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Book Review:
Jelena Madir (Ed.), *Healthtech Law and Regulation*

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ABSTRACT

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While telemedicine and M Health Apps have been credited with increasing life expectancy and quality of life, the Coronavirus pandemic has illustrated many challenges in the efficient application of healthcare technology. For example, digitisation has been a successful addition to healthcare services but has also brought new and unforeseen problems such as outdated anti-virus or anti-malware software issues. *Healthtech Law and Regulation* addresses these new challenges, providing an overview of international treaties and European Union (EU) directives and regulations, as well as domestic European and United States (US) legislation; identifying gaps in existing laws and policies. Though primarily covering EU and US health law and regulation, this edited collection will be of interest to regulators and researchers in all jurisdictions.

The first section of the book deals with the existing laws and policies in both Europe and the US. In Chapter 2, Tom Chakraborti examines data protection laws, focusing on the General Data Protection Regulation (GDPR) as the main source of data protection regulation in the EU. In Chapter 3, Alison Dennis explores domestic EU and United Kingdom (UK) copyright protection legislation and the regulation of digital medical device advertising. In Chapter 4, Mathew DeNoncour examines existing intellectual property protections for healthtech in the US. In Chapter 5, Annabelle Bruyndonckx, Vladimir Murovec and Michael Bulckaert examine EU laws and regulations on safety issues and product liability.

The second section of the book demonstrates the importance of technologies in the healthcare sector through the example of the use of artificial intelligence in diagnosis, therapy, and research. In Chapter 6, Roland Wiring identifies different regulatory challenges associated with artificial intelligence (AI), such as the absence of specific legal instruments to regulate its use and

development and the limited legal framework for establishing liability and copyright protection. He also addresses the question of whether AI can lead to liability for negligence, in the context of German tort law. In Chapter 7, Emeka Chukwu addresses the issue of misidentification of patients, highlighting the importance of health care identification processes and providing illustration through case studies in the US, India, Estonia, Sierra Leone and Nigeria. In Chapter 8, Jelena Madir analyses possible applications of blockchain technology in the health sector, while in Chapter 9 Jane Thomason and Nichola Cooper examine the opportunities and challenges of emerging markets for healthcare technologies, and multi-stockholder and institutional collaboration between government and non-governmental organisations.

Healthtech business is the focus of the final section of the book. Stephen Tainsh illustrates the financial requirements of start-up businesses and addresses the importance of institutional investors to ensure company growth in Chapter 10. Simonetta Giordano, Frederique Potin and Sharon Cohen discuss the possibilities of collaboration structures between Healthtech companies, academic institutions, research institutions, industries, and charities in Chapter 11. Patrick Parkin considers the role of public procurement law in the purchase of health tech goods and services in Chapter 12. In Chapter 13, Trix Mulder examines the regulatory challenges for better use of E Health and M Health, suggesting that reform is necessary. In chapter 14, Richard Cheng and Barrett Robin focus on the challenges, such as infrastructure technology, financial backing and expertise, in providing telemedicine regulation in US health care system. In the final chapter, Donald Combs criticises 'fact-based skill' such as memorisation and clinical clerkships and recommends the need for specialized training in contemporary and practical skills for health professionals.

The limited coverage in the book of the application and implementation of machine learning (ML) and AI in healthcare systems is disappointing. A more comprehensive discussion on medical negligence and professional indemnity relating to ML and AI would have been valuable. It is also frustrating that the book did not provide better coverage of the technology issues arising in developing countries. Nevertheless, *Healthtech Law and Regulation* makes an important contribution in the field of medical technology industry. It will be an invaluable resource for regulators and researchers looking to address the challenges produced by the technological advancement.