THE LAW AND REGULATION OF MEDICINES AND MEDICAL DEVICES

SECOND EDITION

EDITED BY

PETER FELDSCHREIBER

OXFORD

The Law and Regulation of Medicines and Medical Devices

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Second Edition

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Foreword

I am delighted to be asked to supplement my Foreword to the First Edition with a new Foreword to this magnificent, and substantially expanded and updated, Second Edition, save that, twelve years on, I can no longer subscribe myself as 'Queens Bench Division', though I am keeping in touch with litigation by sitting from time to time in the Commercial Court and as an arbitrator! When I wrote the first Foreword, at the invitation of the learned Editor as I was one of the few judges who had dabbled in the new field (as referred to in Chapter 9 now twenty years ago), I described the new work as an exciting addition to the law library. I could have described it as radical, in drawing together the threads of medico-pharmaceutical law for the first time in one place. But, twelve years on, I must now describe this work as more than radical, rather as revolutionary, for it constitutes the consolidation of a new jurisprudence, just at the time it is desperately needed. What timing! As I write this Foreword, we are in continuing lockdown, and the 'new normal' is inevitably going to involve a dramatic increase, first in the need for analysis of legal and regulatory problems and solutions, and then, I am sure, in litigation, as researchers, pharmacologists, doctors, regulators, lawyers, and in due course judges address the ongoing impact of Covid, both in the pharmaceutical field and in the development and resolution of post-Covid disputes. Looking at the breadth and depth of its coverage, this book is not just a useful but a vital tool. Its in-depth analyses and its up-to-date assessments will be invaluable, and I welcome it to the bookshelves and to the front bench.

Sir Michael Burton GBE

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List of Abbreviations

AAVA	adeno-associated virus
ABPI	Association of the British Pharmaceutical Industry
ACD	Appraisal Consultation Document
ACMD	Advisory Council on the Misuse of Drugs
ADE	adverse drug event
ADHD	attention deficient deficit hyperactivity disorder
ADR	adverse drug reaction
AI	artificial intelligence
AIFA	Italian Medicines Agency
AIMD	Directive 90/385/EEC regarding active implantable medical devices
ALS	amyotrophic lateral sclerosis
ARBS	angiotensin receptor blockers
ARMD	adverse reaction to metal wear debris
ATMP	advanced therapy medicinal products
ATPS	adenosine triphosphate
CAR-T	Chimeric Antigen Receptor T cells
CBD	cannabidiol
CBPMs	cannabis-based products for medicinal use in humans
C-CASA	Columbia-Classification Algorithm for Suicide Assessment
CDs	controlled drugs
CGRP	calcitonin gene related peptide
CHM	Commission on Human Medicines
CHMP	Committee for Medicinal Products for Human Use/Committee for Human and Medicinal Products
CHO	Chinese hamster ovary
CI	confidence interval
CIOMS	Council for International Organizations of Medical Sciences
CJEU	Court of Justice of the European Union
CMA	Competition and Markets Authority
CMDh	Co-ordination Group for Mutual Recognition and Decentralised Procedures
CML	chronic myeloid leukaemia
CMO	Chief Medical Officer for England
CMS	Concerned Member States
COMP	Committee for Orphan Medicinal Products
COPD	chronic obstructive pulmonary disease
CPA	Consumer Protection Act 1987
CPAP	continuous positive airway pressure
CPR	Civil Procedure Rules
CPRD	Clinical Practice Research Datalink

CPS	Crown Prosecution Service
CRA	Consumer Rights Act 2015
CRISPR	clustered regularly interspaced short palindromic repeats
CSD	Committee on Safety of Drugs
CSM	Committee on the Safety of Medicines
C-SSRS	Columbia-Suicide Severity Rating Scale
CTA	Clinical Trial Authorisation
CTIS	Clinical Trials Information System
CTR	Clinical Trials Regulations
CTS	common technical specifications
DBS	Disclosure and Barring Service
DEA	Devices Expert Advisory Committee
DFLU	Drugs and Firearms Licensing Unit
DH	dexmedetomidine hydrochloride
DHSC	Department of Health and Social Care
DMF	dimethylfumarate
DPA	Deferred Prosecution Agreement
DPP	Director of Public Prosecutions
DSUR	Development Safety Update Report
EA	Enterprise Act 2002
EAG	Expert Advisory Group
ECDD	Expert Committee on Drug Dependence
ECHR	European Convention on Human Rights
ECJ	European Court of Justice
ECtHR	European Court of Human Rights
EEA	European Economic Area
EMA	European Medicines Agency
EMEA	European Medicines Evaluation Agency
ENCePP	European Network of Centres for Pharmacoepidemiology and Pharmacovigilance
EP	European Patent
EPC 2000	European Patent Convention 2000
EPO	European Patent Office
EPO	erythropoietin
ERG	Evidence Research Group
ERG	Evidence Review Group
EU IVDR	Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU
EUMDR	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
EUTM	European Union Trade mark
FAD	Final Appraisal Document
FDA	Food and Drug Administration (USA)
FEV	forced expiratory volume
FSA	Food Standards Agency

