‘reverse regulatory capture’ as opposed to the regulatory capture hypothesis in research on the regulation of pharmaceuticals (Davis and Abraham, 2011). Unlike the pattern of companies influencing the regulation of pharmaceuticals in their favor that other scholars have identified, the regulatory agency captures the developers and can shape the development of DiGAs from the beginning. This indicates different power relations in regulatory processes between ‘classical’ pharmaceuticals and digital health.

The (incomplete) pharmaceuticalisation of digital health

The third strategy is what we propose to call the – however incomplete – ‘pharmaceuticalisation of digital health’. The explicit requirements reflected in the value objects identified above do not carry equal weight in the approval procedure. In our interviews, for instance, the developers confessed that they were not even aware of all the requirements. “Uhhhhm. User Friendliness? [...] So my guess is that we first designed it the way we think it’s good and then saw what the BfArM had to say about it” (developer). Moreover, the BfArM does not assess all requirements symmetrically. Technical features – usability, information security and privacy, interoperability – were mostly assessed through checklists in the early phase of the regulation (now replaced by certificates). This means that the BfArM examines “manufacturer’s statements about the product qualities” (Federal Institute for Drugs and Medical Devices, 2020: 7), not the technology itself. One developer explained: “The BfArM does not want to check [the require-

ments for data protection and data security] because it can't check them" (developer) due to a lack of expertise in these technical features. By contrast, it scrutinises clinical evidence meticulously. One developer "felt that the big issue at the end, of course, is always the proof of medical benefit." Interviewees suggested that this "extreme focus on the medical stuff" (digital health lobbyist) is due to the institutional history of the BfArM which has historically been the German authority of pharmaceuticals (Daemmrich and Krücken, 2000). As a result, pharmaceuticals and clinical tests are the agency's main areas of expertise. "The BfArM is a medical authority," one developer said, instead of an authority on the digital. The digital health lobbyist concurred: "That is simply their home".

In effect, this strategy bypasses the complexities of digital technologies by treating DiGAs *as if* they were pharmaceuticals. "People are trying hard to force digital health applications into the mold of pharmaceuticals" (digital health lobbyist). This regulatory pharmaceuticalisation manifests in the institutional responsibility of the BfArM and the focus on clinical evidence.⁴ The approval process stretches existing categories, procedures, and institutions to accommodate DiGAs (Faulkner, 2012b; Faulkner and Poort, 2017). However, regulatory pharmaceuticalisation remains incomplete. The characteristics specific to digital complexities resist being subsumed entirely. The BfArM has begun cooperating more closely with other German regulatory bodies to establish criteria and procedures for assessing DiGAs (akin to what Faulkner (2012b: 404) calls "proliferation of organisation structures"). For instance, for the certificates to prove data and information security, the BfArM has collaborated with the German Federal Office for Information Security. Additionally, several interlocutors reported that the BfArM has recently expanded its expertise on digital technologies, illustrating that novel regulations for digital health also transform the institutional identities of regulatory institutions (Lievevrouw et al., 2022a). Finally, the new regulatory category of the 'positive healthcare effect,' encompassing impacts on both health and healthcare, similarly tries to incorporate the affordances of digital tech-

nologies for facilitating orientation in the German healthcare system.

Continuity and agility: Emulating the fluidity of digital apps

Developers are required to report 'significant changes' even after the approval of their app as a DiGA. A "continued close supervision by the BfArM [...] ensures that the interaction between DiGA manufacturers and the BfArM continues even after the listing" (Heimann et al., 2021: 1253). This only seemingly resembles practices of post-marketing pharmaceutical surveillance (Langlitz, 2009) and medical device surveillance (Zippel and Bohnet-Joschko, 2017). The crucial difference is that this continuous monitoring does not concern adverse effects but changes to the app itself. For developers, this constitutes a severe constraint to what digital technologies afford: "In such a super agile environment like software development, where I have the possibility to iteratively adapt things within weeks, to make things better, to react to feedback, we end up again in such a one-way street or in such a dead-end, where we are somehow presented with product cycles from the old economy again" (developer). Supported only by a checklist, developers must decide by themselves what exactly constitutes a significant change. This leads to considerable uncertainty which has particularly high stakes due to the penalty a failure to report a significant change could entail. One developer reported that, in light of this uncertainty, "we have tried to avoid it [changing the app] as far as possible" (developer).

