

Legal Aspects of Medicine

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Note

Healthcare practice and knowledge are constantly changing and developing as new research and treatments, changes in procedures, drugs and equipment become available.

The author and publishers have, as far as is possible, taken care to confirm that the information complies with the latest standards of practice and legislation.

Legal Aspects of Medicine

2nd Edition

by

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Foreword to the first edition

There are several reasons why the law on medicines has become increasingly complicated over the last few years. The creation of a European drug regulatory system (the European Medicines Agency) and the extension of prescribing privileges (and responsibilities) to wider groups of health professionals are only part of the story. Public and professional revulsion over the activities of the late Dr Shipman (who was responsible for poisoning over 200 of his patients), concerns about the increasing use of drugs for recreational purposes, and worries about the extent to which avoidable errors in prescribing lead to serious harm, have all played a role in the way our laws have been – and continue to be – shaped. Professor Dimond's easy and accessible synthesis of the UK's current legal framework for medicines is both appropriate and timely. It will be an essential work of reference for all of us who work in healthcare.

*Professor Sir Michael Rawlins
National Institute for Health and Clinical Excellence, London WC1
August 2005*

Preface to the first edition

Like the other books in this series, this monograph follows the publication of a series of articles in the *British Journal of Nursing* on the law relating to medicines. Those articles, revised and updated, form the basis of a concise publication covering the main concerns which arise in the law relating to medicines in the NHS and private sector.

This book is intended for all health professionals who are likely to be involved in the dispensing, administration, prescribing or supply of medication, whether in hospitals or in the community. It may also be of assistance to others, such as health service managers, patient groups and their representatives, lecturers and clinical supervisors.

Each chapter uses a situation to illustrate the relevant laws so that the law can be explained in a practical jargon-free way. The basic facts of the legal system are briefly set out in the first chapter. The book does not pretend to be encyclopaedic in its coverage; rather, it is intended to introduce readers to the basic principles which apply and the sources of law, so that they can, by following up the further reading and web sites provided, add to their knowledge. Changes in the statutory provisions and new cases will require some amendments over time. The NHS Plan (Department of Health 2000) envisaged that the old demarcations will be shattered and nurses, midwives and therapists would be able to take on a wider range of clinical tasks, including running clinics and discharging patients and pharmacists will be able to take on a new role as they shift away from being paid mainly for dispensing of individual prescriptions towards rewarding overall service. As a consequence, roles in relation to the supply and prescribing of medications and in the role of the hospital and the community pharmacist have changed ever more rapidly over recent years, and this will ultimately have a profound influence on the care of the patient and the organisation of healthcare. This book will provide a baseline on which readers can develop their knowledge and understanding of the law relating to medicines.

Preface to the second edition

Six years have now elapsed since this book was first published and many changes have taken place in the context of medicines supply administration and prescription; many a consequence of the 4th Shipman Inquiry Report. This new edition tracks these developments and also notes the changing legal context: The Mental Capacity Act 2005 implemented in 2007 has filled the gap on decision making on behalf of the mentally incapacitated adult; the Equality Act 2010 has brought the anti-discrimination legislation into one statute; new regulations cover herbal and homeopathic medicines. Within the NHS a revolution is taking place: the Health and Social Care Bill making its way through Parliament will, if enacted, fundamentally change the relationships of GPs and their consortia with the NHS Trusts and private sector providers. Pharmacists are finding that their advisory role is increasing. It is hoped that this book will continue to provide a foundation upon which all those health professions involved in the supply, administration or prescribing of medicines can build their knowledge.

Acknowledgements

Once again I am extremely grateful for the thoroughness and care with which Bette Griffiths has prepared the indexes and read the proofs for the first edition and thank her for her help. I would also like to pay tribute to the support and help provided to me by Helen Scott during her years as editor of the *British Journal of Nursing* in which publication this book took root. Her high standards, awareness, sensitivity and compassion served the journal, its contributors and readers superbly over many years and will be invaluable in her return to nursing. It is to Helen that I dedicate this book.

