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# Medicines, Medical Devices and The Law

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## Contents

Foreword	vii
<i>Sir William Asscher</i>	
Preface	ix
Chapter 1	1
European Regulation of Medical Devices	
<i>C Hodges</i>	
Chapter 2	25
Medicines Regulation	
<i>A Cartwright</i>	
Chapter 3	45
The Supply of Unlicensed Medicines for Particular Patient Use	
<i>J O'Grady</i>	
<i>A Wearing</i>	
Chapter 4	57
The Pharmacist and Supply of Medicines	
<i>S Sharpe</i>	
Chapter 5	71
The Supply and Reimbursement of Medicines Under the Nhs	
<i>I Dodds-Smith</i>	
Chapter 6	99
The Doctor, Professional Responsibility and Legal Duties	
<i>R G Forrester</i>	
Chapter 7	115
Drug Induced Injury	
<i>J O'Grady</i>	
Chapter 8	143
Principles of Civil Liability for Manufactures and Suppliers	
<i>S Pearl</i>	
Chapter 9	155



Responsibilities and Liabilities of Regulatory Agencies <i>M Mildred</i>	
Chapter 10 Causation Issues in Civil Proceedings <i>A Barton</i>	169
Chapter 11 Adjudication and Funding of Claims <i>G Hickinbottom</i>	205
Chapter 12 Plaintiff Support Groups <i>A Simanowitz</i>	243
Chapter 13 No Fault Compensation Schemes <i>M Mildred</i>	255

Chapter 14	273
Medical Ethics in Treatment and Research	
<i>F Wells</i>	
Chapter 15	291
The Criminal Law and the Prescriber	
<i>M Spencer</i>	
Chapter 16	311
Enforcement and Criminal Liability for Medicines and Medical Devices	
<i>M Tyler</i>	
Chapter 17	345
Drug Induced Automatism as a Defence in Criminal Actions	
<i>M Powers QC</i>	
Chapter 18	357
The Medical Expert	
<i>M Bloom</i>	
Chapter 19	381
Medicines in the Coroner's Inquest	
<i>A Barton</i>	
References and Selected Bibliography	393
Index	401

## Foreword

This book is intended to address a number of fundamental issues arising from the increasingly important relationship between medicine and the law. The choice of contributions has been guided by an awareness of the need for clarification and information within three general areas: (1) the responsibilities and rights that accrue to medical personnel and patients in the prescribing and dispensing of drugs; (2) the regulations governing the pharmaceutical and medical devices industries, and the responsibilities and remits of its regulatory bodies; and (3) the complex issues that arise in the law in the determination of liability and causation with respect to medicines and medical devices.

With respect to the first area - the responsibilities and rights associated with the prescription and dispensation of medicines - the important issues are addressed with contributions dealing with subsidiary issues. Chapters by Michael Spencer QC, John Finch and Rex Forrester provide comprehensive analyses of medical practitioners' and suppliers' liability in criminal law for causing injury through action, omission or negligence. Susan Sharpe discusses the regulations governing the legal responsibilities of the pharmacist in the acquisition, storage and dispensation of medicines. On the issue of patients' rights, chapters by Arnold Simanowitz and Garry Hickinbottom discuss the function and organization of plaintiff support groups, such as the AVMA (Action for Victims of Medical Accidents), and the general issue of the funding of civil claims. This is complemented by John O'Grady's discussion on the special responsibilities of the medical practitioner in the prescription and supply of unlicensed medicines to patients. In addition, Mark Mildred examines the potential for a no fault compensation scheme for victims of medical accidents to allay the costs and delay that currently bedevil the civil justice system. Anthony Barton's discussion on medicines in the coroner's inquest provides important information on a subject that has hitherto been inadequately explored.