Still, the regulatory framework acknowledges the potential for digital technologies to develop continuously. Policymakers have conceptualised "law-making as an agile process" (Ludewig et al., 2021: 1205). The regulatory framework is, like the apps it targets, itself continuously and self-reflexively evolving. Importantly, regulatory changes apply retroactively. Developers have to prove the compliance of their DiGA with the changing requirements even if their app has already been approved. Otherwise, they risk that it is stripped of its status. For example, following a novel iteration of the regulation, developers had to submit data and information certificates by April 2023.

The intentional incompleteness of the agile regulatory framework adopted to emulate the fluidity of digital technologies has implications for the status of the regulatory framework and, subsequently, for the work of grounding aiming to turn apps into a stable legal object. To keep up with the developments of digital technologies, the agile regulation only stands still temporarily – until new provisions are introduced. This vitality of the regulatory framework evidently collides with the work of ‘grounding,’ if this means forging relations between the app and the legal text and constituting the app as a stable legal object. This becomes clear when we take the topological implications of grounding seriously: “[A]cts of grounding are [...] closely related to a judgment in which the ground will bring something (the matter of judgment) to a stand (zum-stehen bringen [sic!]) as an object (Gegenstand) when it will have provided a sufficient (vollständig [sic!]) account of it” (van Dijk, 2015: 179). Grounding, i.e. bringing something to a stand on the ground, requires that this ground be solid and able to carry the weight of what is to stand on it. It presupposes that the law is stable. Because the agile regulatory framework for Digital Health Applications is itself fluid, it only provides a slippery ground. Hence, the ontological transition of a health app into a DiGA, which requires a grounding in the regulatory framework, remains forever incomplete. In other words, the strategy of emulating the fluidity of digital apps makes the regulation itself fluid which illustrates the co-emergence of digital health and regulation in their encounter.

Conclusion: Digital health otherwise

Early commentators on the DiGA regulation described it as a “first-of-its-kind opportunity” (Gerke et al., 2020: 5) and a likely blueprint for other countries. Indeed, Belgium and France have introduced regulations to integrate medical health apps into their healthcare systems. Emerging evidence suggests that there are slight differences in the otherwise overall similar architecture of these regulations and their outcomes (Schudt et al., 2022). While it is beyond the scope of this article to go into further detail, we encourage

future research to take a comparative perspective and to tease out these similarities and differences – and their ontological and infrapolitical implications. In this article, we have attempted to lay the groundwork for such explorations by zooming in on the regulation for DiGAs in Germany.

Our study offers so far rare detailed insights into the approval process for health apps as these become integrated into healthcare systems. While scholars of digital health have largely investigated imaginaries or use and design practices of digital health, this focus on regulation has allowed us to pinpoint the challenges that emerge when fluid digital health apps encounter structured regulatory frameworks. Attending to such frictions will become increasingly important as digital health becomes more widely adopted and regulation is applied to other, similarly fluid digital technologies, such as Artificial Intelligence (AI).

We have shown that both digital health and regulation transform when they encounter each other – which we conceptualise as a two-fold “ontological politics” (Mol, 1999). The *being of both* is (re-)negotiated in their encounter. On the one hand, the approval process re-traces the blurry boundary between lifestyle and medical apps by staging what we have termed a ‘reality test’ to assess whether a specific app can exist as a legal object. Regulators must be able to identify and align eight value objects that mediate between the app and the regulatory provisions. Consequently, the power dynamics within the German healthcare system shift as the DiGA, insured persons, healthcare providers, and developers re-emerge as ‘jurimorphs’ with new rights and obligations. For instance, the possibility for insured persons to bypass healthcare providers may signal an increased consumer orientation in the German healthcare system, even though healthcare providers remain responsible for diagnosing the condition a DiGA may address.