Glossary

Accusatorial	A system of court proceedings where the two sides contest the issue (contrast with <i>inquisitorial</i>)
Act	Of Parliament, <i>statute</i>
Action	Legal proceedings
Actionable <i>per se</i>	A court action where the claimant does not have to show loss, <i>damage</i> or harm to obtain compensation eg an action for <i>trespass to the person</i>
<i>Actus reus</i>	The essential element of a crime which must be proved to secure a conviction, as opposed to the mental state of the accused (<i>mens rea</i>)
Adversaria	The approach adopted in an accusatorial system
Advocate	A person who pleads for another: the person could be paid and professional, such as a <i>barrister</i> or <i>solicitor</i> , or might be a lay advocate either paid or unpaid; a witness is not an advocate
Affidavit	A statement given under oath
Alternative	Methods to resolve a dispute without going to court, such as dispute mediation resolution
Appellate court	A court which hears appeals from lower courts, e.g. Court of Appeal and House of Lords
Approved	A social worker qualified for the purposes of the Mental social worker Health Act
Arrestable	An offence defined in section 24 of the Police and Criminal offence Evidence Act 1984 which gives to the citizen the power of arrest in certain circumstances without a warrant
Assault	A threat of unlawful contact (see <i>Trespass to the person</i>)
Barrister	A lawyer qualified to take a case in court
Battery	An unlawful touching (see <i>Trespass to the person</i>)
Bench	The <i>magistrates</i> , Justice of the Peace
Bolam Test	The test laid down by Judge McNair in the case of <i>Bolam v. Friern HMC</i> on the standard of care expected of a professional in cases of alleged <i>negligence</i>

<i>Bona fide</i>	In good faith
Breach	Breaking, usually of a legal duty
Burden of proof	The duty of a party to litigation to establish the facts, or in criminal proceedings the duty of the prosecution to establish both the <i>actus reus</i> and the <i>mens rea</i>
Case citation	The reference to an earlier reported case made possible because of the reference system, e.g. 1981 1 All ER 267 means the first volume of the All England Reports for 1981 at page 267, which is the reference for the case of <i>Whitehouse v. Jordan</i> , where <i>Whitehouse</i> is the plaintiff, <i>Jordan</i> the defendant and 'v' stands for versus, i.e. against. Other law reports include: AC Appeals Court QB Queens Bench Division WLR Weekly Law Reports
Cause of action	The facts that entitle a person to sue
Certiorari	An action taken to challenge an administrative or judicial decision (literally: to make more certain)
Civil action	Proceedings brought in the civil courts
Civil wrong	An act or omission which can be pursued in the civil courts by the person who has suffered the wrong (see <i>Torts</i>)
Claimant	The person bringing a civil action (originally <i>plaintiff</i>)
Committal	Hearings before the magistrates to decide if a person proceedings should be sent for <i>trial</i> in the crown court
Common law	Law derived from the decisions of judges, case law, judge made law
Conditional fees	A system whereby client and lawyer can agree that payment of fees is dependent upon the outcome of the court action; also known as 'no win, no fee'
Criminal courts	Courts such as magistrates' and crown courts hearing criminal prosecutions
Constructive	Knowledge which can be obtained from the circumstances knowledge
Continuous	The length of service which an employee must have served service to be entitled to receive certain statutory or contractual rights

Contract	An agreement enforceable in law
Contract for services	An agreement, enforceable in law, whereby one party provides services, not being employment, in return for payment or other consideration from the other
Contract of service	A contract for employment
Coroner	A person appointed to hold an inquiry (inquest) into a death in unexpected or unusual circumstances
Cross	Questions asked of a witness by the lawyer for the opposing examination side: leading questions can be asked
Criminal wrong	An act or omission which can be pursued in the criminal courts
Damage	Harm which has occurred
Damages	A sum of money awarded by a court as compensation for a tort or breach of contract
Declaration	A ruling by the court, setting out the legal situation
Disclosure	Documents made available to the other party
Dissenting	A judge who disagrees with the decision of the majority of judgment judges
Distinguished	The rules of precedent require judges to follow decisions (of cases) of judges in previous cases, where these are binding upon them. However in some circumstances it is possible to come to a different decision because the facts of the earlier case are not comparable to the case now being heard, and therefore the earlier decision can be 'distinguished'
Domiciliary	At the home
Ethics	The science of morals, moral principles and rules of conduct
Euthanasia	Bringing about gentle and easy death, mercy killing
Examination in chief	The witness is asked questions in court by the lawyer of the party who has asked the witness to attend; leading questions cannot be asked
<i>Ex gratia</i>	As a matter of favour, e.g. without admission of <i>liability</i> , of payment offered to a claimant
<i>Ex parte</i>	On one side only, where the other side is not a party to the action

