

Digital healthcare products

Leveraging opportunities –
developing safe routes to market

STUDY
REPORT

Digital healthcare products

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Study report

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List of abbreviations

Abbreviation	Explanation
afgis	Aktionsforum Gesundheitsinformationssystem e.V. [Action Forum on Health Information Systems]
AMNOG	Gesetz zur Neuordnung des Arzneimittelmarktes [Act on the Restructuring of the Pharmaceuticals Market]
BfArM	Bundesinstitut für Arzneimittel und Medizinprodukte [Federal Institute for Drugs and Medical Devices]
BMG	Bundesministerium für Gesundheit [Federal Ministry of Health]
BSG	Bundessozialgericht [Federal Social Court]
BSI	Bundesamt für Sicherheit in der Informationstechnik [Federal Office for Information Security]
BVMeD	Bundesverband Medizintechnologie e. V. [Federal Association]
CE	Communauté Européenne
DKG	Deutsche Krankenhausgesellschaft e.V. [German Hospital Federation]
EU	European Union
FDA	US Food & Drug Administration
FPV	Fallpauschalenvereinbarung [Case Fees Agreement]
G-BA	Gemeinsamer Bundesausschuss [Federal Joint Committee]
GKV	Gesetzliche Krankenversicherung [statutory health insurance]
GKV SV	GKV-Spitzenverband [National Association of Statutory Health Insurance Funds]
HON	Health On the Net
HTA	Health Technology Assessment
InEK	Institut für das Entgeltsystem im Krankenhaus [Institute for the Hospital Remuneration System]
IQWiG	Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen [Institute for Quality and Efficiency in Health Care]
KHEntgG	Krankenhausentgeltgesetz [Hospital Reimbursement Act]
KHG	Krankenhausfinanzierungsgesetz [Hospital Financing Act]
MDS	Medizinischer Dienst des Spitzenverbandes Bund der Krankenkassen [Medical Service for the National Association of Statutory Health Insurance Funds]
MHRA	Medicines and Healthcare Products Regulatory Agency
MPG	Medizinproduktegesetz [Medical Devices Act]
NHS	National Health Service
NUB	Neue Untersuchungs- und Behandlungsmethoden [new diagnostic and treatment methods]
SGB	Sozialgesetzbuch [Social Code]
SVRV	Sachverständigenrat für Verbraucherfragen [Expert Council for Consumer Issues]
TK	Techniker Krankenkasse
vfa	Verband der forschenden Pharma-Unternehmen [Association of Research-Based Pharmaceutical Companies]

Summary

The use of “health apps” and other software is becoming more widespread in the healthcare sector. In Germany and other industrialised countries, this has sparked a lively debate on the regulatory approach that should be taken to the use of these new digital products within public health systems, given that it is necessary not only to check how safe they are, or in other words whether they should be granted a marketing authorisation, but also for relevant reimbursement arrangements to be put in place under statutory health insurance schemes.

Suitable regulations would strike a judicious balance between patient safety and potential healthcare improvements, without losing sight of the possible economic and political ramifications and the need to nurture a new and rapidly growing industry dominated by small companies.

This study focus on the question of how these authorisation and reimbursement processes should be regulated for products which are targeted at consumers or insured parties and which are aimed at preventing, diagnosing, treating or management specific diseases rather than simply promoting “wellness”.

Our study will cover all forms of software rather than just mobile applications (“apps”), and so we will use the term “digital healthcare products” to describe our area of research.

Chapter 1 will examine the research problem in more depth, and Chapter 2 will then provide an initial brief overview of the market and the current topics of debate in this respect. Previous attempts in the literature to systematically capture the diversity of digital products will also be covered.

The specific issue addressed in this study requires a separate classification system based on the potential health risks associated with the products (Chapter 3). The level of risk becomes greater in step with the increasing personalisation of information and the transition from representing data to issuing recommendations.

Chapter 4 explains that the need for quality assurance also rises concurrently. A quality seal or compliance with data protection and information security regulations may be sufficient for the simple provision of information or collection of data, whereas evidence of accuracy may be required for specific diagnostic or treatment recommendations. Digital healthcare products must achieve at least the same standard as previous forms of healthcare.

One of the unique features of many digital products is that they “learn” over time, and so conditional authorisations, whereby the use of such systems is expanded as they improve, is a conceivable solution.

Decision trees are used to determine the specific authorisation stages which apply to individual digital products.

The regulations required in the field of authorisation can to a certain extent be based on existing regulations for medical devices, pharmaceuticals and other types of software. We recommend that these convergences be leveraged as far as possible. Nevertheless, the heterogeneity of digital healthcare products means that the wholesale adoption or amendment of an individual regulatory system is far from an ideal solution. We therefore recommend creating separate authorisation regulations for digital healthcare products, which could also be included as a sub-category in the Medical Devices Act [Medizinproduktegesetz, MPG].

A regulatory approach must be developed for reimbursement as well as authorisation (Chapter 5). The statutory health insurance market is normally accessed via individual insurance funds which offer digital products e.g. as an optional benefit or under selective contracts. This also provides an option for testing the actual benefit of the product. If no benefit can be identified, reimbursement must be terminated at some point. Otherwise reimbursement should be put on a broader footing, either by copycat competition from other funds or by formally testing the relevant benefits as a precondition for inclusion in standard care models.

The requirements referred to above would therefore be met by means of comparatively rapid authorisation and reimbursement processes which correspond to the industry's short innovation cycles, which are tailored to the specific features of this product category, which guarantee the necessary level of safety and which enable use in care models (Chapter 6).

A series of expert interviews revealed a broad spectrum of opinion on many of the questions addressed in this report, for example data protection regulations or the link between digital products and other medical devices (Chapter 7).

The proposals set out in this study are intended to clarify certain aspects of the regulatory approach governing the authorisation of digital products. Some products should clearly be exempt from authorisation requirements, whereas others should be subject to more stringent requirements in terms of evidence of safety than is currently the case.

These topics must be examined in more depth before any proposals can be put into practice. TK is therefore keen to engage in a debate with stakeholders in the health sector over the coming months (Chapter 8).

1. Introduction – current state of debate and issues addressed by the study

*“The digital revolution is just as fundamental
as the invention of X-rays
or the discovery of antibiotics.”*
(Axel Ekkernkamp)

1.1 Introductory comments

The digitisation of society will change the way in which people – both healthy and sick – are cared for and monitored. A new category of health products is emerging and must be integrated into the current structures of the healthcare system.

Certain diseases can now be detected more easily by software programs than by consultant doctors. Suitable treatments can be identified by databases which process vast quantities of data taken from several hundred thousand genomes, far exceeding human processing capacities.¹ IT will change the healthcare sector and alter the division of roles between doctor, patient and technology.

The use of digital products in the healthcare sector, whether for private use or by the statutory health insurance funds, is constantly on the up. An recent survey of the “App Store” by IGES revealed hundreds of products on offer from statutory health insurance funds, while the number of health-related products offered by private providers was estimated at several tens of thousands.² The CHARISMHA study gave a figure of over 100,000 for the number of health apps available in the stores of the two largest mobile platforms.³

¹ Researchers at the University of Stanford have developed an image recognition algorithm which can detect lung cancer in stained lung biopsies (including the type of cancer, i.e. adenocarcinoma, small-cell bronchial carcinoma etc.) with better rates of sensitivity and specificity than pathologists. Five million biopsies were investigated and around 10,000 attributes and different mathematical models were tested (Castellino 2016). Interestingly, information technology itself is referred to as the party responsible for issuing diagnoses and treatment proposals using genome analysis data from cancer patients: “We supply information systems which provide accurate diagnoses and personalised treatment proposals for doctors at any time and in the shortest possible time, on the basis of genome sequence data.”
<https://www.dkfz.de/de/presse/pressemitteilungen/2014/dkfz-pm-14-24-Individualisierte-Krebsmedizin-fuer-jeden-Patienten.php>, vgl. auch: Zipf 2014

² Cf. e.g. SVRV 01/2016, IGES survey not published.

³ Cf. Albrecht et al. 2016c, Chapter 2 “Health apps and the market”. By way of qualification, it should be noted that the market for German-speaking apps is likely to be significantly smaller.

An increasing number of these products also perform medical functions by supporting patient self-management, explaining medical contexts or claiming direct therapeutic effects. More and more people are therefore asking whether these products should be classified as medical devices and subject to comparable authorisation procedures. According to State Secretary Lutz Stroppe: “The fact that over 100,000 health apps are now available on the market means that it is getting harder every day to sort the wheat from the chaff. That’s why we need reliable quality and data protection standards for citizens.”⁴ The European Union (EU) is currently carrying out a further consultation on the authorisation of health apps for similar reasons.⁵

On the other hand, the question also arises as to whether apps should continue to be funded by private consumers or individual health insurance schemes, or alternatively be incorporated into the general reimbursement structures of the health insurance funds, and – if the latter is the case – the extent to which this should resemble the corresponding procedures for pharmaceuticals and medical devices. Any software, whether app or otherwise, which intervenes in the recovery process and makes claims in relation to diagnosis, recovery, improved disease management or similar, must be tested for its safety and benefit.

At the same time, the idea that the processes which have proven their worth in other sectors can simply be transferred wholesale to other products is concerning in a number of respects. The digital sector is still immature, and too little experience has been built up to gauge the incentive effects which may result from complex authorisation and reimbursement procedures. Some people have objected that previously established procedures cannot be “transferred to this new area of innovation on a 1:1 basis.”⁶ While on the one hand the healthcare sector has a fundamental interest in exploiting the opportunities for innovation in this area for the benefit of parties insured by health insurance funds, there is also an economic argument for promoting a sector which is largely dominated by small and financially weak companies (“start-ups”). These interests must be balanced against patient safety and consumer protection concerns in order to facilitate healthy market development in the interests of all stakeholders.

These questions have already been debated in other forums,⁷ but are by no means conclusively resolved. An in-depth discussion is however urgently required, since digitisation offers opportunities for improved and more efficient provision

⁴ Frankfurter Rundschau dated 8.06.2016

⁵ Cf. European Commission 2016a

⁶ Knöppler et al. 2016b, p. 5

⁷ In addition to the many events held on the topic and the cited study by the Expert Council for Consumer Issues (Sachverständigenrat für Verbraucherfragen, 2016) cf. e.g. Lucht et al. 2015, Knöppler et al. 2016a/b, Albrecht et al. 2016a/d; see also Dienst für Gesellschaftspolitik 23/16, p. 9f.

of care. It should furthermore not be forgotten that a newly flourishing sector of this kind may enhance Germany's standing as a business location. However, medical apps always entail potential risks, and these should be minimised as far as possible.

Investigations must therefore be carried out into the potential uses of innovative digital products by citizens, patients and care providers.⁸ A key question is whether or not such products should be subject to an authorisation procedure. If the answer to this question is yes, can an existing procedure be applied or must a new one be developed? Under which conditions should these products be reimbursed by the statutory health insurance funds?

These questions are the subject of this study, which was drafted between June and September 2016 by the IGES Institute on behalf of Techniker Krankenkasse (TK).

1.2 Definition of the area of research

1.2.1 Questions

The questions addressed by this study can be defined as follows:

What should an authorisation procedure for digital healthcare products look like, and how should these products be reimbursed by the statutory health care funds?

By "authorisation", we mean a basic approval to market a product in Germany. The question of authorisation therefore gives rise to other questions:

- ◆ Is authorisation really necessary for products of this type?
- ◆ Does this apply to all types of digital product?
- ◆ What evidence must be provided for authorisation purposes, and how should this take place?
- ◆ Can authorisations be managed under existing legislation, perhaps with amendments, or would it be more sensible to create a new regulatory framework?

As regards the question of reimbursement, the two alternative options which should be examined are reimbursement by individual health insurance funds and collective reimbursement by the statutory health insurance system as a whole. Reimbursement by individual health insurance funds may take place under a

⁸ All job titles used in this study refer to both genders.

selective contract in accordance with § 140 of Volume V of the Social Code or otherwise, for example as an optional benefit.

1.2.2 Type of digital products examined

The type of products examined in this study can be specified in three respects:

- ◆ By providing a definition:

The term “**digital healthcare products**” is used to restrict the scope of our investigation to software which addresses potential or existing health impairments by supporting detection, cure or management. Products for lifestyle measures which fall under the heading of primary prevention (“jogging apps”) are not examined,⁹ since they pose almost no issues in terms of the need for regulation. We have also excluded products aimed solely at organising the care process, for example the electronic scheduling of appointments.

The scope of our examination includes everything which is available in digital form for the above purposes, regardless of whether the product is designed as an “app” on a mobile end device, has a web-based design or takes another form.

- ◆ By identifying the users:

The study is limited to products used by **private individuals**. All other aspects of “digitisation”, including in particular digitisation within healthcare organisations (doctor or hospital information systems, health insurance fund systems etc.) and between healthcare players (telematics infrastructure, networking projects etc.) are excluded.¹⁰

We also limit ourselves to the area covered by Volume V of the Social Code. Nursing-related uses are not included.

⁹ Lucht M et al (2015) distinguish between “health apps” aimed at general health promotion, “medical apps” for self-management and “medical device apps” for the “detection, prevention, monitoring, treatment or palliation of diseases”. “Digital healthcare products” are primarily a combination of the last two categories.

¹⁰ Software is already used extensively in professional contexts, e.g. when formatting data from imaging procedures, screening moles at GP surgeries and for hospital-specific patient files. However these uses are generally associated with medical devices, which means they are already regulated in most cases. Software programs which support decision-making by doctors represent a further area of investigation, which we believe should be treated separately; however, we also believe that the outcomes of this study are in some cases also applicable to this area.

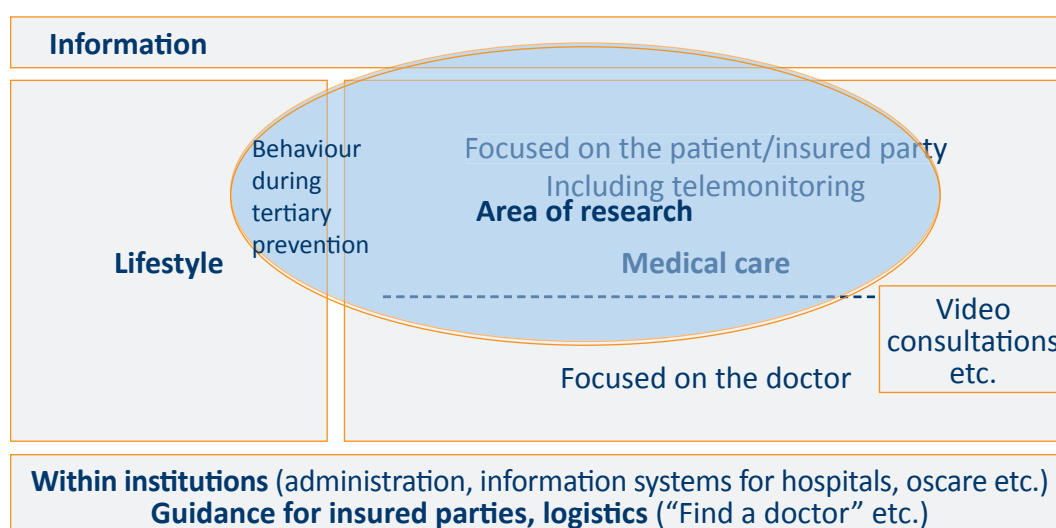
- ◆ By identifying the type of digital products:

The products which are currently on the market represent only a snapshot of a continuing process of development, and sustainable regulations must be aimed at what is over the horizon. **In future, more and more products** will claim to replace all or part of the role played by the care provider, and account has therefore been taken of this fact.

Products which do not process data and merely establish links with care providers via a different medium, such as video consulting, are not covered.

Figure 1: Area of research covered by the study

e-Health/telemedicine functions etc.



Source: IGES

1.3 Procedure and methodology

The study is based on a qualitative and conceptual approach. The existing regulatory systems, current literature and authorisation procedures for digital products in other countries were used as context for our investigations. We analysed typical products and development trends in the market and developed a classification system for different products which makes it possible to answer the questions we posed.

Experts from a number of different areas (ranging from regulatory authorities to start-ups) were surveyed in order to develop and scrutinise existing hypotheses and critically examine the different future prospects for digital products.

In order to do justice to the specific nature of these products, we started from the products themselves in order to identify which type of regulations would be most appropriate, rather than starting with existing regulatory systems and trying to shoehorn digital products into their categories.

At present (autumn 2016), a number of similar proposals are being discussed and others will doubtless follow. Many points are still up in the air, and parts of this study should therefore be regarded as open-ended and a starting point for further discussions.

The study is intended to serve as the basis for a structured series of discussions with various groups of stakeholders in the healthcare sector.

1.4 Overview of content

Answers to the above questions will be set out in eight chapters:

- ◆ Chapter 1 is an introduction, where we provide an overview of the market and the current state of debate. The purpose of the study is explained and differentiated from other issues.
 - ◆ Chapter 2 groups and evaluates the market by categorising and characterising digital health products.
 - ◆ Chapter 3 proposes a separate classification on the basis of product risk.
 - ◆ Chapter 4 proposes specific regulatory approaches to the issue of authorisation and discusses whether this proposal can be implemented under existing regulations or whether a separate system of regulations is required.
 - ◆ Chapter 5 sets out a proposal concerning reimbursement by the statutory health insurance funds.
 - ◆ Chapter 6 examines the suitability of these proposals from the point of view of the different stakeholders.
 - ◆ Chapter 7 contains a summary of the outcomes from the expert interviews.
 - ◆ Chapter 8 summarises the options which have been discussed and provides suggestions for future action.
-

2. Overview of market and literature

Summary

This chapter provides an overview of the current situation in the market for digital healthcare products. After firstly examining the financial significance of the market and the range of products, we will then look at the current debates surrounding the market and a number of attempts which have been made to impose a structure on its diversity. The key takeaways for this section are as follows:

- ◆ The market for digital health products is still relatively small, but is growing rapidly. Diagnostic, therapeutic or self-management products are starting to perform medical functions.
- ◆ There is as yet no consensus over the correct form of regulation for these products, e.g. in respect of data protection or comparability with medical devices.

2.1 Market development

Notwithstanding the large amount of interest in the digital health market shown by expert audiences, a closer look at the figures reveals that its actual impact is still extremely limited. The market studies carried out to date suggest that digital products will still account for less than one per cent of health spending in a few years' time.