On the other hand, we have shown that the approval process incorporates four infrapolitical strategies to get a grip on the ontological fluidity of the – at least potentially – rapidly evolving digital apps. Each strategy comes with new risks and complexities when trying to contain this evolution. (1) We have seen that the extension of the test to the developer company serves to

ensure the company's viability. Conversely, this can limit the pool of developers who can get their app approved. (2) The 'reverse regulatory capture' we have described is a way for the BfArM to intervene at an early stage in developing possible DiGAs. Steering them towards its vision of a digitalised German healthcare system, however, might not entirely meet the needs of patients. (3) What we have called a 'regulatory pharmaceuticalisation' of digital health, the stretching of existing categories, procedures, and institutional responsibilities for pharmaceuticals to digital health remains incomplete. The technical characteristics of DiGAs overflow the focus on their medical contribution. This is illustrated by reports on security flaws (Heidrich and Endres, 2021) or our interlocutors' doubts about whether the procedure in its current form gives due diligence to the characteristics of their digital products and whether a *break* with previous frameworks might not be better. (4) Finally, emulating the fluidity of digital technologies in the regulation renders *both* unstable. One consequence is that DiGAs can only be temporarily stabilised legal objects, undermining their ability to fully exist in a legal mode.

Overall, it therefore remains uncertain whether the regulation is "fit for purpose" (Marelli et al., 2020) and whether the strategies – as is the stated goal – indeed foster "transparency, safety and reliability." For instance, regulatory pharmaceuticalisation may initially create trust because it resembles the tried and tested ways of approving pharmaceuticals. Yet, it may neglect the specific risks of digital technologies. Extending the question of the 'fitness' of regulation, our case raises the broader question of what strategies regulations of other, equally rapidly evolving digital technologies (e.g., AI and machine learning) take and what their (ontological) consequences and implicit politics are.

Finally, this article offers a conceptual contribution. It illustrates the fruitfulness of bringing Latour's legal sociology, or his "Inquiry into Modes of Existence" more generally, into conversation with Boltanski and Thévenot's orders of worth approach. While these research programs undoubtedly diverge in what they consider to be the basic units of reality (networks vs. orders of worth) and where to study them, they speak to

each other in multiple ways and have a history of conceptual exchanges – Boltanski, for instance, adopts and adapts the very concept of reality tests from early Actor-Network Theory (Guggenheim and Potthast, 2012). We have expanded on such exchanges by bringing the notion of reality tests back to speak to Latour's legal sociology and to address what we perceive to be one of its gaps when studying regulation, such as the introduction of DiGAs. While Latour's approach has been fruitful in describing the ontological transition that occurs in the approval process, it has been less so in illuminating the infrapolitics of this procedure. At the same time, the meaning of 'reality tests' changes when it encounters Latour's legal sociology. What is at stake in the reality tests of regulatory processes is whether and how an entity can transition to a legal mode of existence.

Focusing on the regulation of digital health, as we have done here, foregoes some of the crucial questions that critical digital health studies have addressed and that we must also ask about DiGAs, e.g. their desirability or socio-material consequences. Certainly, DiGAs embody a form of 'technological solutionism' (Morozov, 2013), the idea that (digital) technologies can solve the problems healthcare systems are currently facing – even though these may require more structural transformations. Solutions, which always bear the traces of the problems to which they respond, point us to how we frame the problems DiGAs (purportedly) address and who has the power to participate in this framing. Nuanced understandings of different ways of regulating digital health help to open up a space for intervention into how problems are constructed and guide digital health in directions we may find more desirable.

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Notes

- 1 A “unique feature” (Blümel et al., 2020: xxii) of the German healthcare system is the co-existence of statutory and private health insurance. Specific professions (especially public servants) and residents with a salary above a certain threshold can opt out of the mandatory statutory insurance and choose private insurance. As of 2020, this was the case for around 11% of the German population (Blümel et al., 2020). Privately insured residents do not have a legal entitlement to the remuneration of the DiGA and private insurance may cover the prescription of apps not approved by the BfArM.
- 2 This means that the boundary between consumer technology and medical device that digital apps blur has, to a certain extent, already been settled: The app must already be a legal object although it has not become a DiGA.
- 3 Even if this vision of interoperability is not extended beyond the German context, it cannot be disentangled from broader debates. On the one hand, the BfArM presents itself as closely networked with other authorities in Europe, being in “close cooperation at national and European level” (Broich et al., 2021: 1293). On the other hand, the vision dovetails with debates and imaginaries of digital health on the level of the European Union (Felt, 2025).
- 4 This also differs from the way that medical devices are treated according to the EU’s MDR. The MDR calls for clinical trials only for high-risk medical devices. However, DiGAs can only belong to risk classes I or IIa defined by the MDR. Still, for their approval as DiGAs clinical efficacy needs to be proven.