Expert witness	Evidence given by a person whose general opinion based on training or experience is relevant to some of the issues in dispute (contrast with <i>witness of fact</i>)
Re F ruling	A professional who acts in the best interests of an incompetent person who is incapable of giving consent does not act unlawfully if he follows the accepted standard of care according to the <i>Bolam Test</i>
Guardian <i>ad litem</i>	A person with a social work and child care background who is appointed to ensure that the court is fully informed of the relevant facts which relate to a child and that the wishes and feelings of the child are clearly established. The appointment is made from a panel set up by the local authority
Guilty	A finding in a criminal court of responsibility for a criminal offence
Gynaecology	The branch of medicine which devotes itself to the care and prevention of genital tract disorders in women and which for the most part is not concerned with pregnancy
Hearsay	Evidence which has been learnt from another person
Hierarchy	The recognised status of courts which results in lower courts following the decisions of higher courts (see <i>Precedent</i>). Thus decisions of the House of Lords must be followed by all lower courts unless they can be <i>distinguished</i> (see above)
HSC	Health Service Circular issued by Department of Health Security
Indemnity	against loss or damage, compensation for loss occurred
Indictable	Can be tried on an indictment (i.e. before the Crown Court – some crimes are triable either way, i.e. before the Crown Court or summarily before magistrates)
Indictment	Written accusation against a person, charging him with a serious crime, triable by jury
Informal	Of a patient who has entered hospital without any statutory requirements
Injunction	An order of the court restraining a person
Inquisitorial	A system of justice whereby the truth is revealed by an inquiry into the facts conducted by the judge, e.g. Coroner's Court
Invitation to treat	The early stages in negotiating a contract, e.g. an advertisement, or letter expressing interest. An invitation to treat will often precede

an offer which, when accepted, leads to the formation of an agreement which, if there is consideration and an intention to create legal relations, will be binding

Judicial review	An application to the High Court for a judicial or administrative decision to be reviewed and an appropriate order made, e.g. declaration
Judiciary	Judges
Justice of the Peace (JP)	A lay <i>magistrate</i> , i.e. not legally qualified, who hears summary (minor) offences and sometimes indictable (serious) offences in the magistrates court in a group of three (<i>bench</i>)
Liable/liability	Responsible for the wrong doing or harm in civil proceedings
Litigation	Civil proceedings
Magistrate	A person (see <i>Justice of the Peace</i> and <i>Stipendiary magistrate</i>) who hears summary (minor) offences or indictable offences which can be heard in the Magistrates' Court
<i>Mens rea</i>	The mental element in a crime (contrasted with <i>actus reus</i>)
Negligence (1)	A breach by the defendant of a legal duty to take reasonable care not to injure the plaintiff or cause him loss
Negligence (2)	The attitude of mind of a person committing a civil wrong as opposed to intentionally
Next friend	A person who brings a court action on behalf of a minor
Non-executive	A person who does not hold office, used in relation to NHS board members who are directors but who do not hold office within the authority
Notifiable	A disease which must be notified to the authorities by law
Nuisance	A wrong which interferes with the use and enjoyment of a person's land
Obstetrics	The field of medicine dealing with the care of women during pregnancy
Offer	A proposal made by a party which if accepted can lead to a contract. It often follows an <i>invitation to treat</i>
Ombudsman	A Commissioner (e.g. health, Local Government) appointed by the Government to hear complaints
Payment into	An offer to settle a dispute at a particular sum, which is paid into court. The claimant's failure to accept the offer means that the claim

