Simmons & Simmons

Digital Health

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Overview

Digital health, in its various forms, is becoming an increasingly high profile area. From (i) mobile smartphone applications and "wearable" technology which we use to track our sleeping patterns or fitness to (ii) technology which is used to diagnose and treat illnesses or injuries to (iii) social media communities supporting patients suffering from the same conditions; it is ubiquitous and here to stay.

Organisations used to operating along traditional sector lines (such as telecommunications companies, pharmaceutical companies and software developers) and within recognised industry norms are broadening their service offerings to tap into the seemingly limitless potential offered by digital health. This expansion is not without risk. Organisations will need to consider new and unfamiliar issues to ensure that risks associated with this expansion are mitigated appropriately.

Through our multi-disciplinary team of lawyers operating throughout our international network, we can offer organisations what they need: the best business-focused legal advice in a fast-moving sector. Set out below are a number of issues that organisations operating in the digital health sector are likely to need to consider.

The issues

Investment and consolidation

Irrespective of scale, any company seeking to grow in the digital health space is likely, from time to time, to need to raise fresh capital. Funding can range from growth, venture or patient capital, through initial public offerings (IPOs) and other large and complex international debt and equity offerings to bank financings, securitisations and bespoke equity derivatives transactions. This requirement presents attractive opportunities for financial and strategic investors.

An issue that often arises with scale is the desire or need to acquire outside skills or assets (including intangible assets such as intellectual property) through inorganic growth, particularly through mergers & acquisitions, joint ventures or strategic investment, in order to remain competitive. The resulting appetite for deals provides exciting growth and exit opportunities for start-ups and financial investors across an increasingly international market place.

Digital health technologies are starting to transform the provision of healthcare and the management of long-term healthcare conditions, fuel rising patient and consumer expectations and yield major returns for investors. This is placing significant pressures on all life sciences and healthcare companies and investors to pursue investment and M&A opportunities in this area. As in other areas where digitalisation is transforming existing provision, strategic investors are increasingly seeking to access the technologies being developed by very early-stage companies. This can present a wide range of options for monetising these companies' intellectual property and data. It can, however, also present immediate challenges in structuring investments in these companies, and ensuring that these companies are identifying and protecting their intellectual property and complying with data protection laws and other regulatory requirements.

Data protection and "big data"

Digital health almost invariably involves the accessing, use or storage of personal information in some shape or form. This in turn gives rise to potential data protection issues. The risk associated with "getting it wrong" on data protection is on the rise with the new EU Data Protection Regulation which enters into effect on 25 May 2018 and legal developments in this area outside the EU (such as new data protection law regimes in Asia). Ensuring data collection, use and transfers to third parties (including third parties overseas) are lawful and dealing with data security

incidents are key examples of the areas that organisations will need to consider.

Apps and web-based tools are increasingly the medium through which individuals are now choosing to understand and track their health and fitness. As mentioned above, via these apps and tools, substantial amounts of data (including personal data) is collected and processed. It will be important to ensure there are robust data centre arrangements in place to store that data, maintain it and back it up. Physical and electronic security issues will need to be addressed to protect that data from unauthorised access. Operational issues ensuring access, conditions and flexibility to allow for expansion (or contraction) within the data centre will need to be factored into any discussions to procure data centre services.

The collection and commercialisation of large quantities of data (often referred to as "big data") – whether personal information or otherwise – is another area requiring careful consideration. Decision support software and digitalisation in the supply chain, based on big data analysis, are possibly disruptive factors for business models in the pharma and med tech industry. Intellectual property and confidentiality issues, among others, need to be taken into account before engaging in these activities.

Intellectual property

Copyright protection is often the primary form of protection for digital health related apps and web-based tools. If a company is to utilise copyright protection, it is important that appropriate records are maintained to establish when, where and by whom any code is developed. Where code is developed by third parties commercial contracts will be required to transfer ownership of copyright in the code or to establish the existence of a suitable licensing arrangement. Some functional modules within software may be developed using open source software. If this is the case it is important to be aware of the licensing requirements under which such open source software is made available, as the terms may require public disclosure of all proprietary code, or prohibit the commercialisation of products incorporating that open source software code.

Many digital health products address technical issues in innovative ways and occasionally, patent protection may be available for such software-based products. This raises questions about the commercial value of filing for patent protection or whether it is better to rely upon keeping technical aspects confidential. As many patents are granted in the digital health field it may be advisable to undertake patent searches prior to significant investment into, and launch products to assess freedom to operate.

