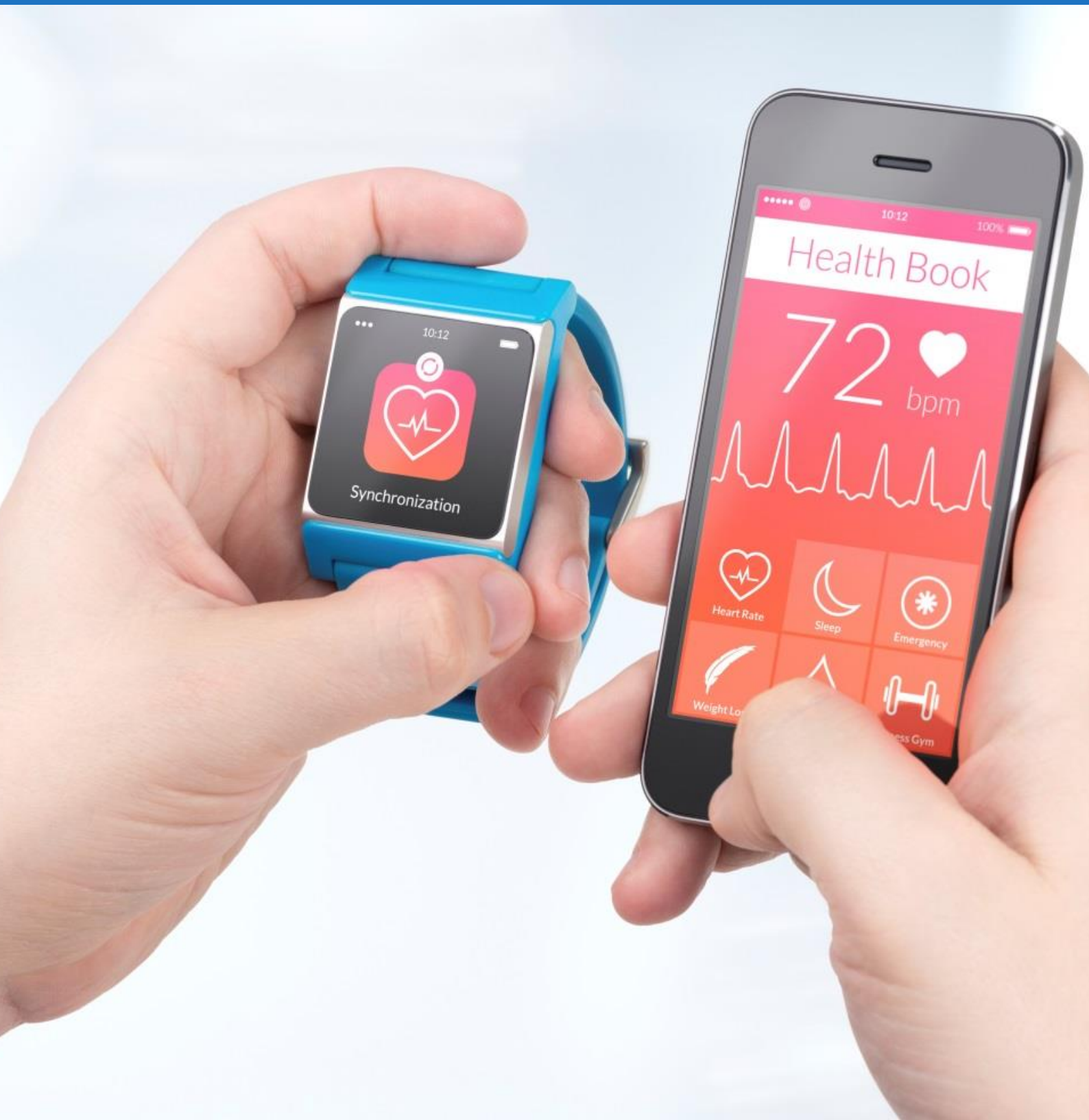
Bird & Bird & Mobile Health

M-health & Medical Apps: The Key Legal Issues



Navigating the Legal Aspects of Mobile Health

Lifestyle, healthcare and medical apps are developing at a fast rate. From fitness apps and cardiometers to drug-dose calculators and glycaemia controllers, m-health is increasingly becoming a part of our daily lives.