According to figures published by the weekly business magazine *The Economist*, the European market in this sector will be worth EUR 6-7 billion in 2018.¹¹ Just under EUR 1 billion of this figure would be spent in Germany, or in other words significantly less than half a per cent of a health market which is currently valued at over EUR 300 billion. The CHARISMHA study also found that the market is still relatively small in financial terms.¹²

Its rate of growth is considerable, however. The afore-cited study estimates the volume for 2013 at under EUR 0.2 billion, which means that sales are expected to increase by a factor of five by 2018. This assessment is backed up by the Ernst & Young Start-Up Barometer, according to which risk capital investments in the "health" sector rose from EUR 11 million to EUR 93 million between the first six months of 2015 and the first six months of 2016. The sector is now the fourth most popular industry in terms of attracting investment, having moved up from tenth place.¹³

¹¹ Cf. *The Economist* 2016

¹² Cf. CHARISMHA-Studie, Kap. 2, Albrecht et al. 2016c

¹³ Cf. Ernst & Young 2016

As well as the above quantitative assessment, we believe it is also important to provide a brief overview of developments in the market by indicating the topics covered by a range of digital healthcare products. The apps are sorted on the basis of the medical healthcare cycle, using the following individual stages:

- ◆ Information
- ◆ Early detection
- ◆ Prevention
- ◆ Diagnosis
- ◆ Treatment decision
- ◆ Treatment
- ◆ After-care/monitoring
- ◆ Self-management

Table 1 provides an overview with examples of apps in each of the above procedural stages. Apps in each of these stages are already available on the market.

A more detailed list of examples can be found in Appendix A1.

Table 1: Market overview of digital health and healthcare products

Category	Example	Description
Information	Husteblume	Provides information e.g. on the nature and level of allergens present in a particular location and on symptoms, and has a diary function.
	Treato	Systematically collects and publishes information on illnesses and treatments from Internet forums.
Early detection	ProstateCheck	Calculates an individual's risk of suffering from prostate cancer
Prevention	ImpfManager	Reminds users of upcoming vaccinations
Diagnosis	Symptomate	Recommends potential diagnoses and courses of action in response to symptoms entered by the user.
	SkinVision	The patient takes a photo of a mole. An algorithm is then used to determine whether or not the mole is malignant. Photos are stored over a period of time in order to document developments.
Treatment decision	Decision Aids	Online decision aids for patients (e.g. when deciding whether to undergo an operation) ¹⁴
Treatment	Tinnitracks	Tinnitus treatment using music which suppresses certain audio frequencies
	Caterna	Visual training for the treatment of amblyopia
	EvokeCare	Speech therapy for stroke patients
After-care/monitoring	LifeGraph	Mental health monitoring using a smartphone. Relatives or doctors/therapists are notified if a patient's condition deteriorates.
Self-management	myCOPD	Support for chronically ill patients suffering from COPD (chronic obstructive pulmonary disease); information, training, medication reminders, patient-doctor communication. Similar apps also exist for other chronic diseases (e.g. asthma, diabetes)

Source: Online information from providers, IGES

¹⁴ More popular in English-speaking countries

2.2 Current state of debate

The increasing significance of wellness- and health-related digital products has led to an intensifying debate in this area. As well as the many different events that have been held, the following publications are particularly worthy of mention since they provide a good overview of the current state of affairs:

1. University Medical Centre Freiburg 2013: GESUNDHEITS- UND VERSORGUNGS-APPS – Hintergründe zu deren Entwicklung und Einsatz [HEALTH AND CARE APPS - Background to their development and use] (Lucht et al. 2015)
2. ZVEI [Zentralverband Elektrotechnik- und Elektronikindustrie e.V., German Electrical and Electronic Manufacturers' Association] 2014: Leitfaden Mobile Geräte und Apps in der Medizin [Guidelines on mobile devices and apps for medical purposes]
3. BfArM [Bundesinstitut für Arzneimittel und Medizinprodukte, Federal Institute for Drugs and Medical Devices] 2015: Orientierungshilfe Medical Apps [Guidelines on Medical Apps]
4. Bertelsmann Foundation 02/2016: Digital-Health-Anwendungen für Bürger [Digital health apps for citizens] (Knöppler et al. 2016a, 2016b)
5. BMG [Bundesministerium für Gesundheit, Federal Ministry of Health] 04/2016: Chancen und Risiken von Gesundheits-Apps [Opportunities and risks associated with health apps] (CHARISMHA, Albrecht 2016)
6. BVMed 05/2016: Die digitale Gesundheitswirtschaft: Potenziale für die MedTech-Branche [The digital health economy: potential opportunities for the medical technology industry]
7. Bertelsmann Foundation 08/2016: Transfer von Digital-Health-Anwendungen in den Versorgungsalltag – Teil 1: Transfermodell, Varianten und Hürden [Transfer of digital health apps to everyday care provision – Part 1: transfer model, variants and obstacles] (Knöppler et al. 2016b)

These publications discuss opportunities and risks, market developments and regulatory approaches from a number of different perspectives. We will briefly summarise some of the key arguments.

Many hopes are often pinned on digital health products, for example that they will encourage compliance among chronically ill patients and promote less resource-intensive care procedures.¹⁵ “According to recent surveys, half of all patients already believe that mHealth will improve the health system. Stakeholders in the healthcare sector, including doctors, health insurance funds and industry representatives, are also aware of the huge potential of mobile health services.”¹⁶ Apps therefore offer new opportunities for participation and interaction between citizens, care providers and payment authorities in the healthcare sector. At the same time, however, certain authors note that health apps have as yet only really penetrated the secondary health market, and are barely visible in the primary health market.¹⁷ A critical examination of the studies carried out to date also reveals that the evidence for specific health benefits is still somewhat limited.¹⁸

All of the publications point out that there are many obstacles that must be overcome before health apps can be launched on the health market. The most significant include regulatory and authorisation procedures and reimbursement procedures, which were designed for pharmaceuticals and medical devices and are not tailored to the needs of digital health products.¹⁹ A further problem relating to current legislation is the lack of adequate definitions (or any definitions at all) for the relevant processes, terminology and objectives, leading to potential issues in terms of transparency, the evaluability of success and project coordination.²⁰ A recent study by the Bertelsmann Foundation also refers to this problem: “There is still a lack of transparency regarding authorisation obligations and criteria for digital health apps aimed at citizens and patients in the EU.”²¹ The problem is circumscribed even more narrowly by the University of Freiburg: “Contrary to the assumptions of many consumers, the CE label means precisely nothing in terms of the quality of an app, let alone its benefit. Consumers have been lulled into a false sense of security, and certain app manufacturers are happy to continue misleading them by promoting the CE label as a particular mark of quality.”²²

¹⁵ Cf. Kuhn und Amelung 2016

¹⁶ BVMed 05/2016 online

¹⁷ Cf. Knöppler et al. 2016a

¹⁸ On the subject of prevention and diagnostics, cf. CHARISMHA Chapter 4 (Kuhn and Amelung 2016, in particular p. 103f.), and Chapter 6 (Rutz et al. 2016, e.g. p. 140 – they are somewhat more optimistic about treatments, p. 143–148.)

¹⁹ Cf. Knöppler et al. 2016a

²⁰ Cf. Albrecht et al. 2016a

²¹ Cf. Knöppler et al. 2016a

²² Lucht et al. 2015, p. 10

This leads to the question of whether or not the health sector's current authorisation processes are suitable for digital health products. Some authors take the view that the distinctive nature of digital healthcare products makes it necessary to "modify existing healthcare instruments and attitudes".²³ The BfArM's Guidelines on Medical Apps are however based on the fundamental assumption that the provisions of the Medical Devices Act [Medizinproduktegesetz, MPG] are sufficient to regulate the market. The Zentralverband Elektrotechnik- und Elektronikindustrie [ZVEI, German Electrical and Electronic Manufacturers' Association] also takes the view that a legislative framework is already in place for medical apps.²⁴

The issue of data protection is raised by almost all commentators. The study by the University of Freiburg states that the level of media competence required by users in order to protect their data effectively is problematic, since users differ widely in this respect. The Bertelsmann Foundation and the CHARISMHA study however emphasise that the existing legislation on data protection is adequately clear.²⁵

The applicability of the information provided is another topic of discussion, since consumers are not necessarily able to identify relevant information among the vast quantities of data provided or assess its quality and reliability.²⁶ There is as yet no standardised procedure for verifying the information provided, although attempts have been made in several other countries to develop corresponding quality standards (cf. Appendix 0).

Another problem recognised by all stakeholders is a lack of transparency, since many apps contain no information on their funding mechanism, the data protection standards they follow or the exact way in which they work.²⁷

The BVMed article includes the following statement on the use of the data collected by apps for research purposes:

"[...] the data are there, but they are not currently available. We must therefore solve the problem of data protection and make increased use of anonymised patient data for healthcare research projects."²⁸

²³ Knöppler et al. 2016b, p. 12

²⁴ ZVEI 2014

²⁵ Cf. Pramann 2016 and Knöppler et al. 2016a

²⁶ Cf. Lucht et al. 2015

²⁷ Albrecht et al. 2016a and c

²⁸ BVMed 2016 online

The CHARISMHA study also includes an entire chapter on research. The authors come out in favour of developments such as separate standards for app-based research tools.²⁹

The study by the University of Freiburg states that good and successful apps consist of more than just reliable content: “Only apps which the user can understand and use (usability) and which the user enjoys using and uses regularly (user experience) have a chance of promoting health by changing behaviours.” The study also mentions the topic of media competence at this point, which is a problem for educationally disadvantaged and older citizens and makes it more difficult for these groups to access digital healthcare products.³⁰

2.3 Previous market categorisation

As we mentioned previously, the complexity of the market has already been lamented on many occasions. Other studies have therefore already attempted to sort products into different categories in order to provide a market overview. The following publications are particularly relevant in this respect:

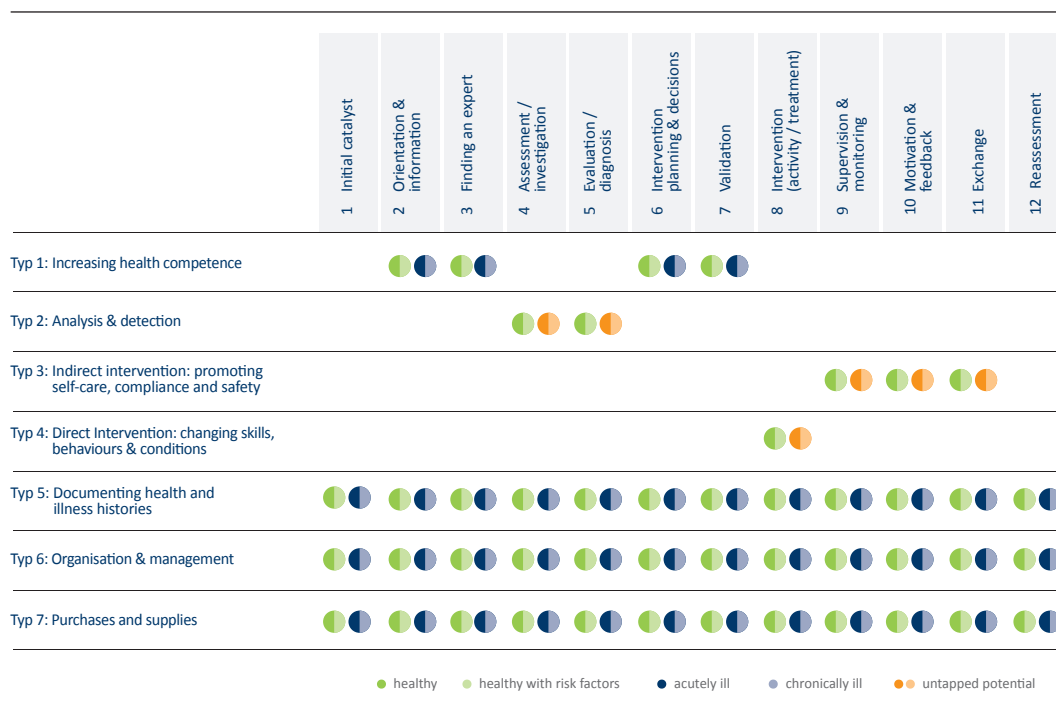
- ◆ Bertelsmann Foundation 02/2016: Digital-Health-Anwendungen für Bürger [Digital health apps for citizens] (Knöppler et al. 2016a)
- ◆ BMG 04/2016: Chancen und Risiken von Gesundheits-Apps [Opportunities and risks associated with health apps] (CHARISMHA, Albrecht 2016d)
- ◆ Gesundheits- und Versorgungs-Apps. Ein Systematisierungsversuch [Health and healthcare apps. An attempt at systematisation]. (Scherenberg and Kramer 2013)

The Bertelsmann Foundation’s study entitled “Digital health apps for citizens” distinguishes between a total of seven types of digital health apps named after their primary effect, as shown in Figure 2. Distinctions are made between *Increasing health competence* or *Analysis and detection*, for example. These seven different types of apps are broken down further according to the individual target groups (healthy/healthy with risk factors/chronically ill) and twelve defined stages of the healthcare cycle, starting with *Initial catalyst* and ranging from *Finding an expert* and *Diagnosis* through to *Reassessment*.

²⁹ Albrecht et al. 2016a

³⁰ Lucht et al. 2015

Figure 2: Overview of app types and target groups according to Knöppler et al. (2016a)



Source: IGES according to Knöppler et al. (2016a)

In addition, the untapped potential of digital apps is evaluated for each possible combination of app type and health cycle stage. For example, the authors believe that such potential is present for Type 2 apps (Analysis and detection) in Stage 4 (Investigation/assessment).

The CHARISMHA study takes a different approach by systematising health apps on the basis of the context in which they are used, for example assessment or support. The “Assessment” context includes e.g. “Apps which perform an inventory of physical or mental health, for example to assess fitness, but also to support diagnostic processes”.³¹ There are a number of parallels between the two studies. The “Management” context in the CHARISMHA study is similar to Types 5 and 6 in the Bertelsmann Foundation study, as shown on the figure.

The third study examined here takes a different approach and categorises apps on the basis of target groups and areas of use. Target groups include laypersons or experts, whereby a distinction is made within the laypersons group between healthy individuals, non-healthy individuals and relatives. Each of the groups is then assigned to particular areas of use (promoting health, primary prevention, secondary prevention and tertiary prevention). The methodology distinguishes

³¹ Albrecht et al. 2016d, p. 55

between a total of seven categories, for example “Secondary prevention for healthy individuals and laypersons”. An example of an app falling into this category would be “Drinking Time Machine”, which visualises the effects of alcohol consumption on the ageing process.

This approach also has certain points of similarity with those referred to above; the category “Promoting health for laypersons/healthy individuals” largely corresponds to the categories “Education” and “Information” in the CHARISMHA study and the category “Increasing health competence” in the study by the Bertelsmann Foundation.

On the whole, each of the categorisations described above provides a useful perspective on the market for digital healthcare products. A separate classification process will however be required to achieve the objective of this study, namely developing a proposal on the necessary regulatory approach to authorisation and reimbursement. This process will be based on the risk associated with individual digital healthcare products.

Products with different levels of risk which therefore require different regulatory approaches may fall into the same category under the categorisation systems referred to above. One example is Category 4 in the figure, e.g. “Direct intervention: Changing skills, behaviours & conditions”, which covers both online courses and the healthcare product Tinnitracks for treating tinnitus. The former merely provide information, whereas Tinnitracks goes much further, since it is a technical system based on the interaction between technology and software and claims to provide treatment. The market therefore needs to be divided according to different criteria.

3. Risk-based categorisation of digital healthcare products

Summary

In this section we present a risk-based categorisation of digital healthcare products, starting with examples of risk classifications from the healthcare sector and other industries, and moving on to examples of the risks which may potentially be associated with digital healthcare products. Building on these examples, the categorisation developed for the purpose of this study is then introduced, with a brief digression on the features specific to development processes for digital healthcare products. The key takeaways for this section are as follows:

- ◆ For the purpose of determining the required regulatory approach, digital products can be grouped into four categories on the basis of increasing risk:
 - Class 1a: Publication of general information
 - Class 1b: Collection of personalised data
 - Class 2: Data-based recommendations aimed at supporting care providers or patients during diagnosis, treatment etc.
 - Class 3: Data-based recommendations aimed at replacing care providers during diagnosis, treatment etc.

3.1 Examples of risk-dependent regulatory approaches

A vital prerequisite for the authorisation and reimbursement of digital products is a classification system which is suitable for this purpose. Grouping by risk is a common classification method aimed at protecting consumer health, and involves the evaluation of risks and the subsequent assignment of products with comparable risk profiles to the same classes. Criteria must be defined as a basis for assigning products to classes, and may include toxicity, duration and invasiveness of use or type of use. This makes it possible to compare different substances or products and to harmonise the need for regulatory action.

Grouping by risk class is commonplace in both the healthcare sector and other areas of everyday life, as demonstrated by the following examples.

3.1.1 Examples from the healthcare sector

Medical devices: Medical devices are grouped into particular classes for risk classification purposes, which are based in legislative terms on the “vulnerability of the human body” to the relevant device. Four different risk classes have been identified which entail different requirements for market access. Overall, the Medical Devices Act provides for four risk classes:

- ◆ Class I (low risk, e.g. walking aids, glasses, bandages)
- ◆ Class IIa (medium risk, e.g. disposable syringes)
- ◆ Class IIb (increased risk, e.g. X-ray machines)
- ◆ Class III or active implants (high risk, e.g. heart valves, hip implants)

Pharmaceuticals: Pharmaceuticals are classified in Germany according to the risk associated with their use. According to § 48 of the Pharmaceuticals Act, pharmaceuticals whose use is associated with particular risks should only be available on prescription. Pharmaceuticals whose use is not associated with any particular risks can be purchased without a doctor’s prescription. The list of pharmaceuticals available only on prescription is drawn up by the Federal Ministry of Health in consultation with the Federal Council, after carrying out expert hearings.

The authorisation rules for both sectors are examined in more detail in Chapter 4 below.

3.1.2 Examples from other industries

Biosafety levels: Pathogens and genetically modified organisms used in scientific procedures are also divided into four risk groups, and the laboratories using them are assigned to four correspondingly defined safety levels. Risk level 1 includes biological substances which are unlikely to cause human disease, whereas risk level 4 includes biological substances which cause serious diseases in humans and represent a major hazard for employees.

Risk classes for investor protection: Financial advisers must assign their customers to a risk class at the start of each consultation using a questionnaire. Customers in Risk Class A are extremely risk averse, whereas customers in risk class E are particularly happy to take risks. The more experienced the customer is deemed to be, the higher the risks they are likely to be happy taking, right up to total loss of the money invested.

3.2 Risks associated with digital healthcare products

We believe that a risk-based classification system is also suitable for digital healthcare products. The risks which may arise in this area can be illustrated using a number of examples.

Apps which record user behaviour or biological parameters, and for example claim to provide an accurate representation of daily energy consumption, have assumed great significance in the public mind. Murakami et al. (2016) look at these devices and compare the measured values for individual energy consumption against the 'doubly labelled water' method, which is the established standard. The devices tested were found to be reliable in terms of the displayed sequence of recorded values, but the actual values differed significantly from those recorded by the established gold standard.

