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Digital Health Are you Ready?



Digital Health: Are You Ready?

The future of healthcare is more digital than ever. Radical technological disruptions and industry convergences are rapidly transforming the delivery of healthcare. It may be daunting to navigate the choppy legal and regulatory waters of “digital health”, especially if one is not ready.

We highlight some of the key issues.

DATA MONETISATION

- Can I obtain intellectual property protection over my algorithms, datasets, and databases?
- Are there restrictions on how I price my data?
- Do I have appropriate security measures in place to ensure that my data assets are secure from third parties?
- Can I collect personal data and export it out to an overseas server?
- I am considering entering into a data licensing agreement. Are there any laws that limit or prohibit my intended licensing agreement?
- I am looking to purchase patient data from hospitals and healthcare organisations. Will I be exposed to any regulatory risks?
- Do our agreements with outsources, cloud providers contain out-licence clauses pertaining to the data we own?
- The company I am licensing data to has wound up. How can I protect my shared data from being auctioned off by creditors?
- I have just purchased datasets from another company. How can I sanitise the data to minimise my exposure to liability?

DATA SHARING

- When will a person be considered to consent to data sharing?
- How do I seek consent if I want to use existing personal data for new purposes?
- Do I still need to seek consent from individuals if I aggregate and/or anonymise their personal data?
- How can I mitigate the cybersecurity risks associated with data sharing?
- I am a telemedicine provider. Am I responsible for keeping patient records in the event that I wind up?
- I am about to enter into a data sharing agreement. What are the key clauses I should look out for?
- Am I subject to additional healthcare specific regulations governing the protection of data?
- How can I protect my confidential or sensitive information in a data sharing agreement?
- How can I ensure that the data I have shared is returned to me at the end of a data sharing agreement?

DIGITAL PROMOTION TO CONSUMERS

- Can I use digital labels (such as QR codes) and direct my customers to my website for further information on indications for use?
- What information can I feature on my corporate websites? Can I promote a health product on social media or send promotional materials to my customers through electronic direct mail?
- What should I do in the event of mal advertising?
- Is the use of influencers or key opinion leaders allowed and if so, what are the disclosure requirements? What if I merely send them complimentary samples or hand out special but optional invitations to our events?
- How do we ensure that all user-generated content which our influencers publish about our products is owned by our company? Is our company responsible for what our influencers publish?
- Can I compare my product with another brand's product?
- Would advertising and promotion laws apply to products sold online by an off-shore seller to customers in the jurisdiction?

- Are there distance selling laws (e.g. cooling-off periods for online sales) I should be aware of?
- Are there any digital tax issues which apply to my company's e-commerce model, and if so, is the model tax efficient?

E-COMMERCE PLATFORMS

- Does my health product need to be registered before I sell them online?
- What licenses should I obtain before selling health products online?
- Do I have to register my e-commerce business?
- Are there specific e-commerce laws that I must comply with?
- I am planning to sell my health products on an international e-commerce website. Do I need to set up a local entity?
- Do any local laws apply to my e-commerce website model?
- What if the consumer enters my international site by being redirected via a local domain? Will that change the regulatory requirements?
- I am a brand owner. How can I guard against the sale counterfeit goods on e-commerce sites?
- An unauthorised party has used my brand on its e-commerce site or in its domain name. What can I do to take this website down?

INSURANCE/REIMBURSEMENT

- Are telemedicine consultations, prescriptions and treatments reimbursed by public health insurance policies?
- Are there laws preventing me from limiting or denying coverage of healthcare services delivered via telemedicine?

- Are there any laws requiring insurance providers to offer coverage for digital health services?

INTERACTIONS WITH HCP

- Can I promote my products to healthcare professionals over the Internet/social media?
- Can I hold an educational or scientific webinar for healthcare professionals to attend?
- Can I send an e-invite to participating healthcare professionals directly?
- I would like to offer refreshments to my participants – can I send them delivery meal vouchers?
- I have invited a few healthcare professionals to moderate and speak during my webinar – can I compensate them for their time and contribution?
- What about tokens of appreciation?
- Can I create a public social media page or group directed to healthcare professionals to increase engagement with key opinion leaders?
- Can I send gifts or donations to healthcare professionals as a show of support during COVID-19?

TELEHEALTH APPLICATIONS

- Do healthcare wearables need to be registered?
- Must I register my mobile medical application if it has real-time monitoring capabilities? What if it only provides educational information?
- Can I promote my healthcare application to the public and healthcare professionals?
- I do not provide healthcare services but would like to host a third party healthcare application – am I subject to any licensing requirements?

- I would like to collaborate with other industry players on a Super App to include other services such as health insurance services apart from health services. Must we register our Super App and if so, who should do it?

- Are there special precautions I should note when handling healthcare data? Can I collect aggregated data from my users?
- What should I do in the event of a data breach or cybersecurity threat?
- How do I protect the software and branding for my application? What about the design of my wearable?

TELEMEDICINE

- Are virtual medical consultations, whether local or cross-border, permissible?
- How should I deliver prescribed medicine to patients remotely?
- Are digital medical certificates permissible?
- Can I collaborate with individual healthcare professionals? Who would be responsible if the patient receives incorrect medication?
- Do I need to have a physical clinic?
- I am a tech company supporting telemedicine services on my mobile platform – do I need to be licensed?
- My application offers virtual consultations with doctors alongside various self-help health and wellness functions – am I subject to any additional licensing requirements?
- If I collaborate with a licensed retail pharmacist to fulfill the prescriptions issued by the doctors will my services still be licensed?

With over five decades of experience in advising healthcare companies, our Firm has been there for clients on the cusp of innovation, and accompanied them through journeys of technological advancement. We continue to keep our fingers on the pulse to help clients stay ahead of the curve; anticipate risks; and capitalize on opportunities. Our extensive footprint and established connections with regulatory bodies also enables us to guide our clients through the panoply of issues locally, regionally and globally.

Baker McKenzie helps clients overcome the challenges of competing in the global economy.

We solve complex legal problems across borders and practice areas. Our unique culture, developed over 70 years, enables our 13,000 people to understand local markets and navigate multiple jurisdictions, working together as trusted colleagues and friends to instill confidence in our clients.

Contact Us

We would be happy to have a chat with you to see how we can assist your business with these issues.



Andy Leck

Principal

Tel: +65 6434 2525
Fax: +65 6337 5100
andy.leck@bakermckenzie.com



Ren Jun Lim

Principal

Tel: +65 6434 2721
Fax: +65 6337 5100
ren.jun.lim@bakermckenzie.com

Baker McKenzie Wong & Leow
8 Marina Boulevard
#05-01 Marina Bay Financial Centre,
Tower 1
Singapore 018981
Tel: +65 6338 1888
Fax: +66 6337 5100

bakermckenzie.com

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