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## Introduction

*P Weedle and L Clarke*

In the predecessor to this book (published in 1991) the then authors concluded in a postscript:

we were warned at the outset that the time was not opportune for producing a book dealing with the legislation affecting medicines. Too many directives and national regulations were still in the pipeline to enable the subject to be covered with any degree of finality. While there was, and is, much truth in that proposition, we were more convinced by a different viewpoint: there will never be an opportune time.

Much has happened in the intervening years with a significant updating of the body of legislation relating to medicines and pharmacy, as was predicted. Major developments have occurred, in particular in the last decade, largely driven by the evolving regulatory system for human and veterinary medicines at European Union (EU) level. The enactment of the Pharmacy Act 2007 has been another highly significant development and a major catalyst in developing the current book.

This book is designed primarily as a reference source for healthcare professionals, in particular, pharmacists, to ensure that they have easily accessible information on legislation relevant to their practice. It is considered, therefore, that only a brief outline of the legal systems giving rise to this legislation is appropriate (Chapter 2). Law students have complete courses of lectures and access to numerous textbooks on legal systems. Chapter 2 is not designed for lawyers, but for those involved with medicines who need to know, in simple terms, the basis of their legal controls.

Following the legal system chapter, a brief historical background is given to the development of medicines and pharmacy legislation over the centuries and an analysis provided of the evolution of EU law on human medicines since

the 1960s (Chapter 3). The purpose of the law then was, as it still is today, to protect the public. The first law controlling medicines was enacted in the sixteenth century; many administrative controls developed much earlier. It was not until the latter part of the nineteenth century that the law took a major and sustained interest in controlling medicines.

The first modern Irish legislation controlling the purity and quality of medicines was the Therapeutic Substances Act 1932. The worldwide concern which followed the tragedy of the teratogenic effects of thalidomide led to controls in the 1960s on the placing of medicinal products on the market in Europe (Chapter 4). Initially these controls took the form of a licensing system to ensure the quality, safety and efficacy of such products. Over the years, other aspects have been regulated, including manufacturing and testing, wholesaling, labelling, advertising, monitoring of side-effects (pharmacovigilance), supply classification and clinical trials, largely driven by EU requirements. The EU is also proactively taking steps to encourage the licensing of medicines for children (paediatric medicines), for rare diseases (orphan medicines) and cell, gene and tissue therapies (advanced therapies). The advent of the EU centralised procedure and the mutual recognition and decentralised procedures for the authorisation of medicinal products have reduced the duplication of work between national regulatory authorities, ensured a growing role for the European Medicines Agency and its Committee for Medicinal Products for Human Use and faster access for European patients to new medicines. The controls on placing medicinal products on the market are reinforced by the rigorous obligations placed on those who manufacture and wholesale such products (Chapter 5) and the controls applicable to their advertising and promotion (Chapter 6).

The law also controls the availability of certain medicines which are considered to require professional selection and advice on their use. The Medicinal Products (Prescription and Control of Supply) Regulations 2003 as amended describe the controls applicable to medicines that may only be supplied on prescription and to those exempted from prescription control. It is noteworthy that the right to prescribe medicinal products has been extended in recent years to nurses, albeit with some restrictions (Chapter 7). Certain drugs which are liable to be abused because of their psychoactive effects (e.g. morphine) are very strictly controlled by the Misuse of Drugs Acts (Chapter 8) to ensure that they are available only for *bona fide* medical purposes.

In the past, controls on the supply of human and veterinary medicines imposed by poisons legislation were a crucial element of the regulatory system for such products. However, as the body of human and veterinary medicines legislation evolved, the need for such controls diminished. Poisons legislation has been totally updated in the last few years and human and veterinary

medicines are now completely removed from its scope. The legislation still has some relevance to modern-day pharmacy practice in terms of poisons sold and supplied for use in agriculture, horticulture etc., albeit far more limited than previously (Chapter 9).