Other digital healthcare products go significantly further by actively supporting patients and doctors with diagnostic or treatment decisions. This broad continuum of products gives rise to different levels of risk for users or patients/doctors. The risks potentially associated with apps that influence treatment or diagnostic decisions are made clear by a number of recent studies.

Huckvale et al. (2015) carried out a systematic evaluation of smartphone apps which calculate insulin doses for diabetics. Of the 46 apps investigated, only one met the assessment criteria defined by the authors. The authors concluded that, "The majority of insulin dose calculator apps provide no protection against, and may actively contribute to, incorrect or inappropriate dose recommendations that put current users at risk of both catastrophic overdose and more subtle harms resulting from suboptimal glucose control."³²

Apps which assess the malignancy of skin blemishes in order to diagnose malignant melanomas provide a similar example. Wolf et al. (2013) analysed a total of four apps. Three of these apps assessed the relevant area of skin using algorithms to analyse a photo taken by the user. The fourth app merely sends the photo to a dermatologist, who then analyses the area of skin without further support from the app. This app demonstrated the highest sensitivity of those investigated (98.1%).³³ Even the best-performing of the other three apps misdiagnosed 30% of skin areas as harmless even though they displayed features that were medically concerning.

Rules must therefore be put in place to deal with potential risks of this kind.

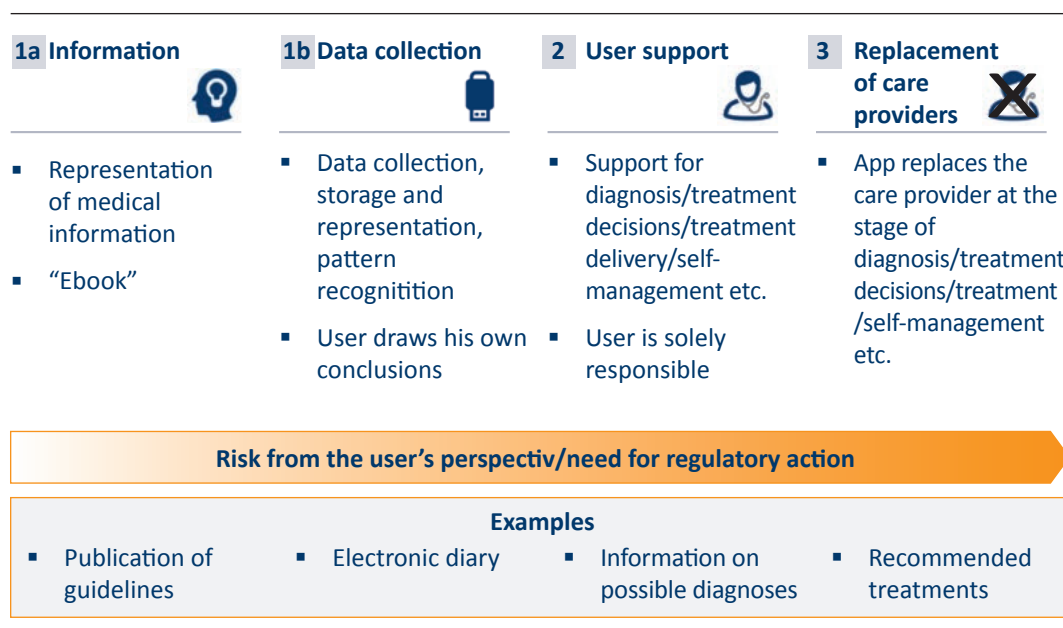
³² Translated from English. Original: „The majority of insulin dose calculator apps provide no protection against, and may actively contribute to, incorrect or inappropriate dose recommendations that put current users at risk of both catastrophic overdose and more subtle harms resulting from suboptimal glucose control.” (Huckvale et al. 2015, p. 1)

³³ Proportion of true-positive test results

3.3 Risk classes for digital healthcare products

Our proposed categorisation method groups digital healthcare products into four classes on the basis of their associated level of risk. Since the products examined are IT-related, the main risk driver is the way in which the product handles information and data.

Figure 3: Overview of risk classes



Source: IGES

3.3.1 Class 1a: General medical information

Class 1a is restricted to products which solely provide medical information without any reference to the user's specific characteristics. Apps of this kind can also be compared to a book or e-book. Examples include:

- ◆ Search tools for ICD diagnosis codes
- ◆ General information on medicines

The data are impersonal and could in principle be published in printed form instead.

3.3.2 Class 1b: Data collection and representation

Class 1b products are used to collect, store and graphically represent personalised data such as blood glucose levels and/or relevant environmental data, e.g. pollen counts for allergy sufferers. The data may also be processed using simple algorithms, with the aim of producing individualised reports so that users can more easily recognise patterns or connections. Individual treatment or diagnostic recommendations are not provided. The products act as an aid to self-management, in particular for users suffering from chronic illnesses.

It is however important to ensure that the system as a whole is always examined in the event that additional devices such as blood glucose monitors are incorporated (point-of-care systems).

Examples include:

- ◆ an allergy app which links the patient's known allergies to relevant environmental data and provides details of the specific allergy risk on a particular day, or
- ◆ an electronic diary for chronically ill patients which links their health readings to behavioural data (and possibly environmental data). This may allow patterns to be identified, e.g. changes in health readings or symptoms as a result of particular behaviours or environmental conditions.

The information in this category is always such that the user could record it independently or compile it from public sources.

3.3.3 Class 2: Data processing for the purpose of supporting users

This class includes products which go beyond merely collecting and representing data, and instead also process the data (whether current or historical). Complex algorithms are used to issue individual prospective diagnostic and treatment recommendations. The products may relate to a number of different medical areas:

- ◆ Early detection: Certain medical data can be recorded and used as a basis for stating whether or not the user is likely to suffer from a particular illness in the near future.
 - ◆ Diagnosis: Algorithms can be used to identify disease markers, with examples already existing for e.g. mental health, cardiovascular disease or cancers.
 - ◆ Treatment decisions: Algorithms can be used to issue specific proposals on the basis of patient data or support patient decisions by asking appropriate
-

questions and providing relevant information, as in the case of the “decision aids” used in the USA and UK.

- ◆ Treatment: Treatment under the supervision of a care provider. Current examples include psychotherapy, speech therapy, guidance for physiotherapy and occupational therapy and treatments for hearing and visual disorders.
- ◆ Monitoring: Ongoing collection of data, e.g. from pacemakers, implantable cardioverter defibrillators or continuous blood glucose monitors. Events are evaluated on the basis of an algorithm, and the treating physician is informed immediately if they are deemed to be hazardous, or otherwise sent a regular summary of logged events.
- ◆ Self-management: A smart insulin pen and the associated mobile app can calculate and recommend the optimum insulin dose on the basis of current data. Similar products are imaginable for patients suffering from allergies, asthma or heart failure.

Products in this category support users at the stage of diagnosis, treatment decisions, treatment and so on. Final decisions are taken by the user (doctor, patient etc.) and remain the responsibility of the latter.

3.3.4 Class 3: Data processing for the purpose of replacing care providers

Class 3 apps replace care providers at the stage of diagnosis, treatment decisions and treatment. There are currently very few products in this category, which can be attributed less to a lack of technical capabilities than to caution on the part of manufacturers, which in turn is due to the fact that underlying legal issues such as liability are still unregulated. Almost all of the examples from the previous class could be included in this class instead if recommendations were issued with a higher degree of authority and without qualifications. Once again, the products may relate to a wide variety of different medical areas:

- ◆ Diagnostic or treatment recommendations based on extensive calculations which cannot be verified in individual cases by a human are generally accepted and implemented by a doctor.³⁴
- ◆ Devices which monitor “remote” pacemakers or implantable cardioverter defibrillators can immediately reprogramme the pacemaker if a hazardous event occurs.

³⁴ Cf. the examples cited in the introduction (Chapter 1.1) concerning the diagnosis of lung cancer and database-supported genome comparisons

- ◆ In theory, a smart insulin pen could also be used by diabetics who have not received any training and who do not verify or query the treatment recommendations, but instead rely entirely on the algorithm's decisions.

3.3.5 Examples

Individual products may fall into almost all of the classes depending on their specific design. Their underlying purpose cannot be identified from their stated indication (e.g. "allergy") or function ("diagnosis").

A number of examples are provided below by way of explanation:

A digital healthcare product for allergy sufferers may...

- ◆ ... provide general information on the illness and treatment options (Class 1a).
- ◆ ... filter relevant environmental factors for a patient with specific allergies and provide a graphical representation of these factors together with tracked symptoms (Class 1b).
- ◆ ... state the type of allergy from which the patient may be suffering (Class 2).
- ◆ ... issue definitive diagnoses and e.g. specify doses of medication depending on the progression of symptoms (Class 3).

The fact that the product is called an "allergy app" does not therefore reveal the class in which it should be grouped; what matters is the specific design.

This applies by analogy to all products. Symptoms can be analysed in a very generalised way; a statement such as "stomach pains in connection with may be a symptom of" could equally well be found in a book, and therefore belongs in Class 1a. A specific recommendation ("on the basis of the other information you have provided, the chest pain you are currently experiencing is not a symptom of a heart attack. You do not need to go to hospital") belongs in Class 2 or 3.³⁵

An examination of the above-mentioned stages of health and illness reveals that products in different risk classes could conceivably be designed for most of these stages, as illustrated by the following figure.

³⁵ Inclusion in Class 3 would be appropriate if the recommendation were issued with as much certainty as in this hypothetical example; more cautious wordings ("...it may be, that... . Please consult a doctor to be sure") may fall into Class 2.

Figure 4: Connection between risk classes and area of application

<div>Care \ Risk</div>	Class 1a	Class 1b	Class 2	Class 3
Information				
Early detection				
Prevention				
Diagnosis				
Treatment decisions				
Treatment				
After-care/ monitoring				
Self-management				

Source: IGES

To sum up, digital healthcare products can and must be grouped according to their potential level of risk for users. This level of risk is closely associated with the type of data they use and the way in which they process this data.

It is difficult to forecast long-term future developments in the digital industry with any degree of certainty, and so the risk classification shown here will need to be refined on the basis of the future shape of the market. Class 3 in particular anticipates developments which are apparent on the horizon but have not yet reached a level suitable for comprehensive analysis.

3.4 Development process for digital healthcare products

Prior to Chapter 4's discussion of the regulatory approach required for each risk class of digital healthcare products, this section will return once again to the specific procedures followed when developing these products, which is of particular relevance for regulatory measures.

The software development industry in general is characterised by the use of specific strategies and approaches advocating flexible or "*agile*" methods when dealing with complex development processes.

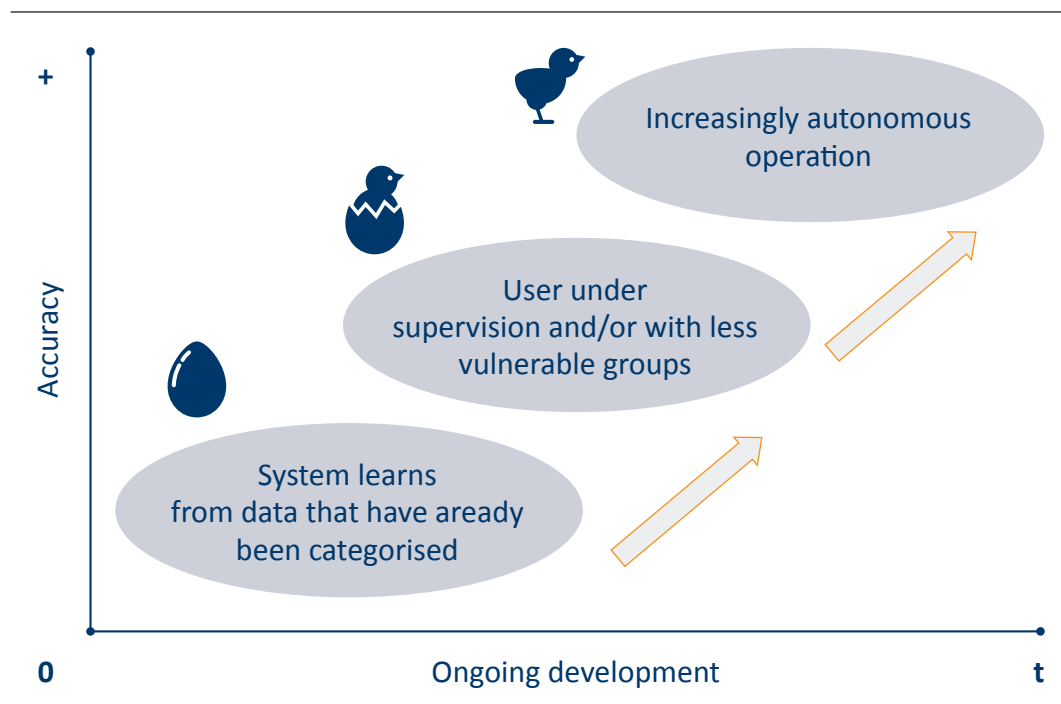
Agile methods are notable for their iterative approach, which involves dividing large projects into individual sub-projects which are completed sequentially. The outcome of each sub-project is tested immediately on end users without waiting for the following sub-processes to be completed.³⁶ In practical terms, this often means that apps are not brought to market as complete products; instead, the end user can almost be said to participate in the gradual development process which the app as a whole undergoes. Key product characteristics of digital healthcare products may therefore change in the course of their use. Iteration, evaluation and permanent optimisation were referred to by many of the experts we interviewed as the very crux of digital solution development.

Alongside this fundamental methodological quirk of software development, account should also be taken of the fact that algorithms are not ready for use as soon as they have been coded; instead, their development passes through several stages. Figure 5 shows these individual stages in the context of medical apps.

During the first stage, the algorithm "learns" using data which have already been classified. The predictive skills acquired by the algorithm in this way can then be assessed in a test environment, either under supervision and/or with less vulnerable groups. As the app gains in autonomy, widespread deployment becomes possible.

³⁶ Cf. Albert and Kumbier 2014

Figure 5: Development stages of digital healthcare products



Source: IGES

An example of system learning using previously classified data is the development of image recognition software for the diagnosis of lung cancer. The software is aimed at doctors and designed to support them in everyday clinical practice. During the first stage, tissue images were prepared from 1017 patients, showing both cancerous tissue and neighbouring healthy tissue. The images were linked in a database to supplementary clinical information and pathology reports for each of the patients. This training dataset could then be used to optimise the algorithm to the point that it could distinguish between healthy and cancerous tissue. The computer was ultimately able to tell healthy tissue apart from adenocarcinomas or squamous cell carcinomas with an accuracy of 85%. Reliable predictions could also be made in respect of patient life expectancy.³⁷

A further example of a digital healthcare product being assessed in a controlled environment is an app for the diagnosis of atrial fibrillation. The app uses a five-minute video recording of the patient's fingertip, taken using a smartphone camera. The software filters particular signals from the video in order to analyse the patient's pulse in more detail. Over 80 test subjects participated in the study in

³⁷ Cf. Castellino 2016. This app is not aimed at medical laypersons, but it is easy to imagine similar procedures for the detection of skin cancer or other diseases, for example.

total, 40 of whom suffered from atrial fibrillation and 40 of whom did not. The test achieved a specificity level of up to 95%, and a sensitivity level of 95% as well.³⁸ The authors themselves refer to their tests as a “proof-of-principle study”.³⁹

This type of system learning offers huge potential, but it also sets digital products apart from other types of products which are essentially complete when they are granted marketing authorisation. Account should be taken of this fact when deciding on the type of authorisation required.

³⁸ The authors tested several specifications of the algorithm using different statistical procedures.

³⁹ Krivoshei et al. 2016, p. 5

4. Proposed procedure for the authorisation of digital healthcare products

Summary

This section discusses the authorisation of digital healthcare products. The need for regulatory action is firstly discussed on the basis of the risk classes defined above, and a concrete proposal is outlined. The criteria which could be used as a starting point for allocating a specific product to a risk class are then examined. National and internal examples of marketing authorisations from a number of different product segments (e.g. pharmaceuticals/aids) are considered next, followed by an exploration of the extent to which these examples are potentially transferable to the authorisation of digital healthcare products in Germany. The banning of individual products is the final topic of discussion. The takeaway findings from Chapter 4 are as follows:

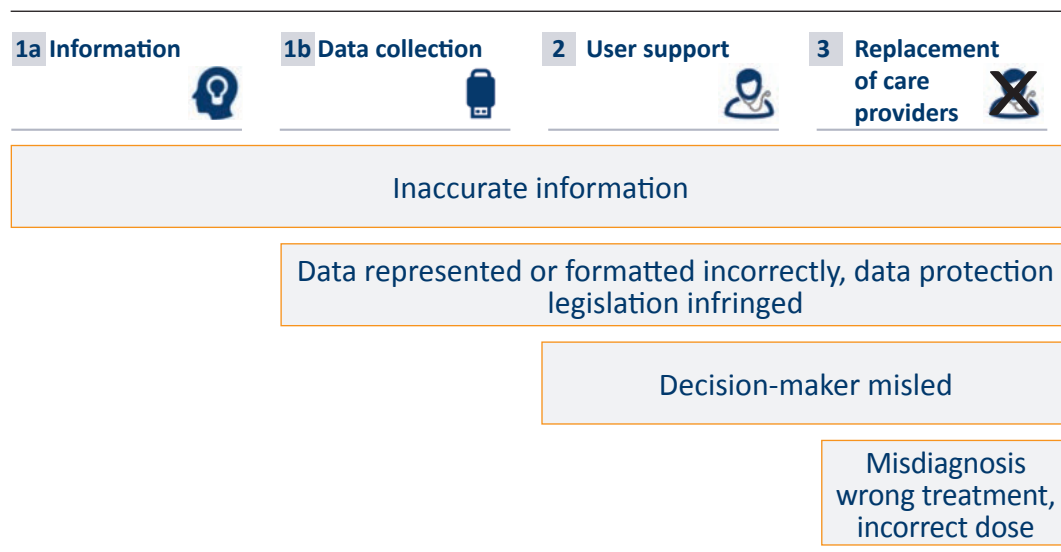
- ◆ Risk levels should be used as a basis for deciding whether authorisation is required and what it should look like.
 - No authorisations are necessary for Class 1a and 1b products.
 - The accuracy of the information provided by Class 1a products may be confirmed by a voluntary quality seal.
 - In the case of Class 1b products, the existing data protection rules must be observed and the proper functioning of algorithms must be guaranteed.
 - Class 2 products should be authorised if the quality of the information they provide is comparable to that which would be provided by a human user (care provider/patient) and they therefore represent a useful aid for human decision-making.
 - The information provided by Class 3 products must be of a quality which exceeds that achieved by typical human care providers. By quality, we mean e.g. diagnostic sensitivity and specificity or the accuracy of recommended dosages.
 - ◆ There are many ways in which the authorisation procedure for digital products will need to differ from the authorisation procedure for medical devices. We therefore recommend that separate rules be adopted within the framework of the Medical Devices Act.
-

4.1 Risk-based regulatory approach

The classes of digital products referred to above are associated with different and increasing levels of risk. The regulations necessary in this respect are cumulative, which means that the regulations for the lower risk classes also apply to the higher classes.

