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Digital health solution

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France, Italy, Germany, Spain, Russia and UK
Top digital health solutions

Germany

In brief

In the wake of the pandemic, the German government is eager to accelerate and intensify the implementation of "telemedicine" (remote medical consultations with online doctors) as well as electronic prescriptions of medicinal products. In doing so, still the considerable focus is put on safeguarding data privacy and sustaining the considerably high standards in this respect.

Moreover, COVID-19 is expected to give a boost to the already intended implementation of a digital infrastructure which outpatient clinics and physicians have to subscribe to on a compulsory basis. This development may compel medical devices manufacturers as well as pharmaceutical companies to further align their communication protocols with digital standards.

Top 4 legal issues to have on your radar

1. Medical Device Regulation

Potential medical device classifications of e-health solutions will also apply to most recent state of the art software applying techniques of machine learning. Any medical purpose will trigger the applicability of requirements such as clinical evaluation and compliance with various harmonized standards, apart from ISO 13485:2016, also EIC 62304 and 82304. A computerized systems validation routine would also have to be implanted.

EU medical device regulation is in a state of transition and comprises the outgoing Directive 93/42 on medical devices (MDD) and the incoming Regulation 2017/745 on medical devices (MDR). The MDR will only fully replace its predecessor, the MDD, on 26 May 2021 (in order to allow manufacturers to focus on COVID-19 responses, the Regulation 2020/561 has postponed the replacement date by one year). During the transition period, devices can be placed on the market under the current MDD, or the new MDR, and the two regimes operate in parallel.

Due to the current context and based on the European Commission Recommendation 2020/403 of 13 March 2020, the German government took exceptional measures regarding the importation of non-CE marked medical devices, that are not applicable to digital health solutions at this stage.

2. The hurdles in using patient data: data privacy, medical confidentiality and cybersecurity

In the EU, organisations using patient data will need to assess whether they act as processor or controller, and comply with corresponding obligations under the GDPR. There can be difficult GDPR questions to

grapple with, such as consents, security measures, and restrictions on transfers of data. But the GDPR is only one part of the jigsaw puzzle when using patient data.

In addition, companies also need to comply with the Federal German Data Protection Act ("Bundesdatenschutzgesetz") and the relevant State Data Protection Act ("Landesdatenschutzgesetz"). Healthcare professionals have to act under strict confidentiality as provided for in the Model Professional Code for Medical Doctors (Muster-Berufsordnung für die in Deutschland tätigen Ärztinnen und Ärzte). Furthermore, healthcare professionals are under a public obligation to report diseases as detailed in German Infection Protection Act ("Infektionsschutzgesetz").

Regarding cybersecurity requirements, there is an abundance of German and EU-based technical and IT standards specific to medical apps, for instance:

- German Federal Office for Information Security ("BSI") Recommendation "Cyber Security Requirements for Network-Connected Medical Devices"
- MDCG 2019-16 Guidance on Cybersecurity for medical devices of December 2019
- IEC 62304 Amendment I - Medical device software — Software life cycle processes
- IEC 60601-4-5 - Medical electrical equipment

The manufacturer of a medical app should have taken applicable standards into account.

3. Telemedicine

Subsequent to the liberalization of telemedicine in Germany in 2018, online platforms offering or facilitating remote medical consultations with HCPs have proliferated, fueled by new demand triggered by COVID-19. The amount of fees chargeable to statutory insurers has been increased. In parallel, patient may opt for out of payments of around 40 € per consultation. By virtue of collective tacit consent, remote medical appointments to advice patients on suspected COVID-19 symptoms have been offered free of charge, in defiance of the general prohibition of free medical advice. Tele-medical services are not subject to a special license to be obtained by HCPs or operators hosting online platforms. However, eligibility for reimbursement by statutory insurers requires a notified body certification of the IT and cybersecurity infrastructure used.

4. Electronic prescriptions (eRx)

Through a new piece of legislation (Stronger Supply Of Medication Reliability Act - Gesetz für mehr Sicherheit in der Arzneimittelversorgung – "GSAV"), which entered into force on August 19, 2019, amongst a multitude of other measures, stakeholders are tasked with implementing the IT infrastructure to enable pharmacies to accept and honour electronic prescriptions (eRx). Specifically, the IT task force in charge (Gematik) has to complete the roll-out until June 20, 2020. Other stakeholders within the German self-regulations system, notably collective organizations of public payers and prescribing physicians, are tasked with updating regulations to enable physicians to use eRx, by March 31, 2020.

The lawmakers aspire to accelerate the ultimate implementation of eRx, and for this purpose presented a draft law, i.e. Draft Law for the Protection of Patent Data within the Telematic Infrastructure of February 4, 2020 (Patientendaten-Schutzgesetz – "Draft PDSG"). Apart from ensuring data privacy in conjunction with electronic patient files, Gematik is supposed to be charged with technically enabling the issuance of eRx by prescribers until June 20, 2020. Until June 30, 2021 measures to create yet more prescription transparency shall be put in place. For managing and transmitting eRx a special app is intended to be established.

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