Digital Health – legal framework for digitalization in the healthcare sector

A Workshop Report

Workshop report drafted by Ada Sofie Altobelli[*], Michael Schüepp[**], Martin P. Werner[***] – together with workshop organizers[****], speakers and participants[*****].

1. Introduction

The digital transformation of economy and society is both a promising and a challenging rapidly changing development that gives – especially in the field of Digital Health – rise to many questions regarding the evolution of new business models and an appropriate legal framework for them.

To approach these questions, the Europa Institute at the University of Zurich (EIZ) held a workshop on Digital Health on 29th January 2020.[1]

2. Business Models – new application fields[2]

Digitalization is leading to rapid market development in the healthcare sector and is influencing all areas of the branch. According to estimates, the digital sector will already account for 8% of the total health budget in 2025.[3] In contrast to the widespread assumption that digitalization will primarily replace or compete with established offers, products and processes, new services are likely to come onto the market in the health care sector that complement the existing range of services.[4] This is illustrated by examples such as Helsana's health app, which promised insurance premium reductions in

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[1]   To encourage an open exchange of ideas, workshop participants agreed that information shared during the workshop may be used freely, but that statements should not be assigned to a specific participant (Chatham House Rule). The discussions on the respective topics were each introduced by a keynote presentation.

[2]   Keynote speaker: lic. iur. Lukas Bühlmann, RA, LL.M.

[3]   Roland Berger GmbH, Future of Health, 2019, p. 7, <https://www.rolandberger.com/de/Publications/Digitalisierung-im-Gesundheitswesen-Handeln-statt-sondieren.html> (visited: 04.02.2020).

[4]   Roland Berger GmbH, What's the market pull for E-Health?, 2016, <https://www.rolandberger.com/publications/publication_pdf/roland_berger_whats_the_market_pull_for_e_health.pdf> (visited: 04.02.2020).

exchange for user data and was challenged by the Federal Data Protection and Information Commissioner before the Swiss Federal Administrative Court.[5] This case inevitably raises the question about the role of insurance companies, which hold a very large amount of personal data. To what extent, for example, should they be allowed to process such data in order to improve their risk calculation?

Digitalization also offers enormous potential for savings in the traditional areas of the industry and will undoubtedly exert considerable pressure on the players in the healthcare sector. For example, the use of data from wearables leads to improvements in diagnosis, and the use of digital twins can increase the effectiveness of therapies. At the same time, in drug development, the knowledge of data scientists or mathematicians is increasingly being used, as illustrated by patent applications in the field of personalized medicine. Companies that do not have the corresponding know-how will hardly be competitive in the long run. According to recent studies, 20% of medical doctors' work is to be replaced by artificial intelligence by 2025.[6] However, a look at the daily work of Swiss medical doctors does not confirm this forecast. This may be due to the fact that the error rate inherent in artificial intelligence applications is much more problematic in the healthcare sector than in other sectors and that errors in the use of such applications are socially less tolerated than errors made by medical doctors in general.

Nevertheless, the examples discussed in the workshop show that the health industry will change significantly in the foreseeable future due to the influence of digital technologies. In addition to the classical product and service sectors (pharmaceuticals, medtech, insurance, etc.), these changes will also affect the fields of activity of health care personnel and ultimately the everyday life of patients.

3. Data as a necessary resource for digitalization[7]

Personal data in the health care sector are both highly sensitive and valuable resources. Only by training with appropriate data sets, many applications of digitalization (especially algorithms, AI) can be developed. When using large, anonymous data sets, such a procedure is widely accepted. Especially in the health care sector, however, a complete anonymization of data is difficult, because many of the personal characteristics (predispositions, behavior, etc.) which make up the information content and thus the value in the first place, are inseparably linked to the individual. Considering that in a recent study on the effective anonymization of data, three characteristics were already sufficient to uniquely identify a vast majority of American citizens (postcode, age, gender),[8] it seems questionable, at least with the current state of technology, to what extent the two goals of protecting privacy and using health data for the development of new applications are compatible.

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[5]   <https://www.bvger.ch/bvger/en/home/media/medienmitteilungen-archiv-2002---2016/medienmitteilungen-2019/datenbearbeitung-bei--helsana---teilweise-rechtswidrig.html> (visited: 04.02.2020).

[6]   Roland Berger GmbH, Future of Health, 2019, p. 12, <https://www.rolandberger.com/de/Publications/Digitalisierung-im-Gesundheitswesen-Handeln-statt-sondieren.html> (visited: 04.02.2020).

[7]   Keynote speaker: lic. iur. et lic.oec.publ. Roland Mathys, RA, LL.M.