Figure 6 shows the risks according to risk class.

Figure 6: Risks associated with each risk class



Source: IGES

4.1.1 Class 1a – Accuracy of information

The general health information provided by Class 1a products does not need to be regulated. In line with the concept of personal responsibility enshrined in § 1 of Volume V of the Social Code, citizens are responsible for the appropriate use of information sources of this kind. Consumers/patients must apply the same level of diligence to their use of electronic apps as to conventional media. The content of a book in electronic format should not be regulated to a greater degree than a paper book. This class also covers lifestyle recommendations. Inclusion in a higher class is only justifiable in a small number of individual cases where apps targeted at specific patients could be potentially damaging, e.g. by providing nutritional recommendations for anorexic patients.

The need for a quality seal similar to the certificates issued by HON (Health On the Net) or afgis (Aktionsforum Gesundheitsinformationssystem [Action Forum on Health Information Systems]) has been expressed by many different commentators, as well as by the experts we interviewed.⁴⁰

The following factors point in favour of a quality seal:

- ◆ the higher degree of trustworthiness which consumers may potentially ascribe to digital products,
- ◆ the novel form of the medium, which may cause more confusion among consumers than printed information,⁴¹
- ◆ the ease with which information of dubious quality can be published on the Internet, and which apparently results in a multitude of poor-quality offerings.⁴²

The following factors militate against the mandatory imposition of a quality seal:

- ◆ the lack of consistency with all other ways of disseminating information (there is no quality seal for books),
- ◆ the problem of differentiation (must an online medium affix a quality seal to individual articles before they can be published?),
- ◆ the fact that only 19% of users are in favour of a quality seal, and are more interested in making information easier to understand; this implies that they are confident in their own ability to distinguish between good-quality and poor-quality information.^{43,44}

We do not recommend a government-mandated quality seal. A number of quality seals have already become established on the market (cf. Appendix A2), and will gain further ground in response to consumer demand. The co-existence of several quality seals is also unproblematic, since self-regulation and self-control

⁴⁰ Examples of German and foreign quality seals and the relevant assessment schemes are provided in Appendix O.

⁴¹ One dozen websites can be read in a shorter time than one dozen books.

⁴² Cf. e.g. <https://www.central.de/presse/praxis-dr-internet/100-gesundheitsseiten-im-qualitaetscheck>, “[...] Over 30% of the websites evaluated were given an overall rating of ‘defective’ or ‘inadequate’. Across all 100 websites, the average rating ‘adequate’ (4+) was only awarded once. [...]”

⁴³ Cf. http://epatient-rsd.com/wp-content/uploads/2015/05/EPatient_Survey_2015_Pressemappe.pdf (accessed on 30.08.16), p. 7

⁴⁴ The options are discussed in a great deal of detail in CHARISMHA, Chapter 13 (Albrecht 2016b).

mechanisms will kick in. Until then, consumers will be solely responsible for examining the information which is provided with the same critical reading skills they would apply to a printed reference book, and for using reliable sources to back up their findings (e.g. information from respected journalistic media, state institutions, health insurance funds or doctors' organisations). Questions can be asked about whether it is also possible to expect consumers not to trust digital information blindly. One of the experts interviewed for this study pointed to a general need to inform the population about how to distinguish between good and bad apps, with a focus on potentially vulnerable groups.

Another interviewee proposed an alternative method of implementing a quality seal, namely by making it clear which authors are responsible for which parts of a product, and which sources they used as a basis for their work (by way of analogy to the approach followed by Wikipedia). Users would then be able to take an independent decision as to the trustworthiness of the information.

4.1.2 Class 1b – Data protection as a prerequisite for safe data collection?

There are two points of debate in relation to this class: It is firstly necessary to guarantee the safety of data input by users, and secondly to ensure that the software functions correctly.

Our expert interviews revealed clearly that there is a continuing expectation that all data entered by users must be safe. This also applies to information which may be regarded as trivial but could potentially be of interest for an insurance company or employer. The wide-ranging debates over data protection in relation to the electronic health card show the depth of public feeling on this matter. Nevertheless, the existing legislative rules can be regarded as essentially adequate.⁴⁵

An app provider who collects and uses data in Germany is subject to the provisions of German data protection legislation and the special provisions of the Telecommunications Act and the Telemedia Act.

According to the Federal Data Protection Act, health data are subject to particular protection (§ 3(9) of the Federal Data Protection Act). A data protection officer must therefore ensure that such data are processed safely (ibid, § 4) unless the data owner consents to use of his data (ibid). This in turn makes it necessary to ensure that the use of data, the consent procedure and the option of revoking consent are transparent for users. This falls under the heading of data and consumer protection and need not be regulated separately in legislation on health products.

⁴⁵ In the same vein, cf. Pramann (2016)

To state it somewhat more vividly: As a basic principle, patients are free to dispose of their own data.⁴⁶ It is therefore not hard to imagine that someone suffering from a serious illness would be prepared to allow data on their illness to be consolidated with data from other patients with a view to gaining potentially helpful insights. The benefits and risks must be weighed up against each other, as is the case everywhere in the healthcare sector. A patient's right to dispose of his own data also includes the freedom to give the data away by consenting to its use. However, he must be fully aware of what he is consenting to and how this consent can be revoked. Apps targeted at individuals rarely achieve this level of transparency, and instead ask users for blanket consents.⁴⁷

The scope of data protection for Class 2 apps could therefore be left to individual judgement and other areas of law. The legislator would merely need to impose clearer transparency requirements in respect of sensitive data such as health data, so that users are aware of the type of use for which consent is being granted and how this consent can be revoked.

This proposal however diverges from the general feeling among many players in the healthcare sector, and is therefore one of the topics which should certainly be re-examined in the course of further debate (cf. Chapters 6 and 8). At the same time, it is easy to imagine that a quality seal could be introduced for apps which meet high standards of data protection.

Two provisos are important:

- ◆ When Class 1b products are distributed by health insurance funds, stricter rules should apply because the consumers will place greater trust in the products. The health insurance funds must seek assurance from the manufacturers that they have complied with German data protection legislation. The nature of the relationship between the health insurance fund offering the app and the data generated must also be clarified: as a basic principle, the health insurance app should not have access to data from patient diaries (for example), because it could be used e.g. for predictive modelling, and the data should be subject to the same stringent protection as is currently the case for social data. In this respect too, however, the use and possibly even linking of data may generate added value in terms of patient health, since patients will benefit from better risk predictions or recommendations of suitable healthcare offerings. Consent-based exceptions should again be possible, provided that users have access

⁴⁶ Cf. Patient Rights Act (Comprehensive right of surrender, § 630g of the Civil Code)

⁴⁷ It is illuminating to compare the public debate on the amended data protection policy for the messaging service WhatsApp, e.g. <http://www.handelsblatt.com/technik/it-internet/datenkrake-facebook-so-laesst-sich-der-daten-austausch-bei-whatsapp-stoppen/14459876.html>

to sufficiently transparent information (i.e. which is not hidden in the small print).

- ◆ Stricter rules, and in principle the rules of medical confidentiality, should apply to products in Class 3 which process large amounts of medical data. Since it is in any case impossible to bring these products to market without authorisation (see below), this point could be checked during the authorisation procedure,

and application and oversight of the existing legislation is therefore sufficient. There is less protection for consumers who use products manufactured abroad, but in this case too the necessary media competence should improve over time and allow users to assess product risks accurately. This is however easier said than done; the Federal Office for Information Security [Bundesamt für Sicherheit, BSI] points out that there are still no system-wide standards for examining the security characteristics of “mobile health management” apps, for example.⁴⁸

In addition to meeting data protection requirements, Class 1b apps should also be reliable in technical terms; devices must correctly represent the values which have been input. This is particularly important when data is presented in graphical form, since the conclusions drawn by the user may influence the way he thinks about an illness. As well as processing data correctly, procedures such as smoothing, interpolation, contrast enhancement etc. must be properly applied in order to prevent misinterpretations. The proper functioning of the software must be guaranteed. Nevertheless, formal authorisations appear superfluous since products in this class by definition do not issue data-based recommendations, and in most cases merely provide a simple representation of previously input values with no or little potential for harm. Similarly to the voluntary quality seal proposed for Class 1a, a conceivable option would be voluntary participation by manufacturers in the many safety certifications schemes offered on the market. Defective products will be unable to gain a foothold in the market.

We do not therefore believe that there is any need for further regulation. The collation of personalised information and external information (e.g. disease symptoms and environmental factors) may suggest particular courses of action to a user; given that the relevant information could also be collected independently by the user, however, this does not differ in any way from the situation today. General warnings (e.g. regarding pollen count) are issued by media outlets today without any form of regulation.

We do not therefore believe that authorisations are required within the health sector for products in this class.

⁴⁸ BSI 2015, p. 19

4.1.3 Class 2 and 3 – evaluations of risk/benefit ratios

Class 2 and 3 products intervene extensively in current decision-making processes and the doctor/patient relationship. They should be tested in different phases, by way of analogy to the studies performed for the purpose of authorising pharmaceuticals.

Two examples can be cited in order to explain the risks: A digital app provides a diagnosis, e.g. that a mole may be a melanoma or that the patient's pulse, measured with a smartphone camera, shows signs of atrial fibrillation. The greatest risk is clearly posed by false-negative diagnoses, i.e. the failure to detect a disease which is actually present. At the same time, however, it is equally undesirable for apps to be excessively cautious and produce large numbers of false-positive diagnoses, worrying patients and wasting healthcare system resources (both time and money) due to unnecessary follow-ups. The app must therefore detect actual risks with a sufficient level of success (high sensitivity) and also clearly detect the absence of risk (specificity)

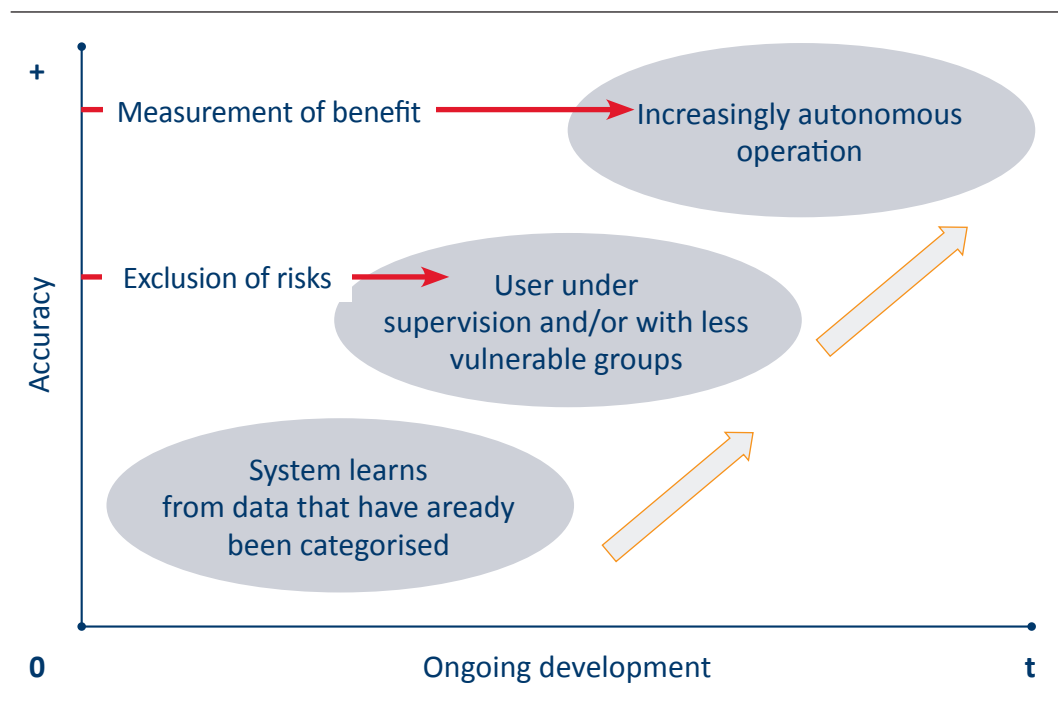
If this principle is applied to other areas of the healthcare cycle, this means that:

- ◆ In the majority of cases, treatment recommendations must correspond to the treatment recommendations that would be issued by a panel of experts.
- ◆ Treatments (e.g. psychotherapy, speed therapy) must deliver at least the same outcomes as a human therapist.
- ◆ The error rate of dosing recommendations issued by apps must not be higher than those issued by humans.⁴⁹
- ◆ During the monitoring phase, e.g. when monitoring the progress of a disease or an implant, warning signals must not be overlooked more frequently than is currently the case.

Accuracy in terms of sensitivity and specificity is therefore almost always the prime concern. Both values depend to a large extent on the maturity of the software.

⁴⁹ Cf. in CHARISMHA the sections on diagnosis, 3.2 App-based diagnostics and treatment (Albrecht and Jungmann 2016)

Figure 7: Authorisation of digital product



Source: IGES

During the first phase, the algorithm is trained using existing data and various mathematical models and attributes are tested. This phase can be compared to a pre-clinical study.⁵⁰ Unlike pharmaceuticals, which are fully developed products by the time they reach the clinical study phase, algorithms learn by being applied to real data and continue to develop. Digital apps in the first market phase may therefore undergo further changes. This means that it is important to process sufficient quantities of data during this phase, or in other words to test the app on as many people as possible. The test subjects should not include vulnerable persons, and the recommendations made by the software must always be compared against recommendations made by care providers.

There are then two potential courses of action:

- a) An app is only authorised once it has achieved an adequately high level of sensitivity and specificity.
- b) An app is granted a gradual and conditional authorisation which means that it can be tested and improved in pilot tests and on small groups. This process is in principle very similar to the development cycle for pharmaceuticals, in which the study population expands continuously from Phase I

⁵⁰ As in the Preventicus app, cf. Preventicus GmbH 2016

to Phase III and the effectiveness of the drug is still monitored after market launch.

Solution a) basically corresponds to the requirements which apply to pharmaceuticals. Authorisation can only be granted once all tests have been completed (even if use of the product is still monitored after this date). In the digital world, however, solution b) will be essential for certain classes of product, since it can be tailored to their short innovation cycles. It also addresses a specific feature of certain digital products, namely that they only “learn” during live operation. The vaunted potential of data analysis techniques can only be realised once data have been collected from many different subjects, since only then can patterns be detected and potential improvements made to the feedback provided to users. There is as yet no conclusive evidence that this works in practice, but the opportunity should remain. The overriding aim of conditional authorisation is therefore always to exclude risks. The more successfully this can be achieved, the more broadly the product can be used and the more human oversight can be reduced. It is however still necessary to ensure that care providers and patients are aware at all times of the stage which has been reached by a relevant product. This makes it possible to exclude risks from the outset and provide evidence of benefit at a later date (cf. Section 4.1.3). Many of the experts we interviewed were in favour of this conditional authorisation approach.

When carrying out studies of this kind in a real-life setting, digital healthcare products will in many cases need to be compared to intervention by a doctor. This may mean that an app aimed at detecting melanomas (for example) does not achieve the same quality outcomes as a dermatologist, but achieves better levels of sensitivity and specificity than a junior GP with very little practical experience.

A product may therefore fall into different risk classes over the course of its development. After simply recording body measurements to start with (Class 1b), it may later provide guidance (Class 2) and then definitive recommendations (Class 3) during subsequent stages of development. A new/supplementary authorisation procedure must be carried out when a product moves into a new class thanks to the addition of enhanced features.

It is much easier to assess risks if existing methods have simply been applied to a new medium. Tinnitus has been treated using modified music since 2005, for example, and the latest smartphone apps are a straight replacement of the CDs which were formerly used. In cases such as these, previous experience can be used as a basis and evidence provided on the basis of analogies.

The performance of many other digital products must however unavoidably be proven through studies. Comparisons with the standard level of care would be necessary for many of the examples described here, which means that - according to tried-and-tested methods of medicine and health economics - “proof of concept” must be obtained as a minimum before an app can be made available for use. The

outcomes for the digital product would then be compared against the outcomes for a group of medical experts.

There are two possible scenarios:

- ◆ an existing care service is supported or replaced by a digital service,
- ◆ an entirely new service is made possible by digital products, e.g. continuous sensor readings or home-based measurements.

The comparison described above is possible in both cases, since the existing standard will simply be lower in the second case. A digital product would merely need to demonstrate that it does not entail higher risks than a de facto lack of monitoring. For example, it must not lull patients into a false sense of security by encouraging them to neglect self-observation habits.

Once again, an analogy can be made with other areas of the healthcare sector: risk/benefit assessments are based on the standard which currently exists. The fewer treatment methods are available for an illness, the greater the risks a patient will be willing to take; conversely, the better the current treatment available, the higher the standard for new methods. It follows that a comparison with current methods is relevant when assessing a new method, as provided for above in the case of Class 2 and 3 digital products.

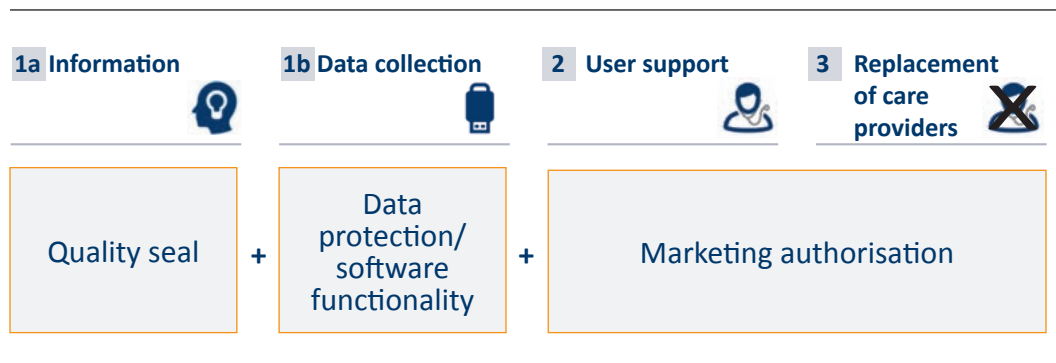
The type of studies required still remains to be defined, and care must be taken to avoid using “gold-standard” medical studies for products aimed at patients suffering from comparatively harmless illnesses, since this could disproportionately raise the barriers to market entry. It would be preferable for the requirements to grow in step with the associated potential health risks, ranging from mere proof of analogy on the basis of a “proof of concept” and monitoring of use, through non-inferiority studies and right up to genuine comparative studies. As in the case of medical devices, blinding will not always be possible, but diagnoses or treatments which may cause serious damage to health must comply with stricter standards of proof.

In view of the dynamic working practices popular in the industry and described in Chapter 3.4, care should also be taken to limit market authorisation procedures to a reasonable timeframe. The experts interviewed for the purpose of this study concurred with this view.