The second general area of concern, that of the regulation of the medical industry and the role of its governing bodies, is a large and complex field in which there has been a growing and continuing need for discussion and debate. The contributions will sharpen that discussion. Chris Hodges provides

important information on the European regulation of medical devices, these being different from the rules governing medicines, focusing on relevant aspects of the directives governing medical devices in European law, including classification, conformity with safety assurance procedures, marketing, clinical investigations and adverse event reporting. Simon Pearl and Mark Tyler cover the general legal principles binding on the manufacture and distribution of medicines, and Anthony Cartwright gives details of the regulations and regulatory procedures governing the research, development and marketing of medicines in European law. Ian Dodds-Smith provides an overview of the system of supply and reimbursement in the National Health Service, and Frank Wells, in an important contribution, looks at the existing ethical guidelines on research and testing in the pharmaceutical industry, with special reference to clinical trials. Mark Mildred, in a second contribution, explores the extent to which, and the legal responsibilities according to which, medical regulatory agencies such as Committee on the Safety of Medicines and the Medicines Control Agency can be held responsible in law for their actions in the licensing and recommendation of medicines. Finally, Margaret Bloom discusses the role of the medical expert, both in law and in the medical industry.

The third area of concern, the question of causation in law, raises issues in legal theory as well as in courtroom procedure and regulatory affairs.

Anthony Barton details the complications surrounding the general concept of causation in law, including proximate causation, material contribution to injury through omission, and malpractice and cause and effect in biostatistics. John O'Grady deals with the scientific problems associated with attributing injury to drug action, which include the classification and mechanism of adverse events and anomalies of pharmacovigilance. Finally, Michael Powers addresses the issue of responsibility for criminal action in cases of drug induced automatism.

John O'Grady and the co-editors deserve high praise for their expert choice of topics and contributors. This book is a must for all concerned with the interface between medicines, medicine and the law. In these days of unprecedented growth in medical litigation, no health-care worker and manager can plead ignorance. This book brings under one cover all the topics needed to cope with medico-legal problems. There has long been a need for such an authoritative work of reference.

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## Preface

In recent years, the need for specialist knowledge of the laws governing the regulation of medicines has become apparent. This is the case among not only lawyers but also hospitals, researchers, prescribers and many others involved in the provision of healthcare. Such a need has been precipitated by a number of factors, including the changing structure of healthcare in the UK and Europe, the increasing specialization in litigation relating to medicines' control and provision, and the various changes in regulation that have arisen both from challenges in the courts and from the intervention of public bodies. However, up until now the information resources available to those involved in the complex interrelations between medicines, medical devices and the law have remained scarce. This book is designed to go some way to correcting this situation by bringing together the knowledge of the laws governing the regulation of medicines of the most experienced and qualified experts in one volume, ranging across all aspects of the field.

The scope of this field is construed as including all aspects of the law relating to the research, development, manufacture, distribution and dispensation of medicines and medical devices in the UK, as well as various topics within the law governing responsibilities, procedure and compensation in cases of malpractice and injury. Our contributors are accordingly also drawn from a wide range of speciality. We have commissioned chapters from lawyers and law theorists experienced in the fields of litigation in relation to malpractice and in the regulation of medicines, and from healthcare professionals with specialist knowledge of the ethics, codes of practice and policies of both the pharmaceutical industry and the national healthcare system.

In the choice of the subject matter for each chapter, we have also been guided by an awareness of the wider readership that could profit from this text. The book will be of interest to lawyers specializing in medical malpractice, law and medical societies, hospital trusts, and other medical and legal personnel.

The law is stated as 1st June 1998

JOHN O'GRADY  
IAN DODDS-SMITH  
NIGEL WALSH

MICHAEL SPENCER

1

# European Regulation of Medical Devices

Christopher Hodges



## Overview

The regulatory system for medical devices is quite different from that for pharmaceuticals. It does not involve the assessment of a product by a medicines agency or the grant of a marketing authorization. Instead, the onus of ensuring and declaring that a product conforms to the legal *essential requirements* is placed on the *manufacturer*, but in many instances this is subject to approval by an independent technical organization (known as a *notified body*).

The manufacturer must apply an appropriate *conformity assessment* procedure to his device to ensure that it complies with the essential requirements, after which he must certify this fact by completing a *declaration of conformity*. There is usually a choice of conformity assessment procedures open to a manufacturer, depending on a risk-based *classification* of the class into which his device falls. The two main approaches to conformity assessment are based either on an approved total quality management system audited to ISO 9000 series standard, as customized for medical devices with EN 46000 series standard, or individual product assessment.

