EXTENDED CONTENTS

List of editor and contributors xiv
Preface xvii
Glossary of key terms xix
Table of cases xxvi
Table of statutes xxix

1. USING TECHNOLOGY TO DELIVER HEALTH SERVICES
   Jelena Madir
   A. INTRODUCTION 1.01
   B. TELEHEALTH AND TELEMEDICINE 1.06
      1. What are telehealth and telemedicine? 1.06
      2. The promise of telemedicine 1.11
      3. Challenges to the wider use of telemedicine 1.22
   C. MHEALTH 1.24
   D. CHALLENGES TO THE SCALE-UP OF NEW TECHNOLOGIES IN HEALTHCARE 1.35
      1. Lack of clarity about evidence 1.36
      2. Regulation of digital products 1.46
      3. Slow procurement 1.49
      4. Partial interoperability 1.53
      5. Unclear data security standards 1.55
      6. Limited change management and digital skills 1.58
   E. FUTURE OF HEALTHCARE 1.63
   F. WHAT CAN HEALTHTECH LEARN FROM FINTECH? 1.73
      1. Big data 1.73
      2. Disruption by tech companies 1.77
      3. Democratisation of data 1.80
   G. CONCLUSION 1.84

PART I REGULATION AND GOVERNANCE OF HEALTHTECH

2. DATA PROTECTION, INFORMATION SECURITY AND INTERNATIONAL DATA TRANSFERS:
   A PRACTICAL GUIDE THROUGH KEY PROVISIONS AND COMPLIANCE TOOLS
   Tom Chakraborti
   A. INTRODUCTION 2.01
   B. MEDICAL DEVICE LEGISLATION 2.03
      1. Medical device definition 2.03
      2. Qualification as a medical device 2.05
   C. DATA PROTECTION LEGISLATION 2.17
      1. General Data Protection Regulation (GDPR) 2.17
   D. DATA PROTECTION – KEY CONCEPTS 2.23
      1. What is personal data? 2.23
      2. What is data processing? 2.27
      3. Who are data subjects and data controllers? 2.33
      4. Who is a data processor? 2.38
      5. Data processing principles 2.42
      6. Processing of sensitive personal data 2.57
      7. Cookies 2.59
## EXTENDED CONTENTS

8. Fair processing notices and consent forms 2.64  
9. Data subject rights 2.66  
10. Enforcement by supervisory authorities 2.67  

**E. MARKETING ACTIVITIES** 2.70  
**F. SECURITY** 2.78  
1. GDPR and security requirements 2.78  
2. Implementing security measures in practice 2.81  
3. Role of the Data Protection Officer 2.93  

**G. INTERNATIONAL DATA TRANSFERS** 2.101  
**H. CONCLUSION** 2.107  

### 3. HEALTHCARE TECHNOLOGY REGULATION IN THE EU AND THE UK: FROM MEDICAL DEVICES TO INTELLECTUAL PROPERTY AND ADVERTISING  
*Alison Dennis*

**A. LEGISLATION OVERVIEW** 3.01  
**B. EU REGULATION OF MEDICAL DEVICES** 3.04  
1. Applicability of the Medical Device Regulation and the *In Vitro* Medical Device Regulation to software 3.05  
2. Economic operators and software 3.29  
3. Software updates 3.33  
**C. INTELLECTUAL PROPERTY RIGHTS PROTECTION** 3.43  
1. Overview of available protections 3.44  
2. Copyright 3.46  
3. Databases 3.53  
4. Patents 3.61  
5. Confidentiality 3.62  
**D. ADVERTISING DIGITAL HEALTH MEDICAL DEVICES** 3.64  
1. Overview of laws on advertising of medical devices 3.64  
2. Comparative advertising in the EU and the UK 3.72  
3. Enforcement 3.74  
4. Distance selling and medical devices 3.76  
**E. PROVIDING MEDICAL SERVICES ACROSS COUNTRY BORDERS VIA DIGITAL HEALTH DEVICES (TELEMEDICINE)** 3.77  
**F. CONCLUSION** 3.86  