Once again, the standards which must be met in terms of accuracy are likely to be higher if the product is subsidised by a health insurance fund, and funds should only use products in strictly monitored model environments during their initial experimental stage.

Figure 8 shows a summary of the regulatory approaches described in Section 4.1.

Figure 8: Regulatory approaches according to risk class

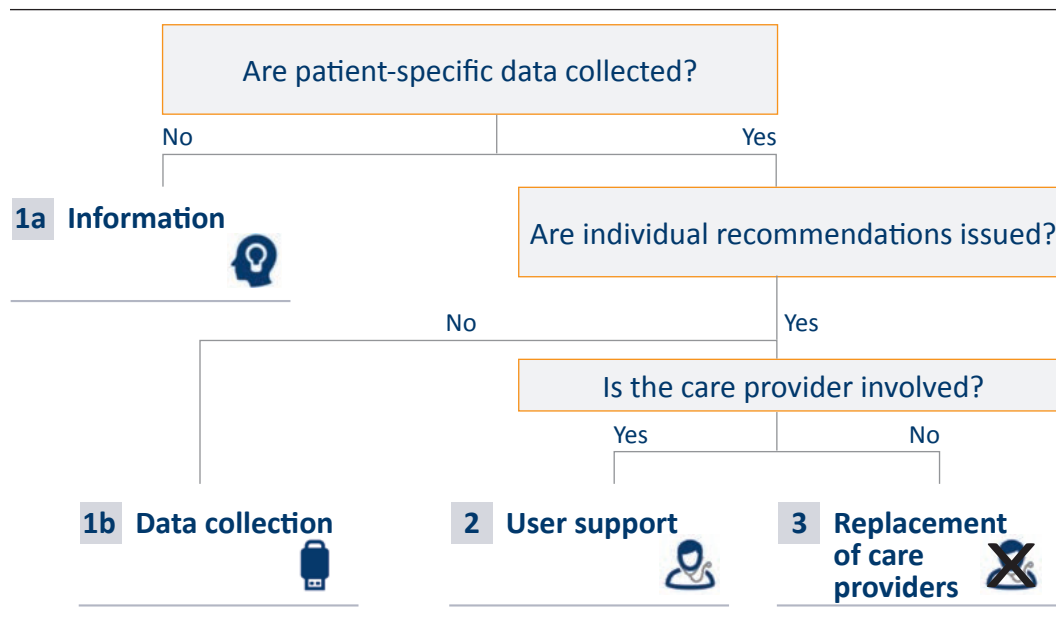


Source: IGES

4.2 Assignment of specific products to risk classes

As shown above, the name and purpose of a product cannot be used as a sole criterion for assigning products to different classes, and decision trees similar to those employed by the FDA or MHRA must therefore be used (cf. Appendix A4). A basic outline of a decision tree which could be used for this purpose is shown below.

Figure 9: Decision tree for the assignment of individual products to risk classes



Source: IGES

For practical purposes, more accurate boundaries should be drawn between the types of data processing permitted for Class 1b products (e.g. simple aggregation of data and representation of patterns). Class 3 products could be further subdivided based on the extent of the associated health risk with a view to requiring more extensive evidence. Insulin misdosing or false negative skin cancer detection entail higher risks than errors in software-supported speech therapy. Applications which could theoretically be assigned to several categories should be included in the highest risk class in order to ensure maximum user safety.

The examples we provided above show that apps which may on the surface appear very similar may in reality belong in very different risk classes. The risk classification of apps should also be checked each time an update is released. The specific rules that should be followed when taking decisions must therefore be further differentiated,⁵¹ starting with the introduction of a systematic approach.

4.3 Ban on non-authorised digital products

The rules set out above must be supplemented with one important point: Class 2 or 3 products for which the necessary evidence has not been supplied must not be allowed access to the German market. The same should apply if a Class 1a/b product gains new functionalities as a result of enhancements (updates) which move it into Class 2.

The legal feasibility of this approach will be left to one side for the time being. There are too many products, in particular in the app stores, for them to be checked comprehensively by an official body; however, it can be assumed that the operators of the app stores and other software will have a vested interest in preventing the distribution of potentially harmful products, and that they will comply with any guidance issued by the legislator in this respect.

The ban could therefore be implemented on the basis of a self-reporting system for manufacturers or assessment systems put in place by the app stores, with oversight measures by state authorities carried out on a random cross-section of products (as is the case in many other areas of life).

⁵¹ Cf. the example already cited above: behavioural recommendations, e.g. nutritional advice, may well be hazardous for seriously ill patients. Exceptions could possibly be made by requiring products targeted at specific patient groups to undergo a Class 2 or 3 quality assurance procedure.

4.4 Background: Marketing authorisation systems for pharmaceuticals and medical devices

After briefly outlining the authorisation system for digital products, in the following sections we describe the procedures which currently apply to medical devices and pharmaceuticals, before examining the extent to which these procedures can be applied to digital health products.

4.4.1 Europe and Germany

4.4.1.1 Pharmaceuticals

Before being granted marketing authorisation for a pharmaceutical, manufacturers must prove that the product is effective, safe and of an appropriate pharmaceutical quality. Products undergo an overall assessment which must show that the benefit of the pharmaceutical drug in question outweighs the associated risks. Manufacturers must prove that the products are of an appropriate pharmaceutical quality e.g. by providing evidence of compliance with particular manufacturing standards. A preparation's effectiveness and safety are evaluated inter alia on the basis of clinical studies and pharmacological/toxicological analyses. An overall evaluation covering all the individual aspects of an authorisation procedure is carried out in order to identify whether the product offers an appropriate risk/benefit ratio.⁵² Marketing authorisations are always issued for limited periods and must be renewed after five years, although it is not always necessary to repeat the entire procedure.

As a basic principle, pharmaceuticals can be authorised in Europe via four possible routes:

- ◆ national procedure
- ◆ mutual recognition procedure
- ◆ decentralised procedure
- ◆ centralised procedure at EU level

The outcome of a national procedure is a marketing authorisation which applies solely to the country in which the application was submitted. National authorisations can be extended to cover other countries in mutual recognition procedures. Non-authorised pharmaceuticals can be authorised in several European countries at once on the basis of a decentralised procedure, whereas the centralised procedure

⁵² Cf. BfArM 2013

results in a pharmaceutical being authorised for use throughout the European Union. The centralised procedure is prescribed by law for individual groups of pharmaceuticals, e.g. oncology or orphan drugs.⁵³

4.4.1.2 Medical devices

In legislative terms, medical devices are subject to the Medical Devices Act [Medizinproduktegesetz, MPG] in Germany. This Act makes explicit reference to software used for diagnostic and treatment purposes and to ensure the smooth functioning of a medical device (cf. § 3 of the Medical Devices Act). The Medical Devices Act and associated regulations transpose the European directives on medical devices (93/42/EEC), in-vitro diagnostic medical devices (98/79/EC) and active implants (90/385/EEC) into national legislation.

A prerequisite for placing medical devices on the market of a country in the European Economic Area or non-EU country on the basis of mutual recognition agreements is the presence of a CE (Communauté Européenne) label. The CE label shows that the medical device meets predefined requirements in terms of safety, suitability and performance,⁵⁴ as proven in the course of a structured procedure. The exact details of the procedure and the evidence that must be supplied in order to prove that the predefined requirements have been met differ according to the relevant product classes. A total of four product classes are provided for under Article 9 of the Medical Devices Directive (93/42/EEC). Assignment to a particular product class indicates the increasing level of potential risk associated with use:⁵⁵

- ◆ Class I (low risk, e.g. walking aids)
- ◆ Class IIa (medium risk, e.g. disposable syringes)
- ◆ Class IIb (increased risk, e.g. X-ray machines)
- ◆ Class III or active implants (high risk, e.g. heart valves, hip implants)

Compliance with the European directive must be confirmed before a CE label can be affixed to a product, and the manufacturers of medical devices can apply to state-

⁵³ Cf. BfArM 2013

⁵⁴ The study by the University of Freiburg points out the limitations of this label: “Contrary to the assumptions of many consumers, the CE label means precisely nothing in terms of the quality of an app, let alone its benefit. Consumers have been lulled into a false sense of security, and certain app manufacturers are happy to continue misleading them by promoting the CE label as a particular mark of quality.” (Lucht et al. 2015, p. 10)

⁵⁵ Cf. BVMed 2016

monitored “notified bodies” which perform compliance assessment procedures for this purpose.⁵⁶

The assessment procedure focuses on technical safety, clinical performance and the defensibility of the risk/benefit ratio for the relevant product. As well as examining technical characteristics, it is therefore also necessary to carry out a clinical evaluation, either on the basis of existing clinical data (literature) or clinical trials (studies). Clinical trials are required for Class III products or active implants if there are insufficient grounds for using existing clinical data. Clinical trials are also essential if particular criteria are met, for example if a product is entirely novel or if the indications of an existing product are expanded.⁵⁷

The compliance assessment procedure typically takes the following format:⁵⁸

1. Application submitted by manufacturer to a notified body
2. Technical and clinical documentation forwarded to the notified body
3. Specialists employed by the notified body evaluate technical documentation; clinical documentation evaluated by independent medical experts at the notified body
4. Queries clarified, documents amended if necessary or additional tests performed
5. Technical and clinical compliance assessment completed
6. Compliance certificate issued for a maximum of five years
7. Compliance declaration issued by manufacturer
8. CE label affixed to product

According to information from a manufacturer and member of the Bundesverband Medizintechnologie [BVMed, Federal Medical Technology Association], who cited the example of an active (cardiac) implant, technical assessment by the notified body takes two or three months, whereas clinical assessment takes between four and six months. This does not include the preceding development phase or the phase during which pre-clinical and clinical trials are carried out. In this case

⁵⁶ Cf. BVMed 2016

⁵⁷ Cf. BVMed 2016

⁵⁸ Cf. BVMed 2016

therefore, the overall process from developing the product through to completion of the compliance procedure was estimated to last five or six years. The quality tests alone, without clinical trials, required an estimated 40,000 man-hours.⁵⁹

Due to the lack of any provisions in the EU Medical Devices Directive (93/42/EEC), the only assistance currently available when assigning software to medical device classes is an MEDDEV document, which takes the form of guidelines drawn up by working groups and available on the EU Commission websites. The current version of these guidelines does not assign software to any product class higher than Class IIb.⁶⁰ It can therefore be concluded that clinical studies have not to date been regarded as mandatory prerequisites for the marketing authorisation of software (only for Class III products or if particular criteria are met).

A review of the European directives, and therefore the rules on the marketing authorisation of medical devices, has been ongoing for some time. A first draft of the new regulation was published back in 2012, but an agreement between the European Parliament and the European Council was not reached until May 2016.⁶¹ The draft was approved in June by the Member States and the European Parliament's Committee on Environment, Public Health and Food Safety. The next steps will include further adoptions, readings in the European Council and publication of the new regulation. Following its publication, the regulation on medical devices will enter into force with a three-year transitional period.⁶²

The new draft regulation published on 15 June 2016 contains a number of changes which directly affect digital health products.

As was previously the case, software which controls a product or influences its use is automatically assigned to the same class as the product itself. The situation has however now changed in relation to software which is used independently of other products. For the purpose of the draft regulation, software of this kind (previously: "standalone software") is now regarded as an active medical device whose classification is defined as follows:⁶³

⁵⁹ Cf. BVMed Presse 2013

⁶⁰ Cf. European Commission MDDEV (2016)

⁶¹ Cf. EU press release 2016

⁶² Cf. EU press release 2016a

⁶³ Cf. European Commission 2016

- ◆ If software is designed to provide information or to assist with diagnostic or treatment decisions, it is categorised as a Class IIa medical device.
- ◆ However, if decisions taken with the help of the software may directly or indirectly lead to...
 - death or permanent deterioration of the user's state of health, they are regarded as **Class III** products.
 - serious deterioration of the user's state of health or a surgical intervention, they are regarded as **Class IIb** products.
- ◆ Software for the monitoring of physiological processes is assigned to Class IIa.
- ◆ Software for the monitoring of vital processes, where the nature of variations is such that it could result in immediate danger to the patient, is assigned to Class IIb.
- ◆ All other software is assigned to Class I.

This means that for the first time, software used independently of other products is officially assigned to Class III in certain cases.

Taken as a whole, the new regulation can be interpreted as tightening up the rules governing the marketing authorisation of medical products, e.g. by means of generally stricter rules on clinical assessment. For particular products (implantable Class III products and active products in Class IIb for the administration of medicines to the body), an additional test procedure - introduced in addition to the compliance assessment procedure - will be carried out by an expert committee at EU level. Additional measures are aimed at increasing transparency in the medical device market, for example by assigning a unique product number to every medical product ("UDI - Unique Device Identification") in order to ensure that it can be identified and traced.⁶⁴

⁶⁴ Cf. BVMed Presse 2016

4.4.1.3 Digital healthcare products under the Medical Devices Act

The issue of when a digital product displays the characteristics of a medical device is central in this respect. According to § 1 of the Medical Devices Act, a medical device must be intended for one of the following purposes:⁶⁵

- ◆ Detection, prevention, monitoring, treatment or alleviation of a disease
- ◆ Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap
- ◆ Investigation, replacement or alteration of anatomical structure or a physiological process
- ◆ Birth control

The Federal Institute for Drugs and Medical Devices [BfArM, Bundesinstitut für Arzneimittel und Medizinprodukte] provides additional guidelines on its websites, which also refer to smartphone apps. According to these guidelines, “reference functions” for the classification of software as a medical product include:⁶⁶

- ◆ Supporting decisions or making decision, e.g. regarding treatment
- ◆ Calculating e.g. drug doses (in contrast to the simple reproduction of a table from which users can calculate doses themselves)
- ◆ Patient monitoring and data collection, e.g. by recording medical readings, insofar as the results influence diagnosis or treatment

Other possible “reference terms” referred to by the Federal Institute for Drugs and Medical Devices for the purpose of determining stated purpose include:⁶⁷ *“alarm, analyse, calculate, detect, diagnose, interpret, convert, measure, control, monitor, reinforce.”*

The terminology of the Medical Devices Act and the guidelines published by the Federal Institute for Drugs and Medical Devices (only) provide a clear indication of when a digital healthcare product should be regarded as a medical device in the legislative sense. As a basic principle, the responsibility for defining and classifying

⁶⁵ Cf. § 1 of the Medical Devices Act

⁶⁶ Cf. Federal Institute for Drugs and Medical Devices [BfArM, Bundesinstitut für Arzneimittel und Medizinprodukte] 2016

⁶⁷ Cf. Federal Institute for Drugs and Medical Devices [BfArM, Bundesinstitut für Arzneimittel und Medizinprodukte] 2016

on the basis of stated purpose lies with the manufacturer who is responsible for first placing a medical device on the market.⁶⁸

As a compliance procedure, the current authorisation process for medical devices is based on the EU Directive, which entered into force some time ago and does not make explicit reference to standalone software in the sense of a digital healthcare product. Apps and other applications are nevertheless approved as medical devices and placed on the market today. The EU rules cannot therefore be assumed to pose a significant barrier at present to market access for products of this kind.

4.5 International approaches to digital products

The supervisory authorities in other key reference markets, including the USA and the UK, have also tackled questions relating to the systematisation and regulation of digital health products.

4.5.1 FDA guidelines

Back in September 2013, the US Food and Drug Administration summarised its views on digital health products in guidelines which provide an insight into the system followed by the authority, and which include accepted definitions and an indication of the regulatory approach it plans to take to digital products. An update of this document (“Mobile Medical Applications: Guidance for Food and Drug Administration Staff”) was published in February 2015.⁶⁹ In connection with its publication, the FDA estimated that in the near future (2018) over 1.7 billion smartphone or tablet users worldwide will have downloaded mobile health apps onto their devices, a figure which serves as a measure of the importance attached by the FDA to this sub-market.

As a basic principle, the FDA’s approach to digital health products, which focuses on “mobile medical apps”, is based on its approach to medical devices. The FDA claims to apply the same standards of effectiveness and safety and to group products into the risk classes used for medical devices.

⁶⁸ Cf. Federal Institute for Drugs and Medical Devices [BfArM, Bundesinstitut für Arzneimittel und Medizinprodukte] 2016

⁶⁹ Cf. FDA (2015)

In the three annexes appended to the document, the FDA subdivides the market as follows:

- ◆ Products which are not medical devices
- ◆ Products which are potentially medical devices and in respect of which the FDA intends to exercise enforcement discretion
- ◆ Products which are a focus of the FDA's regulatory oversight

Each of these product classes is defined predominantly by large numbers of examples rather than on the basis of abstract criteria. The examples are extremely concrete and also extremely heterogeneous, which leads to the conjecture that the FDA has merely grouped the products which are already on the market.

A reference is made to the general approach taken to classifying product risk ("... FDA intends to exercise enforcement ... because they pose lower risk to the public"), but there is no transparent list of adequate and mandatory criteria for assigning individual products to groups. The document as a whole has a preliminary and open-ended feel. The frequent use of the word "may" in the document suggests that the FDA is still in the process of systematising this dynamic sub-market, and is not currently able or willing to provide binding - let alone definitive - opinions on the classifying function of product characteristics and the corresponding authorisation regulations.

It is difficult to identify a generally applicable system by abstracting from the product characteristics shown by the examples. Using terminology borrowed from the field of medical devices, the FDA refers repeatedly to purpose as a criterion for assigning products to groups ("... are intended for general patient education ...", "... are not intended for use in the diagnosis ..."), without however deeming it adequate as a classification criterion.

Overall, the guidelines appear to be:

1. pragmatic, since they are based on concrete products already present on the market
2. open-ended and adaptive, since manufacturers are encouraged to engage in ongoing dialogue with the authority (inter alia as a precautionary measure)
3. closely aligned with the market for medical devices

There is no evidence of any complex systematic approach as presented in the works cited above in Chapter 2. There is no explicit reference to the issue of whether the regulations which already apply to the market for medical devices are

suitable for incorporating in full the regulatory requirements arising as a result of the emergence of mobile health apps.

4.5.2 Medicines & Healthcare Products Regulatory Agency

In August 2016, the UK MRHA published guidelines on its regulatory approach to apps, which state that the current regulations on medical devices are regarded as the key point of reference for health apps as well.⁷⁰ The detailed instructions given for the application of these existing regulations to apps are evidence of the fact that the authority is in favour of attempting to transfer existing solutions, and no separate solutions are offered for digital health products.