It is also affecting healthcare professionals in their day-to-day practices. M-health provides a platform for pharmaceutical companies, the medical devices industry and IT developers and service providers to converge.

We help our clients navigate the issues raised by the rise of m-health with a particular focus on procurement, regulatory, patient privacy, technology contracting, funding, reimbursement, investment and IP issues.

"Handles significant cross-border work, with particular expertise in e-health and m-health work."

Chambers & Partners 2016

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, others as in vitro diagnostic devices, while yet 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, wide-ranging changes to the overall medical devices and in vitro diagnostics regulatory framework are expected once new EU Regulations come into force.

The legislation and guidance governing m-health apps often need detailed consideration, to clarify their applicability and identify the key regulatory hurdles.

Developers of such apps need to fully understand all the implications of the appropriate regulatory framework, and need answers to a range of important questions in order to plan their product launch:

- Which regulatory framework 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 marking etc.)?
- What particular national requirements might apply in the various jurisdictions of interest?
- Will the app work in connection with monitoring or other devices, which may themselves be regulated products?
- How does the current European Commission 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?

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

Questions of reimbursement have been identified as one of the main obstacles for the implementation of m-health, together with the question of insufficient market access for web entrepreneurs. Both issues can be tackled by a precise and compliant application of procurement law. In most Member States of the European Union actors of the public health care systems are obliged to publicly tender all services, goods and devices provided to patients. Through advice on social and procurement law, access to those regulated markets can be achieved.

In addition, innovative proceedings like pre-commercial procurement and public procurement of innovative solutions can be well-suited vehicles to adapt allegedly bureaucratic structures of public entities to the special nature of m-health applications.

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 actors of public health care systems?
- Where can notifications for public tenders be found?
- What information can be obtained from contract notifications?
- Can public contracts be negotiated?
- What are PCP and PPI?
- 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 to do if damage claims arise in publicly tendered contracts?
- How to react if a public authority does not tender an interesting contract in violation of procurement law?
- How will the European Commissions' initiatives on mobile health influence the market?

The majority of contracts on life science related products in Europe are already concluded with public entities. The related chances and benefits on mobile health solution are often unknown to developers of m-health, yet. Advice on procurement and commercial law is therefore crucial for a successful implementation on the market.

Data Protection & m-health

The delivery of health related services through mobile devices invariably involves the collection and use of personal data about m-health services users. The processing of lifestyle and well-being data, information relating to human physiology, patterns of behaviour and development, as well as geolocation data, which is often collected in the course of providing m-health services is strictly regulated under data protection legislation. Health data in particular enjoys a very high level of protection under data protection regimes throughout Europe. Understanding what the rules require across Europe is not always straightforward.

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?
- 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 will the new 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 debate 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 market.

Why Bird & Bird?

We have worked with all of the 15 top-selling pharma corporations in the US market and over 50% of the largest pharma and biotech companies worldwide

240
Lawyers globally dedicated to life sciences and healthcare

28
offices in 18 countries

No.1
Ranked for Life Sciences work in across the major legal guides including Chambers & Partners and Legal 500

Lawyers with significant experience from working in industry or regulatory organisations

Our world leading multidisciplinary Life Sciences and Healthcare team can advise you on every aspect of the business cycle of your product or service. We guide you through incorporation, development, financing, exploitation of IP and portfolio management, regulatory and contractual issues, clinical trials and securing marketing authorisation. Finally, we are leaders in high value litigation of pharmaceutical and life science patents, with a long and successful track record, and have the largest patent litigation group in Europe.

We use Bird & Bird's expertise in IT, IP and strategic partnerships to help our clients deliver smarter healthcare for the 21st century. Our focus on e-health projects, strategic partnerships, outsourcings and large-scale networked IT is complemented by the ecommerce, data protection compliance and regulatory work that Bird & Bird undertakes for clients operating in the healthcare sector, as well as its medical devices work and its world-renowned life-sciences and pharmaceuticals work.

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"Unquestionably one of the most comprehensive and sophisticated Life Sciences practices in the market."

Chambers & Partners, 2016

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