### 4. HEALTHCARE TECHNOLOGY REGULATION IN THE US  
*Matthew DeNoncour*

**A. INTRODUCTION** 4.01  
**B. HEALTHCARE-SPECIFIC LAWS** 4.02  
1. Health Information (HIPAA) 4.03  
2. Financial restrictions on referrals 4.41  
3. Telehealth 4.64  
4. Corporate Practice of Medicine Doctrine 4.68  
5. Regulation of medical devices 4.69  
**C. INTELLECTUAL PROPERTY RIGHTS AND PROTECTIONS** 4.83  
1. Copyright 4.84  
2. Patent 4.87  
3. Trade secret 4.90  
**D. ADVERTISING** 4.92  
1. Commercial advertising 4.93  
2. Patient endorsements and testimonials 4.98  
3. Medical device misbranding 4.99  
**E. GENERAL (NON-HEALTHCARE RELATED) DATA PRIVACY STATUTES** 4.101  
1. Federal data privacy 4.101  
2. California Consumer Privacy Act 4.103  
**F. CONCLUSION** 4.108
5. PRODUCT LIABILITY: COMPLIANCE AND SAFETY ISSUES
Annabelle Bruyndonckx, Vladimir Murovec and Michael Bulckaert
A. INTRODUCTION 5.01
B. ADDRESSING PRODUCT LIABILITY UNDER THE EUROPEAN PRODUCT LIABILITY DIRECTIVE 5.04
2. Application of the Product Liability Directive: key concepts 5.08
3. The victim in action 5.23
4. Producers in action 5.24
5. Product Liability Directive Regime: evaluation and relevance in HealthTech 5.30
C. ADDRESSING PRODUCT LIABILITY RISKS IN HEALTHTECH PRODUCTS COVERED BY THE MEDICAL DEVICES REGULATION 5.36
1. Introduction: product qualification and product safety 5.36
2. HealthTech and liability under the Medical Devices Regulation 5.41
3. Cross-checking Medical Devices Regulation and Product Liability Directive concepts 5.50
4. Addressing safety in HealthTech products covered by the Medical Devices Regulation 5.66
D. CONCLUSION 5.79

PART II FRONTIER TECHNOLOGIES AND MARKETS

6. ARTIFICIAL INTELLIGENCE IN HEALTHCARE
Roland Wiring
A. INTRODUCTION 6.01
B. DEFINING AI 6.04
1. General and narrow AI 6.05
2. Examples of AI technology 6.10
C. ARTIFICIAL INTELLIGENCE USE CASES IN HEALTHCARE 6.21
1. Impact and potential of AI in healthcare 6.22
2. Diagnostics 6.27
3. Therapeutic options 6.34
4. Clinical trials 6.39
5. Surgery robotics 6.43
D. LEGAL CHALLENGES TO THE USE OF ARTIFICIAL INTELLIGENCE IN HEALTHCARE 6.49
1. Regulatory 6.50
2. Liability for the use of AI 6.62
3. Intellectual property 6.77
4. Reimbursement 6.82
E. CONCLUSION 6.85

7. THE ROLE OF DIGITAL ID IN HEALTHCARE
Emeka Chukwu
A. INTRODUCTION 7.01
B. PATIENT IDENTIFICATION SYSTEMS – OVERVIEW 7.05
1. National ID scheme 7.06
2. Health institution ID scheme 7.08
3. Master Patient Index 7.11
4. Other functional patient ID schemes 7.14
C. PATIENT ID: COUNTRY STUDIES 7.18
1. United States 7.19
2. Estonia 7.21
3. Sierra Leone 7.28
4. India 7.30
5. Nigeria 7.34
D. PATIENT ID: DESIGN CONSIDERATIONS 7.37
1. Enrolment 7.38
2. Storage 7.41
3. Authentication 7.44
4. Governance, privacy, security and trust 7.48
6. What types of investments are attractive to business angels and institutional investors? 10.26