4.6 Transferability of existing regulations and the applicability of the Medical Devices Act to digital products

When determining which regulations are most suitable for exercising oversight over the authorisation of digital care products, an obvious first step is to attempt classifying these products under the Medical Devices Act. The existing provisions on medical devices are a self-evident point of reference, not least because of the technical dimension of digital health products. § 3.1 of the Medical Devices Act refers twice to software when defining medical devices, firstly as a standalone component and secondly as a direct component (“...the software used to ensure smooth functioning of the medical device...”). Depending on its particular purpose, software can therefore be understood as a medical device insofar as it functions as a tool or instrument. In simplified terms, a product should be classified as a medical device if it is intended to be used for the purpose of diagnosis or treatment (and the product is not a pharmaceutical). Yet although it appears straightforward to group digital healthcare products within the regulatory scope of the Medical Devices Act, significant problems can be expected to arise during implementation as a result of various factors.

Purpose

The purpose of the device is the linchpin for definitions of medical devices and also the basis for all cross-applicability instructions made available to manufacturers by the supervisory authorities. A glance at these instructions makes it immediately obvious that this cross-applicability process is still extremely complex and immature at present. There are almost no systematic criteria which allow products to be identified as medical devices, let alone an overall systematisation or categorisation

⁷⁰ Cf. Medicines & Healthcare Products Regulatory Agency 2014

of the market. Examples and preliminary groupings are used instead of abstract and workable terms. The Federal Institute for Drugs and Medical Devices [Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM] refers to “key functions” which indicate that a product should be classified as a medical device. Yet it fails to explain what specific classification decisions should be made if such a key function is found to be present. Once a digital healthcare product has been recognised (or defined) as a medical device, similar problems arise when it comes to defining the product’s risk class.

The fact that the manufacturer is initially responsible for recognising and explaining the purpose is a further complicating factor. In a market as dynamic and immature as that for digital health products, it can be assumed that there is also a certain degree of immaturity in terms of the competency to identify medical purpose reliably and correctly. It must further be assumed that an increasing number of players will be relatively new to the health market arena, in comparison to the well-established medical technology industry. Regulations which rely to a large extent on manufacturers’ power of judgement at this early stage of market development may encounter a great many problems, irrespective of the review and correction mechanisms which are implemented. What is more, it is impossible for the potential of many products entering the market to be assessed conclusively since we lack experience of the contexts or use scenarios in which these digital healthcare products may be used, or the ways in which they may be used in combination with other products. Compared to “traditional” medical devices, there are also relatively few reference products which could be used by manufacturers as a basis for classification.

The authorities have not yet completed the process of developing criteria and decision-making algorithms, and it is a challenging task to keep up with the manufacturers’ rapid pace of change and short development cycles.

It is therefore impossible to rule out the risk that products will unlawfully be excluded from the scope of the Medical Devices Act and thus from the safety mechanisms of the relevant regulations. Even today, certain digital products appear to reach the market with an easy-to-obtain CE label when a more thorough review of safety aspects would have been more appropriate.

Placement on the market

Once a digital healthcare product has been correctly classified as a medical device, the next challenge is to assign it properly to the existing risk classes, as a necessary basis for the authorisation procedure, and in particular with a view to determining the scope of effectiveness and safety evidence to be provided.

It is currently still unclear how certain aspects which are relevant during the assessment procedure (technical safety, clinical performance and the defensibility

of the risk/benefit profile of the relevant product) should be applied e.g. to algorithms.

Another unanswered question relates to the study protocols which could be used to provide the required evidence of effectiveness and safety in the event that a product is assigned to a higher risk class. Evidence of this kind must be provided on a systematic basis in the case of entirely novel products. Yet what does “novel” mean in relation to software - the programming language, new program features, or the possibility of mobile use?

The authorisation process is furthermore aimed at the inpatient sector (“subject to prohibition”) rather than at the outpatient sector, on which it initially has no effect (“subject to permission”). From what we can see at present, however, digital healthcare products are used primarily in the outpatient sector.

Transferable provisions from the Pharmaceuticals Act

Given the uncertainties which still exist in relation to the handling of digital healthcare products, a risk-minimising approach would be to allow gradual access to the market or, as a variation of this option, a gradual broadening of market opportunities. Certain provisions of the Pharmaceuticals Act which are relevant in this respect could potentially also be reused for digital healthcare products, although the Pharmaceuticals Act by definition relates to substances or the preparation of substances and therefore not to digital products. The phased authorisation procedure aimed at maximising patient safety could in particular be used as a model when adopting authorisation regulations for digital healthcare products. In most cases the group of users is gradually expanded when carrying out clinical trials, with product effectiveness and safety examined objectively each time. This ensures that damage is limited in the event that the product has no effect or an undesirable effect. Even though the clinical phases provided for under the Pharmaceuticals Act are designed to fall in the period immediately before and after authorisation, the principle could also be applied by gradually expanding the use of products which are already on the market.

Post-marketing surveillance or pharmacovigilance measures which ensure that products are monitored after successful authorisation are present in both pieces of legislation and could also be applied to digital healthcare products. It should not be forgotten, however, that product replacement cycles in the digital world are significantly shorter than for traditional medical devices or pharmaceuticals.

Nature of products

The digital products which form the subject of our study are designed to process data, and their risks arise as a result of the way in which they handle this data,

for example as a basis for issuing recommendations. By way of contrast, the risk associated with a “traditional” medical device stems from its physical interaction with the human body.

The medical devices which are currently on the market have been developed for use by a doctor, whereas a significant proportion of digital products are designed for use by medical laypersons.

Finally, all areas of the digital market are developing so rapidly that it is hard to predict the extent to which future products will differ from current market offerings.

To sum up, the existing regulations on medical devices provide a starting point for the authorisation of digital healthcare products, but do not adequately cover this dynamic and in many respects immature market. An overly extensive definition of reference functions (see above, Section 4.4.1.3) also means that there is a risk that the regulations will have too broad a scope. As things stand at present, the adoption of separate regulations for digital healthcare products would be a disproportionate response, and it would also significantly delay the establishment of a process which meets the needs of the healthcare system. The incorporation of differentiated provisions into the Medical Devices Act therefore appears to be the most appropriate solution. “Digital medical devices” should be created as a separate category with its own risk classification (e.g. on the basis of the grouping proposed here) and specific assessment procedures. The authorisation rules for pharmaceuticals could at the same time be used as a basis for developing a phased model for the authorisation of digital healthcare products. A decision-making algorithm should be developed for the classification of products on the boundary between traditional and digital medical products, e.g. combinations of device and software. The procedure to be chosen should be determined by the component of the product which entails the greatest risk.

It is not necessary to provide any definitive clarification of the issue of jurisdiction at this point. On the basis of our preliminary investigations, there appear to be valid grounds for assigning jurisdiction to an existing organisation such as the Federal Institute for Drugs and Medical Devices [Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM]. Specially trained staff will however need to be employed due to the fundamental differences between software and traditional medical devices.

5. Reimbursement of digital healthcare products by the statutory health funds

Summary

Building on the previous chapter's examination of marketing authorisations, this section looks at the reimbursement of digital healthcare products. After outlining the rules which currently apply to pharmaceuticals and medical devices, we explain which of the options described could already be applied to the reimbursement of digital healthcare products. In the concluding section we discuss what reimbursement arrangements might sensibly look like, and how the transition from selective-contract to collective-contract reimbursement mechanisms might be managed. The key takeaways for this section are as follows:

- ◆ Reimbursement will generally be possible on a selective basis by means of contracts with individual funds.
- ◆ Products which subsequently prove their worth may be moved over to a collective contract. The options for direct access to the standard care system on the basis of a fast-track procedure will also be examined.

5.1 Background: Current regulations

5.1.1 Pharmaceuticals

Since the entry into force of the Act on the Restructuring of the Pharmaceuticals Market [Gesetz zur Neuordnung des Arzneimittelmarktes, AMNOG], all active substances or combinations of active substances placed on the market have been subject to an assessment of benefit, which subsequently forms a basis for price negotiations between the manufacturer and the National Association of Statutory Health Insurance Funds. The manufacturer is allowed to set the product's price during its first year on the market, but its price thereafter depends on the outcome of the benefit assessment, which is carried out by the Federal Joint Committee on the basis of a report by the Institute for Quality and Cost-Effectiveness in the Healthcare Section. The Federal Joint Committee is however not obliged to follow the recommendations issued by this latter.

If no additional benefit can be demonstrated for the treatment, the preparation is assigned to a reference price group, within which reimbursements are only made up to a defined price, based inter alia on the price of other drugs within the group.

If an additional benefit can be proven, price negotiations take place between the manufacturer and the National Association of Statutory Health Insurance Funds,⁷¹ on the basis of three factors:

- ◆ Price of comparable treatment
- ◆ Prices for the preparation in other European countries
- ◆ Price level of comparable pharmaceuticals in the German market

The vfa [Verband Forschender Arzneimittelhersteller, Association of Research-Based Pharmaceutical Companies] has estimated the cost of producing a benefit assessment dossier at between EUR 450,000 and EUR 800,000.⁷²

5.1.2 Medical devices

5.1.2.1 Outpatient sector

CE labelling is a necessary prerequisite for the reimbursement of a novel medical device by the statutory health insurance funds, but does not go far enough on its own. Only medical devices which form part of a recognised investigatory or treatment method are directly eligible for reimbursement as a matter of principle,⁷³ due to the fact that use of a new investigatory or treatment method is legally subject to permission.⁷⁴ This means that the Federal Joint Committee is responsible for deciding whether a new investigatory or treatment method is eligible for reimbursement. In order to do so, the Federal Joint Committee must assess the cost-effectiveness, necessity and medical benefit of the method, which depend to a large extent on use of the medical device. Individual medical devices are not generally assessed by the Federal Joint Committee, with the exception of medical devices which can be prescribed (drug-like devices) which are subject to different regulations and in respect of which manufacturers can submit applications for inclusion in Appendix V to the Pharmaceuticals Guidelines.⁷⁵

The Federal Joint Committee can be requested to carry out evaluations of methods on the basis of the available evidence under § 135 of Volume V of the Social Code

⁷¹ Cf. National Association of Statutory Health Insurance Funds [GKV-Spitzenverband, GKV-SV] 2016a

⁷² Cf. vfa 2014

⁷³ Cf. BVMed 2014

⁷⁴ Cf. § 135 of Volume V of the Social Code

⁷⁵ Cf. § 31(1) in conjunction with § 34(6) of Volume V of the Social Code

by organisations entitled to do so (in particular the statutory health insurance funds and the National Association of Statutory Health Insurance Physicians [Kassenärztliche Bundesvereinigung, KBV]). The Federal Joint Committee can commission a comprehensive “Health Technology Assessment” report (HTA report) from the Institute for Quality and Cost-Effectiveness in the Healthcare Sector, which forms a basis for the Committee’s decision but has no binding force.

Since 2012, it has been possible to initiate a “trial study” if no evidence is available as a basis for an HTA report or a decision by the Federal Joint Committee.⁷⁶ Studies of this kind may be initiated by the Committee itself in the course of ongoing evaluations or decisions, or alternatively by the manufacturers of medical devices used as a key component of a new investigatory or treatment method or by other providers of methods using the relevant medical device. In both cases the relevant method must be positively found to demonstrate potential as a required alternative treatment (e.g. can be expected to replace a more invasive method) in order to allow testing as a matter of principle.

The success of the trial study procedure is however questionable, since the Federal Joint Committee had adopted only 11 decisions on 6 applications by mid-2016, and not a single trial study has been launched to date; observers believe that this is primarily due to the hefty costs involved.⁷⁷

A positive vote by the Federal Joint Committee means that the method will be included in the catalogue of services provided by the statutory health insurance funds. The Joint Evaluation Committee does not ultimately decide on the level of compensation for medical services in respect of the execution (or provision) of new investigatory or treatment methods, or the level of reimbursement for medical devices, the latter being furthermore (and primarily) consumables. The costs of reusable medical devices purchased as capital goods can in practice only be written off indirectly in the outpatient sector on the basis of treatment invoices.

5.1.2.2 Inpatient sector

By way of contrast to the outpatient sector, the use of new methods in the inpatient sector is “subject to prohibition”.⁷⁸ Provided the basic requirements in terms of quality and cost-effectiveness are met,⁷⁹ each hospital is entitled to use new methods and the associated medical devices for treatment purposes. The prohibitory approach means that it is possible for the Federal Joint Committee

⁷⁶ Cf. § 137e of Volume V of the Social Code

⁷⁷ Cf. Wallenfels 2016

⁷⁸ Cf. § 137c of Volume V of the Social Code

⁷⁹ Cf. in particular § 2 of Volume V of the Social Code

to exclude inpatient methods explicitly from obligatory reimbursement by the statutory health insurance funds. On the other hand, authorised organisations (in particular the German Hospital Federation [Deutsche Krankenhausgesellschaft, DKG] and statutory health insurance funds) may apply to the Federal Joint Committee for evaluation of a method, which (if adopted) will in principle be comparable to outpatient methods (cf. outpatient sector). Obligatory reimbursement by the statutory health funds furthermore only covers ongoing costs (including the use of disposable items) rather than capital investments,⁸⁰ which are eligible for public funding under the dual hospital financing system if certain conditions are met.⁸¹

Costs incurred as a result of using particular methods and medical devices are subject to reimbursement using a flat rate per case on the basis of diagnosis-related groups (DRG). The DRG system is updated each year as follows to ensure that new investigatory and treatment methods are automatically taken into consideration: Case costs and additional information (e.g. diagnosis and procedures used) are forwarded to the Institute for the Hospital Remuneration System [Institut für das Entgeltsystem im Krankenhaus, InEK] by a random sample of German hospitals. This Institute uses this information to recalculate flat rates per case for the following year and always amends the representation of medical procedures in the DRG system in order to ensure that new investigatory or treatment methods are permanently represented therein.⁸²

It takes at least three years between the emergence of a new method and its full inclusion in the compensation system, however, due to the time which passes between the collection of case data, the forwarding and evaluation of the data and the recalculation of flat rates per case. What is more, a sufficient number of cases using the new method must occur in the sample to allow the Institute to carry out calculations.

In order to circumvent this delay, each hospital can submit a special request to the Institute once a year in respect of a new investigatory or treatment method. If the request is approved (notified by 31 January of each year), the requesting hospital can reach an agreement on additional compensation for the new investigatory and/or treatment method. This agreement is temporary in nature and only applies to the relevant hospital.⁸³

As of 2016, an assessment of benefit by the Federal Joint Committee pursuant to § 137h is mandatory for new methods based on the use of a medical device in Classes IIb-III when a first special request is submitted or if other conditions are met.⁸⁴

⁸⁰ Cf. Gerlinger 2012

⁸¹ Cf. Hospital Financing Act [Krankenhausfinanzierungsgesetz, KHG]

⁸² Cf. BMG 2016a, FPV 2016, Hospital Fees Act [Krankenhausentgeltgesetz, KHEntgG]

⁸³ Cf. § 6(2) of the Hospital Fees Act [Krankenhausentgeltgesetz, KHEntgG]

⁸⁴ Cf. § 137h of Volume V of the Social Code

5.1.3 Register of approved aids

As a sub-category of medical devices, aids are generally reimbursed on the basis of the register of approved aids for the statutory health insurance funds.⁸⁵ The National Association of Statutory Health Insurance Funds [GKV-Spitzenverband, GKV-SV] is responsible for deciding whether or not to include a product on this register, and it is assisted in this task by the Medical Service for the National Association of Statutory Health Insurance Funds [Medizinischer Dienst des Spitzenverbandes Bund der Krankenkassen, MDS].

The procedure is initiated by the manufacturer's submission of an application for inclusion on the register, which must prove that the product meets the statutory criteria.⁸⁶ In particular, these include:

- ◆ Functionality
- ◆ Safety
- ◆ Compliance with the safety requirements pursuant to § 139(2) of Volume V of the Social Code
- ◆ Proven medical benefit (where required)
- ◆ German-language user information

As a basic principle, the functionality and safety requirements are deemed to have been met if the product has a CE label (see above).⁸⁷ If the aid can be assigned to an existing product group (e.g. wheelchairs to the product group: 18 "Vehicles for conveying patients or disabled persons"), the procedure ends at this point. In the case of aids which cannot be assigned to an existing category, experience has shown that the medical benefit of the product must also be proven⁸⁸ on the basis of clinical data. The Medical Service for the National Association of Statutory Health Insurance Funds is responsible for evaluating the data, and the National Association of Statutory Health Insurance Funds generally takes a decision within three months of receipt of a full application.⁸⁹ If the aid is a new treatment

⁸⁵ Cf. § 139 of Volume V of the Social Code

⁸⁶ Cf. § 139 of Volume V of the Social Code

⁸⁷ Cf. MTD Dialog 2014, § 139 of Volume V of the Social Code

⁸⁸ A distinction should be made at this point between aids which are aimed at alleviating disabilities and aids which are used for treatment purposes. Benefit does not need to be proven for aids intended to alleviate disabilities (e.g. walking frame) (MTD Dialog 2014).

⁸⁹ Cf. § 139 of Volume V of the Social Code

method, the Federal Joint Committee must decide on its inclusion in the register of approved aids for the statutory health insurance funds rather than the National Association of Statutory Health Insurance Funds alone. In such cases the method must be comprehensively assessed by the Federal Joint Committee, with the assistance of the Institute for Quality and Cost-Effectiveness in the Healthcare Sector if necessary.⁹⁰ According to two rulings by the Federal Social Court handed down on 8 July 2015, an aid can be classified as a method if it forms an essential component of a novel treatment method.⁹¹

The register of approved aids does not specify prices for individual products. These are frequently determined on the basis of negotiations between manufacturers and health insurance funds or through tendering procedures.⁹²

5.1.4 Selective contracts and optional benefits

The mechanisms described above are without exception subject to collective contracts. The reimbursement decisions taken in this respect are therefore binding on health insurance funds under the statutory health insurance system in the outpatient and inpatient sector. Options however also exist for the reimbursement by individual health insurance funds of services and products which are not included in the catalogue of services reimbursed by the statutory health insurance funds, mainly involving selective-contract provisions and optional benefits.

Individual health insurance funds can conclude individual agreements with manufacturers and service providers for the compensation and/or provision of services and products under selective-contract provisions. The legal basis for such arrangements was restructured by means of the Act on the Improvement of Care under Statutory Health Insurance [GKV-Versorgungsstärkungsgesetz, GKV-VSG]. As a basic principle, Volume V of the Social Code provides two legal bases for the conclusion of selective contracts in respect of products:⁹³

- ◆ Special care pursuant to § 140a
- ◆ Model project pursuant to § 63 et seq.

The legislative provisions on arrangements under § 140a make explicit provision for the conclusion of contracts between health insurance funds and the manufacturers of medical devices or pharmaceutical companies. Model projects under § 63 et seq.

