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Digital health solution

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Top digital health solutions

Italy

In brief

From the beginning of 2020 the Italian healthcare sector is experiencing an unprecedented number of new challenges.

Indeed, the spread of the COVID-19 pandemic is increasing the demand for health services in a situation of limited available resources. It is also clear that the effect of COVID-19 goes beyond the disease it produces, as the national health system must, at the same time, deal with the existing levels of non-communicable diseases. Moreover, extraordinary measures taken by the Government to prevent and contain the virus are impacting on the possibility to provide medical services leading national and local authorities to adopt new approaches and solutions to meet new health needs and ensure the continuity of care.

In this context, hospitals and medical institutions are accelerating the adoption of digital solutions, such as remote monitoring and telehealth platforms, AI-powered assessment apps and devices, for the delivery of healthcare whereas companies are developing new solutions or adapting those that already exist to meet the relevant demand.

Whether you are still in the development phase or ready to go to market with your digital health product, below are our top 5 legal issues to help you navigate through the digital health space and seize business opportunities.

Top 5 legal issues to have on your radar

1. Medical Device Regulation

If your digital health solution has a medical purpose, it is possible that it will be regulated as a medical device in the EU. Companies should therefore conduct an assessment to determine whether this is the case and the classification of any potential medical device.

As regards products intended to the Italian market, the relevant assessment can be carried out pursuant to the provisions of Legislative Decree No. 46/1997, which implements in Italy Directive 93/42/EEC on medical devices (MDD), or of the incoming Regulation (EU) 2017/745 on medical devices (MDR), which will fully replace the MDD at the end of the relevant transition period. Said transition period, which was initially scheduled to end on May 26, 2020, has been recently extended by one year, until May 26, 2021, in order to relieve the pressure on national authorities, notified bodies, manufacturers and other actors, and to allow them to focus fully on urgent priorities related to the current coronavirus crisis.

Indeed, during the transition period, devices can be placed on the market under the current MDD, as

implemented in Italy by Legislative Decree No. 46/1997, or the new MDR, and the two regimes operate in parallel. In this respect, it should be noted that the MDR establishes new classification rules, specifically for medical device software, and amends certain rules of the MDD, with the consequences that some products which did not classify as medical devices under the MDD could now fall within the scope of the medical device regulation or in a different/higher class of risk.

Whether or not your tool qualifies as medical device, it is noteworthy to mention that, in the current state of health emergency, the Italian Minister for Technological Innovation and Digitalization, the Italian Ministry of Health, the Italian Higher Institute for Health, the World Health Organization and an Interdisciplinary Scientific Committee are jointly launching calls to business and research entities for technology to better monitor, prevent and control the spread of COVID-19. This new initiative is aimed at identifying, amongst others, the best available digital solutions and technologies for telemedicine, home care applications, and active monitoring of the risk of contagion, including:

- Apps and technical solutions for remote assistance of patients suffering from COVID-19 related diseases or other pathologies, even of a chronic character, such as apps, web sites and chatbots for the self-monitoring of health conditions;
- Technologies and solutions for the continuous tracking, alerting, and timely control of the individuals' level of exposure to the risk of contagion and, therefore, of the development of the epidemic outbreak within the Italian territory. Said products include data analysis systems as well as hardware and software for the management of the health emergency.

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

Whether you are still in the development phase or ready to go to market with your device, you are likely to have already met with your legal team to consider the data protection implications arising out of collection and use of patient data. From an EU perspective, the first rule to consider is the principle of privacy by design: your device must be designed from the outset to address privacy and data security implications.

The combination of technology and patient data as such captures the attention of data protection authorities and the Italian authority has included the processing of health-related information via digital devices within the list of processing which should be subject to a prior data protection impact assessment, in order to determine the appropriate measures and safeguards.

The security angle pays a crucial role, as processing patient data lawfully also means to have in place appropriate safeguards to defend against ever evolving cyber-risks, intended as external but also internal risks.

If a lesson can be learnt from the current efforts to combat the spreading of the COVID-19, is that of transparency. Indeed, the discussions on implementation of contact tracing apps, at European as well as national level, illustrate that only when there is complete disclosure about who collects and can access data, how data is used and how long is kept, individuals may be willing to fully engage with the technological tool. Trust, supported by transparency, is thus a key element of success for these technologies.

3. Registration requirements for regulated activities?

In Italy, there is no specific legislation on digital health and/or telemedicine. That said, it should be noted that on March 2014 the Italian Ministry of Health adopted national guidelines providing several rules and principles applicable to telemedicine.

With said guidelines, the Ministry of Health specified that telemedicine is not a separate medical specialty, but rather a method for providing medical services through innovative technologies in situations where the patient and the healthcare professional (or two healthcare professionals) are not in the same location and that, therefore, healthcare structures and operators providing telemedicine services must hold all permits provided for by the applicable legislation for the delivery of health services as well as all additional authorizations which may be required in relation to the specific technologies used to perform said services.

With specific regard to healthcare structures, in Italy the provision of health services is subject to a prior authorization issued by the competent regional health authority after having ascertained that the relevant entity meets the minimum, structural, technological and organization requirements laid down by Legislative Decree No. 502/1992 on "*Reorganization of the health legislation*".

4. Liability

We advise digital health providers to consider and mitigate several potential avenues for liability claims, including:

- Product liability under Legislative Decree No. 206/2005 on Consumer Code;
- Fault-based liability for negligence, including medical negligence claims;

- Contractual liability, depending on the contracts entered into; and
- Exposure to liability under the MDD and MDR.

There is a relatively high, and ever increasing, appetite for medical negligence actions in Italy.

5. Market access and reimbursement

The "*Servizio sanitario nazionale*" (SSN) is by far the largest customer of healthcare products and services in Italy. That said, the award of supply and service agreement by entities belonging to the SSN follows specific rules aimed at ensuring, *inter alia*, the transparency or the relevant public tender procedures as well as the competition amongst economic operators. We advise providers of digital health solutions on public procurement matters in Italy and the complexities of contracting with SSN entities, including the negotiation of public contracts, potential commercial models of supply, and reimbursement.

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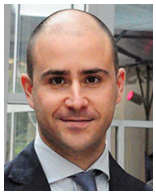

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