C. TRADING VEHICLES 10.30
   1. Limited company 10.31
   2. Advantages of a company 10.33
   3. Disadvantages of a company 10.36

D. COMPANIES: VOTING AND ECONOMIC RIGHTS 10.38
   1. What rules apply to voting and economic rights of companies’ shareholders? 10.38
   2. Who controls a company and how is that control exercised? 10.42

E. LEGAL ISSUES ARISING FROM AN INVESTMENT IN A COMPANY BY AN INSTITUTIONAL INVESTOR 10.53
   1. What process will govern the investment? 10.55
   2. Term Sheet 10.56
   3. Due diligence 10.57
   4. Key transaction documents 10.60

F. CONCLUSION 10.78

11. COLLABORATION AND PARTNERSHIP STRUCTURES IN HEALTHTECH
    Simonetta Giordano, Frédérique Potin and Sharon Cohen
    A. INTRODUCTION 11.01
    B. OVERVIEW OF THE EXISTING COLLABORATION STRUCTURES AND TOOLS ON THE HEALTHTECH MARKET 11.06
       1. Product development process 11.10
       2. Main collaboration structures depending on the development phase of the product 11.12
       3. Observation on the current HealthTech markets: joint venture is the winner 11.30
    C. SUCCESS FACTORS FOR A CONTRACTUAL JOINT VENTURE WITH A HEALTHTECH COMPANY: OVERCOMING PITFALLS 11.38
       1. Governance of the joint venture 11.45
       2. Rights and responsibilities in the joint venture 11.58
       3. Intellectual property issues in joint ventures – some key issues 11.96
    D. CONCLUSION 11.150

12. PROCUREMENT CONSIDERATIONS FOR THE ACQUISITION OF HEALTHTECH PRODUCTS
    Patrick Parkin
    A. INTRODUCTION 12.01
    B. NHS AND COMMERCIAL SECTOR PROCUREMENT 12.07
       1. NHS procurement of HealthTech 12.07
       2. Contrast to commercial sector procurement 12.11
       3. The pace of change and accessing the latest innovations 12.14
    C. KEY PRINCIPLES OF PUBLIC PROCUREMENT LAW IN THE UK 12.16
       1. What are the consequences of breaching public procurement law? 12.21
       2. Which entities are governed by public procurement law? 12.28
       3. When does procurement law apply? 12.40
       4. The available procurement procedures 12.53
    D. CONTRACT MODELS 12.78
       1. Framework agreements 12.78
       2. Dynamic purchasing systems 12.84
    E. EXEMPTIONS FROM THE NEED TO CONDUCT A REGULATED TENDER PROCESS 12.86
       1. Exemption 1: Competition is absent for technical reasons 12.87
       2. Exemption 2: The protection of exclusive rights, including intellectual property rights 12.88
    F. CONCLUSION 12.90

13. THE IMPACT OF THE EUROPEAN MEDICAL DEVICE REGULATIONS ON THE DEVELOPMENT AND USE OF MHEALTH APPS IN EUROPE
    Trix Mulder
    A. INTRODUCTION 13.01
    B. BACKGROUND OF THE MEDICAL DEVICE REGULATION IN EUROPE 13.03

xi
### EXTENDED CONTENTS

5. Anticipatory approach to risk management 15.31  
6. Proprietary technology 15.33  

**E. EMERGING DIGITAL TECHNOLOGIES WILL TRANSFORM THE PRACTICE OF FUTURE HEALTHCARE PROFESSIONALS**
1. Information and artificial intelligence 15.35  
2. Implications for clinical practice 15.42  
3. The educational challenge 15.49  
4. Healthcare as a caring human enterprise 15.51  

**F. ESSENTIAL KNOWLEDGE AND SKILLS FOR THE HEALTHCARE PROFESSIONALS OF THE FUTURE** 15.53  

**G. CONCLUSION** 15.55  

*Index* 399