⁹⁰ Cf. Wortmann 2015

⁹¹ Cf. Federal Social Court [Bundessozialgericht, BSG], ref. no.: B 3 KR 6/14 R and B 3 KR 5/14 R

⁹² MTD Dialog 2014

⁹³ Contracts on GP-centred care pursuant to § 73b will not be examined here in further detail.

are aimed at enhancing care and are limited to a maximum duration of eight years. Projects implemented on this legal basis must be evaluated by an independent body, and the results must be published.⁹⁴

Statutory health insurance funds can also offer services which do not form part of the catalogue of services offered by the statutory health insurance funds as optional benefits, provided that the relevant services have not been explicitly excluded from care provision by the Federal Joint Committee.⁹⁵

5.1.5 Existing arrangements for digital health care products

As a general rule, digital healthcare products (particularly in the sense of software-based products which are independent of other medical devices and which do not form an integral part of a recognised medical investigatory and treatment method) are not standard benefits, and there is no provision for reimbursement under a collective contract.

The following therefore applies to products in risk classes 1a and 1b as defined above: Each health insurance fund is free to provide reimbursement for these products under selective contracts. Within the exception of training materials for the Disease Management Programme (DMP), no provision is made for these products under a collective contract.

Category 2 and 3 products can also be reimbursed without evaluation under selective contracts and by way of analogy to optional benefits. Insofar as they are regarded as a component of medical practice (a method) and the method is regarded as new and within the scope of outpatient treatment, they will only be covered by collective reimbursement after their benefit has been proven and a positive decision⁹⁶ adopted by the Federal Joint Committee. In case of doubt, the issue of whether a particular digital healthcare product should be categorised as a service rather than a method, or is in fact a method, can be investigated as part of the consultancy services provided by the Federal Joint Committee § 137e of Volume V of the Social Code.

⁹⁴ Cf. § 65 of Volume V of the Social Code

⁹⁵ Cf. BMG 2016b

⁹⁶ Cf. § 135 of Volume V of the Social Code

5.2 Proposal for the reimbursement of digital healthcare products by the statutory health insurance funds

The marketing authorisation described in Chapter 4 will in most cases not be sufficient for digital products to gain large user audiences, since only a limited number of German consumers are likely to cover the cost of such products themselves. A substantial “secondary health market” has existed for many years for “wellness and lifestyle”-type products, but most citizens believe that the statutory health insurance funds should cover the costs of apps which pursue a medical purpose within the narrower sense of the word, and are very reluctant to part with their own money.⁹⁷ This is the root cause of a problem often lamented by providers, namely the difficulty of achieving respectable market turnovers. As already explained earlier in this chapter, a wide variety of reimbursement options exist; as well as collective contracts, reimbursement can also take place via individual health insurance funds, for example in the form of a selective contract, an optional benefit or a new aid. There is however as yet no answer to the question of which of these options should be available to digital products.

There are essentially four different options:

- ◆ collective reimbursement only (as is effectively the case for new pharmaceuticals)
- ◆ selective reimbursement only (as per selective contracts)
- ◆ parallel/alternative options allowing e.g. the manufacturer to choose an option
- ◆ phased processes involving e.g. selective tests first and then (if successful) collective tests⁹⁸

A key argument can however be raised against the first two proposals, which are the most extreme options:

- ◆ The collective reimbursement option would take too long and would therefore be impracticable for most providers.
- ◆ A purely selective option might mean withholding useful treatments from the public, even though the initial introduction financed by an individual insurance fund would ultimately be funded from contributions by the entire community of insured persons.

⁹⁷ Some of the experts interviewed expressed concerns over the possible emergence of a secondary market for individual healthcare services in the field of digital healthcare products, with citizens being offered services with dubious medical benefit.

⁹⁸ One of the experts interviewed proposed the funding of pilot studies by the statutory health insurance funds under certain conditions, either in part or wholly.

Not all stakeholders share these objections, but they should be taken into account in order to identify a model likely to find broad acceptance.

We believe that the option involving one or more individual health insurance funds is quicker and less complicated in most cases, but that the collective contract option should be available for products which have proven their worth, and we would propose the following pragmatic and quality-based procedure:

- ◆ As a rule, manufacturers should conclude agreements with an individual health insurance fund which will then include a digital product in its range as an optional benefit, under a selective contract or otherwise, and offer it to its insurees.
- ◆ The health insurance fund may initially test the product on a small group of insured persons, e.g. in a particular region, and increase the size of the group if the outcome of these tests is positive. This would make it possible to monitor the above-outlined development process from the very beginning.
- ◆ The health insurance fund may not offer products subject to mandatory authorisation according to the criteria listed above where no such authorisation has been granted.⁹⁹
- ◆ The health insurance fund will be obliged to evaluate the product. If no positive outcomes can be identified in the long term, the product must be removed from the market in view of the mandatory need for cost-effectiveness.¹⁰⁰ Account should however also be taken of the fact that it may take several years before the effectiveness of certain selective contracts can be established, and expectations in terms of time frames must therefore be realistic.

It should be possible for successful products to be used by a larger number of insured parties. This may be facilitated firstly by means of copycat competition, which involves other health insurance funds concluding contracts with the provider or other providers copying the product. The second option is for the process for inclusion under the collective contract to be initiated by the Federal Joint Committee or the provider.

This would ensure that effective products are included in standard care provision, which was a demand heard from many of the experts interviewed. The withholding

⁹⁹ Several of the experts interviewed suggested that the health insurance funds could however be granted the right to carry out tests of their own.

¹⁰⁰ This does not apply to Class 1 products, which we regard as non-critical in this respect since the statutory health insurance funds are responsible for consulting insured parties (§ 1 of Volume V of the Social Code). § 11.6 may need to be amended as regards Class 2 and 3 products, but in any case § 12.1 must in any case be observed, according to which the measures taken by the health insurance funds must be cost-effective and treatments must not go beyond what is strictly necessary.

of an effective product from the community of insured persons is not in fact currently a problem, since most apps cannot yet provide adequate evidence of effectiveness. It is also an accepted fact among statutory health insurance funds that certain benefits, e.g. better care processes under selective contracts, cannot be made available to all of their insurees. There is no option for contracts under § 140 of Volume V of the Social Code to be moved over to a collective contract, and even under Innovation Fund projects it takes several years at best for the scope of successful projects to be expanded beyond the original target group. It is therefore a generally accepted fact that there may be a significant delay under certain circumstances before improved care is made available to all the statutory health insurance funds.

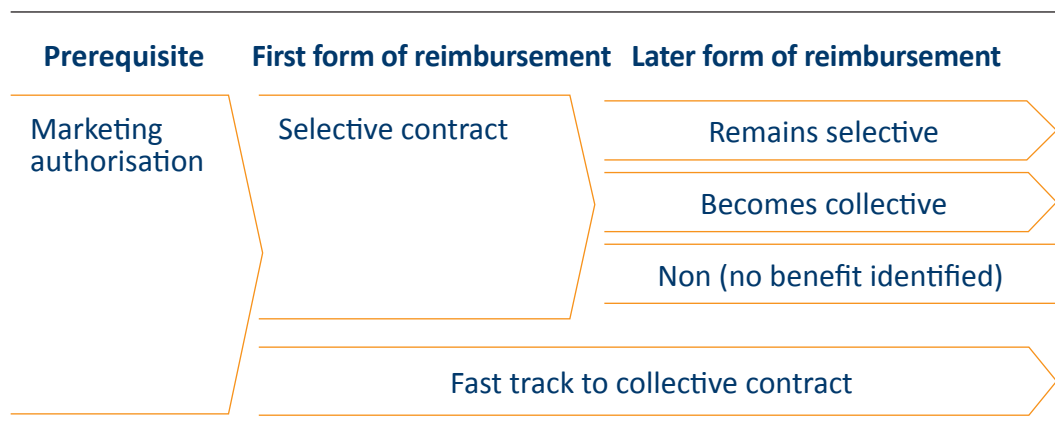
To sum up, we believe that there are several advantages to this procedure. Easier access to reimbursement would make it possible to test products which would otherwise never reach market readiness. Positive examples would encourage the industry as a whole. A primarily selective solution would also open up new scope for quality competition between the insurance funds and the opportunity for differentiation.

One could object that the insurance funds will be in an unequal position for quality competition due to their funding arrangements, but the same argument could also be applied to other areas of quality competition, e.g. selective contracts. It is preferable and more pragmatic for certain insurance funds to invest in testing digital products than for nothing to happen. As already explained, the healthcare sector also tolerates temporary knowledge advantages in respect of improvements to care processes.

It would also be a good idea to ensure that access to a collective contract is not blocked by the delays widely attributed to the Federal Joint Committee. The fast-track option was a controversial subject among the interview partners. Some expressed concern about a proliferation of products due to inadequately high standards, whereas others believed that short-term authorisations with (straightforward) annual evaluations would be better tailored to the industry's special development requirements. Products targeted at diseases which cannot as yet be treated should in particular be eligible for facilitated access, similarly to orphan drugs. Manufacturer would then be able to choose between the selective and collective option.

Figure 10 summarises the proposed regulations for risk classes 2 and 3. With the exception of individual cases such as DMP training under a collective contract, the reimbursement of Class 1 products is not relevant in this respect.

Figure 10: Forms of reimbursement for Classes 2 and 3



Source: IGES

6. Alignment of stakeholder interests

The solution described above is aimed at striking a balance between the interests of the various stakeholders. We will now examine the extent to which this aim is achieved:

- ◆ **Patients:** The legitimate requirements for patient safety and data protection must be weighed up against the need to use new solutions as quickly as possible. This can be achieved by means of a conditional or phased authorisation and relatively prompt reimbursement by individual health insurance funds. The lack of availability to certain groups is an undoubted failing, but patients always have the option of switching to a health insurance fund which offers better apps. Selective coverage is better than none at all.
- ◆ **Doctors:** The phased solution is designed to provide doctors and care providers with a safety-based approach to electronic solutions. It will not overcome all misgivings in this respect, but the opportunities for streamlining routine tasks and concentrating on more interesting activities could certainly be leveraged in the medium term.

- ◆ **Statutory health insurance funds:** Competition within the statutory health insurance funds will be promoted by the introduction of a new facet to quality competition. Although the health insurance funds will be operating with different and therefore unequal levels of funding (as is also the case for competition regarding selective contracts), this problem must be addressed elsewhere, i.e. via the financing system. The fact that the authorisation and testing of individual apps will largely be carried out collectively rather than by the statutory health insurance funds is likely to be a plus for these latter.
- ◆ **Providers, in particular start-ups:** A regulated and transparent procedure would be a huge advantage for providers. There is a good chance of increased turnover if the not insignificant obstacles on the way to marketing Class 3 products can be overcome, offering a greater chance of venture capital funding. Health-sector start-ups already attract six-figure investments¹⁰¹ and the industry will become increasingly professional as it matures, meaning that the proposed studies are also feasible for Classes 2 and 3. Although individual start-ups will experience problems and/or be taken over by large companies,¹⁰² this is normal market practice as observed in other areas of the health product industry. It is important to provide manufacturers with transparent and comprehensible information on authorisation and reimbursement regulations in order to reduce uncertainty in the market. In our opinion and in line with our proposals, an authorisation procedure tailored to the agile and iterative development processes of the digital world, rather than the rehashing of regulations designed for physical products, would be an advantage for start-ups. Ambitious but clear rules are better than confusing rules.

¹⁰¹ Cf. Ernst & Young 2016 and Mack 2016

¹⁰² A number of the experts interviewed called for the rules to be relaxed in case of doubt in order to keep costs low for young companies and protect them from take-overs.

7. Summary of expert interviews

Summary

The main findings from the 20 or so expert interviews we carried out were as follows:

- ◆ The risk classes and proposed regulations were generally welcomed by experts from various areas of the healthcare sector,
- ◆ although there were major differences of opinion in respect of data protection and application of the Medical Devices Act.
- ◆ The experts called for procedures to be clarified as soon as possible through stakeholder dialogue.

Our research and theoretical work was backed up by around two dozen expert interviews, the results of which are briefly summarised below. The interviews were carried out using a questionnaire, between late July and early September 2016 and either by telephone or on a face-to-face basis in Berlin.

The interviews served three purposes. The first of these was to validate and further develop our own ideas, the second was to gain an impression of the general spectrum of opinions, and the third was to hear different views on market development. With particular regard to the second of these goals, our chosen experts represented a range of different perspectives on the use of digital products in the health sector. As well as representatives of traditional healthcare bodies and statutory insurance funds, these also included representatives of government agencies and authorities, start-up entrepreneurs, “digital health” specialists and representatives of industrial companies (medical technology, diagnostics, telecommunications). It was agreed that individual quotes from interviewees would not be used, but all of the interview partners agreed to be named, and a list of names can be found in Appendix A3.

The results of the interviews can be summarised on the basis of our recommendations:

Grouping into risk classes and rules corresponding to these classes

- ◆ The idea of grouping products into risk classes was greeted with universal approval. During the first interviews we suggested an alternative method of grouping apps according to treatment stage (diagnosis, treatment, self-management), but almost everyone regarded this as an inferior option.
-

- ◆ Most interview partners were in favour of a quality seal for Class 1a products (information), while conceding that this would impose a more stringent requirement on apps than on other means of disseminating information (e.g. books). Most interviewees accordingly proposed that regulation should be voluntary and left up to the market. Some interview partners were in favour of laying down mandatory criteria for a quality seal, but none of the interviewees were in favour of a state-operated quality seal.
- ◆ The majority of interview partners agreed that data protection was necessary for Class 1b products, since there is wide acknowledgement of the risks associated with health data and the corresponding need for protection. Our proposal of basing the new regulations on existing legislation from other areas was also welcomed by many of the interview partners, but they remained in the minority (30-40%). This is undoubtedly a point which must be addressed in the course of further debate (see below, Chapter 8). Attention was also drawn to the necessity of safeguarding the quality of the data obtained.
- ◆ The need to regulate Class 2 and 3 products was clearly acknowledged, and almost all of the interviewees were in favour of requiring increasing accuracy on the basis of increasing sensitivity/specificity. By way of a proviso, the representatives of large companies pointed out that they were required to meet much stricter internal requirements before marketing a product, making the issue of market-based product testing irrelevant. With reference to cases which still require clarification or are not yet covered by any rules (a likely occurrence in such a dynamic market), one interviewee suggested that committees should be formed along similar lines to the ethics committees which are commonplace today.
- ◆ Opinions were divided on the classification of digital products under the Medical Devices Act. The different nature of the products, the lack of procedural transparency and the fact that requirements are frequently too low were mentioned as arguments against such a classification. The arguments in favour included in particular the simplicity and pragmatism of this type of approach.

Reimbursement, selective use versus collective contract

- ◆ Differing opinions were also expressed on the ideal form of reimbursement. The majority did not believe that there was any alternative to the dominating selective-access approach, but several experts expressed a clear preference for the collective contract (“Anything which is genuinely good should be available on a collective basis”). In a similar vein, opinions also differed widely on the fast-track option, with opposing preferences for speed and quality assurance.
-

- ◆ A number of interviewees noted that the authorisation procedure could be bypassed if an insurance fund could provide assurance that the rules it applied to use of a particular product were comparable to those used during authorisation. Most interview partners were however in favour of making authorisation a prerequisite for the use of products by insurance funds. Several people even commented that stricter requirements should apply to the use of Class 1a/b products by insurance funds than on the free market.

General market issues

- ◆ Strong reservations were expressed by a number of interviewees in response to the question of whether high-quality software (in Class 3) could replace a human care provider. Many answered that the final decision should always be left to a human (doctor/patient), whereas others assumed that the issue would be decided by patient preference in reality. An even smaller group of interviewees believed that the software should assume all responsibility and therefore legal liability.¹⁰³
- ◆ The interviewees tended to assume that future market developments would be focused on the areas of diagnosis and self-management, but most believed that it was difficult to make any reliable predictions.

Other topics

- ◆ The issue of imitation products was raised twice in two very different contexts. One expert was concerned that any health insurance fund which succeeded in using a product first would gain a quasi-monopoly, whereas another feared that market pioneers would be subject to competition from copycats due to the difficulty of patenting the content of software.
- ◆ Many references were made to the link between regulation on the one hand and the user's media competence/personal responsibility on the other hand. There does not yet appear to be any accurate definition of the level of personal responsibility which can be ascribed to or expected from users in this area.

¹⁰³ It was noted in this connection that this would also mean changes to the doctor's potential liability; what happens if information which is provided by software and which is subsequently found to be correct is ignored or overruled and the patient's health suffers as a result?

- ◆ Finally, a number of proposals were made concerning test environments or platforms on which manufacturers could make their products available for testing purposes, and this idea may merit further investigation.

Many different recommendations were also made regarding future courses of action, as summarised in Chapter 8.

We would like to offer our sincere thanks to all of the experts we interviewed for their willingness to share their ideas with us. The interviews signposted common approaches and many issues which merit further discussion in order to assess and weigh up carefully the best arguments for and against the available alternatives.

8. Conclusion and outlook

“Doing nothing entails the greatest risk.”

(Quote from one of the experts interviewed in relation to the risks associated with digital products)

8.1 Changes in the healthcare sector

There can be no question about the fact that the relationship between patient, doctor and IT will change, and many different possible scenarios were expounded during the interviews. One scenario was based on the assumption that IT applications would specialise in standard cases and doctors would only treat special cases, similarly to an aeroplane pilot who only intervenes in exceptional situations and leaves routine flight tasks to the computer.

In an alternative scenario, decision-making would depend on patient preferences. Some patients will be happy to follow algorithm-based recommendations in future, whereas others will prefer to hear the opinion of a human doctor and follow these latter if they differ in a reasonable and comprehensible way from the machine-based findings.

Patient interactions with software must be regulated, and we must clarify the level of media competence which patients can be expected to have. For example, patients may need to learn to handle large volumes of data without pathologising their everyday behaviour.

What will the apps of the future look like? It currently looks as though the scope for treatments within the narrower sense of this word is still limited. Psychotherapy and areas relating to hearing, vision and speech represent two significant exceptions with great potential. The fact that user-software interaction is limited to acoustic and optical channels determines its possible uses. Most interview partners believe that an increasing number of apps will be developed for “pre” and “post” treatment stages, or in other words early detection, diagnostic support and self-management of chronic illnesses. (Whereby we are deliberately excluding the much larger number of lifestyle apps which fall outside the scope of this study).

In many cases apps will be integrated into a care process rather than being standalone solutions, and this may hold significantly greater potential for changes in care provision.

Most stakeholders are optimistic about the opportunities presented by the new technology, and it should be given the chance to mature, although at some point it must supply evidence - like pharmaceuticals or medical devices - that it delivers proven benefits in terms of avoiding, detecting, treating or managing illnesses. Measuring and interpreting benefit is not always a straightforward matter.

Certain methods are tolerated in the healthcare sector although no benefit can be proven (such as certain alternative treatments) or could even be regarded as potentially harmful (such as certain individual healthcare services). In principle, however, these products too claim to benefit patients. It is therefore reasonable to expect that digital products can provide a reasonable hypothesis of the way in which they benefit patients. As experience has shown in the field of acupuncture or homoeopathy, however, products should be given a period of several years to provide concrete evidence of benefits.

