Digital health in Israel – Opportunities and regulatory aspects

The global digital health market is expanding and is expected to reach revenues of $600bn by 2024 (McKinsey, *The Economist*, 2 December 2020).

In Israel, digital health is thriving and attracting international attention, and in particular increasingly substantial investments. This is due to Israel's unique entrepreneurial ecosystem that includes:

- Over 500 active digital health companies
- 4 HMOs (sick funds) which include all Israeli residents, and well-known hospitals, some of which have access to over 25 years of digital medical data
- Local VCs and accelerators
- Local and global medical device and pharma companies
- Government initiated national programme to accelerate digital health
- World class academic institutions, including the Weizmann Institute and the Technion
- Fifth place in the world for patents per capita

In this article we outline the main regulatory aspects to consider when handling digital health in Israel.

ISRAELI HEALTH CARE SYSTEM – LEGAL AND PRACTICAL BACKGROUND

According to the National Health Insurance Law, every Israeli resident is entitled to be a member of one of the four Israeli HMOs and to healthcare services included in the national 'health basket', which is updated yearly, without charge.

The National Insurance Institute charges a mandatory health tax, and transfers it to the HMOs, according to the portion of the population comprised by their membership. The Ministry of Health (MOH) covers the rest of the HMOs' budgets.

Most Israelis are also registered for supplementary health plans provided by the HMOs, and some are insured by private insurance policies.

Eleven hospitals in Israel are owned by the Israeli government, including Sheba that was announced as one of the ten best hospitals in the world according to *Newsweek*; nine hospitals that are owned by Clalit, the largest HMO; six hospitals that are owned by Assuta, a subsidiary of Maccabi, a big HMO; and certain privately owned hospitals and medical centres.

Israel's hospitals and HMOs initiate and encourage innovation, in part by leveraging their access to high-quality digital medical data.

MAIN REGULATORY ASPECTS

Clinical trials

With access to vast digital medical data, relatively low costs and internationally recognised professional excellence, clinical trials in Israel are considered particularly cost efficient and effective. Clinical trials are conducted in Israel in accordance with the Public Health Regulations (Clinical Trials in Humans) 1980 (the 'Clinical Trial Regulations'), and the MOH clinical trials procedures. Generally, the MOH's procedures follow international guidelines with respect to clinical trials.

Clinical trials require the approval of the hospital's Helsinki Committee, the approval of the director of the hospital, and in certain cases, the approval of MOH Helsinki Committee and the approval of the director-general of the MOH.

Privacy

Data protection and privacy are governed by the Protection of Privacy Law 1981 (Privacy Law), regulations, sector-specific laws and directives.

Subject to certain exceptions, personal data may be used only for the purpose for which it is provided by the data subject. Additional uses, including secondary use of medical data, are generally subject to data subject consent.

In addition to the above, secondary use of medical data and cloud computing of medical data are regulated in MOH procedures which outline the requirements for access to medical data and for processing it, as well as contractual requirements from a cloud computing service.

Data security requirements are more granular than the General Data Protection Regulation (GDPR)'s more general requirements. On the other hand, similar to the GDPR, the Privacy Law and regulations include data export restrictions and notice requirements. Due to the 'adequacy decision' from the European Commission, personal data from the EU can be transferred to Israel without the need for additional measures.

Medical device and pharma

Medical devices are required to undergo a registration procedure by an Israeli resident or an Israeli corporate in the MOH registry according to the Medical Device Law 2012. Israeli registration is typically expedited when the medical device has already been registered and marketed in a recognised country (Austria, Australia, Italy, Iceland, Ireland, the US, Belgium, UK, Germany, Denmark, the Netherlands, Greece, Norway, New Zealand, Spain, Portugal, Finland, France, Canada, Sweden, Switzerland).

Similarly, pharmaceutical products are regulated by the Pharmacists Ordinance and are required to undergo registration by an Israeli resident or a corporate in the MOH drug registry. Subject to certain exceptions, in order to register foreign pharmaceutical products, they must be approved by regulatory authorities in a recognised country (US, Canada, EU country (prior to 2004), Switzerland, Norway, Iceland, Australia, New Zealand and Japan). Pharmaceutical products registered by the FDA and EMA and marketed in recognised countries can expect expedient processing of registration.

To summarise, the Israeli healthcare ecosystem is known for its entrepreneurial spirit, high-tech skills, as well as by its quick and results-oriented attitude.

Please feel free to contact us with any questions regarding digital health in Israel:

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