	ant is liable to pay costs if the final award is the same or less than the payment made
Plaintiff	Term formerly used to describe one who brings an action in the civil courts. Now the term <i>claimant</i> is used
Plea in mitigation	A formal statement to the court aimed at reducing the sentence to be pronounced by the judge
Practice direction	Guidance issued by the head of the court to which they relate on the procedure to be followed
Pre-action	Rules of the Supreme Court provide guidance on action to protocol be taken before legal proceedings commence
Precedent	A decision which may have to be followed in a subsequent court hearing (see <i>Hierarchy</i>)
<i>Prima facie</i>	at first sight, or sufficient evidence brought by one party to require the other party to provide a defence
Privilege	In relation to evidence, being able to refuse to disclose it to the court
Privity	The relationship which exists between parties as the result of a legal agreement
Proof	Evidence which secures the establishment of a claimant's or prosecution's or defendant's case
Prosecution	The pursuing of criminal offences in court
Quantum	The amount of compensation, or the monetary value of a claim
Queen's Counsel (QC)	A senior barrister, also known as a 'silk'
Ratio	The reasoning behind the decision in a court case
Reasonable	To secure a conviction in criminal proceedings the doubt prosecution must establish 'beyond reasonable doubt' the guilt of the accused
<i>Res ipsa loquitur</i>	The thing speaks for itself
Sanctions	Penalties, remedies following civil or criminal wrong
Solicitor	A lawyer who is qualified on the register held by the Law Society
Standard of proof	The level that the party who has the burden of proof must satisfy, e.g. on a balance of probabilities (civil courts); beyond all reasonable doubt (criminal courts)

Statute law (statutory)	Law made by Acts of Parliament
Statutory instrument	Orders and regulations having binding force. They must usually be laid before Parliament and will usually become law if they are confirmed by a simple resolution of both Houses (affirmative resolution). Some become law after they have been laid for a prescribed period unless they are annulled by resolution of either House (negative resolution)
Stipendiary magistrate	A legally qualified magistrate who is paid (i.e. has a stipend)
Strict liability	Liability for a criminal act where the mental element does not have to be proved; in civil proceedings liability without establishing <i>negligence</i>
Subpoena	An order of the court requiring a person to appear as a witness (<i>subpoena ad testifi candum</i>) or to bring records/documents (<i>subpoena duces tecum</i>)
Summary offence	A lesser offence which can only be heard by <i>magistrates</i>
Summary	A procedure whereby the claimant can obtain judgment without the defendant being permitted to defend the action
Tort	A civil wrong excluding breach of contract. It includes: <i>negligence</i> , <i>trespass (to the person, goods or land)</i> , nuisance, breach of statutory duty and defamation
Trespass to the person	A wrongful direct interference with another person. Harm does not have to be proved
Trial	A court hearing before a judge
<i>Ultra vires</i>	Outside the powers given by law (e.g. of a statutory body or company)
Vicarious	The liability of an employer for the wrongful acts of an liability employee committed whilst in the course of employment
Void	Invalid or not legally binding
Voidable	Can be made void
<i>Volenti non fit injuria</i>	To the willing there is no wrong; the voluntary assumption of risk

Ward of court	A minor placed under the protection of the High Court, which assumes responsibility for him or her; all decisions relating to his or her care must be made in accordance with the directions of the court
Wednesbury	The court will intervene to prevent or remedy abuses of principle power by public authorities if there is evidence of unreasonableness or perversity. Principle laid down by the Court of Appeal in the case of Associated Provincial Picture House Ltd v. Wednesbury Corporation [1948] 1 KB 233
Without prejudice	Without detracting from or without disadvantage to. The use of the phrase prevents the other party using the information to the prejudice of the one providing it
Witness of fact	A person who gives evidence of what they saw, heard, did or failed to do (contrast with <i>expert witness</i>)
Writ	A form of written command, e.g. the document which used to commence civil proceedings. Now a claim form is served

Abbreviations

ABPC	Association of the British Pharmaceutical Industry
ACPC	Area Child Protection Committee
ACAS	Advisory, Conciliation and Arbitration Service
ADR	Adverse Drug Reaction
BNF	<i>British National Formulary</i>
CD	Controlled Drugs (comes under the Misuse of Drugs Act 1971 and its regulations)
CHC	Community Health Council
CHI	Commission for Health Improvement
CPD	Continuous Professional Development
CPS	Crown Prosecution Service
CQC	Care Quality Commission
CRHP	Council for the Regulation of Healthcare Professionals(now the CHRE)
CHRE	Council for Healthcare Regulatory Excellence
CSM	Committee on the Safety of Medicines
DHSS	Department of Health and Social Security (divided in 1989into DH and DSS)
DH	Department of Health
DHA	District Health Authority
DMD	Drug Misuse Database
DN	Deoxyribonucleic Acid
DSS	Department of Social Security
EC	European Community
ECR	Extra-Contractual Referral
EEC	European Economic Community
ETP	Electronic Transfer of Prescriptions
EU	European Union
GMC	General Medical Council
GP	General Practitioner
GSL	General Sales List
IV	Intravenous(ly) or Intravenous infusion