Just like any other commercial product, branding and brand protection is important to a product's success in the digital health field. Prior to launch, the availability of a desired trade mark should be checked and appropriate trade mark applications should be filed including, where appropriate for logos and icons for any apps which might be produced. Where a digital health product is web-based, domain names related to the product should also be secured.

Medicines and medical devices regulatory

The Medical Device Directive 93/42/EEC, the Active Implantable Medical Devices Directive 90/385/EEC and the In-vitro Diagnostic Medical Devices Directive 98/79/EEC all envisage standalone software and software incorporated into a medical device, as a possible medical device. Whether software is classified as a medical device will depend on a number of factors, such as whether the software performs an action on data, other than just storage, for the medical benefit of a patient. The European Commission has recently indicated that an app which uses signal data from an external source and processes that data into an ECG waveform for the benefit of diagnosing a patient, is a medical device.

Apps and software which are classified as medical devices will need to comply with the regulatory requirements for the approval of such products prior to their launch. The extent of these requirements varies depending on the category of medical device concerned.

The European Parliament recently adopted a comprehensive revision of European legislation of medical devices – the new Regulations on Medical Devices ("**MDR**") and on In Vitro Diagnostic Medical Devices ("**IVDR**") come into force in May 2017 with a transitional period of 3 and 5 years. Under the MDR software will be generally classified as an active medical device. The MDR and IVDR will place additional regulatory compliance obligations on manufacturers, distributors and healthcare specialists, including traceability requirements such as UDI labelling and an online public-access traceability database. As such, there may be increased impetus to share the risk of any actions connected to medical devices (e.g. product liability claims) up and down the supply chain. Manufacturers will be obliged to obtain product liability coverage proportionate to the risk class, type of device and size of the enterprise.

Product safety and security, and liability

A defect in devices used to provide health related services can cause a number of issues and product liability of the producer. Even if devices are not defective or no loss is suffered by anyone, devices which do not satisfy safety requirements under the general product safety directive

and/or product specific legislation can be subject to corrective actions including product recalls and (in certain jurisdictions) criminal sanctions. The technical requirements which need to be satisfied, the testing that needs to be carried out and technical documents that need to be retained for each device differ depending on the device, its function, or the materials and chemicals used in the device, and therefore need to be clearly understood before the product launch. Product liability cases and corrective actions can be expensive and could also damage the brand.

Supply chain management as well as the design of the device is the key in mitigating the risks associated with the product. Different obligations apply depending on where your business sits within the supply chain (such as a manufacturer, importer, distributor or retailer) and the location of your business (whether established within the EU). It is important to ensure compliance by other parties in the supply chain and enter into appropriate contractual arrangements.

Vigilance

Digital health apps and devices will need to bear in mind two key "vigilance" requirements: (i) vigilance of the performance of the app or device itself in order to identify any malfunction; and (ii) the app's or device's vigilance of the performance of a medicinal product or other device which is being used. In the case of (i), app or device manufacturers will need to have clear processes in place to ensure that any product malfunction is promptly identified and alerted to the manufacturer such that appropriate steps, such as recall of the device, can take place promptly. This type of vigilance will also be important to mitigate the risks of product liability actions in respect of malfunctioning apps or devices. In the case of (ii), app or device manufacturers will need to ensure that the relevant product has appropriate mechanisms in place to alert the manufacturer to any adverse event it identifies as a result of the functioning of a drug or another device which it may be monitoring, in order for the relevant drug or device manufacturer to be informed and the necessary vigilance reporting to be conducted.

Consumer regulatory

Provision of goods, services or digital content (including apps) to consumers online, telephone or via digital content (such as apps) is regulated by various consumer regulations. The requirements and the scope of their application differ depending on, for example, what is offered, to whom they are offered (including whether they are offered to 'vulnerable consumers' with mental or physical infirmity) and the medium used in the provision of the goods, services or content. Promotion of a specific foodstuff to promote health also requires consideration in light of health and nutrition regulations. In the UK, major reforms are in the pipeline, many of which concern consumer empowerment (for example, the introduction of new statutory civil remedies for consumers against misleading practices).

Careful consideration from a consumer law perspective would be necessary, for example in considering the business model for offering digital health products and services and in drafting the terms of supply and advertisement.

Social media

If a digital health app or device is considered to be a medical device, care will also need to be taken in considering its promotion through social media. Digital health providers will need to ensure that not only their own content complies with the requirements under the applicable law and self-regulations on advertising, but also that user generated content such as posts and commentary on the company's or products' social media page or webpage by members of the public comply with these requirements. For example, posts by members of the public on a social media page celebrating a product and making claims about its functions could put the company hosting the page in breach of these requirements.

