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Digital Health II: *Are You Ready?*

Ren Jun Lim | Baker McKenzie Wong & Leow



Agenda

- 1 Conducting Teleconsultations
- 2 Prescribing Medicines Remotely
- 3 Healthcare Wearables & Software Applications



Ren Jun Lim

Principal,
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Questions

1. Click the Q&A button at the bottom of the screen
2. Type your question in the text field
3. Click send



1

Conducting Teleconsultations

Licensing Regime

- National Telemedicine Guidelines
 - No licence required
- Healthcare Services Act
 - Services-based licensing regime



Key Issues

- Standard of care
- Operational readiness
- Technology & equipment



Potential Pitfalls

- Cross-border consultations
- Tortious liability
- Personal data protection



2

Prescribing Medicines Remotely

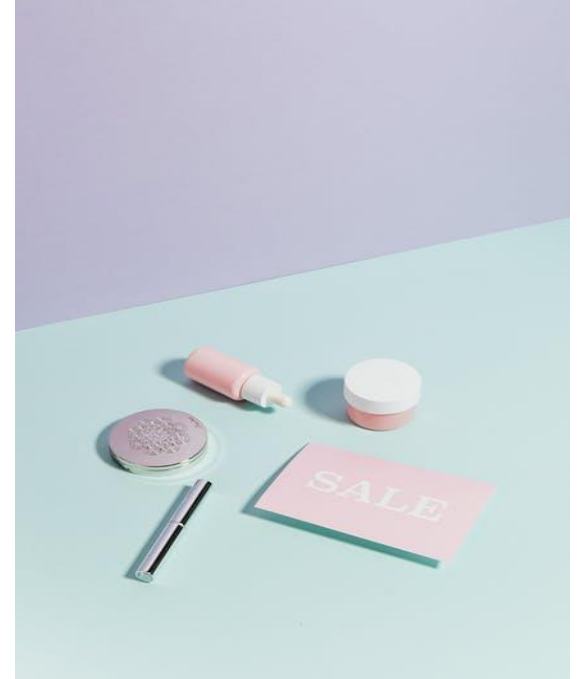
E-Pharmacy

- Registration / licensing
- Supply, storage & delivery of medicines
- Technological infrastructure



E-Labelling

- Permissible for all products?
- Regulatory approval?
- Acceptable format?
- Online videos?
- Asking users for personal information?



3

Healthcare Wearables & Software Applications

Telehealth Product Types

Tele-collaboration



Tele-treatment



Tele-monitoring



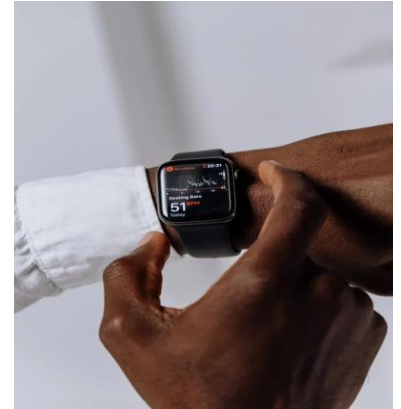
Tele-support



Regulation as A Wellness Device

As a general rule, a Telehealth product **intended for medical purposes** such as investigation, detection, diagnosis, monitoring, treatment or management of any medical condition, disease, anatomy or physiological process; will be classified as a medical device subject to regulatory controls by HSA.

- Function and purpose
- Use of a clarification statement
- But is that enough?



Regulation As A Medical Device

- Depends on marketing, intended purposes, etc.
- Risk-based approach to regulation (impact of failure)



Medical Device Regulatory Obligations

- Do I need to register my product?
- What licence(s) to apply for?
- Post-market duties



Potential Pitfalls

- Counterfeits & lookalikes
- Cybersecurity & personal data protection



3

Q & A

Questions

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Contact us



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