[8]   <https://www.nature.com/articles/s41467-019-10933-3/> (visited: 04.02.2020); Latanya Sweeney, Simple Demographics Often Identify People Uniquely, 2000, p. 30 (http://dataprivacylab.org/projects/identifiability/paper1.pdf).

In this context, the question arises as to who owns or should own the sovereignty over the coveted data, or whether the current possibilities of data protection for individuals are sufficient and sensible. Neither of these questions can be answered quickly and clearly. Recent regulatory developments in the European area are based on the concept of informed and voluntary consent. Every individual should therefore be able to decide knowingly whether, for what purpose and by whom his or her personal data will be used. The fact that the implementation of such a concept is difficult in practice or has several weaknesses is shown by the recent ruling in the BKartA/Facebook case.[9] In its decision the "Bundeskartellamt" accuses Facebook of abusing its dominant position in the market for social media platforms in order to obtain data from its users and third parties. It is not necessary to answer at this point whether the BKartA's argumentation can be approved without any reservations. It is already obvious that the principle "take it or leave it", specifically the use of a certain offer only in return for the consent to Facebook's use of personal data, is a serious problem for the concept of "informed and voluntary consent". Furthermore, it is questionable whether, due to the complexity of the matter, an average person is at all capable of grasping the possible effects of releasing the data to third parties, using a reasonable amount of effort. Especially in the health care system, where "correct" data is of immense value (accuracy of training data is crucial for the results of an AI diagnosis and inaccurate data can result in fatal consequences), there is a strong incentive to use such data for other purposes not covered initially.

The question of an alternative solution, which, in contrast to the existing system of consent, solves the described difficulties better than by ticking a box, is not easy to answer. Because of the high complexity and technicality of the issue, any differentiated consent process requires a corresponding amount of time from the data generators. Other means of justifying the use of personal data, in particular the argument of an overriding private interest, don't work in cases where the medical secrecy comes into play. It has therefore been brought forward that the concept of consent should be abandoned and replaced by a system generally permitting the use of personal data, however restricted by specific provisions prohibiting the use and processing of personal data in cases where the individual's privacy is indeed at risk.

4. Ethics and law as the basis for setting new standards[10]

Although the subject of digitalization is present in political and academic discourse, it usually deals with fundamental questions. It seems widely accepted that the existing ethical and legal frameworks are quite capable of dealing with specific questions of digitalization. The biggest role in principles guidelines and standards, plays the transparency whereas justice and fairness come as close second. In contrast, regulation is not yet that far advanced in specific issues and problem constellations. Challenges in the context of AI arise in the medical sector especially in the domain of human science. In general, the fundamental question arises as to whether, in view of the rapid development, detailed regulation is at all effective or simply promotes the creativity of lawyers.

In contrast to other areas, not many digital innovations are yet available in clinical practice. Most

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[9] <https://www.bundeskartellamt.de/SharedDocs/Meldung/EN/AktuelleMeldungen/2019/11_07_2019_
    decisionFacebook.html> (visited: 04.02.2020).

[10] Keynote speaker: Dr. iur. Julian Mausbach, RA.

registrations of AI inventions in the medical sector are in radiology and dermatology and the research sector anticipates a strong increase of corresponding activities in the nearer future. With the increase of such digital assistants and the associated shift of certain tasks from doctors to digital instruments, another question arises, namely patient confidence in such applications. However, it seems that people tend to ignore such discussion until it affects them. Therefore, no broad discussion of the integration of and changes brought by digitalization is currently taking place in the general public. In view of the scope and depth of the changes brought by digitalization in the health sector, especially regarding the high personal involvement of patients, it seems questionable whether a delegation of this discussion to the SSO[11] and ethics committees is sufficient. The discussion that has meanwhile begun at expert level should therefore be made fruitful in and to a wider social context.[12]

5. Conclusion

For a smooth integration of digital applications into society in general and the healthcare industry in particular, a broad discourse on the possibilities and on the various positive and negative effects of digitalization is urgently needed. This requires not only the identification of new regulatory and ethical standards, but also the conscious definition and shaping of the roles of all stakeholders. This is the only way to ensure contained yet effective regulatory intervention. On the one hand it can set the necessary guard rails to protect important individual interests, but on the other hand it does not generate unnecessary administrative burdens at the expense of entrepreneurs. Already today, the compliance effort for companies in the healthcare sector is enormous and thus inhibits potential innovation.

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[11] Swiss Dental Association.

[12] Building on promising approaches at expert level, such as the Swiss Academy of Medical Sciences and Swiss Science Council activities to «Patient, doctor, big data. Who has the power of definition?».