GBH	grievous bodily harm
GcMAF	Globulin component Macrophage Activating Factor
GCP	glucosamine-containing product
GCP	good clinical practice
GDPR	General Data Protection Regulation
GLO	group litigation order
GMA	global marketing authorisation
GMC	General Medical Council
GMP	good manufacturing practice
GPDR	General Practice Research Database
GPSR	General Product Safety Regulations 2005
GSK	GlaxoSmithKline
HBV	hepatitis B virus
HCV	hepatitis C virus
HIV	human immunodeficiency virus
HMRs	Human Medicines Regulations 2012
HRA	Human Rights Act 1998
HRT	hormone replacement therapy
HST	Highly Specialised Technology
HTA	Health Technology Assessment
ICER	incremental cost-effectiveness ratio
ICH	International Conference on Harmonisation
ICO	Information Commissioner's Office
ICRS	individual case safety reports
Ig	immunoglobulin
IMI	Innovative Medicines Initiative
IMP	investigational medicinal products
INN	international non-proprietary name
IP	intellectual property
IPO	Intellectual Property Office
ISSCR	International Society for Stem Cell Research
IVD	in vitro diagnostic devices
IVDD	Directive 98/79/EC regarding in vitro diagnostic medical devices
IVF	*in vitro* fertilisation
LA	licensing authority
LEA	law enforcement agency
LPP	legal professional privilege
MA	marketing authorisation
MA(IMP)	manufacturer's authorisation for investigational medicinal products
MAOIs	mono-amine oxidase inhibitors
MDA	Misuse of Drugs Act 1971
MDD	Directive 93/42/EEC regarding medical devices
MDEG	Medical Devices Expert Group
MDRS	Misuse of Drugs Regulations 2001
MedRA	Medical Dictionary for Regulatory Activities
MEF	monoethyl fumurate esters
MHRA	Medicines and Healthcare products Regulatory Agency
MLA	Mutual Legal Assistance

MoM	Metal on Metal
mRNA	messenger RNA
MS	multiple sclerosis
NAS	new active substances
NCA	National Crime Agency
NDS	National Drugs Control System
NIBSC	National Institute for Biological Standards and Control
NICE	National Institute for Health and Care Excellence
NIH	National Institutes of Health
NIHR	National Institute for Health Research
NRG	Name Review Group
OTC	over-the-counter
PACE	Police and Criminal Evidence Act 1984
PAGB	Pharmaceutical Association of Great Britain
PCR	polymerase chain reaction
PCT	Patent Cooperation Treaty
PDCO	Paediatric Committee
PDUFA	Prescriptions Drug User Fee Act
PhVWP	Pharmacovigilance Working Party
PIL	patient information leaflet
PIP	Paediatric Investigation Plan
PMCPA	Prescription Medicines Code of Practice Authority
PMDA	Pharmaceutical and Medical Devices Agency (Japan)
PML	progressive multifocal leukodystrophy
POA	Prosecution of Offences Act
POCA	Proceeds of Crime Act 2002
POM	prescription-only medicines
PPE	Personal Protective Equipment
PREP	Public Readiness and Emergency Preparedness
PSA	Psychoactive Substances Act 2016
PSMFs	pharmacovigilance system master files
PSURS	Periodic Safety Update Reports
PUMA	paediatric use marketing authorisation
QALY	quality adjusted life year
QPPV	qualified person responsible for pharmacovigilance
RCT	randomised controlled trials
RMP	Risk Management Plan
RMS	reporting Member State
RNA	ribonucleic acid
RUI	released under investigation
SARs	Suspicious Activity Reports
SFO	Serious Fraud Office
SLS-COPD	Salford Lung Study in chronic obstructive pulmonary disease
SMEs	small and medium-sized enterprises
SPARCL	Stroke Prevention by Aggressive Reduction in Cholesterol Levels
SPC	Summary of Product Characteristics
SPC	supplementary protection certificate
SSP	Serious Shortage Protocol

SUSARs	serious unexpected suspected adverse reactions
SWAN	syndromes without a name
TALENs	transcription activator-like effector nucleases
TFEU	Treaty on the Functioning of the European Union
THC	tetrahydrocannabinol
TM	trade mark
TNF	tumour necrosis factor
TRIPS	(Agreement on) Trade-Related Aspects of Intellectual Property Rights
UKCA	UK Conformity Assessed
UKIPO	UK Intellectual Property Office
UK MDR	the Medical Devices Regulations 2002 (SI 2002/618, as amended)
UKPDS	UK Prospective Diabetes Study
UMC	Uppsala Monitoring Centre
VERICC	Values, Ethics and Rationing in Critical Care Task Force
VIE	vacuum insulated evaporator
WAMD	wet age-related macular degeneration
WHO	World Health Organization
WIPO	World Intellectual Property Organization

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