What others say about us

- Their services and advice are timely, complete and accurate. **Chambers UK 2017**
- Well known for its excellent capabilities in the IP sector, which complements extensive experience of transactional, regulatory and competition matters. **Chambers Europe 2016**
- Clients say that Simmons & Simmons is "able to handle the most complex and largest disputes and transactions with masterful effectiveness", and "eager to offer solutions in difficult deal circumstances and deliver a high-quality product". **Chambers UK 2016**
- "Remarkable for the sheer number of leading lawyers with significant practices in the sector." **Chambers UK 2016**
- "We like their breadth of knowledge and resourceful practitioners." **Chambers UK 2016**

- Simmons & Simmons "provides excellent service and always delivers on time". **Legal500 2016**
- "Significant life sciences practice, characterised by the depth of its expertise." **Chambers UK 2015**

Our experience

Our lawyers' relevant experience includes advising :

- digital health company **Adherium** on a ground-breaking long-term supply and development agreement to supply its 'Smartinhaler'™ to AstraZeneca AB
- **Cegedim**, a provider of digital data flow management systems for healthcare companies, on various data protection compliance issues
- **Clinical Practice Research Datalink** in connection with the licensing of big data to an international pharmaceutical company for use in connection with clinical trials
- **GlaxoSmithKline** on a number of data protection projects, including in respect of:
  - International data transfers;
  - Data protection issues in the context of outsourcing and cloud computing transactions;
  - Disclosure of data relating to payments to healthcare professionals;
  - Social media monitoring
- the **UK Health and Social Care Information Centre** in relation to its strategic review of the Dr Foster Intelligence joint venture and disposal of its 50% stake
- the **UK Medicines and Healthcare Products Regulatory Agency** ("**MHRA**") on the procurement of a significant IT system from Accenture and Oracle and on the outsourcing of IT infrastructure and software development services to Accenture across two generations of outsourcing contracts
- **Private Healthcare Information Network** ("**PHIN**") on its set-up, funding and governance
- **Zephyr Health**, a provider of data analytics and data management solutions to healthcare companies, on data protection compliance issues in a number of EU countries
- **a Japanese digital health apps designer** on UK regulatory issues in relation to the commercialisation of a self-testing male fertility kit
- **a leading manufacturer and service provider** for medical diagnostics on R&D collaboration relating to telemedicine services, funded by the German Federal Ministry of Education and Research
- **a medical devices manufacturer** on liability and ethical aspects of a software tool to predict the mortality of patients with chronic medical conditions
- **a pharmaceutical and medical devices company** on product liability and classification relating to an international project for decision support software, based on IBM Watson
- **a life science company** on a licensing agreement relating to individually developed software for specific use in the life sciences sector
- **a leading pharmaceutical company** on regulatory, ethical and data protection relating to the establishment and operation of bio banks in Germany
- **a pharmaceutical company** on the implementation of a cloud – based data management system, involving cross-border data transfer aspects
- **a pharmaceutical company** on the development of an iPad application for cancer patients
- **a European medical imaging business** on multijurisdictional issues relating to online advertising and promotion
- **a Belgian pharmacy business** with regard to e-commerce of OTC products
- **the Dutch National Institute for Public Health and Environment (RIVM)**, an institute that carries out research for (among others) the Ministry of Health, on legal issues in respect of the content and operation of the Kiesbeter.nl portal
- **a top 10 global pharmaceutical company** on a range of social media campaigns for the local Arabic language market in the United Arab Emirates
- **a top 10 global pharmaceutical company** on digital agency agreements for roll out of social media and internet analytics based campaigns
- **a North American software provider** in contractual negotiations with a French public health authority on implementing the use of mobile technology to monitor patients
- **a US software provider** in relation to an a end-user licence agreement (EULA) relating to cardiology system software for a French end-user
- **a healthcare group** comprising 180 clinics in setting up an online communications platform for healthcare professionals and patients
- **French association of advertisers** – on its participation in the think tank/working group organised between the French Health Product Authority (ANSM) and other stakeholders for the creation of a Charter for the communication and the promotion of health products online
- **Australian manufacturer of products for the treatment of sleep disorders** - on the setting up of a Facebook page presenting a medical device
- **an international pharmaceutical company** on the structure of data flows and the applicable regulatory requirements on the implementation of a platform providing online assistance to patients during the course of their treatment
- **African Medical and Research Foundation** on a 10 month pilot to develop a multi-channel (SMS, USSD, IVR, mobile web, etc.) training and productivity mobile platform to be used by approximately 300 health workers in Kenya

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