Bird & Bird

Mobile Health & Medical Apps

The Key Legal Issues

October 2022

Navigating the Legal Aspects of Mobile Health

The rapid convergence of digital technologies with healthcare, life sciences and IT companies in recent years, further accelerated by the pandemic, has radically transformed the way in which we receive healthcare.

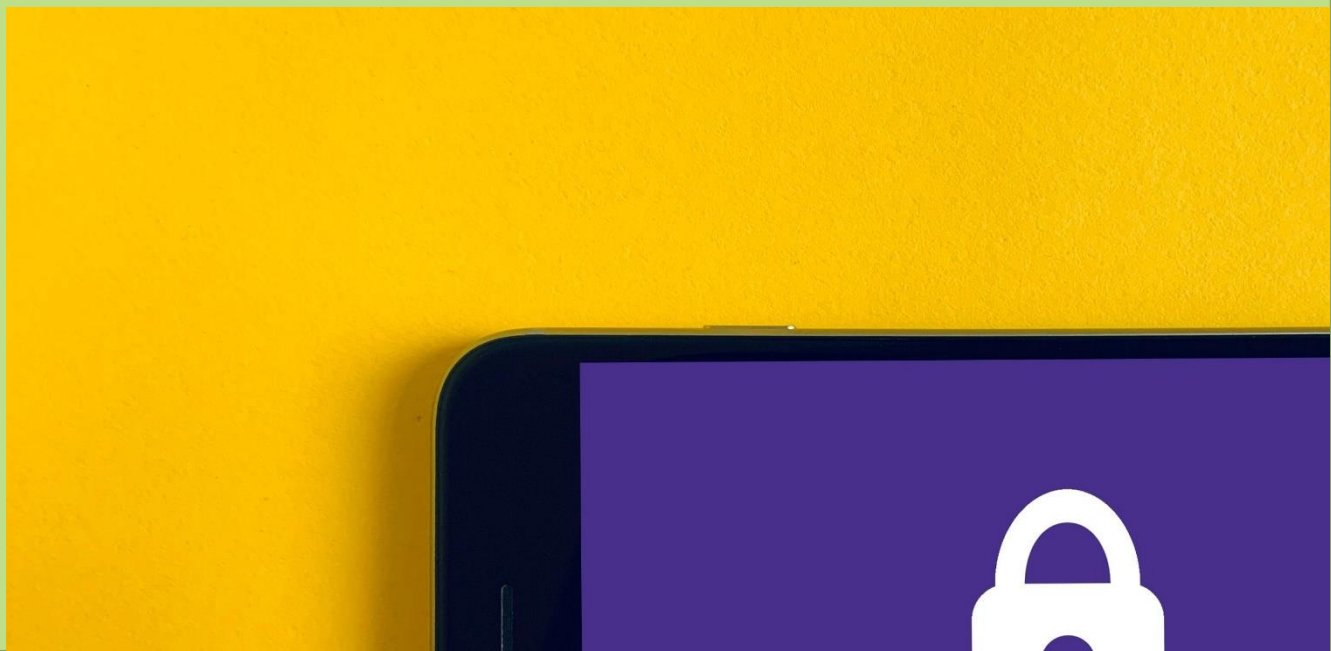
From medical apps, drug-dose calculators, AI diagnostic tools to blood glucose monitors, medical software and electronic personal health records, digital health plays an integral part of how we prevent, treat and manage health conditions.

The result is a patient-centric approach, focused on data-driven solutions and personalised delivery of therapies (pharmaceutical or device/app-based) using information technologies which enable a seamless flow of communication between patients, providers, researchers and health information services.

Mobile health continues to be a major focus not only for the life sciences and healthcare industry, but also for tech, telecoms and retail clients who are expanding their products and services into this space. With our market-leading expertise in the life sciences, healthcare and tech industries, we can help you navigate the complex and exciting opportunities that arise from digital health with a particular focus on **regulation, patient privacy, procurement, technology contracting, funding, reimbursement, investment and IP issues.**

"Bird & Bird is a key resource for international clients operating in the healthcare sector, including those seeking advice on matters related to e-health, IP, IT, and data protection."

Legal 500, 2022



Regulating m-health

Technological developments often push the boundaries of existing regulatory frameworks, and this is very much the case with recent advances in the use of mobile health / fitness / lifestyle apps. Some will be regulated as medical devices, some as in vitro diagnostic devices, and others will fall outside the scope of these definitions.

