

Digital Health Regulation

Challenges and opportunities

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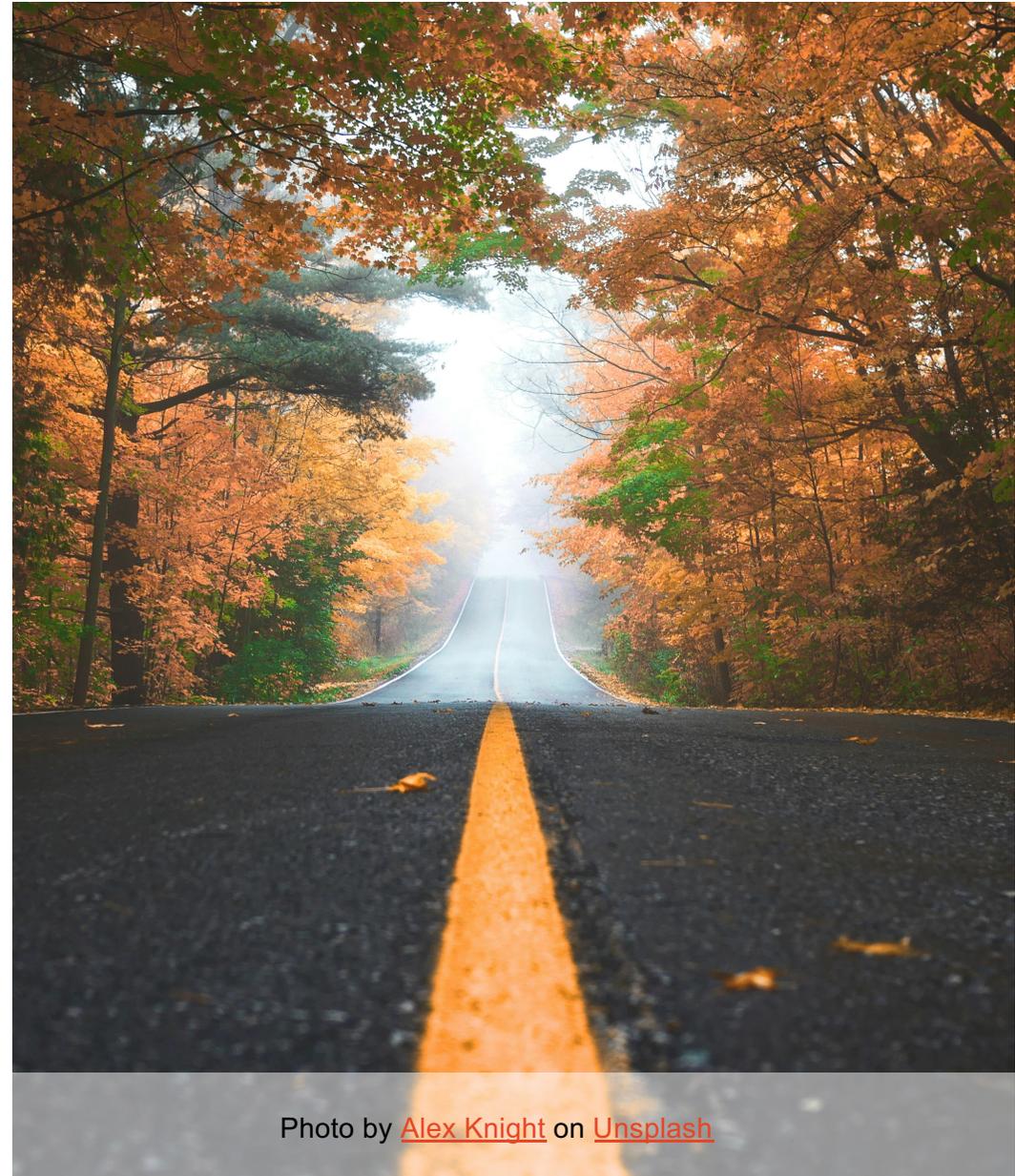
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Why regulate?

- To ensure health products and services are safe and high quality
- To identify and mitigate risks
- To build and maintain public trust in health care and health services



Why regulate digital health?