8.2 The path towards new rules





This study makes a number of regulatory proposals, and other proposals have been published or are at the planning stage. Decisions should be taken in this respect as promptly as possible. As several experts said: Transparent procedures are the number one concern for manufacturers, and even a demanding procedure is better than confusion. There may be an argument for working in stages to provide answers to the relevant questions and following the lead of the FDA, which initially laid down criteria stating what should not be regulated and thereby created clarity for at least part of the market.

Many of the interviewees proposed open and strategic dialogue (and in one case the establishment of a committee) in order to identify authorisation criteria on the basis of exchanges between manufacturers, insurance funds, institutions and others.

It would be a good idea to embark on this process as soon as possible, and if necessary to follow an agile approach (based on partial solutions) in this respect as well. Providing companies with an idea of future developments is a matter of key importance.

The following figure summarises the proposed groupings into risk classes and the characteristics of these classes as well as the authorisation and reimbursement proposals set out in this study.

Figure 11: Overview of risk classes, risks and procedures

Risk class	1a	1b	2	3
Name	Information 	Data collection 	User support 	Replacement of care provider 
Definition	Publication of medical information	<ul style="list-style-type: none"> • Data collection, storage and representation • Support for pattern recognition • User responsible for drawing conclusions 	Diagnostic support Treatment decisions, treatment	<ul style="list-style-type: none"> • App replaces the care provider at the stage of diagnosis, treatment decisions or treatment • Care provider responsible for final decision in some cases
Examples	Reference guide to symptoms	Diary for chronically ill patients	Diagnostic information	Definitive diagnoses, dose adjustments within the framework of self-management, automatic implant monitoring
Use of data	Publication	Collection and reasonably complex processing (e.g. pattern recognition)	Complex processing	Complex processing
Level of personalisation	Generalised	Personalised	Personalised	Personalised
Communicative content	Publication	Publication	Recommendation	Recommendation
Risk areas	Contents	<ul style="list-style-type: none"> • In addition for 1a: • Correct representation and formatting of data • Improper use of data 	In addition for 1b: Decision-maker (care provider/patient) misled	In addition for 2: False negative/positive diagnoses, incorrect treatment decisions, harmful treatments, misdoses
Regulation of authorisations	Quality of information	In addition: Data protection	In addition for 1 and 2: sufficiently accurate recommendations (sensitivity and specificity)	
Reimbursement	No reimbursement under collective contract, reimbursement e.g. under selective contract or as an optional benefit		Reimbursement possible under collective contract and also under selective contract or as an optional benefit	

Source: IGES

The proposals set out in this study are intended to clarify certain aspects of the regulatory approach governing the authorisation of digital products. Class 1a and 1b products should clearly be exempt from authorisation requirements, whereas Class 2 and 3 products should be subject to more stringent requirements in terms of evidence of safety than is currently the case.

8.3 Outlook

Although we can be sure that the sector will continue to develop dynamically, it is very hard to tell at present which trends will dominate. The debate on the regulation of digital healthcare products is still in the starting blocks. In the same vein, the recommendations in this study are intended as starting points for further discussion. TK is keen to continue this debate by discussing them over the coming months with various groups of stakeholders in the healthcare sector, including insured parties, care providers, vendors and others, both in order to hear different perspectives and to refine the proposals.

9. Appendix

A1 Types of digital healthcare products

A2 Examples of quality checks and quality seals

A3 Interview partners

A4 Decision trees

A1 Types of digital healthcare products

In order to provide a basis for evaluating the fields of use of digital healthcare products and the opportunities and risks associated with them, we started with a broad market overview and a search for apps of all kinds throughout the medical healthcare cycle. Selected examples are summarised in the following tables.

Research sources for digital health products

We searched for apps in Google using the following key terms:

- ◆ “Gesundheit App” [“health app”],
- ◆ “mHealth app”,
- ◆ “Digitale Gesundheit Produkte” [“digital health products”],
- ◆ “mHealth start-ups”.

The search terms were also translated into English and/or French where this seemed appropriate. The following sources were also searched for digital health products:

- ◆ <http://www.fda.gov/MedicalDevices/DigitalHealth/MobileMedicalApplications/ucm368743.htm>
- ◆ <http://mhealthintelligence.com/>
- ◆ <http://mobihealthnews.com/>
- ◆ <http://www.jmir.org/>
- ◆ (<http://mhealth.jmir.org/>)

Searches were also carried out for digital health products on the websites of the following incubators, news agencies and portal and review sites:

- ◆ <http://www.helios-hub.com/>
 - ◆ <http://www.digitalhealtheurope.com/>
 - ◆ <https://flyinghealth.com/>
 - ◆ <https://www.grants4apps.com/>
 - ◆ <http://healthcare-startups.de/>
-

- ◆ <http://research2guidance.com/>
- ◆ <http://www.imedicalapps.com/>
- ◆ <http://mhealthintelligence.com/>
- ◆ <https://www.healthon.de/>
- ◆ <http://www.nhs.uk/pages/healthappslibrary.aspx>
- ◆ <http://myhealthapps.net/>

Grouping of products according to treatment stage

Selected results from the research process described above are shown below, allocated to a total of eight categories representing typical stages of treatment. The apps were allocated on a case-by-case basis, and there are undoubtedly valid grounds for alternative decisions.

1. Information

Table 1: Products from the category “Information”

Example	Description
Husteblume	A range of information for allergy sufferers
PatientLikeMe	Connects patients suffering from similar complaints and is also a source of information for the pharmaceutical industry
Pollen-Radar	Pollen count predictions
TK-ICD-Diagnoseauskunft	Makes it possible to search for the ICD code of a particular illness and vice versa.
TK-Klinikführer	Information on in-patient treatment options
TK-Lex mobil	Aid to navigating the healthcare system
Treato	Online platform: Searches forums and acts as an alternative source of information on medicines and their side effects

Source: IGES

2. Early detection

Table 2: Products from the category “Early detection”

Example	Description
Preventicus	An app aimed at the early detection of cardiac arrhythmia
ProstateCheck	Calculates an individual's risk of suffering from prostate cancer

Source: IGES

3. Prevention

Table 3: Products in the category “Prevention”

Example	Description
Kenkodo	Product aimed at “well patients” who wish to understand/ monitor their body better Blood sample used for data analysis
PhysIQ	Determination of baseline (“Well Index”) by compiling measurements from various devices Warning issued if data diverge from the baseline
23andme	Online platform for genetic testing (search for known genetic disease factors)

Source: IGES

4. Diagnosis

Table 4: Products from the category “Diagnosis”

Example	Description
AliveCor	Mobile ECG device which transfers data to a smartphone, which in turn evaluates the risk of atrial fibrillation
CardioSecurActive	Mobile ECG device. Recommends when the user should visit a doctor (either immediately or by making an appointment).
Isabel Symptom Checker	Checks symptoms on the basis of standardised questions and then evaluates the responses to these questions for a particular care provider (e.g. doctor).
iTriage	Checks symptoms on the basis of standardised questions and then evaluates the responses to these questions for a particular care provider (e.g. doctor). Also estimates treatment costs for US-based patients.
Kids Sympton Checker	Checks children's symptoms by body part and then decides how urgently treatment should be sought (e.g. “Call doctor now”).
SkinVision	The patient takes a photo of a mole. An algorithm is then used to determine whether or not the mole is malignant. Photos are stored over a period of time in order to document developments.
Symptomate	Evaluates symptoms on the basis of standardised questions.
Zenikor-ECG	Mobile ECG devices which transfers data to a doctor.

Source: IGES

5. Treatment decision

Table 5: Products in the category “Treatment decision”

Example	Description
Companion Medical	System made up of an insulin syringe and app which e.g. provides suggestions on doses, stores information on past doses and monitors the temperature of the insulin.
DecisionAid	Online decision aid for patients (e.g. whether or not to have a cataract operation)

Source: IGES

6. Treatment

Table 6: Products in the category “Treatment”

Example	Description
Caterna	Visual training for the treatment of amblyopia
Deprexis	Online support during CBT-based psychotherapy
EviveCare	Speech therapy for stroke patients
iFeel Labs	Game-based approach to asthma treatment. The player/patient can only gain points by breathing correctly.
M-sense	Determines the factors which trigger headaches and makes corresponding treatment proposals, and helps the patient to implement these proposals.
Tinnitracks	Tinnitus therapy using music which suppresses certain audio frequencies

Source: IGES

7. After-care/monitoring

Table 7: Products in the category “After-care/monitoring”

Example	Description
LifeGraph	Mental health monitoring using a smartphone. Relatives or doctors/therapists are notified if a patient's condition deteriorates.
MobileTherapy	Connects patients to their psychotherapist, who receives regularly completed questionnaires which can be used to evaluate the patient's condition.

Source: IGES

8. Self-management

Table 8: Products from the category “Self-management”

Example	Description
Clue	Records a woman's menstrual cycle and issues recommendations on the basis of the data provided, e.g. fertile days for women trying for a baby.
Jourvie	Supports patients suffering from eating disorders. Offers e.g. a diary to record eating patterns and suggests coping techniques to avoid overeating or purging.
myCOPD, myDiabetes, myAsthma	Self-management apps for chronically ill patients. Contain e.g.: medication schedules or recommendations on what to do in the event of an emergency.
TK-Diabetes Tagebuch	Systematically records blood glucose values and presents them in the form of a graph. Data can be transferred from the measuring device to the smartphone using a Bluetooth connection.

Source: IGES

A2 Examples of quality checks and quality seals

Germany

There are four main organisations in Germany involved in the quality testing of medical information and products:

- ◆ HealthOn
- ◆ Bundesverband Internetmedizin [BIM, Federal Association for Internet Medicine]
- ◆ Health on the Web Stiftung [HON, Health on the Web Foundation]
- ◆ Aktionsforum Gesundheitsinformationssystem e.V. [afgis, Action Forum on Health Information Systems]

HealthOn bases its approach on user ratings, which it merely collects and presents.¹⁰⁴ The BIM quality seal, on the other hand, is awarded by BIM itself rather than on the basis of user ratings. An app must meet a set list of requirements, which include the requirements for CE certification under the Medical Devices Act, the FDA requirements for medical apps and other criteria defined by BIM.¹⁰⁵ The German branch of the HON Foundation also awards a quality seal, which is aimed not just at apps, but more generally at all providers of health information on the Internet. Its aim is not to guarantee the accuracy of medical information, but to make it clear that the author of the information is aware of the need for “objectivity and transparency”.¹⁰⁶ The afigis seal goes one step further, since it is intended to increase the visibility of verified health information. Certifications are issued for one year.¹⁰⁷

DAK-Gesundheit, a statutory health insurance funds, takes a different approach again. Users are encouraged to work through a list of 12 questions in order to assess the quality of an app. The questions on this list relate to e.g. details of the company which published it and the reliability of the authors.¹⁰⁸

¹⁰⁴ Cf. HealthOn (2016)

¹⁰⁵ Cf. BIM (2016)

¹⁰⁶ HON (2016)

¹⁰⁷ Cf. afigis (2013)

¹⁰⁸ Cf. DAK-Gesundheit (2015)

Outside Germany

Attempts have also been made in other countries to evaluate digital healthcare products. Further details of these approaches are provided below:

- ◆ UK: Health App Library
- ◆ France: Guide de la Santé connectée, mHealthQuality
- ◆ USA: iMedicalApps;

The “Health App Library” was initiated as part of a pilot project in 2013, with the aim of providing doctors and patients with an overview of apps which do not fall under the heading of medical devices and making recommendations. The service is not yet online and is currently at the review stage.¹⁰⁹

The French private insurer “Harmonie Mutuelles” offers the publicly available “Guide de la Santé connectée”, the scope of which is limited to connected devices. It contains information on data protection, CE certification and manufacturers, and users can also rate products themselves.¹¹⁰ The private company DMD+ Santé also offers a service known as mHealth Quality, which rated 1,100 apps in the first three years of its existence and is therefore extremely comprehensive. Each app is reviewed by 10 experts, at least 2 of whom work in the healthcare sector. Ratings are extremely thorough and cover aspects such as ethical standards, accuracy of medical information and data protection.¹¹¹

In the USA, the iMedicalApps website regularly publishes reviews of digital healthcare products written by medical experts.¹¹²

¹⁰⁹ Cf. NHS Choices (2015)

¹¹⁰ Cf. Le guide de la santé connectée (2016)

¹¹¹ Cf. mHealth Quality (2016)

¹¹² Cf. iMedicalApps (2016)

A3 Interview partners

- ◆ Prof. Dr. Volker Amelung, Bundesverband Managed Care [BMC e.V, Federal Association of Managed Care]
 - ◆ Mr Thomas Ballast, Techniker Krankenkasse (TK)
 - ◆ Dr. med. Franz Bartmann, Bundesärztekammer [BÄK, German Medical Association]
 - ◆ Frau Inga Bergen, Welldoo GmbH
 - ◆ Mr Alexander Beyer, Gesellschaft für Telematikanwendungen der Gesundheitskarte mbH [gematik, Society for Telematic Applications of the Health Card]
 - ◆ Dr. Friedrich von Bohlen und Halbach, dievini Hopp BioTech holding GmbH & Co. KG
 - ◆ Prof. Dr. Karl Broich, Bundesinstitut für Arzneimittel und Medizinprodukte [BfArM, Federal Institute for Drugs and Medical Devices]
 - ◆ Dr. Jörg Caumanns, Fraunhofer-Institut für Offene Kommunikationssysteme [FOKUS, Fraunhofer Institute for Open Communication Systems]
 - ◆ Dr. Florian Frensch, Philips GmbH
 - ◆ Mr Frank Greiner, Roche Diagnostics Deutschland
 - ◆ Mr Jörg Land, Sonormed GmbH
 - ◆ Dr. med. Peter Langkafel, Healthcubator GmbH
 - ◆ Dr. Markus Müschenich, Flying Health
 - ◆ Mr Christian Rietz, Bitkom e.V.
 - ◆ Mr Michael Schaper, SAP AG
 - ◆ Mr Oliver Schenk, Bundesministerium für Gesundheit [BMG, Federal Ministry of Health]
 - ◆ Mr Johann-Magnus Frhr. v. Stackelberg, GKV-Spitzenverband [National Association of Statutory Health Insurance Funds]
 - ◆ Dr. Klaus Strömer, Berufsverband der Deutschen Dermatologen e.V. [BVDD, Professional Association of German Dermatologists]
 - ◆ Dr. Thilo Weichert, Netzwerks Datenschutzexpertise [Network Data Protection Expertise]
 - ◆ Ms Juliane Zielonka, start-up bootcamp Digital Health Berlin
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A4 Decision trees

As described above in Chapter 4, a decision tree is necessary for the group of specific products into risk classes. Similar decision trees used by the FDA and the British MHRA are shown below by way of illustration.

Figure 12: Decision tree used by the FDA to identify “wellness products”

VI. Determining whether General Wellness Products are within Scope of the Guidance

The following questions reflect the framework described in this guidance to determine whether general wellness products are within the scope of the guidance. Please note that these questions are intended to be addressed in the context of the full text of the guidance.

A1. Does the product have an intended use that relates to maintaining or encouraging a general state of health or a healthy activity?

Does the product only involve claims about sustaining or offering general improvement to functions associated with a general state of health that do not make any reference to diseases or conditions? Claims in this category include: weight management, physical fitness, relaxation or stress management, mental acuity, self-esteem sleep management, or sexual function.

YES →	Go to A3.
NO →	Go to A2.

A2. Does the product have an intended use that relates the role of healthy lifestyle with helping to reduce the risk or impact of certain chronic diseases or conditions? *(In answering this question, the following two questions must be considered together.)*

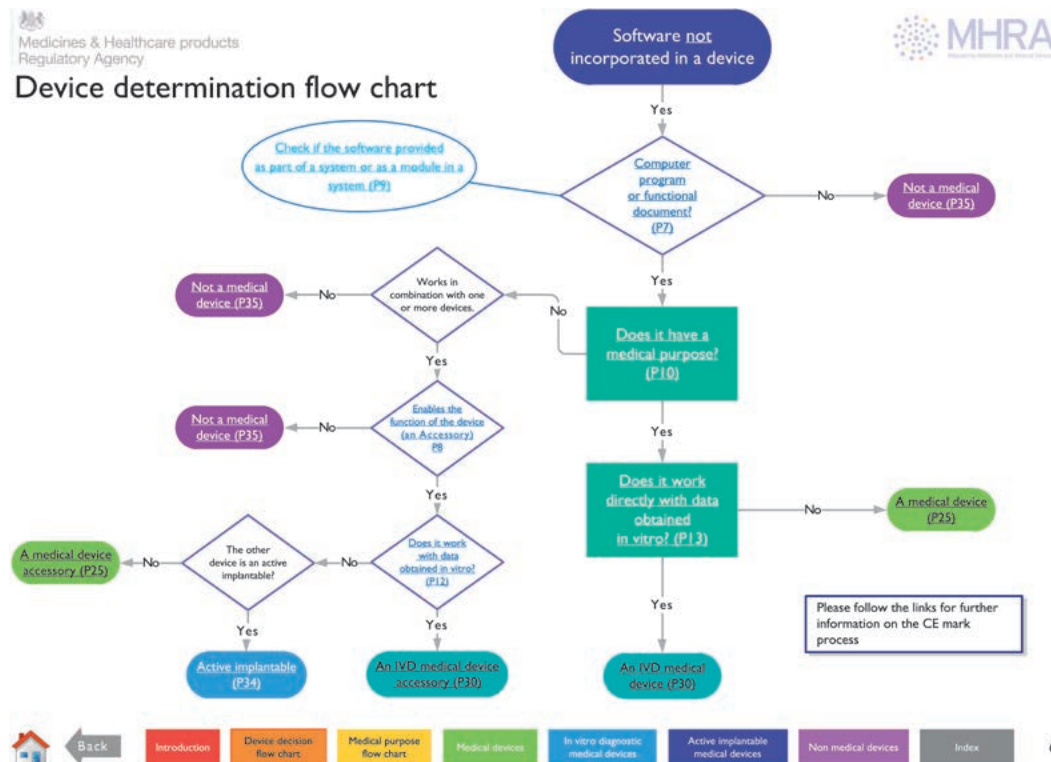
- a) Does the product have an intended use that relates to sustaining or offering general improvement to functions associated with a general state of health while making reference to diseases or conditions, and where it is well understood and accepted that healthy lifestyle choices may play an important role in health outcomes for the disease or condition?

AND

- b) Is the relation between healthy lifestyle and disease specifically expressed as “**may help to reduce the risk of**”, or “**may help live well with**”, a chronic disease or condition?

YES →	Go to A3. Both questions A2(a) and A2(b) must be answered “Yes” in order to proceed to question A3.
NO →	Product is NOT a low risk general wellness product, and is outside the scope of this guidance.

Figure 13: Decision tree used by the MHRA when deciding whether software is a medical device



Source: Medicines & Healthcare products Regulatory Agency (2014)

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