

TOP DIGITAL HEALTH SOLUTIONS

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

Russia

In brief

Digital health is a sensitive area where a balance between doctor-patient confidentiality, cybersecurity, regulatory requirements and accessibility of qualitative high-tech personalized medical solutions for patients must be found. Currently, there is a very limited application of digital health solutions in general and telemedicine in particular in Russia. For example, telemedicine can be used only for primary consultation without making a diagnosis and for further supervision of the patient after an in-person consultation, as well as for communication between healthcare professionals. Moreover, a large percentage of Russian population does not have proper internet and landline connection or does not have necessary skills and technical equipment to be able to fully benefit from digital health solutions.

However, size of the country, disparate population density and current overload of healthcare system due to COVID-19, make further growth of the digital health sector inevitable. This will require regulatory extension of permitted activities, further inclusion of the digital tools in the state medical insurance system and close cooperation between the market participants and regulatory authorities.

Top 5 legal issues to have on your radar

1. Medical Device Regulation

Digital health solution, depending on its functionality, can be seen as a medical device if the solution is used for prophylaxis, diagnostics, treatment and rehabilitation of diseases, monitoring of human's body condition or other medical purposes.

For example, a software is a medical device if it simultaneously (i) is designated for medical care, (ii) interprets certain data from registered medical devices, (iii) is not part of other medical device and (iv) is used to make a clinical decision. For example, a software for review of an anatomical 3D-model based on CT image is a medical device. At the same time, software for text or files exchange between a doctor and a patient is not.

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

In addition to regular data privacy and medical confidentiality regulations, Russia also has two types of uncommon local requirements.

First, companies collecting personal data of Russian nationals in Russia are required to initially record and to initially update or change personal data of such Russian nationals through a database physically located

in Russia. In practice, this usually means that (i) user account details, and (ii) data uploaded from medical devices to the cloud must be initially recorded on a Russian server.

Second, in order to lawfully store and otherwise process user medical data, companies usually need either (a) a state license for medical activities in Russia, or (b) consents for personal data processing in a special written form. Users must fill in their passport details and home address into the relevant consents and sign them with a personal 'wet' signature or a special e-signature used in accordance with local rules.

Digital health service providers usually find these requirements quite challenging, yet some companies apparently managed to fulfil them in practice.

3. Registration requirements for regulated activities?

Telemedicine is a form of medical activities and is therefore subject to the relevant licensing requirements.

Some digital health solutions must obtain additional authorizations such as radio frequency allocation or notification of the Russian Federal Security Service.

4. Liability

The liability of digital health providers depends on the type of their activities. Contractual liability, liability in tort (especially in case of infliction of harm to person's health or adverse effects), liability in accordance with the consumer protection legislation may arise.

In addition, there is an administrative and criminal liability in case of circulation of non-registered medical devices and provisions of medical services without a license.

5. Market access

Current circumstances related to COVID-19 crisis forced the market significantly increase the use of online tools. Providers of digital health solutions, especially of medical devices and medical services, and pharma and medical devices manufacturers may face various challenges connected to marketing and promotion as a part of market access strategy, such as:

- Robust regulations on both off-line and online advertising and active enforcement of these regulations. While developing the online marketing campaign, companies must take into account several restrictions, for instance, restrictions on advertising of medical devices the use of which requires special training, or use of obligatory disclaimers;
- Limited possibilities on interactions with healthcare professionals. During pandemics, these possibilities are narrower - offline visits to healthcare professionals and events dropped down to almost zero while online visits and webinars became the new normal. The companies must adapt to new circumstances and resolve ambiguous legal issues, such as necessity of mandatory reporting of online events and regulation of online visits.

[Back](#)

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