The essential requirements relate to the *safety* in use of the device, including labelling requirements, but are principally expressed in terms of scientific and technical *performance* characteristics. Efficacy, as such, is not a criterion. Confirmation of conformity must include evaluation of clinical data for many devices, generated from either a compilation of scientific literature or the results of *clinical investigations* on the product, from which prior ethical and regulatory approval is required. Conformity of a device with the essential requirements is denoted by affixing *CE marking* to the device. CE marking acts in effect as the passport that authorizes the device to be placed on the market and to circulate freely within the European Economic Area (EEA) and must be marked on the device.

The legal obligation is that a product must comply with the relevant essential requirements but where the manufacturer chooses to apply a national standard which adopts a European *harmonized standard* (EN series) to an aspect of his product, conformity will be *prima facie* presumed in respect of the aspects of the essential requirements covered by that standard. Other national or international standards do not have this regulatory benefit. Compliance with the essential requirements at the time of placing the device on the market, or

declaration of this fact, should mean that the device is safe but it may later transpire that this is not the case. Manufacturers, therefore, have some post-marketing *vigilance* requirements. If a marketed device is unsafe, the *competent authority* of a member state has power under a *safeguard clause* in each Directive to take regulatory action to effect the withdrawal of the product from the market in its jurisdiction: the matter is then referred to the Commission and all member states who then coordinate their actions.

European pharmaceutical regulation has been in existence since the mid-1960s and over 30 years has successively extended from (1) control of the requirements for placing a product on the market and the data necessary to justify this, coupled with (2) control on manufacture, to virtually all aspects of dealing with a medicine, including wholesale dealing, advertising and clinical research. In contrast, systematic regulation of medical devices is more recent and dates from the 1990s. It essentially covers the requirements for placing a product on the market, coupled with aspects of manufacture, labelling and clinical investigation, but does not cover

aspects such as distribution or advertising. The central difference is that many activities with pharmaceuticals require prior competent authority approval, which is not the case with devices.

Before the medical devices Directives came into being, most medical devices were unregulated in most European states. In some states, some were regulated (illogically, but this was the only available mechanism) as if they were medicines. Examples of products formerly regulated as medicines in the UK include contact lens products, intrauterine contraceptives and certain medicated dressings, surgical ligatures and sutures, absorbent or protective materials and dental filling substances.

### Law on Specific Devices

The EEA law on the marketing of medical devices is governed by three principal Directives that each adopts the Community's scheme for product regulation known as the "new approach".<sup>1</sup> The new approach applies to many product sectors, such as machinery, personal protective equipment, low voltage equipment and electromagnetic compatibility requirements but not to pharmaceuticals or cosmetics. The three device Directives are:

Directive 90/385/EEC on Active Implantable Medical Devices ("AIMDD") came into force on 1 January 1993 and is mandatory from 1 January 1995. This covers all powered implants or partial implants that are left in the human body such as a heart pacemaker.

Directive 93/42/EEC on medical devices (MDD) came into force on 1 January 1995 and became mandatory on 14 June 1998. This covers a wide range of devices ranging from first aid bandages, tongue depressors and blood collection bags to hip prostheses and active (powered) devices.

A proposed Directive on *in vitro* diagnostics ("IVDD") expected to be finalized during 1998, to come into force around, perhaps, 2000. This covers products such as pregnancy tests, blood glucose monitoring and tests for transmissible diseases.

A *transitional period* is provided under each of these Directives so that during the period from the coming into force of the Directive until it is mandatory, a manufacturer may choose whether to apply the Directive to his device or the national rules which were in force immediately prior to the date on which the Directive came into force. From the date a Directive becomes mandatory, a

device which is covered by national law implementing that Directive must comply with it.

Under Community law, a Directive is binding on each member state, which is obliged under the EC Treaty to implement the Directive into its national law. A member state has the discretion to choose the manner in which the Directive may be implemented so long as the effect of the Directive is achieved under its national legal order. Most member states transpose Directives into their national law by enacting domestic legislation that follows the text of the

1 Council Resolution of 7 May 1985 on a new approach to technical harmonization and standards, OJ 1985 No. C 136/1, 4.6.85.