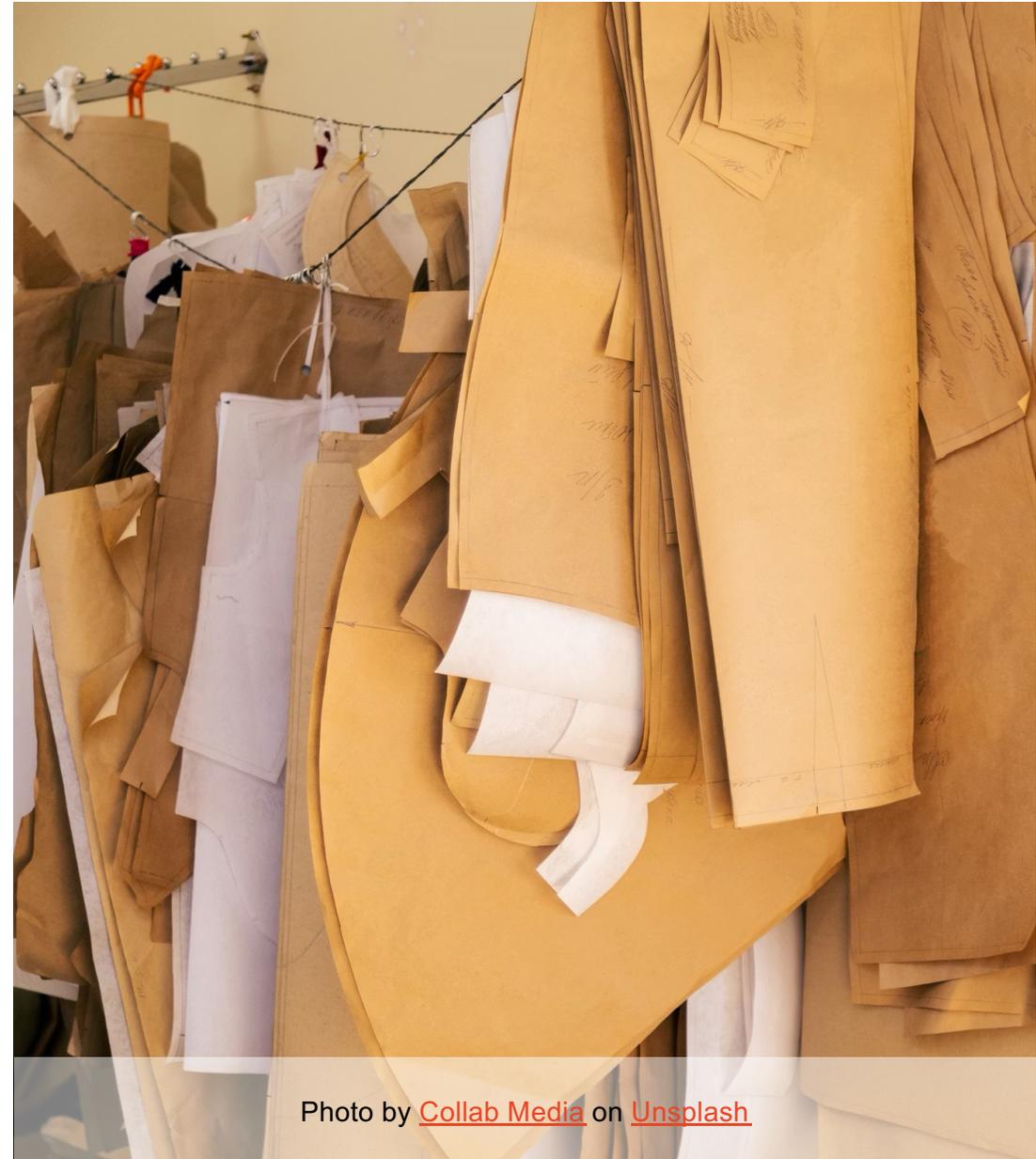
- Growing market
- Public trust/stakeholder trust
- Link between reimbursement and regulation
- Reimbursement models influence equitable access



Our Approach

Understand digital health regulation in Australia by:

- Undertaking a review of policy documents (Mar – Jun 2022)
- Interviewing stakeholders (Jul – Sep 2022):
 - 5 Policymakers
 - 6 HTA experts
 - 3 digital health literacy experts
 - 1 health professional
 - 1 consumer



What does the digital health regulatory landscape look like in Australia?