This fast moving and rapidly expanding area is transforming healthcare and constantly posing new challenges. Moreover, the EU market has recently seen wide-ranging changes to the overall medical devices and in vitro diagnostics regulatory framework with the new EU Regulations recently coming into force. In the UK, the implications of Brexit have already resulted in some divergence in the regulatory framework, with a completely new medical devices regulatory landscape expected to be implemented in the UK during the latter part of 2023.

The legislation and guidance governing m-health apps often need detailed consideration against the technical features of the app in order to clarify their applicability and identify the key regulatory hurdles.

Developers of such apps need to understand fully all the implications of the appropriate regulatory framework, and need answers to a range of important questions, not only in order to plan their product launch, but at all times during the further development of the app's features:

- Which regulatory framework(s) will the product fall within? How will the product be qualified and classified?
- What requirements must be met if the product is to be placed on the market as a medical device or an *in vitro* diagnostic product (conformity assessment, CE/UKCA marking, labelling, marking, etc.)?
- What particular national requirements might apply in the various jurisdictions of interest? Are there additional local standards to be complied with where apps are supplied to national health providers?
- Will the app work in connection with monitoring or other devices, which may themselves be regulated products?
- How does the current European Commission and UK m-health Guidance apply in practice?
- What is the product liability / consumer protection position?
- Is there any case law which needs to be taken into consideration?
- What advertising and promotion will be permitted?
- What supervision / surveillance of the marketed product will be carried out?
- What might the future hold under the new EU Regulations governing devices and *in vitro* diagnostics, and how should developers navigate the uncertain regulatory waters in the UK?

As the technology is moving faster than the rules governing it, these sorts of issues may give rise to significant debate over the correct interpretation of the rules and guidance. Questions may require clarification with national regulatory authorities. It is also crucial to make sure that any contracts put in place fully recognise, and properly address, the various medical app-specific regulatory issues that may arise.

Market access, reimbursement, commercial issues & m-health

Issues relating to reimbursement have been identified as some of the main obstacles for the implementation of m-health, together with the challenge of insufficient market access for web entrepreneurs.

In most Member States of the European Union public healthcare providers are obliged to publicly tender all services, goods and devices provided to patients. While this may require the healthcare provider to follow a regulated procurement process, this does not necessarily present a significant obstacle. With the introduction of new processes, in particular the "innovation partnerships" procedure, public sector providers are now able to purchase more innovative solutions using a flexible approach.

Innovation partnerships (IPs) enable healthcare providers to enter into research and development projects with suppliers and purchase the outcome of the project within a single procurement process. By using this procedure, healthcare providers could select a number of suppliers (or 'partners') to form part of the IP to maximise innovation and increase the possibility of developing a successful and innovative solution.

As part of the procurement process, thought should be given to the terms on which bidders are required to contract, including licensing and ownership of intellectual property rights (IPR), testing and acceptance, security and liability.

Developers of mobile apps need to be aware of the key issues of market access, reimbursement & other commercial aspects, including:

- Under which conditions is a mobile app reimbursable by public sickness funds and other public health care entities?
- Where can notifications for public tenders be found? (For the most part, such opportunities can be found in the Official Journal of the European Union.)
- To what extent can public contracts be negotiated? Note that not all procedures enable face to face interaction with the procuring healthcare provider.
- What are the most common pitfalls for developers of mobile apps in procurement proceedings?
- How can public funding for mobile apps be obtained and what are the risks?
- What are your rights if a public authority does not tender an interesting contract in violation of procurement law?
- How will the European Commission's initiatives on mobile health influence the market? Who will own the IPR in the m-health application? Should pre-existing IPR and specifically developed IPR be distinguished in this regard?
- How will IPR be licensed and on what basis (e.g., term of the licence, number of users, territorial scope, ability to sub-licence, licence restrictions etc.)?
- Will the m-health application be tested and accepted prior to go-live? If so, what is the process?
- What warranties and indemnities are the developer required to provide in relation to the m-health application?
- What are the parties' respective liability positions under the contract (including in respect of data breaches etc.)?
- If a mobile app is regulated as a medical device or *in vitro* diagnostic device, who is responsible for the various regulatory obligations (e.g., obtaining market authorisation, post-market surveillance etc.)?
- Is any element of the solution being subcontracted (e.g., to a hosting provider)? If so, how can obligations and liabilities be backed off in any subcontract?
- Are service levels required? If so, what are the consequences if these are missed?
- Are there any cross-border implications?