Veterinary medicines are controlled in a manner similar to medicines for human use (Chapter 10). Additional controls apply because certain animals are used as a food source for humans and therefore the law is concerned with ensuring that residues in meat, milk and other animal produce do not pose a threat to public health. Most of the controls over medicines for veterinary use originate from the EU in the form of directives and regulations.

Other areas of the law that affect medicines and their supply to the public by pharmacists are also covered, namely the Pharmacy Act (Chapter 12) and Regulations and Rules (Chapter 13) and the Disciplinary System (Chapter 14). Controls on the sale of methylated spirits are also detailed (Chapter 11). Finally, the increasingly important areas of the tort of negligence and the EU Directive on product liability in the provision of medical and pharmaceutical care to patients are discussed (Chapter 15).

There are many other areas of legislation that may impact on a pharmacist in practice (e.g. data protection, employment law, etc.) that could be included in this book. However, the volume of legislation which would need to be covered to comprehensively deal with all these topics is beyond the scope of this book.

A number of conclusions can be drawn from the many legislative developments that have occurred in recent years:

- A comprehensive legal framework now exists through the Pharmacy Act and its accompanying regulations, rules and code of conduct, for the regulation of the pharmacy profession in Ireland. It will be interesting to see how the profession expands and develops within this new regulatory framework in the years ahead.
- In terms of human and veterinary medicines, the regulatory environment created by the EU's pharmaceutical directives and regulations is comprehensive and appropriate given the EU's twin objectives of safeguarding of public health, while at the same time facilitating the development of industry and trade in medicines within the EU. The one aspect of the EU regulatory system that could be rationalised is the system available for the authorisation of medicinal products which comprises three different mechanisms for medicines to be marketed in more than one country (centralised, mutual recognition and decentralised procedures) as well as national systems for medicines that will be marketed in only one member state.

- The expansion in EU regulation has been mirrored by a diminution of controls emanating at national level and, on occasion, some real complexity where it is necessary to marry EU requirements with those in place in national legislation. For example in the area of medicines for use in animals, the Animal Remedies Acts 1993 and 2006 as amended sit alongside various regulations made under the European Communities Acts to implement EU law on veterinary medicinal products. The definition of animal remedy is actually broader than that of the EU's 'veterinary medicinal product'. Another example is the Irish Medicines Board Act 1995 which has been amended by four separate European Communities regulations, primarily to designate the Irish Medicines Board as competent authority for various classes of medical devices. The Irish Medicines Board (Miscellaneous Provisions) Act 2006, as would be expected, amended the 1995 IMB Act but it is interesting to note that it also amended six other acts<sup>1</sup> as well as amending or revoking six statutory instruments; the changes covering matters as diverse as nurse prescribing and dental health services for children. Another example of complexity in legislation is the system for supply classification of medicinal products which is covered in both the Medicinal Products (Control of Placing on the Market) Regulations 2007 and the Medicinal Products (Prescription and Control of Supply) Regulations 2003 as amended. The latter regulations had to be amended by the former to reconcile the requirements of the two sets of regulations.

This complicated approach to legislation, while it may achieve the desired legislative controls and compliance with Ireland's obligations as a member of the EU, gives rise to a body of acts and statutory instruments which are difficult to navigate without expert knowledge of the relevant legislation. The authors believe that this is an area which would benefit from review and streamlining.

It is hoped that this textbook will help those with an interest in pharmacy and medicines law in Ireland to find their way through the maze of legislation as it currently exists. To assist the reader, details of relevant EU directives and regulations have been covered in addition to the relevant national provisions.

Given the vast legislative change that has occurred in the last 20 years, there is a hope that there may be a degree of stability for the foreseeable future. However, given the speed of technical and scientific advances in therapeutics and the ever-expanding reach of the EU, this is probably an unrealistic wish.

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1. Misuse of Drugs Act 1977, Control of Clinical Trials Act 1987, Health Acts 1947, 1970 and 1994 and Animal Remedies Act 1993.