**Fragmented
health
system =
fragmented
digital health
system**

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Digital Health Technologies challenging HTA and quality assurance systems

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**Digital
health that is
regulated is
a tiny portion
of digital
health used**

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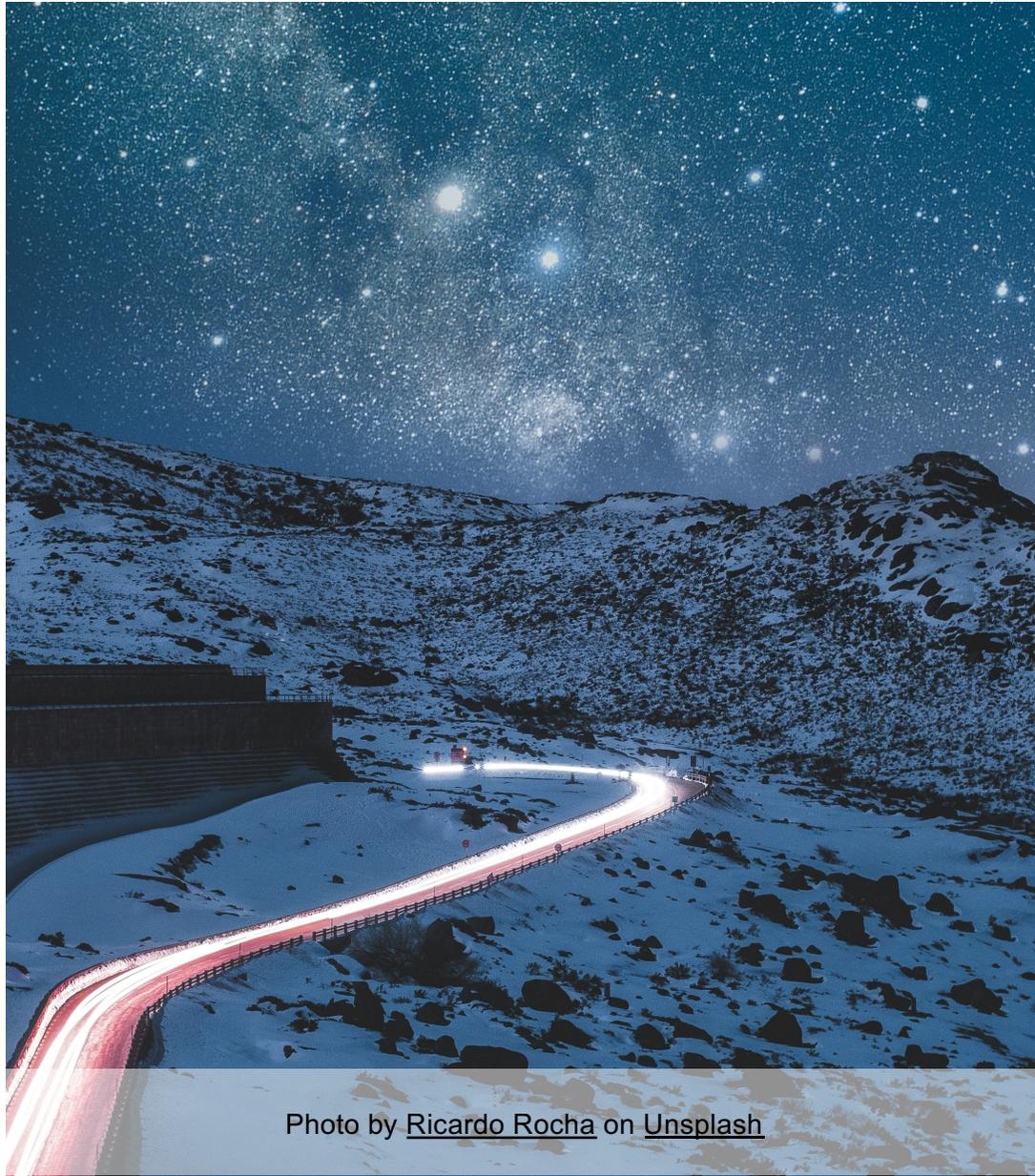


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Key Takeaways

Only a tiny portion of digital health in the market is regulated.

This is a problem because:

- Stakeholders assume someone has checked the safety, efficacy and quality of what is in the market.
- Reimbursement models are linked to regulation
- The cost of digital health access is increasingly being borne by consumers