IVF	In Vitro Fertilisation
JP	Justice of the Peace
LREC	Local Research Ethics Committee
MCA	Medicines Control Agency (now absorbed into the MHRA)
MHRA	Medicines and Healthcare Products Regulatory Agency
NPF	<i>Nurse Prescribers' Formulary</i>
NPEF	<i>Nurse Prescribers' Extended Formulary</i>
NHS	National Health Service
NICE	National Institute for Health and Clinical Excellence
NMC	Nursing and Midwifery Council
NPF	<i>Nurse Prescribers' Formulary</i>
NPEF	<i>Nurse Prescribers' Extended Formulary</i>
NPSA	National Patient Safety Agency
NSF	National Service Framework
PCC	Professional Conduct Committee
PGD	Patient Group Direction
POM	Prescription Only Medicine
PPC	Preliminary Proceedings Committee
PPP	Personal Professional Profile
PREP	Post-Registration Education and Practice
REC	Research Ethics Committee
RPSGB	Royal Pharmaceutical Society of Great Britain
RPS	Royal Pharmaceutical Society
SI	Statutory Instrument
UKCC	United Kingdom Central Council for Nursing, Midwifery and Health Visiting
WHO	World Health Organisation

Table of useful web sites

Audit Commission <http://www.audit-commission.gov.uk/>

British National Formulary <http://www.bnf.org/>

Bristol Inquiry (Kennedy Report) <http://www.bristol-inquiry.org.uk/>

Civil Procedure Rules http://www.open.gov.uk/lcd/civil/procrules_fin/crules.htm

Commission for Racial Equality <http://www.cre.gov.uk/>

Department of Constitutional Affairs <http://www.dca.gov.uk/>

Department of Health <http://www.dh.gov.uk/>

Department of Health (research) <http://www.dh.gov.uk/research/rd1/researchgovernance/>

Department of Trade and Industry <http://www.dti.gov.uk/>

Domestic Violence <http://www.domesticviolence.gov.uk/>

Health and Safety Commission <http://www.hsc.gov.uk/>

Health and Safety Executive <http://www.hse.gov.uk/>

Health Professions Council <http://www.hpc-uk.org/>

Human Fertilisation and Embryology Authority <http://www.hfea.gov.uk/>

Human Rights <http://www.humanrights.gov.uk/>

Medicines and Healthcare Products Regulatory Agency <http://www.mhra.gov.uk/>

MIDIRS <http://www.midirs.gov.uk/>

National Audit Office <http://www.nao.gov.uk/>

National Patient Safety Agency <http://www.npsa.org.uk/>

National Service Framework (older people) <http://www.doh.gov.uk/NSF/olderpeople/>

National Treatment Agency <http://www.nta.nhs.uk/>

NHS <http://www.nhs.uk/>

NHS Direct <http://www.nhsdirect.nhs.uk/>

NHS Professionals <http://www.nhsprofessionals.nhs.uk/>

NICE <http://www.nice.org.uk/>

Nursing and Midwifery Council <http://www.nmc-uk.org/>

Open Government <http://www.open.gov.uk/>

Pain website <http://www.pain-talk.co.uk/>

Royal College of Midwives <http://www.rcm.org.uk/>

Royal College of Nursing <http://www.rcn.org.uk/>

Royal Pharmaceutical Society <http://www.rpharms.com/>

Shipman Inquiry <http://www.the-shipman-inquiry.org.uk/reports.asp>

Stationery Office <http://www.hmso.gov.uk/>

UK Parliament <http://www.parliament.uk/>

Victoria Climbié Inquiry <http://www.victoria-climbie.org.uk/>