While the majority of contracts for life sciences related products in Europe are already undertaken with public entities, the opportunities and risks of mobile health solutions are as yet often unknown to developers of m-health. Advice on procurement and commercial law is therefore crucial for a successful implementation on the market.

Data Protection & m-health

The testing and delivery of health-related services through mobile devices typically involves the collection and use of personal data about m-health service users. The processing of lifestyle and wellbeing data, information relating to human physiology, patterns of behaviour and development, as well as geolocation data is strictly regulated under data protection legislation. Health data, in particular, enjoys a very high level of protection under data protection regimes throughout Europe and the UK. Complying with the variety of rules across Europe and the UK, and moving that data around the world (for instance to overseas datacentres and analysts), is not always straightforward. Finally, the use of data during the development or "beta testing" of an m-health service risks counting as regulated "research".

If m-health offerings are to be data protection compliant, app developers, device manufacturers, m-health service providers as well as advertisers working in the m-health environment, all need a shared understanding of data protection rules and of their respective obligations. Key questions to consider include:

- What are the respective legal responsibilities of developers, publishers, advertisers and device manufacturers?
- What type of data is covered by data protection legislation? When is data truly anonymous?
- How does data protection law regulate the collection and use of information about health and lifestyle?
- When is consent required and how should it be collected in the m-health environment?
- What information needs to be provided to App users about the use of their data? How and when should this information be supplied?
- Can data m-health data be shared with third parties?
- On what basis is transferring of m-health data to third countries or international organisations permitted?
- What security measures need to be put in place?
- What is meant by “privacy by design” and why is it important in the m-health space?
- Is the transfer of m-health data to the US for back up and technical support permitted? What are the restrictions and how can they be addressed?
- How does the EU data protection legal framework provided by the General Data Protection Regulation affect m-health?

M-health is a hot topic. The potential value of m-health data for ‘Big Data’ projects puts m-health at the centre of current debates regarding the balance to be struck between personal privacy and the public health benefits that Big Data can deliver. Data Protection Authorities keep a critical eye on developments in this area, emphasising the potential impact of poorly regulated m-health on personal dignity and fundamental rights. A data protection compliant offering is therefore essential for any successful m-health related product and service on the EU and UK markets.

About Bird & Bird

We are a truly international firm, supporting organisations being changed by the digital world or those leading that change. We combine exceptional legal expertise with deep sector knowledge and refreshingly creative thinking, to help clients realise their ambitions.

Everything is connected.

With more than 1,400 lawyers and legal practitioners across a worldwide network of 31 offices, Bird & Bird delivers expertise across a full range of legal services. Our specialisms include advice on commercial, corporate, EU and competition, intellectual property, dispute resolution, employment, finance and real estate matters.

The key to our success is our constantly evolving sector-focused approach. Our clients build their businesses on technology and intangible assets, and operate in regulated markets. To better meet their needs we have developed deep industry understanding of key sectors, including automotive, aviation & defence, energy & utilities, financial services, life sciences & healthcare, retail & consumer, media, entertainment & sport and tech & comms.

- What this means for you:
- Expertise in the legal and regulatory framework relating to each sector.
- A more practical, commercial approach, supported by advisors with decades of experience working in the relevant industries.

International reach

We have offices in key business centres across the globe:

Europe: Amsterdam, Bratislava, Brussels, Budapest, Copenhagen, Dublin, Düsseldorf, Frankfurt, The Hague, Hamburg, Helsinki, London, Luxembourg, Lyon, Madrid, Milan, Munich, Paris, Prague, Rome, Stockholm and Warsaw.

Middle East, Asia-Pacific & North Africa: Abu Dhabi, Beijing, Dubai, Hong Kong, Shanghai, Singapore, Sydney and Casablanca.

North America: San Francisco.

We were the first truly international firm with a presence in Denmark, Finland and Sweden, ideally positioning us to support companies looking to invest in the Nordic region.

In 2018 we opened a representative office in San Francisco to better support our US-based clients, and our recently opened Casablanca office enables us to further support our clients in Africa.

In addition, focus groups for Africa, India, Japan and Russia, and extensive cooperation agreements with local firms increase our reach to other key jurisdictions.

Excellence in client service

We operate as one truly international partnership: our goals, accounting and profit pool are all shared, as is our commitment to providing our clients with advice from the right lawyers, in the right locations. Our open and engaged business culture allows us to configure quickly and effectively to the commercial pressures and opportunities faced by our clients.

Bird and Bird "has a strong international network, and its people are really knowledgeable and great to work with."

Chambers Global, 2022

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